Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K110179 - 885 pages
COMPANY:	INCONTROL MEDICAL, LLC (INCOMEDI)
PRODUCT:	STIMULATOR, ELECTRICAL, NON-IMPLANTABLE, FOR INCONTINENCE (KPI)
SUMMARY:	Product: INCONTROL
DATE REQUESTED:	Mar 28, 2016
DATE PRINTED:	Mar 28, 2016
Note:	Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510(k) Summary for InControl InTone

FEB 2 2 2012

Submitter:	InControl Medical, LLC
Address:	3225 Gateway Road, Suite 250 Brookfield, Wisconsin 53045
Corporate Contact:	Herschel Peddicord, President InControl Medical, LLC
Telephone:	Ph: (414) 429-2625
Establishment Registration #:	to be registered following 510(k)
Submission Contact:	Michael J. Leigh, consultant 12715 Falcon Drive Brookfield, Wisconsin 53005 Ph: (262) 957-6797
Trade Name:	InControl InTone
Predicate Device:	Otto Bock STIWELL med, K080950 MyoTrac Infiniti, K053434 Hollister evadri, K050483
Common Name:	Stimulator, Electrical, Non-Implantable, for Incontinence

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
876.5320	KPI	Non-implanted electrical continence device	II

Device Description:

The device includes three parts; an insertion probe and a hand-held control unit. The insertion probe features an inflatable balloon that provides more adaptable fit for intra-vaginal use. The probe includes stainless steel electrodes to deliver electro-stimulation. The hand-held control and display device records, stores, and displays the results of electro-stimulation and patient generated pelvic floor exercises. It allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. It also stores data on contraction pressure for later review. The PC application allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

Intended Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

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Performance Data:

Complete EMC, electrical, mechanical, safety (operator and patient), temperature/humidity, and software testing demonstrate compliance with applicable standards. The results demonstrate that the InControl InTone device is in compliance with the guidelines and standards referenced in the FDA reviewer's guides, and that it performed within its specifications and functional requirements for the device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with FDA requirements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Feature/ Function	InControl InTone (new device)	Otto Bock STIWELL med4 (K080950)	MyoTrac Infiniti (K053434)	Hollister evadri (K050483)	Comparison
Labeling					
Intended Use An explicit description of all clinical functions performed by the device, **Indications for Use** Explain when the device is to be clinically used and the intended patient population	The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.	The STIWELL med4 is a neuromuscular electronic stimulator for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions: • Acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of the pelvic floor muscles. • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles. As a biofeedback device the STIWELL med4 is indicated for the following conditions: • Biofeedback, relaxation and muscle re-education purposes.	Treatment of urinary incontinence EMG biofeedback The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.	The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary or fecal (electromyographic biofeedback) incontinence.	Equivalent
Warnings or Precautions	(see product labeling)	(see product labeling)	(see product labeling)	(see product labeling)	Equivalent

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Contraindications Explain when the device is not to be clinically used	• This device is not intended for diagnostic purposes or critical patient monitoring. • The device is not defibrillator proof. • The device should not be used on patients with cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance. • Do not use if patient has symptoms of an active urinary tract infection. • Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms. • Do not use if patient has undiagnosed pain. • Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation. • Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings. • Do not use if patient is currently pregnant or attempting to get pregnant. • Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit. • Do not use if the patient has irregular menstrual bleeding cycles. • Do not use if the patient has a history or symptoms of urinary retention. • Do not use if the patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra). • Do not use if the patient has overflow incontinence caused by evacuation problems. • Do not use if the patient has severe urine retention in the upper urethras. • Do not use if the patient has complete peripheral denervation of the pelvic floor. • Do not use if the patient has an intestinal clamp.	• Patients with pacemakers or other electronic emitters. • No stimulation in the proximity of metal implants. • Pregnancy • Feverish or infectious diseases • Skin disorders subject to inflammation or tumors in the stimulation area, as well as thrombosis or phlebitis • Patients with extra-urethral incontinence (fistula, ectopic urethra) • Patients with overflow incontinence caused by evacuation disorders • Patients with serious urine retention in the upper urethra • Patients with total peripheral denervation of the pelvic floor • Patients with intestinal clamps	• Patients with an implanted electronic device (for example cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained. • Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions • Stimulation should not be applied over cancerous lesions • Not for use with patients with undiagnosed pain conditions. • Do not use if you have symptoms of bladder infection. • Do not use with diminished mental capacity or physical competence limiting the use of the device • Safety of powered muscle stimulators during pregnancy has not been established.		Equivalent
Labeling Summary Clarity to insure safer or more effective use	User Manual	User Manual	User Manual	User Manual	Identical (to all)
Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)
Power Source	4/5 AA nickel metal hydride battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Method of line current isolation	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Patient leakage current	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)
Regulated current or voltage?	Regulated voltage	Regulated current	Unknown	Unknown	Equivalent
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic No-Load Trip?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display **On/Off Status** **Low Battery**	 Yes Yes	 Yes Yes	 Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	dual phase, rectangular pulses	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency **Mixed** **Stress** **Urge**	 50 Hz - -	 35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Within range (of MyoTrac, Hollister)
Pulse width **Mixed** **Stress** **Urge**	 200 µs/phase - -	 300 µs/phase 500 µs/phase	0.2 ms	0.3 or 1 ms	Within range
Time **On** **Off**	 20 secs 10 secs	 9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	 2 - 20 secs 2 - 50 secs	 1 - 80 secs 0 - 80 secs	Equivalent
Total Session Time	12 mins	5 - 25 mins	0 - 120 mins	1 - 30 mins	Within range
Max output voltage (500Ω)	50 Vdc	50 Vdc	30 Vdc	30 Vdc	Identical (to Otto Bock)
Max output current (500Ω)	100 mA	100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)	50 µC	50 µC	60 µC	Unknown	Identical (to Otto Bock)
Electrode surface area	10.5 cm^2 x 2	21.2 cm^2	Various, 1.53 cm^2 to 10.5 cm^2	unknown	Equivalent
Max current density	4.7 mA/ cm^2	4.7 mA/ cm^2	Various, 4.7 mA/ cm^2 to 32 mA/ cm^2		Identical
Maximum power density (500Ω)	14.3 µW/ cm^2	23.5 µW/ cm^2	Various, 11.32 µW/ cm^2 to 22.84 µW/ cm^2	Unknown	Equivalent
Biofeedback	Air pressure, 0 - 2 psi	EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)
Materials					

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Dimensions	8 x 5 x 4 inches	175 x 95 x 30 mm	102 x 152 x 51 mm	100 x 70 x 130 mm	Equivalent
Control housing	ABS plastics	plastics	plastics	plastics	Equivalent
Insertion material	Silicone, plastics	plastics	plastics	plastics	Equivalent
Packaging or Expiration Dating	1 year for insertion unit	N/A	N/A	N/A	
Sterilization	N/A	N/A	N/A	N/A	
User Interaction and Software					
Operational Method: Clinical Use e.g., ambulatory use, home use	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Identical (to all)
Patient Interaction: Functions Controllable An explanation of how the device interacts with the patient.	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.				Equivalent
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	None, programming can only be changed by clinician	None, programming is locked by clinician	None, programming is locked by clinician		Equivalent (to Otto Bock, MyoTrac)
Override	Yes	Yes			Identical (to Otto Bock)
Patient Interaction: Operator Requirements Knowledge or training required of the operator,	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Identical (to all)
Software Level of Concern A statement indicating the Level of Concern and a description of the rationale for that level.	Moderate				

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Feature/ Function	InControl InTone (new device)	Otto Bock STIWELL med4 (K080950)	MyoTrac Infiniti (K053434)	Hollister evadri (K050483)	Comparison
Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)
Power Source	Nickel metal hydride battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)
Regulated current of voltage?	Regulated voltage	Regulated current	Unknown	Unknown	Equivalent
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display **On/Off Status** **Low Battery**	 Yes Yes	 Yes Yes	 Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	dual phase, rectangular pulses	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency **Mixed** **Stress** **Urge**	50Hz - -	 35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Identical (to MyoTrac, Hollister)
Pulse width **Mixed** **Stress** **Urge**	200 µs/phase - -	 300 µs/phase 500 µs/phase	0.2 ms	0.3 or 1 ms	Within range
Time **On** **Off**	 20 secs 10 secs	 9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	 2 - 20 secs 2 - 50 secs	 1 - 80 secs 0 - 80 secs	Within range
Total Session Time	12 mins	5 - 25 mins	0 - 120 mins	1 - 30 mins	Within range
Max output voltage (500Ω)	50 Vdc	50 Vdc	30 Vdc	30 Vdc	Identical (to Otto Bock)
Max output current (500Ω)	100 mA	100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)	50 µC	50 µC	60 µC	Unknown	Identical (to Otto Bock)
Electrode surface area	10.5 cm^2 x 2	21.2 cm^2	Various, 1.53 cm^2 to 10.5 cm^2	unknown	Equivalent
Max current density	4.7 mA/ cm^2	4.7 mA/ cm^2	Various, 4.7 mA/ cm^2 to 32 mA/ cm^2		Identical
Maximum power density (500Ω)	14.3 µW/ cm^2	23.5 µW/ cm^2	Various, 11.32 µW/ cm^2 to 22.84 µW/ cm^2	Unknown	Equivalent
Biofeedback	Air pressure, 0 2 psi	EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

InControl Medical, LLC
% Mr. Michael J. Leigh
Consultant
12715 Falcon Drive
BROOKFIELD WI 53005

FEB 2 2 2012

Re: K110179
Trade/Device Name: InControl InTone
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: January 24, 2011
Received: January 31, 2012

Dear Mr. Leigh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Indications for Use

510(k) Number (if known): K110179

Device Name: InControl InTone

Indications For Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110179

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K110179 | A1

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
APR 1 2011
Received

Re: K110179

March 28, 2011

Dear Ms. Morris

This letter is in response to your letter dated February 25, 2011 received March 4. The response includes exhibits for each item, as available. Some items are not yet available. For this reason, we would like to request an extension.

1. This term has been removed. It was an inadvertent editing error from an earlier draft. See Exhibit 1.
2. The original submittal included requirements specifications. This update includes design specifications and drawings. Specifically,
   a. See Exhibit 2.
   b. The principle new feature of the device is the inflatable insertion unit. This allows an adjustable fit for each patient. All other features of the device are meant to parallel similar products on the market.
   c. Dimensions and weights are included in sections 2 and 6 of the specification in Exhibit 2.
   d. Descriptions of the user controls, displays, and functions are included in section 3 of the specification in Exhibit 2. This will be expanded in the User Manual update.
   e. The control unit has a DB-9 connector. This connector has two uses, but only one can be employed at a time. It is the connection to the insertion unit, providing control during a session. It can also be used with a custom cable to connect to a personal computer via a type A USB port. When connected to a computer, the control unit's battery is recharged. Data can also be downloaded in a comma delimited file. See Exhibit 3 for drawings of the control unit, insertion unit, and their connection.
   f. See drawings in Exhibit 3.
   g. The connection between the control and insertion units are described, with specifications, in section 4 of the specification in Exhibit 2. Also, see Exhibit 3 for drawings of the connector assembly.
3. Information regarding the setting was originally in the User Manual. It has now been expanded in the Section 6 of the specification in Exhibit 2.
4. Battery specifications have been included in section 5 of the specification in Exhibit 2.
5. The insertion unit is reusable but intended for single patient use only. This has been clarified in the User Manual. An updated draft will be provided later.
6. The following table identifies the materials used control unit, insertion unit, and electrodes. Due to the nature of the materials and their molding characteristics, no additional processing materials are requried. Material data sheets are included in Exhibit 4. The electrodes are rigid, semi-tubular, 304/304L stainless steel.

	Control Unit enclosure	**Insertion Unit outer surface**	**Connector assembly outer surface**
Chemical Name	ABS acrylonitrile, butadiene, styrene	Silicone	ABS connector PVC coated umbilical

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Supplier	(b)(4)		
Supplier trade name			
Polymer formulation			
Processing description			
Processing materials	None	none	none

7. The entire outside surface of the insertion unit is (b)(4) This material has complete cytotoxicity, sensitization, and irritation testing as shown in Exhibit 4. Where adhesive is required, on inner surfaces, (b)(4) used. This material also has complete cytotoxicity, sensitization, and irritation testing as shown in Exhibit 4.
8. I have requested copies of the electrical safety test results. Due to the changes made to the product since January, I expect a delay in receiving these.
9. I have requested copies of the electromagnetic compatibility test results. Due to the changes made to the product since January, I expect a delay in receiving these.
10. The information on software has been expanded. See Exhibit 5. This information will be further expanded on a subsequent update.
11. The waveforms included showed the limits of the adjustment. Specific waveforms for each setting will be included in a subsequent update.
12. The silicone material has an 18 month usable life. A one year shelf life has been defined for the insertion unit. This has been added to the User Manual. An update will be provided later.
13. The User Manual has been updated with the following. There will be an additional revision to the User Manual, to be provided in a subsequent response. This later revision will include updates to the user instructions.
    a. The User Manual describes all features, functions, output modalities, and specifications. See Exhibit 6.
    b. The User Manual includes expanded descriptions of the updated controls. These will be further updated and expanded in the subsequent response.
    c. The front panel and a draft back label are included in Exhibit 7. The indicators are described in the User Manual.
    d. The size and type of electrodes are described in the Specifications section of the User Manual.
    e. The User Manual includes a section for cleaning. No other maintenance is required.
    f. The warning statement has been added to the User Manual. See page 8.
    g. The caution statement has been added to the User Manual. See page 8.
    h. The caution statement has been added to the User Manual. See page 8.
    i. The caution statement has been added to the User Manual. See page 8.
    j. The statement has been added to the User Manual. See page 8.
    k. The caution statement has been added to the User Manual. See page 8.
    l. The statement has been added to the User Manual. See page 8.
    m. The statement has been added to the User Manual. See page xx.
    n. The adverse reaction statement has been added to the User Manual. See page 8.
    o. The contraindication has been added to the User Manual. See page 9.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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p. The contraindication has been added to the User Manual. See page 9.
q. The contraindication has been added to the User Manual. See page 9.
r. The contraindication has been added to the User Manual. See page 9.
s. The contraindication has been added to the User Manual. See page 9.
t. The statement has been removed.

14. Device labeling includes the User Manual and back label of the control unit. Promotional and advertising materials are not available at this time. See Exhibit 7 for the control unit front panel and back label.
15. The 510(k) Summary has been updated. A copy will be provided in a subsequent response.

We would like to request an extension to provide the documentation listed above. The subsequent response will include an updated manual draft, final electrical safety testing, final electromagnetic capability testing, final software testing, and an updated 510(k) Summary.

If you have any questions regarding the additional information provided in this submittal, please don't hesitate to contact me. Thank you for your time and consideration.

Sincerely,

Michael J. Leigh
consultant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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EXHIBIT 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SECTION 7B: INFORMATION ON NEW DEVICE

Device Description

The general description of the InControl InTone, including required features, functionality and interface, user options, and packaging, is equivalent to that of the predicate devices, Otto Bock STIWELL med 4, MyoTrac Infiniti, and Hollister evadri devices.

The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

The device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

Comparison to Predicate

The principle difference between the InControl device and the predicates is that the InControl device includes an inflatable insertion unit. The unit is manually inflated by the patient after insertion. This provides a better fit for the patient population. The electrical parameters and controls are similar to the predicate devices. There are no differences in the intended use or indications for use.

The following comparison information illustrates differences and similarities between the legally marketed predicate prescription devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483), and the InControl device, including intended use and functional characteristics. The FDA guidance documents used to prepare this comparison as well as this 510(k) are:

FDA Guidance Title	Revision Date
Format for Traditional and Abbreviated 510(k)s	November 17, 2005
Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence	September 19, 2008
General Principles of Software Validation	January 11, 2002
Content of Premarket Submission for Software contained in Medical Devices	May 11, 2005
ODE Bluebook Memo G91-1 "Device Labeling Guidance"	March 8, 1991
Medical Device Patient Labeling	April 19, 2001
Labeling - Regulatory Requirements for Medical Devices	FDA89-4203

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Statement of Substantial Equivalence

The proposed device, InControl continence device, is substantially equivalent to the Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), and Hollister evadri (K050483). When compared to the predicate devices:

- The changes are not due to a recall or corrective action.
- The indications for use are the same. There are no changes in contraindications.
- The user's manual provides equivalent instructions for use, along with equivalent warnings.
- There are no significant differences in features, fundamental technology, or functionality.

The InControl device and the predicate devices all provide pulsed biphasic current to stimulate the pelvic floor muscles. Each includes provision for biofeedback. The InControl device is not significantly different from the predicates. The InControl device does not raise new safety or effectiveness issues. It has the same intended use and basic functions.

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Intended Use

The intended use InControl is the same as the predicates.

> The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

The intended use and indications of the device, as described in its labeling are the same as the intended use and indications for the predicate devices.

Labeling

User Manual

The InControl *User Manual* uses text and graphics to lead the user through hardware setup and use. Each piece of equipment appears in a bulleted list with a brief description illustrating each step for ease of use.

SAFETY and PRODUCT INFORMATION

The document also provides maintenance, troubleshooting, repair, warranty, and customer service information. The *User Manual*, provides comprehensive safety information, product specifications and guidelines. The document can be found in "Attachment A" of this 510(k) submission.

Notes on Guidance and Information Labeling:

The manual provides the concepts and instructions needed to install, program, use, and maintain the InControl device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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EXHIBIT 2

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System Requirements Specification:
InControl InTone

Date	Rev	Author	Section(s) changed description
01/15/11	A	E Palatnik	Initial release.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.0 Introduction

1.1 Purpose

The purpose of this document is to define the system requirements of the developed product.

1.2 Scope

This document includes the materials, power, controller, and other design decisions for the InTone product.

2.0 Control Unit

2.1 Features

InTone device is a hand-held instrument, which controls stimulation and provides bio-feedback. It is battery operated. It has a set of controls and displays to provide appropriate user interface.

The device is capable of storing stimulation parameters in its memory. Stimulation parameters are sent to the device from the PC via USB port.

The device is capable of storing the results of bio-feedback training sessions, with further downloading into PC program.

2.2 Dimensions

4.83" x 2.4" x 1.1"

2.3 Weight

5 oz

3.0 User Interface

3.1 User Controls, and Their Functions

The user controls are shown on the picture below:

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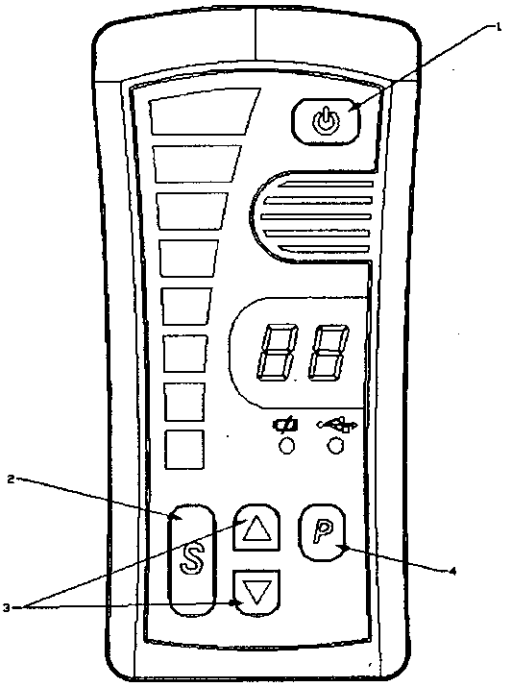

1 – ON/OFF button
2 – Start button. Starts the stimulation / bio-feedback session
3 – Volume increase / decrease buttons
4 – Pause button, to temporarily pause the session

3.2 User Displays, Sound Devices, and Their Functions

The user displays and sound devices are shown on the picture below:

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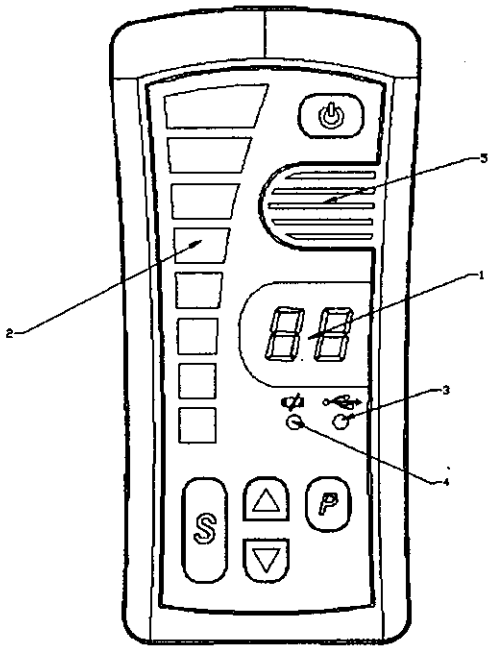

1 – Timer, shows time in seconds
2 – Bar graph, showing muscle effort during bio-feedback session
3 – USB communication; is lit when unit is connected to the PC via USB link
4 – Battery. When unit is running in a battery, this light shows low battery condition. When unit is being charged, flashing of this light indicate charging in progress.
5 – Speaker, used to give voice prompts during bio-feedback session

4.0 Description of the Computer Connection

The unit is connected to the PC via a custom USB cable. The connection port is used for three functions:

1 – USB link
2 – Charging the internal battery
3 – Connection with the insertion device

Since only one cable can be plugged at a time, neither USB nor power supply could be electrically connected to the patient in any circumstances. This assures electrical safety.

The location of the interface connector is shown below:

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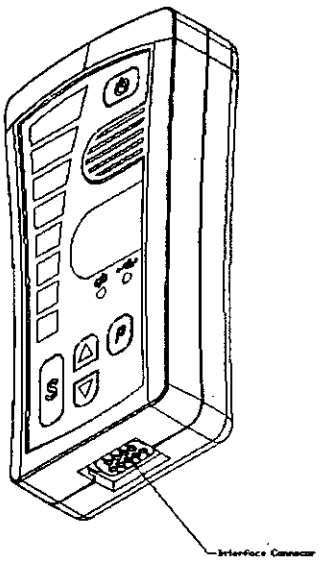

The connector is a standard D-type 9-pin connector.
Each cable (see pp 1, 2 and 3 above) has jumper shorts in mating connector, providing information for the device which cable is plugged; thus device can configure its function appropriately.

If the USB cable is plugged, all the buttons are disables, the bar graph and timer are disabled, the USB light is on, and unit communicates with the PC.

If the power supply is plugged, all the buttons are disabled, the bar graph and timer are disabled, the battery light is slowly flashing, and unit is charging its battery.

If the cable to the insertion device is plugged, the unit operates in its normal simulation and bio-feedback mode.

5.0 Battery

Two AA batteries
Battery pack size – 1.75" x 1.145" x 0.57".
Battery capacity – 1200mAh
Battery voltage – 2.4V
Charge current – 0.235A
Discharge current – (b)(4)
Charging time – 5 hours
Charging frequency – defined by the user

6.0 Insertion Unit

6.1 Features

InTone insertion unit is inflatable to provide a comfortable fit for each individual.

6.2 Dimensions

5" long

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0.5" diameter, uninflated

6.3 Weight
12 oz

6.4 Description of Size and Type of Electrodes
The electrodes are made of rigid semi-tubular (b)(4) stainless steel, each electrode approximately 2" x 0.75".

6.5 Stimulation Characteristics

6.5.1 Urge Incontinence
Treatment Durations: (b)(4)
Frequency:
Pulse Width:
On Time:
Off Time:
Maximum Intensity:

6.5.2 Stress Incontinence
Treatment Durations: (b)(4)
Frequency:
Pulse Width:
On Time:
Off Time:
Maximum Intensity:

6.5.3 Mixed Incontinence
Treatment Durations: (b)(4)
Frequency:
Pulse Width:
On Time:
Off Time:
Maximum Intensity:

6.5 Biofeedback parameters

Air Pressure: (b)(4)
Response Time:

7.0 Material Specs and Molding Processes

7.1 Control Unit
The hand-held device will be molded from (b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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7.2 Insertion Unit

The insertion device is molded out of (b)(4) The molded silicone has a shelf-life of 18 months. To allow for distribution and user handling, a one year expiration date is used.

Where adhesive is required to secure the silicone cover, (b)(4) be used.

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EXHIBIT 3

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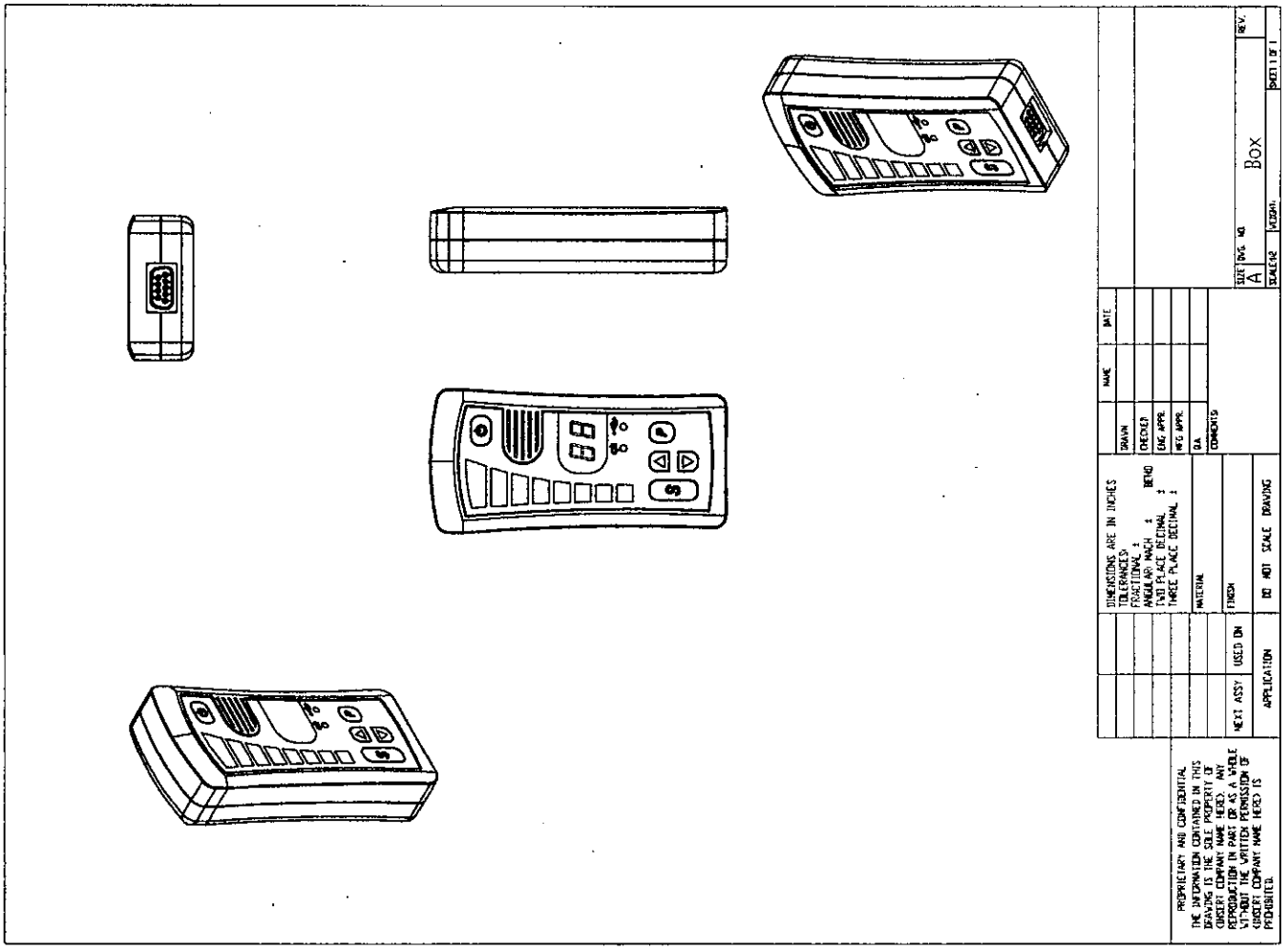

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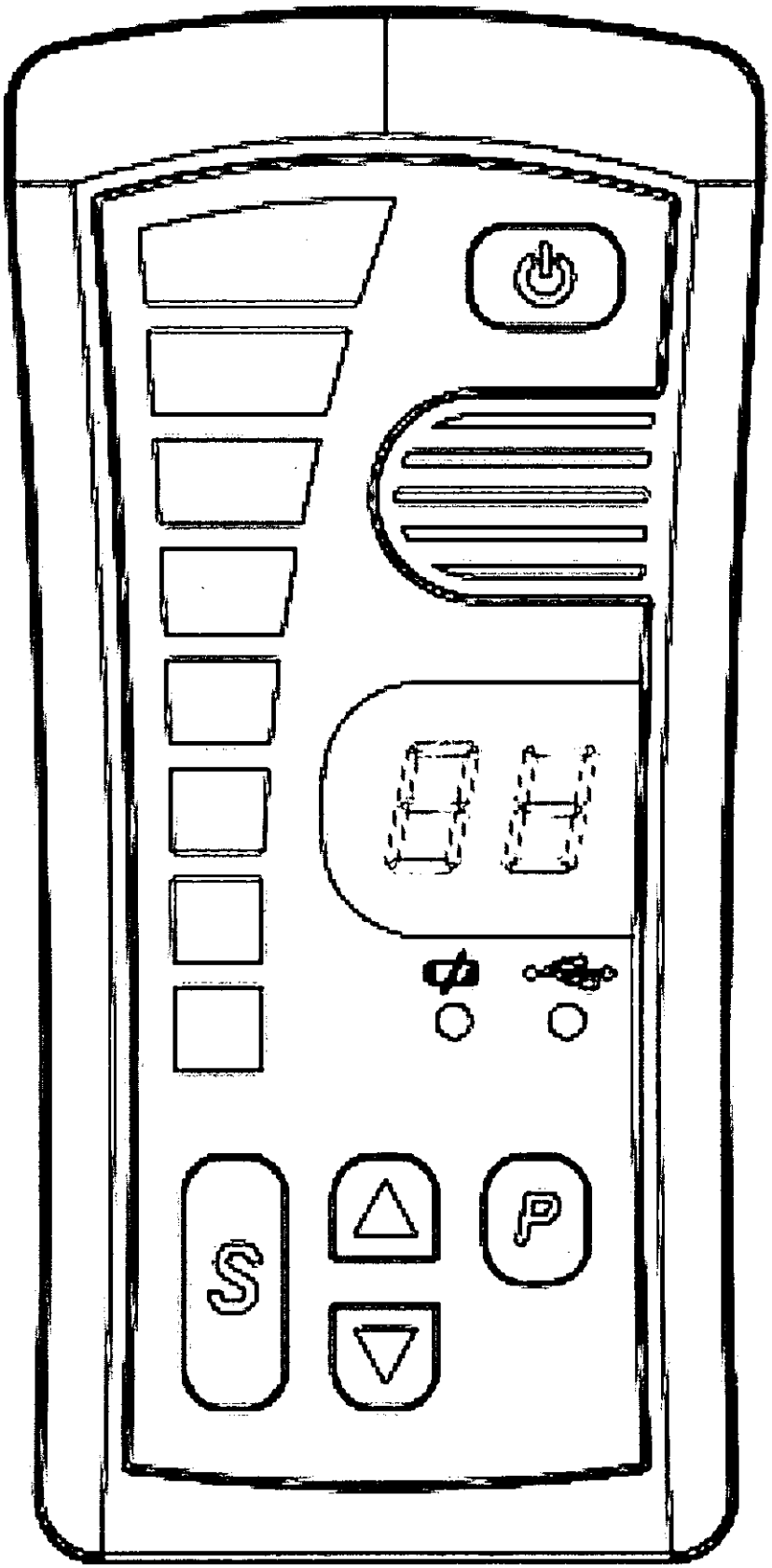

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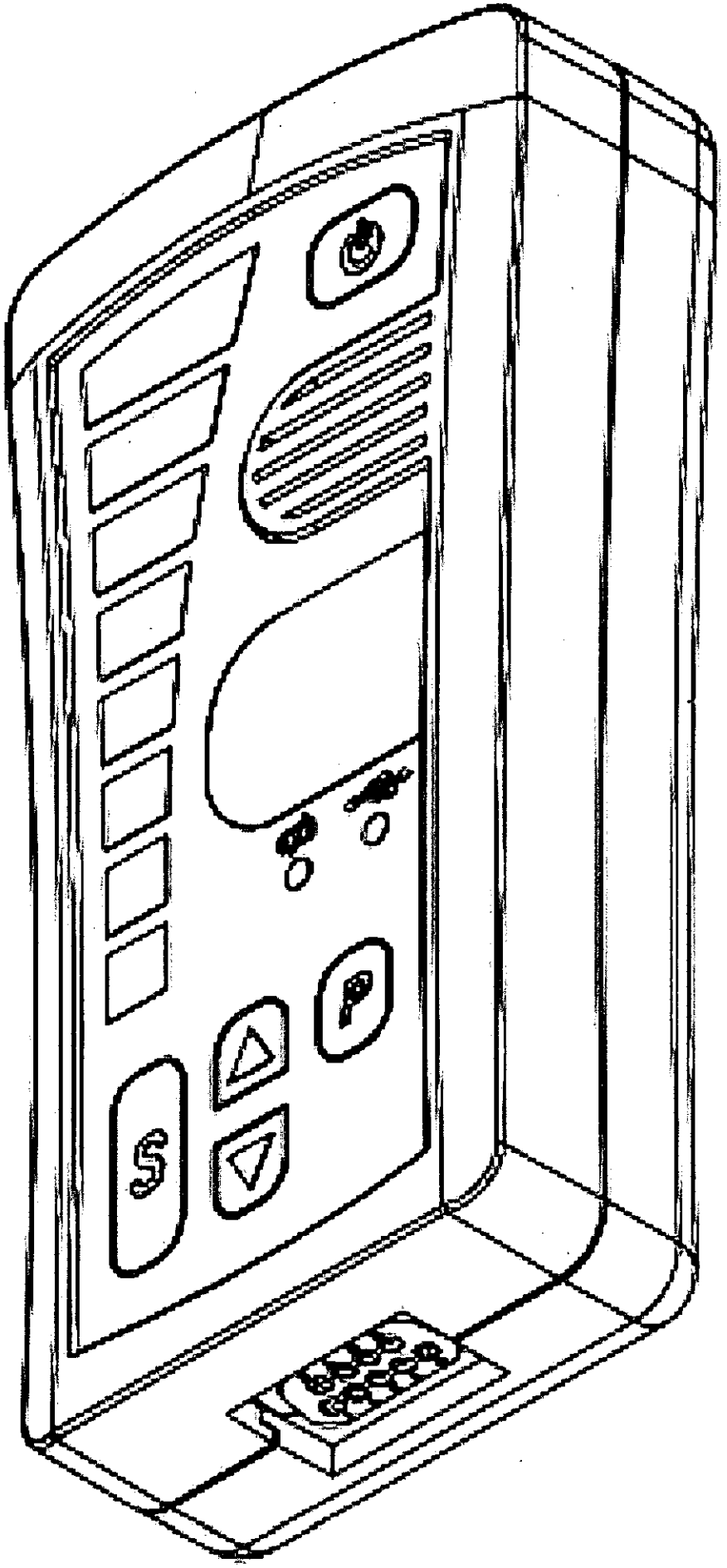

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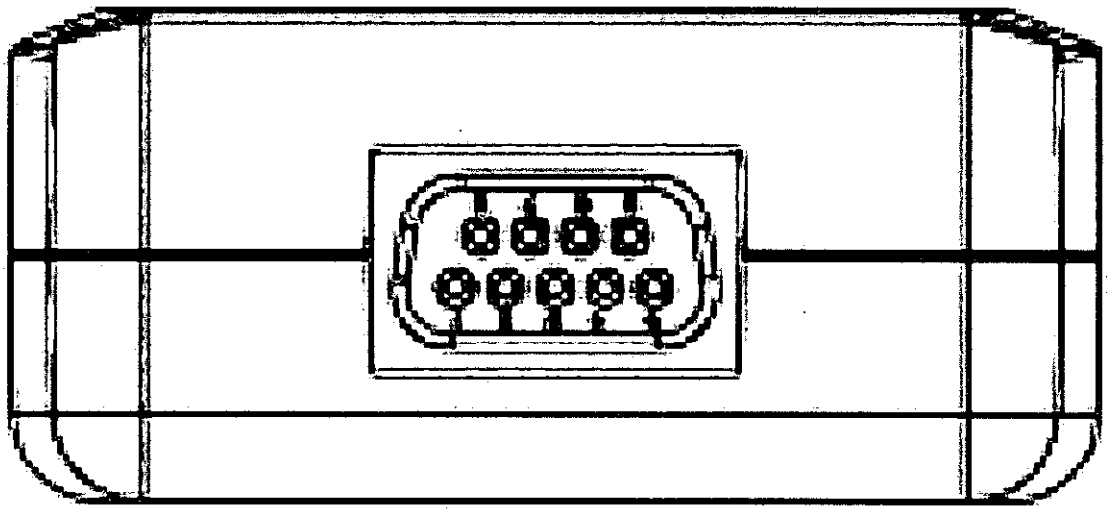

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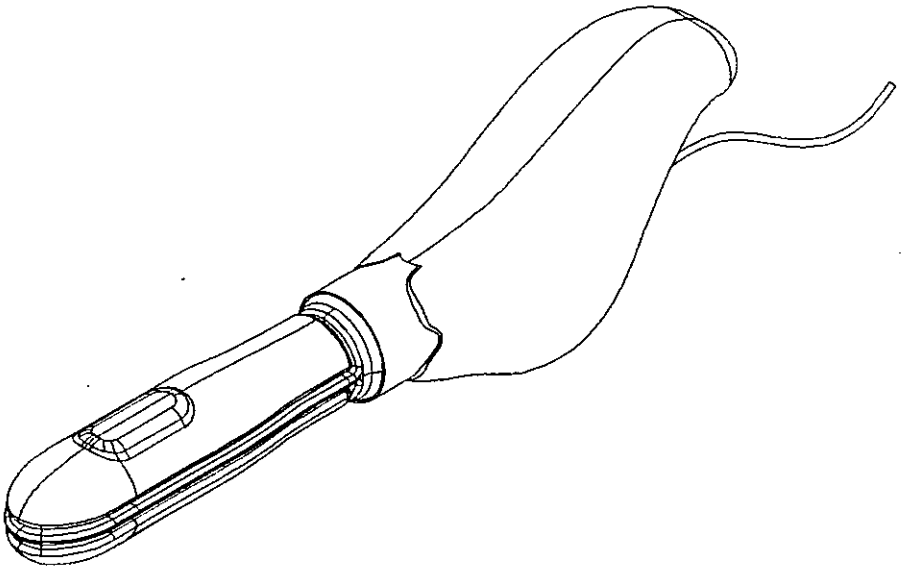

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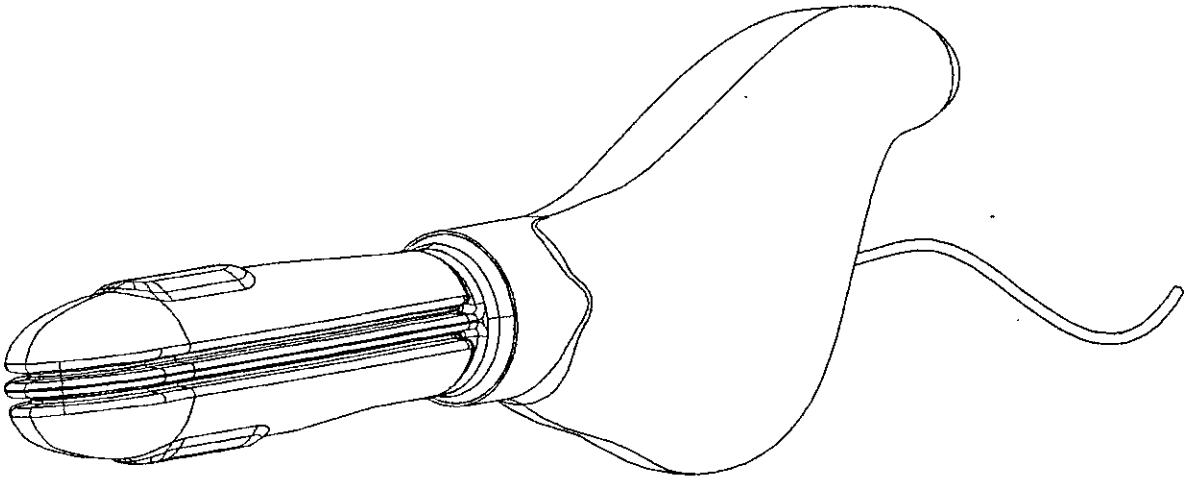

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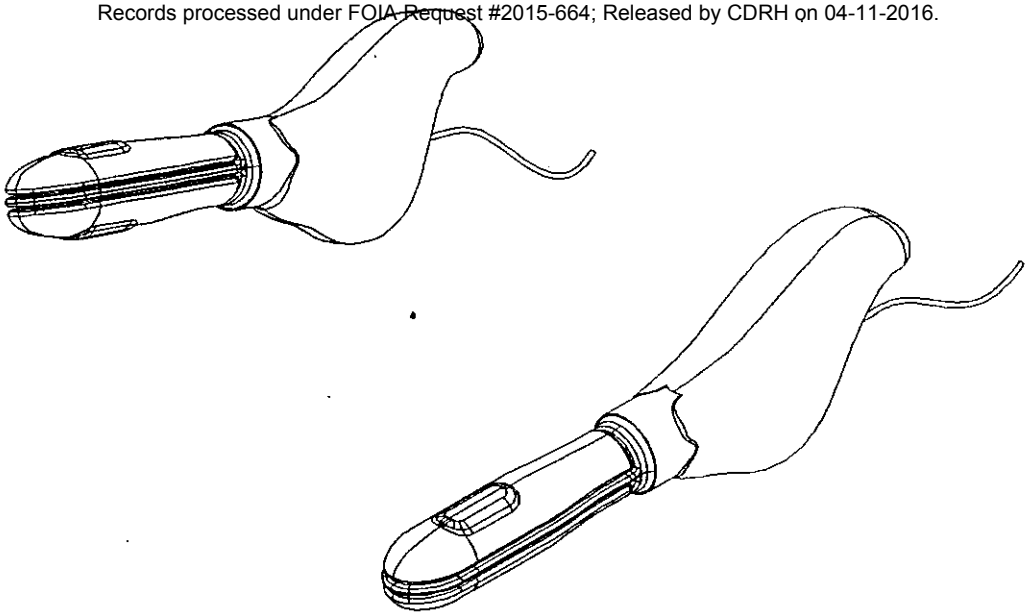

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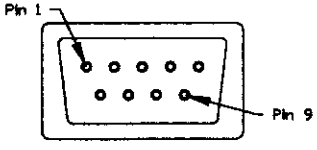
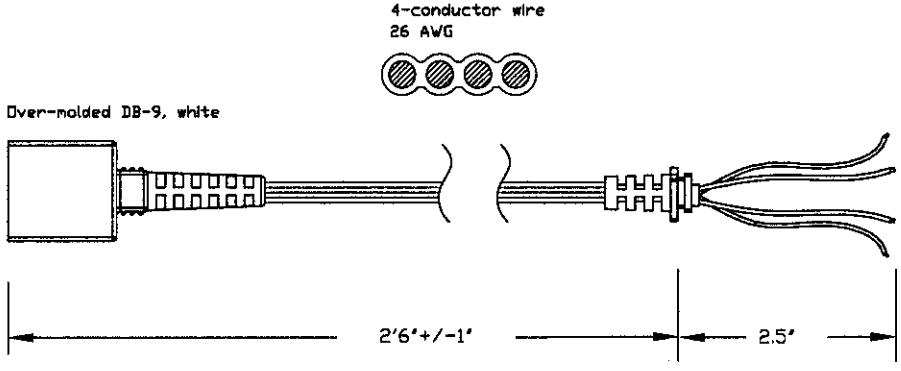
DWG NO: InTone 102	
REV.	DESCRIPTION
A	Initial Release 2-28-11



DB-9 Male, view from the front



Pin 1 - N/C
Pin 2 - N/C
Pin 3 - N/C
Pin 4 - wire 4
Pin 5 - N/C
Pin 6 - N/C
Pin 7 - wire 1
Pin 8 - wire 2
Pin 9 - wire 3

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DRN BY: ESP		ENG:
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FINISH: N/A		
TITLE: Sensor Cable	DWG NO: InTone 102	REV. A
	SHT. 1 OF 1	

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Software Specification:
InControl InTone

Date	Rev	Author	Section(s) changed description
01/15/11	A	E Palatnik	Initial release.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.0 Introduction

1.1 Purpose

The purpose of this document is to define the system requirements of the developed product.

1.2 Scope

This document includes the materials, power, controller, and other design decisions for the InTone product.

2.0 Level of Concern

If the software in the InTone were to fail it could cause a non-serious injury to a patient, therefore the software is considered to present a moderate level of concern.

3.0 Description

The InTone is a stand-alone device, controlled by two microcontrollers. One PIC in the insertion unit; another TI MSP in the hand-held device. Two microcontroller communicate and provide constant mutual verification. Should one of them stop communicating, the stimulation session would be terminated immediately.

The embedded software loaded into the PIC microcontroller controls the following functions of the device:

- Creating stimulus patterns
- Measuring pressure
- Communication

The embedded software loaded into the MSP microcontroller controls the following functions of the device:

- User interface
- Voice prompts generation
- Communication with the PC
- Communication with PIC
- Data storage and trending
- Power off function
- Battery charging

Software is written in C language. The Software is written and compiled in a PC environment, but then downloaded and tested on the InTone unit. An in-circuit J-TAG loader is used to program the microcontroller FLASH memory. The device does not contain an operating system nor does it utilized any off-the-shelf software.

4.0 Device Hazard Analysis

See InTone Risk Analysis document

5.0 Software Requirements Specifications

See InTone SRS document

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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6.0 Hardware Requirements
See InTone SRS document

7.0 Programming Language Requirements
See InTone SRS document

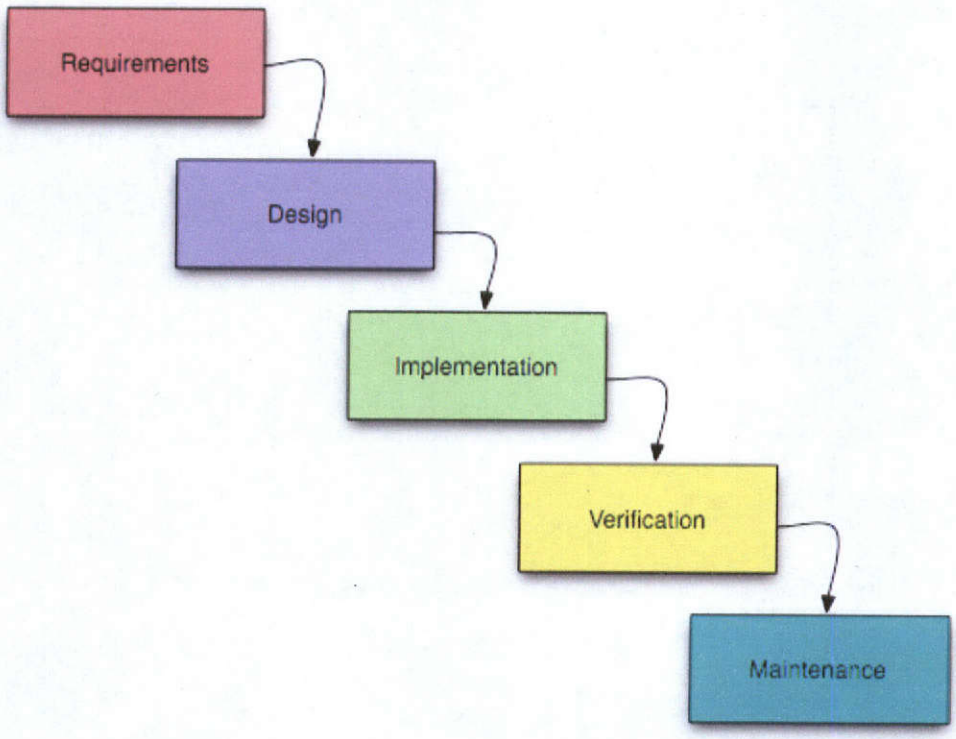
8.0 Interface Requirements
See InTone SRS document

9.0 Software Performance and Functional Requirements
See InTone SDS document

10.0 Architecture Design Chart
See InTone Flow Diagram and Thread of Control document

11.0 Traceability Analysis
See InTone Traceability Matrix

12.0 Software Development Environment Description
The waterfall software development model is used for the development and maintenance of the InTone's software.



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The software is revision controlled. Any changes to the software will increase the software revision. The specification and design documents and test protocols will be updated to reflect the changes. A regression analysis will be performed to identify the parts of the software that are affected by the changes and those sections will be validated before placing the software into use.

13.0 Verification and Validation Documentation

Software Validation
Electromagnetic Compatibility
Bench Testing
Clinical Testing
Comparison Testing
All testing passed the requirements as stated in the protocols for the test documents.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8718

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InTone User Manual

PN: xxxxxx-B | **Draft Date: 3/12/11**

Users must read this Guide before using the Product

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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This chapter provides instructions for using the system. It includes both therapeutic treatment and biofeedback use instructions. 17

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[illegible] ..... [illegible]

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Preface

Overview

The InTone device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

This guide provides procedures for setting up and using the InControl InTone incontinence device.

Intended Use

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary

For more information about InControl products, go to www.xxxxx.com. For technical support, questions or comments about documentation, contact (800) xxx-xxxx or (262) xxx-xxxx.

Product Warranty

Product Warranty information can be found with your original system proposal and invoice.

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Symbols Used

The following symbols are used in this manual or on the product.

Attention! Please follow the instructions in the User Manual.

Type BF applied part. Internally powered.

The Control Unit can be damaged by ElectroStatic Discharge. The pins of the Control Unit connectors should not be touched unless ESD precautions are taken.

Warnings and Notes

Warnings and Notes are used in this manual. A Warning is used when failure to follow the instructions may result in injury or device damage. Notes are used to provide clarification or advice. The following Warnings are used in this manual.

⚠ **Caution:** Federal law restricts this device to sale by or on the order of a physician.

⚠ **Warning:** Electro-Stimulation is one part of a total therapy program. It is meant to be used in conjunction with counseling and feedback. Do no undertake therapy without the advice of a care provider.

⚠ **Warning:** Do Not use a charger other than supplied by InControl LLC. The incorrect charger can result in damage to the unit.

⚠ **Warning:** Read all instructions prior to use. Failure to follow these directions may result in personal injury or damage to the equipment.

⚠ **Warning:** Only use approved antiseptics that leave no residue.

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⚠ **Warning:** The InControl system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

⚠ **Warning:** Therapy is defined on an individual basis, dependant on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

⚠ **Warning:** Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

⚠ **Warning:** Do not operate device within 10 feet of operating televisions, arc welders, radio thermal treatment equipment, X-ray machines, MRI machines, or any other equipment that produces magnetic fields, sparks, or radio transmissions. RF communications equipment can affect this device

⚠ **Warning:** The reusable Insertion Unit presents a potential risk of cross-infection, particularly if used on broken skin.

⚠ **Warning:** Explosion hazard: Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen enriched environments.

⚠ **Warning:** Do not use with electrodes other than those specified by InControl Medical.

⚠ **Warning:** Take care in arranging patient and cables to avoid risk of entanglement, tripping, or strangulation.

⚠ **Warning:** Use of any equipment should be discontinued upon any signs of treatment related stress or discomfort.

⚠ **Warning:** The device should not be used while walking, driving, operating machinery, or any other activity in which involuntary muscle contraction may put the user at risk.

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⚠ **Warning:** Do not use the device while in the bath, swimming, or otherwise submerged.

⚠ **Warning:** The long-term effects of chronic electrical stimulation are unknown.

⚠ **Caution:** Caution should be used for patients with suspected or diagnosed heart problems.

⚠ **Caution:** Caution should be used for patients with suspected or diagnosed epilepsy.

⚠ **Caution:** Caution should be used when there is a tendency to hemorrhage following acute trauma or fracture.

⚠ **Caution:** Electrode placement and stimulation settings should be based on the guidance of the prescribing praticioner.

⚠ **Caution:** Patients with a total/partial prolapse of the uterus/vagina must be stimulated with extreme caution.

⚠ **Caution:** Patients with urethritis must be treated before commencing stimulation.

⚠ **Caution:** Worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they are applied.

⚠ **Caution:** Adverse reactions have been reported. Skin irritations and burns beneath the electrodes have been reported with the use of powered stimulators.

Contraindications

- This device is not intended for diagnostic purposes or critical patient monitoring.
- The device is not defibrillator proof.
- The device should not be used on patients with cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance.
- Do not use if patient has symptoms of an active urinary tract infection.
- Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms.

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- Do not use if patient has undiagnosed pain.
- Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation.
- Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings.
- Do not use if patient is currently pregnant or attempting to get pregnant.
- Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit.
- Do not use if the patient has irregular menstrual bleeding cycles.
- Do not use if the patient has a history or symptoms of urinary retention.
- Do not use if the patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra).
- Do not use if the patient has overflow incontinence caused by evacuation problems.
- Do not use if the patient has severe urine retention in the upper urethras.
- Do not use if the patient has complete peripheral denervation of the pelvic floor.
- Do not use if the patient has an intestinal clamp.

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Chapter 1

Equipment Overview

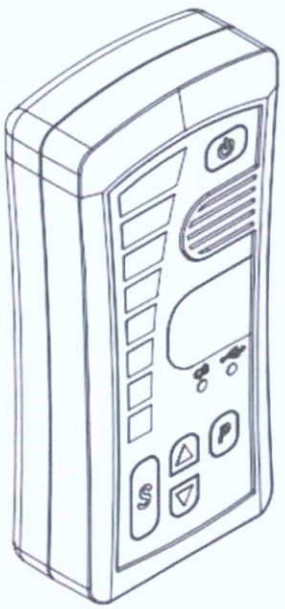
This chapter provides an overview of the equipment included in the InControl InTone System.

Control Unit

The Control Unit is a display device used to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

The Control Unit has the following features and functions.

- select and lock in the correct amount of current necessary to stimulate pelvic floor contraction
- provide biofeedback program to measure and record pressure generated by patient pelvic floor exercises
- display contraction force (as pressure)
- allow downloading of data to personal computer through custom USB cable or flash drive and allow graphing in commercially available software (e.g. Excel)
- provide single button stop to discontinue electrical pulses if necessary
- ability to clean with common, commercially available cleaners



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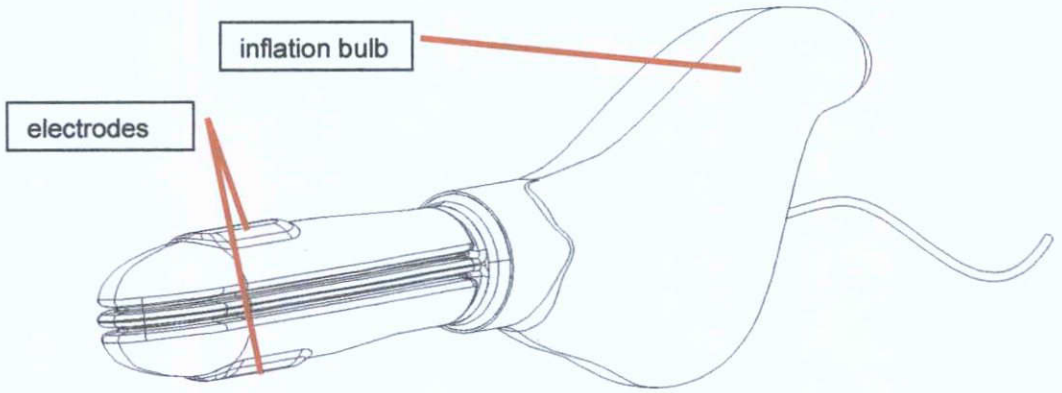
Insertion Unit

The Insertion Unit is an inflatable balloon for intra-vaginal use. The unit has a semi-rigid core to allow insertion. The core also carries inflation air and electrical conductors. The core is surrounded by an inflatable balloon that carries the electrodes. The insertion unit connects to the control unit through a flexible connection.

The Insertion Unit has the following features and functions.

- for self or clinician insertion in the patient's vagina,
- provide manual inflation of balloon to fill the vagina to a comfortable level,
- when inflated, provide full contact of electrodes to vaginal wall (to prevent arcing),
- provide programmed electro-stimulation of pelvic floor muscles,
- ability to clean with common, commercially available cleaners.



PC Cable

The PC Cable allows the Control Unit to be connected to the USB port of a personal computer. This connection recharges the Control Unit battery and allows the transfer of data to the PC. The unit cannot be used while it is being charged.

⚠ **Warning:** Do Not attempt to use a charger other than supplied by InControl LLC. The incorrect charger can result in damage to the unit.

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Chapter 2

Setting up the Components

This chapter provides procedures on how to set up the InControl units for use.

The components in the InControl system ship in kits, consisting of assembled units and parts. These kits should be kept together until you are ready to use them.

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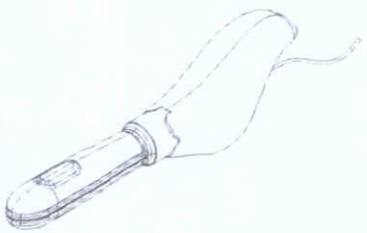
⚠ **Caution:** Federal law restricts this device to sale by or on the order of a physician.

⚠ **Warning:** Electro-Stimulation is one part of a total therapy program. It is meant to be used in conjunction with counseling and feedback. Do not undertake therapy without the advice of a care provider.

⚠ **Caution:** Worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they are applied.

Connecting the Insertion Unit to the Control Unit



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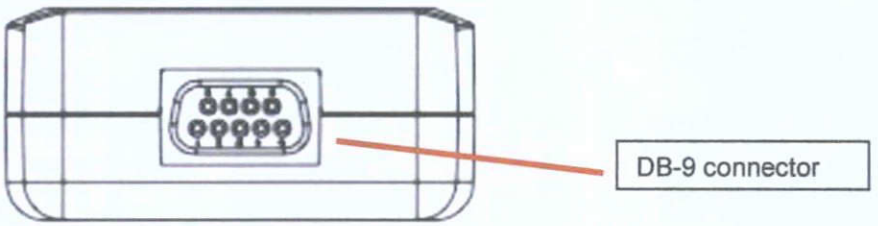
1. Align the connectors of the Insertion and Control Units. The DB-9 connector is on the bottom of the control unit.



2. Gently press the connector into place.

Disconnecting the Insertion Unit from the Control Unit

1. Gently pull the DB-9 connectors apart.

Tip: Do not touch the conductors in the connector. This could cause damage to the pins or control unit.

Charging the Battery

The battery should be charged when the low battery indicator is shown, or if charging will not be available for a time.

1. Disconnect the Insertion Unit.
2. Connect the DB-9 connector of the USB cable to the Control Unit.
3. Connect the USB connector to your personal computer.
4. When charging is complete, unplug the cable from the Control Unit.

Tip: Ensure battery is charged prior to use. Control unit cannot be used when the USB cable is connected.

Cleaning the Insertion Unit

Following use, the Insertion Unit should be cleaned.

1. Turn **off** the Control Unit.
2. Disconnect the Insertion Unit from the Control Unit.
3. Wash the outside of the Insertion Unit with warm soapy water. Do not soak.
4. Rinse thoroughly.

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Tip: Do not attempt to fill the Insertion Unit with water or any other liquid. If water enters the Unit, thoroughly dry prior to re-use.

5. The outside of the Insertion Unit may be wiped with alcohol or other antiseptic in accordance with the care provider's infection control procedures.

Warning: Only use approved antiseptics that leave no residue.

6. Allow Unit to air dry.
7. The control unit can be wiped with alcohol or a damp cloth. Do not immerse or spray.

Approved Antiseptics

The following cleaners can be used with the InControl Insertion Unit. This list is based on material compatibility.

- isopropyl alcohol
- hydrogen peroxide, <10%
- sodium hypochlorite, <10%

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Chapter 3

Programming the System

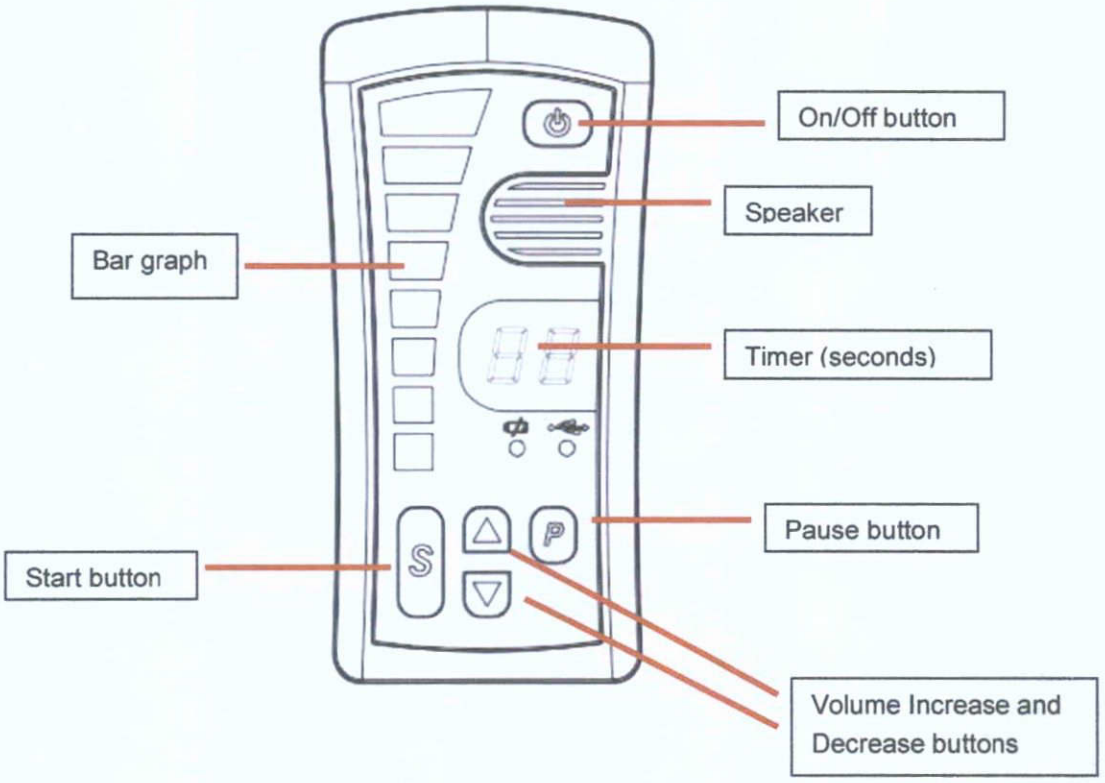
Introduction

This chapter provides procedures on how to program the InControl Control Unit. The system must be programmed before it is used by patients. It is programmed for one patient at a time.

⚠ **Warning:** The System menus do not time out. You must manually exit them when finished.

Program Selection

The front panel of the Control Unit provides information on the status of the system and its operation.



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1. TO BE UPDATED in rev C
2. Turn **on** power.
3. Select **program therapy** from the menu. If the key is not in the device, the display will remain at the main menu.
4. Select treatment type from the menu.

Changing Settings

5. The current settings will be displayed.
6. Pressing the up arrow key (⇑) or down arrow (⇓) increases of decreases the intensity.
7. Adjust each setting as desired for the intended patient.
8. Press **save**. The display will return to the main menu. The unit is ready to use for therapy.

Clearing Programs

Settings can be reverted to factory default settings to provide a consistent starting point for programming. All default settings are the lowest in their range.

1. TO BE UPDATED in rev C.
2. Turn **on** power.
3. Insert key into the side of the unit. Programming cannot be changed without the key.
4. Select **clear therapy programs** from the menu. If the key is not in the device, the display will remain at the main menu.
5. The device will display a question asking you to confirm that you want to erase programmed therapy settings and revert to factory default settings. Press **yes** if you wish to revert all settings to factory default. Press no if you do not.
6. The display will return to the main menu.

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Chapter 4

Using the System

This chapter provides instructions for using the system. It includes both therapeutic treatment and biofeedback use instructions.

⚠ **Warning:** The InControl system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

Electro-stimulation and biofeedback are treatments used to train and strengthen the pelvic floor muscles in a controlled manner. Electro-stimulation is used to strengthen muscles. In particular, it improves the ability of muscles to hold a contraction of an extended period of time. It is a treatment for urinary incontinence in conjunction with coaching and biofeedback. During a session, electrical impulses are delivered to specific muscles to stimulate their contraction. This contraction exercises the muscles and also helps the patient recognize which muscles to condition.

Biofeedback provides audible and visual confirmation of the patient's voluntary muscle contractions.

⚠ **Warning:** Therapy is defined on an individual basis, dependant on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

Insertion Unit Positioning

A quiet, private place is recommended to aid relaxation.

The Control Unit should be placed on a table or other solid, flat surface.

1. The patient lies on her back, relaxed with the upper body slightly elevated. The legs should be upright and tilted out slightly. The legs may be supported to aid relaxation.
2. A small amount of water-based lubricant may be used on the Insertion Unit.
3. Gently insert the Insertion Unit into the vagina. Ensure the stimulation pads are fully within the vagina.
4. Use the hand pump bulb to inflate the Insertion Unit. The Probe should be snug, but not uncomfortable. The release valve can be used to deflate the Unit.

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Therapeutic Treatment

The front panel of the Control Unit provides information on the status of the system and its operation.

1. Press the POWER button.
2. Press the START button.
3. TO BE UPDATED in rev C.

Tip: Treatment can be stopped at any time by pressing the PAUSE button. The interrupted sessions data is saved.

Changing Settings During Therapeutic Treatment

It may be desired to change settings while the patient is receiving therapy. This is particularly true during the first and follow-up office sessions.

1. Turn off power by pressing the POWER button.
2. Disconnect the insertion unit. Programming cannot be changed with the insertion unit connected.
3. TO BE UPDATED in rev C
4.

Retrieving Treatment Data

The front panel of the Control Unit provides information on the status of the system and its operation.

1. TO BE UPDATED in rev C.
2. .
3. .
4. .
5. .

Biofeedback Session

The front panel of the Control Unit provides information on the status of the system and its operation. 557

1. Insert the insertion unit, as described above.

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2. Press the POWER button.
3. The patient voluntarily contracts her vaginal muscles as instructed. The resulting pressure is displayed on the screen. The device also provides audible feedback.
4. Press the POWER button.

Retrieving Biofeedback Data

The front panel of the Control Unit provides information on the status of the system and its operation.

1. TO BE REVISED in rev C
2. Connect control unit to PC using the cable.
3. .
4. .
5. .
6. The most recent session is displayed on the screen along with the date and time the data was created.

Downloading Saved Data

The front panel of the Control Unit provides information on the status of the system and its operation.

1. TO BE REVISED in rev C
2. Connect control unit to PC using the cable.
3. .
4. .
5. .
6. .
7. .
8. .

Erasing Saved Data

The front panel of the Control Unit provides information on the status of the system and its operation.

1. TO BE REVISED in rev C
2. .
3. .

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Chapter 5

Testing the System

This chapter provides procedures to test the InControl system prior to use. It is important to test the overall functionality of each component prior to putting the system into service. Additionally, it is important to periodically verify the continuing proper operation of each component.

Tip: You should test all of the system components prior to use to verify proper operation.

Warning: Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

1. Visually inspect the Insertion Unit, Control Unit, and connectors for damage.
2. Connect the Insertion Unit to the Control Unit.
3. Turn on the Control Unit.
4. An error will be displayed if the connection is not complete.

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Chapter 6

Servicing and Troubleshooting the System

This chapter provides procedures on how to service and troubleshoot the InControl System. If you have consistent issues with the system, please contact InControl Technical Support at 1-800-xxx-xxxx.

Troubleshooting the Insertion and Control Unit

Prior to use or any troubleshooting,

1. Verify that the Control Unit battery is charged. If the low battery indicator is shown, recharge the battery.
2. The Control Unit will not function when the PC cable is connected.
3. Inspect the Insertion Unit for damage. If the silicon covering or any cables appear damaged, the Unit must be replaced.
4. Disconnect the Insertion Unit from the Control Unit. Inspect the connectors for damage. If the pins are not straight, or otherwise appear damaged, the Unit must be replaced.
5. Carefully reconnect the Insertion Unit to the Control Unit.
6. If the assembled Units still do not function correctly, contact InControl Technical Support.

Patient cannot feel pelvic contractions

1. Check that InControl control unit is on and the batteries are charged.
2. Have patient manually reposition the insertion unit with her fingertip until pelvic contractions are perceivable
3. Have patient use a water-based lubricant prior to insertion.

Patient complains of painful insertion of the unit

1. Have patient use a water-based lubricant prior to insertion.
2. Check patient for vaginal irritation or infection.

Patient complains of pain in rectum with pelvic contractions

1. Tell patient not to insert the unit as deep into the vagina.
2. Instruct patient not to dangle her legs or feet during a session: lie in a reclined position with both feet evenly placed in front of her.

Patient stops feeling contractions during a session

1. Have patient manually reposition the unit with her fingertip until pelvic contractions are perceivable again.
2. Instruct patient not to stand or move about during a session.
3. Check that device is on and the batteries are charged.

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Patient complains of painful pelvic contractions

1. Have patient manually reposition the unit with her fingertip until pelvic contractions are more comfortable.
2. Verify settings. Adjust if necessary.
3. Check patient for vaginal irritation or infection.
4. Consider lower therapy settings.

Replacing an Insertion or Control Unit

Insertion Units and Control Units can be replaced and used interchangeably. Disconnect the Insertion Unit and connect the new Unit as described in Chapter 2.

Replacing a Control Unit Battery

The Control Unit battery pack can be replaced. Use only AA battery packs as designated in the product's specifications. Properly maintaining the batteries' charge will extend life.

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Chapter 7

Specifications

This chapter provides specifications for the InControl InTone system components. The InTone system is a class II medical device with internal power. It must only be used indoors.

Control Unit

Size:	4.83" x 2.4" x 1.1"
Weight:	5 oz
Enclosure:	(b) [redacted]
Battery:	two AA batteries Battery pack size – 1.75" x 1.145" x 0.57" Battery capacity – 1200mAh Battery voltage – 2.4V Charge current – 0.235A Discharge current – (b)(4) Charging time – 5 hours, charge complete will be displayed typically 6 to 8 hours use between charges, user determines
Low Battery:	shown on display approximately 15 minutes before unit shuts down
PC interface:	USB, 1.1 and 2.0 compatible
Waveform:	(b)(4) [redacted]

Program for Urge Incontinence Treatments:

Treatment Duration:	(b)(4) [redacted]
Frequency:	
Pulse Width:	
On Time:	
Off Time:	
Maximum Intensity:	

Program for Stress Incontinence Treatments:

Treatment Duration:	(b)(4) [redacted]
Frequency:	
Pulse Width:	
On Time:	
Off Time:	
Maximum Intensity:	

Program for Mixed Incontinence Treatments:

Treatment Duration:	(b)(4) [redacted]
Frequency:	
Pulse Width:	
On Time:	

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Off Time: (b)(4)
Maximum Intensity:

Biofeedback: (b)(4)
Air Pressure:
Response Time:

Insertion Unit

Single Patient Use

Size:	5 inches long 0.5 inch diameter, uninflated up to 3 inches diameter, inflated
Method of Inflation:	Hand pump bulb, with release knob
Outer Material:	silicone
Electrode Size:	two stainless steel, rigid, semi-tubular, each approximately 2" x 0.75"
Shelf Life:	one year

Computer Connection

via USB 2.0, Type A plug

AC Charger

via USB, custom cable with D-type 9-pin connector

Input Voltage:	110-120 VAC
Input Frequency:	60Hz
Input Current Draw:	up to 100 mA
Output:	4.4 to 5.25 VDC

Environmental Conditions

Operating Conditions:

Temperature:	32 to 130F
Relative Humidity:	10% - 90%, non-condensing

Storage and Transportation Conditions:

Temperature:	-30 to 150F
Relative Humidity:	10% to 90%, non-condensing

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EXHIBIT 6

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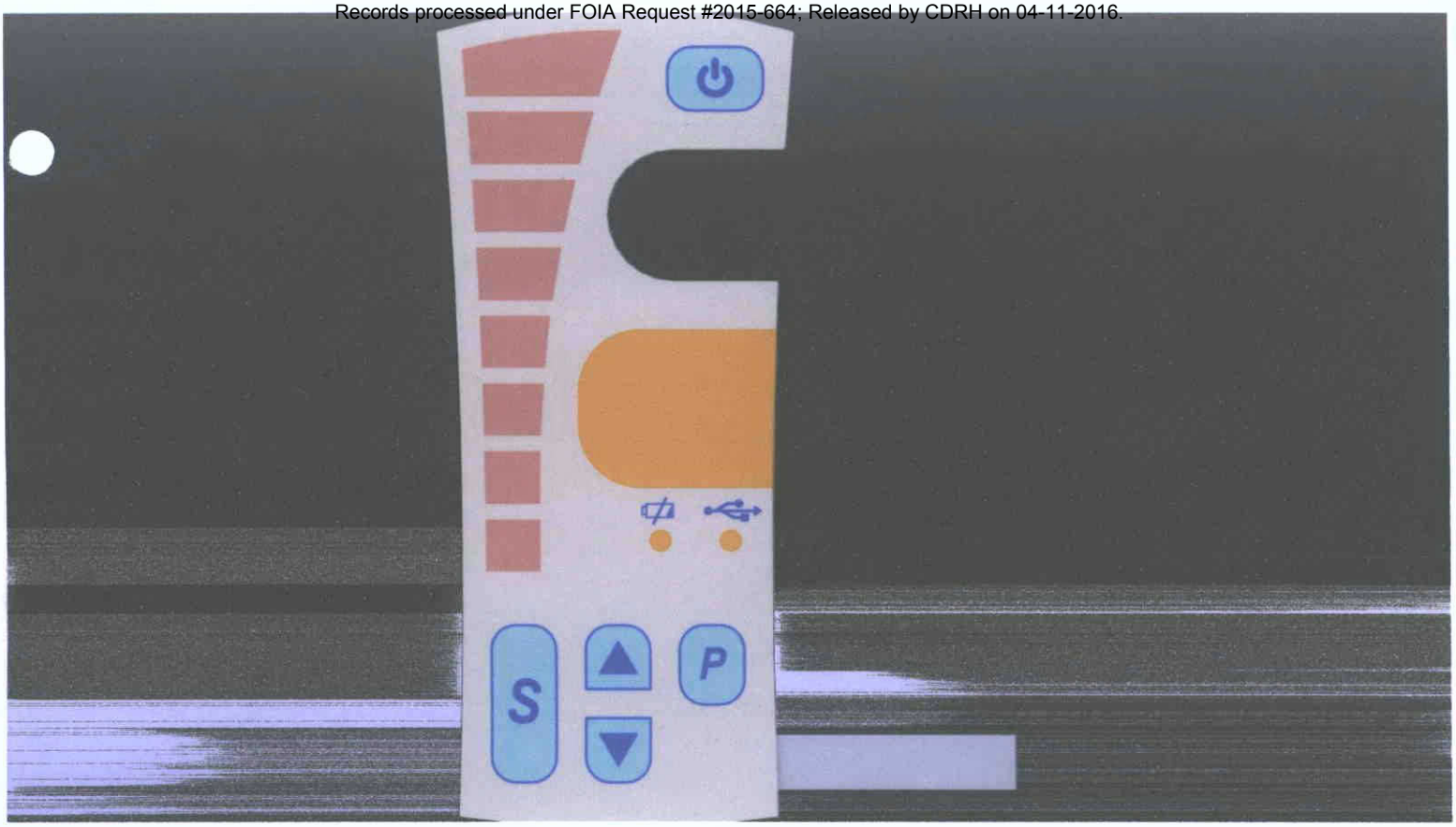

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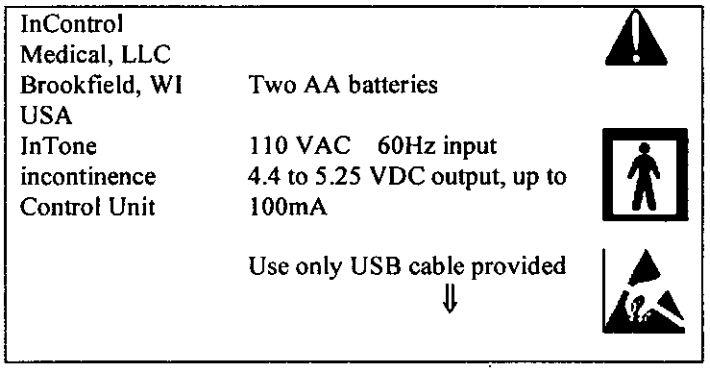

Control Unit back label

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Software Validation Report

A record of the testing and results for the InTone system.

Software Versions:
Intone: **1.00**
Clinician PC Tools: **1.00**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Revision History

Rev	Date	Who Changed	Description
1	2011-08-01	Eric Wurtz	Document Created

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Purpose

This test procedure was created and executed to test the fundamental and critical operation of the InTone system. The InTone system software consists of a PC application the clinician will use to interact with the InTone handset, the InTone handset firmware, and the insertion probe firmware. Except in the case of setting up the correct stimulation level on the probe, each of the three configurations (charging the handset, handset connected to probe, handset connected to PC) was tested independently.

Terms used and defined

The following is a listing of some of the terminology used in this report and their respective definitions:

Stimulation level or amplitude:

> The power level of electrical stimulation used during the stimulation portion of a session.

Handset or device:

> The actual InTone module which may be connected to an insertion probe, PC using USB, or battery charger.

Session data or log entry:

> The data recorded on the InTone which contains patient performance metrics of a session.

Probe or Insertion Probe:

> The actual module which a patient inserts. This will provide stimulation as well as measure a patients performance.

Charge state:

> Either in a charging mode or trickle charge mode when the battery is full.

Pressure waveform:

> The probe streams the current pressure exerted on it to the handset. This stream of data is a pressure waveform.

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Setup level:

Is a temporary stimulation level which is only used during the setup of the InTone under the guidance of a clinician.

Handset Connected to PC

The system configuration of the handset being connected to the PC was tested as follows:

**Proper error handling of opening an invalid or not ready serial port on the PC application.

Procedure:

Open a COM port in a separate application first and then attempt to open the port in the application under test.

Expected Results:

A message box popping up informing the user the open attempt failed.

Results Obtained:

A message box popped up informing the user of the failed operation, and the program continued to execute without error.

**Proper handling of the PC application requesting the status of the handset.

Procedure:

Using the PC application with an open valid serial port connection to the device, request the handsets current status.

Expected Results:

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All the values including: the current date and time, software version, audio version, stimulation level, date and time of the last log entry, and the amount of log entries on the device should populate correctly on the main form of the PC application.

Results Obtained:

All the data correctly populated the correct location on the form.

**Proper handling of the PC application setting the current date and time.

Procedure:

Using the PC application with an open valid serial port connection to the device, select the option to set the date and time; disconnect the handset from the PC and power it down; wait amount of time; connect the handset back up to the PC; and request the status to receive the data and time from the handset.

Expected Results:

The date and time will be retrieved from the device and be very close to what the PC is currently set with.

Results Obtained:

The date and time was accurately, stored, maintained, and retrieved.

**Proper reading of log data from the handset to the PC application.

Procedure:

Using the PC application with an open valid serial port connection to the device and using a handset with several sessions of data already recorded on the device; select the option to retrieve the log data from the device.

Expected Results:

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All the log data will be pulled from the device and written to files on the PC.

Results Obtained:

Data for all the stored sessions was properly retrieved from the device and stored to the PC.

**Proper erasing of log data from the handset

Procedure:

Using the PC application with an open valid serial port connection to a handset with several sessions of data already recorded on the device; select the option to erase the log data from the device. Then read the status from the device and make note of the amount of records on the device

Expected Results:

All the log data will be removed from the device and the amount of records will be reported as zero.

Results Obtained:

The log data was properly deleted from the device as evident by the amount of records being reported as zero.

**Proper handling of power when the handset is connected to the PC

Procedure:

Connect the handset to the PC, allowing it to power up, and then remove the PC cable from the handset.

Expected Results:

The device will immediately power down.

Results Obtained:

The device powered down immediately.

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**Proper operation of the USB indicator

Procedure:

Turn on the handset; ensure the USB indicator is off. Then, connect the handset to the PC using a USB cable, and verify the indicator is on.

Expected Results:

The USB indicator will remain off until the handset is connected to the PC using a USB cable.

Results Obtained:

The USB indicator was on whenever and only when the handset was connected to the PC using a USB cable.

Handset connected to Battery Charger

The system configuration of the handset being connected to the battery charger was tested as follows:

**Proper charging of an uncharged or partially charged battery

Procedure:

On multiple units, using the probe, run down the battery of the handsets to varying degrees. Allow some to completely discharge and some to discharge slightly or not at all. Then plug the handsets into chargers.

Expected Results:

The handsets will remain in the charge state relative to the amount that the batteries have been discharged. The handsets which have not been discharged at all will only be in the charge state for a brief period of time before returning to the fully charged state.

Results Obtained:

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The handsets all completed the charge cycle properly with the handsets which were discharged slightly or not at all completing the charge cycle quickly while the handsets which were completely discharged taking a much longer time to charge.

**Proper handling of power when the handset is connected to the charger

Procedure:

Connect the handset to the charger, allowing it to power up, and then remove the charger cable from the handset.

Expected Results:

The device will immediately power down.

Results Obtained:

The device powered down immediately.

Handset connected to Probe

The system configuration of the handset being connected to the insertion probe was tested as follows:

**Proper handling of the software controlled power when the handset is connected to the insertion probe.

Procedure:

Press power when the handset is off to have the device power up. Press power when the handset is on to have the device power down.

Expected Results:

The device will power up and power down correctly.

Results Obtained:

The device powered up and powered down appropriately.

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**Proper handling of low battery.

Procedure:

Run the device continuously until the low battery comes on. Charge the device and unplug from charger, and power up to determine if low battery stays off

Expected Results:

The low battery will eventually come on after continued use. The indicator will turn off after being charged.

Results Obtained:

After much use on a charged handset, the low battery indication turned on. After charging the handset for a while, unplugging, and powering up, the low battery indicator was no longer active.

**Proper handling of the audio volume controls.

Procedure:

Start a patient session and use the up and down arrows to raise and lower the volume.

Expected Results:

The audio volume will raise and lower with the key presses.

Results Obtained:

The audio volume properly changed with the manipulation of the volume control keys.

**Proper handling of a patient session.

Procedure:

a) The handset will be connected to the simulator and a session started.

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b) The simulator will be used to simulate the insertion and contractions of the patient, generating a simulated pressure waveform, along with required stimulation data.

d) The simulator will display the requested stimulation state, stimulation amplitude, and simulated pressure to verify correct operation of the handset.

e) A session will be started by pressing the start key once the initial power on prompts are completed. While the session is occurring, the prompts and activities of the handset will be compared to the session script. Every part of the session scrip will be verified to have been executed by the handset in the correct order

f) After the completion of the session, the handset will be plugged into a PC and the session data retrieved. The session data will be compared against what would be expected from the simulated data.

Expected Results:

Every part of the patient session script will be properly executed. The session data will be properly retrieved by the PC and contain the proper values which reflect the pressure values sent by the simulator.

Results Obtained:

Every part of the patient session script was properly executed in the correct order. The session data retrieved from the handset properly represented the data sent by the simulator.

**Proper display of real time pressure on the handset.

Procedure:

Using a simulator, start a patient session. During contractions set the pressure output on the simulator to varying levels and ensure the bar graph depicting the relative pressure changes. A value in each range of the bar graph will be output.

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Expected Results:

The bar graph on the handset will light up the correct amount of bars given an input pressure.

Results Obtained:

Starting with the lowest pressure and going up to the end of the graph, the bar graph would increase by one level when the simulated pressure was set to a value in the range represented by the next higher block.

The bar graph remained fully lit when a simulated pressure above the pressure represented by the top bar was sent by the simulator; and remained off when a simulated pressure below the pressure represented by the lowest bar was sent by the simulator.

**Proper capturing and recording of session data

Procedure:

Using a simulator, start a patient session. Set the simulator to a specific pressure to use during each contraction. By using a specific non-varying pressure on each set of averaged contractions, the value can be directly compared to the session data retrieved by the PC.

Expected Results:

The pressure reported in the session data should accurately reflect the simulated pressure sent by the simulator.

Results Obtained:

The average pressures were lower in the log data then what was sent by the simulator. What happens is the handset begins storing and averaging pressure samples from the simulator as soon as the handset prompts the user to begin the contraction. If there is any delay in instructing the simulator to begin the simulated contraction after prompted, a small period of time of low pressure is averaged in. This is probably representative of how a real patient would behave.

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**Proper storage of a significant amount of session data.

Procedure:

First erase any existing log data on the handset. Then, using a simulator, start patient sessions four times an hour for eight hours. Before each start, the simulator will be set to use a different pressure so the session data can be accurately correlated to each session.

Expected Results:

There will be 32 sessions of data on the Handset. For each session, the average pressure for all the measured contractions will be exactly the same as what the simulator was set to before the start of the contraction. It should be noted that this would be the same as if a person was contracting the entire session, with the exact same pressure, not letting up before or after the handset prompts the user to do so; testing the ability of the handset to hold data accurately, but does not reflect how a patient would really behave using the device.

Results Obtained:

The handset had 32 sessions of data on after the eight hour testing. The timestamps were roughly 15 minutes apart for each session, and the pressure values for each session was exactly what the simulator was configured to send for each session.

**Proper handling of pausing and resuming a session

Procedure:

Start a patient session and use the pause feature:

a) outside of a contraction during a prompt
b) outside of a contraction during silence
c) during a contraction
d) during the stimulation

Expected Results:

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When the pause button is pressed and the session pauses, a P will flash while paused on the numeric display. The effect of the pause differs depending on the section paused:

a) The current prompt will immediately pause. When resumed, the prompt will begin playing over again.
b) Silence between prompts and contractions are nothing more then waiting. The wait will immediately be paused. When resumed, the current wait time restart.
c) The recording of the contraction will immediately end, along with any prompt for the contraction. When resumed, the start of the prompt instructing the patient to perform a contraction will start over along with the recording of the contraction
d) The stimulation will immediately turn off, and the timer for the amount of stimulation will pause. When resumed, the time for the stimulation will resume. If a prompt was playing during the stimulation, that prompt will restart.

Results Obtained:

a) The prompt paused as it should. When the pause button was pressed again to resume, the prompt began playing over again.
b) Once paused, the next part of the script did not come. When the session was resumed, after the required amount of time, the prompt came for the next contraction.
c) The countdown immediately stopped on the display, along with the audio prompt. When resumed, the prompt immediately instructed the patient to perform a contraction. If the patient is not ready they can miss the beginning; however, the patient may pause and resume again to restart.
d) The stimulation immediately shut off. The device was paused for one minute and then resumed and the total simulation was one minute longer as it should have been.

Patient Setup

To setup the device for a patient the handset is first connected to a PC, the PC application is then used to instruct to the handset to enter a setup mode. When in a setup mode the bar graph on the device will slowly flash the bar graph between full and off and will not turn off when unplugged form the PC. Powering off the unit at this point will take it out of setup mode. The handset is then

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attached to the probe. The current setup stimulation level is displayed on the numeric display. Pressing the arrows may adjust the level up or down. Pressing S starts the stimulation while pressing P stops. Under the direction of the clinician, the user will turn on the stimulation and adjust the level. The level may be adjusted using the arrow keys until it is at the desired amount. When the stimulation is enabled, the bar graph will flash quickly between full and off. Once at the desired level, the stimulation should be turned off and the handset connected up with the PC again. The PC application is then used to configure the setup level as the stimulation level used during treatment sessions. Once configured, the handset is no longer in setup mode.

The setup of the stimulation level was tested as follows:

**Proper handling of the unit being powered off

Procedure:

Put the handset into setup mode, detach from the PC, and power it down. Then power the handset back up.

Expected Results:

The handset will power back up and not be in setup mode.

Results Obtained:

The handset powered up and was not in setup mode.

**Proper handling of adjusting the setup level outside of the allowable range

Procedure:

Put the handset into setup mode, detach from the PC and connect to a probe. Adjust the setup stimulation level to the minimum value and attempt to decrease more; then adjust the setup stimulation level to the maximum value and attempt to increase more.

Expected Results:

The setup stimulation level will not go below the minimum value or above the maximum value.

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Results Obtained:

The value would not go below the minimum or above the maximum values.

**Proper storage and usage of the stimulation level.

Procedure:

Using the PC application, go though the procedure to configure the handset with a stimulation level two different times using two different levels. After each time the stimulation level is set onto the handset, the handset will be turned off, then on and connected to the PC simulator. A session will be started and the stimulation level will be seen on the simulation application and compared against what was set as the stimulation level.

Expected Results:

The stimulation level seen on the simulation application will match the level set using the clinician's configuration application.

Results Obtained:

The stimulation level shown on the simulation application was the same as what the clinician's configuration application set the handset with.

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K18

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FDA CDRH DMC

AUG 23 2011

Received

InControl Medical, LLC
c/o Mr. Michael J. Leigh
Consultant
12715 Falcon Drive
BROOKFIELD WI 53005

FEB 25 2011

Re: K110179
Trade Name: InControl
Dated: January 17, 2011
Received: January 21, 2011

K 18

Dear Mr. Leigh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

1. We are not aware of a legally marketed predicate device indicated for the improvement of urethral sphincter closure. Please remove this or provide scientific evidence of improvement of urethral sphincter closure.

2. You provide a device description, however some key elements are missing. The configuration of your electrodes is not provided and the biofeedback feature of your device is not explained. Please clarify the description of your device to include, the following for all components of your device:

   a. Device specifications;

   b. any new features of the device;

   c. identification of the relevant dimensions and weight of the device and accessories;

   d. a description of all user controls, displays, and functions;

   e. a description of how the device interconnects with other components;

   f. engineering drawings and/or photographs of the device; and,

   g. length, construction, material, and connections between the stimulator device and the electrodes.

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3. You provide output characteristics of your device. However, it is unclear whether there are separate parameters for the treatment of stress, urge, and mixed urinary incontinence and the biofeedback setting. Please clarify the parameters for all three possible stimulation settings and the biofeedback setting including but not limited to time, maximum phase charge, maximum power density, and net charge. For example, you did not provide the frequency and pulse width for the mixed urinary incontinency setting.

4. You state that your device will use a Li ion battery. However you did not provide enough information about the battery. Please provide the size, capacity, voltage, charge and discharge currents, and estimate how long it will take to recharge the battery and the frequency of charging intervals.

5. On page 7 of 25 in your user manual, you state that the insertion unit is reusable. In order to ensure the safety of your device, please indicate which components of your device are reusable, whether the components are reusable for a single patient only, and if they can be reusable for multiple patients.

6. You state that the outer material of the insertion unit is silicone and that the control unit is made with plastics. However, you do not provide complete information about the materials used in the components of your device (insertion unit, electrodes, control unit). Please provide the following material information for your device:

   a. A table identifying all of the generic materials by chemical name, supplier trade name, supplier name, and device component location;

   b. polymer component formulations (to include generic chemical component names and amounts specified as weight or volume percentages); and,

   c. sufficient processing information to include any processing materials (and amounts) that could impact on biocompatibility.

7. You state that there are no biocompatibility issues for your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility testing. In order to ensure the safety of your device, please provide complete cytotoxicity, sensitization, and irritation or intracutaneous reactivity testing on your final device.

8. You did not provide any electrical testing. In order to ensure the safety and efficacy of your device, please provide electrical testing preferably in accordance with an FDA recognized standard such as IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-1:2000 Medical electrical equipment Part 1-1: General requirements for safety - Safety requirements for medical electrical systems or provide an adequate justification for why this testing is not necessary. Other potentially useful standards are IEC 60601-2-10:2001 Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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and IEC 60601-1-4:2000 Medical electrical equipment Part 1-4: General requirements for safety –Programmable electrical medical systems.

9. You did not provide electromagnetic compatibility testing for your device. In order to review the safety and efficacy of your device please provide electromagnetic compatibility testing preferably in accordance with an FDA recognized standard such as ISO 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).

10. You provided information about the software used in your device. However, your software description was not detailed and some elements were missing. In order to complete the review of your device, please provide software design specifications, a development plan, verification and validation testing, a revision level history, and unresolved anomalies. These elements are necessary for the review of your device and are consistent with the required information necessary for software with a moderate level of concern. For further information please refer to the Guidance for the Content of Premarket Submission for Software contained in Medical Devices located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf and General Principles of Software Validation; Final Guidance for Industry and FDA Staff located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf

11. You provided waveform representations of maximum voltage output but did not provide representations of each stimulation setting (urge, stress, and mixed urinary incontinence). In order to review the safety and efficacy of your device, please provide waveform representations of each of your stimulation settings.

12. You state that there is no expiration date for your device. The vaginal probes and electrodes used with the predicate devices identified in your submission that are similar to your insertion unit have shelf life dates. In order to ensure the safety and efficacy of your device, please provide an expiration date and the results from your device aging data or a justification for why this data is not necessary.

13. You provide a user manual in your submission. To adequately inform users, your manual requires additional information including:

    a. A description of all features, functions, output modalities, and specifications,

    b. a description of all user-accessible controls,

    c. indicators, markings, and/or labels on the device which provide information regarding the function or meaning of each control, display, output jack, etc.,

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d. a description of the size and type of electrodes to be used with the device,

e. cleaning and/or maintenance instructions. Please be aware that cleaning instructions are required in your user manual for reusable components. A mucosal contacting device, such as your insertion unit, must be thoroughly cleaned and undergo a high level of disinfection including subjection to a germicidal process with a broad spectrum of activity. Please be sure that your instructions are understandable, comprehensive and include disinfection and rinsing steps.

f. a warning statement indicating that the long-term effects of chronic electrical stimulation are unknown,

g. a statement indicating caution should be used for patients with suspected or diagnosed heart problems,

h. a statement indicating caution should be used for patients with suspected or diagnosed epilepsy,

i. a statement indicating caution should be used when there is a tendency to hemorrhage following acute trauma or fracture,

j. a statement indicating that electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner,

k. a statement indicating that patients with a total / partial prolapse of the uterus / vagina must be stimulated with extreme caution,

l. a statement indicating that for patients with urethritis, the disease must be treated before commencing stimulation,

m. a statement indicating that worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they are applied,

n. an adverse reaction statement indicating that skin irritation and burns beneath the electrodes have been reported with the use of powered stimulators,

o. a contraindication for patients with extra-urethra incontinence (syrinx, ectopic urethra),

p. a contraindication for patients with overflow incontinence caused by evacuation problems,

q. a contraindication for patients with severe urine retention in the upper urethras,

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r. a contraindication for patients with complete peripheral denervation of the pelvic floor,

s. a contraindication for patients with an intestinal clamp; and,

t. the removal of fast twitch and slow twitch muscle stimulation. (For example, these terms are located in page 9 of 25 of your user manual.)

14. You did not provide sample labeling to show the information as required by 21 CFR 801.109. In order for the Agency to complete its review, please provide sample labeling for your device as well as all available promotional and advertising materials. You may find additional guidance for labeling using the following:

a. ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm

b. Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070801.pdf

c. Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf

15. You provide a 510(k) Summary in your submission. However, several of the sections are incomplete. Please revise your 510(k) Summary to be in accordance with 21 CFR 807.92.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Ms. Dulciana Chan at (301) 796-2592. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

James P. Scholl FOR

Janine M. Morris
Chief, Urology and Lithotripsy
Devices Branch
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-9116.

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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
AUG 23 2011
Received

Re: K110179

August 18, 2011

K18

Dear Ms. Morris

This letter is in response to your letter dated February 25, 2011 received March 4. The response includes an update to the premarket notification, 510(k). The location of updates is referenced for each item below.

1. This term has been removed. It was an inadvertent editing error from an earlier draft. See new Intended Use.
2. The original submittal included requirements specifications. This update includes additional design specifications and drawings. Specifically,
   a. See Appendices.
   b. The principle new feature of the device is the inflatable insertion unit. This allows an adjustable fit for each patient. All other features of the device are meant to parallel similar products on the market.
   c. Dimensions and weights are included in the specification in the Appendix.
   d. Descriptions of the user controls, displays, and functions are included in the specification in the Appendix. These have been expanded in the User Manual update.
   e. The control unit has a DB-9 connector. This connector has three purposes, but only one can be employed at a time. It is the connection to the insertion unit, providing control during a session. It can also be used with a custom cable to connect to a personal computer via a type A USB port. When connected to a computer, data can be downloaded to an Excel file. The port is also used to connect an AC charger to recharge the battery pack. See the Appendix for drawings of the control unit, insertion unit, and their connection.
   f. See drawings in the Appendix.
   g. The connection between the control and insertion units are described, with specifications, in the specification in the Appendix. The Appendix also includes drawings of the connector assembly.
3. Information regarding the settings was originally in the User Manual. It has now been expanded in the Section 6 of the specification in the Appendix. Further, the options have been limited to a single mode for mixed incontinence and one treatment time, 12 minutes. The only parameter that can be adjusted is the voltage. It can only be adjusted by the clinician.
4. Battery specifications have been included in section 5 of the specification in the Appendix.
5. The insertion unit is reusable but intended for single patient use only. This has been clarified in the User Manual.
6. The following table identifies the materials used in the control unit, insertion unit, electrodes, and cable. Material data sheets are included in the Appendix.

	Control Unit enclosure	**Insertion Unit outer surface**	**Electrodes**	**Connector assembly outer**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

				surface
Chemical Name	ABS, acrylonitrile, butadiene, styrene	Liquid Rubber Silicone	(b)(4) stainless steel	PVC, poly vinyl chloride
Supplier	(b)(4)			
Supplier trade name				
Polymer formulation				
Processing description				
Processing materials	None	none	(b)(4)	none

7. The entire outside surface of the insertion unit is molded of (b)(4). This material has complete cytotoxicity, sensitization, and irritation testing as shown in the Appendix. Where adhesive is required, on inner surfaces, (b)(4) (b)(4) adhesive is used. This material also has complete cytotoxicity, sensitization, and irritation testing as shown in the Appendix.
8. Electrical safety test results are included in the Appendix. Evaluation to IEC6061-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance by an independent lab, Underwriter's Laboratory.
9. Electromagnetic compatibility test results are included in the Appendix. Evaluation to IEC6061-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility by an independent lab, Underwriter's Laboratory.
10. The information on software has been expanded. See the Software Specifications in the Appendix.
11. The waveforms included in the Appendix show the limits of the adjustment. Only one mode is now available.
12. The silicone material has an 18-month usable life. A one year shelf life has been defined for the insertion unit. This has been added to the User Manual.
13. The User Manual has been updated with the following specific items. This revision also includes updates to the user instructions.
    a. The User Manual describes all features, functions, output modalities, and specifications. See the Appendix.
    b. The User Manual includes expanded descriptions of the updated controls. These will be further updated and expanded in the subsequent response.
    c. The front panel and a draft back label are included in the Appendix. The indicators are described in the User Manual.
    d. The size and type of electrodes are described in the Specifications section of the User Manual.
    e. The User Manual includes a section for cleaning. No other maintenance is required.
    f. The warning statement has been added to the User Manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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g. The caution statement has been added to the User Manual.
h. The caution statement has been added to the User Manual.
i. The caution statement has been added to the User Manual.
j. The statement has been added to the User Manual.
k. The caution statement has been added to the User Manual.
l. The statement has been added to the User Manual.
m. The statement has been added to the User Manual.
n. The adverse reaction statement has been added to the User Manual.
o. The contraindication has been added to the User Manual.
p. The contraindication has been added to the User Manual.
q. The contraindication has been added to the User Manual.
r. The contraindication has been added to the User Manual.
s. The contraindication has been added to the User Manual.
t. The statement has been removed.

14. Device labeling includes the User Manual and back label of the control unit. Promotional and advertising materials are not available at this time. See the Appendix for the control unit front panel and back label.
15. The 510(k) Summary has been updated.

If you have any questions regarding the additional information provided in this submittal, please don't hesitate to contact me. Thank you for your time and consideration.

Sincerely,

Michael J. Leigh
consultant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010 See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)

Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

INCONTROL MEDICAL LLC
3225 GATEWAY RD
BROOKFIELD WI 530455134
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****7150

2. CONTACT NAME
Michael Leigh

2.1 E-MAIL ADDRESS
mike-leigh@earthlink.net

2.2 TELEPHONE NUMBER (include Area code)
262-9576797

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center

[X] CDRH
[ ] CBER

3.2 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA [X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted] 17-Nov-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
January 17, 2011	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other (specify):
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other (describe submission):
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number (if known)		
InControl Medical, LLC			
Division Name (if applicable)	**Phone Number (including area code)**		
	414-429-2625		
Street Address	**FAX Number (including area code)**		
3225 Gateway Road, Suite 250			
City	**State / Province**	**ZIP/Postal Code**	**Country**
Brookfield	WI	53045	USA
Contact Name			
Herschel Peddicord			
Contact Title	**Contact E-mail Address**		
President	hommed_1@yahoo.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)	**Phone Number (including area code)**		
	262-957-6797		
Street Address	**FAX Number (including area code)**		
12715 Falcon Drive			
City	**State / Province**	**ZIP Code**	**Country**
Brookfield	WI	53005	USA
Contact Name			
Michael Leigh			
Contact Title	**Contact E-mail Address**		
consultant	mike-leigh@earthlink.net		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent/Applicant
  - ☐ Design/Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	KPI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [X] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K080950	STIWELL Med4	Otto Bock
2	K053434	Infiniti	MyoTrac
3	K050483	evadri	Hollister
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Stimulator, Electrical, Non-Implantable, for Incontinence

	Trade or Proprietary or Model Name for This Device	Model Number
1	InControl	
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included In Submission

- [X] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
KPI	870.5320	[ ] Class I [X] Class II
Classification Panel		[ ] Class III [ ] Unclassified
Gastroenterology - Urology Devices		

Indications *(from labeling)*

The InControl device is a non-implanted electrical stimulator for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral sphincter closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: InControl Medical, LLC		Establishment Registration Number
Division Name (if applicable)		Phone Number (including area code): 414-429-2625
Street Address: 3225 Gateway Road, Suite 250		FAX Number (including area code)
City: Brookfield	State / Province: WI	ZIP Code: 53045 / Country: USA
Contact Name: Herschel Peddicord	Contact Title: President	Contact E-mail Address: hommed_1@yahoo.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name (if applicable)		Phone Number (including area code)
Street Address		FAX Number (including area code)
City	State / Province / ZIP Code / Country	
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name (if applicable)		Phone Number (including area code)
Street Address		FAX Number (including area code)
City	State / Province / ZIP Code / Country	
Contact Name	Contact Title	Contact E-mail Address

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *Declaration of Conformity to a Recognized Standard* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

January 17, 2011

RE: 510(k) Application for InControl continence device

Dear Sir or Madam:

InControl Medical hereby submits this InControl, *Traditional 510(k) Application: New Product* for your review. This is a new product. The predicate devices are the Otto Bock STIWELL med4 (K080950), the MyoTrac Infiniti (K053434), and the Hollister evadri (K050483).

The InControl device has the same scientific technology and intended use as the predicate devices. It incorporates pulsed biphasic current to stimulate the pelvic floor muscles in the treatment of female urinary incontinence.

The FDA Fee Payment Identification Number for this InControl submission is MD6052847-956733. Payment has been sent separately.

Thank you for your consideration of the InControl application.

Sincerely,

Michael J. Leigh
consultant

Attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

November 15, 2010

Dear Sir/Madam:

This letter authorizes Michael Leigh to represent InControl Medical, LLC in medical device regulatory matters with the US Food and Drug Administration. Mr. Leigh is an independent consultant with more than fifteen years of experience in the medical device industry. He has been contracted to prepare and submit premarket notifications (510(k)) and respond to any requests for additional information.

Sincerely,

Herschel Peddicord
President, Chief Executive Officer
InControl Medical, LLC
Brookfield, WI 53045

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

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inControl response, August 17, 2011
2 Medical Device User Fee Coversheet (FDA-3601)
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3 Table of Contents
4 Statement of Indications for Use
5 510(k) Summary
6 Truthful and Accuracy Statement
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7b Information on New Device
- Device Description
- Comparison to Predicate
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- Labeling
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8 Intended Use Comparison Statement
8b Comparison Information
9 Design Control Activity Summary
- Design and Development Planning
- Design Input
- Risk Analysis
- Design Output
- Design Review
- Verification and Validation
- Design Transfer

10 Additional Information
- Compliance
- Sterilization
- Biocompatibility
- Software
- Expiration Date

Appendices
A - InTone Product Requirements Specification
B - Risk Analysis Summary
C - Software Specifications
D - Material Data Sheets
E - Output Waveforms
F - Device Labels
G - Validation Results Summary
H - Electrical Safety evaluation results
I - EMC evaluation results

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

J - InControl User Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Indications for Use

510(k) Number (if known): K110179

Device Name: InControl InTone

Indications For Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

510(k) Summary for InControl InTone

Submitter:	InControl Medical, LLC
Address:	3225 Gateway Road, Suite 250 Brookfield, Wisconsin 53045
Corporate Contact:	Herschel Peddicord, President InControl Medical, LLC
Telephone:	Ph: (414) 429-2625
Establishment Registration #:	to be registered following 510(k)
Submission Contact:	Michael J. Leigh, consultant 12715 Falcon Drive Brookfield, Wisconsin 53005 Ph: (262) 957-6797
Trade Name:	InControl InTone
Predicate Device:	Otto Bock STIWELL med, K080950 MyoTrac Infiniti, K053434 Hollister evadri, K050483
Common Name:	Stimulator, Electrical, Non-Implantable, for Incontinence

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
870.5320	KPI	Non-implanted electrical continence device	II

Device Description:

The device includes two parts; an insertion probe and a hand-held control unit. The insertion probe features an inflatable balloon that provides more adaptable fit for intra-vaginal use. The probe includes stainless steel electrodes to deliver electro-stimulation. The hand-held control and display device records, stores, and displays the results of electro-stimulation and patient generated pelvic floor exercises. It allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. It also stores data on contraction pressure for later review.

Intended Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Performance Data:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Complete EMC, electrical, mechanical, safety (operator and patient), temperature/humidity, and software testing demonstrate compliance with applicable standards. The results demonstrate that the InControl device is in compliance with the guidelines and standards referenced in the FDA reviewer's guides, and that it performed within its specifications and functional requirements for the device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with FDA requirements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Feature/ Function	InControl InTone (new device)	Otto Bock STIWELL med4 (K080950)	MyoTrac Infiniti (K053434)	Hollister evadri (K050483)	Comparison
Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)
Power Source	Nickel metal hydride battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)
Regulated current of voltage?	Regulated voltage	Regulated current	Unknown	Unknown	Equivalent
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic No-Load Trip?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display **On/Off Status** **Low Battery** **Volt/Curr Level**	 Yes Yes Yes	 Yes Yes Yes	 Yes Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	[redacted] (b)(4)	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency **Mixed** **Stress** **Urge**	[redacted]	 35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Identical (to MyoTrac, Hollister)
Pulse width **Mixed** **Stress** **Urge**	[redacted]	 300 µs/phase 500 µs/phase	0.2 ms	0.3 or 1 ms	Within range
Time **On** **Off**	[redacted]	 9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	 2 - 20 secs 2 - 50 secs	 1 - 80 secs 0 - 80 secs	Within range
Total Session Time	[redacted]	5 - 25 mins	0 - 120 mins	1 - 30 mins	Within range
Max output voltage (500Ω)	[redacted]	50 Vdc	30 Vdc	30 Vdc	Identical (to Otto Bock)
Max output current (500Ω)	[redacted]	100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)	[redacted]	50 µC	60 µC	Unknown	Identical (to Otto Bock)
Electrode surface area	[redacted]	21.2 cm^2	Various, 1.53 cm^2 to 10.5 cm^2	unknown	Equivalent
Max current density	[redacted]	4.7 mA/ cm^2	Various, 4.7 mA/ cm^2 to 32 mA/ cm^2		Identical
Maximum power density (500Ω)	[redacted]	23.5 µW/ cm^2	Various, 11.32 µW/ cm^2 to 22.84 µW/ cm^2	Unknown	Equivalent
Biofeedback	[redacted]	EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-9118.

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Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President of InControl Medical, LLC, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Herschel Peddicord
President, Chief Executive Officer
InControll Medical LLC

1/19/2011
(Date)

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*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SECTION 7: GENERAL COMPANY AND DEVICE INFORMATION

Company	InControl Medical, LLC 3225 Gateway Road, Suite 250 Brookfield, WI 53045
Establishment No.	To be registered following 510(k)

Common Name	Stimulator, Electrical, Non-Implantable, for Incontinence
Trade Name	InControl InTone
Proprietary Name	InControl InTone
Reason for 510(k) – Additional or Expanded Indications	New device

Predicate Device(s)	• Otto Bock STIWELL med 4, K08950 • MyoTrac Inifiniti, K053434 • Hollister evadri, K050483
Device Classification	Class II
Product Code	KPI
Regulation	21 CFR 876.5320
Panel	Gastroenterology/Urology

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SECTION 7B: INFORMATION ON NEW DEVICE

Device Description

The general description of the InTone, including required features, functionality and interface, user options, and packaging, is equivalent to that of the predicate devices, Otto Bock STIWELL med 4, MyoTrac Infiniti, and Hollister evadri devices.

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

The device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

Comparison to Predicate

The principle difference between the InControl InTone device and the predicates is that the InTone device includes an inflatable insertion unit. The unit is manually inflated by the patient after insertion. This provides a better fit for the patient population. The electrical parameters and controls are similar to the predicate devices. There are no differences in the intended use or indications for use.

The following comparison information illustrates differences and similarities between the legally marketed predicate prescription devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483), and the InControl device, including intended use and functional characteristics. The FDA guidance documents used to prepare this comparison as well as this 510(k) are:

FDA Guidance Title	Revision Date
Format for Traditional and Abbreviated 510(k)s	November 17, 2005
Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence	September 19, 2008
Software Contained in Medical Devices	May 11, 2005

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Statement of Substantial Equivalence

The proposed device, InControl InTone continence device, is substantially equivalent to the Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), and Hollister evadri (K050483). When compared to the predicate devices:

- The changes are not due to a recall or corrective action.
- The indications for use are the same. There are no changes in contraindications.
- The user's manual provides equivalent instructions for use, along with equivalent warnings.
- There are no significant differences in features, fundamental technology, or functionality.

The InControl InTone device and the predicate devices all provide pulsed biphasic current to stimulate the pelvic floor muscles. Each includes provision for biofeedback. The InTone device is not significantly different from the predicates. The InTone device does not raise new safety or effectiveness issues. It has the same intended use and basic functions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Intended Use

The intended use InControl InTone is the same as the predicates.

> The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: improvement of urethral closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

The intended use and indications of the device, as described in its labeling are the same as the intended use and indications for the predicate devices.

Labeling

User Manual

The InControl InTone *User Manual* uses text and graphics to lead the user through hardware setup and use. Each piece of equipment appears in a list with a brief description illustrating each step for ease of use.

SAFETY and PRODUCT INFORMATION

The document also provides maintenance, troubleshooting, repair, warranty, and customer service information. The *User Manual*, provides comprehensive safety information, product specifications and guidelines. The document can be found in "Attachment A" of this 510(k) submission.

Notes on Guidance and Information Labeling:

The manual provides the concepts and instructions needed to install, program, use, and maintain the InControl InTone device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

PREMARKET NOTIFICATION

INTENDED USE COMPARISON

I state that the intended use(s) and indications of the new device, as described in its labeling, are the same as the intended uses and indications for the predicate devices.

Herschell Peddicord, President, Chief Executive Officer

InControll Medical, LLC

11/22/2010

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SECTION 8b: Comparison Information

Review of Substantial Equivalence

The following comparison matrix illustrates differences between the legally-marketed predicate devices,Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483), and the InControl device, including intended use and technological characteristics.

Feature/ Function	InControl InTone (new device)	Otto Bock STIWELL med4 (K080950)	MyoTrac Infiniti (K053434)	Hollister evadri (K050483)	Comparison
Labeling					
Intended Use An explicit description of all clinical functions performed by the device, **Indications for Use** Explain when the device is to be clinically used and the intended patient population	The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.	The STIWELL med4 is a neuromuscular electronic stimulator for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions: • Acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of the pelvic floor muscles. • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles. As a biofeedback device the STIWELL med4 is indicated for the following conditions: • Biofeedback, relaxation and muscle re-education purposes.	Treatment of urinary incontinence EMG biofeedback The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.	The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary or fecal (electromyographic biofeedback) incontinence.	Equivalent
Warnings or Precautions	(see product labeling)	(see product labeling)	(see product labeling)	(see product labeling)	Equivalent

Contraindications Explain when the device is not to be clinically used	• This device is not intended for diagnostic purposes or critical patient monitoring. • The device is not defibrillator proof. • The device should not be used on patients with cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance. • Do not use if patient has symptoms of an active urinary tract infection. • Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms. • Do not use if patient has undiagnosed pain. • Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation. • Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings. • Do not use if patient is currently pregnant or attempting to get pregnant. • Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit. • Do not use if the patient has irregular menstrual bleeding cycles. • Do not use if the patient has a history or symptoms of urinary retention. • Do not use if the patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra). • Do not use if the patient has overflow incontinence caused by evacuation problems. • Do not use if the patient has severe urine retention in the upper urethras. • Do not use if the patient has complete peripheral denervation of the pelvic floor. • Do not use if the patient has an intestinal clamp.	• Patients with pacemakers or other electronic emitters. • No stimulation in the proximity of metal implants. • Pregnancy • Feverish or infectious diseases • Skin disorders subject to inflammation or tumors in the stimulation area, as well as thrombosis or phlebitis • Patients with extra-urethral incontinence (fistula, ectopic urethra) • Patients with overflow incontinence caused by evacuation disorders • Patients with serious urine retention in the upper urethra • Patients with total peripheral denervation of the pelvic floor • Patients with intestinal clamps	• Patients with an implanted electronic device (for example cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained. • Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions • Stimulation should not be applied over cancerous lesions • Not for use with patients with undiagnosed pain conditions. • Do not use if you have symptoms of bladder infection. • Do not use with diminished mental capacity or physical competence limiting the use of the device • Safety of powered muscle stimulators during pregnancy has not been established.		Equivalent
Labeling Summary Clarity to insure safer or more effective use	User Manual	User Manual	User Manual	User Manual	Identical (to all)
Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Power Source	4/5 AA nickel metal hydride battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent
Method of line current isolation	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Patient leakage current	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)
Regulated current or voltage?	Regulated voltage	Regulated current	Unknown	Unknown	Equivalent
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic No-Load Trip?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display On/Off Status Low Battery Volt/Curr Level	 Yes Yes Yes	 Yes Yes Yes	 Yes Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	[redacted] (b)(4)	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency Mixed Stress Urge	 	 35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Within range (of MyoTrac, Hollister)
Pulse width Mixed Stress Urge	 	 300 µs/phase 500 µs/phase	0.2 ms	0.3 or 1 ms	Within range
Time On Off	 	 9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	 2 - 20 secs 2 - 50 secs	 1 - 80 secs 0 - 80 secs	Equivalent
Total Session Time		5 - 25 mins	0 - 120 mins	1 - 30 mins	Within range
Max output voltage (500Ω)		50 Vdc	30 Vdc	30 Vdc	Identical (to Otto Bock)
Max output current (500Ω)		100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)		50 µC	60 µC	Unknown	Identical (to Otto Bock)
Electrode surface area		21.2 cm^2	Various, 1.53 cm^2 to 10.5 cm^2	unknown	Equivalent
Max current density		4.7 mA/ cm^2	Various, 4.7 mA/ cm^2 to 32 mA/ cm^2		Identical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Maximum power density (500Ω)	[redacted] (b)(4)	23.5 μW/ cm²	Various, 11.32 μW/ cm² to 22.84 μW/ cm²	Unknown	Equivalent
Biofeedback	Air pressure, 0 - 2 psi	EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)
Materials					
Dimensions	8 x 5 x 4 inches	175 x 95 x 30 mm	102 x 152 x 51 mm	100 x 70 x 130 mm	Equivalent
Control housing	ABS plastics	plastics	plastics	plastics	Equivalent
Insertion material	Silicone, plastics	plastics	plastics	plastics	Equivalent
Packaging or Expiration Dating	1 year for insertion unit	N/A	N/A	N/A	
Sterilization	N/A	N/A	N/A	N/A	
User Interaction and Software					
Operational Method: Clinical Use e.g., ambulatory use, home use	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Identical (to all)
Patient Interaction: Functions Controllable An explanation of how the device interacts with the patient.	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.				Equivalent
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	None, programming can only be changed by clinician	None, programming is locked by clinician	None, programming is locked by clinician		Equivalent (to Otto Bock, MyoTrac)
Override	Yes	Yes			Identical (to Otto Bock)
Patient Interaction: Operator Requirements Knowledge or training required of the operator,	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Identical (to all)
Software Level of Concern A statement indicating the Level of Concern and a description of the rationale for that level.	Minor				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8108.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Device Hazard Analysis Tabular description of identified hardware and software hazards, including severity assessment and mitigations.	Per risk assessment	No adverse event reports	No adverse event reports	No adverse event reports	Equivalent

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SECTION 9: DESIGN CONTROL ACTIVITY SUMMARY

The InControl device was developed in accordance with the design control requirements in the Quality System Regulation, 21CFR820. The key points of this process include the following.

Design and Development Planning

The development project is initiated through documented plans that describe the development activities, including schedule, responsibilities, deliverables, and interfaces between functional groups.

Design Input

The design inputs are documented in the System Requirements Specification. The initial version was reviewed during the project to resolve any conflicting or ambiguous requirements. Updates were reviewed and approved by the specifiers as necessary during the project.

The concept includes an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. It offers the same functionality for stimulation and feedback as compatible peripheral device(s).

Risk Analysis

Product risk analysis, using a Failure Modes and Effects Analysis (FMEA) approach and a cross functional team, is conducted three times during the project. The first session is at the beginning of the project. It identifies potential risks based on the specifications, design concept, and previous experience with similar products. Risks requiring mitigation are addressed in development. The second and third session provide updates to the first. Near the end of development, a second FMEA session is conducted. The purpose is to ensure that major risks identified in the first session were addressed. It also identifies new potential risks resulting from design decisions. The third risk analysis is conducted following verification and validation testing. Its primary purpose is to verify that the identified major risks have been adequately mitigated. It may also identify new potential risks as a result of testing. Such new risks may require additional mitigation, testing, and another risk analysis session.

Risk assessment for InControl InTone device was conducted and then compared to adverse event reports and specifications for similar devices. The risk assessment for InControl InTone did not identify any new safety risks when compared other devices on the market. There were no adverse event reports in the target product codes. The product has the same user population and same function, which results in a similar assessment. There are no new hazards. The risk assessment ensured that previously mitigated or new hazards were not introduced in the project.

See the attached Risk Analysis Summary.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Design Output

Design decisions are documented in specifications and architecture documents. These are reviewed and approved. The final product requires cross functional approval to release to market.

Design Review

Design reviews are held at several levels throughout the project. Product requirements are reviewed by a cross functional team. Routine, periodic project meetings provide updates to all functions on design decisions and project progress. Formal, cross functional reviews are held at the end of each major phase to review results required for that phase. All objectives for the phase must be achieved in order to proceed.

Verification and Validation

Verification testing of the product design is conducted to ensure that all requirements have been met. This testing is conducted according to documented procedures traceable to the product specifications.

Validation testing is conducted by an independent group to ensure users' needs and expectations are met. This testing is conducted according to documented procedures based on expected use (and misuse) of the product.

All verification and validation activities, required by the risk analysis, were performed by the designated individuals. The results of the activities demonstrated that the predetermined acceptance criteria were met.

Design Transfer

Upon release of the product, the validated design will be released for distribution as a controlled item. The facility is in conformance with the design control procedure requirements as specified in 21CFR820.30.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SECTION 10: ADDITIONAL INFORMATION

Compliance

The InControl InTone device has demonstrated electrical safety as defined in IEC60601-1. The device was evaluated by an independent laboratory, Underwriter's Laboratory. See attached report.

The InTone device complies with electromagnetic compatibility requirements defined in IEC60601-2-1 and FCC part 15. See attached report.

The InTone device complies with 21CFR898 for patient leads. From IEC601-1:

56.3a	Connectors provide separation required by Sub-clause 17g	Yes
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	Yes, only one connection
	Medical gas connections not interchangeable	n/a
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	Yes, circuit cannot be energized if connection not made.
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	Yes, connector is enclosed.

Sterilization

There are no sterilization requirements for the InControl InTone device, as there are none for any of the predicate devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483).

Biocompatibility

The InTone device uses materials that have demonstrated biocompatibility in accordance with USP XXIII Class 6 and ISO10993. See attached data sheets.

Software

Software is verified through code review and error checking. It is validated in the device through functional testing. Due to the intended use, low voltage energy, and mitigations in the hardware, the software is classified as of Minor Concern. There is no chance that a failure or latent flaw could indirectly result in minor injury. A malfunction of the software cannot result in death or serious injury. There have been no adverse reports for any of the predicate devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483).

Expiration Date

The insertion probe has a one year shelf life, based on the silicone manufacturer's 18-month shelf life.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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System Requirements Specification:
InControl InTone

Date	Rev	Author	Section(s) changed description
01/15/11	A	M. Leigh	Initial release.
3/30/11	B	M. Leigh	Updates to controls and material specifications
8/15/11	C	M. Leigh	Updates to battery, stimulation characteristics. Confirmation of all specifications
8/15/11	D	Wurtz	Provided more details on power button functionality.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.0 Introduction

1.1 Purpose

The purpose of this document is to define the system requirements of the developed product.

1.2 Scope

This document includes the materials, power, controller, and other design decisions for the InTone product.

2.0 Control Unit

2.1 Features

InTone device is a hand-held instrument, which controls stimulation and provides bio-feedback. It is battery operated. It has a set of controls and displays to provide appropriate user interface.

The device is capable of storing stimulation parameters in its memory. Stimulation parameters are sent to the device from the PC via USB port.

The device is capable of storing the results of bio-feedback training sessions, with further downloading into PC program.

2.2 Dimensions

4.83" x 2.4" x 1.1"

2.3 Weight

5 oz

3.0 User Interface

3.1 User Controls, and Their Functions

The user controls are shown on the picture below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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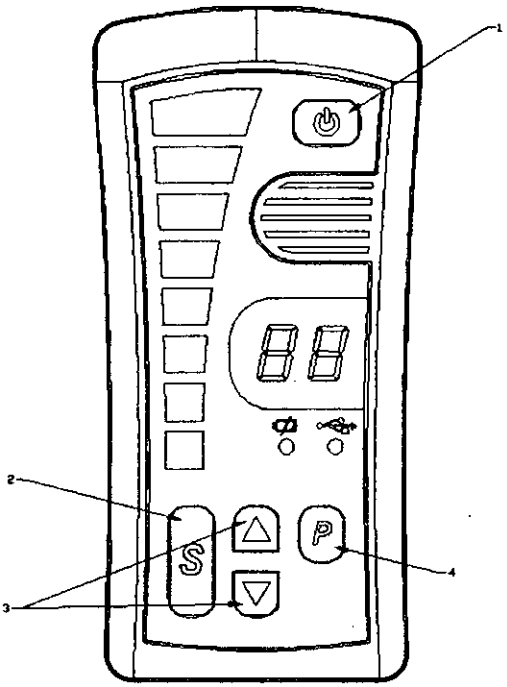


1 – ON/OFF button
2 – Start button. Starts the stimulation / bio-feedback session
3 – Volume increase / decrease buttons
4 – Pause button, to temporarily pause the session

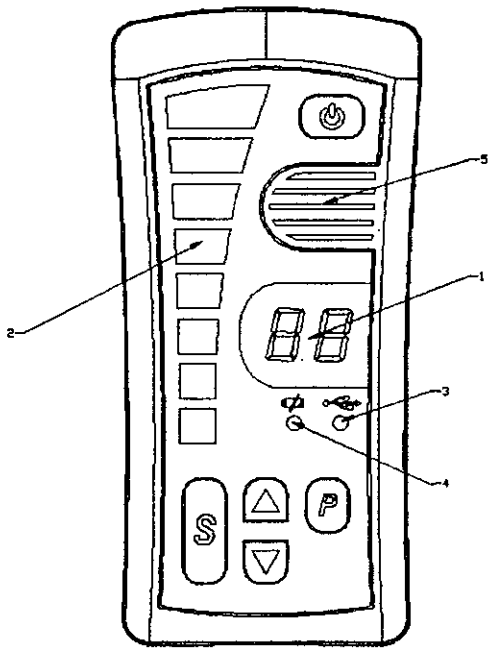
The On/Off button is only functional while the control unit is connected to the insertion unit. The power will always be on when connected to the battery charger or the PC. Once removed from the battery charger or PC, the device will immediately power off.

3.2 User Displays, Sound Devices, and Their Functions

The user displays and sound devices are shown on the picture below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



1 – Timer, shows time in seconds
2 – Bar graph, showing muscle effort during bio-feedback session
3 – USB communication; is lit when unit is connected to the PC via USB link
4 – Battery. When unit is running in a battery, this light shows low battery condition. When unit is being charged, flashing of this light indicate charging in progress.
5 – Speaker, used to give voice prompts during bio-feedback session

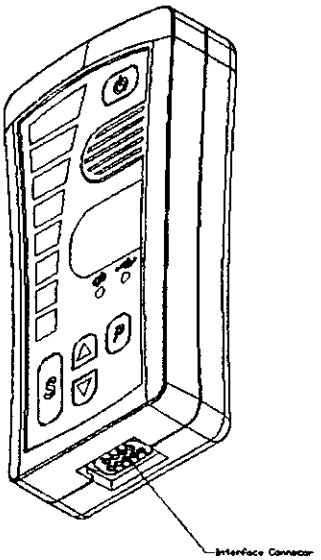
4.0 Description of the Computer Connection

The unit is connected to the PC via a custom USB cable. The connection port is used for three functions:
1 – USB link
2 – Charging the internal battery
3 – Connection with the insertion device
Since only one cable can be plugged at a time, neither USB nor power supply could be electrically connected to the patient in any circumstances. This assures electrical safety.

The location of the interface connector is shown below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



The connector is a standard D-type 9-pin connector.
Each cable (see pp 1, 2 and 3 above) has jumper shorts in mating connector, providing information for the device which cable is plugged; thus device can configure its function appropriately.

If the USB cable is plugged, all the buttons are disabled, the bar graph and timer are disabled, the USB light is on, and unit communicates with the PC.

If the power supply is plugged, all the buttons are disabled, the bar graph and timer are disabled, the battery light is slowly flashing, and unit is charging its battery.

If the cable to the insertion device is plugged, the unit operates in its normal stimulation and bio-feedback mode.

5.0 Battery

Two 4/5 AA batteries, nickel metal hydride
Battery pack size – 1.75" x 1.145" x 0.57".
Battery capacity – 1200mAh
Battery voltage – 2.4 V
Charge voltage – 6 VDC
Charge current – 0.24 A
Discharge current – 0.15 A
Charging time – 5 hours
Charging frequency – defined by the user, up to 8 hours use

6.0 Insertion Unit

6.1 Features

InTone insertion unit is inflatable to provide a comfortable fit for each individual.

6.2 Dimensions

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8018.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

5" long
1.25" diameter, uninflated
up to 2.5" diameter, inflated

6.3 Weight
12 oz

6.4 Description of Size and Type of Electrodes
The electrodes are made of rigid semi-tubular 300/304L stainless steel, each electrode approximately 2" x 0.75".

6.5 Stimulation Characteristics

6.5.1 Mixed Incontinence

Treatment Durations:	(b)(4)
Frequency:	
Pulse Width:	
On Time:	
Off Time:	
Intensity:	
Maximum Current:	

6.5 Biofeedback parameters

Air Pressure:	0 to 2.0 psi
Resolution:	0.1 psi
Response Time:	0.01 seconds

7.0 Material Specs and Molding Processes

7.1 Control Unit
The hand-held device will be molded from medical (b)(4)

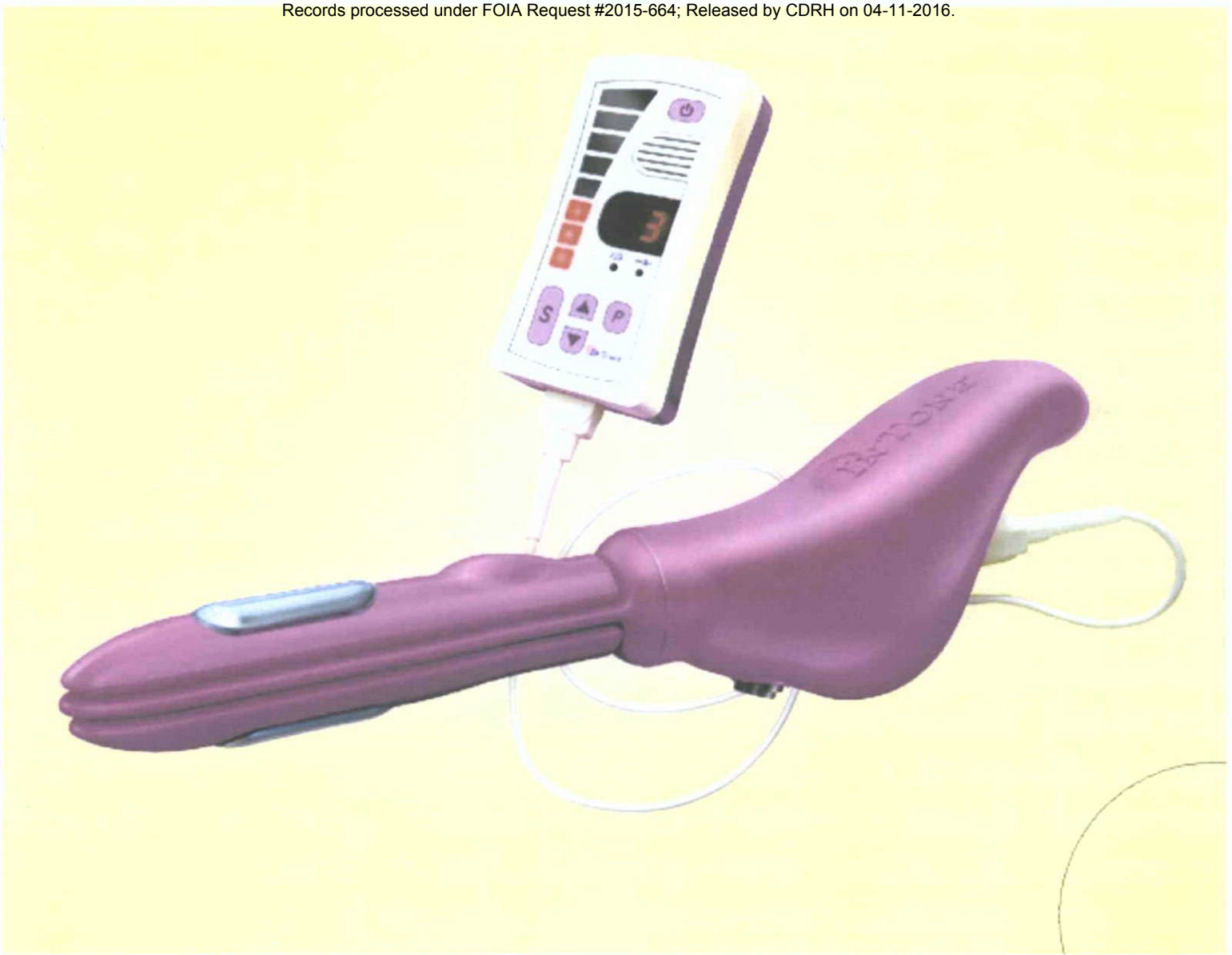
7.2 Insertion Unit
The insertion device is molded out of (b)(4) The molded silicone has a shelf-life of 18 months. To allow for distribution and user handling, a one year expiration date is used.

Where adhesive is required to secure the silicone cover, (b)(4) is be used.

All exposed material must meet USP XXIII Class VI and ISO10993 for cytotoxicity, sensitization, and irritation or intracutaneious reactivity.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-3118.

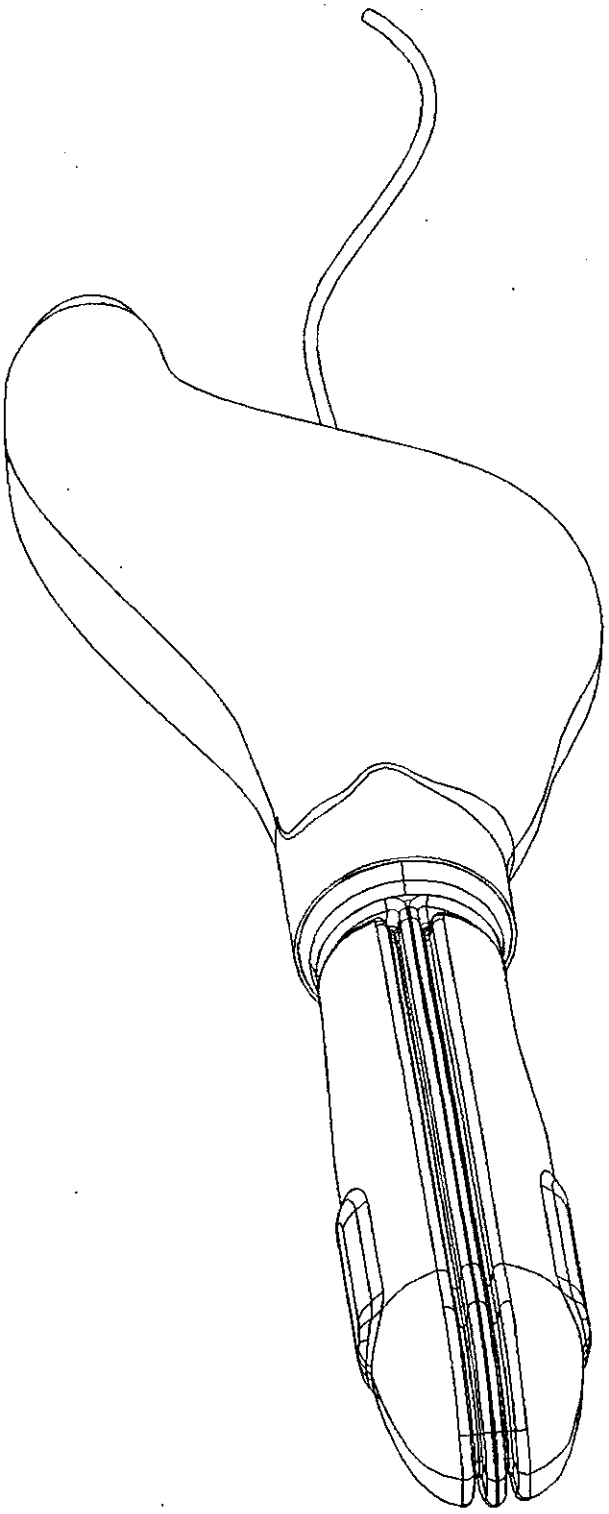
Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



200

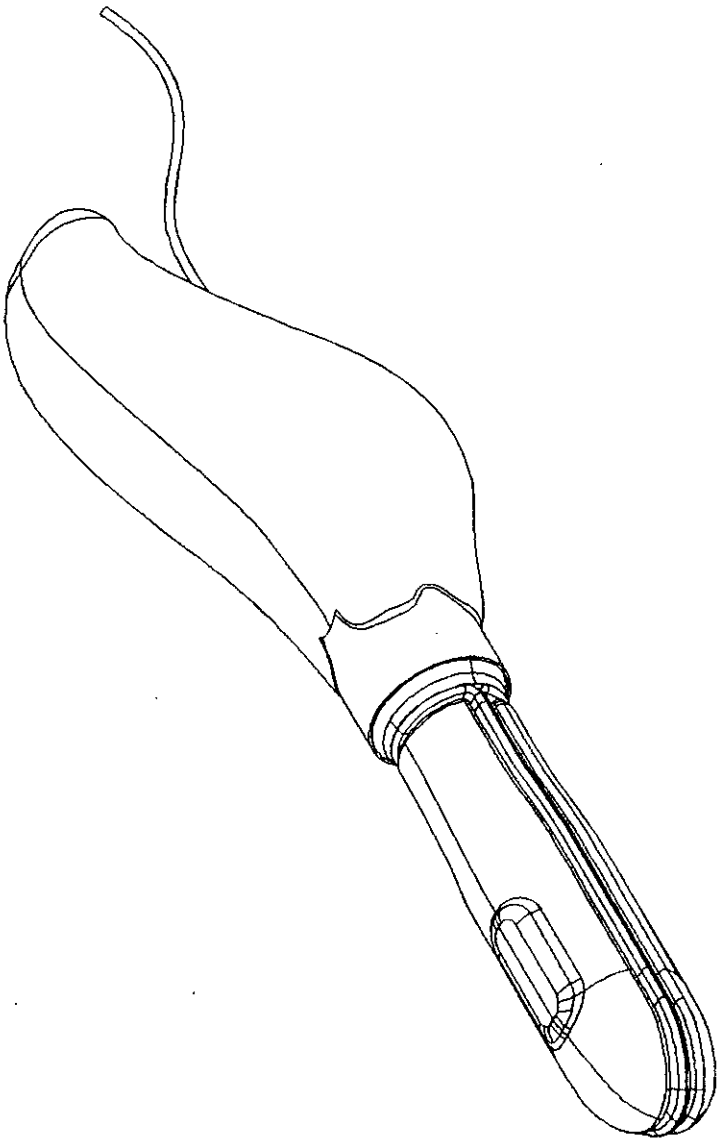
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



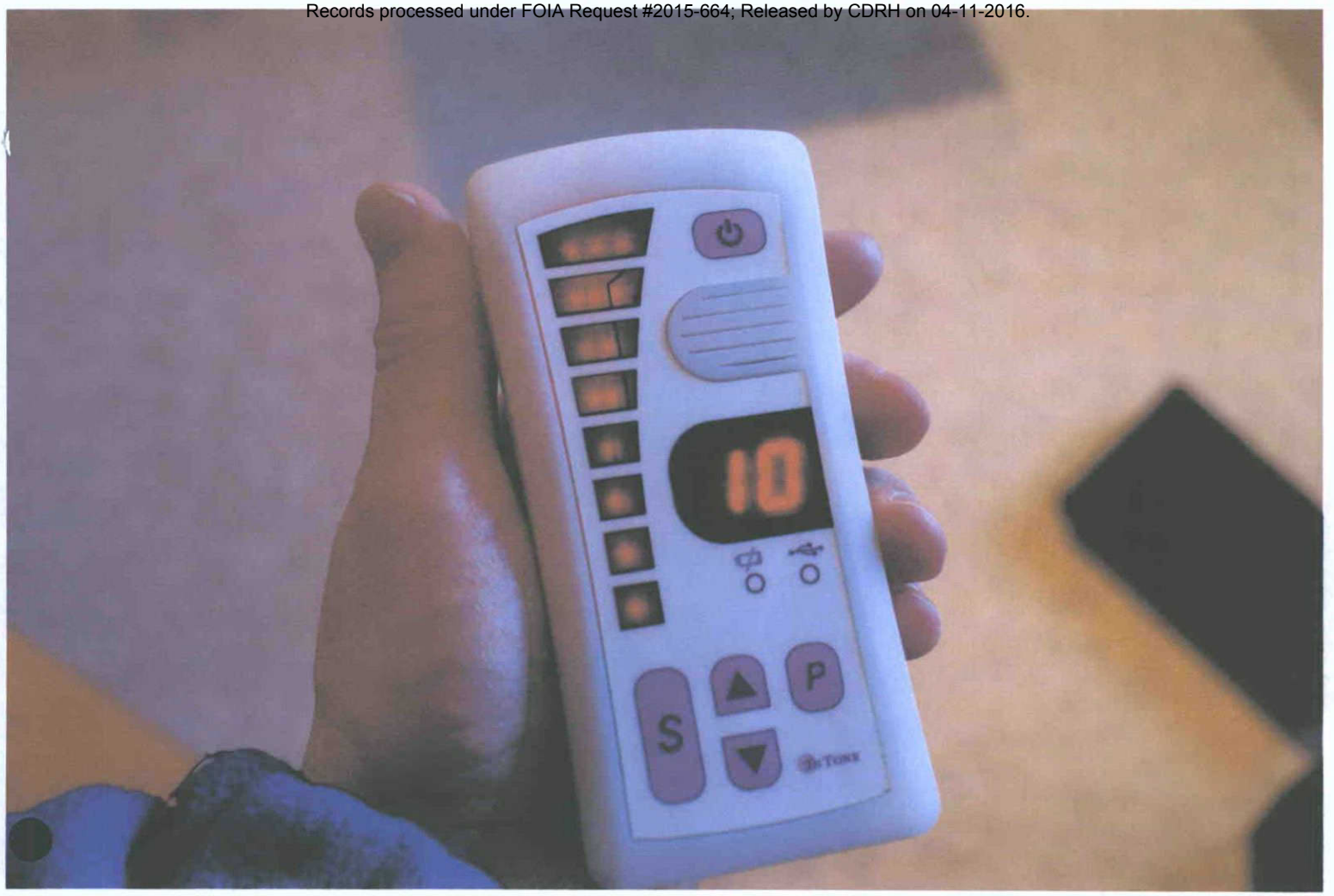
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



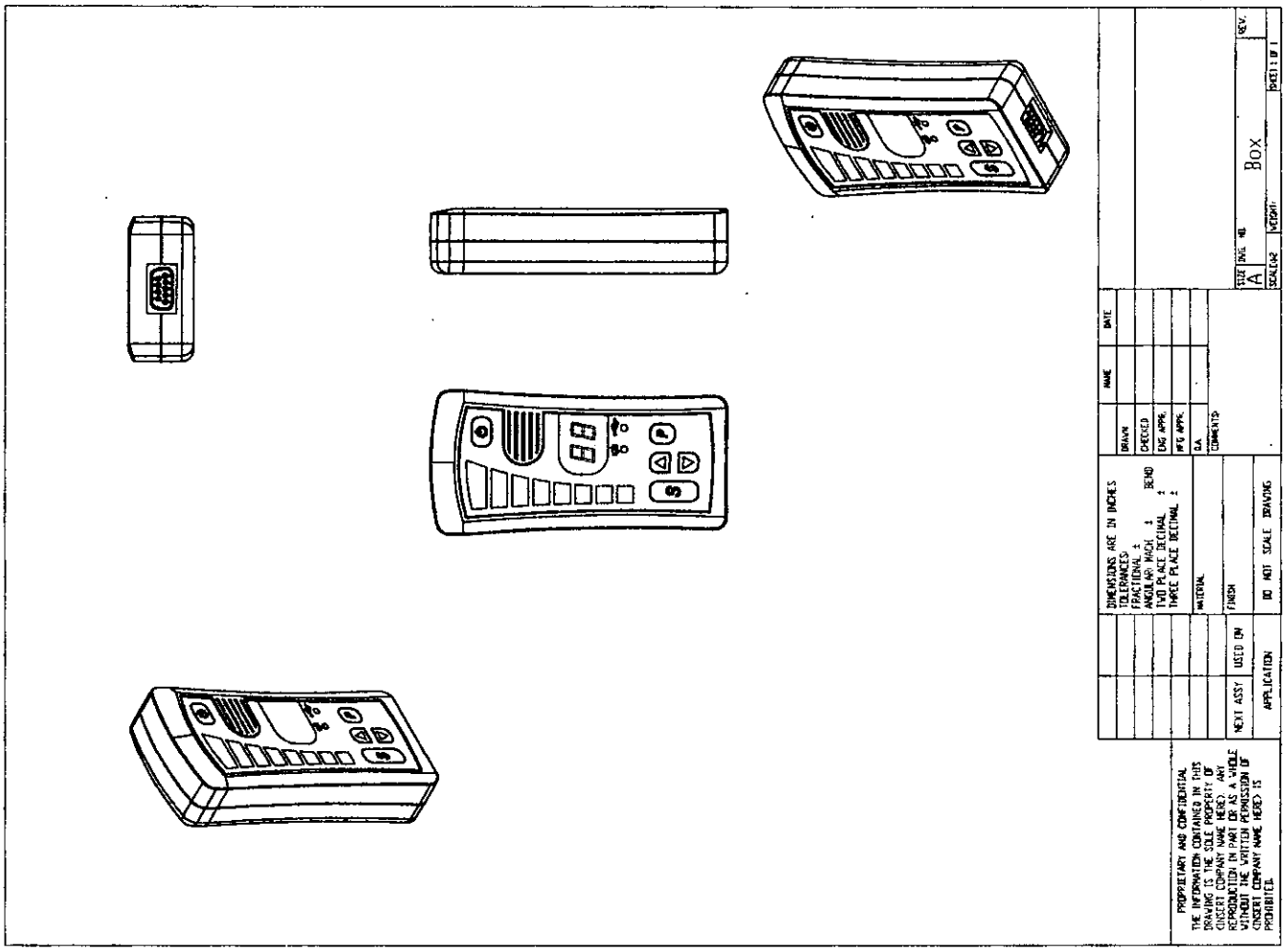
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



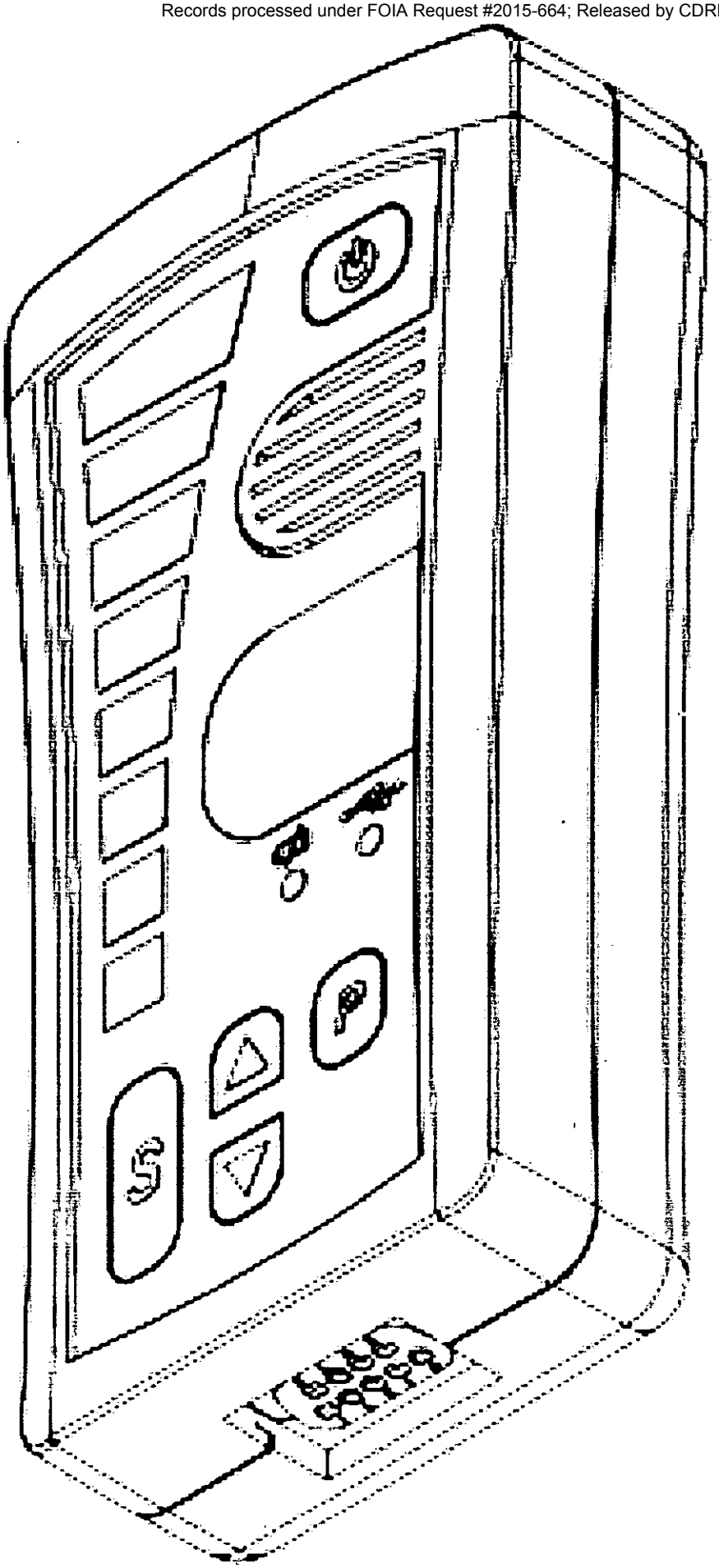
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



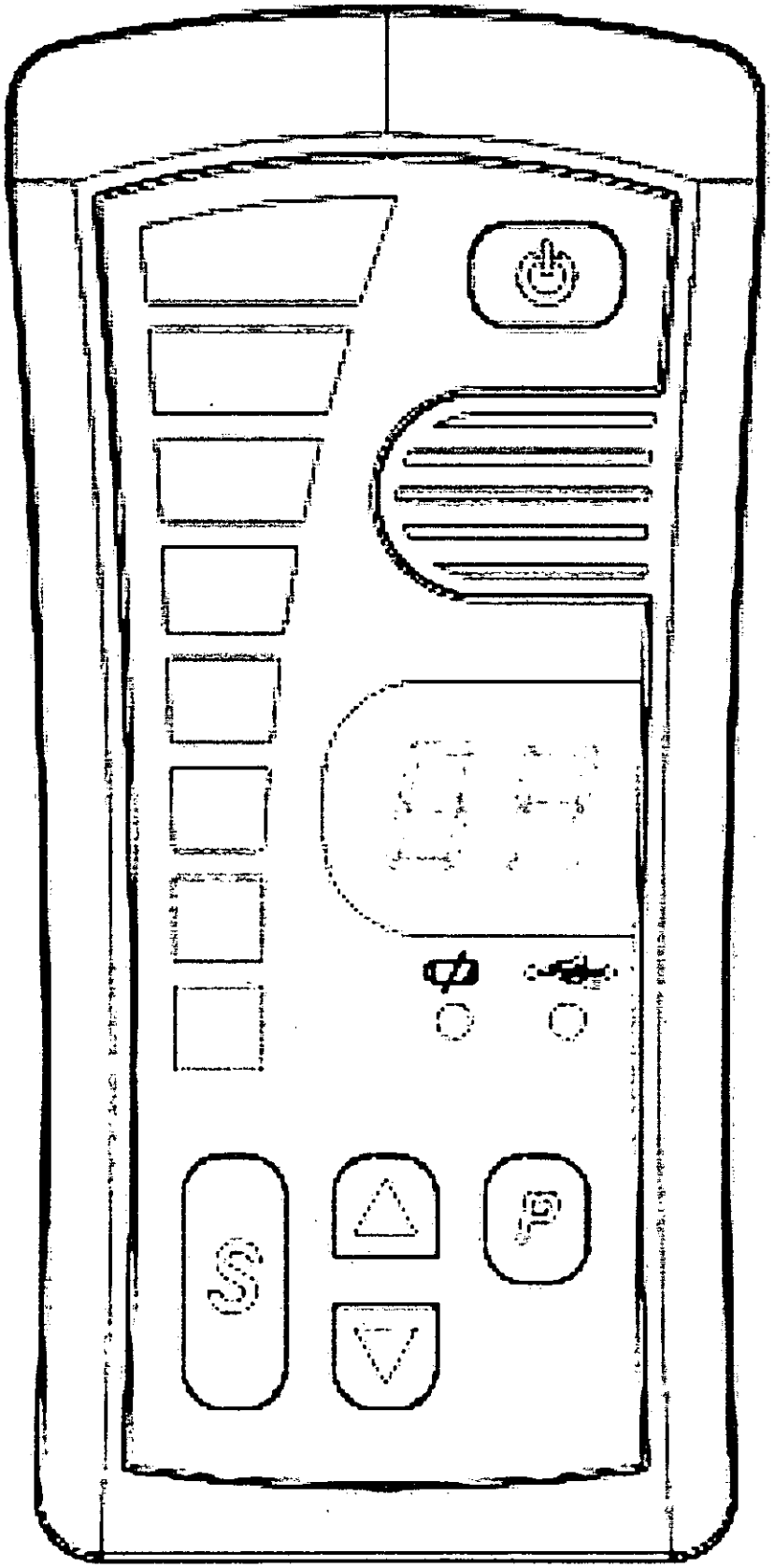
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



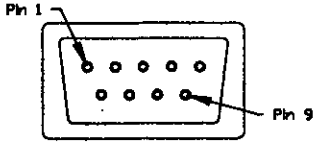
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



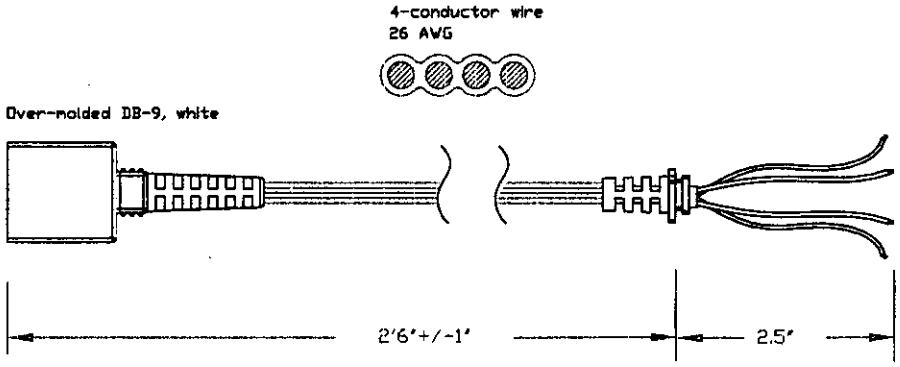
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

DWG NO: InTone 102	
REV.	DESCRIPTION
A	Initial Release 2-28-11



DB-9 Male, view from the front

Pin 1 - N/C
Pin 2 - N/C
Pin 3 - N/C
Pin 4 - wire 4
Pin 5 - N/C
Pin 6 - N/C
Pin 7 - wire 1
Pin 8 - wire 2
Pin 9 - wire 3



	ITEC Engineering LLC	
DRN BY: ESP		ENG:
DATE: 2-28-11		DATE:
SCALE: NTS	DO NOT SCALE PRINT	Q.A.:
THIS DOCUMENT CONTAINS CONFIDENTIAL AND/OR PROPRIETARY INFORMATION AND IS NOT TO BE REPRODUCED, DISTRIBUTED OR DISCLOSED WITHOUT PRIOR APPROVAL OF ITEC Engineering LLC OR ITS DESIGNATED AGENT.		DATE:
		MFG:
		DATE:
MATERIAL: See Notes		UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCE: XX ± .020 XXX ± .005 ANGLES ± 1°
FINISH: N/A		
TITLE: Sensor Cable		DWG NO: InTone 103 REV: A1
		SHT: 1 OF 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Risk Assessment F[illegible]n and Summary

Process/Product Name:	InControl InTone incontinence device

Phase 2 Prepared by:	M. Leigh, K. Tabor
Phase 3 Prepared by:	M. Leigh, K. Tabor, E. Patnik, J. Lemke, E. Wurtz
Phase 4 Prepared by:	M. Leigh, K. Tabor, E. Patnik, J. Lemke, E. Wurtz

There are no Medical Device Reports for predicate devices, product code KPI

Stage 3									Stage 4		Stage 5						
No.	Harm (Effects of Failure)	Hazard (Failure Mode)	Causes of Failure	Failure T	S	P	D	RPN Score	Risk Reduction Method	Responsibility	Verification	Failure T	S	P	D	RPN Score	Is Residual Risk Acceptable? Explain.
1	shock	electrical	leakage current		2	3	4	24	battery power, low voltage, comply with safety standards	Engineering	design review		3	1	1	3	broadly acceptable
2	shock, fire	electrical	current overload		2	2	4	16	battery power, circuit includes overload trip, comply with safety standards	Engineering	design review, testing		3	1	1	3	broadly acceptable
[illegible]	shock	electrical	energize with no load		2	3	5	30	circuit includes no-load trip	Engineering	design review, testing		3	1	1	3	broadly acceptable
[illegible]	shock	electrical	lack of patient isolation, charger		2	2	5	20	one connection at a time, Control Unit use disabled when charger connected, comply with safety standards	Engineering	design review, testing		3	1	1	3	broadly acceptable
[illegible]	shock	electrical	lack of patient isolation, USB		2	2	5	20	once connection at a time, Control Unit use disabled when USB device connected, comply with safety standards	Engineering	design review, testing		3	1	1	3	broadly acceptable
[illegible]	tissue trauma	overinflation			2	2	2	8	manual inflation, maximum size limited	Engineering	design review, testing		2	1	1	2	broadly acceptable
[illegible]	burn	arcing	probe too small, providing a gap		3	2	5	30	inflatable probe ensures contact, insertion unit detection prevents use if not in place	Engineering	design review		3	1	3	9	as low as practical
[illegible]	muscle strain	stimulation signal too strong	incorrect setting, software error		2	2	3	12	manual stop, adjustable level only accessible by clinician, defined electrical characterisitics consistent with predicate devices	Engineering	testing		2	2	2	8	broadly acceptable
[illegible]	shock	electrical conductor exposed	damage		3	1	3	9	battery power, low voltage	Engineering	design review, testing		1	1	4	4	broadly acceptable
[illegible]	mucous membrane irritation, toxity	biocompatability	material selection		3	2	5	30	use materials compliant with USP, ISO10993, no latex, address risk in labeling	Engineering	design review, material certification		3	1	3	9	broadly acceptable
11	unnecessary change in treatment	biofeedback incorrect - shows improvement or lack of improvement incorrection	pressure transducer fails or out of calibration, software error		1	2	3	6	level only accessible by clinician, pressue indicates difference only	Engineering	design review, testing		1	2	2	4	broadly acceptable
12	unintended chage in treatment	EMC, ESD	cicuit layout		1	3	3	9	circuit layout, comply with EMC standards	Engineering	design review, testing		1	1	2	2	broadly acceptable
13	burn	surface overheats	circuit design		2	3	3	18	circuit design, component selection, comply with safety standards	Engineering	design review, testing		3	1	3	9	broadly acceptable
								0								0	
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Software Requirements Specification:
InControl InTone

Date	Rev	Author	Section(s) changed description
01/15/11	A	E Palatnik	Initial release.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.0 Introduction

1.1 Purpose

The purpose of this document is to define the system requirements of the developed product.

1.2 Scope

This document includes the materials, power, controller, and other design decisions for the InTone product.

2.0 Level of Concern

If the software in the InTone were to fail it could cause a non-serious injury to a patient, therefore the software is considered to present a moderate level of concern.

3.0 Description

The InTone is a stand-alone device, controlled by two microcontrollers. One (b)(4) in the insertion unit; another (b)(4) in the hand-held device. Two microcontroller communicate and provide constant mutual verification. Should one of them stop communicating, the stimulation session would be terminated immediately.

The embedded software loaded into the (b)(4) microcontroller controls the following functions of the device:

- Creating stimulus patterns
- Measuring pressure
- Communication

The embedded software loaded into the (b)(4) microcontroller controls the following functions of the device:

- User interface
- Voice prompts generation
- Communication with the PC
- Communication with (b)(4)
- Data storage and trending
- Power off function
- Battery charging

Software is written in C language. The Software is written and compiled in a PC environment, but then downloaded and tested on the InTone unit. An in-circuit J-TAG loader is used to program the microcontroller FLASH memory. The device does not contain an operating system nor does it utilized any off-the-shelf software.

4.0 Device Hazard Analysis

See InTone Risk Analysis document

5.0 Product Requirements Specifications

See InTone SRS document

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-9118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

6.0 Hardware Requirements
See InTone SRS document

7.0 Programming Language Requirements
See InTone SRS document

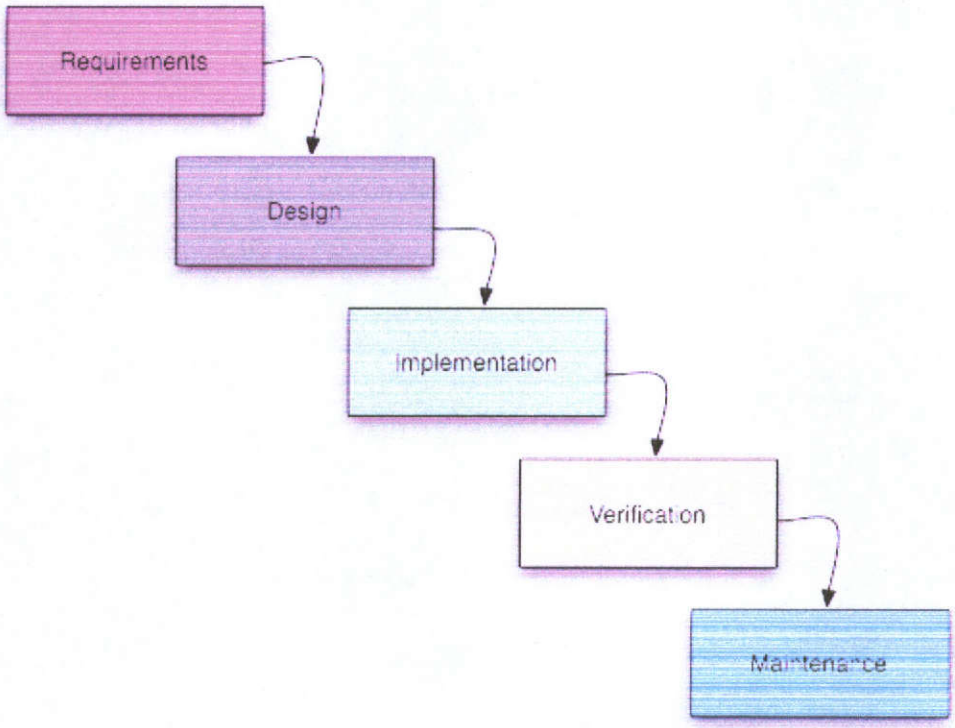
8.0 Interface Requirements
See InTone SRS document

9.0 Software Performance and Functional Requirements
See InTone SRS document

10.0 Architecture Design Chart
See InTone Flow Diagram and Thread of Control document

11.0 Traceability Analysis
See InTone Traceability Matrix

12.0 Software Development Environment Description
The waterfall software development model is used for the development and maintenance of the InTone's software.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The software is revision controlled. Any changes to the software will increase the software revision. The specification and design documents and test protocols will be updated to reflect the changes. A regression analysis will be performed to identify the parts of the software that are affected by the changes and those sections will be validated before placing the software into use.

13.0 Verification and Validation Documentation

Software Validation
Electromagnetic Compatibility
Bench Testing
Clinical Testing
Comparison Testing
All testing passed the requirements as stated in the protocols for the test documents.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8718.

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silicone used for Insertion Unit cover

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

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ABS used for Hand-Held Control Unit enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

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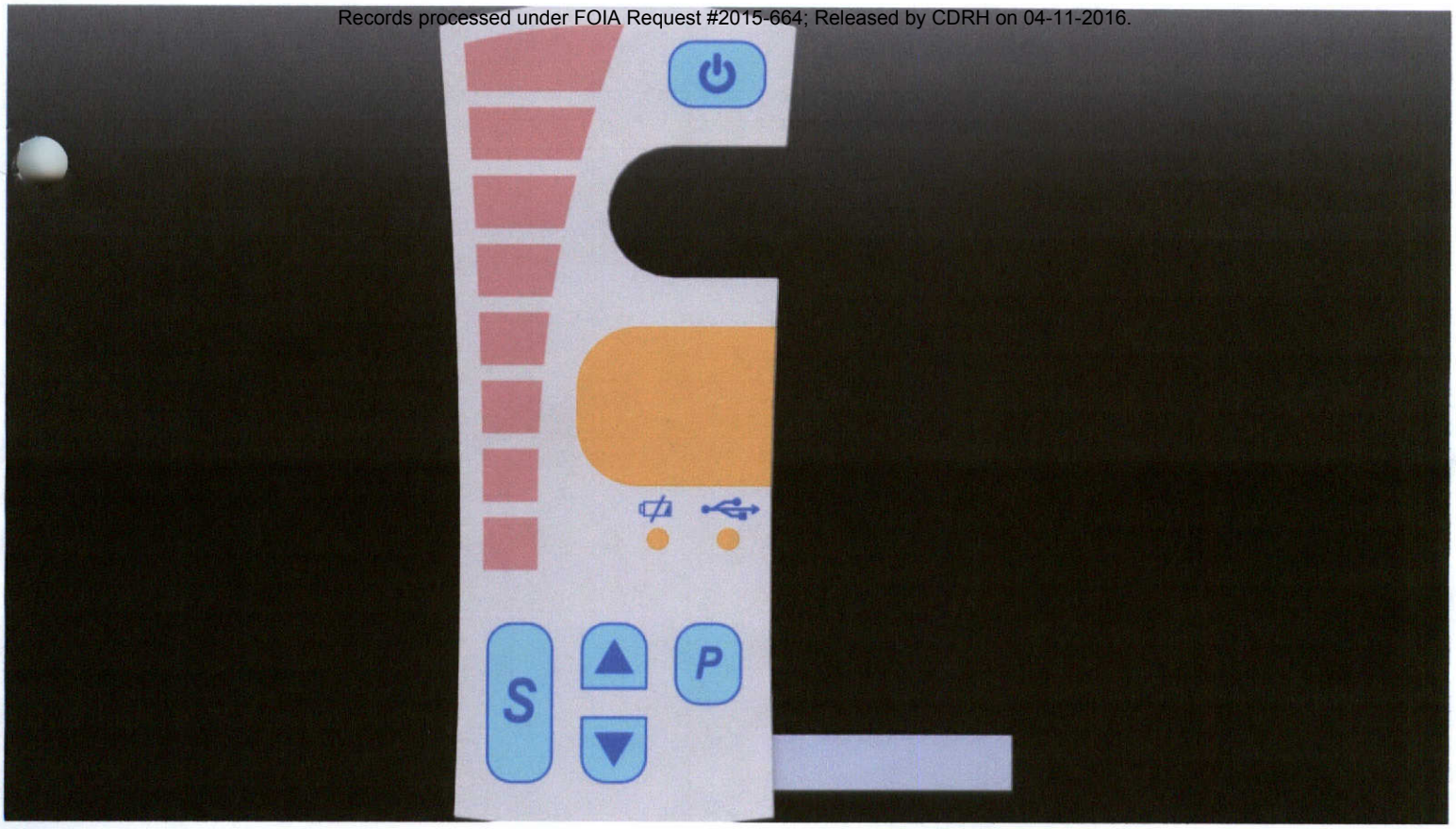

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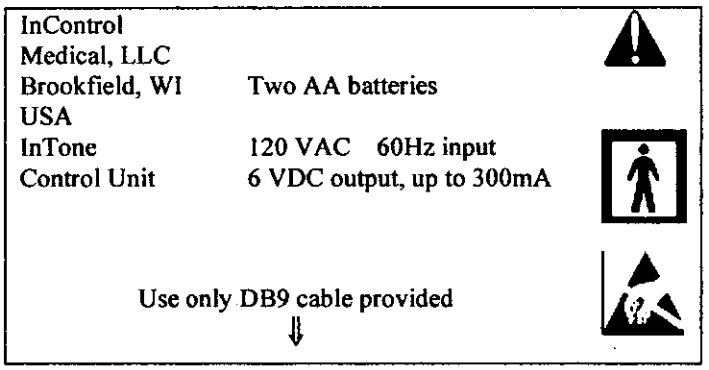

Control Unit back label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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the standard in safety

Underwriters Laboratories

2011/08/15

Mr. Jason Lemke
INCONTROL MEDICAL L L C
Suite 250 3225 Gateway Rd
Brookfield, WI 53045
United States

Reference: File E348953 Project 11CA39621

Subject: TESTING OF STIMULATION DEVICE MODEL INTONE PER REQUIRIMENTS OF IEC 60601-1

Dear Mr. Lemke,

Any information and documentation involving UL Mark services are provided on behalf of Underwriters Laboratories Inc. (UL) or any authorized licensee of UL.

We have completed testing of Model Model InTone with acceptable results.

We have completed our engineering investigation under project 11CA39621 for Model InTone, according to the requirements of IEC 60601-1 "Medical Electrical Equipment – Part 1: General Requirements for Safety"

This letter will serve to report the results of the tests that have been completed on the subject product. Per your request only testing has been conducted under this project. Please refer to the attached Appendices for details:

Title	Content
Appendix A.doc	IEC-Style Informative Test Report
Appendix B.pdf	Datasheet Package
Appendix C.pdf	Ball Pressure Test Datasheet Package

The issuance of this report does not in any way imply Listing, Classification, or Recognition by Underwriters Laboratories Inc., and does not authorize the use of any UL Mark or reference to Underwriters Laboratories Inc. in connection with this product.

This completes the work anticipated under Project 11CA39621, and we are closing the project with this letter. You will be invoiced for the charges incurred to date.

245

Underwriters Laboratories Inc.
333 Pfingsten Road, Northbrook, IL 60062-2096 USA
T:: 847.272.8800 / F:: 847.272.8129 / W:: ul.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Should you have any questions or comments concerning the above, please feel free to contact the undersigned.

Sincerely,

Silvia Ankova
Engineer Sr Project
3013JNBK
Tel: 847-664-2337

silvia.ankova@us.ul.com

Reviewed by:

Paul Hilgeman
Project Engineer
3013JNBK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Test Report issued under the responsibility of:

Underwriters Laboratories Inc.

Underwriters Laboratories

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1:General requirements for safety

Report Reference No ..... :	E348953-A1
Date of issue ..... :	
Total number of pages ..... :	110
CB Testing Laboratory ..... :	
Address ..... :	
Applicant's name ..... :	INCONTROL MEDICAL L L C
Address ..... :	SUITE 250 3225 GATEWAY RD BROOKFIELD WI 53045 UNITED STATES
Test specification:	
Standard ..... :	IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure ..... :	Informative Draft Report
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1c/97-04
Test Report Form originator ..... :	Underwriters Laboratories Inc
Master TRF ..... :	dated 97-04

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If this test Report is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Test item description ..... :	Electrical stimulator	
Trade Mark ..... :	None	
Manufacturer ..... :	INCONTROL MEDICAL L L C SUITE 250 3225 GATEWAY RD BROOKFIELD WI 53045 UNITED STATES	
Model/Type reference ..... :	InTone	
Rating ..... :	Battery charger: Input Voltage: Output: Control Unit: 2.4V, 1200mAh	 120 VAC, 60Hz 6VDC, 300mA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Testing procedure and testing location:		
[X]	**Testing Laboratory**	
	Testing location / address.....:	333 Pfingsten Road, Northbrook IL 60062
[ ]	**Associated CB Test Laboratory**	
	Testing location / address.....:	
	Tested by (name + signature) .....:	
	Approved by (+ signature) .....:	
[ ]	**Testing Procedure: TMP**	
	Tested by (name + signature) .....:	
	Approved by (+ signature) .....:	
	Testing location / address.....:	
[ ]	**Testing Procedure: WMT**	
	Tested by (name + signature) .....:	
	Witnessed by (+ signature).....:	
	Approved by (+ signature) .....:	
	Testing location / address.....:	
[ ]	**Testing Procedure: SMT**	
	Tested by (name + signature) .....:	
	Approved by (+ signature) .....:	
	Supervised by (+ signature) .....:	
	Testing location / address.....:	
[ ]	**Testing Procedure: RMT**	
	Tested by (name + signature) .....:	
	Approved by (+ signature) .....:	
	Supervised by (+ signature) .....:	
	Testing location / address.....:	

List of Attachments

National Differences (6 pages)
Enclosures (pages)

Summary Of Testing

Unless otherwise indicated, all tests were conducted at . Underwriters Laboratories Inc. 333 Pfingsten Rd Northbrook, IL 60062

	Tests performed (name of test and test clause)	Testing location / Comments
	Power Input (7.1)	
	Leakage Current (19)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Dielectric Voltage Withstand (20.4)
Enclosure Mechanical Strength (21A, B)
Drop Impact (21.5)
Temperature (42)
Humidity Preconditioning Treatment (44.5)
Overflow, Spillage, Leakage, Cleaning, Sterilization and Disinfection, Harmful Ingress of Liquids (44)
Abnormal Operation and Fault Conditions (52)
Mold Stress Relief (55)
Cord Anchorages (57.4A)
Working Voltage Measurement (20.3)
Interruption of Power Supply (49)
Power Availability (52.4.1)
Ball Pressure (59.2)
Summary of Compliance with National Differences:
List of countries addressed: US The product fulfills the requirements of: Since the battery charger is not used in the patient vicinity, IEC 60601-1-1 Report is attached.

Copy of Marking Plate – Not Provided

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8218

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Test item particulars :				
Classification of installation and use		Hand-held		
Supply connection		Internally powered		
Accessories and detachable parts included in the evaluation		None		
Options included		None		
Possible test case verdicts:				
- test case does not apply to the test object		N / A		
- test object does meet the requirement		P(Pass)		
- test object does not meet the requirement		F(Fail)		
Abbreviations used in the report:				
- normal condition	N.C.	- single fault condition		S.F.C.
- operational insulation	OP	- basic insulation		BI
- basic insulation between parts of opposite polarity:	BOP	- supplementary insulation		SI
- double insulation	DI	- reinforced insulation		RI
Testing:				
Date(s) of receipt of test item		2011-08-01		
Date(s) of Performance of tests		2011-08-05 to 2011-08-11		

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

List of test equipment must be kept on file and be available for review.

"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

Manufacturer's Declaration per SubClause 6.25 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory and a declaration form the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... Not Applicable

When differences exist, they shall be identified in the General Product Information section.

Name and address of Factory(ies):	INCONTROL MEDICAL L L C SUITE 250 3225 GATEWAY RD BROOKFIELD WI 53045 UNITED STATES

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

Product Description

The In Control InToneTM device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises.

Model Differences

N/A

Additional Information

N/A

Technical Considerations

- The product was investigated to the following additional standards:: IEC 60601-1-1, EN 60601-1: 1990 + A1:1993 + A2:1995, CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada), (except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4),
- The product was not investigated to the following standards or clauses:: Clause 52.1, Programmable Electronic Systems (IEC 601-1-4), Clause 48, Biocompatibility (ISO 10993-1), Clause 36, Electromagnetic Compatibility (IEC 601-1-2), IEC 60601-2-10
- The product is Classified only to the following hazards:: Shock, Fire, Casualty
- The degree of protection against harmful ingress of water is:: Ordinary
- The mode of operation is:: Intermittent
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock:: No
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No

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3	**GENERAL REQUIREMENTS**		Pass
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)		Pass
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained		N/A

5	**CLASSIFICATION**		Pass
5.1	Type of protection against electric shock		Pass
	Class I equipment		N/A
	Class II equipment		N/A
	Internally powered equipment	Rechargeable 6Vdc battery pack located in the control unit	Pass
5.2	Degree of protection against electric shock		N/A
	Type B applied part		N/A
	Type BF applied part		Pass
	Type CF applied part		N/A
	Not classified - no applied parts		N/A
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1).....:		N/A
5.4	Methods of sterilization or disinfection		N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures		Pass
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		Pass
	-continuous operation		Pass
	-short-time operation, specified operation; period .:		-
	-intermittent operation, specified operation; rest period .....:		-
	-continuous operation with short-time, stated permissible loading time .....:		-
	-continuous operation with intermittent, stated permissible loading/rest time.....:		-

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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INSULATION DIAGRAM

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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	TABLE: to insulation diagram						
Area	Insulation type: operational / basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	DI	120	-	-	-	-	Charger is not used in patient vicinity, evaluated to UL1310, See Table 3.201, Enclosure 11-02
B	DI	120	-	-	-	-	Charger is not used in patient vicinity, evaluated to UL1310, See Table 3.201, Enclosure 11-02
C	DI	6	-	-	-	-	Charger is not used in patient vicinity, evaluated to UL1310, See Table 3.201, Enclosure 11-02
D	DI/BI	3/240	3.4/4.0	1.6/2.5	5	5	
E	DI/BI	51.2/240	4.6/4.0	4.0/2.5	5	5	
F	DI/BI	51.2/240	4.6/4.0	4.0/2.5	5.5	5.5	
G	OP	51.2/240	-	-	-	-	

INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional.
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

6	**IDENTIFICATION, MARKING AND DOCUMENTS**		Pass
6.1	Marking on the outside of equipment or equipment parts		Pass
6.1c	Markings of the specific power supply affixed	manual indicates to use only power supply supplied by Incontrol Medical; the power supply employs a unique connector mating with the connector of the control unit.	N/A

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6.1d	If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	no labels provided	Need More Information
6.1e	Name and/or trademark of the manufacturer or supplier.....:	no labels provided	Need More Information
6.1f	Model or type reference.....:	no labels provided	Need More Information
6.1g	Rated supply voltages or voltage range(s)	battery charger	Pass
	Number of phases.....:		N/A
	Type of current.....:	AC - battery charger	Pass
6.1h	Rated frequency or rated frequency range(s) (Hz) :	60Hz- battery charger	Pass
6.1j	Rated power input (VA, W or A).....:	battery charger evaluated to UL 1310	N/A
6.1k	Power output of auxiliary mains socket - outlets		N/A
6.1l	Class II symbol	battery charger evaluated to UL 1310	N/A
	Symbol for degree of protection against ingress of water provided.....:	IPX0	N/A
	Symbol for protection against electric shock.....:	Type BF, no labels provided	Need More Information
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N/A
	Symbol for protection of defibrillation-proof applied parts		N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
6.1m	Mode of operation (if no marking, suitable for continuous operation)	continuous operation	Pass
6.1n	Types and rating of external accessible fuses.....:		N/A
6.1p	Ratings of external output:.....:		N/A
6.1q	Symbol for physiological effect(s):		Need More Information
	- attention, consult accompanying documents	no labels provided	Need More Information
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A
6.1r	Anaesthetic-proof symbol: AP or APG .....:		N/A
6.1s	Dangerous voltage symbol		N/A
6.1t	Special cooling requirements		N/A
6.1u	Limited mechanical stability	Hand held device.	N/A

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6.1v	Protective packing requirement(s)		N/A
	- Marking(s) for unpacking safety hazard(s)		N/A
	- Equipment or accessories supplied sterile, marked as sterile	Not Sterile	N/A
6.1y	Potential equalization terminal		N/A
	- Functional earth terminal		N/A
6.1z	Removable protective means		N/A
	Durability of marking test	label is molded on the enclosure	N/A
6.2	Marking on the inside of equipment or equipment parts		N/A
6.2a	Nominal voltage of permanently installed equipment		N/A
6.2b	Maximum power loading for heating elements or holders for heating lamps		N/A
6.2c	Dangerous voltage symbol		N/A
6.2d	Type of battery and mode of insertion	Manual indicates "Use only battery packs supplied by InTone"	N/A
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator		N/A
6.2e	Fuses accessible with a tool identified either by type and rating or by a reference to diagram		N/A
6.2f	Protective earth terminal		N/A
6.2g	Functional earth terminal		N/A
6.2h	Supply neutral conductor in permanently installed equipment (N)		N/A
6.2j	Markings required in 6.2 f), h), k), and l) remain visible after connection and are not affixed to parts which have to be removed		N/A
	- Markings comply with IEC 445		N/A
6.2k	For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A
6.2l	Statement for suitable wiring materials at temperatures over 75°C		N/A
6.2n	Capacitors and/or circuit parts marked as required in Sub-clause 15c		N/A
6.3	Marking of controls and instruments		Pass
6.3a	Mains switch clearly identified		N/A
	- ON and OFF positions marked according to		N/A

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	Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light		
6.3b	Indication of different positions of control devices and switches	control unit	Pass
6.3c	Indication of the direction in which the magnitude of the function changes, or an indicating device		Pass
6.3f	The functions of operator controls and indicators are identified	control unit	Pass
6.3g	Numeric indications of parameters are in SI units except for units listed in Am. 2		N/A
6.4	Symbols		Pass
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	no labels provided	Need More Information
6.5	Colors of the insulation of conductors		N/A
6.5a	Protective earth conductor has green/yellow insulation		N/A
6.5b	All insulations of internal protective earth conductors are green/yellow at least at their terminations		N/A
6.5c	Only protective or functional earthing, or potential equalization conductors are green/yellow		N/A
6.5d	Color of neutral conductor .....:		N/A
6.5e	Colors of phase conductor(s) .....:		N/A
	- Compliance with IEC 227 and IEC 245		N/A
6.5f	Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A
6.6	Medical gas cylinders and connections		N/A
6.6a	In accordance with ISO ISO/R 32		N/A
6.6b	Identification of connection point		N/A
6.7	Indicator lights and push-buttons		N/A
6.7a	Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N/A
	- Yellow used to indicate caution or attention required		N/A
	- Green used to indicate ready for action		N/A
6.7b	Color red used only for push-buttons by which a function is interrupted in case of emergency		N/A
6.8	ACCOMPANYING DOCUMENTS		Pass
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer		Pass

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	Classifications specified in Clause 5 included in both the instructions for use and the technical description		Pass
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		Pass
	Warning statements and the explanation of warning symbols provided in the accompanying documents		Pass
6.8.2	Instructions for use		Pass
6.8.2a	General information provided in instructions for use		Pass
	- state the function and intended application of the equipment		Pass
	- include an explanation of: the function of controls, displays and signals		Pass
	- the sequence of operation		Pass
	- the connection and disconnection of detachable parts and accessories		Pass
	- the replacement of material which is consumed during operation		N/A
	- information regarding potential electromagnetic or other interference and advice regarding avoidance		Pass
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		N/A
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance		Pass
	General information provided in instructions:		Pass
	- information for the safe performance of routine maintenance		Pass
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied		Pass
	- explanation of figures, symbols, warning statements and abbreviations on the equipment		Pass
6.8.2c	Signal output or signal input parts intended only for connection to specified equipment described	No SIP/SOPs.	N/A
6.8.2d	Details about acceptable cleaning, disinfection or sterilization methods included		Pass
6.8.2e	Warning statement for mains operated equipment with additional power source		N/A
6.8.2f	A warning to remove primary batteries if equipment is not likely to be used for some time		Pass
6.8.2g	Instructions to ensure safe use and adequate		Pass

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	maintenance of rechargeable batteries		
6.8.2h	Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	battery charger provided with the device	Pass
6.8.2j	Identification of any risks associated with the disposal of waste products, residues, etc.		N/A
	- Advice in minimizing these risks		N/A
6.8.3	Technical description		Pass
6.8.3a	All characteristics essential for safe operation provided		Pass
6.8.3b	Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N/A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		N/A
6.8.3c	Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		N/A
6.8.3d	Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		Pass

7	**POWER INPUT**		Pass
	Power Input Measurements		Pass

10	**ENVIRONMENTAL CONDITIONS**		Pass
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer		Pass
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment		Pass
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA	battery charger	Pass
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz	battery charger	Pass
10.2.2b	Internal replaceable electrical power source specified		N/A

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14	**REQUIREMENTS RELATED TO CLASSIFICATION**	N/A

15	**LIMITATION OF VOLTAGE AND/OR ENERGY**	N/A

16	**ENCLOSURES AND PROTECTIVE COVERS**		Pass
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)		Pass
	Insertion or removal of lamps - protection against contact with live parts provided	No lamps.	N/A
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	No top opening.	N/A
16c	Conductive parts accessible after the removal of handles, knobs, levers		N/A
	- have a resistance of not more than 0.2 Ohm	No accessible parts.	N/A
	- separated from live parts by one of the means described in Sub-clause 17g		N/A
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact		N/A
16e	Removable enclosures protecting against contact with live parts		N/A
	- Removal possible only with the aid of a tool		N/A
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts .....:	None	N/A
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	None	N/A

17	**SEPARATION**		Pass
17a	Separation method of the applied part from live parts:		Pass
	1) basic insulation: applied part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation		Pass
	5) by protective impedances limiting current to applied part	Device supplies intentional energy limited by impedances.	N/A
	- Additional leakage current test in single fault		N/A

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	conditions		
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N/A
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N/A
17g	Separation method of accessible parts other than applied parts from live parts:		Pass
	1) basic insulation: accessible part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A
	4) by double or reinforced insulation		Pass
	5) by protective impedances limiting current to accessible part	Device supplies intentional energy limited by impedances.	N/A
	- Additional leakage current test in single fault conditions		N/A
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator	Not Defibrillation proof.	N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function	Not Defibrillation proof.	N/A

18	**PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION**	N/A

19	**CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS**		Pass
19.1b	Leakage currents	(see appended table 19)	Pass
	- earth leakage current		N/A
	- enclosure leakage current		Pass
	- patient leakage current		Pass
	- patient auxiliary current		Pass

20	**DIELECTRIC STRENGTH**		Pass
	Overall compliance with Clause 20	(see appended table 20)	Pass

21	**MECHANICAL STRENGTH**	Pass

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21a	Sufficient rigidity of an enclosure tested by: force of 45 N	(see appended table 21)	Pass
21b	Sufficient strength of an enclosure tested by: impact hammer	(see appended table 21)	Pass
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test	Handheld.	N/A
21.3	No damage to parts of patient support and/or immobilization system after the loading test	Handheld.	N/A
21.5	Hand held equipment or equipment parts are safe after drop test		Pass
21.6	Portable and mobile equipment is able to withstand rough handling	Handheld.	N/A

22	**MOVING PARTS**	N/A

23	**SURFACES, CORNERS AND EDGES**	N/A

24	**STABILITY IN NORMAL USE (see appended table 24)**	N/A

25	**EXPELLED PARTS**	N/A

28	**SUSPENDED MASSES**	N/A

29	**X-RADIATION**	N/A

36	**ELECTROMAGNETIC COMPATIBILITY**	N/A

37	**COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT**	N/A

42	**EXCESSIVE TEMPERATURES**		Pass
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	(see appended table 42)	Pass
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient	(see appended table 42)	Pass

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42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		Pass
42.5	Guards to prevent contact with hot surfaces removable only with a tool		N/A

43	**FIRE PREVENTION**		Pass
	Strength and rigidity necessary to avoid a fire hazard		Pass

44	**OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION**		Pass
44.2	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	No applicable reservoir.	N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)		N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		Pass
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N/A
44.5	Equipment sufficiently protected against the effects of humidity		Pass
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	IPX0	N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions		Pass

45	**PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE**	N/A

48	**BIOCOMPATIBILITY**	N/A

49	**INTERRUPTION OF THE POWER SUPPLY**	N/A

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51	**PROTECTION AGAINST HAZARDOUS OUTPUT**	N/A

52	**ABNORMAL OPERATION AND FAULT CONDITIONS**		Pass
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)		Pass
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	Not evaluated by UL.	N/A
52.5.2	Failure of thermostats presents no safety hazards		N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard		N/A
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	No applicable parts.	N/A
52.5.6	Locking of moving parts presents no safety hazard	No applicable parts.	N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard		N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N/A
52.5.9	Failure of one component at a time presents no safety hazard	(see appended table 52.5)	Pass
52.5.10	Overload of heating elements presents no safety hazard	No applicable parts.	N/A
52.5.10f	Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N/A
52.5.10h	Equipment with three-phase motors can safely operate with one phase disconnected		N/A

56	**COMPONENTS AND GENERAL ASSEMBLY**		Fail
	List of critical components	(see appended table critical components)	Fail
56.1b	Ratings of components not in conflict with the conditions of use in equipment		Need More Information
	Ratings of mains components are identified	battery charger	Pass
56.1d	Components, movements of which could result in a safety hazard mounted securely	No applicable parts.	N/A
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		Pass

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56.3a	Connectors provide separation required by Sub-clause 17g		Pass
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment		N/A
	Medical gas connections not interchangeable		N/A
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken		N/A
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		Pass
56.4	Connections of capacitors		N/A
	Not connected between live parts and non-protectively earthed accessible parts	No applicable parts.	N/A
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14		N/A
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		N/A
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		N/A
56.6	Temperature and overload control devices		N/A
56.6a	Thermal cut-outs which have to be reset by a soldering not fitted in equipment		N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N/A
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N/A
	Non-self resetting over-current releases operated 10 times		N/A
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N/A
56.6b	Thermostats with varying temperature settings		N/A

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	clearly indicated		
	Operating temperature of thermal cut-outs indicated		N/A
56.7	Batteries		Pass
56.7a	Battery compartments:		Pass
	- adequately ventilated		Pass
	- accidental short-circuiting is prevented		Pass
56.7b	Incorrect polarity of connection prevented	Battery is polarity protected.	Pass
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		Pass
	- to indicate that equipment is energized		Pass
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N/A
	- to indicate when output exists if a safety hazard could result		Pass
	- charging mode indicator provided	no charging mode indicator provided on the control unit	Fail
56.10	Actuating parts of controls		N/A
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use		N/A
	Controls are secured to prevent the movement relative to scale marking (safety related only)	No scale markings.	N/A
	Detachable indicating devices are prevented from incorrect connection without the use of tool	No applicable parts.	N/A
56.10c	Stops are provided on rotating controls:		N/A
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard	No applicable parts.	N/A
	- to prevent damage to wiring		N/A
56.11	Cord-connected hand-held and foot-operated control devices		Fail
56.11a	Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g	No applicable parts.	N/A
56.11b	Hand-held control devices comply with the requirement and test of Sub-clause 21.5		Pass
	- Foot-operated control devices designed to support the weight of an adult human being		N/A
56.11c	Devices not change their setting when inadvertently placed		Pass
56.11d	Foot-operated control devices are at least IPX 1		N/A
	- For surgical use, electrical switching parts are IPX 8		N/A

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56.11e	Adequate strain relief at the cord entry provided	no strain relief provided on the insertion unit, the cord is attached with silicone to the unit	Fail

57	**MAINS PARTS, COMPONENTS AND LAYOUT**		Pass
57.1	Isolation from supply mains		Pass
57.1a	Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	battery charger	Pass
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		Pass
57.1d	Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328		N/A
57.1f	Mains switches not incorporated in a power supply cord		N/A
57.1h	Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		N/A
57.1m	Fuses and semiconductor devices not used as isolating devices		N/A
57.2	Mains connectors and appliance inlets		N/A
57.2e	Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug		N/A
57.2g	Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment		N/A
57.3	Power supply cords		N/A
57.3a	Not more than one connection to a particular supply mains		N/A
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N/A
	The mains plug has only one power supply cord		N/A
	Non-permanently connected equipment provided with power supply cord or appliance inlet		N/A
57.3b	Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		N/A
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		N/A

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57.3c	Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		N/A
57.3d	Stranded conductors not soldered if fixed by any clamping means		N/A
57.4	Connection of power supply cords		N/A
57.4a	Cord anchorages		Requires Testing
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting		N/A
	Tying the cord into a knot or tying the ends with string not used		N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N/A
	Cord anchorages made of metal provided with an insulating lining		N/A
	Clamping screws do not bear directly on the cord insulation		N/A
	Screws associated with cable replacement are not used to secure other components		N/A
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N/A
57.4b	Power supply cord protected against excessive bending		N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N/A
57.5	Mains terminal devices and wiring of mains part		N/A
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods		N/A
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		N/A
	Screws and nuts which clamp external conductors not serve to fix any other component		N/A
57.5b	Terminals closely grouped with any protective earth terminal		N/A
	Mains terminal devices accessible only with use of a tool		N/A

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	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		N/A
57.5c	Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N/A
57.5d	Cord terminals not require special preparation of the conductor		N/A
57.6	Mains fuses and overcurrent releases		N/A
	Fuses or over-current releases provided accordingly for Class I and Class II		N/A
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		N/A
	Protective earth conductor not fused		N/A
	Neutral conductor not fused for permanently installed equipment		N/A
57.8	Wiring of the mains part		N/A
57.8a	Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC Publications 227 or 245, treated as bare conductor		N/A
57.8b	Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord		N/A
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		N/A
57.9	Mains supply transformers		Pass
57.9.1	Overheating	battery charger evaluated to UL 1310	Pass
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		Pass
57.9.1a	Short-circuit of secondary windings not caused excessive temperature		Pass
57.9.1b	Overload of secondary windings not caused excessive temperature		Pass
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		Pass
57.9.4	Construction		Pass

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57.9.4a	Separation of primary and secondary windings		N/A
	- separate bobbins or formers		N/A
	- one bobbin with insulating partition		Pass
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		N/A
	- concentrically wound on one bobbin with windings separated by double insulation		N/A
57.9.4c	Means provided to prevent displacement of end turns		Pass
57.9.4d	Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N/A
57.9.4e	Insulation between the primary and secondary in transformers with double insulation		Pass
	- 1 insulation layer having a thickness of at least 1 mm		Pass
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N/A
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation		N/A
57.9.4g	Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding		N/A
57.10	Creepage distances and air clearances		Pass
57.10a	Values: compliance with at least the values of Table XVI		Pass
	Creepage distances for slot insulation of motors at least 50% of the specified values		N/A
57.10b	Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard		N/A
57.10c	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts		N/A

58	**PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS**	N/A

59	**CONSTRUCTION AND LAYOUT**	Pass

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59.1	Internal wiring		Pass
59.1a	Cables and wiring protected against contact with a moving part		N/A
	Wiring having basic insulation only protected by additional fixed sleeving		N/A
	Components are not likely to be damaged in the normal assembly or replacement of covers		Pass
59.1b	Movable leads are not bent around a radius of less than five times the outer diameter of the lead		Pass
59.1c	Insulating sleeving adequately secured		N/A
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test	No applicable parts.	N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N/A
59.1d	Aluminum wires of less than 16 mm2 cross-section not used	No applicable parts.	N/A
59.1f	Connecting cords between equipment parts considered as belonging to the equipment		Pass
59.2	Insulation		Pass
59.2b	Mechanical strength and resistance to heat and fires retained by all types of insulation	(see appended table additional tests)	Pass
59.2c	Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		Pass
	Parts of rubber resistant to ageing	No rubber parts.	N/A
59.3	Excessive current and voltage protection		N/A
	Internal electrical power source provided with device for protection against fire hazard		N/A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		N/A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N/A
59.4	Oil containers		N/A
	Oil containers adequately sealed	No applicable parts.	N/A
	Container allow for the expansion of the oil		N/A
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

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6.1	**TABLE: marking durability**	N/A
Marking tested		Remarks
supplementary information:		

7	**TABLE: power input**					Pass
Operating condition	Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks	
supplementary information: See attached datasheets(Appendix B)						

15b	**TABLE: residual voltage in attachment plug**										N/A
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
supplementary information:											

15c	**TABLE: residual voltage or energy in capacitors**				N/A
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (µF)	Residual energy (mJ)	Remarks
supplementary information:					

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17h1	**TABLE: defibrillation-proof applied parts**				N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
supplementary information:					

17h2	**TABLE: defibrillation-proof recovery time**			N/A
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks
supplementary information:				

18	**TABLE: protective earthing**			N/A
Test location	Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks
supplementary information:				

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19	**TABLE: leakage current**			Pass
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
supplementary information: See attached datasheets(Appendix B)				
ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA - Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device		A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition		

20	**TABLE: dielectric strength**			Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks
supplementary information: See attached datasheets(Appendix B) -				

21	**TABLE: mechanical strength**	Pass
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks
supplementary information: See attached datasheets(Appendix B)		

24	**TABLE: - stability**	N/A
Part under test	Test condition	Remarks
supplementary information:		

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29	**TABLE: X - radiation**		N/A
Part under test	Test condition	Measured radiation (mR)	Remarks
supplementary information:			

42	**TABLE: normal temperature**		Pass
Supply voltage: Ambient temperature:	Test Condition:		
Measuring location		Measured temperature (°C)	Remarks
COR - indicates measurements taken using change-of-resistance method			
supplementary information: See attached datasheets(Appendix B) -			

44	**TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, desinfection**	Pass
Test type and condition	Part under test	Remarks
supplementary information: See attached datasheets(Appendix B) -		

45	**TABLE: hydrostatic pressure and pressure-relief device cycling test**		N/A
Test type and condition	Part under test	Test pressure	Remarks
supplementary information:			

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52	**TABLE: abnormal operation**	Pass
Test type, condition and clause reference	Observed results	Remarks
supplementary information: See attached datasheets(Appendix B)		

56.1	**TABLE: list of critical components**				Pass
object/part or Description	(b)(4) CCI	type/model	technical data	standard (Edition/ year)	mark(s) of conformity[1])
Battery charger		LF06300D-08	Input: 120V, 60Hz, output: 6Vdc, 300mA,	UL 1310	UL, -
Enclosure plastic, Control unit		2020001B1(front plastic), 2020002B1 (Back Plastic), Same plastic material (internal numbers)			
Control unit, output connector		182-009-213R161			
Enclosure plastic, Insertion Unit		2020003B1 (right half), 2020004B1 (left half)			
Control unit overlay		(b)(4) (b)(4) CCI	2020016B1	-	-, -
Battery, control unit		HHR-120 AA	Ni-MH, 2 provided, rechargeable	-	-, -
Resistor (Limits total current delivery)		ERJ-14YJ5R1U, 5.1 Ohm		-	-, -
Constant Current Source (Limits total current delivery)		LM317MDCYR	-	-	-, -
Internal wires, electrode wires		1010023A1		-	-, -
Supplementary information: [1]) Provided evidence ensures the agreed level of compliance. See OD-CB2039.					

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56.10	TABLE: actuating parts and controls	N/A
Part under test	Torque applied	Remarks
-	-	-
supplementary information:		

56.11b	TABLE: foot operated control devices-loading	N/A
Part under test	Observed results	Remarks
supplementary information:		

57.4	TABLE: cord anchorages			N/A
Cord under test	Mass of equipment	Pull	Torque	Remarks
supplementary information:				

57.4b	TABLE: cord bending		N/A
Cord under test	Test mass	Measured curvature	Remarks
supplementary information:			

57.9.1a	TABLE: transformer short circuit					N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
supplementary information:						

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57.9.1b	**TABLE: overload**						N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
supplementary information:							

57.9.2	**TABLE: transformer dielectric strength**			N/A
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks
supplementary information:				

	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	Verdict
supplementary information: See attached datasheets(Appendix B & C)			

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Enclosure

National Differences

USA

* No National Differences Declared

** Only Group Differences

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USA - Differences to IEC 60601-1:1988 + A1:1991 + A2:1995			
3.100.1a	Printed wiring boards comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.		Need More Information
3.100.1b	Lithium batteries comply with U.S. National or internationally harmonized component standards		N/A
3.100.1c	Optical isolators comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.		N/A
3.100.1d	Wiring and tubing comply with U.S. National or internationally harmonized component standards unless they are connected totally in a SELV circuit limited to 15 W, or less, maximum available power and whose failure will not result in a Safety Hazard.		Need More Information
3.100.1e	CRT's > 5 inches comply with U.S. National or internationally harmonized component standards		N/A
3.101.1	Primary circuit components up to isolation transformer meet U.S. national or international harmonized component standards	Battery charger complies with UL 1310	Pass
6	a) All words except the signal words in "CAUTION", WARNING", and "DANGER" markings at least 1.6 mm (1/16 inch) high	no labels provided	Need More Information
6	b) Signal words "CAUTION", WARNING", and "DANGER" at least 2.8 mm (7/64 inch)	no labels provided	Need More Information
6	c) Letters in contrast color to the background		N/A
6	Equipment capable of emitting ionizing radiation provided with warning statement		N/A
6	If equipment produced in more than one factory, factory identification marked on the equipment		N/A
6	Multiple-voltage equipment intended for permanent connection marked with voltage for which it is connected when shipped		N/A
6.2l	Statement for suitable wiring materials at temperatures over 60 °C		N/A
6.6a	Identification of the content of gas cylinders in accordance with the color coding requirement of ANSI/NFPA99.		N/A
6.8	Cord-connected equipment provided with instructions to indicate type of attachment plug for alternate voltage		N/A

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10.2.2a	Rated voltage not exceeding 250 Vdc or single phase ac or 600 V polyphase ac for equipment up to 4kVA	battery charger	Pass
10.2.2a	Rated voltage not exceeding 600 V for all other equipment		N/A
14	Fixed equipment and permanent equipment is Class I		N/A
18m	Earthing of X-ray equipment: All parts operating at over 600 V ac, 850 V dc, or 850 V peak are enclosed in protectively earthed enclosures		N/A
18m	Earthing of X-ray equipment: Connections from high-voltage equipment to other high voltage components made with high voltage shielded cables		N/A
18n	Accessible non-current carrying conductive parts are protectively earthed		N/A
19	Enclosure and earth leakage currents comply with U.S. limits		Pass
22	When risk of injury can occur, end stops are provided	No applicable parts.	N/A
22	End stops have mechanical strength as determined by the test		N/A
22.4	Dangerous movements of equipment parts which may cause physical injury to the patient or operator are possible only by the continuous activation by the operator		N/A
22.7a	Emergency off switch has red actuator		N/A
22.7a	Emergency off switch: once actuated, maintains the equipment in "off" condition until action, different from that used to actuate, is performed		N/A
22.7a	Emergency off switch is readily accessible to operator		N/A
22.7b	Emergency off switch is marked with word "STOP" or symbol 5110 of IEC 878 in compliance with U.S. Clause 6		N/A
22.7b	Emergency off switch: separate and independent of the intended movement control		N/A
28.3	No evidence of damage to a safety catch after test		N/A
28.3	Safety catch marking provided		N/A
28.4	No damage to structural parts as a result of loading test		N/A
42	Insulation systems with measured temperatures		Pass

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	exceeding Class A 105°C (based on 40°C ambient) comply with UL1446		
55	Polymeric enclosures and external combustible surfaces		Pass
55	Polymeric enclosures comply with: Conductive coatings applied to nonmetallic surfaces comply with UL 746C	No conductive coating.	N/A
55	External combustible surface of more than 9.47 m2 or single dimension of 3.7 m have flame spread rating not exceeding 75 (Steiner Tunnel Test)		N/A
55	External combustible surface of more than 4.74 m2 but not exceeding 9.47 m2 have flame spread rating not exceeding 75 (Radiant Panel or Steiner Tunnel Test)		N/A
55	Polymeric enclosures for transportable equipment rated 94V-2 or better	need information on the enclosure material and results from power availability	Need More Information
55	Polymeric enclosures for fixed or stationary equipment rated 94V-0 or better		N/A
55	Polymeric enclosures withstand 6.78 Nm impact test	Handheld	N/A
55	Polymeric enclosures: no deformation after mold stress test	(see appended table additional tests)	Pass
55	Polymeric enclosures of hand-held equipment withstands 1.22 m drop test	(see appended table 21)	Pass
56.3a	Connector, pin, plug attached to patient connected lead or contact cannot engage any part on the equipment, including separable cord set		Pass
56.3a	Connector, pin, plug attached to patient connected lead or contact cannot make contact with live parts of power receptacle outlet (if product can be used without professional supervision)		N/A
57	Permanently connected equipment provided with field wiring provision in accordance with NEC, ANSI/NFPA 70	No applicable parts.	N/A
57.2	Power cord mains plug is "Hospital Grade" type		N/A
57.2	Grounding reliability marking provided		N/A
57.2	Plug for radiography equipment acceptable for current not less than 50 % of maximum input		N/A
57.2	Plug acceptable for use with current not less than 125 % of rated current		N/A
57.2	Plug acceptable for voltage for which the equipment is configured when shipped		N/A
57.2	Polarized plug wired such that the center contact of edison-base lampholder, single-pole switch or		N/A

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	single-pole overcurrent device connected in ungrounded side		
57.3b	Detachable power supply cord unlikely to become detached accidentally		N/A
57.3b	Flexible cord is of type acceptable for application		N/A
57.3b	Flexible cord not smaller than 18 AWG		N/A
57.3b	Flexible cord complies with serviceability requirements		N/A
57.5b	If leads are provided for connection to branch circuit, the free end is in separate compartment		N/A
57.5b	If leads are provided for connection to branch circuit, the free length of leads inside field-wiring compartment is at least 152 mm long		N/A
58.2	Connections are mechanically secured in addition to soldering		N/A
59.1	Installation of connecting cords between parts of equipment in compliance with NEC	No applicable parts.	N/A
59.1	Cable type acceptable for external interconnection		N/A
400	Oxygen		N/A
400.1	At least one of the following three requirements is satisfied:		N/A
400.1.1	Electrical components separated by barrier per 400.2		N/A
400.1.2	Compartments with electrical components ventilated per 400.3		N/A
400.1.3	Electrical components comply with 400.4 so that cannot be a source of ignition		N/A
400.2	Barrier required by 400.1 is sealed at all joints and holes		N/A
400.3	Ventilation required by 400.1 is such that oxygen content does not exceed 4% above ambient		N/A
400.4	Under N.C. and S.F.C. the product of the value of no load rms voltage and short circuit rms current less than 10 VA		N/A
400.4	Surface temperature of components below 300°C in N.C. and S.F.C		N/A
400.5	External exhaust gas outlets located at least 20 cm from any electrical component mounted on the outside		N/A
400.6	Hospital beds intended for use with oxygen administering equipment provided with required markings		N/A
400.7	Pendant controls on hospital beds with oxygen		N/A

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	administering equipment marked as required		
400.8	Instructions for installation are in compliance with requirements of this clause		N/A
600.1	Separate power units packed with equipment		N/A
600.1	Separate power units provided with correlation marking		N/A
600.2.1	Direct plug-in unit construction and performance comply with required sections of UL1310		Pass
600.2.2	Direct plug-in unit external temperature rise during overheating test do not exceed 65°C	battery charger evaluated to UL 1310	Pass
600.2.3	If direct plug-in unit provided with a mounting tab - unit marked as required by UL1310		N/A

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Enclosures

Type	Supplement Id	Description
Marking Plate		
Collateral	11-02	IEC 60601-1-1
Particular		
Photographs	3-01	charger
Photographs	3-02	control unit inside view
Photographs	3-03	control unit
Photographs	3-04	insertion unit
Photographs	3-05	insertion unit inside
Photographs	3-06	insertion unit PCB 1
Photographs	3-07	insertion unit PCB 2
Photographs	3-08	insertion unit PCB
Photographs	3-09	insertion unit strain rleif
Diagrams		
Schematics + PWB	5-01	STIMULATOR SCHEMATIC
Schematics + PWB	5-02	HANDHELD SCHEMATICS
Manuals	6-01	Manual
Miscellaneous		
Licenses		

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Collateral ID 11-02

Test Report issued under the responsibility of:

Working for a safer world

TEST REPORT
IEC 60601–1–1

Medical electrical equipment
Part 1-1 - Collateral Standard: Safety Requirements for Medical Electrical Systems

Report Reference No. ..... :	E348953-A1
Date of issue ..... :	See main report
Total number of pages	12
Testing Laboratory ..... :	UL Northbrook
Address ..... :	333 Pfingsten Rd, Northbrook, IL 60062
Applicant's name ..... :	See main report
Address ..... :	See main report
Test specification:	
Standard ..... :	IEC 60601-1-1: 2000 (Second Edition) for use with IEC 60601-1 (1988), Amts 1 (1991) and 2 (1995)
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1_1D
Test Report Form(s) Originator ..... :	Underwriters Laboratories Inc.
Master TRF ..... :	Dated 2006-09

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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description ..... :	See main report
Trade Mark ..... :	See main report
Manufacturer ..... :	See main report

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Model/Type reference	:	See main report
Ratings	:	See main report

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Testing procedure and testing location:
☐ **CB/CCA Testing Laboratory**:
Testing location/ address.....:
☐ **Associated CB Laboratory:**
Testing location/ address.....:
Tested by (name + signature).....: See main report
Approved by (+ signature) .....: See main report
☐ Testing procedure: TMP
Tested by (name + signature).....:
Approved by (+ signature) .....:
Testing location/ address.....:
☐ Testing procedure: WMT
Tested by (name + signature).....:
Witnessed by (+ signature).....:
Approved by (+ signature) .....:
Testing location/ address.....:
☐ Testing procedure: SMT
Tested by (name + signature).....:
Approved by (+ signature) .....:
Supervised by (+ signature).....:
Testing location/ address.....:
☐ Testing procedure: RMT
Tested by (name + signature).....:
Approved by (+ signature) .....:
Supervised by (+ signature).....:
Testing location/ address.....:

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Summary of testing:	
Tests performed (name of test and test clause): **See main report**	**Testing location: UL Northbrook**
Summary of compliance with National Differences:	
Copy of marking plate **See main report**	

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Test item particulars ..... :	
Classification of installation and use ..... :	See IEC 60601-1 Test Report
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	P (Pass)
- test object does not meet the requirement ..... :	F (Fail)
Testing ..... :	
Date of receipt of test item ..... :	
Date (s) of performance of tests ..... :	

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

Throughout this report a comma (point) is used as the decimal separator.

This Test Report contains the general safety requirements as related to the programmable electrical medical systems. It can only be used together with IEC 60601-1 Test Report.

General product information:

See main report

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3	**GENERAL REQUIREMENTS**		P
	Situation No.(s) from Table BBB.201 with indication which parts of the system are considered as Equipment A, which are Equipment B. (If none of the examples applies description of the system) .....:		—
	Indicate solutions used to mitigate hazards arising from interconnection of different equipment (refer to Table BBB.201) .....:		—
3.201	System after installation or subsequent modification causes no safety hazard for the patient, the operator or surroundings		P
	System within the patient environment provides the same level of safety as Medical Equipment complying with IEC 60601-1		P
	System outside the patient environment provides the level of safety appropriate for non-medical equipment complying with other IEC or ISO standards	Power supply is evaluated to UL1310	P
3.201.1	Medical Equipment complies with IEC 60601-1 and relevant particular standards	(See appended Table 3.201)	P
3.201.2	Non-medical equipment complies with relevant IEC or ISO standards	(See appended Table 3.201)	P
	Equipment in which protection relies on basic insulation only shall not be used in a system		P
3.201.3	A specified power supply according to 10.2.2.201 meets the requirements of IEC 60601-1 or demonstrates an equivalent degree of safety		N/A
3.201.4	After installation or subsequent modification, the system is in compliance with the requirements of this collateral standard		P

6	**IDENTIFICATION, MARKING AND DOCUMENTS**		P
6.8.201	System accompanied by documents containing all the data necessary for safe and intended use		P
	Documents provided with the system include required documents:		P
	a) accompanying documents for each item of medical equipment		P
	b) equivalent documents for each item of non-medical electrical equipment		P
	c) The following information is provided:		P

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	- instruction for cleaning, sterilization, or disinfection of each item of the system		P
	- additional safety measures which should be applied during installation of the system		P
	- which parts of the system are suitable for use within the patient environment		N/A
	- additional measures which should be applied during preventive maintenance		P
	- a warning that Multiple Portable Socket-Outlets (MPSO) shall not be placed on the floor		N/A
	- a warning that an additional MPSO or extension cord shall not be connected to the system		N/A
	- a warning not to connect items which are not specified as part of the system		N/A
	- the maximum permitted load for any MPSO(s)		N/A
	- instruction that MPSO provided with the system shall only be used for powering equipment which forms part of the system		N/A
	- explanation of the risks of connecting a non-medical equipment, which has been supplied as a part of the system, directly to the wall outlet when the system is supplied via MPSO with a separating transformer		N/A
	- explanation of the risks of connecting electrical equipment which, has not been supplied as a part of the system, to the MPSO		N/A
	- any restrictions in the environmental conditions to ensure safety		P
	- instructions to the operator not to touch parts referred to in clause 16.201 and the patient simultaneously		N/A
	d) advice to the installer, recommending that the system be installed in a way that enables the user to achieve optimal use		N/A
	- advice to the user, to carry out all cleaning, adjustment, sterilization and disinfection procedure specified herein		P

10	**ENVIRONMENTAL CONDITIONS**		N/A
10.2.2.201	A power supply from another equipment for use in a system equipment is specified by the manufacturer.		N/A

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16	**ENCLOSURES AND PROTECTIVE COVERS**		N/A
16.201	Within the patient environment parts of non-medical electrical equipment which, after removal of covers (without use of a tool) may be contacted by the operator:		N/A
	- operate at a voltage not exceeding 25 V ac, or 60 V dc		N/A
	- peak value supplied from a source, which is separated from the supply mains by one of the methods from 17g of IEC 60601-1		N/A

17	**SEPARATION**		N/A
17.201	Separation device is provided - if leakage current limits could be exceeded by connecting different parts of the system		N/A
	Separating device has the dielectric strength, creepage distances and air clearances for the highest voltage occurring across the device during a fault condition.	(See appended Table 17.201)	N/A

19	**LEAKAGE CURRENTS**		N/A
19.201.1	Enclosure leakage current in NC measured from or between parts of the system within the patient environment does not exceed 0.1 mA	(See Table 19.201.1)	N/A
	Enclosure leakage current in the event of interruption of any non-permanently installed protective earth conductor (SFC) does not exceed 0.5 mA	(See Table 19.201.1)	N/A
	If system or part of the system is supplied from a MPSO, leakage current in the protective earth conductor of the MPSO does not exceed 0.5 mA	(See Table 19.201.1)	N/A
19.201.2	Patient leakage current in NC does not exceed 0.1 mA for Type B and BF and 0.01 mA for Type CF	(See Table 19.201.1)	
19.201.3	If SIP/SOPs of medical equipment are specified in accompanying documents for exclusive connection to a Class I device, than the specific device is connected:		N/A
	- to the common protective earth of the system		N/A
	- to a separation device		N/A

22	***MOVING PARTS***		N/A
22.7	If movement of equipment/parts in a system may cause safety hazard, the system is provided with a protective means in accordance with 22.7 of IEC 60601-1.	(See Table "Additional Tests")	N/A

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44	***OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION, AND COMPATIBILITY***		
44.7.201	System is installed in such a way that the user is able to carry out the necessary cleaning, sterilization or disinfection.	SEE MAIN REPORT	

49	***INTERRUPTION OF THE POWER SUPPLY***		
49.201	Interruption and restoration of the power supply to any single equipment in the system does not result in a safety hazard.	(See appended Table "Additional Tests") SEE MAIN REPORT	

56	***COMPONENTS AND GENERAL ASSEMBLY***		P
56.3.201	Design and construction of accessible connections, removable without the use of a tool, prevent a SAFETY HAZARD		P
	- Connectors comply with Clause 17g of the General Standard		P
	- Patient leads cannot be connected to other outlets on the same system, which are likely to be located in the patient environment		P

57	***MAINS PARTS, COMPONENTS AND LAYOUT***		N/A
57.2.201	Multiple Portable Socket-Outlet		N/A
	Connection of equipment used in medical practice to MPSO is only possible by using a tool, or MPSO is supplied via separating transformer.		N/A
	Separating transformer and MPSO complies with Annex EEE.		N/A
57.10.201	Separation Device		N/A
	Separation device complies with required creepage and air clearance from Table 201.	(See appended Table 17.201)	N/A

58	***PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS***		N/A
58.201	Protective earth connection is made in such a way		N/A

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	that removal of any single item of the system does not interrupt protective earth connection to any part of the system, without at the same time disconnecting the supply		
	Protective earth conductors are routed together with the power supply cord.		N/A
	Additional Protective Earth Conductor:		N/A
	Permanently connected to non-mobile item of System		N/A
	Detachable only with the use of a tool		N/A

59	***CONSTRUCTION AND LAYOUT***		P
59.201	Conductors connecting different items of equipment within the system are protected from mechanical damage		P

	ANNEX EEE - REQUIREMENTS FOR MPSO		N/A
EEE.1	**MPSO With Separating Transformers**		N/A
	Separating transformer complies with IEC 60989 with exception of rated output power and IP protection	(See Enclosure No.)	N/A
	Transformer assembly is Class I		N/A
	If necessary transformer assembly has a specified protection against ingress of water as detailed in IEC 60529.		N/A
	In addition to marking requirements of IEC 60989, the transformer assembly marked according to 6.1 and 6.2 of IEC 60601-1.		N/A
	MPSO is marked with maximum allowed output		N/A
	MPSO is permanently connected to the transformer.		N/A
	Socket-outlet does accept mains plug made according to IEC/TR3 60083		N/A
	MPSO is marked with Symbol 14 of Table D1, IEC 60601-1		N/A

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EEE.2	**MPSO**		N/A
	MPSO complies with IEC 60884-1 and as follows:		N/A
	- Creepage and air clearances comply with Cl. 57.10 of IEC 60601-1		N/A
	- MPSO is Class I and protective earth conductor is connected to earthing contacts of the output sockets.		N/A
	- Protective earthing terminals and connections comply with Cl. 58 of IEC 60601-1.		N/A
	- Enclosures comply with Cl. 16 of IEC 60601-1.		N/A
	- Mains terminal devices comply with Cl. 57.5 of IEC 60601-1.		N/A
	- Ratings of components do not conflict with condition of use.		N/A
	- Connections comply with Cl. 56.3 of IEC 60601-1.		N/A
	- Power supply cord complies with Cl. 57.3 and 57.4 of IEC 60601-1.		N/A
	- Protective earthing complies with Cl. 18 of IEC 60601-1.		N/A
	- MPSO is marked with Symbol 14 of Table D1, IEC 60601-1.		N/A

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3.201	TABLE: System Configuration				F
Component of the system	Intended use			Certification (IEC, ISO standard)	Certifier
	In patient environment (yes/no)	Outside patient environment			
		In medically-used room (yes/no)	Non-medically used room (yes/no)		
Power supply	no	no	yes	UL 1310	UL
Control unit	yes	-	-	IEC 60601-1	UL
Insertion unit	yes	-	-	IEC 60601-1	UL
PC	no	no	yes	IEC 60950 or IEC 60601-1	
Supplementary information: the Manual does not indicate that the PC should meet the applicable safety standard (UL/IEC60950)					

17.201	TABLE: Dielectric Test for Separating Devices						N/A
Device	Reference Voltage	Test Voltage	Required		Measured		Remarks
			Air Clearance	Creepage	Air Clearance	Creepage	
Supplementary information:							

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19.201.1	TABLE: System Leakage Current		
Leakage current measured from or between the following parts:	Measured Value (NC)	Measured Value (SFC)	Remarks
Supplementary information: see main report			

AT	TABLE: Additional Tests	
Clause	Test type and condition	Remarks and observed results
Supplementary information: see main report		

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TRF No. IEC601_1_1D

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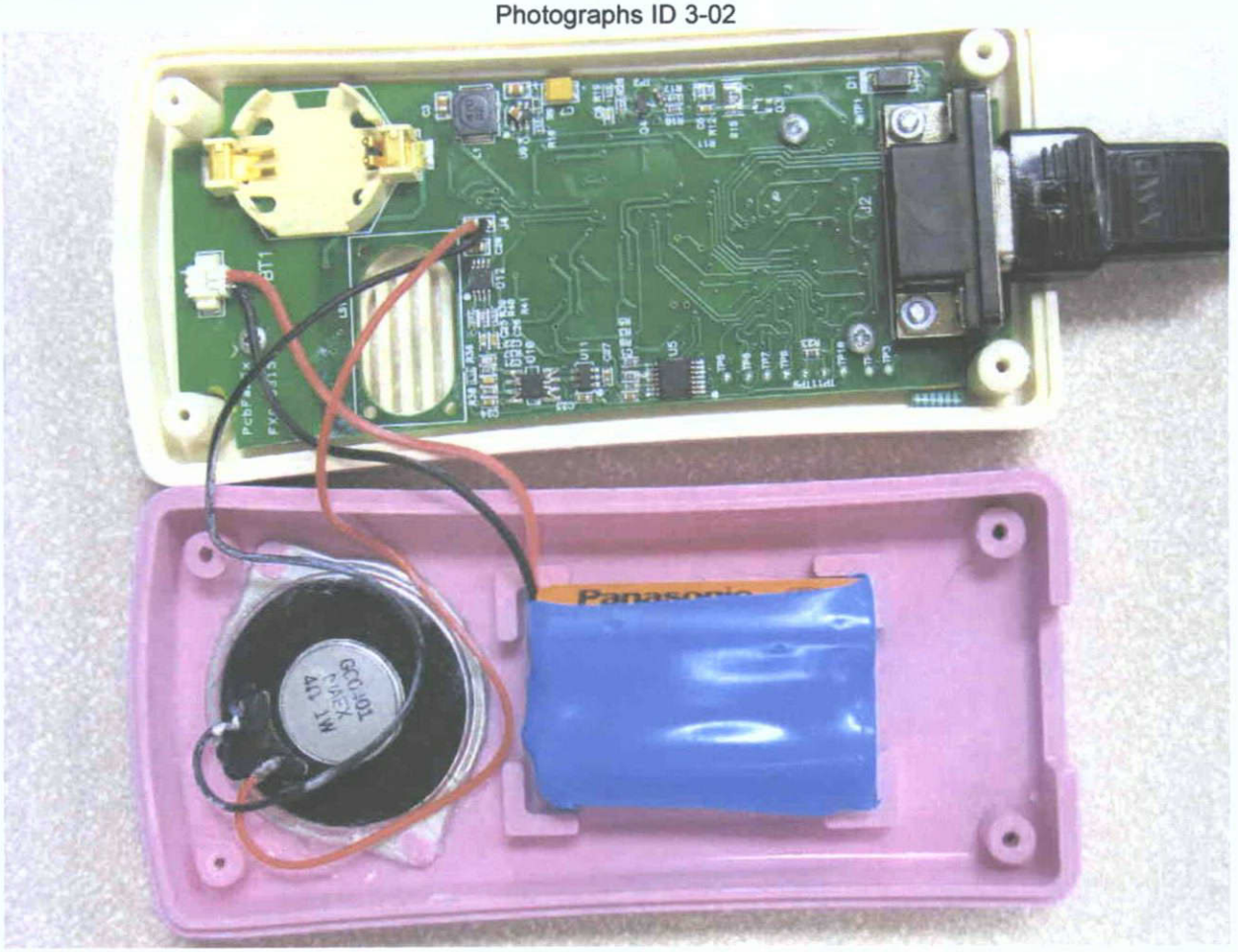
Photographs ID 3-02



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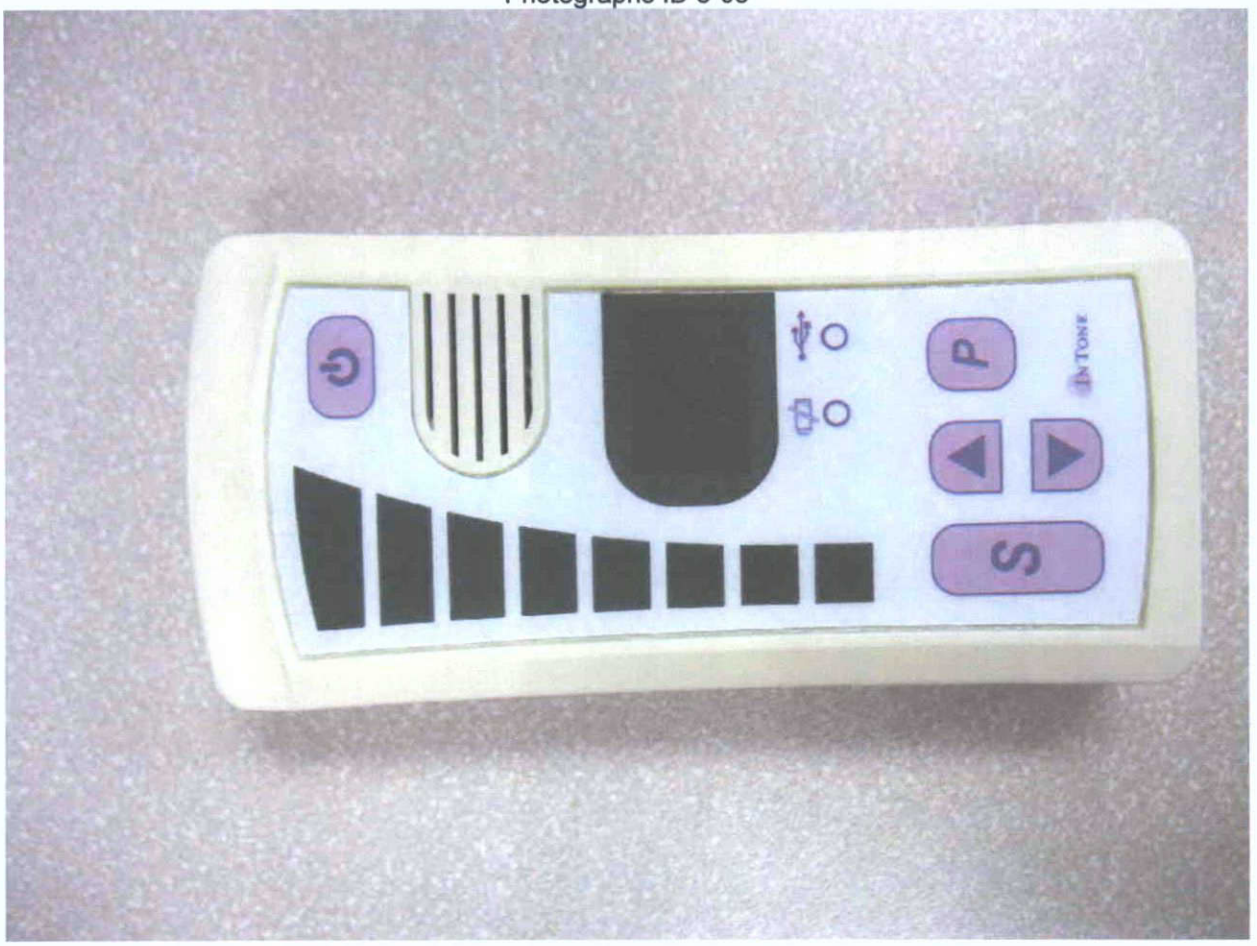
Photographs ID 3-03



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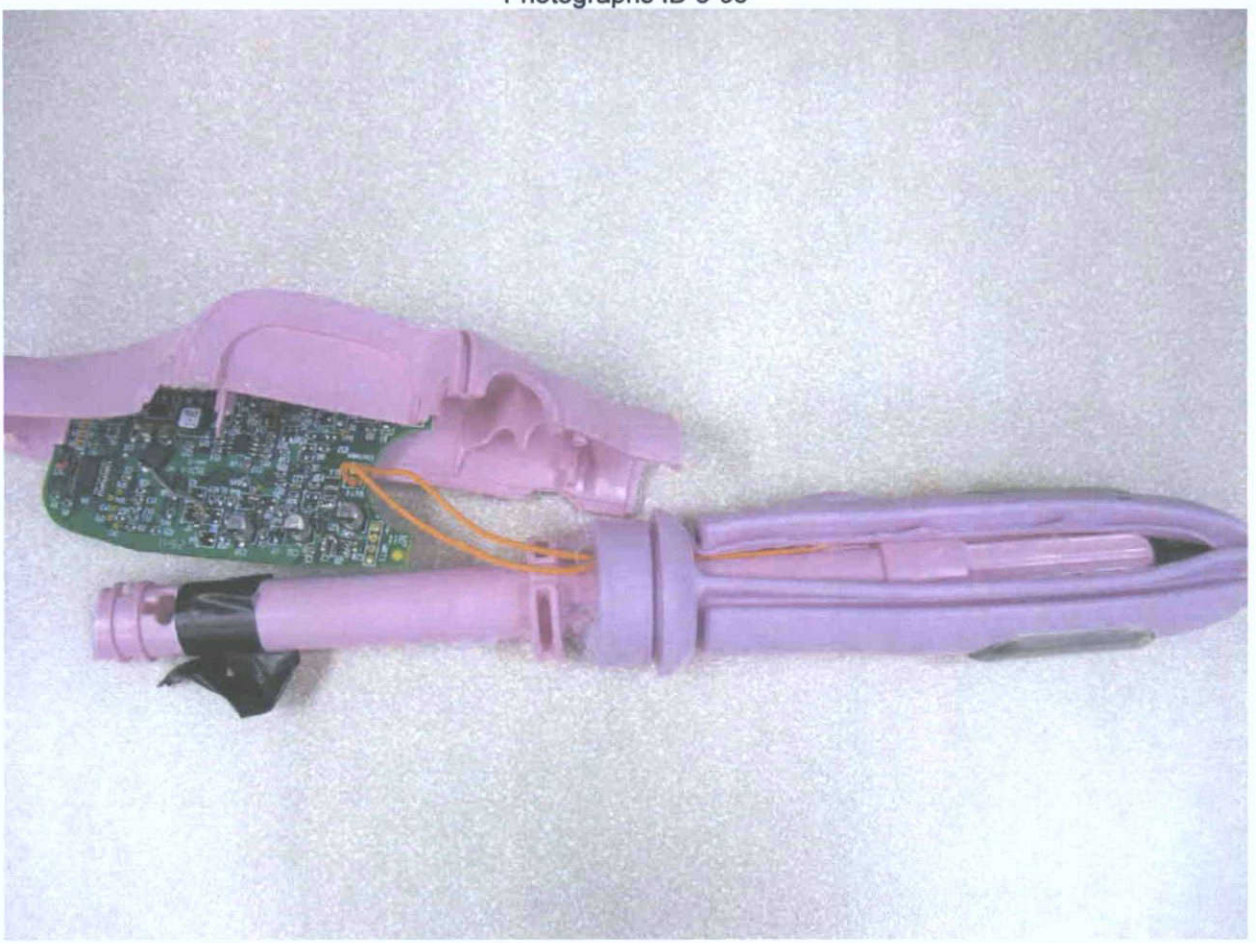
Photographs ID 3-05



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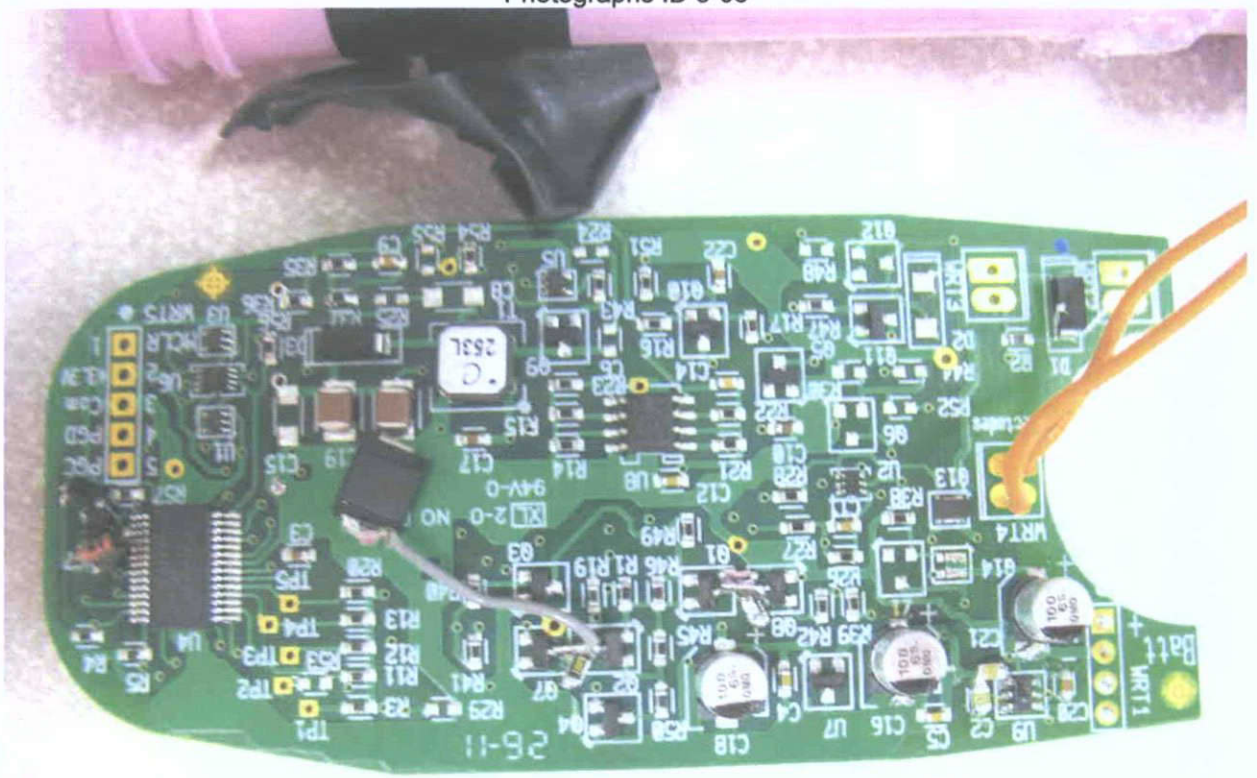

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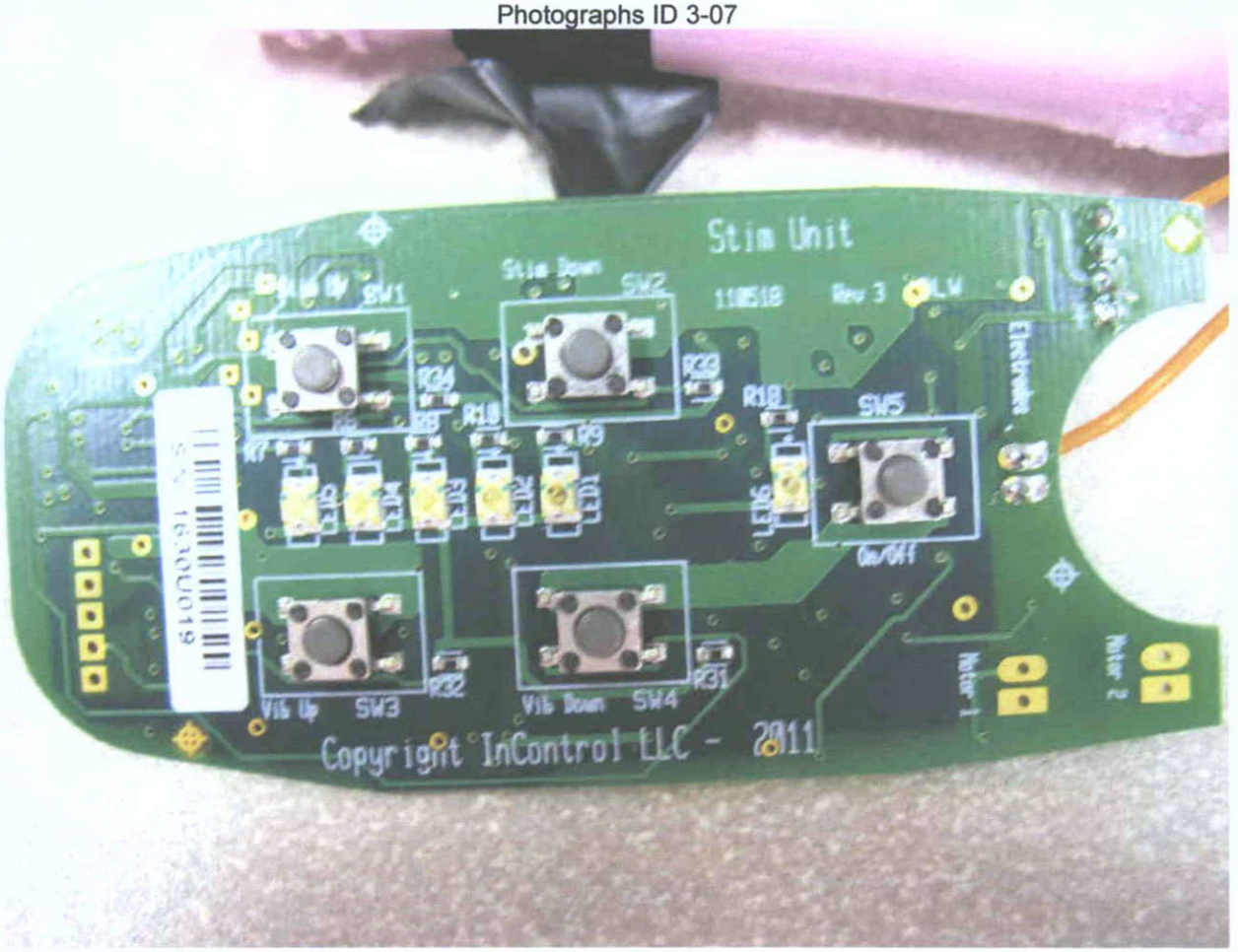

TRF No. IEC601_1_1D

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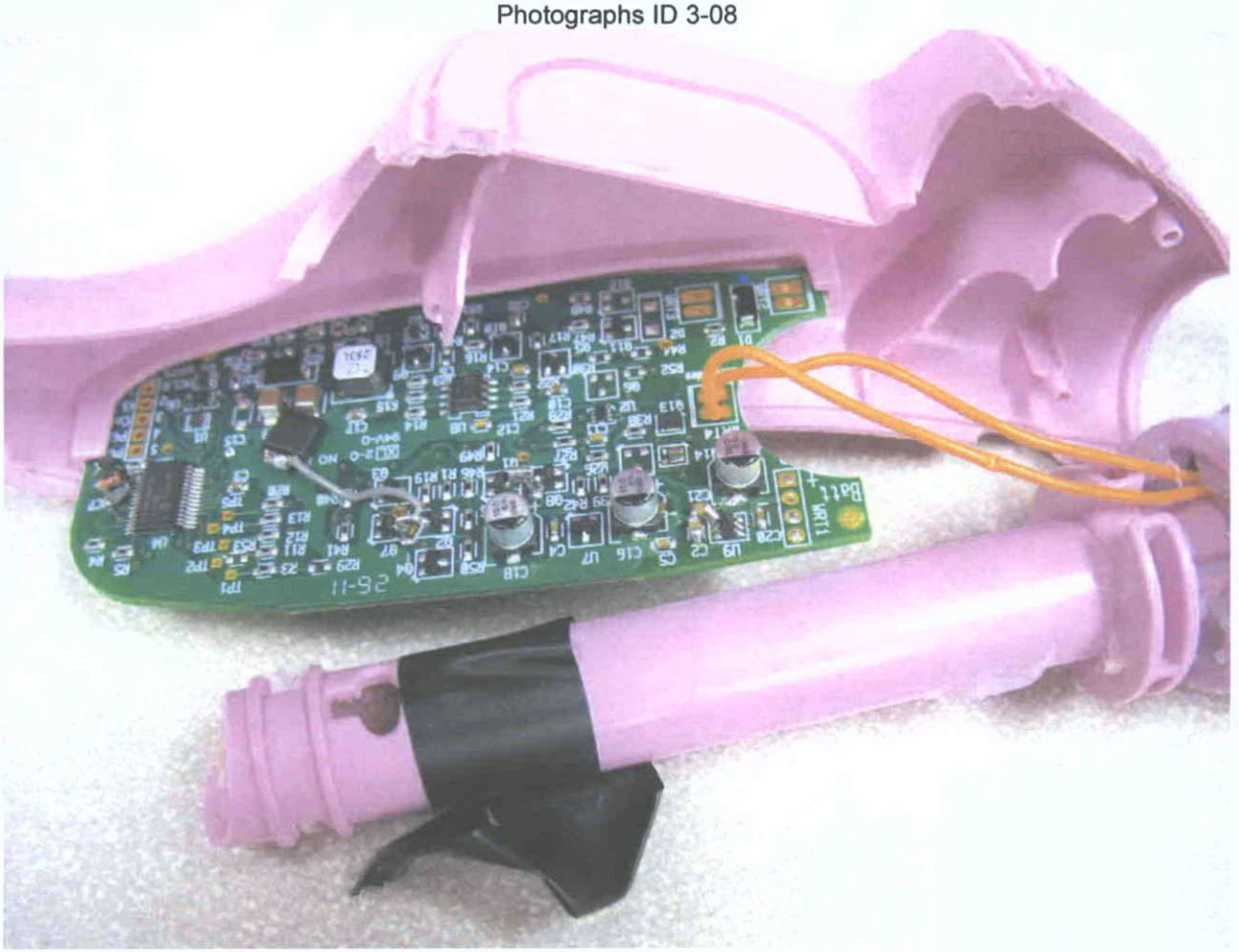

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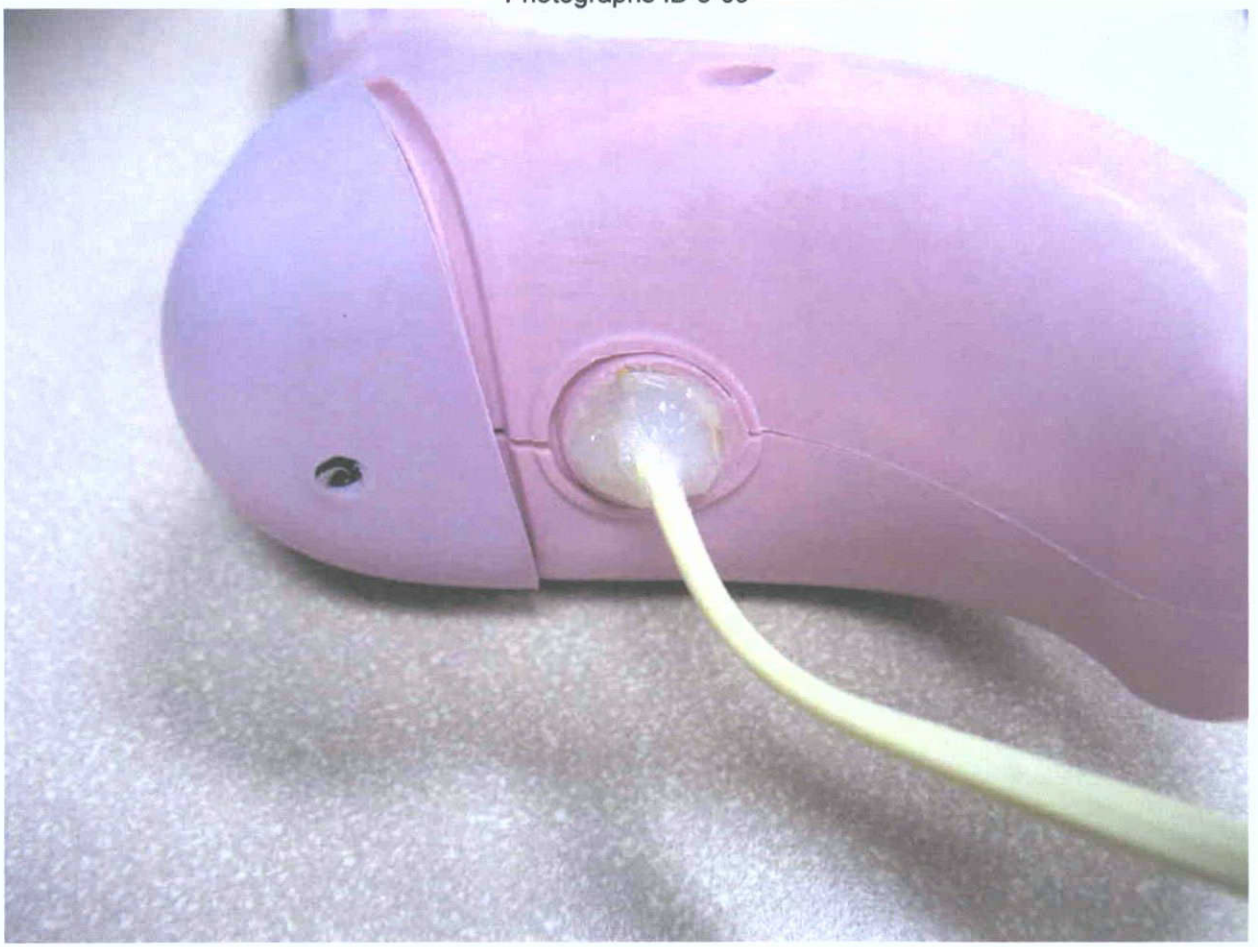
Photographs ID 3-09



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Schematics + PWB ID 5-01

(b)(4) TS

TRF No. IEC601_1_1D

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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Schematics + PWB ID 5-02

(b)(4) TS

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Schematics + PWB ID 5-02

(b)(4) TS

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Schematics + PWB ID 5-02

(b)(4) TS

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Schematics + PWB ID 5-02

(b)(4) TS

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Schematics + PWB ID 5-02

(b)(4) TS

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InTone™ User Manual

PN: xxxxxx-C | Draft Date: 7/28/11

Users must read this Guide before using the Product

TRF No. IEC601_1_1D

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DATA PACKAGE INFORMATION SHEET

Applicant Information	Name / Address:	INCONTROL MEDICAL L L C SUITE 250 3225 GATEWAY RD BROOKFIELD WI 53045 UNITED STATES

Product Information	Standard:	IEC 60601-1:1988 + A1:1991 + A2:1995
	CCNs:	PIDF
	Product:	Electrical stimulator
	Models:	InTone

Test Location Information

DAP and UL: [ ] CTDP [ ] TCP [ ] TPTDP [ ] WTDP [x] UL

CB Scheme: [ ] CBTL [ ] RMT [ ] SMT [ ] TMP [ ] WMT

Test Location Name/Address: Underwriters Laboratories, 333 Pfingsten Rd, Northbrook, IL 60062

Tests Conducted By**:	Sign	Silvia Ankova
	Print	Silvia Ankova

** When all tests are conducted by one person, the printed name and signature can be inserted here instead of on each page containing data

Authorized Signatory or TCP Reviewer:	Sign	
	Print	
	Date	
UL WTDP / WMT Witness:	Sign	
	Print	

Reviewed & Accepted By	Qualified Project Handler:	Sign	Silvia Ankova
		Print	Silvia Ankova

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LIST OF TESTS

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Special Instructions - Unless specified otherwise in the individual Methods, the tests shall be conducted under the following ambient conditions. Confirmation of these conditions shall be recorded at the time the test is conducted.

Standard	Ambient Temperature, °C	Relative Humidity, %	Barometric Pressure, mBar
	±	±	±
60065	25 ± 10	Max 75	Not specified
60601-1	+10 to +40	30 to 75	700 to 1060 hPA
60950	Not specified	Not specified	Not specified
60950-1	Not specified	Not specified	Not specified
61010-1	+15 to +35	Max 75	75 to 106 kPa
61215	Not specified	Not specified	Not specified
61646	Not specified	Not specified	Not specified
61730	Not specified	Not specified	Not specified

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TEST SAMPLE IDENTIFICATION

The table below is to provide correlation of sample numbers to specific product related information. Refer to this table when a test identifies a test sample by "Sample No." only.

Sample Number	Sample Card Number	Date Received	Manufacturer, Product Identification and Ratings
1,2	1165547	08/01/2011	INCONTROL MEDICAL L L C, Model InTone, charger rated input 120Vac, 60Hz
Sampling Procedure (if used) :			

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TEST INSTRUMENTS REFERENCE LIST

Instr. Code	Instrument I.D.	Instrument Type	Range Used Or ***	Make and Model **	Calibration Date	
					Last	Due

"Chamber setting(s) [was] [were] monitored to ensure that the setting(s) [was] [were] stable throughout the test time frame. Any deviations from the setting(s) are noted below.

Date	Test	Instrument Code	Time period of deviation	Setting(s)

** Information to be recorded when tests are conducted at a non-UL facility.
*** Refer to specific data sheet for individual scale used.

[x] Test equipment information is recorded on UL's Laboratory Project Management (LPM)/Laboratory Equipment Management (LEM) database. (This statement may be selected only if datasheets are completed at a UL facility)

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Tested by: _____ (signature) Tested by: _____ (print) Test date: _____

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

~~MARKING DURABILITY TEST (IEC 60601-1, SUB-CLAUSE 6.1)~~

~~METHOD~~

~~Each specified marking in Table 6.1 was rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked in methylated spirit at ambient temperature, and then for 15 s with a cloth rag soaked with isopropyl alcohol. The duration of rubbing with each fluid was recorded under Remarks.~~

~~RESULTS~~

~~TABLE 6.1: Marking Durability~~	
~~Marking Tested~~	~~Remarks~~
	~~Start time Stop time Duration (sec)~~
	~~T-w -~~
	~~T-m -~~
	~~T-i -~~
~~Supplementary Information:~~ ~~T-w = Time with distilled water~~ ~~T-m =Time with methylated spirit~~ ~~T-i = Time with isopropyl alcohol~~	

~~[ ] The markings [did not work] [worked] loose and [did not curl] [curled] at the edges.~~

~~[ ] The markings [were] [were not] clearly readable.~~

~~For testing purposes, a methylated spirit is considered to be any commercially available denatured alcohol containing a minimum 90% ethanol by volume.~~

The test is not applicable – the label is molded in the enclosure – SA 2011/08/11

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Tested by: _____ (signature) Tested by: Silvia Ankova (print) Test date: 2011-08-10

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C 26.3 Ambient Humidity, % 44.2 Ambient Pressure, mBar 985.4

POWER INPUT TEST: (IEC 60601-1, SUB-CLAUSE 7.1)

METHOD

The unit was operated under the conditions specified in Table 7 until the input reached a stable value. The current or power input was measured and recorded for each operating condition.

The input current was measured with a true rms meter. The ratings of the device were compared to the measured values.

RESULTS

TABLE 7: Power Input

Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
Charger charging completely discharge battery	120	60	0.04	1.86	
Charger charging completely discharge battery	8.5Vdc	dc	0.05	0.38	

Supplementary Information:

The measured input [current] [~~power~~] [did not exceed] [~~exceeded~~] [110] [~~115~~] [~~125~~] percent of the unit's ratings.

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Tested by: _____ (signature) Tested by: Silvia Ankova (print) Test date: 2011-08-09

Sample # : 1,2 Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

LEAKAGE CURRENT TEST: (IEC 60601-1, SUB-CLAUSE 19)

METHOD

GENERAL SETUP (SUB-CLAUSE 19.1 - 19.4)

A. Measuring Condition:

- Testing was conducted after thermal stabilization and was repeated following Humidity Preconditioning. Following the humidity conditioning (see Humidity Conditioning Test for further details), the equipment was located in an environment with a temperature approximately equal to t where t is the temperature of the humidity cabinet and a relative humidity between 45% and 65% and was conducted 1 hour after the end of the humidity preconditioning treatment.
- In Normal Condition and in the specified Single Fault Conditions (19.2)
- With the Equipment energized in stand-by and fully operating and with any switch in the Mains Part in any position.
- With the equipment connected to a supply source with the highest rated supply frequency and 110% of the highest rated Mains Voltage as indicated in the RESULTS table.

B. The measuring supply circuit was connected to the indicated supply mains:

[x] Fig. 10 - Supply circuit with one side of the supply at ground potential.

[ ] Fig. 11 - Supply circuit symmetrical to ground potential.

[ ] Fig. 12 - Supply Circuit for polyphase equipment specified for connection to a polyphase Supply Mains.

[ ] Fig. 13 - Supply Circuit for single phase equipment specified for connection to a polyphase Supply Mains. (Center Tap Leakage-DO NOT USE SWITCH BOX)

[ ] Fig. 14 - Supply Circuit for a specified Class I or II single-phase power supply. For Class II equipment, the protective earth connection and S8 were not used.

Measurements which do not energize the equipment were made first.

C. Connection of Equipment to the Measuring Supply Circuit:
Charger is plug in, control unit and insertion unit are internally powered

[ ] Equipment provided with a Power Supply Cord - Tested using the cord provided.

[ ] Equipment provided with an Appliance Inlet - Use Detachable power supply cord having a length of 3 M or Type _____, Length _____ as specified by manufacturer.

[ ] Equipment specified for Permanent Installation - Tested while connected to the supply via the shortest possible connection.

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Tested by: _____ (signature) Tested by: _____ (print) Test date: _____

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

D. Measuring Arrangement:

The supply circuit and each measuring circuit were positioned as far as possible from unscreened power supply leads.

External parts of the Applied Parts, including Patient cords, were placed on an insulating surface with a dielectric constant of approximately 1 (e.g. expanded polystyrene) and approximately 200 mm above an earthed metal surface.

E. Measuring Device (MD) and Instrument:

The Measuring Device (MD) shown in Fig. 15 of IEC 60601-1 Second Edition was used. It consisted of a 1 kΩ resistor (R2) in parallel of a 10 KΩ resistor (R1) which is in series with a 0.015 µf capacitor (C1).

The measuring instrument had an impedance of approximately 1 MΩ or more for frequencies from d.c. up and including 1 MHz. It shall indicate the true r.m.s. value of the voltage across the MD. Review Clause 19.4e for appropriate Measuring Device (MD).

[ ] A suitably rated oscilloscope with probe having an impedance > 1 MΩ was used. The capacitance of the measuring device and its connecting leads to earth and to the body of the equipment was kept as low as possible.

All recorded leakage current measurements were in microamperes unless otherwise specified.

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Tested by: _____ (signature) Tested by: _____ (print) Test date: _____

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

[ ] EARTH LEAKAGE (SUB-CLAUSE 19.4f)

METHOD

The equipment was connected to the indicated voltage and frequency. Earth leakage current was measured through the indicated Figure of IEC 60601-1.

[ ] Fig. 16 - Class I equipment with or without an Applied Part.

[ ] Fig. 17 - Equipment for use with a specified Class I single-phase power supply, using the measuring supply circuit of Fig. 14. If the equipment is Protectively Earthed, the measurement with MD2 was also performed.

[ ] Switch S12 was connected between earth and F-Type Applied Part _____.

Measurements were made using switches S1, S5, [ ] S10, [ ] S12.

Lab: Please contact project handler if maximum earth leakage current exceeded [ ] 300 uA (US Dev.) [ ] 500 uA (IEC) under NC and 1 mA under SFC (US and IEC).

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Tested by: _____ (signature) Tested by: _____ (print) Test date: _____

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

[x] ENCLOSURE LEAKAGE (SUB-CLAUSE 19.4g)

METHOD

The equipment was connected to the indicated voltage and frequency. Enclosure leakage current was measured through the indicated Figure of IEC 60601-1.

[x] Fig. 18 - Class I or Class II equipment with or without an Applied Part except for Class II equipment test without S7 and PE connection.

[ ] Fig. 19 - Equipment for use with a specified Class I or Class II single-phase power supply, using the measuring supply circuit of Fig. 14, except for Class II, test without S7 and PE connection.

[ ] Switch S12 was connected between earth and F-Type Applied Part: _____.

MD1 was connected between earth and the following parts of the enclosure not PE. The maximum leakage current results were recorded.

1. _____charger enclosure_____

2. _____

MD2 was connected between the following parts of the enclosure not PE. The maximum leakage current results were recorded.

1. _____

2. _____

3. _____

[x] A piece of 20 cm x 10 cm metal foil was applied in intimate contact with a pressure of approximately 0.5 N/cm² with each of the above enclosure locations made of insulating material.

[ ] A voltage of _____V ac, 60 Hz (110% of the highest rated Mains voltage) was applied between earth and SIP/SOP _____.

Measurements were made using switches S1, S5, S7, [ ] S9, [ ] S10, [ ] S12.

Lab: Please contact project handler if maximum enclosure leakage current measured exceeded 100 uA under NC or [ ] 300 uA (US Dev), [ ] 500 uA (IEC) under SFC.

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Tested by: _____ Tested by: _____ Test date: _____
signature print

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

[x] PATIENT LEAKAGE (SUB-CLAUSE 19.4h)

METHOD

The equipment was connected to the indicated voltage and frequency. Patient leakage current was measured through the indicated Figure of IEC 60601-1.

[ ] Fig. 20 - Class I or Class II equipment with an Applied Part except for Class II equipment, tested without S7 and PE connections.

Equipment for use with a specified single-phase power supply was tested using the measuring supply circuit of Fig. 14, except for Class II Equipment, which was tested without S7 and PE connections.

[ ] Fig. 22 - Class I or Class II equipment with an Applied Part with an external voltage on a SIP/SOP, except for Class II equipment, was tested without S7 and PE connections.

[x] Fig. 23 - Internally Powered Equipment with an Applied Part.

[ ] Fig. 25 - Internally Powered Equipment with an Applied Part, with an external voltage on a SIP/SOP.

Patient leakage current was measured:

[ ] with all patient connections of a single Type B Applied Part connected together: _____ .

[ ] with all patient connections of a single function Type BF Applied Part connected together to another single function Type BF Applied Part. See IEC 60601-1 Appendix K. _____

[ ] with applied part _____ loaded with _____.

[x] A piece of 20 cm x 10 cm metal foil was applied in intimate contact with a pressure of approximately 0.5 N/cm² to the following Applied Parts made of insulating material:

1. _____control unit_____

2. _____

3. _____

4. _____

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Tested by: _____ Tested by: _____ Test date: _____
signature print

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

[ ] The size of the foil was increased to correspond to the area of contact on the following Applied Parts since the actual contact area was considerably greater than 20 x 10 cm.:

1._____

2._____

3._____

4._____

[ ] The Applied Part made of insulating material was immersed in saline solution.

[ ] A voltage of _____ V ac, 60 Hz (110% of the highest rated Mains voltage) was applied between earth and the indicated SIP/_____

[ ] A voltage of _____ V ac, 60 Hz (110% of the highest rated Mains voltage) was applied between earth and the indicated accessible metal parts not PE:
_____.

[ ] Switch S13 was connected between earth and following accessible metal parts not protectively earthed:
_____.

Measurements were made using switches S1, S5, [ ] S7, [ ] S10, [ ] S13.

Lab: Please contact project handler if maximum patient leakage current measured was greater than 100 uA under NC and 500 uA under SFC *Type B or BF Applied Parts* and 10 uA under NC and 50 uA under SFC for type CF Applied Parts.

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Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

[x] PATIENT LEAKAGE WITH MAINS VOLTAGE ON F-TYPE ISOLATED AP (SUB-CLAUSE 19.4h)

METHOD

The equipment was connected to the indicated voltage and frequency. Patient leakage current was measured through the indicated figures of IEC 60601-1.

[ ] Fig. 21 - Class I or Class II equipment with an Applied Part except for Class II equipment, test without S7 and PE connections.

Equipment for use with a specified single-phase power supply was tested using the measuring supply circuit of Fig. 14, except for Class II Equipment, test without S7 and PE connections.

[x] Fig. 24 - Internally Powered Equipment.

Switches S1 and S7 remained closed for all measurements.

[x] A voltage of __250__ V ac, 60 Hz (110% of the highest rated Mains voltage) was connected to the indicated patient Type BF or CF Applied Part through the MD and resistor R rated [ ] 22 kΩ (100-120V ac) [x] 47 kΩ (220-240V ac) [ ] 100 kΩ (polyphase).

[x] A piece of 20 cm x 10 cm metal foil was applied in intimate contact with a pressure of approximately 0.5 N/cm² to Applied Parts made of insulating material.

[ ] The size of the foil was increased to correspond to the area of contact on the Applied Parts since the actual contact area was considerably greater than 20 x 10 cm.

[ ] The Applied Part made of insulating material was immersed in saline solution.

[ ] Switch S13 was connected between earth and following accessible metal parts not protectively earthed: _____.

Measurements were made using switches S1, S5, [ ] S7, [ ] S9, [ ] S10, [ ] S13.

Lab: Please contact project handler if maximum patient leakage current measured exceeded 5 mA for Type BF Applied Part and 0.05 mA for Type CF Applied Part.

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Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

[x] PATIENT AUXILIARY CURRENT TEST (SUB-CLAUSE 19.4j)

METHOD

The equipment was connected to the indicated voltage and frequency. Patient auxiliary current was measured through the indicated figures of IEC 60601-1.

[ ] Fig. 26 - Class I or Class II equipment with an Applied Part except for Class II equipment, test without S7 and PE connections.

Equipment for use with a specified single-phase power supply was tested using the measuring supply circuit of Fig. 14, except for Class II Equipment, test without S7 and PE connections.

[x] Fig. 27 - Internally Powered Equipment.

[x] A piece of 20 cm x 10 cm metal foil was applied in intimate contact with a pressure of approximately 0.5 N/cm² to the following Applied Parts made of insulating material

[ ] The size of the foil was increased to correspond to the area of contact on the Applied Parts since the actual contact area was considerably greater than 20 x 10 cm.

The measuring device (MD) was placed between any single Patient connection and all other Patient connections connected together and ground as noted in Results.

Measurements were made using switches S1, S5, S7, [ ] S10.

Lab: Please contact project handler if maximum patient leakage current measured exceeded 0.1 mA in NC and 0.5 mA in SFC for Type B or BF Applied Parts and 0.01 mA in NC and 0.05 mA in SFC for Type CF Applied Part.

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Tested by: _____ (signature) Tested by: Silvia Ankova (print) Test date: 2011-08-11

Sample # : 1,2 Instrument Code / Range: _____

Ambient Temperature, °C 25 Ambient Humidity, % 44 Ambient Pressure, mBar 982

RESULTS

All measured leakage currents [did not exceed] ~~[exceeded]~~ allowable limits.

TABLE 19: Leakage Current

Type of Leakage Current and Test Condition (Including Single Faults)	Supply Voltage (V)	Supply Frequency (Hz)	Measured Max. Value (µA)	Remarks
Figure 16, Earth Leakage	**(V)**	**(Hz)**	**Before/After HUMIDITY (µA)**	
Figure 18, Enclosure Leakage	**(V)**	**(Hz)**	**Before/After Humidity (µA)**	
EN, NC, S1 = 1, S5 = N, S7 = 1, S9 = N, S12 = 0	132	60	5.0/5.0	charger/power supply, measured on the output of the power supply
EN, NC, S1 = 1, S5 = R, S7 = 1, S9 = N, S12 =	132	60	5.0/5.0	
EN, NC, S1 = 1, S5 = N,	132	60	4.9/4.9	Control unit
EN, NC, S1 = 1, S5 = R,	132	60	4.9/4.9	Control unit
EN, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1, S9 = N, S12 = 0	132	60	5.5/-	charger/power supply, measured on the output of the power supply
EN, SFC (Neutral Open), S1 = 0, S5 = R, S7 = 1, S9 = N, S12 = 0	132	60	5.5/-	
EN, SFC (Neutral Open), S1 = 0, S5 = N,	132	60	4.9/4.9	Control unit
EN, SFC (Neutral Open), S1 = 0, S5 = R,	132	60	4.9/4.9	Control unit
EN, SFC after charging circuit abnormal	132	60	4.9/4.9	Control unit

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TABLE 19: Leakage Current

Type of Leakage Current and Test Condition (Including Single Faults)	Supply Voltage (V)	Supply Frequency (Hz)	Measured Max. Value (μA)	Remarks
Figure 23, Patient Leakage	**(V)**	**(Hz)**	**BEFORE/AFTER Humidity (μA)**	
P, NC,	3	dc	4.0/4.0	Insertion unit
P, NC,	3	dc	0.3/0.5	Control unit
Patient functional current	3	dc	35mA/-	Insertion unit between the electrodes with 1KOhms load
Patient functional current	3	dc	70mA/-	Insertion unit between the electrodes with 500Ohms load
P, SFC after abnormal tests on the insertion unit),	3	dc	0.3/-	Electrodes to insertion unit handle
Figure 24, Patient Leakage with Mains on AP	**(V)**	**(Hz)**	Before/After **Humidity (μA)**	
PM, SFC,	3	dc	13.6/13.6	Insertion unit
PM, SFC,	3	dc	39.6/39.6	Control unit
PM, SFC, S1 = 1, S5 = R, S7 = 1, S9 = R, S13 = 0				
Figure 26, Patient Auxiliary Current between _____ and _____	**(V)**	**(Hz)**	**Before/After Humidity (μA)**	
PA, NC,	3	dc	4.0/4.0	Between insertion unit and the control unit
PA, SFC, after abnormal tests on the insertion unit	3	dc	0.3/-	Between insertion unit and the control unit

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TABLE 19: Leakage Current

Type of Leakage Current and Test Condition (Including Single Faults)	Supply Voltage (V)	Supply Frequency (Hz)	Measured Max. Value (μA)	Remarks

Supplementary Information:

Abbreviations used:

ER - Earth leakage current
EN - Enclosure leakage current
P - Patient leakage current
PM - Patient leakage current with mains on the applied parts
PSM - Patient leakage current with mains on SIP/SOPS
PA - Patient auxiliary current
IP - Internally powered leakage current
MD - Measuring device
Fig. 15 - Refers to Fig. 15 in IEC 60601-1

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition
AA - After Abnormal
S1 - Mains neutral conductor
S5 - Mains polarity
S7 - Protective Earth Conductor
S9 - Mains on patient polarity
S12 - Grounded patient leads

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Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

Review Clause 19.4e for appropriate Measuring Device (MD)

EARTH	N.C.	S.F.C.
For General Equipment	500 uA/(300 uA^{+})/(500 uA^{++})	1 mA
Permanently Connected Equipment	5 mA	10 mA
No P.E. Accessible parts Provides no P.E. and [1]	2.5 mA	5 mA
Class II Equipment with Ground	(150 uA^{+})/(250 uA^{++})	1 mA
ENCLOSURE	N.C.	S.F.C.
All	100 uA	500 uA/(300 uA^{+})
PATIENT	N.C.	S.F.C.
B and BF (ac)	100 uA	500 uA
B and BF (dc)	10 uA	50 uA
CF (ac & dc)	10 uA	50 uA
PATIENT - MAINS ON APPLIED PARTS	N.C	S.F.C
BF (SIP/SOPs Earthed for test per 19.4 h 2)		5 mA
CF (SIP/SOPs Earthed for test per 19.4 h 2)		50 uA
PATIENT - MAINS ON SIP/SOPS	N.C	S.F.C
B		5 mA
PATIENT AUXILIARY	N.C	S.F.C
B and BF (ac)	100 uA ac	500 uA ac
CF (ac)	10 uA ac	50 uA ac
All (dc)	10 uA dc	50 uA dc

[1] Mobile X-ray equipment and mobile equipment with mineral insulation

$^{+}$ US Deviation: (For these limits, testing conducted at highest rated mains voltage; minimum 120 VAC and 240 VAC for equipment with marked voltage ranges of 105-120 VAC and 240 VAC respectively)

$^{++}$ US Deviation: Equipment with all surfaces likely to be contacted in patient's vicinity constructed of nonconductive materials (For these limits, testing conducted at highest rated mains voltage; minimum 120 VAC and 240 VAC for equipment with marked voltage ranges of 105-120 VAC and 240 VAC respectively)

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011-08-11

Sample # : 1 Instrument Code / Range: _____

Ambient Temperature, °C 25 Ambient Humidity, % 44 Ambient Pressure, mBar 982

DIELECTRIC VOLTAGE WITHSTAND: (IEC 60601-1, SUB-CLAUSE 20.4)

METHOD

The test was conducted with the equipment under conditions specified in Table 20. Initially not more than 50 percent of the test voltage was applied. The test voltage was raised to its full value within a period of 10 s. The test voltage was held at full value for 1 min. The test voltage was lowered over a period of 10 s to less than 50 percent of the full value.

RESULTS

There [was no] ~~[was]~~ indication of dielectric breakdown.

TABLE 20: Dielectric Strength

Insulation Under Test (Area From Insulation Diagram)	Insulation Type: (OP-Operational / BI-Basic / SI-Supplementary / DI-Double / RI-Reinforced	Reference Voltage (V)	Test Voltage (V)	Remarks
E (control unit circuit to enclosure)	BI	240	1500	
F (insertion unit input circuit to "handle" enclosure)	BI	240	1500	
F (insertion unit electrodes to "handle" enclosure)	BI	240	1500	
Supplementary Information:				

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011-08-05

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C 24 Ambient Humidity, % 43 Ambient Pressure, mBar 982

ENCLOSURE MECHANICAL STRENGTH: (IEC 60601-1, SUB-CLAUSE 21A,B)

METHOD

[x] Force Test (21a) - A sample of the unit was subjected to inward directed force of 45 N (10.23 lb) applied to different parts of the enclosure over an area of 625 mm² as indicated in Table 21.

[x] Impact (21b) - The strength of an enclosure was tested by application of blows with an impact energy of 0.5 ± 0.05 J. (See App. G for test apparatus.) The unit was rigidly supported and three blows were applied to the locations indicated in Table 21.

RESULTS

TABLE 21: Mechanical Strength

Part Under Test	Test (Mechanical Strength, Handle Loading, Patient Support, Footrest/Chair, Drop Impact, Rough Handling - Drop, Off Step)	Remarks
Control unit	Force Test (21a)	
Insertion unit	Force Test (21a)	
Control unit	Impact (21b)	
Insertion unit	Impact (21b)	
Supplementary Information:		

There [was no] ~~[was]~~ cracking of the enclosure.

There [were no] ~~[were]~~ live parts that became accessible.

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Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C 24 Ambient Humidity, % 43 Ambient Pressure, mBar 982

DROP IMPACT TEST: (IEC 60601-1, SUB-CLAUSE 21.5), (US DEVIATION 55)

METHOD

Each sample(s) indicated in Table 21 was dropped [nine] times, each [at a different angle from a height of] 1.22 m (4 ft.)] onto a [[a tile covered, concrete surface]. After all drops were completed, the interior and exterior of the sample were examined.

RESULTS

TABLE 21: Mechanical Strength

Part Under Test	Test (Mechanical Strength, Handle Loading, Patient Support, Footrest/Chair, Drop Impact, Rough Handling - Drop, Off Step) Also indicate angle/position of drop	Remarks
Control unit	Drop Impact	
Insertion unit	Drop Impact	
Supplementary Information:		

There [was no] ~~[was]~~ damage to the interior or exterior of the tested sample which caused exposure to live parts or increased risk of electric shock.

For Pendant Controls and Other Hand Held Equipment

US Deviation 55:

- each of three was dropped three times OR one nine times
- 1.22 m (4 ft.) for polymeric enclosures
- a tile covered, concrete surface
- specify angle/position of drop

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011-08-10

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

TEMPERATURE: (IEC 60601-1, SUB-CLAUSE 42)

METHOD

GENERAL

[ ] All necessary connections for the change-of-resistance measurement for the windings specified below were made. Initial ambient temperature and a cold resistance of the windings were measured and recorded.

[x] Type _J___ thermocouples were placed at the [other] locations noted below. If the temperature of a winding was determined by thermocouples, the allowable limits of Table Xa were reduced by 10°C.

The sample was positioned in the test corner as noted below. The test corner consists of two walls at right angles, a floor and, if necessary, a ceiling. The walls were formed from dull black painted plywood of 20 mm thick extending at least 115% of the linear dimension of the equipment under test.

The sample was then connected to a supply source as indicated in Table 42 and operated as indicated under Test Conditions for 2½ hours or until thermal equilibrium, whichever is shorter. Thermal equilibrium was considered to exist only if temperatures did not increase in 1 hour by more than 2°C.

[x] Rechargeable batteries /battery packs were completely discharged at the beginning of the test.

SAMPLE PLACEMENT IN THE TEST CORNER

[ ] Equipment normally used on a floor or a table was placed as [ ] as near to [ ] ____in./mm from the walls as possible.

[ ] Equipment normally fixed to a wall was mounted on one of the walls, [ ] as near to [ ] ___in./mm from the other wall and to the floor or ceiling as is likely to occur in Normal Use.

[ ] Equipment normally fixed to a ceiling was fixed to the ceiling as near to the walls as is likely to occur in Normal Use.

[x] Other equipment was tested in the position of Normal Use: bench test

[ ] Hand-held equipment was suspended in _____, in still air.

[ ] Equipment intended for installation in a cabinet or wall was built in as required by installation instructions, using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the installation instructions so specify and 20 mm thick when representing building walls.

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Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

TEST CONDITIONS

[ ] **Short-Time Operation Equipment** - The sample was operated for the RATED operating time of _

[ ] **Intermittent Operation Equipment** - The sample was operated over consecutive cycles of operation until thermal-equilibrium conditions were established. The "ON" and "OFF" periods being the RATED "ON" and "OFF" periods

[x] **Continuous Operation Equipment** - The sample was operated until thermal-equilibrium or 2½ hours, whichever was shorter.

[ ] _____

NOTES TO LAB:

[ ] At the conclusion of all tests, contact the Project Handler to determine the voltage and frequency required to perform the Impairment of Cooling Tests. See corresponding data sheets.

FOR ENGINEERING USE ONLY:

Supply Source

	EQUIPMENT WITH	
Voltage Rating	Heating Element	(Heating Element and Motor) and Other
V_1 / V_2	110% V_1 & V_2	[90% V_1 & 110% V_1] and [90% V_2 & 110% V_2]
V_L - V_H	110% V_H	90% V_L & 110% V_H
V_{1L} - V_{1H}/ V_{2L}- V_{2H}	110% V_{1H} & V_{2H}	[90% V_{1L} & 110% V_{1H}] and [90% V_{2L} & 110% V_{2H}]

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Tested by: _____ (signature) Tested by: Silvia Ankova (print) Test date: 2011-08-10

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

RESULTS

[ ] During the test thermal cutouts [did not operate] [operated].

[ ] Sealing or potting compound [did not flow] [flowed out].

[x] The temperatures obtained [did not exceed] [~~exceeded~~] the allowable limits for Tables Xa and Xb.

[x] The temperatures of the applied parts [did not exceed] [~~exceeded~~] 41°C.

Testing of battery charger

TABLE 42: Normal Temperature		
Supply Voltage / Frequency: 132V, 60Hz	Test Condition:	See below
Ambient Temperature: See below °C		
Measuring Location	Measured Temperature [°C]	Remarks
		Charging (with battery completely discharged) 2.5 hrs
Charger enclosure	33.2	
Control unit enclosure	27.1	
Control unit PCB by the battery	29.5	
Battery	28.1	
ambient	25	
		Battery charging circuit abnormal until thermal stabilization (2.5 hrs)
Control unit enclosure	35.5	
Control unit PCB by the battery	51.6	
Battery	49.2	
ambient	24.8	
COR - Indicates measurements taken using change-of-resistance method		
Supplementary Information:		

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011-08-10

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C 25.2 Ambient Humidity, % 42.7 Ambient Pressure, mBar 982

Testing of insertion and control units

TABLE 42: Normal Temperature		
Supply Voltage / Frequency: 3Vdc	Test Condition:	"On" 2.5 hrs – maximum setting
Ambient Temperature: 25.2 °C		
Measuring Location	Measured Temperature [°C]	Remarks
Control unit battery	27.1	
Control unit enclosure	25.5	
Control unit PCB by the battery	26.9	
electrodes	25.4	
Insertion unit enclosure (handle)	26.6	
Insertion unit transformer T1	27.2	
COR - Indicates measurements taken using change-of-resistance method		
Supplementary Information:		

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Tested by: _____ (signature) Tested by: _____ (print) Test date: _____

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

CHANGE OF RESISTANCE CALCULATION: (IEC 60601-1; Sub-Clause 42.3)

The following formula was used to calculate the value of the temperature rise of a copper winding:

$$\Delta t = \frac{R2 - R1}{R1} (234.5 + t_1) - (t_2 - t_1)$$

where: Δt = Temperature rise (°C)
R1 = Resistance at the beginning of the test (Ω)
R2 = Resistance at the end of the test (Ω)
t_1 = Ambient temperature at the beginning of the test (°C)
t_2 = Ambient temperature at the end of the test (°C)

Resistance of winding and Ambient temperatures:					
Winding:	R1 (Ω)	R of Patch Cord (Ω)	R1 w/o Patch Cord (Ω)	t_1 (°C)	t_2 (°C)

Resistance of winding at t seconds after end of test						
Winding:	5 sec. (Ω)	10 sec. (Ω)	15 sec. (Ω)	20 sec. (Ω)	25 sec. (Ω)	30 sec. (Ω)

Note: R2, resistance of the winding at the end of the test, should be determined from a Resistance vs Time curve based on the above data. The resistance should be at time equals to zero on the curve.

When patch cords were used, use only the resistance without the patch cord for calculation.

Results			
Winding:	R2 (Ω)	Δt (°C)	t (°C)

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011-08-11

Sample # : 1 Instrument Code / Range: _____

Ambient Temperature, °C 24.5 Ambient Humidity, % 43 Ambient Pressure, mBar 982

HUMIDITY PRECONDITIONING TREATMENT: (IEC 60601-1, SUB-CLAUSE 44.5)

METHOD

A humidity chamber having relative humidity of 90 to 96 percent was set to any convenient Temperature T between 20 and 32°C. The unit, before being placed in the chamber was brought to a temperature between T and T + 4°C and kept at this temperature a minimum of 4 h. Then the sample was placed in the humidity chamber and kept there for the time specified in Table 44. During this time the temperature of the air in the chamber was maintained at T ± 2°C. Immediately after the treatment and while still in the chamber, the sample was subjected to Dielectric Voltage Withstand Test. Then the unit was removed from the chamber, placed in normal environment (temperature approximately T, humidity 45 - 65 percent) and 1 h later Leakage Current Test was performed.

RESULTS

TABLE 44: Humidity

Test Type and Condition	Part Under Test	Remarks	Pre-chamber			Chamber					Post-chamber			
			T (°C)	Start Time	Stop Time	Humidity (%)	T (°C)	Start Date & Time	Stop Date & Time	Duration (hrs)	Humidity (%)	T (°C)	Start Time	Stop Time
48 hrs	Charger, Insertion unit, control unit							2011/08/09 4:30PM	2011/08/11 4:30PM	48				

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Supplementary Information:														

There [was no] ~~[was]~~ dielectric breakdown.

Ordinary Equipment: 2 days (48 h)
IPX1 or greater: 7 days (168 h)

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011-08-10

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C 24 Ambient Humidity, % 44 Ambient Pressure, mBar 982

OVERFLOW, SPILLAGE, LEAKAGE, CLEANING, STERILIZATION AND DISINFECTION, HARMFUL INGRESS OF LIQUIDS: (IEC 60601-1, SUB-CLAUSE 44)

METHOD

The equipment was subjected to tests described in Table 44.

[ ] Overflow (44.2) - The liquid reservoir or storage chamber was filled completely and a further quantity equal to 15 percent of the capacity of the reservoir was poured in steadily over a period of 1 min.

[ ] Transportable equipment was subsequently tilted up to 15° in a direction or directions such that water might be spilled over live parts when the equipment was tilted.

[ ] Immediately following the overflow condition, the Dielectric Strength Test was repeated. After that, the equipment was examined for signs of wetting of uninsulated live parts and/or electrical insulation.

[x] Spillage (44.3) - The equipment was positioned as in normal use. A quantity of 200 ml of water was poured steadily on the top surface of the equipment. Immediately following the spillage condition, the Dielectric Strength Test was repeated. Following the Dielectric Withstand Test, the equipment was examined for signs of wetting of uninsulated live parts and/or electrical insulation.

[ ] Leakage (44.4) - Drops of water were applied by means of a pipette to couplings, to seals and to hoses specified in Table 44. Following the leakage condition, the Dielectric Voltage Withstand Test was repeated.

[x] Cleaning (44.7) - The equipment was cleaned as specified in the accompanying documents. After an adequate cooling and drying period, the unit was subjected to a Dielectric Voltage Withstand Test.

[ ] Sterilization (44.7) - The equipment was subjected to saturated steam at 134°C ± 4°C for 20 cycles, each of 20 min duration (with intervals until the equipment was cooled to room temperature). After an adequate cooling and drying period, the unit was subjected to a Dielectric Voltage Withstand Test.

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011-08-10

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C 24 Ambient Humidity, % 44 Ambient Pressure, mBar 982

RESULTS

TABLE 44: Humidity, Harmful Ingress of Liquids, Overflow, Spillage, Leakage, Cleaning, Sterilization, Disinfecting		
Test Type and Condition	Part Under Test	Remarks
Spillage	Insertion unit	Leakage current measured: Electrode to handle 4.2 µA Electode to control unit 6.1 µA
Cleaning	Insertion unit	1. Wash the outside of the Insertion Unit with warm soapy water. 2. Rinse thoroughly. 3. isopropyl alcohol 4. hydrogen peroxide, <10% 5. sodium hypochlorite, <10% Leakage current measured: Electrode to handle 4.2 µA Electode to control unit 6.1 µA
Cleaning	Control unit	wipe with antispectic or a damp cloth: 1. isopropyl alcohol 2. hydrogen peroxide, <10% 3. sodium hypochlorite, <10% Leakage current measured 4.9 µA
Supplementary Information:		

[x] The equipment [complied] ~~[did not comply]~~ with the requirements of Clause 44.

[x] The equipment [did not show] ~~[showed]~~ signs of wetting of uninsulated live parts.

[x] There [was no] ~~[was]~~ dielectric breakdown.

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Tested by: _____ (signature) Tested by: _____ (print) Test date: _____

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

ABNORMAL OPERATION AND FAULT CONDITIONS: (IEC 60601-1, CLAUSE 52)

METHOD

The device was operated as indicated in Table 52 until ultimate results were obtained. All final results were recorded in Table 52. If required, final temperatures were measured and recorded in Table 52.

[ ] The unit was positioned in the same way as for the Temperature Test.

[ ] Failure of Thermostats (52.5.2) - The thermostat or thermal control noted in Table 52 was short circuited/interrupted, disabling the control that served to limit the temperatures.

[ ] Impairment of Cooling (52.5.5) - In accordance with instructions in Table 52, either the cooling fan was disconnected or enclosure ventilation openings were blocked.

[ ] Locking of Moving Parts (52.5.6) - Moving parts as indicated in Table 52 were locked one at a time. The sample was operated for the time specified in the table or until ultimate results.

[ ] Interruption and Short-Circuiting of Motor Capacitors (52.5.7) - Motors indicated in Table 52 were operated with a locked rotor, with the capacitor short-circuited or open-circuited in turn.

[x] Failure of Components (52.5.9) - The points indicated in Table 52 were either short circuited or opened, one at a time.

[ ] Heating Element Running Overload (52.5.10d) - The unit was operated at 110% of the maximum rated voltage source or supply. The thermostat or thermal control was short-circuited. The unit was operated for the unit's recommended operating time until thermal equilibrium was reached or until the measured temperature did not increase by more than 2°C/h or for 2.5 hours, whichever is shorter.

[ ] Motor Running Overload (52.5.10f) - The motor indicated in Table 52 was operated starting from cold condition at rated voltage or upper limit of the rated voltage range until the measured temperature did not increase by more than 2°C/h.

[ ] The load current was then increased by 5 percent with the supply voltage maintained at its original value. When steady thermal conditions were again established, the load was again increased. These steps were continued until the overload protector operated or until thermal stability was reached.

[ ] [Short time] [Intermittent] Motor Running Overload (52.5.10g) - The motor indicated in Table 52 was operated starting from cold condition at normal load, at rated voltage or upper limit of the rated voltage range until steady thermal conditions were established or until a protective device operated.

[ ] Open Phase Protection (52.5.10h) – The 3 phase motor indicated in Table 52 was operated starting from cold condition. Under normal load, after one phase has been disconnected, the motor was operated until steady thermal condition is reached.

The appliance was covered with a single layer of cheesecloth and operated on a tissue covered softwood surface. Temperatures were monitored on the outer surface of the enclosure, and on easily touchable parts.

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011-08-09

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C 25 Ambient Humidity, % 44 Ambient Pressure, mBar 982

RESULTS

TABLE 52: Abnormal Operation		
Test Type, Condition and Clause Reference	Observed Results	Remarks
Failure of Components (52.5.9) insertion device		
Short Q8	No output current, leakage current 0.3 µA	Insertion device, load 500Ohms
Short Q2	No output current, leakage current 0.2 µA	Insertion device, load 500Ohms
Shorted electrodes	No output current, leakage current 0.2 µA	
Failure of Components (52.5.9) control device		
Short U7 and Q3 in battery charging circuit	The temp did not exceed the limits , See Table 42 Leakage current did not exceed the limits, See Table 19	
Supplementary Information:		

There ~~[was]~~ [was no] glowing, flaming, or charring of the cheesecloth.

There ~~[was]~~ [was no] glowing, flaming, or charring of the tissue paper.

[ ] Self-resetting thermal cutouts [did not operate] [operated].

[ ] The setting of any thermostat, thermal cutout or overload release [did not change] [changed] due to heating, vibration or other causes.

[x] The measured temperatures [did not exceed] ~~[exceeded]~~ allowable limits.

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Tested by: _____ (signature) Tested by: Silvia Ankova (print) Test date: 2011/08/10

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C 25 Ambient Humidity, % 44 Ambient Pressure, mBar 982

MOLD STRESS RELIEF TEST: (IEC 60601-1, SUB-CLAUSE 55, US DEVIATION)

METHOD

The samples were placed in an air-circulating oven, maintained under conditions specified in Table 55. After that period, the samples were examined for warping, cracking, breaking or other alterations.

RESULTS

TABLE U.S. 55: Mold Stress Relief

Part Under Test	Temperature + (°C)	Time (h)	Remarks
Insertion unit	70	7	
Control unit	70	7	
Power supply /charger	70	7	

+ 70°C or Max. Temp. + 10°C

Supplementary Information:

There [was no] [~~was~~] warping, cracking or breaking.

There [was no] [~~was~~] exposure of live parts.

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Tested by: _____ (signature) Tested by: _____ (print) Test date: _____

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

~~CORD ANCHORAGES: (IEC 601, IEC 60601-1, SUB-CLAUSE 57.4A)~~

~~METHOD~~

~~The sample was securely mounted. All internal electrical connections to the cord were severed. Initial positions of the conductor ends were marked. A mark was made on the cord sheath at a distance of approximately 2 cm from the cord anchorage. The cord was subjected 25 times to a pull indicated in Table 57.4. The pull was applied without jerks, each time for 1 s. The longitudinal displacement of the mark on the cord sheath was measured while the cord was subjected to the last pull. Immediately afterwards, the cord was subjected for 1 min to a torque value indicated in the table. Following the Pull and Torque Tests, the cord was subjected to an inward force.~~

~~RESULTS~~

~~TABLE 57.4: Cord Anchorages~~

~~Cord/Anchor Under Test~~	~~Mass of Equipment~~	~~Pull~~	~~Torque~~	~~Remarks~~
~~Insertion unit strain relief~~	~~≤ 1 kg:~~	~~30 N Pull~~	~~0.1 Nm~~	
~~Supplementary Information:~~				

~~[ ] The longitudinal displacement [did not exceed] [exceeded] 2 mm.~~

~~[ ] The movement of the conductor ends [did not exceed] [exceeded] 1 mm.~~

~~[ ] It [was not] [was] possible to push the cord into equipment to such an extent that the cord, or internal parts of the equipment could be damaged.~~

No samples provided to conduct the test – SA - 2011/08/09

≤ 1 kg: 30 N Pull, 0.1 Nm Torque
over 1 through 4 kg: 60 N Pull, 0.25 Nm Torque
>4 kg: 100 N Pull, 0.35 Nm Torque

1 kg = 2.205 lbs. 1 lb = 0.454 kg
1 N = 0.225 lbs. Force 1 lb force = 4.448 N
1 Nm = 0.738 ft lbs. Force 1 ft lb force = 1.356 Nm

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011/08/05

Sample # : 1 Instrument Code / Range: _____

Ambient Temperature, °C 24 Ambient Humidity, %43 _____ Ambient Pressure, mBar 982

INTERRUPTION OF POWER SUPPLY: (IEC 60601-1 SUBCLAUSE 49)

METHOD

The sample was run in normal conditions and the power supply was interrupted and restored. There shall be no safety hazard other than interruption of its intended function.

RESULTS

TABLE: Additional Tests

Clause	Test Type and Condition	Remarks and Observed Results	Verdict
49	INTERRUPTION OF POWER SUPPLY, insertion unit disconnected from the control unit	insertion unit stopped working, no hazard	P

Supplementary Information:

The results [complied] ~~[did not comply]~~ with the requirements of the Standard.

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Tested by: _____ (signature) Tested by: Silvia Ankova (print) Test date: 2011/08/09

Sample # : 2 Instrument Code / Range: _____

Ambient Temperature, °C 25 Ambient Humidity, % 44 Ambient Pressure, mBar 982

WORKING VOLTAGE MEASUREMENT: (IEC 60601-1 SUBCLAUSE 20.3)

METHOD

The reference voltage to which the relevant insulation is subject in normal use and at rated supply voltage was measured. The voltage and measurement points were recorded.

RESULTS

TABLE: Additional Tests

Clause	Test Type and Condition	Remarks and Observed Results	Verdict
20.3	WORKING VOLTAGE MEASUREMENT	Peak voltage 51.2V positive and 51.2V negative. Reference voltage for dielectric test – 36.2V	

Supplementary Information:

The results [complied] ~~[did not comply]~~ with the requirements of the Standard.

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Tested by: _____ (signature) Tested by: _____ (print) Test date: 2011-08-05

Sample # : 1 Instrument Code / Range: _____

Ambient Temperature, °C 24 Ambient Humidity, % 43 Ambient Pressure, mBar 982

POWER AVAILABILITY: (IEC 60601-1 SUBCLAUSE 52.4.1)

METHOD

An external resistive load was connected to the points specified in the table. The load was adjusted to draw maximum power for 1 min. Operator controls were adjusted to maximize the available power.

RESULTS

TABLE: Additional Tests

Clause	Test Type and Condition	Remarks and Observed Results	Verdict
52.4.1	POWER AVAILABILITY	Battery charger - 2.7W	
52.4.1	POWER AVAILABILITY	Control unit (fully charged battery) – 9.4W	

Supplementary Information:

The results [complied] ~~[did not comply]~~ with the requirements of the Standard.

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Tested by: _____ (signature) Tested by: _____ (print) Test date: _____

Sample # : _____ Instrument Code / Range: _____

Ambient Temperature, °C _____ Ambient Humidity, % _____ Ambient Pressure, mBar _____

See separate datasheets – SA – 2011-08-12

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DATA PACKAGE INFORMATION SHEET

Applicant Information	Name / Address:	INCONTROL MEDICAL L L C SUITE 250 3225 GATEWAY RD BROOKFIELD WI 53045 UNITED STATES

Product Information	Standard:	UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety) IEC 60601-1:1988 + A1:1991 + A2:1995
	CCNs:	PIDF
	Product:	Electrical stimulator
	Models:	InTone

Test Location Information	DAP and UL:	[ ] CTDP [ ] TCP [ ] TPTDP [ ] WTDP [x] UL	
	CB Scheme:	[ ] CBTL [ ] RMT [ ] SMT [ ] TMP [ ] WMT	
	Test Location Name/Address:	Underwriters Laboratories Inc., 333 Pfingsten Rd., Northbrook, IL 60062	
	Tests Conducted By**:	Sign	*Mark York/Reviewed by Steve Herman*
		Print	Mark York
	** When all tests are conducted by one person, the printed name and signature can be inserted here instead of on each page containing data		
	Authorized Signatory or TCP Reviewer:	Sign	
		Print	
		Date	
	UL WTDP / WMT Witness:	Sign	
		Print	

Reviewed & Accepted By	Qualified Project Handler:	Sign	Silvia Ankova
		Print	Silvia Ankova

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LIST OF TESTS

Test Name **Page**

BALL PRESSURE: (IEC 60601-1 Subclause 59.2) 5

Special Instructions - Unless specified otherwise in the individual Methods, the tests shall be conducted under the following ambient conditions. Confirmation of these conditions shall be recorded at the time the test is conducted.

Standard	Ambient Temperature, °C	Relative Humidity, %	Barometric Pressure, mBar
	±	±	±
60065	25 ± 10	Max 75	Not specified
60601-1	+10 to +40	30 to 75	700 to 1060 hPA
60950	Not specified	Not specified	Not specified
60950-1	Not specified	Not specified	Not specified
61010-1	+15 to +35	Max 75	75 to 106 kPa
61215	Not specified	Not specified	Not specified
61646	Not specified	Not specified	Not specified
61730	Not specified	Not specified	Not specified

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TEST SAMPLE IDENTIFICATION

The table below is to provide correlation of sample numbers to specific product related information. Refer to this table when a test identifies a test sample by "Sample No." only.

Sample Number	Sample Card Number	Date Received	Manufacturer, Product Identification and Ratings
3	1165547	08/01/2011	enclosure by (b) (4) [redacted]
Sampling Procedure (if used) :			

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TEST INSTRUMENTS REFERENCE LIST

Instr. Code	Instrument I.D.	Instrument Type	Range Used Or ***	Make and Model **	Calibration Date	
					Last	Due

"Chamber setting(s) [was] [were] monitored to ensure that the setting(s) [was] [were] stable throughout the test time frame. Any deviations from the setting(s) are noted below.

Date	Test	Instrument Code	Time period of deviation	Setting(s)

** Information to be recorded when tests are conducted at a non-UL facility.
*** Refer to specific data sheet for individual scale used.

[x] Test equipment information is recorded on UL's Laboratory Project Management (LPM)/Laboratory Equipment Management (LEM) database. (This statement may be selected only if datasheets are completed at a UL facility)

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Tested by: Mark York (signature) Tested by: Mark York (print) Test date: 2011-08-11

Sample # : 3 Instrument Code / Range:

Ambient Temperature, °C 24.1 Ambient Humidity, % 46.2 Ambient Pressure, mBar 990

BALL PRESSURE: (IEC 60601-1 SUBCLAUSE 59.2)

METHOD

A sample of each external part of insulating material indicated in the table was subjected to a Ball Pressure Test using the test apparatus shown in Fig. 48 of IEC 60601-1. (In this apparatus, a steel ball of 5 mm diameter exerts a force of 20 N when pressed against a surface). The apparatus and a fire (or sand) brick were placed in an air-circulating oven. Once the apparatus and brick attained the temperature shown below, the sample was placed in the oven on top of the brick. The steel ball was then positioned such that the apparatus was balanced on the surface of the sample. After 1 h, it was removed and the diameter of the impression made by the ball was measured and the resulting impression diameter measurement was recorded in the RESULTS under the "Remarks and Observed Results: column. The impression of less than 2 mm was considered as a passing result.

RESULTS

TABLE: Additional Tests

Clause	Test Type and Condition	Remarks and Observed Results (include impression diameter measurement in mm)	Verdict
59.2	BALL PRESSURE, enclosure @ 75°C	1.32 mm	Pass

Supplementary Information:

The results [complied] [~~did not comply~~] with the requirements of the Standard.

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Test Report issued under the responsibility of:

Underwriters Laboratories Inc.®

TEST REPORT
IEC 60601-1-2
Medical Electrical Equipment
PART 1-2: General Requirements for Basic Safety and Essential Performance
Collateral Standard: Electromagnetic Compatibility

Report Reference No. ..... :	11CA38346
Date of issue..... :	August 16, 2011
Total number of pages	52
CB Testing Laboratory ..... :	Underwriters Laboratories Inc
Address..... :	333 Pfingsten Rd. Northbrook, IL 60062
Applicant's name ..... :	InControl Medical LLC
Address..... :	Suite 250 3225 Gateway Rd
Test specification:	
Standard ..... :	IEC 60601-1-2: Second Edition and Third Edition
Test procedure..... :	CB
Non-standard test method.....:	N/A
Test Report Form No. ..... :	IEC60601_1_2BEMC
Test Report Form(s) Originator .... :	Underwriters Laboratories Inc.
Master TRF ..... :	Dated 2008-06

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This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description..... :	Stimulation Device
Trade Mark..... :	InControl Medical
Manufacturer ..... :	InControl Medical LLC
Model/Type reference..... :	InTone
Ratings..... :	Battery / 120V/60Hz

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1.0 **Testing Program Details**

Testing procedure and testing location:	
☒ **CB Testing Laboratory:**	**Underwriters Laboratories Inc**
Testing location/ address.....:	**333 Pfingsten Rd. Northbrook, IL 60062**
☐ **Associated CB Test Laboratory:**	
Testing location/ address.....:	
Tested by (name + signature)	**Bartlomiej Mucha**
Approved by (name + signature) :	**Michael Ferrer**
☐ **Testing procedure: TMP**	
Tested by (name + signature) .....:	
Approved by (name + signature) :	
Testing location/ address.....:	
☐ **Testing procedure: WMT**	
Tested by (name + signature) .....:	
Witnessed by (name + signature):	
Approved by (name + signature) :	
Testing location/ address.....:	
☐ **Testing procedure: SMT**	
Tested by (name + signature) .....:	
Approved by (name + signature) :	
Supervised by (name+ signature):	
Testing location/ address.....:	
☐ **Testing procedure: RMT**	
Tested by (name + signature) .....:	
Approved by (+ signature).....:	
Supervised by (+ signature).....:	
Testing location/ address.....:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Summary of testing:	
Tests performed (name of test and test clause): **See Section 1.6**	**Testing location:** **Underwriters Laboratories Inc** **333 Pfingsten Rd. Northbrook, IL 60062**
Summary of compliance with National Differences: None	
Copy of marking plate: Not available at the time of testing	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Test item description		
Trade Mark ..... :		InControl Medical
Manufacturer..... :		**InControl Medical**
Model/Type reference ..... :		**InTone**
Ratings ..... :		**120V/60Hz and Internal Battery**
Possible test case verdicts:		
- test case does not apply to the test object	:	**N/A**
- test object does meet the requirement...:		**P (Pass)**
- test object does not meet the requirement	:	**F (Fail)**
Testing.....:		
Date of receipt of test item.....:		**August 4, 2011**
Date (s) of performance of tests .....:		**August 15, 2011**

General remarks:

The test results presented in this report relate only to the object tested.

The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report.

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"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.

Throughout this report the decimal separator is point. (Select one).

General product information: "The In Control InToneTM device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1.1 Equipment Description

"The In Control InToneTM device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction."

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1.1.1 Equipment Marking Plate

Not available at time of testing

1.1.2 Supporting Equipment Used During Test:

Use*	Product Type	Manufacturer	Model	Comments
EUT	Medical Device	InControl Medical LLC	InTone	Stimulator
EUT	Control Box	InControl Medical LLC	InTone	-
AE	USB to RS232	-	-	Used for data transfer
AE	Charger	-	-	Used for charging only
SIM	Laptop Computer	Dell	PP19S	Used for data transfer

Note:
EUT - Equipment Under Test
AE - Auxiliary/Associated Equipment
SIM - Simulator (Not Subjected to Test)

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1.1.3 **Input/Output Ports:**

Port No.	Name	Type*	Cable Max. >3m	Cable Shielded	Comments
0	Enclosure	N/E	—	—	None
1	Mains	AC	N	N	AC/DC transformer used for charging only
2	InTone Cable	AC	N	N	Connection between stimulation device and control box
3	USB to RS232	I/O	N	N	Used only for data transfer

*Note: AC = AC Power Port DC = DC Power Port N/E = Non-Electrical
I/O = Signal Input or Output Port (Not Involved in Process Control)
TP = Telecommunication Ports

1.1.4 **EUT Internal Operating Frequencies:**

Frequency	Description
(b)(4) TS	Stimulation frequency

1.1.5 **Power Interface**

Mode No.	Voltage (V)	Current (A)	Power (W)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
1	-	-	-	DC-Battery	-	Normal Use Mode
2	120	-	-	AC-60	-	Charging Mode Only
3	-	-	-	DC-Battery	-	Data transfer / exchange mode

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1.2 **EUT Operation Modes:**

Mode #	Description
1	**Normal Use Mode, treatment. For conducted immunity, magnetic immunity and esd the output electrode outputs were monitored using oscilloscope.**
2	**Charging Mode**
3	**Data transfer / exchange mode**

1.3 **EUT Configuration Modes**

Mode #	Description
1	**EUT was setup on 80cm support above ground plane**
2	**EUT was setup on 10cm support above ground plane**

1.4 **Immunity Performance Criteria**

Medical Equipment Performance Criteria - unacceptable operating conditions / responses are:

- **component failures;**
- **changes in programmable parameters;**
- **reset to factory defaults (manufacturer's presets);**
- **change of operating mode;**
- **false alarms;**
- **cessation or interruption of any intended operation, even if accompanied by an alarm;**
- **initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;**
- **error of a displayed numerical value sufficiently large to affect diagnosis or treatment;**
- **noise on a waveform in which the noise is indistinguishable from physiologically-produced signals or the noise interferes with interpretation of physiologically-produced signals;**
- **artefact or distortion in an image in which the artefact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;**
- **failure of automatic diagnosis or treatment EQUIPMENT and SYSTEMS to diagnose or treat, even if accompanied by an alarm.**

Medical Specific Compliance Criteria for the Voltage Dips and Interruptions Test:

Clause 6.2.7.1 b) - the equipment is allowed a deviation from the requirements of 6.2.1.10 at the immunity levels specified in Table 11 (<5% / >95% / 5s), provided the equipment remains safe, experiences no component failures and is restorable to the pre-test state with operator intervention.

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1.5 Compliance Summary

The Applicant did not request the labelling and documentation evaluation/inspection/test required by IEC / EN 60601-1-2: 2007, Section 5. It is the manufacturer's responsibility to ensure that proper labelling is utilized on the product. Also, it is the responsibility of the manufacturer to ensure the accompanying documentation provided is in accordance to IEC 60601-1-2: 2007, 5.2.

1.6 Result Summary

Clause	Requirement – Test	Result/Comments	Verdict
6.1	Emissions		PASS
6.1.1.1	Classification		—
	Class B..... :	Class B	—
	Group 1 or 2 ..... :	Group 1	—
	CISPR 11..... :	CISPR11	—
6.1.1.2	Limits of mains terminal disturbance voltage :		PASS
	Limits for radiated disturbance..... :		PASS
6.1.3.1	Harmonic Current Emissions per IEC61000-3-2..:		PASS
6.1.3.2	Voltage Fluctuations and Flicker per IEC61000-3-3		PASS
6.2	Immunity		
6.2.2	Electrostatic Discharges (ESD)..... :		PASS
6.2.3	Radiated RF electromagnetic Fields.....:		*PASS
6.2.4	Electrical Fast Transients and bursts ..... :		PASS
6.2.5	Surges..... :		PASS
6.2.6	Conducted Disturbances, induced by RF fields :		PASS
6.2.7	Voltage Dips, Interruptions, and variations .... :		PASS
6.2.8	Power-frequency Magnetic Fields ..... :		PASS
* Radiated Immunity in data transfer mode was conducted on one side only in the entire frequency range.			

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1.7 **Test Conditions and Results – Conducted Emissions**

CISPR 11	TEST: Limits of mains terminal disturbance voltage		Verdict
Method: The AMN placed 0,8 m from the boundary of the unit under test and bonded to a ground reference plane. This distance was between the closest points of the AMN and the EUT. All other units of the EUT and associated equipment were at least 0,8 m from the AMN. All power was connected to the system through Artificial Mains Network (AMN). Conducted voltage measurements on mains lines were made at the output of the AMN.			PASS
Laboratory Parameters	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	22°C	
Relative Humidity	10 to 90 %	53%	
Fully configured sample scanned over the following frequency range	Frequency range on each side of line	Measurement Point	
	150kHz to 30MHz	Mains	
Equipment mode	Power interface mode	2	
	EUT configurations mode	1	
	Operation mode	2	

Limits - Group 1 and 2 - Class B *		
Frequency (MHz)	Limit dB (μV)	
	Quasi-Peak	Average
0.15 to 0.50	66 to 56	56 to 46
0.50 to 5	56	46
5 to 30	60	50

Supplementary information: None

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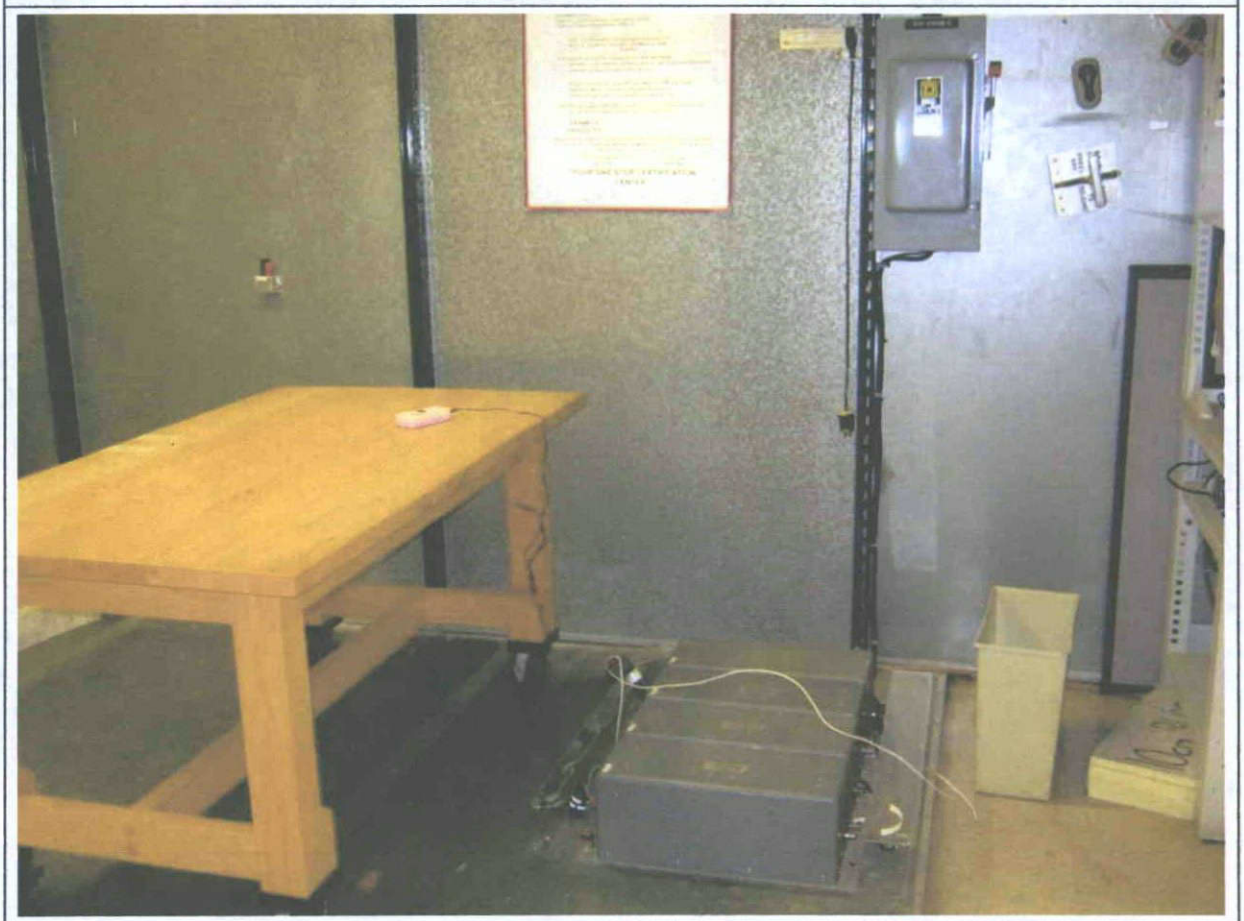
Description	Manufacturer	Model	Identifier
EMI Test Receiver	Rohde & Schwarz	ESCI	EMC4328
Transient Limiter	Electro-Metrics	EM7600-2	EMC4224
HighPass Filter	Solar Electronics	2803-150	885551
Attenuator	HP	8494B	2831A00838
LISN - L1	Solar	8602-50-TS-50-N	EMC4052
LISN - L2	Solar	8602-50-TS-50-N	EMC4064

Photo of test setup for Mains Terminal Disturbance Voltage



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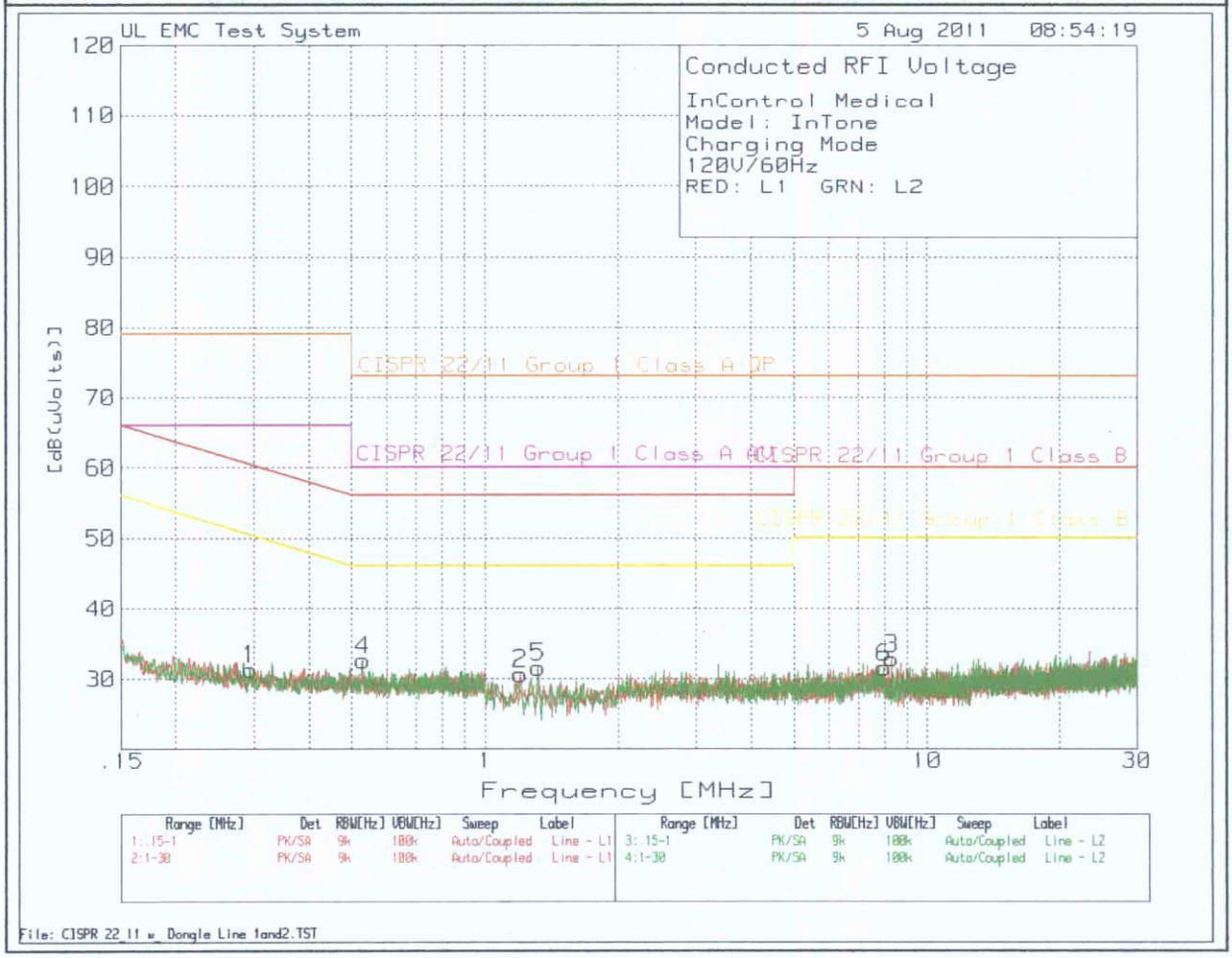
Graphical representation of Mains Terminal Disturbance Voltage Measurement



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Tabulated Results for Mains Terminal Disturbance Voltage

InControl Medical
Model: InTone
Charging Mode
120V/60Hz
RED: L1 GRN: L2

Test Frequency	Meter Reading	Detector	EMC4052 L1 9k-30m w dongle TYP [dB]	GP5 L1 HPFltr STAtt 0db 150k-3 [dB]	[dB(uVolts)]	CISPR 22/11 Group 1 Class A QP	Margin	CISPR 22/11 Group 1 Class A AV	Margin	CISPR 22/11 Group 1 Class B QP	Margin	CISPR 22/11 Group 1 Class B AV	Margin
Line - L1													
.29412	19.78	PK	.7	10.9	31.38	79	-47.62	66	-34.62	60.4	-29.02	50.4	-19.02
1.19704	19.87	PK	.2	10.6	30.67	73	-42.33	60	-29.33	56	-25.33	46	-15.33
8.30216	21.56	PK	.4	10.9	32.86	73	-40.14	60	-27.14	60	-27.14	50	-17.14
Line - L2													
.52856	21.51	PK	.3	10.8	32.61	73	-40.39	60	-27.39	56	-23.39	46	-13.39
1.31295	20.76	PK	.2	10.7	31.66	73	-41.34	60	-28.34	56	-24.34	46	-14.34
7.98341	20.25	PK	.3	11	31.55	73	-41.45	60	-28.45	60	-28.45	50	-18.45

PK - Peak detector

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1.8 Test Conditions and Results – Radiated Emissions

CISPR 11	TEST: Limits for radiated disturbance 30 MHz –1 GHz		Verdict
Method: Measurements were made in a 10-meter semi-anechoic chamber or Open Area Test Site that complies to CISPR 16. Preliminary (peak) measurements were performed at an antenna to EUT separation distance of 10 meter. The EUT was rotated 360° about its azimuth with the receive antenna located at various heights in horizontal and vertical polarities. Final measurements (quasi-peak) were then performed by rotating the EUT 360° and adjusting the receive antenna height from 1 to 4 m. All frequencies were investigated in both horizontal and vertical antenna polarity, where applicable.			PASS
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	22°C	
Relative Humidity	10 to 90 %	43%	
Fully configured sample scanned over the following frequency range	Frequency range on each side of line	Measurement Point	
	30MHz – 1GHz	10 m measurement distance	
Equipment mode	Power interface mode	1,2,3	
	EUT configurations mode	1	
	Operation mode	1,2,3	
Limits – Group 1 Class B			
Frequency (MHz)	Limit dB (μV/m)		
	Quasi-Peak		
30 to 230	30		
230 to 1000	37		
Supplementary information: None			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Description	Manufacturer	Model	Identifier
EMI Test Receiver	Rohde & Schwarz	ESU	EMC4323
Bicon Antenna	Chase	VBA6106A	EMC4078
Log-P Antenna	Chase	UPA6109	EMC4258

Photo of test setup for Radiated Disturbance

Charging Mode

Treatment Mode

Data Transfer Mode

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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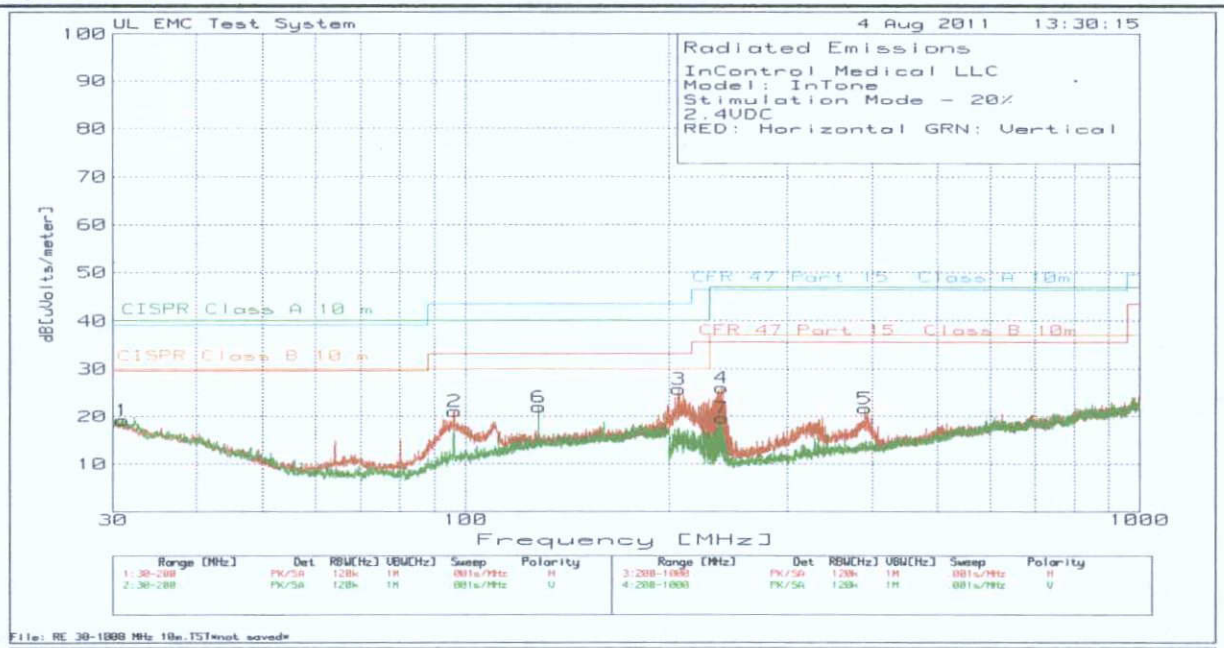
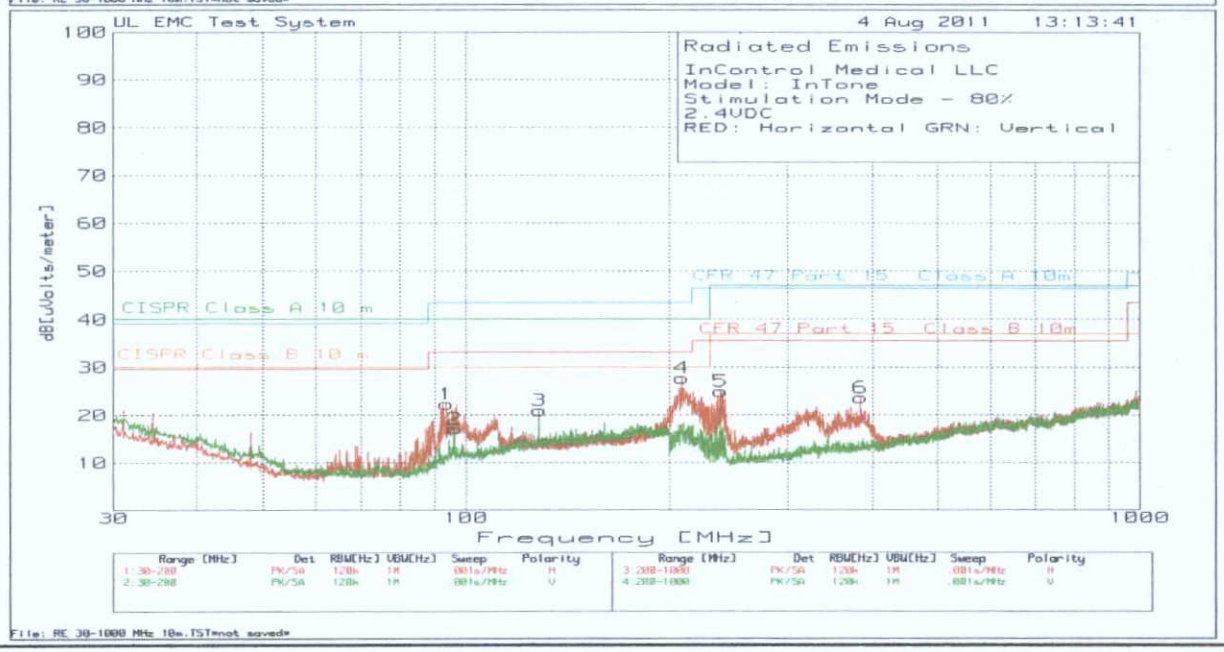
Graphical representation of Radiated Disturbance Measurement – Treatment Mode (20% output and 80% output Levels)





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Tabular representation of Radiated Disturbance Measurement – Treatment Mode (20% output Levels)

InControl Medical LLC
Model: InTone
Stimulation Mode - 20%
2.4VDC
RED: Horizontal GRN: Vertical

Test Frequency	Meter Reading	Detector	Antenna Factor	Path Loss	dB[uVolts/meter]	CISPR Class B 10 m	Margin	CFR 47 Part 15 Class B 10m	Margin	Height [cm]	Polarity
30.9345	31.89	PK	17.7	-30.4	19.19	30	-10.81	29.6	-10.41	400	Horz
96.1819	41.01	PK	10	-30	21.01	30	-8.99	33.1	-12.09	250	Horz
128.2109	38.11	PK	13.8	-30	21.91	30	-8.09	33.1	-11.19	99	Vert
206.6622	48.05	PK	10.9	-33.3	25.65	30	-4.35	33.1	-7.45	400	Horz
239.4404	47.88	PK	11.2	-33.1	25.98	37	-11.02	35.6	-9.62	400	Horz
390.8061	38.33	PK	15.4	-32.1	21.63	37	-15.37	35.6	-13.97	199	Horz
239.4404	41.5	PK	11.2	-33.1	19.6	37	-17.4	35.6	-16	399	Vert

Test Frequency	Meter Reading	Detector	Antenna Factor	Path Loss	dB[uVolts/meter]	CISPR Class B 10 m	Margin	CFR 47 Part 15 Class B 10m	Margin	Azimuth [Degs]	Height [cm]	Polarity
206.67	46.39	QP	10.9	-33.3	23.99	30	-6.01	33.1	-9.11	139	369	Horz

PK - Peak detector
QP - Quasi-Peak detector

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Tabular representation of Radiated Disturbance Measurement – Treatment Mode (80% output Levels)

InControl Medical LLC
Model: InTone
Stimulation Mode - 80%
2.4VDC
RED: Horizontal GRN: Vertical

Test Frequency	Meter Reading	Detector	VBA6106A SN1246 EMC4078	West 30-200MHz with Miteq [dB]	dB[uVolts/meter]	CISPR Class B 10 m	Margin	CFR 47 Part 15 Class B 10m	Margin	Height [cm]	Polarity
93.6332	42.79	PK	9.6	-30.1	22.29	30	-7.71	33.1	-10.81	400	Horz
96.1819	37.11	PK	10	-30	17.11	30	-12.89	33.1	-15.99	100	Vert
128.2109	37.13	PK	13.8	-30	20.93	30	-9.07	33.1	-12.17	100	Vert
209.0606	50.23	PK	10.8	-33.3	27.73	30	-2.27	33.1	-5.37	399	Horz
238.3744	46.94	PK	11.1	-33.1	24.94	37	-12.06	35.6	-10.66	399	Horz
384.4104	40.8	PK	15.1	-32.3	23.6	37	-13.4	35.6	-12	299	Horz

InControl Medical LLC
Model: InTone
Stimulation Mode - 80%
2.4VDC
RED: Horizontal GRN: Vertical

LogP Horizontal 200 - 1000MHz

Test Frequency	Meter Reading	Detector	UPA6109 SN1060 08-20-11 10M H [dB]	East 200-1000MHz with Miteq [dB]	dB[uVolts/meter]	CISPR Class B 10 m	Margin	CFR 47 Part 15 Class B 10m	Margin	Azimuth [Degs]	Height [cm]	Polarity
209.184359	46.45	QP	10.8	-33.3	23.95	30	-6.05	33.1	-9.15	116	367	Horz

PK - Peak detector
QP - Quasi-Peak detector

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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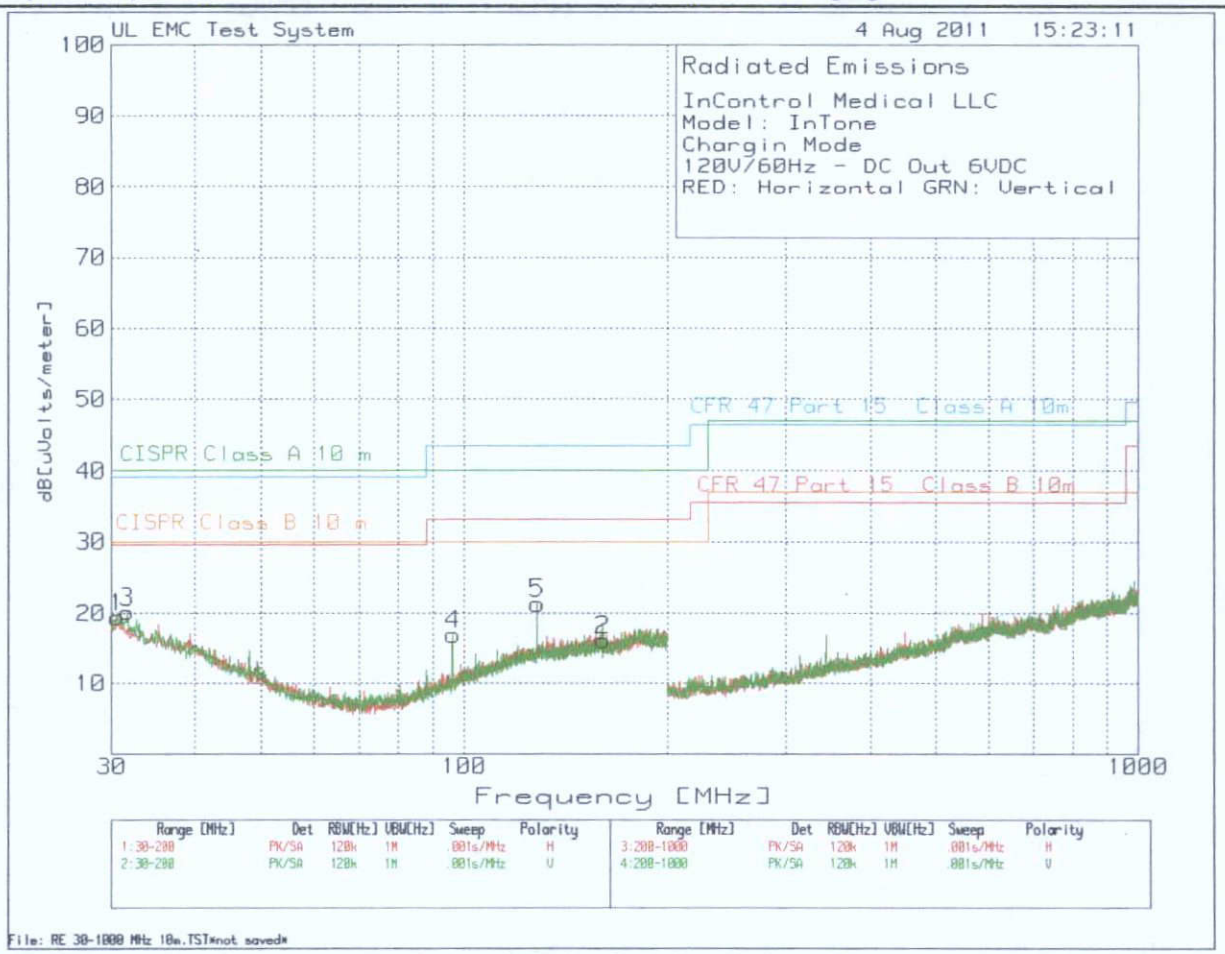
Graphical representation of Radiated Disturbance Measurement – Charging Mode



Sufficient margin exist between the limit and the level of all emissions. Measurements not required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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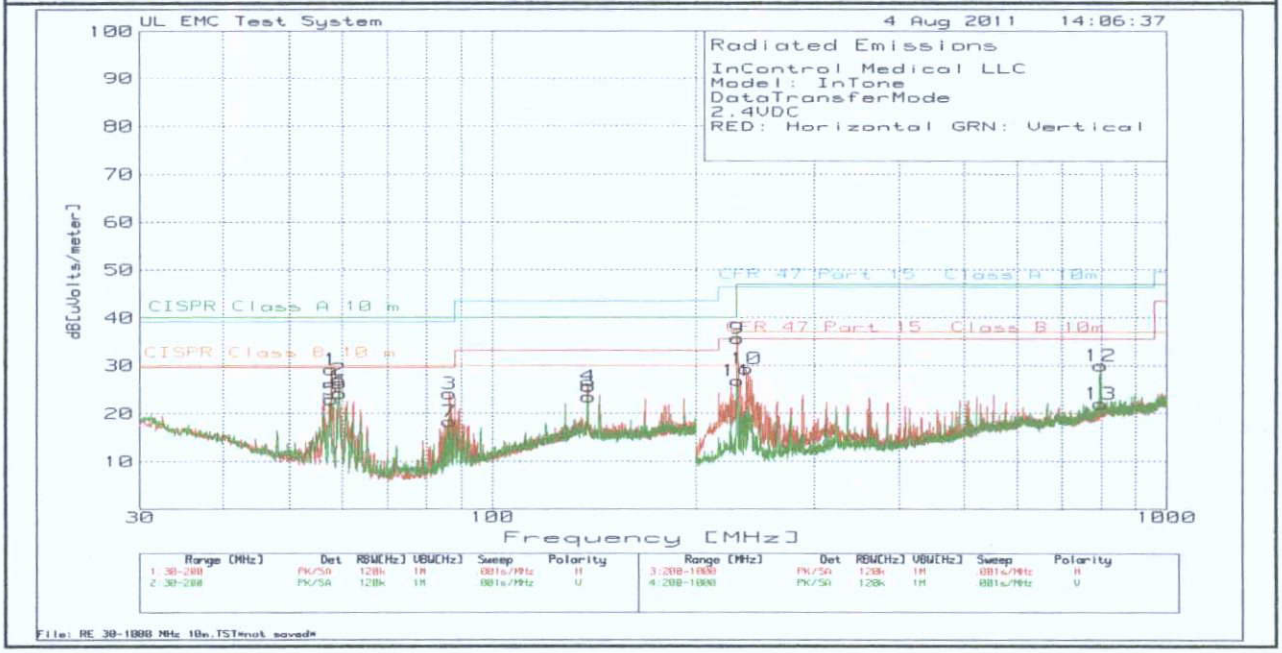
Graphical representation of Radiated Disturbance Measurement – Data Transfer Mode



InControl Medical LLC
Model: InTone
DataTransferMode
2.4VDC
RED: Horizontal GRN: Vertical

Test Frequency	Meter Reading	Detector	Antenna Factor	Path Loss Factor	dB[uVolts /meter]	CISPR Class A	Margin	CISPR Class B	Margin	Height [cm]	Polarity
57.6962	52.1	PK	7.3	-30.2	29.2	40	-10.8	30	-.8	400	Horz
59.2254	50.22	PK	7	-30.2	27.02	40	-12.98	30	-2.98	400	Horz
86.4118	45.8	PK	8.4	-30.1	24.1	40	-15.9	30	-5.9	250	Horz
138.4908	41.34	PK	14.3	-30	25.64	40	-14.36	30	-4.36	400	Horz
57.6962	45.77	PK	7.3	-30.2	22.87	40	-17.13	30	-7.13	299	Vert
59.3103	47.4	PK	7	-30.2	24.2	40	-15.8	30	-5.8	299	Vert
86.4118	40.01	PK	8.4	-30.1	18.31	40	-21.69	30	-11.69	299	Vert
138.4908	39.15	PK	14.3	-30	23.45	40	-16.55	30	-6.55	99	Vert
230.3797	58.1	PK	10.7	-33.2	35.6	47	-11.4	37	-1.4	399	Horz
237.8414	51.3	PK	11.1	-33.1	29.3	47	-17.7	37	-7.7	399	Horz
799.0673	31.78	PK	21.7	-31.5	21.98	47	-25.02	37	-15.02	99	Horz
230.3797	49.31	PK	10.7	-33.2	26.81	47	-20.19	37	-10.19	399	Vert
798.0013	39.87	PK	21.6	-31.5	29.97	47	-17.03	37	-7.03	199	Vert

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Test Frequency	Meter Reading	Detector	VBA6106A SN1246 EMC4078	West 30-200MHz with	dB[uVolts /meter]	CISPR Class A	Margin	CISPR Class B	Margin	Azimuth [Degs]	Height [cm]	Polarity
57.743	43.52	QP	7.3	-30.2	20.62	40	-19.38	30	-9.38	329	399	Horz
57.78	42.91	QP	7.3	-30.2	20.01	40	-19.99	30	-9.99	306	398	Horz
59.26641	41.98	QP	7	-30.2	18.78	40	-21.22	30	-11.22	306	398	Horz
86.48	36.75	QP	8.4	-30.1	15.05	40	-24.95	30	-14.95	183	312	Horz
138.32	40.46	QP	14.3	-30	24.76	40	-15.24	30	-5.24	293	397	Horz
59.267	38.52	QP	7	-30.2	15.32	40	-24.68	30	-14.68	263	228	Vert
230.549	58.1	QP	10.7	-33.2	35.6	47	-11.4	37	-1.4	17	394	Horz
230.549	57.93	QP	10.7	-33.2	35.43	47	-11.57	37	-1.57	26	389	Horz
230	41.65	QP	10.7	-33.2	19.15	40	-20.85	30	-10.85	26	389	Horz

PK - Peak detector
QP - Quasi-Peak detector

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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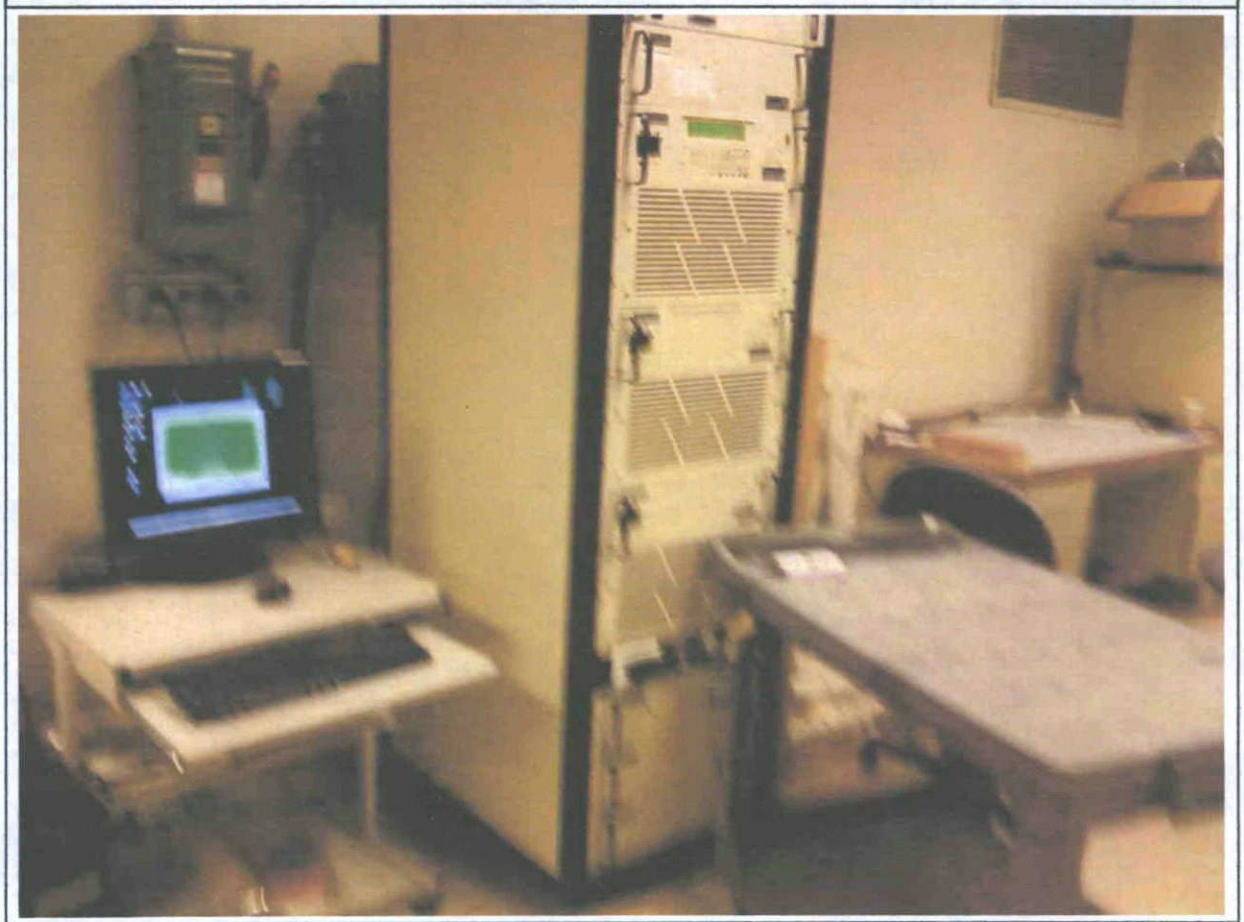
1.9 Test Conditions And Results – Limits for Harmonic Current Emissions

61000-3-2	TEST: Limits for Harmonic current emissions (IEC 61000-3-2:2006)	Verdict
Method: This test consists on the measurement of harmonics components of the input current which may be produced by equipment having an input current up to and including 16 A per phase, and intended to be connected to public low-voltage distribution systems. The equipment is tested under specified conditions of operation.		PASS

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	23°C
Relative Humidity	30 to 60 %	43%
Equipment mode	Power interface mode	2
	EUT configurations mode	1
	Operation mode	2
Classification of Equipment.....:		Class A
Supplementary information: None		

Description	Manufacturer	Model	Identifier
Power Analyzer	California Instruments	PACS-3	EMC4181
Power Source	Pacific Power Source	360AMXT-UPC-32/M6331	EMC4099

Photo of test setup for Harmonic Current Emissions



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

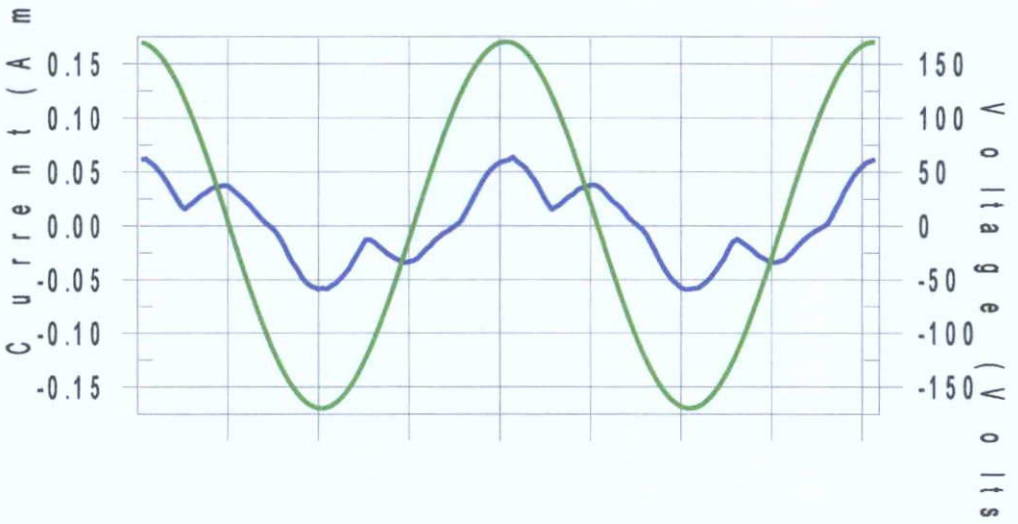
Tabulated Results for Harmonic Current Emissions

Harmonics – Class-A per Ed. 3.0 (2005-11)(Run time) incl. inter-harmonics

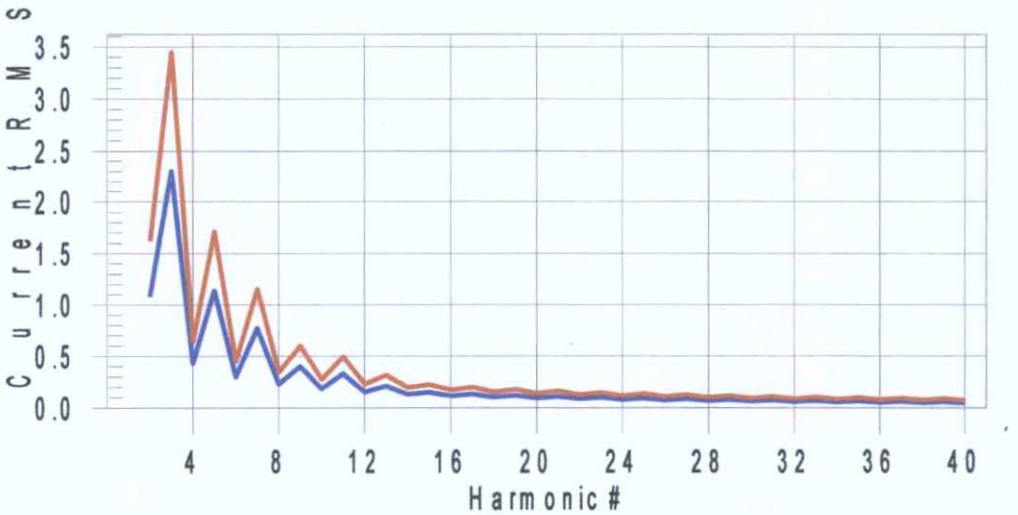
EUT: InTone **Tested by: BM**
Test category: Class-A per Ed. 3.0 (2005-11) (European limits) **Test Margin: 100**
Test date: 8/15/2011 **Start time: 11:12:22 AM** **End time: 11:15:02 AM**
Test duration (min): 2.5 **Data file name: H-000664.cts_data**
Comment: Charging Mode
Customer: InControl Medical

Test Result: Pass **Source qualification: Normal**

Current & voltage waveforms



Harmonics and Class A limit line **European Limits**



Test result: Pass Worst harmonic was #3 with 0.42% of the limit.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Current Test Result Summary (Run time)

EUT: InTone **Tested by: BM**
Test category: Class-A per Ed. 3.0 (2005-11) (European limits) **Test Margin: 100**
Test date: 8/15/2011 **Start time: 11:12:22 AM** **End time: 11:15:02 AM**
Test duration (min): 2.5 **Data file name: H-000664.cts_data**
Comment: Charging Mode
Customer: InControl Medical

Test Result: Pass **Source qualification: Normal**
THC(A): 0.01 **I-THD(%): 44.17** **POHC(A): 0.000** **POHC Limit(A): 0.251**
Highest parameter values during test:

V_RMS (Volts):	120.28	Frequency(Hz):	60.00
I_Peak (Amps):	0.077	I_RMS (Amps):	0.037
I_Fund (Amps):	0.033	Crest Factor:	2.168
Power (Watts):	3.6	Power Factor:	0.826

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.001	1.080	0.1	0.001	1.620	0.09	Pass
3	0.013	2.300	0.6	0.015	3.450	0.42	Pass
4	0.001	0.430	0.2	0.001	0.645	0.12	Pass
5	0.005	1.140	0.4	0.005	1.710	0.30	Pass
6	0.000	0.300	0.1	0.000	0.450	0.05	Pass
7	0.002	0.770	0.2	0.002	1.155	0.16	Pass
8	0.000	0.230	0.1	0.000	0.345	0.08	Pass
9	0.001	0.400	0.2	0.001	0.600	0.18	Pass
10	0.000	0.184	0.1	0.000	0.276	0.09	Pass
11	0.001	0.330	0.2	0.001	0.495	0.14	Pass
12	0.000	0.153	0.1	0.000	0.230	0.04	Pass
13	0.001	0.210	0.2	0.001	0.315	0.18	Pass
14	0.000	0.131	0.1	0.000	0.197	0.09	Pass
15	0.000	0.150	0.2	0.000	0.225	0.18	Pass
16	0.000	0.115	0.1	0.000	0.173	0.09	Pass
17	0.000	0.132	0.2	0.000	0.199	0.20	Pass
18	0.000	0.102	0.1	0.000	0.153	0.07	Pass
19	0.000	0.118	0.2	0.000	0.178	0.16	Pass
20	0.000	0.092	0.1	0.000	0.138	0.09	Pass
21	0.000	0.107	0.2	0.000	0.161	0.19	Pass
22	0.000	0.084	0.1	0.000	0.125	0.09	Pass
23	0.000	0.098	0.2	0.000	0.147	0.14	Pass
24	0.000	0.077	0.1	0.000	0.115	0.09	Pass
25	0.000	0.090	0.2	0.000	0.135	0.14	Pass
26	0.000	0.071	0.1	0.000	0.106	0.11	Pass
27	0.000	0.083	0.2	0.000	0.125	0.16	Pass
28	0.000	0.066	0.2	0.000	0.099	0.13	Pass
29	0.000	0.078	0.2	0.000	0.116	0.14	Pass
30	0.000	0.061	0.1	0.000	0.092	0.11	Pass
31	0.000	0.073	0.2	0.000	0.109	0.16	Pass
32	0.000	0.058	0.1	0.000	0.086	0.10	Pass
33	0.000	0.068	0.2	0.000	0.102	0.13	Pass
34	0.000	0.054	0.2	0.000	0.081	0.12	Pass
35	0.000	0.064	0.2	0.000	0.096	0.14	Pass
36	0.000	0.051	0.2	0.000	0.077	0.13	Pass
37	0.000	0.061	0.2	0.000	0.091	0.16	Pass
38	0.000	0.048	0.1	0.000	0.073	0.11	Pass
39	0.000	0.058	0.2	0.000	0.087	0.15	Pass
40	0.000	0.046	0.2	0.000	0.069	0.14	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Voltage Source Verification Data (Run time)

EUT: InTone **Tested by: BM**
Test category: Class-A per Ed. 3.0 (2005-11) (European limits) **Test Margin: 100**
Test date: 8/15/2011 **Start time: 11:12:22 AM** **End time: 11:15:02 AM**
Test duration (min): 2.5 **Data file name: H-000664.cts_data**
Comment: Charging Mode
Customer: InControl Medical

Test Result: Pass **Source qualification: Normal**

Highest parameter values during test:

Voltage (Vrms):	120.28	Frequency(Hz):	60.00
I_Peak (Amps):	0.077	I_RMS (Amps):	0.037
I_Fund (Amps):	0.033	Crest Factor:	2.168
Power (Watts):	3.6	Power Factor:	0.826

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.203	0.241	84.42	OK
3	0.136	1.082	12.59	OK
4	0.071	0.241	29.70	OK
5	0.041	0.481	8.53	OK
6	0.030	0.240	12.61	OK
7	0.033	0.361	9.23	OK
8	0.028	0.240	11.55	OK
9	0.022	0.240	9.15	OK
10	0.019	0.241	8.01	OK
11	0.022	0.120	18.59	OK
12	0.015	0.120	12.56	OK
13	0.015	0.120	12.69	OK
14	0.015	0.120	12.52	OK
15	0.015	0.120	12.28	OK
16	0.011	0.120	9.00	OK
17	0.013	0.120	10.93	OK
18	0.009	0.120	7.67	OK
19	0.011	0.120	9.09	OK
20	0.009	0.120	7.20	OK
21	0.011	0.120	9.08	OK
22	0.007	0.120	5.91	OK
23	0.009	0.120	7.65	OK
24	0.007	0.120	5.71	OK
25	0.009	0.120	7.27	OK
26	0.007	0.120	5.54	OK
27	0.009	0.120	7.55	OK
28	0.006	0.120	4.77	OK
29	0.008	0.120	6.27	OK
30	0.006	0.120	4.79	OK
31	0.006	0.120	5.38	OK
32	0.005	0.120	4.25	OK
33	0.007	0.120	5.56	OK
34	0.005	0.120	4.42	OK
35	0.007	0.120	5.53	OK
36	0.005	0.120	4.01	OK
37	0.006	0.120	4.99	OK
38	0.005	0.120	3.99	OK
39	0.006	0.120	4.75	OK
40	0.004	0.120	3.65	OK

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.10 Test Conditions and Results – Limitation of Voltage Fluctuations and Flicker

61000-3-3	TEST: Limitation of Voltage Fluctuations And Flicker (IEC 61000-3-3:2008)	Verdict
Method: The test circuit consists of a test supply voltage, reference impedance, the equipment under test and a flicker meter compliant with IEC 60868. The equipment shall be tested in the condition in which the manufacturer supplies it.		PASS

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	°C
Relative Humidity	30 to 60 %	%
Equipment mode	Power interface mode.....:	2
	EUT configurations mode .....:	1
	Operation mode.....:	2
Control Method of Equipment (see below).....:		1

1 - without additional conditions

2 - switched manually, or
switched automatically more frequently than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds), or manual restart, after a power supply interruption.

3 - attended while in use (for example: hair dryers, vacuum cleaners, kitchen equipment such as mixers, garden equipment such as lawn mowers, portable tools such as electric drills), or switched on automatically, or is intended to be switched on manually, no more than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds) or manual restart, after a power supply interruption.

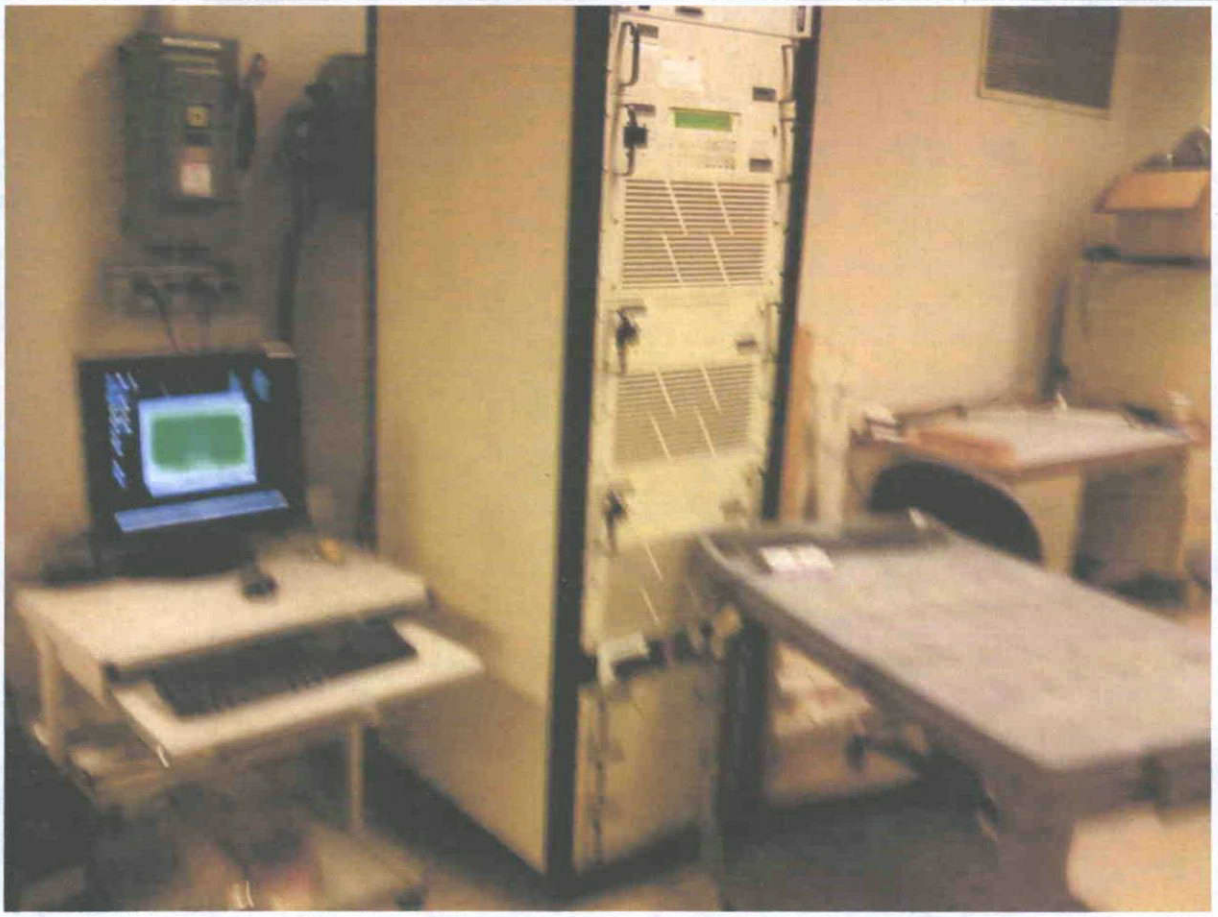
Supplementary Information: None

Description	Manufacturer	Model	Identifier
Power Analyzer	California Instruments	PACS-3	EMC4181
Power Source	Pacific Power Source	360AMXT-UPC-32/M6331	EMC4099
Impedance Module	Pacific Power Source	-	EMC4099

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Photo of test setup for Voltage Fluctuations And Flicker



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Tabulated Results for Voltage Fluctuations And Flicker

Flicker Test Summary per EN/IEC61000-3-3 (Run time)

EUT: InTone **Tested by: BM**
Test category: All parameters (European limits) **Test Margin: 100**
Test date: 8/15/2011 **Start time: 12:19:35 PM** **End time: 12:29:56 PM**
Test duration (min): 10 **Data file name: F-000666.cts_data**
Comment: Charging Mode
Customer: InControlMedical

Test Result: Pass **Status: Test Completed**

Parameter values recorded during the test:

Vrms at the end of test (Volt):	120.24			
Highest dt (%):	0.00	Test limit (%):	3.30	Pass
Time(mS) > dt:	0.0	Test limit (mS):	500.0	Pass
Highest dc (%):	0.00	Test limit (%):	3.30	Pass
Highest dmax (%):	0.00	Test limit (%):	4.00	Pass
Highest Pst (10 min. period):	0.160	Test limit:	1.000	Pass
Highest Plt (2 hr. period):	0.070	Test limit:	0.650	Pass

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.11 Test Conditions and Results – Immunity to Electrostatic Discharges

61000-4-2	TEST: Electrostatic discharges (IEC 61000-4-2:2008)	Verdict
Method: The test is intended to demonstrate the immunity of equipment subjected to static electricity discharges from operators directly and to adjacent objects. The tabletop equipment under test is placed on a wooden table, 0.8 m high, standing on the ground reference plane. A horizontal coupling plane (HCP), 1.6 x 0.8 m, is placed on the table. The EUT and the cables are isolated from the coupling plane by an insulating support 0.5 mm thick. The floor standing equipment is isolated from the ground reference plane by an insulating support about 0.1 m thick. The vertical coupling plane (VCP) of dimensions 0.5 m x 0.5 m is placed parallel to, and positioned at a distance of 0.1 m from, the EUT.		PASS

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	15 to 35 °C	23°C
Relative Humidity	30 to 60 %	53%
Equipment mode	Power interface mode	1,2,3
	EUT configurations mode	1
	Operation mode	1,2,3

Test Levels

Discharge type	Discharge Level (kV)		Number of discharges per location (each polarity)
	Positive	Negative	
Air – Direct	2, 4, 8	2, 4, 8	10
Contact – Direct	2, 4, 6	2, 4, 6	10
Contact – Indirect	2, 4, 6	2, 4, 6	10
Discharge location	See photo documentation of the test set-up All external locations accessible by hand, Horizontal plate (HCP) Vertical coupling plate (VCP)		

Supplementary information: None

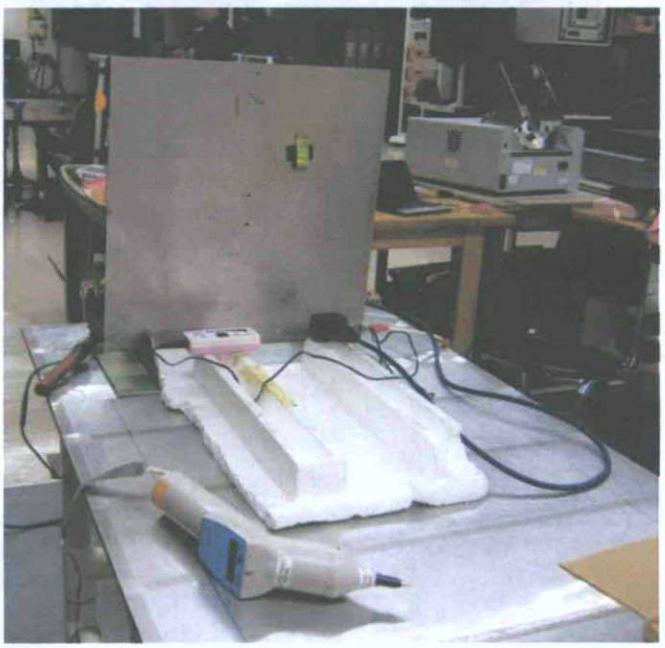
Description	Manufacturer	Model	Identifier
ESD Gun	HV Technologies	ESD3000	EMC4302
ESD Module	EMC Partner	ESD3000DM1	EMC4303
Temp / Humidity Meter	Oakton	35710-10	EMC4279

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Photo of test setup for Immunity to Electrostatic Discharges

Treatment Mode



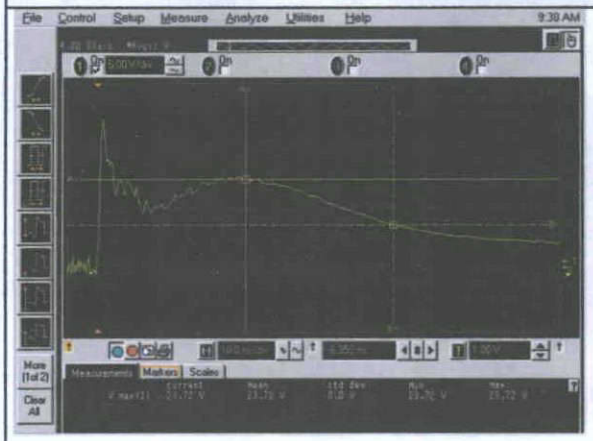
Charging Mode

Data Transfer Mode

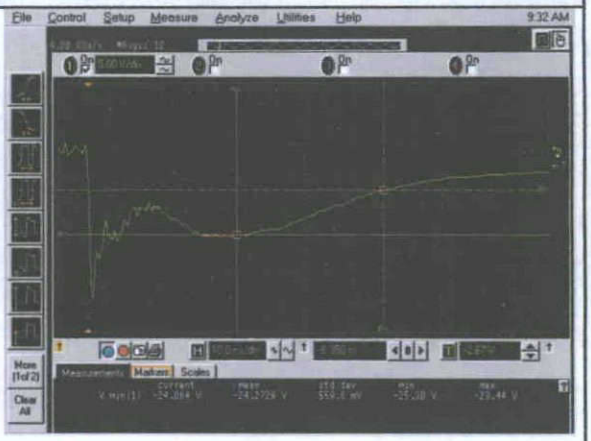
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

ESD Waveform Verification



Positive 6000V Amplitude



Negative 6000V Amplitude

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Tabulated Results for Electrostatic Discharges – Mode 1, Temp 24degC, 48%RH						
Nominal Voltage (V) .....:				battery		
Nominal Frequency (Hz).....:				DC		
Direct discharges: Air and Contact						
Discharge location	Positive			Negative		
	2kV	4kV	6kV	2kV	4kV	6kV
Box – Enclosure Screws	1	1	1	1	1	1
InTone – Electrodes	1	1	1	1	1	1
VCP – Four Sides	1	3	3	1	1	1
HCP – Four Sides	3	3	3	1	3	3
Discharge location	Positive			Negative		
	2kV	4kV	8kV	2kV	4kV	8kV
Box – Seam	1	1	1	1	1	1
Box – Speaker (Front – Back)	1	1	1	1	1	1
Box – Connector Shell	1	1	1	1	1	1
Box – Display / Buttons	1	1	1	1	1	1
InTone – Air Valve	1	1	1	1	1	1
InTone – Release Valve	1	1	1	1	1	1
InTone – Cable Conn / Hole	1	1	1	1	1	1

X – Not performed, nor required
1 – Compliant – No perceived discharge, no observed response from EUT
2 – Compliant – Discharge Observed, no observed response from EUT
3 – Complaint - At few sides of the EUT the treatment stops. Manufacturer declared during testing that it is acceptable and intended for the device it interrupt treatment when abnormal conditions are detected.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Tabulated Results for Electrostatic Discharges – Mode 2, Temp 24degC, 48%RH						
Nominal Voltage (V) .....:				120		
Nominal Frequency (Hz).....:				60		
Direct discharges: Air and Contact						
Discharge location	Positive			Negative		
	2kV	4kV	6kV	2kV	4kV	6kV
Box – Enclosure Screws	1	1	1	1	1	1
VCP – Four Sides	1	1	1	1	1	1
HCP – Four Sides	1	1	1	1	1	1
Discharge location	Positive			Negative		
	2kV	4kV	8kV	2kV	4kV	8kV
Box – Seam	1	1	1	1	1	1
Box – Speaker (Front – Back)	1	1	1	1	1	1
Box – Connector Shell	1	1	1	1	1	1
Box – Display / Buttons	1	1	1	1	1	1
Charger / PS	1	1	1	1	1	1

X – Not performed, nor required
1 – Compliant – No perceived discharge, no observed response from EUT
2 – Compliant – Discharge Observed, no observed response from EUT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8138

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Tabulated Results for Electrostatic Discharges – (usb mode 3) Temp 23degC, 35%RH						
Nominal Voltage (V) .....:				Battery		
Nominal Frequency (Hz).....:				DC		
Direct discharges: Air and Contact						
Discharge location	Positive			Negative		
	2kV	4kV	6kV	2kV	4kV	6kV
Box – Enclosure Screws	1	1	1	1	1	1
VCP – Four Sides	1	1	1	1	1	1
HCP – Four Sides	1	1	1	1	1	1
Discharge location	Positive			Negative		
	2kV	4kV	8kV	2kV	4kV	8kV
Box – Seam	1	1	1	1	1	1
Box – Speaker (Front – Back)	1	1	1	1	1	1
Box – Connector Shell	1	1	1	1	1	1
Box – Display / Buttons	1	1	1	1	1	1
Connector	1	1	1	1	1	1
Cable	1	1	1	1	1	1

X – Not performed, nor required
1 – Compliant – No perceived discharge, no observed response from EUT
2 – Compliant – Discharge Observed, no observed response from EUT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

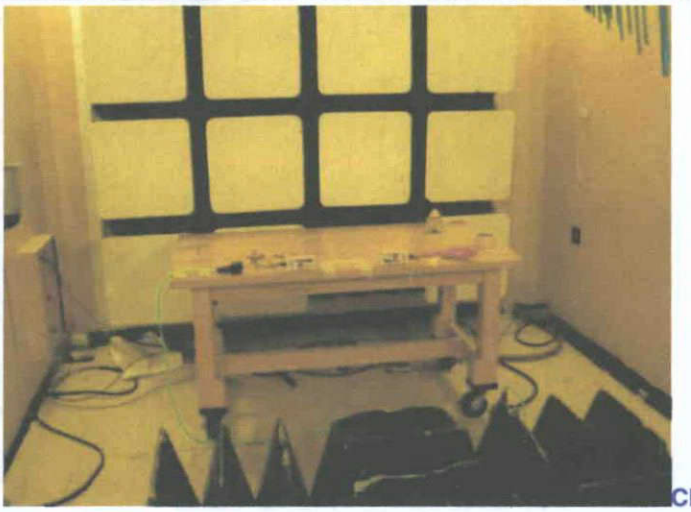
1.12 Test Conditions and Results - Immunity to Radio Frequency Electromagnetic Fields

<table>
<tr><td colspan="2">61000-4-3</td><td colspan="3">TEST: RF electromagnetic fields (IEC 61000-4-3:2010)</td><td>Verdict</td></tr>
<tr><td colspan="5">Method: The test allows estimating of the radiated immunity of electrical and electronic equipment to electromagnetic disturbances coming from intended radio-frequency (RF) transmitters in the frequency range 80 MHz to 2500 MHz. The interference is applied on the enclosure of the equipment by using transmitting antennas.</td><td>PASS</td></tr>
<tr><td colspan="2">Laboratory Parameters:</td><td colspan="2">Required prior to the test</td><td colspan="2">During the test</td></tr>
<tr><td colspan="2">Ambient Temperature</td><td colspan="2">15 to 35 °C</td><td colspan="2">23°C</td></tr>
<tr><td colspan="2">Relative Humidity</td><td colspan="2">30 to 60 %</td><td colspan="2">48%</td></tr>
<tr><td colspan="2">Equipment mode</td><td colspan="2">Power interface mode</td><td colspan="2">1,2,3</td></tr>
<tr><td colspan="2"></td><td colspan="2">EUT configurations mode</td><td colspan="2">1</td></tr>
<tr><td colspan="2"></td><td colspan="2">Operation mode</td><td colspan="2">1,2,3</td></tr>
<tr><td colspan="6">Test specifications</td></tr>
<tr><td colspan="3" rowspan="2">Calibration Requirements</td><td rowspan="2">Uniform field area (UFA)</td><td colspan="2">1.5 m x 1.5 m, 16 points with a minimum UFA size
0.5 m x 0.5 m</td></tr>
<tr><td colspan="2">75 % of calibration points within specifications if UFA is larger than 0.5 m x 0.5 m. 100 % (all 4 points) in the specifications for 0.5 x 0.5 m UFA</td></tr>
<tr><td colspan="3">Frequency bandwidth</td><td colspan="3">80 MHz to 2500 MHz</td></tr>
<tr><td rowspan="2">Level</td><td rowspan="2">Non-Life Supporting Equipment</td><td colspan="3">3 V/ m</td></tr>
<tr><td>Amplitude modulation</td><td colspan="2">80 % / 1 KHz sine wave</td></tr>
<tr><td colspan="3">Frequency step</td><td colspan="3">1% with 3s dwell time</td></tr>
<tr><td colspan="6">Supplementary information: EUT powered at one of the Nominal input voltages and frequencies.</td></tr>
</table>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

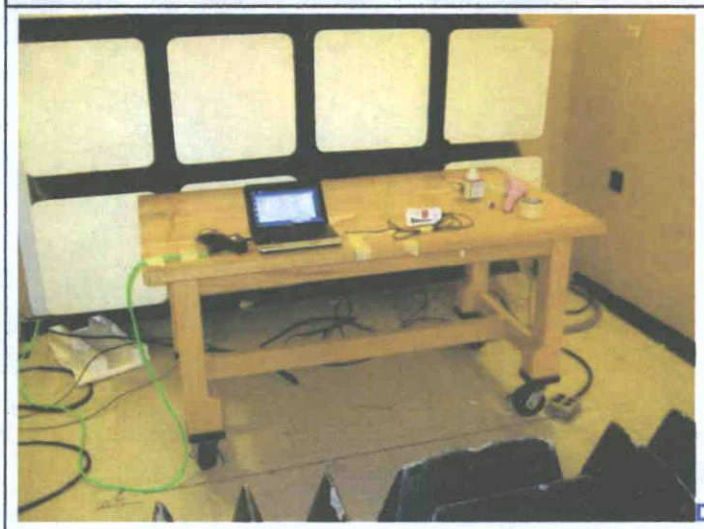
Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Photo of test setup for Radio Frequency Electromagnetic Fields



Charging Mode and Treatment Mode

Photo of test setup for Radio Frequency Electromagnetic Fields



Data Transfer Mode

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Tabulated Results for RF Electromagnetic Field 80 MHz to 2500 MHz – Mode 1 and Mode 2				
		Nominal Voltage (V) .....:	120V & Battery	
		Nominal Frequency (Hz) .....:	60Hz, DC	
Side of the equipment under test	Frequency (MHz)	Antenna polarization (V/H)	Remark	
			Treat	Charge
Front	80-1000	H	1	1
	80-1000	V	1	1
	1000-2500	H	1	1
	1000-2500	V	1	1
Back	80-1000	H	1	1
	80-1000	V	1	1
	1000-2500	H	1	1
	1000-2500	V	1	1
Left	80-1000	H	1	1
	80-1000	V	1	1
	1000-2500	H	1	1
	1000-2500	V	1	1
Right	80-1000	H	1	1
	80-1000	V	1	1
	1000-2500	H	1	1
	1000-2500	V	1	1
NOTE: None				

X – Test not conducted
1 – Compliant, no response from EUT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Tabulated Results for RF Electromagnetic Field 80 MHz to 2500 MHz			
		Nominal Voltage (V) .....:	6Vdc
		Nominal Frequency (Hz) .....:	dc-
Side of the equipment under test	Frequency (MHz)	Antenna polarization (V/H)	Remark
Front	80-1000	H	1
	80-1000	V	1
	1000-2500	H	1
	1000-2500	V	1
NOTE: Only Front of the EUT was tested for I/O Computer Mode			

X – Test not conducted
1 – Compliant, no response from EUT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.13 Test Conditions and Results – Electrical Fast Transients

61000-4-4	TEST: Fast Transients – (IEC61000-4-4:2011)	Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond all sides of the system under test. Mains power tests were conducted with the product connected to a Coupling/Decoupling Network (CDN). I/O lines were tested in a Capacitive Coupling Clamp. One of each unique interface was tested for a period of one (1) minute per polarity.		PASS

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	23°C
Relative Humidity	10 to 90 %	48%

Fully configured sample subject to the levels shown below.	Measurement Point	
	Input a.c. Power Ports Input d.c. Power Ports Signal Ports longer than 3 meters	
Equipment mode	Power Interface mode	2
	EUT configurations mode	2
	Operation mode	2

Applied Level		
Application Point	(kV)	Repetition Frequency (kHz)
Input a.c. Power Ports	±2	5
Signal Ports	±1	5

Supplementary Information: Test is performed at the minimum and maximum RATED input voltages at any nominal frequency. Manufacturer declares that the USB to Ethernet cable and the interconnecting cable will never be longer then 1m.

Description	Manufacturer	Model	Identifier
Controller / Generator	Teseq	NSG 3040	EMC4340
Variac	Teseq	VAR 3005	EMC4341

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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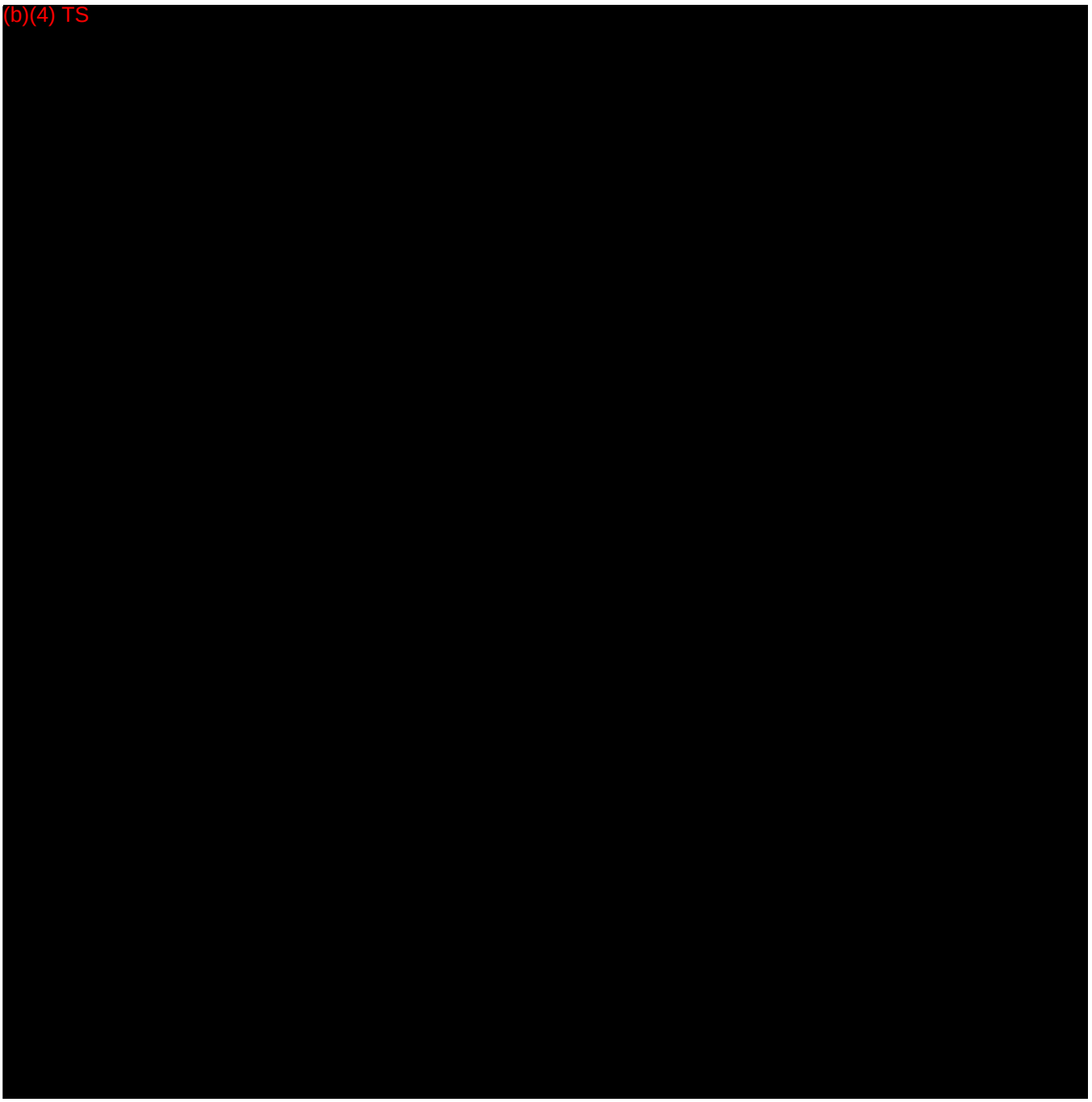
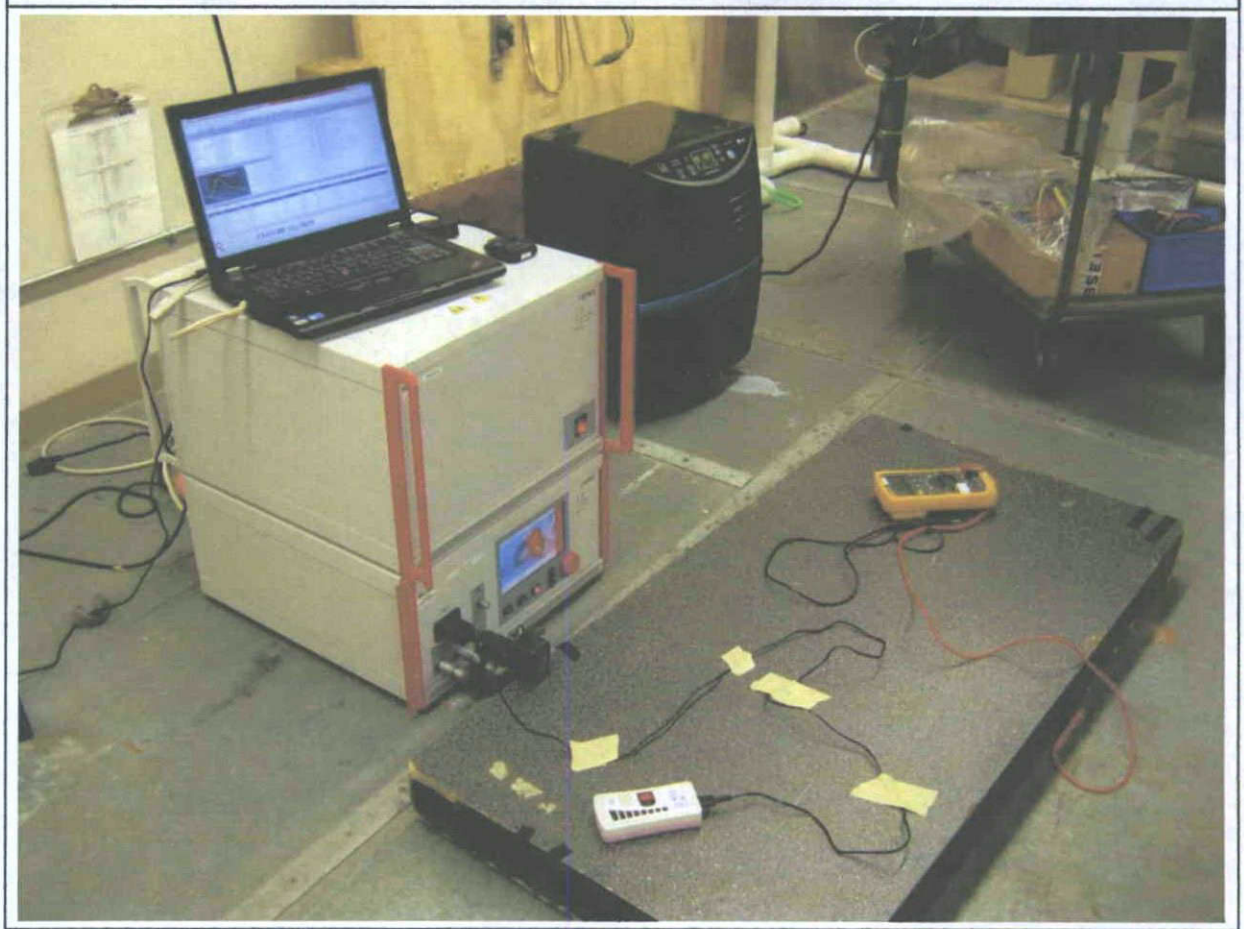


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Photo of test setup for Electrical Fast Transients


Tabulated Results – Mode 2, charging	
Minimum Rated Voltage (V).....:	120
Nominal Rated Frequency (Hz) :	60

Point of application	Comments/Results
Mains	1

X - Not performed
1 – Compliant - No observed response from EUT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.14 Test Conditions and Results – Surge Immunity

61000-4-5	TEST: Surge Immunity Test – (IEC61000-4-5:2005)	Verdict
Method: Mains power tests were conducted with the product connected to a Coupling/ Decoupling Network (CDN). The test voltage was increased from the lowest indicated level up to the maximum level. Five (5) positive surges and five (5) negative surges were applied at each of phases of the a.c. waveform: 0°, 90°, 180° and 270°. Each surge was applied 60 seconds after the previous surge. Signal and Telecommunications ports were subject to five (5) positive and five (negative) surges applied through the appropriate Coupling/Decoupling Network (CDN).		Pass

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	23°C
Relative Humidity	10 to 90 %	48%
Fully configured sample subject to the levels shown below.	Measurement Point	
	Input a.c. Power Ports Input d.c. Power Ports	
Equipment mode	Power interface mode	2
	EUT configurations mode	2
	Operation mode	2

Applied Level		
Application Point	[kV]	Required Surge Waveform
Input Power Ports	0.5 and 1.0 (Line to Line)	Combination Wave (2μs x 50μs Voltage, 8μs x 20μs Current)

ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at _ 2 kV line(s) to earth and _ 1 kV line(s) to line(s).

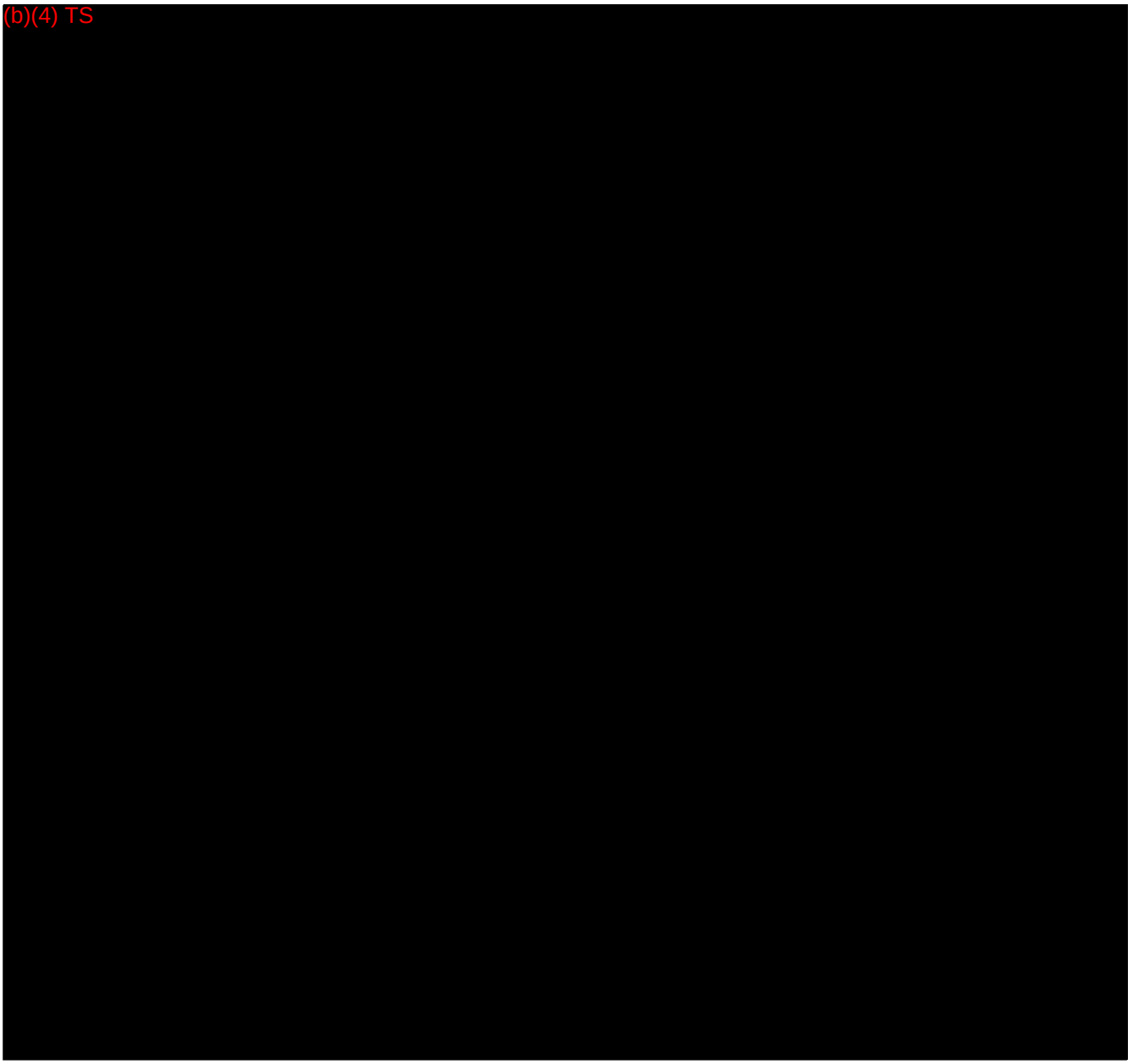
Supplementary information: Test is performed at the minimum and maximum RATED input voltages and at any nominal frequency.

Description	Manufacturer	Model	Identifier
Controller / Generator	Teseq	NSG 3040	EMC4340
Variac	Teseq	VAR 3005	EMC4341

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

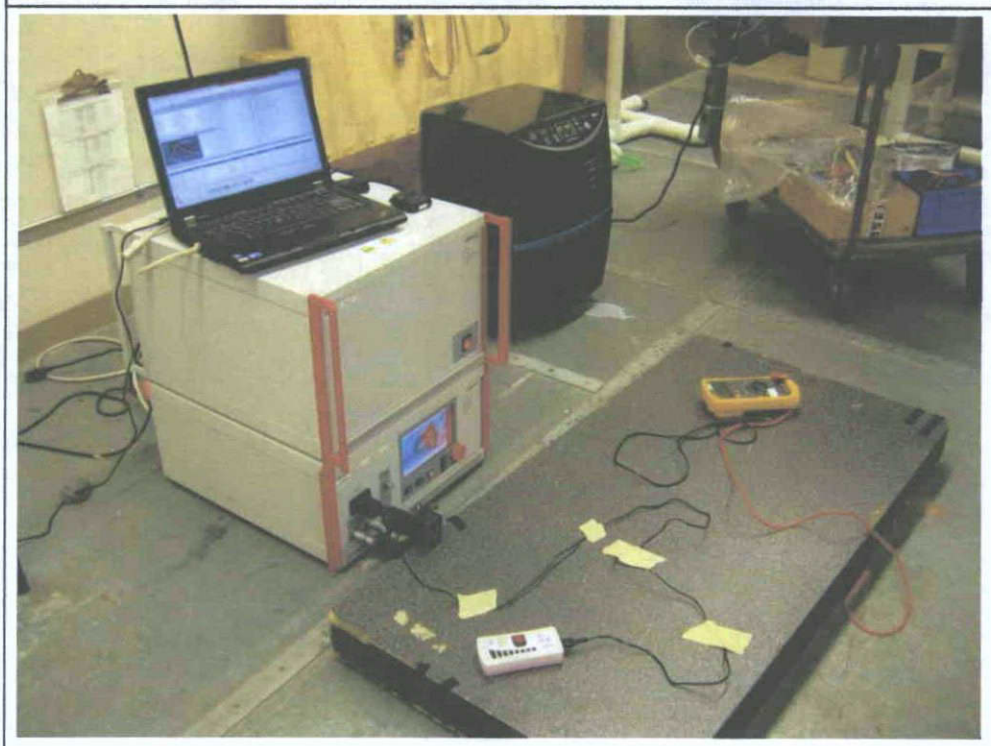
(b)(4) TS



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Photo of test setup for Surge Immunity



Tabulated Results for Surges for Minimum Input Voltage			
Minimum Rated Voltage (V)			120
Nominal Rated Frequency (Hz)			60
Mode of Application – Mains	Level	Polarity	Comments/Results
Line 1 to Line 2 (Differential mode)	0.5kV	Positive	1
		Negative	1
	1.0kV	Positive	1
		Negative	1

X – Not performed

1 – Compliant – No observed response from EUT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.15 Test Conditions and Results – Conducted Disturbances Immunity

61000-4-6	TEST: RF Continuous Conducted – (IEC61000-4-6: 2003 + A1:2004 + A2:2006)	Verdict
Method: Measurements were made on a ground plane that extends 0.5-meter minimum beyond all sides of the system under test. The EUT was located 10cm above the reference ground plane and any associated I/O cables attached to the EUT were located between 30mm and 50mm above the ground plane. The indicated field was pre-calibrated prior to placement of the system under test.		PASS

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	22°C
Relative Humidity	10 to 90 %	36%

Equipment mode		
Power interface mode		1,2,3
EUT configurations mode		2
Operation mode		1,2,3

Test Specifications:	Frequency range	Measurement Point
Fully configured sample scanned over the following frequency range	150kHz to 80MHz	Input a.c. Power Ports Input d.c. Power Ports Signal Ports

Level	Non Life Supporting Equipment		
		3 V rms	
		Amplitude modulation	80 % / 1 kHz sine min 1 sec dwell
Frequency step size		1%	

Supplementary Information: EUT powered at one of the Nominal input voltages and frequencies.

Description	Manufacturer	Model	Identifier
Signal Generator	Rohde & Schwarz	SML 03	EMC4284
RF Amplifier 10kHz - 220MHz	IFI	M406D	EMC4275
CDN	FCC	FCC-801-M2-50A	EMC4081
Clamp	ARA	ICP-1230	EMC4252
Spectrum Analyzer	Advantest	R3261C	EMC4089
Power Meter	HP	438A	EMC4285
Power Sensor	HP	8482A	EMC4262
Current Clamp	FCC	F-65A	EMC4198

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-5118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Photo of test setup for Conducted Disturbances
Charging Mode
Treatment Mode
Photo for Data transfer mode is not available. The BCI clamp was placed on the cable near the control box for the EUT.

Tabulated Results for Conducted Disturbances		
	Nominal Rated Voltage (V).....	Battery / 120 / Battery
	Nominal Rated Frequency (Hz)	DC / 60 / DC
Point of Application	Comments/Results	
Mode 1 – Cable between control box and device – BCI Clamp	2	
Mode 2 – AC Input – CDN	1	
Mode 3 – cable between control box and computer – BCI Clamp	3	

X – Not performed
1 – Compliant – No observed/perceived response from EUT.
2 – Compliant – some distortion present on the scope during test (the test was influencing the scope), however the level of the voltage peaks remained unchanged. After the test was done the wave form on the scope returned to normal.
3 – Compliant, around 44Mhz the communication gets interrupted. It restores after the range of frequencies is passed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1.16 Test Conditions and Results – Voltage Dips, Interruptions, and Variations

61000-4-11	TEST: Voltage Dips and Interruptions – (IEC61000-4-11)	Verdict
Method: The product was subjected to voltage dips and interruptions. Testing was performed with the product connected directly to a generator capable of simulating the voltage drops and interrupts as described.		PASS

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	23°C
Relative Humidity	10 to 90 %	48%

Fully configured subjected to the levels indicated below.	Measurement Point	
	Input A.C. Power Ports	
Equipment mode	Power interface mode	2
	EUT configurations mode	2
	Operation mode	2

Applied Levels		
Voltage Dips % U_T	Period (Cycles)	Sync Angle [degrees]
30	25	0
60	5	0
>95	0.5	0
Voltage Interruption % U_T	Seconds	Sync Angle [degrees]
>95	5	0

0 degrees is the crossover point of the voltage waveform.

Test is performed at the minimum and maximum RATED input voltages and at the minimum rated frequency.

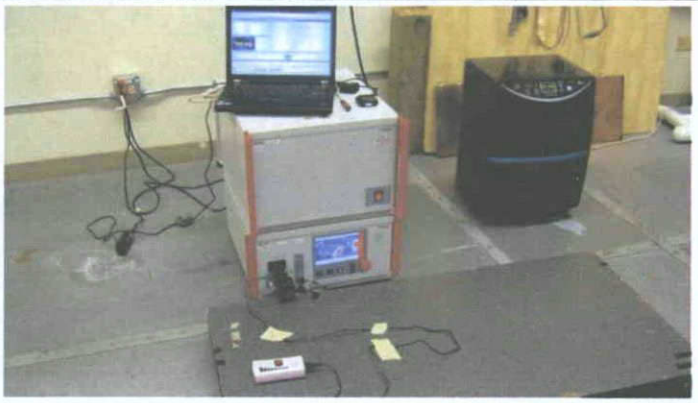
Supplementary information: None

Description	Manufacturer	Model	Identifier
Controller / Generator	Teseq	NSG 3040	EMC4340
Variac	Teseq	VAR 3005	EMC4341

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Photo of test setup for Voltage Dips, Interruptions, and Variations



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) TS

Power Interface Mode #	EUT Configurations Mode #	EUT Operation Mode #
1	1	1
Supplementary information: None		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Tabulated Results for Voltage Dips and Interruptions			
		Minimum Rated Voltage (V)	120
		Maximum Rated Frequency (Hz)	60
Point of application	Voltage reduction	Period (Cycles)	Comments/Results
Mains	30	25	1
Mains	60	5	1
Mains	>95	0.5	1
Point of application	Voltage reduction	Seconds	Comments/Results
Mains	>95	5	1
Supplementary Information: None			

X - Not performed
1 – Compliant - No observed/perceived response from EUT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1.17 Test Conditions and Results – Power- Frequency Magnetic Fields

61000-4-8	TEST: Power-frequency magnetic field – (IEC61000-4-8: - use latest edition)	Verdict
Method: Measurements were made on a ground plane that extends 1-meter minimum beyond sides of the system under test. Tabletop EUT is located 80cm above the reference ground plane and floor-standing EUT is located 10cm above the reference ground plane. The indicated field was pre-calibrated prior to placement of the EUT under test.		PASS

Laboratory Parameters:	Required prior to the test	During the test
Ambient Temperature	10 to 40 °C	°C
Relative Humidity	10 to 90 %	%
Equipment mode	Power interface mode	1,2,3
	EUT configurations mode	2
	Operation mode	1,2,3
Fully configured sample tested at the power line frequency (See Note 1)	Frequency	Application Point
	50Hz and 60 Hz [1]	Enclosure

Frequency (Hz)	Test Level (A/m)
50	3
60	3

Tested at 50Hz and 60Hz powered at any one of its NOMINAL RATED input voltages.

Supplementary information: Note 1: The test is performed at both 50 Hz and 60 Hz, with the exception that me equipment rated for use only at one of these frequencies need only be tested at that frequency.

Description	Manufacturer	Model	Identifier
Ammeter	Fluke	336	EMC4291
Loop	UL	UL-LOOP	EMC4277

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Photo of test setup for Power- Frequency Magnetic Fields

Treatment Mode

Charging Mode

Data Transfer Mode

Tabulated Results for Power Frequency Magnetic Field		
Nominal Rated Voltage (V)	120	
Point of application	Results for all three modes	
	50 Hz	60 Hz
X-Axis	1	1
Y-Axis	1	1
Z-Axis	1	1
Supplementary information: Results for all three operating modes.		

X - Not performed or not required.
1 – Compliant - No observed response from EUT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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INCONTROL

InTone™ User Manual

PN: xxxxxx-C | **Draft Date: 7/28/11**

Users must read this Guide before using the Product

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Preface

Overview

The In Control InTone™ device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

This guide provides procedures for setting up and using the InControl InTone™ incontinence device.

Intended Use

The InControl InTone™ device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Intended Audience

The InTone™ User Manual is intended for users of the system, including care providers and patients. The product is intended to be used under the direction of the care provider.

Contact Information

For more information about InControl products, go to www.incontrolmedical.com. For technical support, questions or comments about documentation, contact (800) xxx-xxxx or (262) xxx-xxxx.

Product Warranty

Product Warranty information can be found with your original system proposal and invoice.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Symbols Used

The following symbols are used in this manual or on the product.

Attention! Please follow the instructions in the User Manual.

Type BF applied part. Internally powered.

The Control Unit can be damaged by ElectroStatic Discharge. The pins of the Control Unit connectors should not be touched unless ESD precautions are taken.

Warnings and Notes

Warnings and Notes are used in this manual. A Warning is used when failure to follow the instructions may result in injury or device damage. Notes are used to provide clarification or advice. The following Warnings are used in this manual.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Warning: Electro-Stimulation is one part of a total therapy program. It is meant to be used in conjunction with counseling and feedback. Do no undertake therapy without the advice of a care provider.

Warning: Do Not use a charger other than supplied by InControl Medical LLC. The incorrect charger can result in damage to the unit.

Warning: Remove battery pack if the equipment is not to be used for an extended period of time.

Warning: Read all instructions prior to use. Failure to follow these directions may result in personal injury or damage to the equipment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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⚠ **Warning:** Only use approved antiseptics that leave no residue.

⚠ **Warning:** The InControl system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

⚠ **Warning:** Therapy is defined on an individual basis, dependent on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

⚠ **Warning:** Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

⚠ **Warning:** Do not operate device within 10 feet of operating televisions, arc welders, radio thermal treatment equipment, X-ray machines, MRI machines, or any other equipment that produces magnetic fields, sparks, or radio transmissions. RF communications equipment can affect this device

⚠ **Warning:** The reusable Insertion Unit presents a potential risk of cross-infection, particularly if used on broken skin.

⚠ **Warning:** Explosion hazard: Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen enriched environments.

⚠ **Warning:** Take care in arranging patient and cables to avoid risk of entanglement, tripping, or strangulation.

⚠ **Warning:** Use of any equipment should be discontinued upon any signs of treatment related stress or discomfort.

⚠ **Warning:** The device should not be used while walking, driving, operating machinery, or any other activity in which involuntary muscle contraction may put the user at risk.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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⚠ **Warning:** Do not use the device while in the bath, swimming, or otherwise submerged.

⚠ **Warning:** The long-term effects of chronic electrical stimulation are unknown.

⚠ **Caution:** Caution should be used for patients with suspected or diagnosed heart problems.

⚠ **Caution:** Caution should be used for patients with suspected or diagnosed epilepsy.

⚠ **Caution:** Caution should be used when there is a tendency to hemorrhage following acute trauma or fracture.

⚠ **Caution:** Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

⚠ **Caution:** Patients with a total/partial prolapse of the uterus/vagina must be stimulated with extreme caution.

⚠ **Caution:** Patients with urethritis must be treated before commencing stimulation.

⚠ **Caution:** Worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they are applied.

⚠ **Caution:** Adverse reactions have been reported. Skin irritations and burns beneath the electrodes have been reported with the use of powered stimulators.

Contraindications

- This device is not intended for diagnostic purposes or critical patient monitoring.
- The device is not defibrillator proof.
- The device should not be used on patients with cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance.
- Do not use if patient has symptoms of an active urinary tract infection.
- Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

- Do not use if patient has undiagnosed pain.
- Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation.
- Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings.
- Do not use if patient is currently pregnant or attempting to get pregnant.
- Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit.
- Do not use if the patient has irregular menstrual bleeding cycles.
- Do not use if the patient has a history or symptoms of urinary retention.
- Do not use if the patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra).
- Do not use if the patient has overflow incontinence caused by evacuation problems.
- Do not use if the patient has severe urine retention in the upper urethras.
- Do not use if the patient has complete peripheral denervation of the pelvic floor.
- Do not use if the patient has an intestinal clamp.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Chapter 1

Equipment Overview

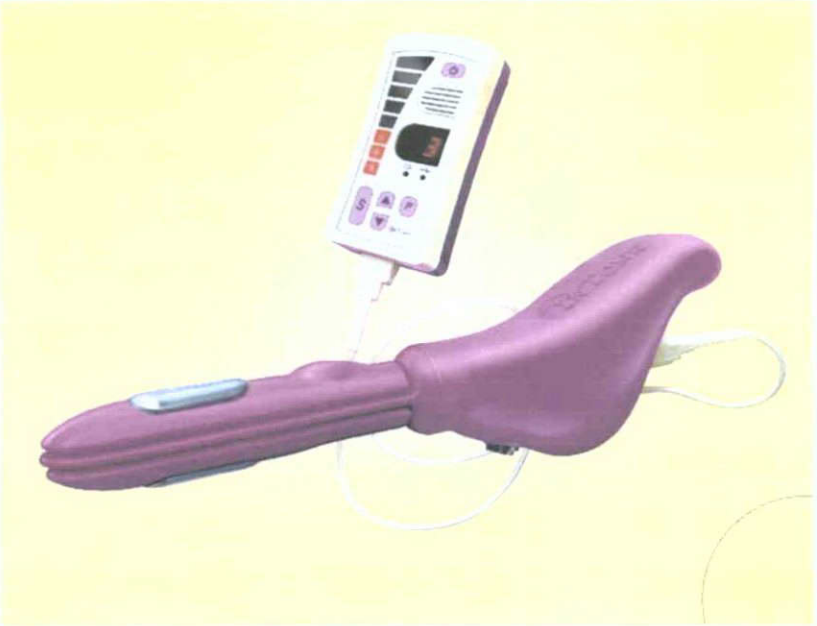
This chapter provides an overview of the equipment included in the InControl InTone System.

Control Unit

The Control Unit is a display device used to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. An external PC monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

The Control Unit has the following features and functions.

- select and lock in the correct amount of current necessary to stimulate pelvic floor contraction
- provide biofeedback program to measure and record pressure generated by patient pelvic floor exercises
- display contraction force (as pressure)
- allow downloading of data to personal computer through custom USB cable and allow graphing in commercially available software (e.g. Excel)
- provide verbal exercise session coaching
- provide single button stop to discontinue electrical pulses if necessary
- ability to clean with common, commercially available cleaners



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Insertion Unit

The Insertion Unit is an inflatable balloon for intra-vaginal use. The unit has a semi-rigid core to allow insertion. The core also carries inflation air and electrical conductors. The core is surrounded by an inflatable balloon that carries the electrodes. The insertion unit connects to the control unit through a flexible connection.

The Insertion Unit has the following features and functions.

- for self or clinician insertion in the patient's vagina,
- provide manual inflation of balloon to fill the vagina to a comfortable level,
- when inflated, provide full contact of electrodes to vaginal wall,
- provide programmed electro-stimulation of pelvic floor muscles,
- ability to clean with common, commercially available cleaners.

PC Cable

The PC Cable allows the Control Unit to be connected to the USB port of a personal computer. This connection allows the transfer of data to the PC. The unit cannot be used while it is being connected.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Chapter 2

Setting up the Components

This chapter provides procedures on how to set up the InTone units for use.

The components in the InTone system is provided as a kits, consisting of assembled units and parts. These kits should be kept together until you are ready to use them.

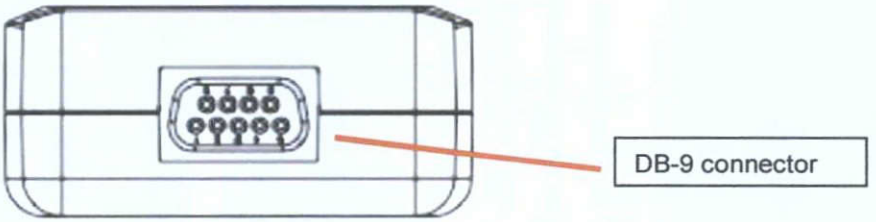
⚠ **Warning:** Read all instructions prior to use. Failure to follow these directions may result in personal injury or damage to the equipment.

⚠ **Caution:** Federal law restricts this device to sale by or on the order of a physician.

⚠ **Warning:** Electro-Stimulation is one part of a total therapy program. It is meant to be used in conjunction with counseling and feedback. Do not undertake therapy without the advice of a care provider.

Connecting the Insertion Unit to the Control Unit

1. Align the connectors of the Insertion and Control Units. The DB-9 connector is on the bottom of the control unit.



Gently press the connector into place.

Disconnecting the Insertion Unit from the Control Unit

1. Gently pull the DB-9 connectors apart.

ⓘ **Tip:** Do not touch the conductors in the connector. This could cause damage to the pins or control unit.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Charging the Battery

The battery should be charged when the low battery indicator is shown, or if charging will not be available for a time.

1. Disconnect the Insertion Unit.
2. Connect the wall charger to the Control Unit.
3. When charging is complete, unplug the cable from the Control Unit.

Tip: Ensure battery is charged prior to use. Control unit cannot be used when the USB cable is connected.

Warning: Do Not attempt to use a charger other than supplied by InControl Medical LLC. The incorrect charger can result in damage to the unit.

Cleaning the Insertion Unit

Following use, the Insertion Unit should be cleaned.

1. Turn **off** the Control Unit.
2. Disconnect the Insertion Unit from the Control Unit.
3. Wash the outside of the Insertion Unit with warm soapy water. Do not soak.
4. Rinse thoroughly.

Tip: Do not attempt to fill the Insertion Unit with water or any other liquid. If water enters the Unit, thoroughly dry prior to re-use.

5. The outside of the Insertion Unit may be wiped with alcohol or other antiseptic in accordance with the care provider's infection control procedures.

Warning: Only use approved antiseptics that leave no residue. Do NOT soak.

6. Allow Unit to air dry.
7. The control unit can be wiped with antispectic or a damp cloth. Do not immerse or spray.

Approved Antiseptics

The following cleaners can be used with the InTone Insertion Unit. This list is based on material compatibility.

- isopropyl alcohol
- hydrogen peroxide, <10%
- sodium hypochlorite, <10%

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Chapter 3

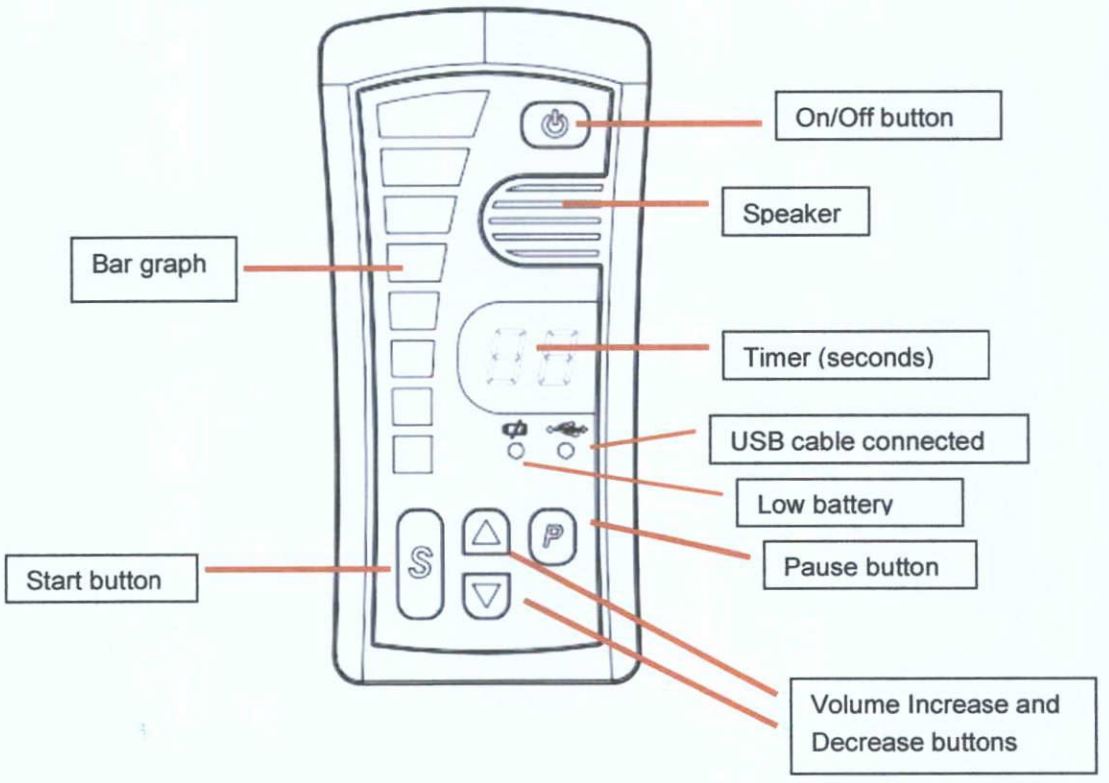
Programming the System

Introduction

This chapter provides procedures on how to program the InControl Control Unit. The system must be programmed before it is used by patients. It is programmed for one patient at a time.

Programming - Clinician Only

The front panel of the Control Unit provides information on the status of the system and its operation.



466

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1. Connect USB cable to Control Unit and clinician PC.
2. Turn control unit power **on**.

Changing Settings

3. The current settings will be displayed on the PC.
4. The up arrow key (⇑) or down arrow (⇓) increases or decreases the intensity.
5. Adjust the setting as desired for the intended patient.
6. Press **save**. The display will return to the main menu. The unit is ready to use for therapy.

Clearing Programs

Settings can be reverted to factory default settings to provide a consistent starting point for programming. All default settings are the lowest in their range.

1. Connect USB cable to Control Unit and clinician PC.
2. Turn Control Unit **on**.
3. Select **clear therapy programs** from the menu.
4. The device will display a question asking you to confirm that you want to erase programmed therapy settings and revert to factory default settings. Press **yes** if you wish to revert all settings to factory default. Press **no** if you do not.
5. The display will return to the main menu.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Chapter 4

Using the System

This chapter provides instructions for using the system. It includes both therapeutic treatment and biofeedback use instructions.

⚠ **Warning:** The InTone system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

Electro-stimulation and biofeedback are treatments used to train and strengthen the pelvic floor muscles in a controlled manner. Electro-stimulation is used to strengthen muscles. In particular, it improves the ability of muscles to hold a contraction of an extended period of time. It is a treatment for urinary incontinence in conjunction with coaching and biofeedback. During a session, electrical impulses are delivered to specific muscles to stimulate their contraction. This contraction exercises the muscles and also helps the patient recognize which muscles to condition.

Biofeedback provides audible and visual confirmation of the patient's voluntary muscle contractions.

⚠ **Warning:** Therapy is defined on an individual basis, dependant on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

Patient Use

A quiet, private place is recommended to aid relaxation. Many women prefer to do their sessions while in bed.

1. The patient lies in a semi-reclined position with knees slightly bent. The legs should be upright and tilted out slightly.
2. Press **Power** to initiate session and follow prompts.
3. Apply a small amount of water-based lubricant to the inflatable portion of the device.
4. Apply a moderate amount of InTone electrode gel to the steel electrodes.
5. Gently insert the Insertion Unit into your vagina. Ensure the stimulation pads are fully within the vagina.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

6. After insertion, press the inflation bulb and inflate the device until the number 3 appears on the Control Unit. (If inflated incorrectly, InTone will prompt the user to deflate the unit and re-inflate until the number 3 is displayed.)

Tip: Treatment can be stopped at any time by pressing the **P** (pause) button. The interrupted sessions data can be restarted by pressing the pause key again. If the session is not restarted within five minutes, the device will turn off.

7. Follow the audio prompts. The bar graph reflects contraction force. The display reflects the timing of contractions relative to the voice commands.

Retrieving Treatment Data - Clinician Only

The Clinician may review treatment data by connecting the control unit to his/her PC using the USB cable. Treatment data is automatically displayed in an Excel spreadsheet for each day treatment is completed. The file may be saved as with other Excel files.

Erasing Saved Data

The front panel of the Control Unit provides information on the status of the system and its operation.

1. The Clinician connects the control unit to his/her PC.
2. Select "Erase Saved Data" and press enter.
3. The device will display a question asking you to confirm that you want to erase saved data. Press **yes** if you wish to erase all data. Press **no** if you do not.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Chapter 5

Testing and Servicing the System

This chapter provides procedures to test the InTone system prior to use. It is important to test the overall functionality of each component prior to putting the system into service. Additionally, it is important to periodically verify the continuing proper operation of each component.

Tip: You should test all of the system components prior to use to verify proper operation.

Warning: Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

1. Visually inspect the Insertion Unit, Control Unit, and connectors for damage.
2. Connect the Insertion Unit to the Control Unit.
3. Turn on the Control Unit.
4. An error will be displayed if the connection is not complete.

Replacing a Control Unit Battery

The Control Unit battery pack can be replaced. Use only battery packs supplied by InTone. Properly maintaining the batteries' charge will extend life.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Chapter 6

Troubleshooting the System

This chapter provides procedures on how to service and troubleshoot the InTone System. If you have consistent issues with the system, please contact InControl Technical Support at 1-800-xxx-xxxx.

Troubleshooting the Insertion and Control Unit

Prior to use or any troubleshooting,

1. Verify that the Control Unit battery is charged. If the low battery indicator is shown, recharge the battery.
2. Inspect the Insertion Unit for damage. If the silicone covering or any cables appear damaged, the Unit must be replaced.
3. Disconnect the Insertion Unit from the Control Unit. Inspect the connectors for damage. If the pins are not straight, or otherwise appear damaged, the Unit must be replaced.
4. Carefully reconnect the Insertion Unit to the Control Unit.
5. If the assembled Units still do not function correctly, contact InControl Technical Support.

Patient cannot feel pelvic contractions

1. Check that InTone control unit is on and the batteries are charged.
2. Have patient manually reposition the insertion unit with her fingertip until pelvic contractions are perceivable
3. Have patient use electrode gel prior to insertion.

Patient complains of painful insertion of the unit

1. Have patient use a water-based lubricant prior to insertion.
2. Check patient for vaginal irritation or infection.
3. Ensure the unit is partially inflated.

Patient complains of pain in rectum with pelvic contractions

1. Tell patient not to insert the unit as deep into the vagina.
2. Instruct patient not to dangle her legs or feet during a session: lie in a reclined position with both feet evenly placed in front of her.

Patient stops feeling contractions during a session

1. Have patient manually reposition the unit until pelvic contractions are perceivable again.
2. Instruct patient not to stand or move about during a session.
3. Check that device is on and the batteries are charged.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Chapter 7

Specifications

This chapter provides specifications for the InControl InTone system components. The InTone system is a class II medical device with internal power. It must only be used indoors.

Control Unit

Size:	4.83" x 2.4" x 1.1"
Weight:	5 oz
Enclosure:	ABS
Battery:	Battery pack size – 1.75" x 1.145" x 0.57" Battery capacity – 1200mAh Battery voltage – 2.4V Charge current – 0.235A Discharge current – (b)(4) Charging time – 5 hours, charge complete will be displayed typically 6 to 8 hours use between charges, user determines
Low Battery:	shown on display approximately 15 minutes before unit shuts down
PC interface:	USB, 1.1 and 2.0 compatible
Waveform:	low-frequency, dual-phase, direct current, rectangular pulses

Program for Mixed Incontinence Treatments:

Treatment Duration:	(b)(4) TS [redacted]
Frequency:	
Pulse Width:	
On Time:	
Off Time:	
Maximum Intensity:	

Biofeedback:	(b)(4) TS [redacted]
Air Pressure:	
Response Time:	

Insertion Unit

Single Patient Use

Size:	5 inches long 1.25 inch diameter, uninflated up to 2.5 inches diameter, inflated
Method of Inflation:	Hand pump bulb, with release knob
Outer Material:	silicone
Electrode Size:	two stainless steel, rigid, semi-tubular, each approximately 2" x 0.75"
Shelf Life:	one year

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Computer Connection

via USB 2.0, Type A plug

AC Charger

Input Voltage:	120 VAC
Input Frequency:	60Hz
Input Current Draw:	up to 300 mA
Output:	6 VDC

Environmental Conditions

Operating Conditions:

Temperature:	10 to 40C
Relative Humidity:	10% - 90%, non-condensing

Storage and Transportation Conditions:

Temperature:	10 to 40C
Relative Humidity:	10% to 90%, non-condensing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

InControl Medical, LLC
% Mr. Michael J. Leigh
Consultant
12715 Falcon Drive
BROOKFIELD WI 53005

FEB 2 2 2012

Re: K110179
Trade/Device Name: InControl InTone
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: January 24, 2011
Received: January 31, 2012

Dear Mr. Leigh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Indications for Use

510(k) Number (if known): K110179

Device Name: InControl InTone

Indications For Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110179

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b) (6)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 31, 2012

INCONTROL MEDICAL, LLC
12715 FALCON DRIVE
BROOKFIELD, WISCONSIN 53005
ATTN: MICHAEL LEIGH

510k Number: K110179

Product: INCONTROL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 07, 2011

INCONTROL MEDICAL, LLC
12715 FALCON DRIVE
BROOKFIELD, WISCONSIN 53005
ATTN: MICHAEL LEIGH

510k Number: K110179
Product: INCONTROL

Extended Until: 03/05/2012

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
DEC - 7 2011
Received

Re: K110179

November 28, 2011

Dear Ms. Morris

This letter is in response to your letter stamped "Oct 04, 2011" and received November 7. The letter references your receipt of "October 7, 2011."

We would like to request an 90 day extension to provide the requested documentation. All items will be addressed in the subsequent response.

If you have any questions regarding the additional information provided in this submittal, please don't hesitate to contact me. Thank you for your time and consideration.

Sincerely,

Michael J. Leigh
consultant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

InControl Medical, LLC
c/o Michael J. Leigh
12715 Falcon Drive
Brookfield, WI 53005

OCT 0 4 2011

Re: K110179
Trade Name: InControl InTone
Dated: September 14, 2011
Received: October 7, 2011

Dear Mr. Leigh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because you did not completely respond to the deficiencies listed in our February 25, 2011 letter. To complete the review of your submission, we require the following information:

1. You provided a device description. However, some information remains unclear. In order for the Agency to complete its review, please indicate whether the external monitor and hand pump bulb are included with the device.

2. You provided software documentation in Appendix C and via email. However, some requirement elements necessary for software with a moderate level of concern are not complete. In order to complete the review of your device, please provide the following:

    a. a complete traceability analysis which links requirements, specifications, identified hazards and mitigation, and verification and validation testing;

    b. a more detailed verification testing report. This report should document how specified requirements have been fulfilled;

    c. a revision history log that provides release version numbers and dates; and

    d. a list of unresolved software anomalies, bugs, or defects that remain with an explanation of its impact on the usage of your device.

3. You reduced your stimulation settings to be for mixed urinary incontinence and provided most output characteristics for your device. However, there are several characteristics that were not provided. In order to accurately describe your device,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

please provide the maximum power density, net charge, and indicate whether there is a burst mode and if so, the output characteristics of burst mode.

4. You provided EMC testing, however some of the testing was incomplete. In order to ensure the safety of your device, please provide the following testing:

    a. emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker missions testing in stimulation and data transfer mode. These tests were performed only with the device in charging mode;

    b. radiation emission testing on your device in stimulation mode at 100% stimulation or provide an adequate justification for the lower stimulation output. Your testing was performed in stimulation mode at 20% and 80% stimulation output; and

    c. repeated immunity to electrostatic discharges testing or an adequate justification for the behavior of your device during testing. During testing in stimulation mode, treatment stops on a few sides of the device. The report stated that it is intended for the device to interrupt treatment when abnormal conditions are detected. However, treatment does not stop at all areas of the device.

5. You provided biocompatibility information and the processing description for the raw materials used in your device. It is inadequate to determine the biocompatibility of your device only based on the provided description of processing for the raw materials used in your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility evaluation for cytotoxicity, irritation, and sensitization per ISO 10993-1:2009 and the FDA blue book memo #G95-1. In lieu of biocompatibility testing of the final device, biocompatibility evaluation may be acceptable based on proper chemical analysis of leachables from your final device and adequate toxicity risk assessment with existing toxicity data of each chemical identified from the chemical analysis using principles outlined in ISO 10993-17:2002. Therefore, to determine the biocompatibility of your device, please provide biocompatibility testing on the final insertion unit or assessment of the insertion unit as suggested above.

6. You provided a user manual in your submission. However, there is a mistake and several omissions in the manual. To adequately inform users, please revise the following:
    a. an explanation for the connection of the hand pump bulb to the insertion unit for proper inflation;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

b. the pulse width to be the correct value, (b) (4) On page 20 of 22, you stated the pulse width of your device is (b) (4) and

c. EMC tables to your user manual. You stated conformance with EMC testing required by ISO 60601-1-2. However, you did not include the EMC tables required by ISO 60601-1-2. (Annex C of ISO 60601-1-2 provides examples of properly completed tables.)

7. You provided a 510(k) Summary in your submission. However, there are several mistakes in your output characteristics. In order to accurately describe your device, please revise the frequency and pulse width in the 510(k) Summary.

8. You provided a label for the control unit. However you did not provide labeling for the insertion unit. Also, symbols on your label were not accompanied by a description on the product label. In order for the Agency to complete its review, please provide sample labeling for the insertion unit and revise the control unit label to describe the symbols used. You may find additional guidance for labeling using the following:

   a. ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm

   b. Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Ms. Dulciana D. Chan at (301) 796-2592. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Chief, Urology and Lithotripsy
Devices Branch
Division of Reproductive, Gastro-Renal,
and Urology Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K110179/S001

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
DRGUD/ULDB	Dulciania				
ULDB	Morris	11/4			

Drafted: DChan 11/3/11
Final: DChan:moa:11.04.11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 20, 2011

INCONTROL MEDICAL, LLC
12715 FALCON DRIVE
BROOKFIELD, WISCONSIN 53005
ATTN: MICHAEL LEIGH

510k Number: K110179

Product: INCONTROL

Extended Until: 08/24/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

475

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K110179

JUN 20 2011

June 8, 2011

Dear Ms. Chan,

This letter is a request for extension of the hold currently on premarket submittal K110179. The 510(k) was placed on hold in mid-April for 60 days. I would like to extend the hold another 90 days. Other factors have delayed my client, InControl Medical. A complete response will be available within the total 180 day time limit.

If you have any questions, please don't hesitate to contact me. Thank you for your time and consideration.

Sincerely,

Michael J. Leigh
consultant

K-47

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 12, 2011

INCONTROL MEDICAL, LLC
12715 FALCON DRIVE
BROOKFIELD, WISCONSIN 53005
ATTN: MICHAEL LEIGH

510k Number: K110179
Product: INCONTROL

Extended Until: 06/23/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

InControl Medical, LLC
c/o Mr. Michael J. Leigh
Consultant
12715 Falcon Drive
BROOKFIELD WI 53005

FEB 25 2011

Re: K110179
Trade Name: InControl
Dated: January 17, 2011
Received: January 21, 2011

Dear Mr. Leigh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following additional information:

1. We are not aware of a legally marketed predicate device indicated for the improvement of urethral sphincter closure. Please remove this or provide scientific evidence of improvement of urethral sphincter closure.

2. You provide a device description, however some key elements are missing. The configuration of your electrodes is not provided and the biofeedback feature of your device is not explained. Please clarify the description of your device to include, the following for all components of your device:

   a. Device specifications;

   b. any new features of the device;

   c. identification of the relevant dimensions and weight of the device and accessories;

   d. a description of all user controls, displays, and functions;

   e. a description of how the device interconnects with other components;

   f. engineering drawings and/or photographs of the device; and,

   g. length, construction, material, and connections between the stimulator device and the electrodes.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

3. You provide output characteristics of your device. However, it is unclear whether there are separate parameters for the treatment of stress, urge, and mixed urinary incontinence and the biofeedback setting. Please clarify the parameters for all three possible stimulation settings and the biofeedback setting including but not limited to time, maximum phase charge, maximum power density, and net charge. For example, you did not provide the frequency and pulse width for the mixed urinary incontinency setting.

4. You state that your device will use a Li ion battery. However you did not provide enough information about the battery. Please provide the size, capacity, voltage, charge and discharge currents, and estimate how long it will take to recharge the battery and the frequency of charging intervals.

5. On page 7 of 25 in your user manual, you state that the insertion unit is reusable. In order to ensure the safety of your device, please indicate which components of your device are reusable, whether the components are reusable for a single patient only, and if they can be reusable for multiple patients.

6. You state that the outer material of the insertion unit is silicone and that the control unit is made with plastics. However, you do not provide complete information about the materials used in the components of your device (insertion unit, electrodes, control unit). Please provide the following material information for your device:

   a. A table identifying all of the generic materials by chemical name, supplier trade name, supplier name, and device component location;

   b. polymer component formulations (to include generic chemical component names and amounts specified as weight or volume percentages); and,

   c. sufficient processing information to include any processing materials (and amounts) that could impact on biocompatibility.

7. You state that there are no biocompatibility issues for your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility testing. In order to ensure the safety of your device, please provide complete cytotoxicity, sensitization, and irritation or intracutaneous reactivity testing on your final device.

8. You did not provide any electrical testing. In order to ensure the safety and efficacy of your device, please provide electrical testing preferably in accordance with an FDA recognized standard such as IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-1:2000 Medical electrical equipment Part 1-1: General requirements for safety - Safety requirements for medical electrical systems or provide an adequate justification for why this testing is not necessary. Other potentially useful standards are IEC 60601-2-10:2001 Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

and IEC 60601-1-4:2000 Medical electrical equipment Part 1-4: General requirements for safety –Programmable electrical medical systems.

9. You did not provide electromagnetic compatibility testing for your device. In order to review the safety and efficacy of your device please provide electromagnetic compatibility testing preferably in accordance with an FDA recognized standard such as ISO 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).

10. You provided information about the software used in your device. However, your software description was not detailed and some elements were missing. In order to complete the review of your device, please provide software design specifications, a development plan, verification and validation testing, a revision level history, and unresolved anomalies. These elements are necessary for the review of your device and are consistent with the required information necessary for software with a moderate level of concern. For further information please refer to the Guidance for the Content of Premarket Submission for Software contained in Medical Devices located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf and General Principles of Software Validation; Final Guidance for Industry and FDA Staff located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf

11. You provided waveform representations of maximum voltage output but did not provide representations of each stimulation setting (urge, stress, and mixed urinary incontinence). In order to review the safety and efficacy of your device, please provide waveform representations of each of your stimulation settings.

12. You state that there is no expiration date for your device. The vaginal probes and electrodes used with the predicate devices identified in your submission that are similar to your insertion unit have shelf life dates. In order to ensure the safety and efficacy of your device, please provide an expiration date and the results from your device aging data or a justification for why this data is not necessary.

13. You provide a user manual in your submission. To adequately inform users, your manual requires additional information including:

    a. A description of all features, functions, output modalities, and specifications,

    b. a description of all user-accessible controls,

    c. indicators, markings, and/or labels on the device which provide information regarding the function or meaning of each control, display, output jack, etc.,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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d. a description of the size and type of electrodes to be used with the device,

e. cleaning and/or maintenance instructions. Please be aware that cleaning instructions are required in your user manual for reusable components. A mucosal contacting device, such as your insertion unit, must be thoroughly cleaned and undergo a high level of disinfection including subjection to a germicidal process with a broad spectrum of activity. Please be sure that your instructions are understandable, comprehensive and include disinfection and rinsing steps.

f. a warning statement indicating that the long-term effects of chronic electrical stimulation are unknown,

g. a statement indicating caution should be used for patients with suspected or diagnosed heart problems,

h. a statement indicating caution should be used for patients with suspected or diagnosed epilepsy,

i. a statement indicating caution should be used when there is a tendency to hemorrhage following acute trauma or fracture,

j. a statement indicating that electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner,

k. a statement indicating that patients with a total / partial prolapse of the uterus / vagina must be stimulated with extreme caution,

l. a statement indicating that for patients with urethritis, the disease must be treated before commencing stimulation,

m. a statement indicating that worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they are applied,

n. an adverse reaction statement indicating that skin irritation and burns beneath the electrodes have been reported with the use of powered stimulators,

o. a contraindication for patients with extra-urethra incontinence (syrinx, ectopic urethra),

p. a contraindication for patients with overflow incontinence caused by evacuation problems,

q. a contraindication for patients with severe urine retention in the upper urethras,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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r. a contraindication for patients with complete peripheral denervation of the pelvic floor,

s. a contraindication for patients with an intestinal clamp; and,

t. the removal of fast twitch and slow twitch muscle stimulation. (For example, these terms are located in page 9 of 25 of your user manual.)

14. You did not provide sample labeling to show the information as required by 21 CFR 801.109. In order for the Agency to complete its review, please provide sample labeling for your device as well as all available promotional and advertising materials. You may find additional guidance for labeling using the following:

a. ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm

b. Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070801.pdf

c. Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf

15. You provide a 510(k) Summary in your submission. However, several of the sections are incomplete. Please revise your 510(k) Summary to be in accordance with 21 CFR 807.92.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Ms. Dulciana Chan at (301) 796-2592. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

James P. Seibel FOR

Janine M. Morris
Chief, Urology and Lithotripsy
Devices Branch
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

K110179 – InControl Medical, LLC

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
ULDB	MORRIS	3/25			

Drafted: DChan 2/24/11
FINAL:DulcianaChan:lrm:2.24.2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 21, 2011

INCONTROL MEDICAL, LLC
12715 FALCON DRIVE
BROOKFIELD, WISCONSIN 53005
UNITED STATES
ATTN: MICHAEL LEIGH

510k Number: K110179
Received: 1/21/2011
Product: INCONTROL

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)

Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

INCONTROL MEDICAL LLC
3225 GATEWAY RD
BROOKFIELD WI 530455134
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****7150

2. CONTACT NAME
Michael Leigh

2.1 E-MAIL ADDRESS
mike-leigh@earthlink.net

2.2 TELEPHONE NUMBER (include Area code)
262-9576797

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

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V-5
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA [X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) TS [redacted] 17-Nov-2010

Form FDA 3601 (01/2007)

"Close Window" "Print Cover sheet"

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
January 17, 2011	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
InControl Medical, LLC			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	414-429-2625		
Street Address	FAX Number *(including area code)*		
3225 Gateway Road, Suite 250			
City	State / Province	ZIP/Postal Code	Country
Brookfield	WI	53045	USA
Contact Name			
Herschel Peddicord			
Contact Title	Contact E-mail Address		
President	hommed_1@yahoo.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	262-957-6797		
Street Address	FAX Number *(including area code)*		
12715 Falcon Drive			
City	State / Province	ZIP Code	Country
Brookfield	WI	53005	USA
Contact Name			
Michael Leigh			
Contact Title	Contact E-mail Address		
consultant	mike-leigh@earthlink.net		

PSC Graphics (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent/Applicant
  - ☐ Design/Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	KPI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K080950	1	STIWELL Med4	1	Otto Bock
2	K053434	2	Infiniti	2	MyoTrac
3	K050483	3	evadri	3	Hollister
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Stimulator, Electrical, Non-Implantable, for Incontinence

	Trade or Proprietary or Model Name for This Device		Model Number
1	InControl	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
KPI	870.5320	[ ] Class I [x] Class II

Classification Panel

Gastroenterology - Urology Devices

[ ] Class III [ ] Unclassified

Indications *(from labeling)*

The InControl device is a non-implanted electrical stimulator for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral sphincter closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: InControl Medical, LLC		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: 414-429-2625	
Street Address: 3225 Gateway Road, Suite 250		FAX Number *(including area code)*	
City: Brookfield	State / Province: WI	ZIP Code: 53045	Country: USA
Contact Name: Herschel Peddicord	Contact Title: President	Contact E-mail Address: hommed_1@yahoo.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

K110179

JAN 21 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC
JAN 22 2011
Received

January 17, 2011

RE: 510(k) Application for InControl continence device

Dear Sir or Madam:

InControl Medical hereby submits this InControl, *Traditional 510(k) Application: New Product* for your review. This is a new product. The predicate devices are the Otto Bock STIWELL med4 (K080950), the MyoTrac Infiniti (K053434), and the Hollister evadri (K050483).

The InControl device has the same scientific technology and intended use as the predicate devices. It incorporates pulsed biphasic current to stimulate the pelvic floor muscles in the treatment of female urinary incontinence.

The FDA Fee Payment Identification Number for this InControl submission is MD6052847-956733. Payment has been sent separately.

Thank you for your consideration of the InControl application.

Sincerely,

Michael J. Leigh
consultant

Attachment

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

November 15, 2010

Dear Sir/Madam:

This letter authorizes Michael Leigh to represent InControl Medical, LLC in medical device regulatory matters with the US Food and Drug Administration. Mr. Leigh is an independent consultant with more than fifteen years of experience in the medical device industry. He has been contracted to prepare and submit premarket notifications (510(k)) and respond to any requests for additional information.

Sincerely,

Herschel Peddicord
President, Chief Executive Officer
InControl Medical, LLC
Brookfield, WI 53045

600

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

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1 CDRH Premarket Review Submission Coversheet (FDA-3514)
2 Cover Letter
Authorization Letter
3 Table of Contents
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5 510(k) Summary
6 Truthful and Accuracy Statement
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- Comparison to Predicate
- Intended Use
- Labeling
- Statement of Substantial Equivalence

8 intended Use Comparison Statement
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- Risk Analysis
- Design Output
- Design Review
- Verification and Validation
- Design Transfer

10 Additional Information
- Compliance
- Sterilization
- Biocompatibility
- Software
- Expiration Date

Appendix
InControl Product Requirements Specification
Risk Analysis Summary
InControl User Manual
Output Waveforms

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Indications for Use

510(k) Number (if known):

Device Name: InControl

Indications For Use:

The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral sphincter closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

510(k) Summary for InControl

Submitter:	InControl Medical, LLC
Address:	3225 Gateway Road, Suite 250 Brookfield, Wisconsin 53045
Corporate Contact:	Herschel Peddicord, President InControl Medical, LLC
Telephone:	Ph: (414) 429-2625
Establishment Registration #:	to be registered following 510(k)
Submission Contact:	Michael J. Leigh, consultant 12715 Falcon Drive Brookfield, Wisconsin 53005 Ph: (262) 957-6797
Trade Name:	InControl
Predicate Device:	Otto Bock STIWELL med, K080950 MyoTrac Infiniti, K053434 Hollister evadri, K050483
Common Name:	Stimulator, Electrical, Non-Implantable, for Incontinence

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
870.5320	KPI	Non-implanted electrical continence device	II

Intended Use:

The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral sphincter closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Performance Data:

Complete EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing demonstrate compliance with applicable standards. The software validation results demonstrate that the InControl device is in compliance with the guidelines and standards referenced in the FDA reviewer's guides, and that it performed within its specifications and functional requirements for software.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with FDA requirements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President of InControl Medical, LLC, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Herschel Peddicord
President, Chief Executive Officer
InControll Medical LLC

1/17/2011
(Date)

---

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SECTION 7: GENERAL COMPANY AND DEVICE INFORMATION

Company	InControl Medical, LLC 3225 Gateway Road, Suite 250 Brookfield, WI 53045
Establishment No.	To be registered following 510(k)

Common Name	Stimulator, Electrical, Non-Implantable, for Incontinence
Trade Name	InControl
Proprietary Name	InControl
Reason for 510(k) – Additional or Expanded Indications	New device

Predicate Device(s)	• Otto Bock STIWELL med 4, K08950 • MyoTrac Inifiniti, K053434 • Hollister evadri, K050483
Device Classification	Class II
Product Code	KPI
Regulation	21 CFR 876.5320
Panel	Gastroenterology/Urology

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SECTION 7B: INFORMATION ON NEW DEVICE

Device Description

The general description of the InControl, including required features, functionality and interface, user options, and packaging, is equivalent to that of the predicate devices, Otto Bock STIWELL med 4, MyoTrac Infiniti, and Hollister evadri devices.

The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral sphincter closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

The device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

Comparison to Predicate

The principle difference between the InControl device and the predicates is that the InControl device includes an inflatable insertion unit. The unit is manually inflated by the patient after insertion. This provides a better fit for the patient population. The electrical parameters and controls are similar to the predicate devices. There are no differences in the intended use or indications for use.

The following comparison information illustrates differences and similarities between the legally marketed predicate prescription devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483), and the InControl device, including intended use and functional characteristics. The FDA guidance documents used to prepare this comparison as well as this 510(k) are:

FDA Guidance Title	Revision Date
Format for Traditional and Abbreviated 510(k)s	November 17, 2005
Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence	September 19, 2008
Software Contained in Medical Devices	May 11, 2005

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Intended Use

The intended use InControl is the same as the predicates.

> The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral sphincter closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

The intended use and indications of the device, as described in its labeling are the same as the intended use and indications for the predicate devices.

Labeling

User Manual

The InControl *User Manual* uses text and graphics to lead the user through hardware setup and use. Each piece of equipment appears in a bulleted list with a brief description illustrating each step for ease of use.

SAFETY and PRODUCT INFORMATION

The document also provides maintenance, troubleshooting, repair, warranty, and customer service information. The *User Manual*, provides comprehensive safety information, product specifications and guidelines. The document can be found in "Attachment A" of this 510(k) submission.

Notes on Guidance and Information Labeling:

The manual provides the concepts and instructions needed to install, program, use, and maintain the InControl device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Statement of Substantial Equivalence

The proposed device, InControl continence device, is substantially equivalent to the Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), and Hollister evadri (K050483). When compared to the predicate devices:

- The changes are not due to a recall or corrective action.
- The indications for use are the same. There are no changes in contraindications.
- The user's manual provides equivalent instructions for use, along with equivalent warnings.
- There are no significant differences in features, fundamental technology, or functionality.

The InControl device and the predicate devices all provide pulsed biphasic current to stimulate the pelvic floor muscles. Each includes provision for biofeedback. The InControl device is not significantly different from the predicates. The InControl device does not raise new safety or effectiveness issues. It has the same intended use and basic functions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

PREMARKET NOTIFICATION

INTENDED USE COMPARISON

I state that the intended use(s) and indications of the new device, as described in its labeling, are the same as the intended uses and indications for the predicate devices.

Herschell Peddicord, President, Chief Executive Officer

InControll Medical, LLC

11/22/2010

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SECTION 8b: Comparison Information

Review of Substantial Equivalence

The following comparison matrix illustrates differences between the legally-marketed predicate devices,Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483), and the InControl device, including intended use and technological characteristics.

DONE ULDB (3rd Party) ULDB (NOA)

Feature/ Function	InControl (new device)	Otto Bock STIWELL med4 (K080950)	MyoTrac Infiniti (K053434)	Hollister evadri (K050483)	Comparison
Labeling					
Intended Use An explicit description of all clinical functions performed by the device, **Indications for Use** Explain when the device is to be clinically used and the intended patient population	The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: ~~improvement of urethral~~ sphincter closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.	The STIWELL med4 is a neuromuscular electronic stimulator for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions: • Acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of the pelvic floor muscles. • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles. As a biofeedback device the STIWELL med4 is indicated for the following conditions: • Biofeedback, relaxation and muscle re-education purposes.	Treatment of urinary incontinence EMG biofeedback The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.	The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary or fecal (electromyographic biofeedback) incontinence.	Equivalent
Warnings or Precautions	(see product labeling)	(see product labeling)	(see product labeling)	(see product labeling)	Equivalent

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Contraindications Explain when the device is not to be clinically used	• This device is not intended for diagnostic purposes or critical patient monitor. • The device is not defibrillator proof. • The device should not be used on patients with cardiac pacemaker or a history of rate or conductive disturbance. • Do not use if patient has symptoms of an active urinary tract infection. • Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms. • Do not use if patient has undiagnosed pain. • Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation. • Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings. • Do not use if patient is currently pregnant or attempting to get pregnant. • Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit. • Do not use if the patient has irregular menstrual bleeding cycles. • Do not use if the patient has a history or symptoms of urinary retention	• Patients with pacemakers or other electronic emitters. • No stimulation in the proximity of metal implants. • Pregnancy • Feverish or infectious diseases • Skin disorders subject to inflammation or tumors in the stimulation area, as well as thrombosis or phlebitis • Patients with extra-urethral incontinence (fistula, ectopic urethra) • Patients with overflow incontinence caused by evacuation disorders • Patients with serious urine retention in the upper urethra • Patients with total peripheral denervation of the pelvic floor • Patients with intestinal clamps	• Patients with an implanted electronic device (for example cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained. • Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions • Stimulation should not be applied over cancerous lesions • Not for use with patients with undiagnosed pain conditions. • Do not use if you have symptoms of bladder infection. • Do not use with diminished mental capacity or physical competence limiting the use of the device • Safety of powered muscle stimulators during pregnancy has not been established.		Equivalent
Labeling Summary Clarity to insure safer or more effective use	User Manual	User Manual	User Manual	User Manual	Identical (to all)
Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)
Power Source	Li-Ion battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent
Method of line current isolation	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Patient leakage current	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)

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Regulated current of voltage?	Regulated current	Regulated current	Unknown	Unknown	Identical (to Otto Bock)
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic No-Load Trip?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display **On/Off Status** **Low Battery** **Volt/Curr Level**	 Yes Yes Yes	 Yes Yes Yes	 Yes Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	[redacted] (b)(4) TS	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency **Stress** **Urge**		35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Identical (to Otto Bock)
Pulse width **Stress** **Urge**		300 µs/phase 500 µs/phase	0.2 ms	0.3 or 1 ms	Identical (to Otto Bock)
Time **On** **Off**		9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	2 - 20 secs 2 - 50 secs	1 - 80 secs 0 - 80 secs	Equivalent
Total Session Time		5 - 25 mins	0 - 120 mins	1 - 30 mins	Identical (to Otto Bock)
Max output voltage (500Ω)		50 Vdc	30 Vdc	30 Vdc	Identical (to MyoTrac and Hollister)
Max output current (500Ω)		100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)		50 µC	60 µC	Unknown	Identical (to Otto Bock)
Electrode surface area		21.2 cm^2	Various, 1.53 cm^2 to 10.5 cm^2	unknown	Equivalent
Max current density		4.7 mA/ cm^2	Various, 4.7 mA/ cm^2 to 32 mA/ cm^2		Identical
Maximum power density (500Ω)		23.5 µW/ cm^2	Various, 11.32 µW/ cm^2 to 22.84 µW/ cm^2	Unknown	Equivalent
Biofeedback		EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)
Materials					
Dimensions		175 x 95 x 30 mm	102 x 152 x 51 mm	100 x 70 x 130 mm	Equivalent
Control housing		plastics	plastics	plastics	Identical (to all)
Insertion material		plastics	plastics	plastics	Identical (to all)

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Packaging or Expiration Dating	N/A	N/A	N/A	N/A	Identical (to all)
Sterilization	N/A	N/A	N/A	N/A	Identical (to all)
User Interaction and Software					
Operational Method: Clinical Use e.g., ambulatory use, home use	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Identical (to all)
Patient Interaction: Functions Controllable An explanation of how the device interacts with the patient.	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.				Equivalent
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	None, programming is locked by clinician	None, programming is locked by clinician	None, programming is locked by clinician		Equivalent (to Otto Bock, MyoTrac)
Override	Yes	Yes			Identical (to Otto Bock)
Patient Interaction: Operator Requirements Knowledge or training required of the operator,	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Identical (to all)
Software Level of Concern A statement indicating the Level of Concern and a description of the rationale for that level.	Minor				
Device Hazard Analysis Tabular description of identified hardware and software hazards, including severity assessment and mitigations.	Per risk assessment	No adverse event reports	No adverse event reports	No adverse event reports	Equivalent

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SECTION 9: DESIGN CONTROL ACTIVITY SUMMARY

The InControl device was developed in accordance with the design control requirements in the Quality System Regulation, 21CFR820, and ISO 13485, as documented in InControl procedures. The key points of this process include the following.

Design and Development Planning

The development project is initiated through documented plans that describe the development activities, including schedule, responsibilities, deliverables, and interfaces between functional groups.

Design Input

The design inputs are documented in the System Requirements Specification. The initial version was reviewed during the project to resolve any conflicting or ambiguous requirements. Updates were reviewed and approved by the specifiers as necessary during the project.

The concept includes an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. It offers the same functionality for stimulation and feedback as compatible peripheral device(s).

Risk Analysis

Product risk analysis, using a Failure Modes and Effects Analysis (FMEA) approach and a cross functional team, is conducted three times during the project. The first session is at the beginning of the project. It identifies potential risks based on the specifications, design concept, and previous experience with similar products. Risks requiring mitigation are addressed in development. The second and third session provide updates to the first. Near the end of development, a second FMEA session is conducted. The purpose is to ensure that major risks identified in the first session were addressed. It also identifies new potential risks resulting from design decisions. The third risk analysis is conducted following verification and validation testing. Its primary purpose is to verify that the identified major risks have been adequately mitigated. It may also identify new potential risks as a result of testing. Such new risks may require additional mitigation, testing, and another risk analysis session.

Risk assessment for InControl device was conducted and then compared to adverse event reports and specifications for similar devices. The risk assessment for InControl did not identify any new safety risks when compared other devices on the market. There were no adverse event reports in the target product codes. The product has the same user population and same function, which results in a similar assessment. There are no new hazards. The risk assessment ensured that previously mitigated or new hazards were not introduced in the project.

See the attached Risk Analysis Summary.

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Design Output

Design decisions are documented in specifications and architecture documents. These are reviewed and approved. The final product requires cross functional approval to release to market.

Design Review

Design reviews are held at several levels throughout the project. Product requirements are reviewed by a cross functional team. Routine, periodic project meetings provide updates to all functions on design decisions and project progress. Formal, cross functional reviews are held at the end of each major phase to review results required for that phase. All objectives for the phase must be achieved in order to proceed.

Verification and Validation

Verification testing of the product design is conducted to ensure that all requirements have been met. This testing is conducted according to documented procedures traceable to the product specifications.

Validation testing is conducted by an independent group to ensure users' needs and expectations are met. This testing is conducted according to documented procedures based on expected use (and misuse) of the product.

All verification and validation activities, required by the risk analysis, were performed by the designated individuals. The results of the activities demonstrated that the predetermined acceptance criteria were met.

Design Transfer

Upon release of the product, the validated design will be released for distribution as a controlled item. The facility is in conformance with the design control procedure requirements as specified in 21CFR820.30. Records are available for review.

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SECTION 10: ADDITIONAL INFORMATION

Compliance

The InControl device complies with 21CFR898 for patient leads. From IEC601-1:

56.3a	Connectors provide separation required by Sub-clause 17g	Yes
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	Yes, only one connection
	Medical gas connections not interchangeable	n/a
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	Yes, circuit cannot be energized if connection not made.
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	Yes, connector is enclosed.

Sterilization

There are no sterilization requirements for the InControl device, as there are none for any of the predicate devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483).

Biocompatibility

There are no biocompatibility issues for the InControl device, as there are none for any of the predicate devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483).

Software

Software is verified through code review and error checking. It is validated in the device through functional testing. Due to the intended use and low voltage energy, the software is classified as of Minor Concern. There is no chance of a malfunction of the InControl device resulting in death or serious injury. There have been no adverse reports for any of the predicate devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483).

Expiration Date

There is no expiration date for the InControl device, as there are none for any of the predicate devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483).

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INCONTROL

Product Requirement Specification:
InControl

Date	Rev	Author	Section(s) changed description
08/01/2010	A	M. Leigh	Initial release.

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1.0 Introduction

1.1 Purpose

The purpose of this document is to define the requirements of the product to review and achieve company wide consensus for further development.

1.2 Scope

This document consists of identifying the users, their needs, the intended use, resultant functionality, system performance, limitations, and constraints of the xxx product.

1.3 Reference Documents

Tries, J. & Eisman, E. (2003a). M.E. Schwartz and F. Andrasik (Eds.) Guilford: N.Y.	Urinary incontinence: evaluation and treatment.

1.4 Glossary

Interpret this document with the definition of all terms, acronyms, and abbreviations shown below in the tables.

Table 1 Definition

Table 2 Acronyms and Abbreviations

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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2.0 Product Definition

2.1 Overview

The device for urinary incontinence includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvice floor contracton.

2.2 User Requirements

2.2.1 Patient

The patient is seeing a clinician as part of a program to improve urinary continence. The patient may have urge or stress incontinence.

Requirements
Needs and Intended Use:
• easy insertion • comfortable fit laterally and longitudinally • ability to manually inflate insertion unit for comfortable fit • one-button start capability • one-button stop capability • visual and audible instruction • visual indication of contraction performance (pressure and time) • visual and audible recognition of improvement in contraction performance • notification if contraction appears to be maladaptive (i.e. abdominal) based on comparison to previously locked correct contractions • portable unit that can be used discreetly in the home • easy to clean
System Performance:
• Meet Needs and Intended Use • No operational difficulties that would inhibit use.

Design Validation	
Plan	
Procedure	
Results	
Review	

2.2.2 Clinician

The clinician is the primary care giver. The clinician sets the parameters of the device, monitors use, reviews data, and provides coaching and other care to improve continence.

Requirements
Needs and Intended Use:
• abilty to select electro-stimulation levels based on patient response and urge or stress incontinence treatment • able to select programs for urge or stress incontinence • ability to record and lock wave form from pelvic contraction to use as baseline • baseline will help differentiate vaginal from abdominal contractions • ability to record quick contraction, sustained contraction, and ramp-up contraction sessions for biofeedback • visual indication of contraction (pressure and time) visible for entire session • ability to download patient data for further review, exported data must be granular enough to allow evaluation of the quality of the contraction, not just its overall strength • ability to teach patient to use at home, without direct supervision • ability to clear and reset unit for new patient

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2.2.2 Clinician

The clinician is the primary care giver. The clinician sets the parameters of the device, monitors use, reviews data, and provides coaching and other care to improve continence.

- able to adjust time and current settings
- able to lock baseline contraction
- able to prevent patient from changing settings while allowing the patient to interrupt a session
- easy to clean and maintain organization's infection prevention policies

System Performance:

- display size, time span covers one complete session
- pressure measurement range: 0 to 150 cm H2O, 0.01 second response
- Meet Needs and Intended Use
- No operational difficulties that would inhibit use.

Power Source	Li-Ion battery
Method of line current isolation	n/a (battery powered)
Patient leakage current	n/a (battery powered)
Number of output modes	1
Number of output channels	1
Regulated current of voltage?	Regulated current
Firmware controlled?	Yes
Automatic Overload Trip?	Yes
Automatic No-Load Trip?	Yes
Automatic Shut Off?	Yes
Indicator Display **On/Off Status** **Low Battery** **Volt/Curr Level**	 Yes Yes Yes
Waveform, shape	(b)(4) TS [redacted]
Frequency **Stress** **Urge**	
Pulse width **Stress** **Urge**	
Time **On** **Off**	
Total Session Time	
Max output voltage (500Ω)	
Max output current (500Ω)	
Maximum phase charge (500Ω)	
Electrode surface area	
Max current density	
Maximum power density (500Ω)	
Biofeedback	

Design Validation	
Plan	
Procedure	
Results	
Review	

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3.0 Functional Requirements

3.1 Control Unit

A display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

Requirements
Needs and Intended Use:
• select and lock in the correct amount of current necessary to stimulate pelvic floor contraction • provide selection of fast twitch and slow twitch muscle stimulation programs • provide biofeedback program to measure and record pressure generated in by patient pelvic floor exercises • display contraction force (as pressure) for entire session • allow downloading of data to personal computer through commercially available USB cable and allow graphing in commercially available software (e.g. Excel) • provide single button stop to discontinue electrical pulses if necessary • ability to clean with common, commercially available cleaners
System Performance:
• 8 inches wide x 5 inches high x 4 inches deep • battery operated (only) to last at least 25 minutes of continuous use and up to eight hours between charges • AC rechargeable. Unit cannot be used while recharging • therapy and biofeedback sessions cannot be run with charger or USB connected • therapy and biofeedback sessions cannot be run if Insertion Unit is not fully connected • pressure measurement response time no more than 0.01 seconds • ability to wipe unit with alcohol, bleach, or hydrogen peroxide wipes

Design Validation	
Plan	
Procedure	
Results	
Review	

3.2 Insertion Unit

An inflatable balloon for intra-vaginal use. The unit has a semi-rigid core to alllow insertion. The core also carries inflation air and electrical conductors. The core is surrounded by an inflatable balloon that carries the electrodes. The insertion unit connects to the control unit through a flexible connection.

Requirements
Needs and Intended Use:
• For self or clinician insertion in the patient's vagina. • provide manual inflation of balloon to fill the vagina to a comfortable level • when inflated, provide full contact of electrodes to vaginal wall (to prevent arcing) • provide programmed electro-stimulation of pelvic floor muscles. • ability to clean with common, commercially available cleaners
System Performance:
• between 5 and 5.5 inches long • approximately 0.5 inch diameter when not inflated, inflated diameter up to 3 inches • generally regarded safe, medical grade materials. No latex or PVC (with DEHP) will be used. • ability to wipe unit with alcohol, bleach, or hydrogen peroxide wipes

Design Validation	
Plan	
Procedure	
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Review	

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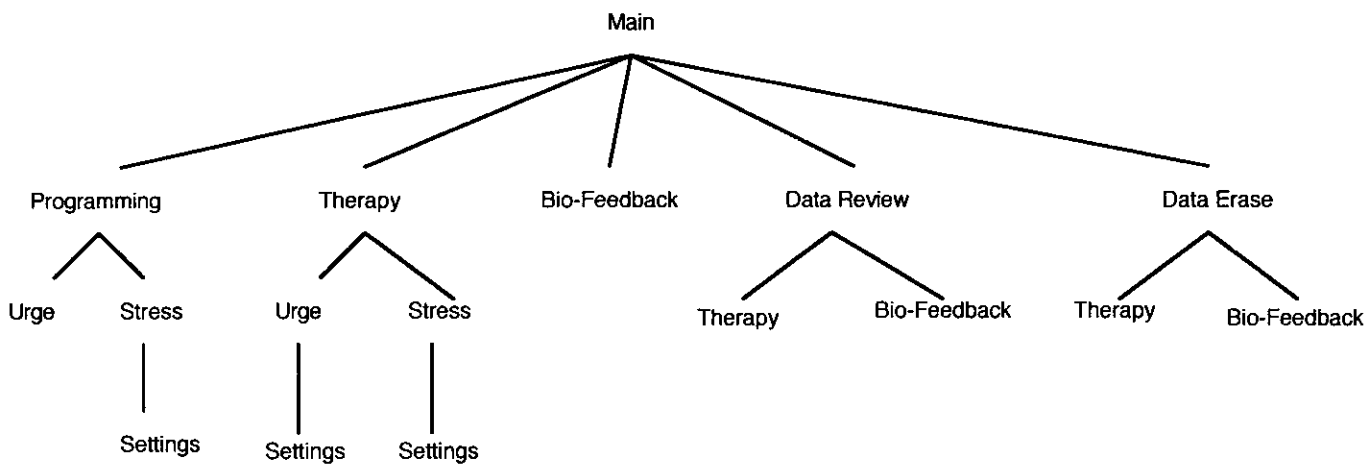
4.0 Architecture

4.1 System



Esc anywhere returns to Main

4.2 Interfaces

USB connection to PC to download comma delimitated data file can be imported into Excel or other commercially available office software applications. Able to use USB 1.1 or 2.0.

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5.0 Design Constraints and Limitations

5.1 Regulatory

5.1.1 Agency Approvals

Product is a Class II medical device in the United States. It will be submitted for premarket notification (510(k)).

5.1.2 Third Party Listings

Independent listing is not required but may be desirable.

5.1.3 Mandatory Standards

Section 56.3 of IEC 601-1

5.1.4 Voluntary Standards

Commonly recognized standards include IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-10.

5.2 Manufacturing

Technologies and design shall be such that it can be contract manufactured according to the Device Master Record without unique capabilities beyond typical electronic assembly companies.

5.3 Compatibility

Product does not work directly with any other devices or operating environments.

5.4 Foreign Language

Initial release will be US English only. Other languages may be added later. Hardware, software design must allow the addition of other languages. If display includes characters, they must allow Roman and non-Roman types.

5.5 Training

User manual should be sufficient for clinician to understand device's use and train patient.

5.6 Service

User service will be limited to replacing the control or insertion unit. The control or insertion units may be exchanged independently. Battery cannot be changed by user.

Control unit will not require calibration after initial manufacturing qualification.

5.7 Environment

5.7.1 Use

The device is intended for indoor use only. Indoor space may be conditioned or not, and so may include normal conditions expected in North America.

Temperature:	32F - 130F
Relative Humidity:	15 - 95% (non-condensing)

5.7.2 Storage and Shipping

Temperature:	-30F - 150F
Relative Humidity:	15 - 95% (non-condensing)

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6.0 Development Tools

6.1 Hardware

The product will use off-the-shelf components wherever possible. It is assumed that the Control Unit enclosure, circuit board and labeling, and the insertion unit will be custom molded. The display and electronic components will be commercially available.

6.2 Software

The embedded firmware language will be commercially available and easily transferred in a manufacturing setting.

Data will be stored in a format that allows exported by USB 1.1 or 2.0 and imported into Excel.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Risk Assessment Plan and Summary

Process/Product Name:	InControl incontinence device

Phase 2 Prepared by:	M. Leigh, K. Tabor
Phase 3 Prepared by:	M. Leigh, K. Tabor
Phase 4 Prepared by:	M. Leigh, K. Tabor

There are no Medical Device Reports for predicate devices, product code KPI

Stage 3									Stage 4		Stage 5						
				Failure				RPN				Failure				RPN	Is Residual Risk Acceptable?
No.	Harm (Effects of Failure)	Hazard (Failure Mode)	Causes of Failure	T	S	P	D	Score	Risk Reduction Method	Responsibility	Verification	T	S	P	D	Score	Explain.
1	shock	electrical	leakage current		3	3	5	45	battery power, low voltage	Engineering	design review		3	1	1	3	broadly acceptable
	shock, fire	electrical	current overload		4	3	5	60	circuit includes overload trip	Engineering	design review, testing		3	1	1	3	broadly acceptable
	shock	electrical	energize with no load		3	3	5	45	circuit includes no-load trip	Engineering	design review, testing		3	1	1	3	broadly acceptable
	shock	electrical	lack of patient isolation, charger		3	3	5	45	Control Unit use disabled when charger connected	Engineering	design review, testing		3	1	1	3	broadly acceptable
	shock	electrical	lack of patient isolation, USB		3	3	5	45	Control Unit use disabled when USB device connected	Engineering	design review, testing		3	1	1	3	broadly acceptable
	tissue trauma	overinflation			2	2	2	8	manual inflation, maximum size limited	Engineering	design review, testing		2	1	1	2	broadly acceptable
	burn	arcing	probe too small, providing a gap		3	3	5	45	inflatable probe ensures contact, insertion unit detection prevents use if not in place	Engineering	design review		3	1	3	9	as low as practical
	muscle strain	stimulation signal too strong			2	2	3	12	manual stop, adjustable level, defined electrical characterisitics consistent with predicate devices	Engineering	testing		2	2	2	8	broadly acceptable
	shock	electrical conductor exposed			3	1	4	12	battery power, low voltage	Engineering	design review		1	1	4	4	as low as practical
	skin irritation	biocompatability	material selection		3	2	5	30	use GRAS materials for contact surfaces, no latex, address risk in labeling	Engineering	design review		3	1	3	9	broadly acceptable
	unnecessary change in treatment	biofeedback incorrect - shows improvement or lack of improvement incorrection	pressure transducer fails or out of calibration		1	2	3	6	program differentiates larger than expected changes in pressure	Engineering	design review, testing		1	2	2	4	broadly acceptable
								0								0	
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INCONTROL

User Manual

PN: xxxxxx-A | **Draft Date: 10/8/10**

Users must read this Guide before using the Product

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Preface

Overview

The device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

This guide provides procedures for setting up and using the InControl incontinence device.

Intended Use

The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral sphincter closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Intended Audience

The InControl User Manual is intended for users of the system, including care providers and patients. The product is intended to be used under the direction of the care provider.

Contact Information

For more information about InControl products, go to www.xxxxx.com. For technical support, questions or comments about documentation, contact (800) xxx-xxxx or (262) xxx-xxxx.

Product Warranty

Product Warranty information can be found with your original system proposal and invoice.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Symbols Used

The following symbols are used in this manual or on the product.

Attention! Please follow the instructions in the User Manual.

Type BF applied part. Internally powered.

The Control Unit can be damaged by ElectroStatic Discharge. The pins of the Control Unit connectors should not be touched unless ESD precautions are taken.

Warnings and Notes

Warnings and Notes are used in this manual. A Warning is used when failure to follow the instructions may result in injury or device damage. Notes are used to provide clarification or advice. The following Warnings are used in this manual.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Warning: Electro-Stimulation is one part of a total therapy program. It is meant to be used in conjunction with counseling and feedback. Do no undertake therapy without the advice of a care provider.

Warning: Do Not use a charger other than supplied by InControl LLC. The incorrect charger can result in damage to the unit.

Warning: Read all instructions prior to use. Failure to follow these directions may result in personal injury or damage to the equipment.

Warning: Only use approved antiseptics that leave no residue.

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⚠ **Warning:** The InControl system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

⚠ **Warning:** Therapy is defined on an individual basis, dependant on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

⚠ **Warning:** Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

⚠ **Warning:** Do not operate device within 10 feet of operating televisions, arc welders, radio thermal treatment equipment, X-ray machines, MRI machines, or any other equipment that produces magnetic fields, sparks, or radio transmissions. RF communications equipment can affect this device

⚠ **Warning:** The reusable Insertion Unit presents a potential risk of cross-infection, particularly if used on broken skin.

⚠ **Warning:** Explosion hazard: Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen enriched environments.

⚠ **Warning:** Do not use with electrodes other than those specified by InControl Medical.

⚠ **Warning:** Take care in arranging patient and cables to avoid risk of entanglement, tripping, or strangulation.

⚠ **Warning:** Use of any equipment should be discontinued upon any signs of treatment related stress or discomfort.

⚠ **Warning:** The device should not be used while walking, driving, operating machinery, or any other activity in which involuntary muscle contraction may put the user at risk.

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⚠ **Warning:** Do not use the device while in the bath, swimming, or otherwise submerged.

Contraindications

- This device is not intended for diagnostic purposes or critical patient monitor.
- The device is not defibrillator proof.
- The device should not be used on patients with cardiac pacemaker, implanted defrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance.
- Do not use if patient has symptoms of an active urinary tract infection.
- Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms.
- Do not use if patient has undiagnosed pain.
- Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation.
- Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings.
- Do not use if patient is currently pregnant or attempting to get pregnant.
- Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit.
- Do not use if the patient has irregular menstrual bleeding cycles.
- Do not use if the patient has a history or symptoms of urinary retention.

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Chapter 1

Equipment Overview

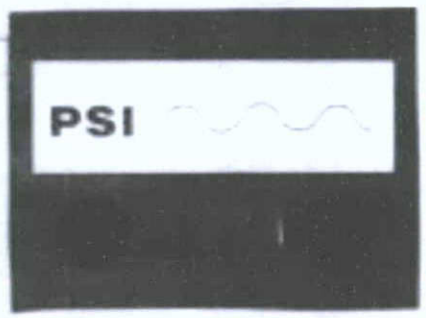
This chapter provides an overview of the equipment included in the InControl System.

Control Unit

The Control Unit is a display device used to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

The Control Unit has the following features and functions.

- select and lock in the correct amount of current necessary to stimulate pelvic floor contraction
- provide selection of fast twitch and slow twitch muscle stimulation programs
- provide biofeedback program to measure and record pressure generated by patient pelvic floor exercises
- display contraction force (as pressure) for entire session
- allow downloading of data to personal computer through commercially available USB cable or flash drive and allow graphing in commercially available software (e.g. Excel)
- provide single button stop to discontinue electrical pulses if necessary
- ability to clean with common, commercially available cleaners



Insertion Unit

The Insertion Unit is an inflatable balloon for intra-vaginal use. The unit has a semi-rigid core to allow insertion. The core also carries inflation air and electrical conductors. The core is surrounded by an inflatable balloon that carries the electrodes. The insertion unit connects to the control unit through a flexible connection.

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The Insertion Unit has the following features and functions.

- for self or clinician insertion in the patient's vagina,
- provide manual inflation of balloon to fill the vagina to a comfortable level,
- when inflated, provide full contact of electrodes to vaginal wall (to prevent arcing),
- provide programmed electro-stimulation of pelvic floor muscles,
- ability to clean with common, commercially available cleaners.

AC Charger

The AC Charger can be used to recharge the control unit battery. The unit cannot be used while it is being charged.

⚠ **Warning:** Do Not use a charger other than supplied by InControl LLC. The incorrect charger can result in damage to the unit.

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Chapter 2

Setting up the Components

This chapter provides procedures on how to set up the InControl units for use.

The components in the InControl system ship in kits, consisting of assembled units and parts. These kits should be kept together until you are ready to use them.

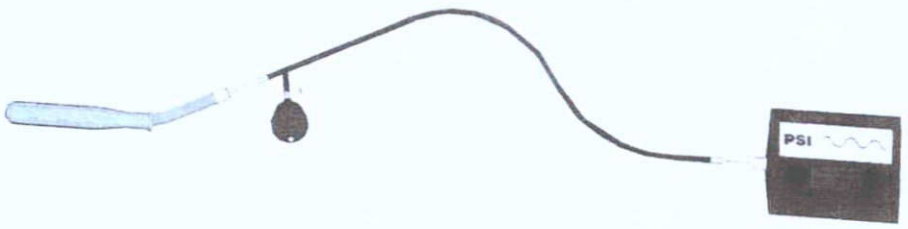
⚠ **Warning:** Read all instructions prior to use. Failure to follow these directions may result in personal injury or damage to the equipment.

⚠ **Caution:** Federal law restricts this device to sale by or on the order of a physician.

⚠ **Warning:** Electro-Stimulation is one part of a total therapy program. It is meant to be used in conjunction with counseling and feedback. Do not undertake therapy without the advice of a care provider.

Connecting the Insertion Unit to the Control Unit

1. Align the connectors of the Insertion and Control Units.
2. Gently press into place and hold.
3. Engage threads on the connector ring and turn the ring clockwise until fully seated.



ⓘ **Tip:** Do not over tighten the connection. This could cause damage to the connector or difficulty in disassembly.

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Disconnecting the Insertion Unit from the Control Unit

1. Turn the connector ring counter-clockwise until threads are released.
2. Gently pull the connectors apart.

Tip: Do not touch the conductors in the connector. This could cause damage to the pins or control unit.

Charging the Battery

The battery should be charged when the low battery indicator is shown, or if charging will not be available for a time.

1. Connect the charger to the control unit.
2. Plug the charger into a 110V AC wall outlet.
3. When charging is complete, unplug the charger from the wall and disconnect from the Control Unit.

Tip: Ensure battery is charged prior to use. Control unit use is disabled when the charger is connected.

Cleaning the Insertion Unit

Following use, the Insertion Unit should be cleaned.

1. Turn **off** the Control Unit.
2. Disconnect the Insertion Unit from the Control Unit.
3. Wash the outside of the Insertion Unit with water. Do not soak.

Tip: Do not fill the Insertion Unit with water or any other liquid. If water enters the Unit, thoroughly dry prior to re-use.

4. If desired, the outside of the Insertion Unit may be wiped with alcohol or antiseptic in accordance with the care provider's infection control procedures.

Warning: Only use approved antiseptics that leave no residue.

5. Allow Unit to air dry.
6. The control unit can be wiped with alcohol or a damp cloth.

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Chapter 3

Programming the System

Introduction

This chapter provides procedures on how to program the InControl Control Unit. The system must be programmed before it is used by patients. It is programmed for one patient at a time.

⚠ **Warning:** The System menus do not time out. You must manually exit them when finished.

Program Selection

The front panel of the Control Unit provides information on the status of the system and its operation.

1. Turn **on** power.
2. Insert key into the side of the unit. Programming cannot be changed without the key.
3. Select **program therapy** from the menu. If the key is not in the device, the display will remain at the main menu.
4. Select treatment type from the menu.

Changing Settings

5. The current settings will be displayed.
6. Pressing the left arrow key (⇐) or right arrow (⇒) moves the cursor between settings.
7. Adjust each setting as desired for the intended patient.
8. Press **save**. The display will return to the main menu. The unit is ready to use for therapy.

Locking Program(s) for the Patient.

9. With the display at the main menu, remove the key from the unit.

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Clearing Programs

Settings can be reverted to factory default settings to provide a consistent starting point for programming. All default settings are the lowest in their range.

1. Turn **on** power.
2. Insert key into the side of the unit. Programming cannot be changed without the key.
3. Select **clear therapy programs** from the menu. If the key is not in the device, the display will remain at the main menu.
4. The device will display a question asking you to confirm that you want to erase programmed therapy settings and revert to factory default settings. Press **yes** if you wish to revert all settings to factory default. Press no if you do not.
5. The display will return to the main menu.

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Chapter 4

Using the System

This chapter provides instructions for using the system. It includes both therapeutic treatment and biofeedback use instructions.

⚠ **Warning:** The InControl system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

Electro-stimulation and biofeedback are treatments used to train and strengthen the pelvic floor muscles in a controlled manner. Electro-stimulation is used to strengthen muscles. In particular, it improves the ability of muscles to hold a contraction of an extended period of time. It is a treatment for urinary incontinence in conjunction with coaching and biofeedback. During a session, electrical impulses are delivered to specific muscles to stimulate their contraction. This contraction exercises the muscles and also helps the patient recognize which muscles to condition.

Biofeedback provides audible and visual confirmation of the patient's voluntary muscle contractions.

⚠ **Warning:** Therapy is defined on an individual basis, dependant on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

Insertion Unit Positioning

A quiet, private place is recommended to aid relaxation.

The Control Unit should be placed on a table or other solid, flat surface.

1. The patient lies on her back, relaxed with the upper body slightly elevated. The legs should be upright and tilted out slightly. The legs may be supported to aid relaxation.
2. A small amount of water-based lubricant may be used on the Insertion Unit.
3. Gently insert the Insertion Unit into the vagina. Ensure the stimulation pads are fully within the vagina.
4. Use the hand pump bulb to inflate the Insertion Unit. The Probe should be snug, but not uncomfortable. The release valve can be used to deflate the Unit.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Therapeutic Treatment

The front panel of the Control Unit provides information on the status of the system and its operation.

1. Turn **on** power.
2. Select **therapy** from the menu.
3. Select treatment type from the menu.
4. Confirm the settings to be used for this session.
5. Select **start**.
6. The session will be displayed on the screen as it is performed.
7. Press **esc** to return to the main menu.

Tip: Treatment can be stopped at any time by pressing the STOP button. The display will revert to the therapy menu. The key is not required to stop the session. The interrupted sessions data is saved.

Changing Settings During Therapeutic Treatment

It may be desired to change settings while the patient is receiving therapy. This is particularly true during the first and follow-up office sessions.

1. Turn **on** power.
2. Insert key into the side of the unit. Programming cannot be changed without the key.
3. Select **program therapy** from the menu. If the key is not in the device, the display will remain at the main menu.
4. Pressing the left arrow key (⇐) or right arrow (⇒) moves the cursor between settings.
5. Starting at a low setting. Adjust intensity up in small increments.
6. Press **single pulse**. The unit will pulse once at the intensity and time selected.
7. Ask the patient if the pulse was comfortable. The intent is to reach the maximum intensity that is still tolerable to the patient. If it is too low or high, adjust settings.
8. Press **save**. The display will return to the main menu. The unit is ready to use for therapy.
9. With the display at the main menu, remove the key from the unit.

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Retrieving Treatment Data

The front panel of the Control Unit provides information on the status of the system and its operation.

1. Turn **on** power.
2. Select **therapy data review** from menu.
3. The most recent session is displayed on the screen along with the date and time the data was created.
4. Previous sessions can be reviewed by pressing the left arrow key (⇐). The right arrow (⇒) moves the display back through later sessions.
5. Press **esc** to return to the main menu.

Biofeedback Session

The front panel of the Control Unit provides information on the status of the system and its operation.

1. Turn **on** power.
2. Select **biofeedback** from the menu.
3. Select **start**.
4. The patient voluntarily contracts their vaginal muscles as instructed. The resulting pressure is displayed on the screen. The device also provides audible feedback.
5. When complete, press **save** if you wish to save the biofeedback session data.
6. Press **esc** to return to the main menu.

Retrieving Biofeedback Data

The front panel of the Control Unit provides information on the status of the system and its operation.

1. Turn **on** power.
2. Select **data review** from menu.
3. Select **biofeedback data review** from the menu.
4. The most recent session is displayed on the screen along with the date and time the data was created.
5. Previous sessions can be reviewed by pressing the left arrow key (⇐). The right arrow (⇒) moves the display back through later sessions.
6. Press **esc** to return to the main menu.

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Downloading Saved Data

The front panel of the Control Unit provides information on the status of the system and its operation.

1. Turn **on** power.
2. Insert a USB flash drive or USB cable into the USB port. If a cable is used, verify that the other end is connect to your PC.
3. Select **data download** from menu.
4. Select **biofeedback data** or **therapy data** from the menu.
5. All sessions in memory will be downloaded. Each will be named "InC-T" (for therapy) or "InB" (for biofeedback followed by numbers indicated the date and time they were originally created.
6. Press **esc** to return to the main menu.

Erasing Saved Data

The front panel of the Control Unit provides information on the status of the system and its operation.

1. Turn **on** power.
2. Select **data erase** from menu.
3. Select **therapy data** or **biofeedback data** from the menu.
4. Press **erase memory**.
5. The device will display a question asking you to confirm that you want to erase therapy or biofeedback data. Press **yes** if you wish to erase the data. Press **no** if you do not.
6. The display will return to the main menu.

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Chapter 5

Testing the System

This chapter provides procedures to test the InControl system prior to use. It is important to test the overall functionality of each component prior to putting the system into service. Additionally, it is important to periodically verify the continuing proper operation of each component.

Tip: You should test all of the system components prior to use to verify proper operation.

Warning: Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

1. Visually inspect the Insertion Unit, Control Unit, and connectors for damage.
2. Connect the Insertion Unit to the Control Unit.
3. Turn on the Control Unit.
4. An error will be displayed if the connection is not complete.

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Chapter 6

Servicing and Troubleshooting the System

This chapter provides procedures on how to service and troubleshoot the InControl System. If you have consistent issues with the system, please contact InControl Technical Support at 1-800-xxx-xxxx.

Troubleshooting the Insertion and Control Unit

Prior to use or any troubleshooting,

1. Verify that the Control Unit battery is charged. If the low battery indicator is shown, recharge the battery.
2. When the battery is charged, disconnect the charger. The Control Unit will not function when the charger or a USB device is connected.
3. Inspect the Insertion Unit for damage. If the silicon covering or any cables appear damaged, the Unit must be replaced.
4. Disconnect the Insertion Unit from the Control Unit. Inspect the connectors for damage. If the pins are not straight, or otherwise appear damaged, the Unit must be replaced.
5. Carefully reconnect the Insertion Unit to the Control Unit.
6. If the assembled Units still do not function correctly, contact InControl Technical Support.

Patient cannot feel pelvic contractions

1. Check that InControl control unit is on and the batteries are charged.
2. Have patient manually reposition the insertion unit with her fingertip until pelvic contractions are perceivable
3. Have patient use a water-based lubricant prior to insertion.

Patient complains of painful insertion of the unit

1. Have patient use a water-based lubricant prior to insertion.
2. Check patient for vaginal irritation or infection.

Patient complains of pain in rectum with pelvic contractions

1. Tell patient not to insert the unit as deep into the vagina.
2. Instruct patient not to dangle her legs or feet during a session: lie in a reclined position with both feet evenly placed in front of her.

Patient stops feeling contractions during a session

1. Have patient manually reposition the unit with her fingertip until pelvic contractions are perceivable again.
2. Instruct patient not to stand or move about during a session.
3. Check that device is on and the batteries are charged.

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Patient complains of painful pelvic contractions

1. Have patient manually reposition the unit with her fingertip until pelvic contractions are more comfortable.
2. Verify settings. Adjust if necessary.
3. Check patient for vaginal irritation or infection.
4. Consider lower therapy settings.

Replacing an Insertion or Control Unit

Insertion Units and Control Units can be replaced and used interchangeably. Disconnect the Insertion Unit and connect the new Unit as described in Chapter 2.

Replacing a Control Unit Battery

The Control Unit battery cannot be replaced. It is a Li-ion battery meant to last many years without replacement. Properly maintaining its charge will extend its life.

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Chapter 7

Specifications

This chapter provides specifications for the InControl system components. The InControl system is a class II medical device with internal power. It must only be used indoors.

Control Unit

Size:	8 inches wide x 5 inches high x 4 inches deep
Battery:	Li-ion battery, 11.1 V typically 6 to 8 hours use between charges
Battery Charge Time:	typically 2 to 3 hours, charge complete will be displayed
Low Battery:	shown on display approximately 15 minutes before unit shuts down
PC interface:	USB, 1.1 and 2.0 compatible

(b)(4) TS

[redacted]

Biofeedback:
Air Pressure: (b)(4) TS [redacted]
Response Time:

Insertion Unit

Size:	5 inches long 0.5 inch diameter, uninflated up to 3 inches diameter, inflated
Method of Inflation:	Hand pump bulb, with release knob
Outer Material:	silicone
Electrode Size:	two, each 1.6 sq. inches

649

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

AC Charger

Input Voltage:	110-120 VAC
Input Frequency:	60Hz
Input Current Draw:	0.1 to 5 A
Output:	1 to 18 VDC

Environmental Conditions

Operating Conditions:

Temperature:	32 to 130F
Relative Humidity:	10% - 90%, non-condensing

Storage and Transportation Conditions:

Temperature:	-30 to 150F
Relative Humidity:	10% to 90%, non-condensing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) TS

(b)(4) TS

(b)(4) TS

(b)(4) TS

(b)(4) TS

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Thelma Valdez

Subject: 510(k) Number K110179/S3

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8148.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Neonate/Newborn (Birth to 28 days)	✓
Infant (29 days -< 2 years old)	✓
Child (2 years -< 12 years old)	✓
Adolescent (12 years -< 18 years old)	✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)	✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.* ✓

Regulation Number	**Class***	**Product Code**
21 CFR 876.5320	II	KPI, ~~HCC~~

(*If unclassified, see 510(k) Staff)

Additional Product Codes: HCC

Review: James P. Seiler (ACTING) (Branch Chief) ULDB (Branch Code) 2/24/2012 (Date)

Final Review: (Division Director) 2/22/12 (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Valdes, Thelma

From: De Luca, Robert J.
Sent: Tuesday, February 21, 2012 12:56 PM
To: Valdes, Thelma
Subject: RE: K110179 In Control - Software

Hi Thelma,

Yes, based on the satisfactory response to the remaining issues, I concur with your SE recommendation.

Thanks,
Bob

-----Original Message-----
From: Valdes, Thelma
Sent: Tuesday, February 21, 2012 10:44 AM
To: De Luca, Robert J.
Subject: FW: K110179 In Control - Software

Hi Bob,

I got a satisfactory response from the firm, and I believe this file is ready now for an SE decision.
Do you concur?
I have updated my memo too, to reflect the updates.

Thank you,
elma

-----Original Message-----
From: mjleigh@wi.rr.com [mailto:mjleigh@wi.rr.com]
Sent: Sunday, February 19, 2012 5:55 PM
To: Valdes, Thelma
Subject: RE: K110179 In Control - Software

Ms. Valdes,

Attached are three files for the two documents addressing the points in your email.

The first two are the updated 510(k) Summary. The first of these has the referenced regulation corrected. The second is the landscape comparison table.

The third attachment is an updated User Manual with the warning on page 7 removed.

Thanks,
Michael Leigh

---- "Valdes wrote:
> Mr. Leigh,
>
> Thank you again. We have just a couple of minor, additional concerns, that I would ask u address by COB Monday 2/20.

>
> 1. The 510(k) Summary has the incorrect regulation number. It should be 876.5320.
>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

> 2. Please revise the labeling to delete the warning on page 7 that states, "The reusable Insertion Unit presents a potential risk of cross-infection, particularly if used on broken skin." The warning I had asked you to add is much clearer, making the other warning unnecessary.

Thank you very much,
>
> Thelma Valdes
>
>
>
>
>
>
> -----Original Message-----
> From: mjleigh@wi.rr.com [mailto:mjleigh@wi.rr.com]
> Sent: Thursday, February 16, 2012 11:14 PM
> To: Valdes, Thelma
> Subject: RE: K110179 In Control - Software
>
> Ms. Valdes,
>
> Attached is a FDA 3654 for each standard: IEC60601-1, IEC60601-1-2, ISO10993-5, and ISO10993-10. There were not deviations, but each electrical standard requires choice as to the type and group of equipment. These are identified.
>
> Michael Leigh
>
>
> ---- "Valdes wrote:
> > Mr. Leigh,
> >
> > I cannot locate your FDA forms 3654, which lists all of the standards that you used, id asks if there were any deviations.
> > Please let me know where I can locate them or please fill them out and return to me by COB Friday, 2/16.
> >
> > Thank you,
> > Thelma Valdes
> >
> > http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf
> >
> > ---
> > Thelma Valdes, Ph.D.
> > Biomedical Engineer
> > The Food and Drug Administration
> > Center for Devices and Radiological Health
> > Office of Device Evaluation
> > Division of Reproductive, Gastro-Renal, and Urological Devices
> > Urology and Lithotripsy Devices Branch
> > WO66 Room G274
> > 10903 New Hampshire Ave.
> > Silver Spring, MD 20993-0002
> > tel. (301) 796-9621
> > thelma.valdes@fda.hhs.gov
> >
> >
> > -----Original Message-----
> > From: mjleigh@wi.rr.com [mailto:mjleigh@wi.rr.com]
> > Sent: Thursday, February 16, 2012 2:07 PM
> > To: Valdes, Thelma
> > Cc: Seiler, Jim; Chan, Dulciana
> > Subject: Re: K110179 In Control - Software
> >
> > Ms. Valdes,
> >
> > There are two revision history documents included in the latest update; one for the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.
Control Unit's embedded firmware, and one for the clinical PC application. These each summarize the changes made. The histories primarily cover the period from the first release candidate last January through January of this year. These changes are the result of continuing development to improve the product based on design team (and their consultants') feedback. This evening, I can provide the specific document numbers, if necessary. If the summary is not adequate, we can provide the specific code with "was" and "is" comparisons. Do you wish the analyze the actual code changes?
> >
> > The test records included in this update reference the versions that were tested. They are also dated (as is the updates in the revision histories. Each test is planned based on its objectives and the changes made since the previous test pass. The set of tests records provided in the most recent update includes the most recent examples in each area of testing.
> >
> > Michael Leigh
> >
> >
> >
> > ---- "Valdes wrote:
> > > Mr. Leigh,
> > >
> > > We continue to review your submission, and some questions have come up on the Software validation.
> > >
> > > Could you please provide a table, or bullet list for us (or let us know where in the submission we can find it) listing :
> > >
> > > * The specific changes you have made to the software in this submission and
> > > * The location of these changes in the validation report
> > >
> > > Having this information readily available to us, will expedite our continuing review process.
> > > If you could provide to me as soon as possible, I would greatly appreciate it.
> > >
> > >
> > > Thank you,
> > > Thelma
> > >
> > >
> > >
> > > ---
> > > Thelma Valdes, Ph.D.
> > > Biomedical Engineer
> > > The Food and Drug Administration
> > > Center for Devices and Radiological Health
> > > Office of Device Evaluation
> > > Division of Reproductive, Gastro-Renal, and Urological Devices
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> > > Silver Spring, MD 20993-0002
> > > tel. (301) 796-9621
> > > thelma.valdes@fda.hhs.gov
> > >
> > >
> > >
> >

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K110179/ S2

Date: February 21, 2012
To: The Record
From: Thelma Valdes, Ph.D.
Office: Office of Device Evaluation/CDRH/DRGUD

510(k) Holder: InControl Medical, LLC
Device Name: InControl InTone
Product Code: KPI; HCC

Contact: Michael J. Leigh
Phone: 262-957-6797
Email: mjleigh@wi.rr.com (previously mike-leigh@earthlink.net)

I. Purpose and Submission Summary:

Purpose: The purpose of this 510(k) is to obtain marketing clearance for the InControl InTone Device. The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Review Summary: This memo was written from excerpts from the review memos prepared by Ms. Dulciana Chan (ULDB), who reviewed this device for the first two rounds. Formal deficiencies were sent to the sponsor as AI letters, dated February 25, 2011 (original round). The sponsor submitted amendments on April 1, 2011 and August 23, 2011 to the file. The sponsor was sent additional deficiencies in response to their S1 submission, on November 4, 2011 (letter was erroneously stamped October 4, 2011). The sponsor submitted their final formal response, on January 31, 2011, in which the review team (Myself, Dulciana Chan, and James Sieler, all ULDB) found that most deficiencies had been met. These deficiencies were concerning biocompatibility, device description, and software validation. Some questions and concerns were raised by me regarding biocompatibility and labeling, and these were addressed interactively. Overall, the sponsor addressed all concerns.

Recommendation: The sponsor has addressed all concerns regarding this device, and it is recommended that an SE letter be sent to the sponsor.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

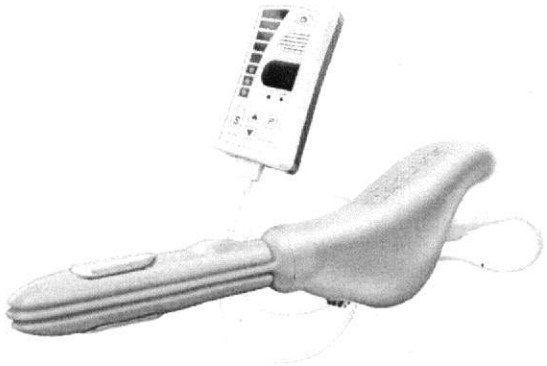
II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: **Prescription** or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form #3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf	X		
Clinical Trials Form http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf			X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?	X		

The device includes 2 parts; an inflatable balloon for intra-vaginal use and external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises (See Figure 1). Other components include the external monitor, AC charger and PC cable



InTone Urinary Incontinence Solution

Figure 1. In Tone Urinary Incontinence Solution

The control unit is a display device used to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. Other features include:

- select and lock in the correct amount of current necessary to stimulate pelvic floor contraction
- provide biofeedback program to measure and record pressure generated by patient pelvic floor
- exercises
- display contraction force (as pressure)
- allow downloading of data to personal computer through custom USB cable and allow graphing in commercially available software (e.g. Excel)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

- provide verbal exercise session coaching
- provide single button stop to discontinue electrical pulses if necessary

The Insert unit is an inflatable balloon for intra-vaginal use. The balloon is attached to a hand pump bulb with release knob. The balloon has a semi-rigid core to allow insertion. The core also carries inflation air and electrical conductors. The insertion unit connects to the control unit through a flexible connection.

The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulated pelvic floor contraction.

The AC charger is used to recharge the control unit battery. The unit cannot be used while it is being charged.

The PC Cable allows the Control Unit to be connected to the USB port of a personal computer. This connection allows the transfer of data to the PC. The unit cannot be used while it is being connected.

Although the sponsor provided a device description, after the S1 round, it was still unclear whether the external monitor or hand pump bulb is included with the device. Therefore, the following was sent to the sponsor:

Deficiency 1 (sent Nov 4, 2011, but stamped Oct 4, 2011):
You provided a device description. However, some information remains unclear. In order for the Agency to complete its review, please indicate whether the external monitor and hand pump bulb are included with the device.

Response to Deficiency 1:
The sponsor states that the device set includes the Insertion Unit with integral hand pump, hand-held Control Unit, and clinician PC software. The device description has been updated to clarify the complete device. The sponsor refers the reviewed to the updated device description in document 002 information on New Device.

Review of Deficiency 1:
I verified the changes made to "Section 7b: Information on New Device" by comparing to the previous submission. In the previous submissions, the sponsor states:

> The device includes two parts; an inflatable balloon for intra-vaginal use and an external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

The sponsor modifies this third paragraph to read as follows:

> The device includes an insertion unit with inflatable balloon for intra-vaginal use, an external hand-held control unit to initiate and control treatment sessions, record and store results of electro-stimulation and patient generated pelvic floor exercises, and a PC-based software application to program the hand-held unit and store and display the results of electro-stimulation and patient generated pelvic floor exercises. The application allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. The insertion unit includes an integral inflation bulb and valve to provide a custom fit for the inflatable balloon.

I find that this description is adequate. Therefore, I find that this deficiency has been adequately met.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

IV. Indications for Use

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Predicate K080350
As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions:

- Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles

As a biofeedback device the STIWELL med4 is indicated for the following conditions:

- Biofeedback, relaxation and muscle re-education purposes

Predicate K053434

The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.

The MyoTrac Infiniti system is also indicated for the ongoing treatment of the following conditions: Relaxation of Muscle Spasms, Prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion and Stroke Rehab by Muscle re-education. It is also used for Biofeedback, Relaxation & Muscle Re-Education purposes.

Predicate K050483

The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary and fecal (electromyographic biofeedback) incontinence.

The indications for use of the subject device is equivalent to the predicates. The indication does not changes the intended therapeutic effect of the device.

V. Predicate Device Comparison

	InControl (subject device)	Otto Bock STIWELL med4 K080950	MyoTrac Infiniti K053434	Hollister evadri K050483
Power Source	2 AA Batteries Nickel metal hydride battery	Battery pack Li-ion 1V	4 AAA 1.5V Alkaline or rechargeable NiMH batter pack 6VDC-15W power adapter (class II)	?
Method of line	n/a (battery)	n/a (battery)	?	?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

current isolation				
Patient leakage current	n/a (battery)	n/a (battery)	?	?
# output modes Feedback	1	1 0	?	?
# output channels Feedback	1	1 0	?	?
Regulated current or voltage Feedback	Regulated voltage	Regulated current n/a	?	?
Firmware controlled	Yes	Yes	?	?
Automatic Overload Trip	Yes	Yes	?	?
Automatic No-load trip	Yes	Yes	?	?
Automatic shut off	Yes	Yes (10 min.)	?	?
Indicator Display **On/Off Status** **Low Battery** **Volt/Curr Level**	 Yes Yes Yes	 Yes Yes Yes	?	?
Waveform, shape	(b)(4) TS	Biphasic symmetrical, rectangular	Asymmetrical balanced pulsed current	Biphasic, balanced
Frequency Stress Urge Mixed Feedback		 35 Hz 10 Hz 5-60 Hz n/a	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz
Pulse Width Stress Urge Mixed Feedback		 300 µs 500 µs 350-500 µs n/a	0.2 ms	0.3 ms
Time Stress On Off Urge On Off Mixed On Off Feedback		 9-12 secs 7-8 secs 13 secs 3 secs 9-11 secs 3-6 secs n/a	 2-20 s 2-50 s	Urinary incontinence 1-80 s 0-80 s
Total session time	12 min	5-25 min	1-120 min	1-30 min
Max output voltage			?	?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 14

	(b)(4) TS			
500 Ω 2 kΩ 10 kΩ		50 V 115 V n/a		
Max output current 500 Ω 2 kΩ 10 kΩ		100 mA 58 mA n/a	100 mA	?
Max phase charge (500 Ω) Stress Urge Mixed Feedback		30 µC 50 µC 50 µC n/a	60µC	?
Electrode surface area		21.2 cm^2	7.4 cm^2 x 2(St-Cloud) 10.5 cm^2 x 2 (Femelex)	?
Max current density (500Ω)		4.7 mA/cm^2	6.76 mA/cm^2 (St-Cloud) 4.76 mA/cm^2 (Femelex)	?
Max power density (500 Ω) Stress Urge Mixed Feedback		105 $\mu W/cm^2$ 23.5 $\mu W/cm^2$ .42 mW/cm^2 n/a	22.84 mW/cm^2 (St-Cloud) 11.32 mW/cm^2 (Femelex)	?
Biofeedback			?	Air pressure
Sterile	No		No	?
Biocompatibility	No	Applicators yes	Applicators yes	?
Patient Override Control	yes	Yes	?	?
Net Charge µC/pulse (500Ω)		0 µC	?	?
Burst Mode		n/a	?	?
Probes	Vaginal	Vaginal electrode – EMG	Vaginal Anal Vaginal-EMG	Vaginal anal

The maximum power density, net charge, and whether there is a burst mode should be provided.

Deficiency #3

You reduced your stimulation settings to be for mixed urinary incontinence and provided most output characteristics for your device. However, there are several characteristics that were not provided. In order to accurately describe your device, please provide the maximum power density, net charge, and indicate whether there is a burst mode and if so, the output characteristics of burst mode.

Response to Deficiency #3

The maximum power density at (b)(4) TS The net charge (maximum phase) at (b)(4) TS (b) These have been included in the 510(k) Summary (Document 024) and manual (Document 022). There is no burst mode for this device.

Review of Deficiency #3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Ms. Dulciana Chan reviewed this question and found the response adequate. Therefore this deficiency is considered adequate.

Battery

Two AA batteries, nickel metal hydride
Battery pack size – 1.75" x 1.145" x 0.57".
Battery capacity – 1200mAh
Battery voltage – 2.4 V
Charge voltage – 6 VDC
Charge current – 0.24 A
Discharge current - (b)(4)
Charging time – 5 hours
Charging frequency – defined by the user, up to 8 hours use

VI. Labeling

A user manual which includes instructions for use and an appropriate prescription statement as required by 21 CFR 801.109(b). was provided.

A sample back label of the control unit was provided in Appendix F.

A label for the insertion unit was not provided.

Deficiency #8:
You provided a label for the control unit. However you did not provide labeling for the insertion unit. Also, symbols on your label were not accompanied by a description on the product label. In order for the Agency to complete its review, please provide sample labeling for the insertion unit and revise the control unit label to describe the symbols used. You may find additional guidance for labeling using the following:

a. ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm

b. Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf

Response and Review of #8:
The sponsor provides 2 new labels in Section 025 and 026, for the Insertion Unit cord label and an updated Control Unit back label. These were reviewed by Ms. Dulciana Chan, who found them to be satisfactory. Therefore, this deficiency has been met.

The user manual erroneously states stress and urge incontinence and improvement of urethral closure on page 5 of 22. (b)(4) TS

EMC tables are needed in the user manual.

(b)(4) TS

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Deficiency #7:
You provided a 510(k) Summary in your submission. However, there are several mistakes in your output characteristics. In order to accurately describe your device, please revise the frequency and pulse width in the 510(k) Summary.

Response and Review for #7:
The sponsor states that the output characteristics in the 510(k) Summary were correct to ensure that they match the Manual and other documents. The updated Summary was found in documents 024. In the 510(k) summary the sponsor shows a frequency of (b)(4), (b)(4) TS [redacted]. This matches the manual. Therefore, this deficiency is adequately addressed.

The user manual should be updated to show how to connect the hand pump bulb to the insertion unit for proper inflation.

The following deficiency was sent as part of the November 4, 2011 letter:

Deficiency #6
You provided a user manual in your submission. However, there is a mistake and several omissions in the manual. To adequately inform users, please revise the following:

c. an explanation for the connection of the hand pump bulb to the insertion unit for proper inflation;
d. (b)(4) TS [redacted]
e. EMC tables to your user manual. You stated conformance with EMC testing required by ISO 60601-1-2. However, you did not include the EMC tables required by ISO 60601-1-2. (Annex C of ISO 60601-1-2 provides examples of properly completed tables.)

Response and Review of Deficiency #6 (as reviewed by Ms. Dulciana Chan):

a. an explanation for the connection of the hand pump bulb to the insertion unit for proper inflation;

The sponsor stated that the hand pump bulb was incorporated into the insertion unit between the original submittal in January and the update in August 2011. The bulb cannot be connected, disconnected, or otherwise removed. The instructions for inflation and deflation have been expanded in the Manual (Document 022). This is adequate.

(b)(4) TS [redacted]

The pulse width in the Manual (see Document 022, p 26) was corrected (b)(4) TS [redacted]

c. EMC tables to your user manual. You stated conformance with EMC testing required by ISO 60601-1-2. However, you did not include the EMC tables required by ISO 60601-1-2. (Annex C of ISO 60601-1-2 provides examples of properly completed tables.)

EMC tables were added to the updated manual and includes tables 201, 204, and 206, as required by the standard (See Document 022, p24-25). This is adequate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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VII. Sterilization/Shelf Life/Reuse

The device is not sterile.

The insertion unit has an expiration date of 1 year since the silicone material used in the insertion date has shelf life of 18 months.

On page 7 of 22 of the user manual, it states that the insertion unit is reusable. It is assumed that the control unit is reusable.

Note: The vaginal area is considered a non-sterile area of the body and therefore this device is considered as a non-critical device being subject to cleaning only and low level disinfection. The sponsor proposes to wash the device with soap and hot water, and then wipe with alcohol. This process is considered sufficient and I verified this with ULDB Microbiologist, Shanil Haugen.

On page 20 of 22 of the user manual, it states the insertion unit for a single patient.

On February 15, 2012, I emailed the sponsor in order to ask them to put a warning statement in their labeling regarding the single patient use, in order to ensure that clinicians and patients alike are aware that hits device cannot be used on multiple patients. On the same day, the sponsor replied with a response that they had added the following statement on pg. 7 and pg 18 of the User's Manual:

"Warning: The InTone system is intended for single patient use only. Do not share use of your InTone devices. Improper treatment or cross-infection may occur."

In addition, on 2/18, I asked the sponsor to delete the statement: "The reusable Insertion Unit presents a potential risk of cross-infection, particularly if used on broken skin." This statement was believed to be confusing as found by Mr. Bob De Luca and Dr. Shanil Haugen (Both ULDB). On 2/19, the sponsor replied with updated labeling. (See page 7 of 26 on the User Manual).

Cleaning instructions as follows were included in the manual and are adequate:

On page 10-11 of 22 you state that the device can be cleaned with common, commercially available cleaners. On page 13 of 22 of the user manual, you state that the insertion unit can be wiped with alcohol or other antiseptic in accordance with the care provider's infection control procedures.

On page 13 of 22 of the user manual,
Wash the outside of the Insertion Unit with warm soapy water. Do not soak.
The control unit can be wiped with antiseptic or a damp cloth. Do not immerse or spray.

Approved Antiseptics
The following cleaners can be used with the InTone Insertion Unit. This list is based on material compatibility.
- isopropyl alcohol
- hydrogen peroxide, <10%
- sodium hypochlorite, <10%

This is adequate.

VIII. Biocompatibility

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	Control Unit enclosure	Insertion Unit outer surface	Electrodes	Connector assembly outer surface	Insertion unit
Chemical Name	ABS, acrylonitrile, butadiene, styrene	Liquid Rubber Silicone	(b)(4) stainless steel	PVC, poly vinyl chloride	(b)(4) CCI
Supplier	(b)(4) CCI				
Supplier trade name					
Polymer formulation					
Processing description					
Processing materials					

The insertion unit has mucosal membrane surface contact for a limited duration (<24 hours).
The sponsor was sent the following deficiency in the November 4, 2011 letter sent to them:

Deficiency #5:
You provided biocompatibility information and the processing description for the raw materials used in your device. It is inadequate to determine the biocompatibility of your device only based on the provided description of processing for the raw materials used in your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility evaluation for cytotoxicity, irritation, and sensitization per ISO 10993-1:2009 and the FDA blue book memo #G95-1. In lieu of biocompatibility testing of the final device, biocompatibility evaluation may be acceptable based on proper chemical analysis of leachables from your final device and adequate toxicity risk assessment with existing toxicity data of each chemical identified from the chemical analysis using principles outlined in ISO 10993-17:2002. Therefore, to determine the biocompatibility of your device, please provide biocompatibility testing on the final insertion unit or assessment of the insertion unit as suggested above.

Response to Deficiency #5
The sponsor states that biocompatibility testing of the finished insertion unit has been completed. It included cytotoxicity, irritation, and sensitization testing per ISO 10993-1:2009. The sponsor includes this in documents 08-021.

Review of Deficiency #5:
The following items were submitted by the sponsor. Whenever possible, I used the biocompatibility check lists, which are included at the end of this memo. The following were reviewed.

- Document 018: Cytotoxicity Test; used biocompatibility checklist
- Document 019: Vaginal Irritation Test: No checklist used.
- Document 020: Dermal Maximization CSO Test; used biocompatibility checklist
- Document 021: Dermal Maximization NaCl Test; used biocompatibility checklist (same as for CSO test)

Vaginal irritation test: I followed the ANSI/AAMI/ISO 10993-10:2010 standard to verify that the vaginal irritation test was performed correctly. The sponsor does follow the standard according to procedure and the following tables, which coincide with the one on the standard (pg. 55 of 88):

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Reaction	Numerical Grading
1. Epithelium	
Normal, intact	0
Cell degeneration or flatting	1
Metaplasia	2
Focal erosion	3
Generalized erosion	4
2. Leucocyte infiltration (per high power field)	
Absent	0
Minimal (less than 25)	1
Mild (26 to 50)	2
Moderate (51 to 100)	3
Marked (greater than 100)	4
3. Vascular congestion	
Absent	0
Minimal	1
Mild	2
Moderate	3
Marked, with disruption of vessels	4
4. Oedema	
Absent	0
Minimal	1
Mild	2
Moderate	3
Marked	4

Irritation Index	
Average Grade	**Description of Response**
0	None
1 to 4	Minimal
5 to 8	Mild
9 to 11	Moderate
12 to 16	Severe
Other adverse changes of the tissues should be recorded and included in the assessment of the response.	

According the standard, the following should be included in the report:

The test report shall include:

a) a description of the test samples;

b) the intended use/application of the test samples;

c) a detailed description of the method employed in preparing the test samples;

d) a description of the test animals;

e) the method of application;

f) how the site readings were performed;

g) a record of the observations;

h) the histological evaluation;

i) assessment of the results.

The vaginal test passed contained all of these elements above (as stipulated by the standard, specifically for the vaginal test). However, the description of the test samples was lacking (items a and c) , as it was in the other test reports.

In particular, for <u>all</u> the tests provided:

- It is unclear what parts/portions of the device were tested/extracted.
- It is also unclear if the testing was conducted on finished, sterilized or un-sterilized devices, especially since the device is to be sold non-sterile.

With interactive review, I clarified with the sponsor whether or not testing was conducted on finished, devices, and whether these devices were sterilized (since they are to be sold non-sterile). (Email 2/14/12)

On 2/15, the sponsor replied that:

"InControl has followed up with the lab that performed biocompatibility testing on the InTone device. Their answer is attached. The exterior of the insertion unit was extracted for the testing. This is the part of the device that comes in contact with vaginal mucous membranes. Also, the part is not sold sterile and was not sterilized prior to this testing."

Upon checking with ULDB Toxicologist, Xin Fu, this is considered acceptable, because of the amount of time that the device is in contact with the vaginal tissue is minimal. Furthermore, the sponsor extracted

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the device for a long time period, 50C, 72 hrs which far exceeds the normal contact time. After examining all data submitted, and consulting with Dr. Fu, I find that this deficiency has been adequately addressed.

The control unit and connector assembly have skin surface contact for a limited duration (<24 hours). Since contact is on hand (thick skin) no biocompatibility testing is necessary.

IX. Software

Version:

Level of Concern: Moderate

This level is appropriate because there is a small risk of thermal injury if the device delivers too much energy to the body as a result of a software failure.

	Yes	No
Software description: (See S1/Appendix C)	X	
Device Hazard Analysis: Hardware and software hazards, including severity assessment and mitigation were provided in S1/Appendix B.	X	
Software Requirements Specifications: The software requirements were provided in S1/Appendix C.	X	
Architecture Design Chart: (See Data Flow Diagram and Thread of Control document sent via email)	X	
Design Specifications: The design specifications are listed in section 11.	X	
Traceability Analysis/Matrix: Traceability among requirements, specifications, identified hazards and mitigation(s), and Verification and Validation testing was provided in S1/Appendix B.		X
Development: (see S1/Appendix C)	X	
Verification & Validation Testing: Validation testing in Appendix G.		X
Revision level history:		X
Unresolved anomalies:		X

No traceability analysis, verification testing, revision level history, or unresolved anomalies were provided as part of the S1 submission. Therefore, the following was sent to the sponsor:

Deficiency #2 (sent Nov 4, 2011, stamped Oct 4, 2011)
You provided software documentation in Appendix C and via email. However, some requirement elements necessary for software with a moderate level of concern are not complete. In order to complete the review of your device, please provide the following:

f. a complete traceability analysis which links requirements, specifications, identified hazards and mitigation, and verification and validation testing;

g. a more detailed verification testing report. This report should document how specified requirements have been fulfilled;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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h. a revision history log that provides release version numbers and dates; and

i. a list of unresolved software anomalies, bugs, or defects that remain with an explanation of its impact on the usage of your device.

Response to Deficiency #2:

a. *The sponsor states that a traceability analysis has been updated to include reference to requirements, specifications and design features, identified hazards and mitigations, and verification and validation testing.*
b. *The sponsor states that previously provided test reports included the system waveform verification report, EMC report, electrical safety (IEC 60601-1) report and the system verification /validation report. They now include additional verification and validation reports in this update, including:*
    - *Physical dimensions and inflation report*
    - *Battery test report*
    - *Short Circuit test report*
    - *Air Pressure Test report*
    - *Audio Volume test report*
    - *Software Validation Report V102*
    - *Software Validation Report V103*
    - *Software Validation Report V104*
    - *InTone Abnormal Usage Test Report*

c. *The revision histories for the PC application and embedded firmware for the hand-held control unit are included*
d. *A list of unresolved anomalies for the PC application and control unit firmware are included. The list includes a description of each, its potential impact on the user, and the current disposition. (the reviewer is referred to Document 015 SPR List).*

Review of Deficiency #2
I consulted with Mr. Jim Seiler, who provided me a consult for this deficiency. On February 16, 2011, the sponsor was asked for the specific changes that were made in the software.

The reader is referred to Mr. Seiler's assessment at the end of this memo. The reader is referred to Mr. Seiler's review of the Software validation. Mr. Seiler suggests that "the lead reviewer should determine what changes in software are relative to what was previously reviewed for this file and determine whether these are important comparison features to the predicate for the conditions that the device is intended to treat."

I spoke to the original reviewer, Ms. Dulciana Chan about this matter. Ms. Chan stated that this device is intended for the "acute an ongoing treatment of mixed urinary incontinence." As stated in pg. 4 of this memo:

- *Predicate K080350 is indicated for* acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles
- *Predicate K053434 is indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence.*

These indications encompass more than just mixed urinary incontinence, and therefore, if the software is validated for just mixed urinary incontinence, then I am satisfied that this device is substantially equivalent to the predicates (i.e. there is no 'creep' in the indication).

Therefore, I find that this deficiency has been met.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The submission states that electrode lead wires and patient cables comply with 21 CFR Part 898.

Electrical safety test results were provided in Appendix H in accordance with:
IEC60601-1:1995, Medical Electrical Equipment - Part 1: General Requirements for Safety

This includes thermal safety, mechanical strength, leakage current, and dielectric strength testing.

IEC 60601-1-1:2000 Medical electrical equipment Part 1-1: General requirements for safety - Safety requirements for medical electrical systems

This is adequate.

EMC Testing:
EMC testing results were provided in Appendix I in accordance with
ISO 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).

According to CISPR 11: 2003+A1:2004, *Industrial, Scientific and Medical radio-frequency equipment – Electromagnetic disturbance characteristics – limits and methods of measurement*, the device is classified as Group 1, Class A.(intentional RF energy in a non domestic establishment).

Equipment Limits: Conduction emissions		
Frequency band (MHz)	Quasi-peak dB(μV)	Average dB(μV)
0.15-0.5	100	90
0.5-5	86	76
5-30	70→90	60→80
Device	Pass 0.15-30 MHz	Pass 0.15-30 MHz

Testing was only performed in Charging Mode.

Immunity to electrostatic discharges (ESD)			
	Test level	Compliance level	Humidity
IEC 60601-1-2	± 6 kV contact ± 8 kV air		≥ 30%
Device	2, 4, 6 kV contact 2, 4, 8 kV air	Pass	53 %

There were testing failures in Stimulation (operation) mode.

Immunity to radiated radio frequency interference in the 80-2500 MHz range at 3 V/m at 2 and 3 m
Pass in all modes

Equipment Limits: Radiation disturbance (CISPR 11 table 3)(Emissions)		
Frequency band (MHz)	Quasi-peak dB(μV)	
30-230	40 at 10 m	
230-1000	47 at 10 m	
Subject Devices	Pass 30-1000 MHz	All modes *Testing was performed at 20% and 80% stimulation output.*

Immunity to Electrical Fast Transients/Bursts		
	Test level	Compliance level

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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IEC 60601-1-2	± 2 kV power supply lines	
Device	± 2 kV	Pass *Testing was only performed in Charging Mode.*

Immunity to Surge Transients		
	Test level	Compliance level
IEC 60601-1-2	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode
Device	0.5, 1 kV differential mode 0.5, 1 2 kV common mode	Pass *Testing was only performed in Charging Mode and differential model.* -

Immunity to Voltage Dips and Interruptions			
	Test level	Compliance level	Duration
IEC 60601-1-2 Voltage Dip	<5% 40% 70%	>95% 60% 30%	0.5 periods 5 periods 25 periods
Device	Pass *Testing was only performed in Charging Mode.*		
IEC 60601-1-2 Interruption	<5%	>95%	5 sec
Device	Pass *Testing was only performed in Charging Mode.*		

Immunity to Power Frequency Magnetic Field		
	Test level	Compliance level
IEC 60601-1-2	3 A/m	3A/m
Subject device	Power frequency (50,60 Hz)	Not susceptible at 3 A/m in all modes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Harmonic Emissions

Done in accordance with EN 61000-3-2-2006: "Electromagnetic Compatibility – Part 3-2: Limits – Limits for Harmonic Current Emissions (Equipment Input Current ≤ 16 Amps Per Phase).

Testing was only performed in Charging Mode.

Voltage Fluctuations/flicker emissions

Done in accordance with EN 61000-3-3-2008: "Electromagnetic Compatibility – Part 3-3: Limits – Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems for Equipment with Rated Current ≤ 16 Amps Per Phase and not Subject to Conditional Connection + Amendment A1: 2001.

Testing was only performed in Charging Mode.

The following deficiency was sent to the sponsor on November 4, 2011:

Deficiency #4:
You provided EMC testing, however some of the testing was incomplete. In order to ensure the safety of your device, please provide the following testing:

a. emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker missions testing in stimulation and data transfer mode. These tests were performed only with the device in charging mode;

b. radiation emission testing on your device in stimulation mode at 100% stimulation or provide an adequate justification for the lower stimulation output. Your testing was performed in stimulation mode at 20% and 80% stimulation output; and

c. repeated immunity to electrostatic discharges testing or an adequate justification for the behavior of your device during testing. During testing in stimulation mode, treatment stops on a few sides of the device. The report stated that it is intended for the device to interrupt treatment when abnormal conditions are detected. However, treatment does not stop at all areas of the device.

Response and Review (as stated by Ms. Dulciana Chan)

a. emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker missions testing in stimulation and data transfer mode. These tests were performed only with the device in charging mode;

The sponsor stated that the device was tested in three modes; charging mode, use mode, and data transfer mode. The charging mode is the only mode in which the device is connected to mains power and thus potentially exposed to electrical fast transients/bursts, surge transients, voltage dips and intemrptions, harmonic emissions, and voltage fluctuations/flicker. In the other two modes, the unit is not connected to mains power and operates on battery. This applies to Conducted emission, harmonic emissions testing as well. The sponsor has provided an adequate justification and no further testing is necessary.

b. radiation emission testing on your device in stimulation mode at 100% stimulation or provide an adequate justification for the lower stimulation output. Your testing was performed in stimulation mode at 20% and 80% stimulation output; and

The UL test engineer reported that preliminary scans were made at 100%. Full testing was conducted at 20% and 80% because these lower levels showed more noise than the 100% level, however there was little difference between them. Since no significant difference in emissions was measured, testing was completed at these levels

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8188

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(Document 017). This is an adequate justification for testing at 20% and 80% stimulation output.

c. repeated immunity to electrostatic discharges testing or an adequate justification for the behavior of your device during testing. During testing in stimulation mode, treatment stops on a few sides of the device. The report stated that it is intended for the device to interrupt treatment when abnormal conditions are detected. However, treatment does not stop at all areas of the device.

The impact of electrostatic discharge may be different in different orientations or test points. The InTone processor will stop treatment if it detects abnormal conditions. The same discharge may not create abnormal conditions in the processor in every orientation. Some orientations may be parallel to the field and other perpendicular. Treatment was able to continue normally in some orientations (Document 017). This explanation is adequate and repeated immunity testing is not necessary.

XI. Performance Testing – Bench

(b)(4) TS

[redacted]

XII. Performance Testing – Animal – n/a

XIII. Performance Testing – Clinical –n/a

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		X	If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: n/a
2. Explain why there is or is not a new effect or safety or effectiveness issue: n/a

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3. Describe the new technological characteristics: The new characteristic is the inflatable insertion unit. This allows an adjustable fit for each patient.
4. Explain how new characteristics could or could not affect safety or effectiveness: The inflatable insertion unit could not affect safety or effectiveness because the insertion unit will still provide stimulation to the vaginal wall without inflation.

5. Explain how descriptive characteristics are not precise enough: n/a
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used: n/a
8. Explain what performance data is needed: n/a
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: n/a

XV. Deficiencies from the original 510(k)

The following deficiencies (in bold) were sent to the sponsor in our February 25, 2011 additional information letter. The sponsors' responses are below each deficiency.

1. **You provided an indications for use that is different from your predicate devices. Your intended use includes "improvement of urethral sphincter closure" which is not contained in any known predicates and changes the intended therapeutic effect of your device. Please remove this or provide scientific evidence of improvement of urethral sphincter closure.**

   The improvement of urethral sphincter closure has been removed. The indication for use has been revised to be the following:
   The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

   This is adequate.

2. **You provided a device description, however some key elements are missing. The configuration of your electrodes is not provided and the biofeedback feature of your device is not explained. Please clarify the description of your device to include, the following for all components of your device:**
   a. **Device specifications;**
   b. **Any new features of the device;**
   c. **Identification of the relevant dimensions and weight of the device and accessories;**
   d. **A description of all user controls, displays, and functions;**
   e. **A description of how the device interconnects with other components;**
   f. **Engineering drawings and/or photographs of the device; and**
   g. **Length, construction, material, and connections between the stimulator device and the electrodes.**

   The device specifications, features, dimensions, functions, engineering drawings, photographs, and electrode specifications were provided. The connection with the hand pump bulb is necessary. This is inadequate.

3. **You provided output characteristics of your device. However, it is unclear whether there are separate parameters for the treatment of stress, urge, and mixed urinary incontinence and the biofeedback setting. Please clarify the parameters for all three possible stimulation settings and the biofeedback setting including but not limited to time,**

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maximum phase charge, maximum power density, and net charge. For example, you did not provide the frequency and pulse width for the mixed urinary incontinency setting.

The sponsor removed the treatment of stress and urge incontinence from the device. The output characteristics of the mixed incontinence treatments were provided. This is adequate.

4. **You state that your device will use a Li ion battery. However you did not provide enough information about the battery. Please provide the size, capacity, voltage, charge and discharge currents, and estimate how long it will take to recharge the battery and the frequency of charging intervals.**

   The battery information was provided and is adequate.

5. **On page 7 of 25 in your user manual, you state that the insertion unit is reusable. In order to ensure the safety of your device, please indicate which components of your device are reusable and whether the components are reusable for a single patient only and if they can be reusable for multiple patients.**

   The sponsor has stated that the insertion unit is for single patient use only on page 20 of 22 of the user manual. This is adequate.

6. **You state that the outer material of the insertion unit is silicone and that the control unit is made with plastics. However, you do not provide complete information about the materials used in the components of your device (insertion unit, electrodes, control unit). Please provide the following material information for your device:**

   a. **Table identifying all of the generic materials by chemical name, supplier trade name, supplier name, and device component location;**
   b. **Polymer component formulations (to include generic chemical component names and amounts specified as weight or volume percentages); and**
   c. **Sufficient processing information to include any processing materials (and amounts) that could impact on biocompatibility.**

   The sponsor provided material information in section D of the August 23, 2011 response. This is adequate.

7. **You state that there are no biocompatibility issues for your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility testing. In order to ensure the safety of your device, please provide complete cytotoxicity, sensitization, and irritation or intracutaneous reactivity testing on your final device.**

   Biocompatibility testing on the final device was not provided. This is inadequate.

8. **You did not provide any electrical testing. In order to ensure the safety and efficacy of your device, please provide electrical testing preferably in accordance with an FDA recognized standard such as IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-1:2000 Medical electrical equipment Part 1-1: General requirements for safety - Safety requirements for medical electrical systems or provide an adequate justification for why this testing is not necessary. Other potentially useful standards are IEC 60601-2-10:2001 Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators and IEC 60601-1-4:2000 Medical electrical equipment Part 1-4: General requirements for safety –Programmable electrical medical systems.**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Electrical safety test results were provided in Appendix H in accordance with IEC6061-1:1995, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance by an independent lab, Underwriter's Laboratory. This is adequate.

9. **You did not provide electromagnetic compatibility testing for your device. In order to review the safety and efficacy of your device please provide electromagnetic compatibility testing preferably in accordance with an FDA recognized standard such as ISO 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).**

   The EMC testing was provided but is not adequate.

10. **You provided information about the software used in your device. However, your software description was not detailed and some elements were missing. In order to complete the review of your device, please provide software design specifications, a development plan, verification and validation testing, a revision level history, and unresolved anomalies. These elements are necessary for the review of your device and are consistent with the required information necessary for software with a moderate level of concern. For further information please refer to the Guidance for the Content of Premarket Submission for Software contained in Medical Devices located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf and General Principles of Software Validation; Final Guidance for Industry and FDA Staff located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf**

    The software documentation is inadequate.

11. **You provided waveform representations of maximum voltage output but did not provide representations of each stimulation setting (urge, stress, and mixed urinary incontinence). In order to review the safety and efficacy of your device, please provide waveform representations of each of your stimulation settings.**

(b)(4) TS

[redacted]

12. **You state that there is no expiration date for your device. The vaginal probes and electrodes used with the predicate devices identified in your submission that are similar to your insertion unit have shelf life dates. In order to ensure the safety and efficacy of your device, please provide an expiration date and the results from your device aging data or a justification for why this data is not necessary.**

    The insertion unit has an expiration date of 1 year since the silicone material used in the insertion date has shelf life of 18 months. This is adequate.

13. **You provide a user manual in your submission. To adequately inform users, your manual requires additional information including:**

    a. **A description of all features, functions, output modalities, and specifications;**
       The user manual has been updated and is adequate.
    b. **A description of all user-accessible controls;**
       The user manual has been updated and is adequate.
    c. **Indicators, markings, and/or labels on the device which provide information regarding the function or meaning of each control, display, output jack, etc.;**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The user manual has been updated and is adequate.

d. **A description of the size and type of electrodes to be used with the device;**
Electrode information has been provided and is adequate.

e. **Cleaning and/or maintenance instructions. Please be aware that cleaning instructions are required in your user manual for reusable components. A mucosal contacting device, such as your insertion unit, must be thoroughly cleaned and undergo a high level of disinfection including subjection to a germicidal process with a broad spectrum of activity. Please be sure that your instructions are understandable, comprehensive and include disinfection and rinsing steps.**
Cleaning instructions were added and are adequate.

f. **A warning statement indicating that the long-term effects of chronic electrical stimulation are unknown.**
This was added to the user manual and is adequate.

g. **A statement indicating caution should be used for patients with suspected or diagnosed heart problems.**
This was added to the user manual and is adequate.

h. **A statement indicating caution should be used for patients with suspected or diagnosed epilepsy.**
This was added to the user manual and is adequate.

i. **A statement indicating caution should be used when there is a tendency to hemorrhage following acute trauma or fracture;**
This was added to the user manual and is adequate.

j. **A statement indicating that electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.**
This was added to the user manual and is adequate.

k. **A statement indicating that patients with a total / partial prolapse of the uterus / vagina must be stimulated with extreme caution;**
This was added to the user manual and is adequate.

l. **A statement indicating that for patients with urethritis, the disease must be treated before commencing stimulation;**
This was added to the user manual and is adequate.

m. **A statement indicating that worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they are applied;**
This was added to the user manual and is adequate.

n. **An adverse reaction statement indicating that skin irritation and burns beneath the electrodes have been reported with the use of powered stimulators;**
This was added to the user manual and is adequate.

o. **A contraindication for patients with extra-urethra incontinence (syrinx, ectopic urethra);**
This was added to the user manual and is adequate.

p. **A contraindication for patients with overflow incontinence caused by evacuation problems;**
This was added to the user manual and is adequate.

q. **A contraindication for patients with severe urine retention in the upper urethras;**
This was added to the user manual and is adequate.

r. **A contraindication for patients with complete peripheral denervation of the pelvic floor;**
This was added to the user manual and is adequate.

s. **A contraindication for patients with an intestinal clamp; and**
This was added to the user manual and is adequate.

t. **The removal of fast twitch and slow twitch muscle stimulation. (For example, these terms are located in page 9 of 25 of your user manual.)**
These terms were removed and are adequate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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14. **You did not provide sample labeling to show the information as required by 21 CFR 801.109. In order for the Agency to complete its review, please provide sample labeling for your device as well as all available promotional and advertising materials. You may find additional guidance for labeling using the following:**

    a. **ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm**

    b. **Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070801.pdf**

    c. **Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf**

    A label for the control unit was provided. It contained symbols without wording. This is inadequate.

15. **You provide a 510(k) Summary in your submission. However, several of the sections are incomplete. Please revise your 510(k) Summary to be in accordance with 21 CFR 807.92.**

    The 510(k) Summary still contains some erroneous information that should be revised. This is inadequate.

XVI. Contact History

Dulciana Chan called Mr. Leigh on October 31, 2011 to ask for software documentation (InTone SRS document, InTone Flow Diagram and Thread of Control document, and the InTone Traceability Matrix) that was not included in the submission and left a voice mail. He returned my call on November 1, 2011 and it was agreed that he would send me software documentation via email by November 3, 2011. He stated that the SRS document was Appendix A which was named the System Requirements Specifications. On November 2, 2011 Mr. Leigh emailed me the InTone Flow Diagram and Thread of Control document and the InTone Traceability Matrix (attached).

XVII. Deficiencies to S1 (addressed throughout submission)

1. You provided a device description. However, some information remains unclear. In order for the Agency to complete its review, please indicate whether the external monitor and hand pump bulb are included with the device.

2. You provided software documentation in Appendix C and via email. However, some requirement elements necessary for software with a moderate level of concern are not complete. In order to complete the review of your device, please provide the following:

    a. a complete traceability analysis which links requirements, specifications, identified hazards and mitigation, and verification and validation testing;

    b. a more detailed verification testing report. This report should document how specified requirements have been fulfilled;

    c. a revision history log that provides release version numbers and dates; and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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d. a list of unresolved software anomalies, bugs, or defects that remain with an explanation of its impact on the usage of your device.

3. You reduced your stimulation settings to be for mixed urinary incontinence and provided most output characteristics for your device. However, there are several characteristics that were not provided. In order to accurately describe your device, please provide the maximum power density, net charge, and indicate whether there is a burst mode and if so, the output characteristics of burst mode.

4. You provided EMC testing, however some of the testing was incomplete. In order to ensure the safety of your device, please provide the following testing:

   e. emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker missions testing in stimulation and data transfer mode. These tests were performed only with the device in charging mode;

   f. radiation emission testing on your device in stimulation mode at 100% stimulation or provide an adequate justification for the lower stimulation output. Your testing was performed in stimulation mode at 20% and 80% stimulation output; and

   g. repeated immunity to electrostatic discharges testing or an adequate justification for the behavior of your device during testing. During testing in stimulation mode, treatment stops on a few sides of the device. The report stated that it is intended for the device to interrupt treatment when abnormal conditions are detected. However, treatment does not stop at all areas of the device.

5. You provided biocompatibility information and the processing description for the raw materials used in your device. It is inadequate to determine the biocompatibility of your device only based on the provided description of processing for the raw materials used in your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility evaluation for cytotoxicity, irritation, and sensitization per ISO 10993-1:2009 and the FDA blue book memo #G95-1. In lieu of biocompatibility testing of the final device, biocompatibility evaluation may be acceptable based on proper chemical analysis of leachables from your final device and adequate toxicity risk assessment with existing toxicity data of each chemical identified from the chemical analysis using principles outlined in ISO 10993-17:2002. Therefore, to determine the biocompatibility of your device, please provide biocompatibility testing on the final insertion unit or assessment of the insertion unit as suggested above.

6. You provided a user manual in your submission. However, there is a mistake and several omissions in the manual. To adequately inform users, please revise the following:

   h. an explanation for the connection of the hand pump bulb to the insertion unit for proper inflation;

   i. (b)(4) TS [redacted]

   j. EMC tables to your user manual. You stated conformance with EMC testing required by ISO 60601-1-2. However, you did not include the EMC tables required by ISO 60601-1-2. (Annex C of ISO 60601-1-2 provides examples of properly completed tables.)

7. You provided a 510(k) Summary in your submission. However, there are several mistakes in your output characteristics. In order to accurately describe your device, please revise the frequency and pulse width in the 510(k) Summary.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

8. You provided a label for the control unit. However you did not provide labeling for the insertion unit. Also, symbols on your label were not accompanied by a description on the product label. In order for the Agency to complete its review, please provide sample labeling for the insertion unit and revise the control unit label to describe the symbols used. You may find additional guidance for labeling using the following:

    k. ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm

    l. Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf

XVIII. Recommendation

Regulation Number: 21 CFR 876.5320
Regulation Name: Stimulator, Electrical, Non-implantable, for incontinence
Regulatory Class: Class II
Product Code: KPI, HCC – biofeedback device

It is recommended that the sponsor be sent an SE letter. All deficiencies have been addressed.

Reviewer — Date: 21 Feb 2012

Branch Chief (ACTING) — Date: 2/21/2012

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8138.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

ISO In Vitro Cytotoxicity Study (ISO 10993-5:2009) – L929	
Test Report Documentation	
Report #: JN11L0256 Report Date: January 3, 2012 Test Facility Name: Geneva Laboratories Facility City, State: Elkhorn, WI	FDA Submission Number: **K 110179 S2** Submission page/Att: Sec 018 S2 submission

ISO In Vitro Cytotoxicity Study (ISO 10993-5:2009) – L929 (Qualitative and Quantitative Test)			
Device Tested			
Test Article	☐ Finished sterilized device ☒ Other* Finished, non-sterilized devices. This is considered acceptable, given that the device will be used in a non-sterile area of the body (vagina).		*Describe test article and check with focal point on acceptability of the justification for not testing the finished sterilized device.
Were only the direct and indirect patient contacting portions of the device tested?	☒ Yes	☐ No*	*If No, describe what has been tested and check with focal point on acceptability of the justification for not testing only the direct and indirect patient contacting portions of the device.
Was the study done under GLP conditions?	☒ Yes	☐ No*	*If No, ask sponsor to justify why not done under GLP requirements (for IDE and PMA submissions).
Extraction Conditions			
Test Article Extraction Ratio	☐ 6 cm^2: ml (<0.5mm thick) ☒ 3 cm^2: ml (>0.5mm thick) Test Article and negative and positive controls ☐ 1.25 cm^2: ml (elastomer >1mm thick) ☐ 0.2 g: ml (elastomers)* ☐ 0.1 g: ml (non-elastomers)* ☐ Other*:		*Check with focal point if weight based extraction conditions or non-traditional extraction conditions are used.
Extraction Vehicle(s)	☒ Culture medium with serum ☐ Culture medium without serum* ☐ Physiological saline solution* ☐ Other suitable solvent*		* Check with focal point if non-traditional extraction vehicles are used.
Time/ Temperature	☒ 24 h at 37°C (required for Culture medium with serum) ☐ 50°C for 72h* ☐ 70°C for 24h* ☐ 120°C for 1h* ☐ Other*:		* Check with focal point on acceptability of time/temperature conditions.
pH Adjustment made to the sample extract	☐ Yes*	☒ No	*If Yes, describe the adjustment and check with focal point on the acceptability of the justification for adjusting the pH.
The Sample extract is filtered, centrifuged, diluted or processed in any other way	☐ Yes*	☒ No	*If Yes, describe the adjustment and check with focal point on the acceptability of the justification for the dilution.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

ISO In Vitro Cytotoxicity Study (ISO 10993-5:2009) – L929 (Qualitative and Quantitative Test)			
Study Controls	☒ Extraction vehicles without test material ☒ Extract of material with no cytotoxic response* ☒ Extract of material with cytotoxic response* ☐ Other*: _____		* Check with focal point on acceptability of controls.
Appearance of Extract	☒ Clear ☐ Cloudy* ☐ Particulates present in solution* ☐ Color*: _____		* Ask sponsor to explain extract appearance and justify validity of test results.
Extract Storage Conditions	☒ Used immediately ☐ Not mentioned in report* ☐ Storage Time*: 24 hrs_____ ☐ Storage Temperature*: Room Temp____		* Ask for updated test report to include description of storage conditions, and/or ask sponsor to justify why storage will not affect results, and check with focal point on validity of justification.
Methods			
Test System	☒ L-929 Mouse fibroblasts ☐ Suspension ☒ Monolayer ☐ Other*: _____		* Check with focal point on acceptability of test system.
Assessment Times after Treatment	☒ Required: 24h at 37°C ☐ Other*_____		* Check with focal point if assessments do not include 24h time point and/or if non-traditional assessment times are included.
Assessment Methods (Qualitative Score of 2 or less may be acceptable)	☒ Qualitative evaluation: Test and control cultures assessed microscopically for changes in general morphology, vacuolization, detachment, cell lysis, and membrane integrity. Graded according to the following scale: 0 = No cytotoxicity 1 = Slight cytotoxicity 2 = Mild cytotoxicity 3 = Moderate cytotoxicity 4 = Severe cytotoxicity ☐ Quantitative evaluation: Measure cell death, inhibition of cell growth, cell proliferation or colony formation. The number of cells, amount of protein, release of enzymes, release of vital dye, reduction of vital dye or any other measurable parameter may be quantified by objective means (e.g., >30% reduction of cell viability is considered cytotoxic). * ☐ Other*: _____		* Check with focal point if non-traditional methods were used or if any quantitative parameters are observed.
Deviations	☐ Yes*	☒ No	*If Yes, describe the deviation, and check with focal point on acceptability of the justification for how the deviation may impact the results of the study.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

ISO In Vitro Cytotoxicity Study (ISO 10993-5:2009) – L929 (Qualitative and Quantitative Test)			
Results			
Did Study Cells Appear Normal Throughout the Study?	☒ Yes GIVEN "0" RESULT OBTAINED FROM BOTH NEGATIVE CONTROLS	☐ No*	* Check with focal point on acceptability of results.
Cell abnormalities reported?	☐ Yes*	☒ No	*If Yes, check with focal point to assess whether deaths are related to the use of the treatment extract, or to procedural issues.
Cytotoxicity Scores in Controls and Treated Cells Different?	☐ Yes*	☒ No	*If Yes, check with focal point to assess the extract should be considered cytotoxic.
Conclusion			
Cytotoxic Potential	☒ Non-Cytotoxic ☐ Cytotoxic*		*If the extract has cytotoxic potential, check with focal point.
Other comments			
Recommendation			
☒ Acceptable ☐ Unacceptable If Unacceptable, please discuss what the company will need to provide to resolve this issue:			

Draft: MTB 8-29-07
Revisesd: MTB 9-14-07
Revised: ESM 10-25-07; RKP 11/26/07, JZM/JLG 10/12/10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

ISO Maximization Sensitization Study (ISO 10993-10:2002)	
Test Report Documentation	
Report #: JN11L0258 and JN11L0257 Report Date: January 16, 2012 Test Facility Name: Geneva Laboratories Facility City, State: Elkhorn, WI	FDA Submission Number: K110179 S2 Submission page/Att: Sec 020, S2

ISO Maximization Sensitization Study (ISO 10993-10:2002)			
Device Tested			
Test Article	☐ Finished sterilized device ☒ Other* Finished, non-sterilized devices. This is considered acceptable, given that the device will be used in a non-sterile area of the body (vagina) and given that the extraction time and temperature far exceeded the clinical time and any leachables would be extracted.		*Describe test article and check with focal point on acceptability of the justification for not testing the finished sterilized device.
Were only the direct and indirect patient contacting portions of the device tested?	☐ Yes	☐ No*	*If No, describe what has been tested and check with focal point on acceptability of the justification for not testing only the direct and indirect patient contacting portions of the device.
Was the study done under GLP conditions?	☒ Yes	☐ No*	*If No, ask the sponsor to justify why not done under GLP requirements (for IDE and PMA submissions).
Extraction Conditions			
Test Article Extraction Ratio	☐ 6 cm^2: ml (<0.5mm thick) ☒ 3 cm^2: ml (>0.5mm thick) test articles ☐ 1.25 cm^2: ml (elastomer >1mm thick) ☐ 0.2 g: ml (elastomers)* ☐ 0.1 g: ml (non-elastomers)* ☐ Other*:		*Check with focal point if weight based extraction conditions or non-traditional extraction conditions are used.
Extraction Vehicle(s)	☒ Required: 0.9% Sodium chloride [P]* (In report #JN11L0257) ☐ Required: Vegetable oil [NP]* ☒ Other*: Cotton Seed Oil (In report #JN11L0258)		* Check with focal point if test does not include both polar [P] and non-polar [NP] extracts and/or if non-traditional extraction vehicles are used.
Time/Temperature	☐ 37°C for 120h ☐ 37°C for 72h* ☒ 50°C for 72h ☐ 70°C for 24h ☐ 121°C for 1h ☐ Other*:		* Check with focal point on acceptability of time/temperature conditions.
pH Adjustment	☐ Yes*	☒ No	*If Yes, describe the adjustment and check with focal point on the acceptability of the justification for adjusting the pH.
Dilution	☐ Yes*	☒ No	*If Yes, describe the adjustment and check with

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ISO Maximization Sensitization Study (ISO 10993-10:2002)		
		focal point on the acceptability of the justification for the dilution.
Study Controls	☒ Extraction vehicles without test material ☐ Other*:	* Check with focal point on acceptability of controls.
Positive Controls	☒ Dinitrochlorobenzene (DNCB)* ☐ Same source, strain, and treatment methods used for positive control testing and done within 3 months of test article test date?*	* If not, then the company should be asked to justify why testing should be considered capable of detecting a positive sensitizing response.
Appearance of Extract	☒ Clear ☐ Cloudy* ☐ Particulates present in solution* ☐ Color*: _____	* Ask sponsor to explain extract appearance and justify validity of test results.
Extract Storage Conditions	☒ Used immediately ☐ Not mentioned in report* ☐ Storage Time*: _____ ☐ Storage Temperature*: _____	* Ask for updated test report to include description of storage conditions, and/or ask sponsor to justify why storage will not affect results, and check with focal point on validity of justification.
Methods		
Test System	☒ 10 test and 5 guinea pigs /extract (5 for Positive and 5 for negative controls) # Male animals: _____ # Female animals: 20___ Source: Charles River Laboratories_____ Strain: _____ ☒ If female animals used, the report states that the animals are nulliparous and not pregnant* ☐ Other*:	*Check with focal point on acceptability of test system. Note: Pregnant female animals are less likely to demonstrate a positive sensitization reaction with known sensitizing agents.
Induction Phase I	☒Three pair of intrademal injections given on the backs of test animals: Test animals 1. 0.1 ml of a 1:1 FCA†/vehicle mixture 2. 0.1 ml of test extract 3. 0.1 ml of a 1:1 mixture of the 1:1 FCA and test extract Control animals 1. 0.1 ml of a 1:1 FCA†/vehicle mixture 2. 0.1 ml of vehicle 3. 0.1 ml of a 1:1 mixture of the 1:1 FCA and test extract ☐ Other*: _____	* Check with focal point on acceptability of the alternate method used.
Preparation for Induction II	☒ Day 6 after injection (approximately 24h before Induction II), injection sites clipped and treated with a 10% sodium lauryl sulfate (SLS) in petroleum jelly. Any remaining SLS to be removed prior to Induction II treatment. ☐ Other*: _____	* Check with focal point on acceptability of the alternate method used
Induction Phase II	☒ Day 7 after injection, 2x4 cm filter paper patches saturated	* Check with focal point on

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ISO Maximization Sensitization Study (ISO 10993-10:2002)			
	(~0.3 ml) with test extract or control vehicle applied to injection area for 48 hours. Patches removed after 48 hours. ☐ Other*: _____		acceptability of the alternate method used
Challenge Phase	☒ Fourteen days after removal of Induction patches, the right and left flank areas of each guinea pig is clipped and 2x2 cm patches saturated (~0.3 ml) with test extract or control vehicle are prepared. One flank is treated with patch containing the test extract, while the other flank is treated with the control vehicle. Patches are left in place for 24 hours before removal. ☐ Other*:		* Check with focal point on acceptability of the alternate method used
Assessment Times after Challenge Patch removal	☒ Required: 24h* ☒ Required: 48h* ☒ 72h* ☐ Other*: _____		* Check with focal point if assessments do not include 4h, 24h, 48h, and 72h time points and/or if non-traditional assessment times are included.
Scoring of Challenge Patch Treatment Sites	☒ Test and control challenge patch sites assessed according to the following scale: * 0 = no visible change 1 = Discrete erythema 2 = Moderate erythema 3 = Severe erythema and edema ☐ Other*: _____		* Check with focal point if non-traditional methods were used.
Deviations	☐ Yes*	☒ No	*If Yes, describe the deviation, and check with focal point on acceptability of the justification for how the deviation may impact the results of the study.
Results			
Did Study Animals Appear Normal Throughout the Study?	☒ Yes	☐ No*	* Check with focal point on acceptability of results.
Deaths reported?	☐ Yes*	☒ No	*If Yes, check with focal point to assess whether deaths are related to the use of the treatment extract, or to procedural issues.
Erythema and Edema Scores in Extract Controls and Treated Animals Different?	☐ Yes*	☒ No	*If Yes, check with focal point to assess whether erythema and edema scores reported suggest the extract should be considered a potential sensitizer.
Erythema and Edema Scores in Positive Controls and Treated Animals Different?	☒ Yes	☐ No*	*If No, check with focal point to assess whether erythema and edema scores reported suggest the extract should be considered a potential sensitizer.
Conclusion			
Sensitizing Potential	☒ Non-Sensitizing		*If the extract has

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ISO Maximization Sensitization Study (ISO 10993-10:2002)		
	☐ Sensitization Potential*	sensitizing potential, check with focal point.
Other comments		
Recommendation		
☒ Acceptable ☐ Unacceptable If Unacceptable, please discuss what the company will need to provide to resolve this issue:		

†FCA – Freund's Complete Adjuvant
Draft: MTB 8-29-07
Updated: MTB 9-12-07
Revised: jlg 9-19-07

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Valdes, Thelma

From: mjleigh@wi.rr.com
Sent: Thursday, February 16, 2012 11:14 PM
To: Valdes, Thelma
Subject: RE: K110179 In Control - Software

Attachments: FDA3654 - IEC60601-1.pdf; FDA3654 - IEC60601-1-2.pdf; FDA3654-ISO10993-5.pdf; FDA3654-ISO10993-10.pdf

FDA3654 - C60601-1.pdf (2 MB)

FDA3654 - IEC60601-1-2.pdf (2 ...

FDA3654-ISO10993 -5.pdf (868 KB...

FDA3654-ISO10993 -10.pdf (885 K...

Ms. Valdes,

Attached is a FDA 3654 for each standard: IEC60601-1, IEC60601-1-2, ISO10993-5, and ISO10993-10. There were not deviations, but each electrical standard requires choice as to the type and group of equipment. These are identified.

Michael Leigh

---- "Valdes wrote:
> Mr. Leigh,
>
> I cannot locate your FDA forms 3654, which lists all of the standards that you used, and asks if there were any deviations.
> Please let me know where I can locate them or please fill them out and return to me by COB Friday, 2/16.

> Thank you,
> Thelma Valdes
>
> http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf
>
> ---
> Thelma Valdes, Ph.D.
> Biomedical Engineer
> The Food and Drug Administration
> Center for Devices and Radiological Health
> Office of Device Evaluation
> Division of Reproductive, Gastro-Renal, and Urological Devices
> Urology and Lithotripsy Devices Branch
> WO66 Room G274
> 10903 New Hampshire Ave.
> Silver Spring, MD 20993-0002
> tel. (301) 796-9621
> thelma.valdes@fda.hhs.gov
>
>
> -----Original Message-----
> From: mjleigh@wi.rr.com [mailto:mjleigh@wi.rr.com]
> Sent: Thursday, February 16, 2012 2:07 PM
> To: Valdes, Thelma
> Cc: Seiler, Jim; Chan, Dulciana
> Subject: Re: K110179 In Control - Software
>
> Ms. Valdes,

> There are two revision history documents included in the latest update; one for the Control Unit's embedded firmware, and one for the clinical PC application. These each summarize the changes made. The histories primarily cover the period from the first

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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release candidate last January through January of this year. These changes are the result of continuing development to improve the product based on design team (and their consultants') feedback. This evening, I can provide the specific document numbers, if necessary. If the summary is not adequate, we can provide the specific code with "was" `d "is" comparisons. Do you wish the analyze the actual code changes?

> The test records included in this update reference the versions that were tested. They are also dated (as is the updates in the revision histories. Each test is planned based on its objectives and the changes made since the previous test pass. The set of tests records provided in the most recent update includes the most recent examples in each area of testing.
>
> Michael Leigh
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>
> ---- "Valdes wrote:
> > Mr. Leigh,
> >
> > We continue to review your submission, and some questions have come up on the Software validation.
> >
> > Could you please provide a table, or bullet list for us (or let us know where in the submission we can find it) listing :
> >
> > * The specific changes you have made to the software in this submission and
> > * The location of these changes in the validation report
> >
> > Having this information readily available to us, will expedite our continuing review process.
> > If you could provide to me as soon as possible, I would greatly appreciate it.
> >
> >
> Thank you,
> Thelma
> >
> >
> >
> > ---
> > Thelma Valdes, Ph.D.
> > Biomedical Engineer
> > The Food and Drug Administration
> > Center for Devices and Radiological Health
> > Office of Device Evaluation
> > Division of Reproductive, Gastro-Renal, and Urological Devices
> > Urology and Lithotripsy Devices Branch
> > WO66 Room G274
> > 10903 New Hampshire Ave.
> > Silver Spring, MD 20993-0002
> > tel. (301) 796-9621
> > thelma.valdes@fda.hhs.gov
> >
> >
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1:1988+A1:1991+A2:1995 Medical Electrical Equipment Part 1: General Requirements for Safety

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 5-4		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1 = 1988 + A1 = 1991 + A2 = 1995

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.2	Degree of Protection against shock	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •
Type BF Applied Part

DESCRIPTION
Device necessarily comes in contact with patient

JUSTIFICATION
Device has conductive contact with patient

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.5	Equipment not suitable for use in the presence of flammable mixtures	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION
Device not intended for use in the presence of flammable mixtures

JUSTIFICATION
Device has conductive surfaces and is not intended for use around flammable mixtures

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.1	Type of Protection against electric Shock	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •
Internally powered equipment

DESCRIPTION

JUSTIFICATION
Device is battery operated

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

• Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2 = 2nd and 3rd Editions Medical Electrical Equipment - Part 1-2 = General Requirements for Basic Safety and Essential Performance - Collateral Standard

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-28	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-2 = 2nd and 3rd Editions Medical Electrical Equipment = Part 1-2 General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.1.1.1	Classification	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •
Class B Group 1

DESCRIPTION Class B = suitable for use in domestic establishments and establishments directly connected to a low voltage power supply. Group 1 = un-intentional transmitter

JUSTIFICATION
Devices is for use in homes and healthcare facilities, RF energy is necessary for function.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

• Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]
ANSI/AAMI/ISO 10993-5:2009(E) Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 2-153		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of ISO 10993 ..."

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and delayed-type hypersensitivity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 2-87		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of ISO 10993..."

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication].

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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Valdes, Thelma

rm: mjleigh@wi.rr.com
nt: Sunday, February 19, 2012 5:55 PM
To: Valdes, Thelma
Subject: RE: K110179 In Control - Software

Attachments: 510(k) Summary.pdf; 510(k) Summary.2.pdf; manual Rev1g draft.pdf

510(k) Summary.pdf (90 KB) 510(k) Summary.2.pdf (157 KB) manual Rev1g draft.pdf (830 KB...

Ms. Valdes,

Attached are three files for the two documents addressing the points in your email.

The first two are the updated 510(k) Summary. The first of these has the referenced regulation corrected. The second is the landscape comparison table.

The third attachment is an updated User Manual with the warning on page 7 removed.

Thanks,
Michael Leigh

---- "Valdes wrote:
Mr. Leigh,

> Thank you again. We have just a couple of minor, additional concerns, that I would ask you address by COB Monday 2/20.
>
>
> 1. The 510(k) Summary has the incorrect regulation number. It should be 876.5320.
>
> 2. Please revise the labeling to delete the warning on page 7 that states, "The reusable Insertion Unit presents a potential risk of cross-infection, particularly if used on broken skin." The warning I had asked you to add is much clearer, making the other warning unnecessary.
>
> Thank you very much,
>
> Thelma Valdes
>
>
>
>
>
>
> -----Original Message-----
> From: mjleigh@wi.rr.com [mailto:mjleigh@wi.rr.com]
> Sent: Thursday, February 16, 2012 11:14 PM
> To: Valdes, Thelma
> Subject: RE: K110179 In Control - Software
>
> Ms. Valdes,

Attached is a FDA 3654 for each standard: IEC60601-1, IEC60601-1-2, ISO10993-5, and ISO10993-10. There were not deviations, but each electrical standard requires choice as to the type and group of equipment. These are identified.
>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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> Michael Leigh
>
>
> ---- "Valdes wrote:
> Mr. Leigh,
> >
> > I cannot locate your FDA forms 3654, which lists all of the standards that you used, and asks if there were any deviations.
> > Please let me know where I can locate them or please fill them out and return to me by COB Friday, 2/16.
> >
> > Thank you,
> > Thelma Valdes
> >
> > http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf
> >
> > ----------
> > Thelma Valdes, Ph.D.
> > Biomedical Engineer
> > The Food and Drug Administration
> > Center for Devices and Radiological Health
> > Office of Device Evaluation
> > Division of Reproductive, Gastro-Renal, and Urological Devices
> > Urology and Lithotripsy Devices Branch
> > WO66 Room G274
> > 10903 New Hampshire Ave.
> > Silver Spring, MD 20993-0002
> > tel. (301) 796-9621
> > thelma.valdes@fda.hhs.gov
> >
> >
> > -----Original Message-----
> > From: mjleigh@wi.rr.com [mailto:mjleigh@wi.rr.com]
> > Sent: Thursday, February 16, 2012 2:07 PM
> > To: Valdes, Thelma
> > Cc: Seiler, Jim; Chan, Dulciana
> > Subject: Re: K110179 In Control - Software
> >
> > Ms. Valdes,
> >
> > There are two revision history documents included in the latest update; one for the Control Unit's embedded firmware, and one for the clinical PC application. These each summarize the changes made. The histories primarily cover the period from the first release candidate last January through January of this year. These changes are the result of continuing development to improve the product based on design team (and their consultants') feedback. This evening, I can provide the specific document numbers, if necessary. If the summary is not adequate, we can provide the specific code with "was" and "is" comparisons. Do you wish the analyze the actual code changes?
> >
> > The test records included in this update reference the versions that were tested. They are also dated (as is the updates in the revision histories. Each test is planned based on its objectives and the changes made since the previous test pass. The set of tests records provided in the most recent update includes the most recent examples in each area of testing.
> >
> > Michael Leigh
> >
> >
> >
> > ---- "Valdes wrote:
> > > Mr. Leigh,
> > >
> > > We continue to review your submission, and some questions have come up on the Software validation.
> > >
> > > Could you please provide a table, or bullet list for us (or let us know where in the submission we can find it) listing :

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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> > >
> > > * The specific changes you have made to the software in this submission and
> > > * The location of these changes in the validation report
> > >
> > Having this information readily available to us, will expedite our continuing review process.
> > > If you could provide to me as soon as possible, I would greatly appreciate it.
> > >
> > >
> > > Thank you,
> > > Thelma
> > >
> > >
> > >
> > > ---
> > > Thelma Valdes, Ph.D.
> > > Biomedical Engineer
> > > The Food and Drug Administration
> > > Center for Devices and Radiological Health
> > > Office of Device Evaluation
> > > Division of Reproductive, Gastro-Renal, and Urological Devices
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510(k) Summary for InControl InTone

Submitter:	InControl Medical, LLC
Address:	3225 Gateway Road, Suite 250 Brookfield, Wisconsin 53045
Corporate Contact:	Herschel Peddicord, President InControl Medical, LLC
Telephone:	Ph: (414) 429-2625
Establishment Registration #:	to be registered following 510(k)
Submission Contact:	Michael J. Leigh, consultant 12715 Falcon Drive Brookfield, Wisconsin 53005 Ph: (262) 957-6797
Trade Name:	InControl InTone
Predicate Device:	Otto Bock STIWELL med, K080950 MyoTrac Infiniti, K053434 Hollister evadri, K050483
Common Name:	Stimulator, Electrical, Non-Implantable, for Incontinence

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
876.5320	KPI	Non-implanted electrical continence device	II

Device Description:

The device includes three parts; an insertion probe and a hand-held control unit. The insertion probe features an inflatable balloon that provides more adaptable fit for intra-vaginal use. The probe includes stainless steel electrodes to deliver electro-stimulation. The hand-held control and display device records, stores, and displays the results of electro-stimulation and patient generated pelvic floor exercises. It allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. It also stores data on contraction pressure for later review. The PC application allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

Intended Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

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Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Performance Data:

Complete EMC, electrical, mechanical, safety (operator and patient), temperature/humidity, and software testing demonstrate compliance with applicable standards. The results demonstrate that the InControl InTone device is in compliance with the guidelines and standards referenced in the FDA reviewer's guides, and that it performed within its specifications and functional requirements for the device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with FDA requirements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Feature/ Function	InControl InTone (new device)	Otto Bock STIWELL med4 (K080950)	MyoTrac Infiniti (K053434)	Hollister evadri (K050483)	Comparison
Labeling					
Intended Use An explicit description of all clinical functions performed by the device, **Indications for Use** Explain when the device is to be clinically used and the intended patient population	The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.	The STIWELL med4 is a neuromuscular electronic stimulator for use under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions. As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions: • Acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscles through reflexive mechanisms and strengthening of the pelvic floor muscles. • Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles. As a biofeedback device the STIWELL med4 is indicated for the following conditions: • Biofeedback, relaxation and muscle re-education purposes.	Treatment of urinary incontinence EMG biofeedback The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge, or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detruser muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.	The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary or fecal (electromyographic biofeedback) incontinence.	Equivalent
Warnings or Precautions	(see product labeling)	(see product labeling)	(see product labeling)	(see product labeling)	Equivalent

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8[illegible]

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Contraindications Explain when the device is not to be clinically used	• This device is not intended for diagnostic purposes or critical patient monitoring. • The device is not defibrillator proof. • The device should not be used on patients with cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance. • Do not use if patient has symptoms of an active urinary tract infection. • Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms. • Do not use if patient has undiagnosed pain. • Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation. • Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings. • Do not use if patient is currently pregnant or attempting to get pregnant. • Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit. • Do not use if the patient has irregular menstrual bleeding cycles. • Do not use if the patient has a history or symptoms of urinary retention. • Do not use if the patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra). • Do not use if the patient has overflow incontinence caused by evacuation problems. • Do not use if the patient has severe urine retention in the upper urethras. • Do not use if the patient has complete peripheral denervation of the pelvic floor. • Do not use if the patient has an intestinal clamp.	• Patients with pacemakers or other electronic emitters. • No stimulation in the proximity of metal implants. • Pregnancy • Feverish or infectious diseases • Skin disorders subject to inflammation or tumors in the stimulation area, as well as thrombosis or phlebitis • Patients with extra-urethral incontinence (fistula, ectopic urethra) • Patients with overflow incontinence caused by evacuation disorders • Patients with serious urine retention in the upper urethra • Patients with total peripheral denervation of the pelvic floor • Patients with intestinal clamps	• Patients with an implanted electronic device (for example cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained. • Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions • Stimulation should not be applied over cancerous lesions • Not for use with patients with undiagnosed pain conditions. • Do not use if you have symptoms of bladder infection. • Do not use with diminished mental capacity or physical competence limiting the use of the device • Safety of powered muscle stimulators during pregnancy has not been established.		Equivalent
Labeling Summary Clarity to insure safer or more effective use	User Manual	User Manual	User Manual	User Manual	Identical (to all)
Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)
Power Source	4/5 AA nickel metal hydride battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Method of line current isolation	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Patient leakage current	n/a (battery)	n/a (battery)	n/a (battery)	unknown	Identical (to Otto Bock, MyoTrac)
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)
Regulated current or voltage?	Regulated voltage	Regulated current	Unknown	Unknown	Equivalent
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic No-Load Trip?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display **On/Off Status** **Low Battery**	Yes Yes	Yes Yes	Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	[redacted] (b)(4) TS	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency **Mixed** **Stress** **Urge**		35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Within range (of MyoTrac, Hollister)
Pulse width **Mixed** **Stress** **Urge**		300 µs/phase 500 µs/phase	0.2 ms	0.3 or 1 ms	Within range
Time **On** **Off**		9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	2 - 20 secs 2 - 50 secs	1 - 80 secs 0 - 80 secs	Equivalent
Total Session Time		5 - 25 mins	0 - 120 mins	1 - 30 mins	Within range
Max output voltage (500Ω)		50 Vdc	30 Vdc	30 Vdc	Identical (to Otto Bock)
Max output current (500Ω)		100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)		50 µC	60 µC	Unknown	Identical (to Otto Bock)
Electrode surface area		21.2 cm^2	Various, 1.53 cm^2 to 10.5 cm^2	unknown	Equivalent
Max current density		4.7 mA/ cm^2	Various, 4.7 mA/ cm^2 to 32 mA/ cm^2		Identical
Maximum power density (500Ω)		23.5 µW/ cm^2	Various, 11.32 µW/ cm^2 to 22.84 µW/ cm^2	Unknown	Equivalent
Biofeedback		EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)
Materials					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016

Dimensions	8 x 5 x 4 inches	175 x 95 x 30 mm	102 x 152 x 51 mm	100 x 70 x 130 mm	Equivalent
Control housing	ABS plastics	plastics	plastics	plastics	Equivalent
Insertion material	Silicone, plastics	plastics	plastics	plastics	Equivalent
Packaging or Expiration Dating	1 year for insertion unit	N/A	N/A	N/A	
Sterilization	N/A	N/A	N/A	N/A	
User Interaction and Software					
Operational Method: Clinical Use e.g., ambulatory use, home use	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Clinic or Home use, under direction of physician	Identical (to all)
Patient Interaction: Functions Controllable An explanation of how the device interacts with the patient.	The patient can control the starting and stopping of each session. However, the device will stop on its own once the session in normally completed.				Equivalent
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	None, programming can only be changed by clinician	None, programming is locked by clinician	None, programming is locked by clinician		Equivalent (to Otto Bock MyoTrac)
Override	Yes	Yes			Identical (to Otto Bock)
Patient Interaction: Operator Requirements Knowledge or training required of the operator,	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Identical (to all)
Software Level of Concern A statement indicating the Level of Concern and a description of the rationale for that level.	Moderate				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8119.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Feature/ Function	InControl InTone (new device)	Otto Bock STIWELL med4 (K080950)	MyoTrac Infiniti (K053434)	Hollister evadri (K050483)	Comparison
Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)
Power Source	Nickel metal hydride battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)
Regulated current of voltage?	Regulated voltage	Regulated current	Unknown	Unknown	Equivalent
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display **On/Off Status** **Low Battery**	Yes Yes	Yes Yes	Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	[redacted] (b)(4) TS	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency **Mixed** **Stress** **Urge**		35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Identical (to MyoTrac, Hollister)
Pulse width **Mixed** **Stress** **Urge**		300 µs/phase 500 µs/phase	0.2 ms	0.3 or 1 ms	Within range
Time **On** **Off**		9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	2 - 20 secs 2 - 50 secs	1 - 80 secs 0 - 80 secs	Within range
Total Session Time		5 - 25 mins	0 - 120 mins	1 - 30 mins	Within range
Max output voltage (500Ω)		50 Vdc	30 Vdc	30 Vdc	Identical (to Otto Bock)
Max output current (500Ω)		100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)		50 µC	60 µC	Unknown	Identical (to Otto Bock)
Electrode surface area		21.2 cm^2	Various, 1.53 cm^2 to 10.5 cm^2	unknown	Equivalent
Max current density		4.7 mA/ cm^2	Various, 4.7 mA/ cm^2 to 32 mA/ cm^2		Identical
Maximum power density (500Ω)		23.5 µW/ cm^2	Various, 11.32 µW/ cm^2 to 22.84 µW/ cm^2	Unknown	Equivalent
Biofeedback		EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

⚠ **Warning:** Only use approved antiseptics that leave no residue.

⚠ **Warning:** The InTone system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

⚠ **Warning:** The InTone system is intended for single patient use only. Do not share use of your InTone devices. Improper treatment or cross-infection may occur.

⚠ **Warning:** Therapy is defined on an individual basis, dependent on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

⚠ **Warning:** Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

⚠ **Warning:** Do not operate device within 10 feet of operating televisions, arc welders, radio thermal treatment equipment, X-ray machines, MRI machines, or any other equipment that produces magnetic fields, sparks, or radio transmissions. RF communications equipment can affect this device

⚠ **Warning:** Explosion hazard: Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen enriched environments.

⚠ **Warning:** Take care in arranging patient and cables to avoid risk of entanglement, tripping, or strangulation.

⚠ **Warning:** Use of any equipment should be discontinued upon any signs of treatment related stress or discomfort.

⚠ **Warning:** The device should not be used while walking, driving, operating machinery, or any other

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8138

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Valdes, Thelma

From: mjleigh@wi.rr.com
nt: Wednesday, February 15, 2012 2:32 PM
To: Valdes, Thelma
Subject: K110179

Attachments: Fwd: FW: InControl Medical's InTone testing question

Fwd: FW: InControl Medical's I...

Ms. Valdes,

InControl has followed up with the lab that performed biocompatibility testing on the InTone device. Their answer is attached. The exterior of the insertion unit was extracted for the testing. This is the part of the device that comes in contact with vaginal mucous membranes. Also, the part is not sold sterile and was not sterilized prior to this testing.

Mike
Michael Leigh

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Valdes, Thelma

From: Michael Leigh [michaeljamesleigh62@gmail.com]
Sent: Wednesday, February 15, 2012 2:27 PM
To: mjleigh@wi.rr.com
Subject: Fwd: FW: InControl Medical's InTone testing question

---------- Forwarded message ----------
From: **Jason Lemke** <jlemke@incontrolmedical.com>
Date: Wed, Feb 15, 2012 at 1:04 PM
Subject: FW: InControl Medical's InTone testing question
To: "Michael J. Leigh (michaeljamesleigh62@gmail.com)" <michaeljamesleigh62@gmail.com>

See below for Geneva Lab's reply.

Thanks,

Jason

From: Vince Lazzaroni [mailto:vlazzaroni@preservationsolutions.com]
Sent: Wednesday, February 15, 2012 10:30 AM
To: Jason Lemke
Cc: Pat Brotzman
Subject: Fw: InControl Medical's InTone testing question

Hi Jason,

As we had discussed when originally setting up the series of biocompatibility tests, we had sealed off the opening of the unfinished devices with a medical grade silicone so that the complete exterior surface could be extracted. (So the in answer to Question 1, the entire exterior surface was extracted/tested...) There was, however, no sterilization of the devices before testing. (Is this device intended to be sterilized before use, or only sanitized/disinfected?)

Thanks, and let me know if there are any additional questions.

Vince Lazzaroni

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Department Manager - Microbiology
Geneva Laboratories, Inc.
Ph (262)723-6715 (c/o PSI) Fax (262)723-4015
vlazzaroni@preservationsolutions.com

----- Original Message -----

From: Pat Brotzman

To: 'Vince Lazzaroni'

Sent: Wednesday, February 15, 2012 7:31 AM

Subject: FW: InControl Medical's InTone testing question

From: Jason Lemke [mailto:jlemke@incontrolmedical.com]
Sent: Tuesday, February 14, 2012 6:47 PM
To: Pat Brotzman
Cc: Shannon Butler; Lani Smith
Subject: InControl Medical's InTone testing question

Hi Pat,

The FDA has sent an email requesting some information regarding the extraction process that was performed on our devices. Could you or any personnel best suited answer the following as detailed as possible?

1. **What parts/portions of the device were tested/extracted?**

2. **Was the testing was conducted on finished, sterilized or un sterilized devices?**

Thank you very much for your time!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Jason

Jason Lemke

Director In-House Technical Solutions

InControl Medical LLC

262-373-0422 (business)

920-285-1104 (Cell)

262-373-0463 (fax)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Valdes, Thelma

From: mjleigh@wi.rr.com
Sent: Wednesday, February 15, 2012 8:10 PM
To: Valdes, Thelma
Cc: michaeljamesleigh62@gmail.com
Subject: RE: K110179

Attachments: manual Rev1f draft.pdf

manual Rev1f draft.pdf (831 KB...

Thelma,

Attached is an update to the manual with the following warning added on pages 7 and 19.

Warning: The InTone system is intended for single patient use only. Do not share use of your InTone devices. Improper treatment or cross-infection may occur.

Thank you,
Mike

---- "Valdes wrote:
> Mr. Leigh,
>
> I know the device is intended for a single patient use, but there is no statement in the beling that confirms this. Could you please add a statement to your labeling in the Warning" sections that this device is intended for single patient use? We would need to have that be very explicit in the labeling, so there is no confusion that 1 device could be used on multiple patients.
>
> If you could provide me the updated labeling by mid-day Friday 2/17, I would greatly appreciate it.
>
> Thank you,
>
> Thelma
>
> -----Original Message-----
> From: mjleigh@wi.rr.com [mailto:mjleigh@wi.rr.com]
> Sent: Wednesday, February 15, 2012 2:32 PM
> To: Valdes, Thelma
> Subject: K110179
>
> Ms. Valdes,
>
> InControl has followed up with the lab that performed biocompatibility testing on the InTone device. Their answer is attached. The exterior of the insertion unit was extracted for the testing. This is the part of the device that comes in contact with vaginal mucous membranes. Also, the part is not sold sterile and was not sterilized prior to this testing.
>
> Mike
> Michael Leigh

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Chapter 4

Using the System

This chapter provides instructions for using the system. It includes both therapeutic treatment and biofeedback use instructions.

⚠ **Warning:** The InTone system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

Electro-stimulation and biofeedback are treatments used to train and strengthen the pelvic floor muscles in a controlled manner. Electro-stimulation is used to strengthen muscles. In particular, it improves the ability of muscles to hold a contraction of an extended period of time. It is a treatment for urinary incontinence in conjunction with coaching and biofeedback. During a session, electrical impulses are delivered to specific muscles to stimulate their contraction. This contraction exercises the muscles and also helps the patient recognize which muscles to condition.

Biofeedback provides visual confirmation of the patient's voluntary muscle contractions.

⚠ **Warning:** The InTone system is intended for single patient use only. Do not share use of your InTone devices. Improper treatment or cross-infection may occur.

⚠ **Warning:** Therapy is defined on an individual basis, dependant on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

Patient Use

A quiet, private place is recommended to aid relaxation. Many women prefer to do their sessions while in bed.

1. The patient lies in a semi-reclined position with knees slightly bent. The legs should be upright and tilted out slightly.
2. Press the On/Off button and follow the voice guided instructions

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8116

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

⚠ **Warning:** Only use approved antiseptics that leave no residue.

⚠ **Warning:** The InTone system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

⚠ **Warning:** The InTone system is intended for single patient use only. Do not share use of your InTone devices. Improper treatment or cross-infection may occur.

⚠ **Warning:** Therapy is defined on an individual basis, dependent on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

⚠ **Warning:** Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

⚠ **Warning:** Do not operate device within 10 feet of operating televisions, arc welders, radio thermal treatment equipment, X-ray machines, MRI machines, or any other equipment that produces magnetic fields, sparks, or radio transmissions. RF communications equipment can affect this device

⚠ **Warning:** The reusable Insertion Unit presents a potential risk of cross-infection, particularly if used on broken skin.

⚠ **Warning:** Explosion hazard: Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen enriched environments.

⚠ **Warning:** Take care in arranging patient and cables to avoid risk of entanglement, tripping, or strangulation.

⚠ **Warning:** Use of any equipment should be discontinued upon any signs of treatment related stress or discomfort.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8018.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Memo to the Record

Date: February 14, 2012

From: Dulciana D. Chan, Biomedical Engineer
Urology and Lithotripsy Devices Branch, DRGUD/ODE

Subject: K110179S/2
InControl Medical, LLC
InControl InTone

To: Thelma Valdes
Urology and Lithotripsy Devices Branch, DRGUD/ODE

Background:

This submission consists of responses to our November 4, 2011 additional information letter. I will review deficiencies numbered 3, 4, and 6.

Intended Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Submission Contents:

The deficiencies below (in bold) are from our November 4, 2011 additional information letter and followed by the sponsor responses:

3. You reduced your stimulation settings to be for mixed urinary incontinence and provided most output characteristics for your device. However, there are several characteristics that were not provided. In order to accurately describe your device, please provide the maximum power density, net charge, and indicate whether there is a burst mode and if so, the output characteristics of burst mode.

(b)(4) TS

[redacted]

4. You provided EMC testing, however some of the testing was incomplete. In order to ensure the safety of your device, please provide the following testing:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

a. emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker missions testing in stimulation and data transfer mode. These tests were performed only with the device in charging mode;

The sponsor stated that the device was tested in three modes; charging mode, use mode, and data transfer mode. The charging mode is the only mode in which the device is connected to mains power and thus potentially exposed to electrical fast transients/bursts, surge transients, voltage dips and intemrptions, harmonic emissions, and voltage fluctuations/flicker. In the other two modes, the unit is not connected to mains power and operates on battery. This applies to Conducted emission, harmonic emissions testing as well. The sponsor has provided an adequate justification and no further testing is necessary.

b. radiation emission testing on your device in stimulation mode at 100% stimulation or provide an adequate justification for the lower stimulation output. Your testing was performed in stimulation mode at 20% and 80% stimulation output; and

The UL test engineer reported that preliminary scans were made at 100%. Full testing was conducted at 20% and 80% because these lower levels showed more noise than the 100% level, however there was little difference between them. Since no significant difference in emissions was measured, testing was completed at these levels (Document 017). This is an adequate justification for testing at 20% and 80% stimulation output.

c. repeated immunity to electrostatic discharges testing or an adequate justification for the behavior of your device during testing. During testing in stimulation mode, treatment stops on a few sides of the device. The report stated that it is intended for the device to interrupt treatment when abnormal conditions are detected. However, treatment does not stop at all areas of the device.

The impact of electrostatic discharge may be different in different orientations or test points. The InTone processor will stop treatment if it detects abnormal conditions. The same discharge may not create abnormal conditions in the processor in every orientation. Some orientations may be parallel to the field and other perpendicular. Treatment was able to continue normally in some orientations (Document 017). This explanation is adequate and repeated immunity testing is not necessary.

6. You provided a user manual in your submission. However, there is a mistake and several omissions in the manual. To adequately inform users, please revise the following:

a. an explanation for the connection of the hand pump bulb to the insertion unit for proper inflation;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The sponsor stated that the hand pump bulb was incorporated into the insertion unit between the original submittal in January and the update in August 2011. The bulb cannot be connected, disconnected, or otherwise removed. The instructions for inflation and deflation have been expanded in the Manual (Document 022). This is adequate.

(b)(4) TS

[redacted]

The pulse width in the Manual (see Document 022, p 26) was corrected to (b)(4) and is now adequate.

c. EMC tables to your user manual. You stated conformance with EMC testing required by ISO 60601-1-2. However, you did not include the EMC tables required by ISO 60601-1-2. (Annex C of ISO 60601-1-2 provides examples of properly completed tables.)

EMC tables were added to the updated manual and includes tables 201, 204, and 206, as required by the standard (See Document 022, p24-25). This is adequate.

Recommendation:
The sponsor has adequately responded to deficiencies 3, 4, and 6.

_____
Dulciana D. Chan

Concurrence: _____
Janine M. Morris, Chief, ULDB

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Valdes, Thelma

From: mjleigh@wi.rr.com
Sent: Wednesday, February 15, 2012 8:10 PM
To: Valdes, Thelma
Cc: michaeljamesleigh62@gmail.com
Subject: RE: K110179

Attachments: manual Rev1f draft.pdf

manual Rev1f draft.pdf (831 KB...

Thelma,

Attached is an update to the manual with the following warning added on pages 7 and 19.

Warning: The InTone system is intended for single patient use only. Do not share use of your InTone devices. Improper treatment or cross-infection may occur.

Thank you,
Mike

---- "Valdes wrote:
> Mr. Leigh,
>
> I know the device is intended for a single patient use, but there is no statement in the labeling that confirms this. Could you please add a statement to your labeling in the "Warning" sections that this device is intended for single patient use? We would need to have that be very explicit in the labeling, so there is no confusion that 1 device could be used on multiple patients.
>
> If you could provide me the updated labeling by mid-day Friday 2/17, I would greatly appreciate it.
>
> Thank you,
>
> Thelma
>
> -----Original Message-----
> From: mjleigh@wi.rr.com [mailto:mjleigh@wi.rr.com]
> Sent: Wednesday, February 15, 2012 2:32 PM
> To: Valdes, Thelma
> Subject: K110179
>
> Ms. Valdes,
>
> InControl has followed up with the lab that performed biocompatibility testing on the InTone device. Their answer is attached. The exterior of the insertion unit was extracted for the testing. This is the part of the device that comes in contact with vaginal mucous membranes. Also, the part is not sold sterile and was not sterilized prior to this testing.
>
> Mike
> Michael Leigh

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional
Consulting Review
K110179/S002

Date: February 16, 2012
To: Thema Valdes, Ph.D. Office: ODE
From: James P. Seiler Division: DRGUD
510(k) Holder: InControl, Inc.
Device Name: InTone Device
Contact: Michael J. Leigh, Consultant

The consult request concerned Deficiency 2 (software) response to the January 24, 2011, additional information letter.

2. **You provided software documentation in Appendix C and via email. However, some requirement elements necessary for software with a moderate level of concern are not complete. In order to complete the review of your device, please provide the following:**

   a. **a complete traceability analysis which links requirements and specifications, identified hazards and mitigation, and verification and validation testing;**

   The firm states that it updated its traceability analysis to reference requirements, specifications with design features, identified hazards and mitigations, and verification and validation testing (Document 3 - Traceability Matrix).

   The matrix of two tables in the first table correlates each section number of the software requirement specification to the software module which implements that requirement along with the validation test and passing result used to verify that particular function.

   The second table correlates 13 hazards with the mitigation (design features) and the validation tests with results to address the validity of the mitigation to reduce each of the 13 identified risks.

   Collectively these tables provide a way to trace the requirement specifications to the device hazards and mitigations supported by related validation and verification tests.

   The response adequately addresses this portion of the software deficiency.

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b. a more detailed verification testing report. This report should document how specified requirements have been fulfilled;

Previously provided test reports included the system waveform verification report, EMC report, electrical safety (IEC60601-1) report, and the system verification/validation report.

The firm provided additional verification and validation reports outlined below, , however the other than the software reports, the remaining reports are unneeded to address this question focused on software (Documents 004 – 012). The other reports are more performance based reports which do not focus specifically on the software requirements and how the implementation of those requirements was verified.

- **Physical Dimensions and Inflation report** (Document 004, 2 pages) – Device measurements.

- **Battery test report** (Document 005, 4 pages) – The battery functional performance and specifications, expected lifetime, and recharge capabilities were verified.

- **Short Circuit test report** (Document 006, 4 pages) – Electrical testing to verify the response of the control unit to short circuit conditions. The tests cover a short of the U7 charger, U8 axillary power, and U9 main power. Each test condition did not result in measured hazardous conditions but were safely functioning in each short condition.

- **Air Pressure test report** (Document 007, 3 pages) – Air pressure measurements of the inTone pump confirmed the control circuit functions. Each of the 8 bars (each segments includes 2 brightness levels) of the device graphical display was verified to be 2 psi and within the specified operating range.

- **Audio Volume test report** (Document 008, 2 pages) – The audio volume was confirmed to be a minimum of 52 dB with a maximum of 85 dB.

- **Software Validation Report v102** (Document 009, 22 pages) -

  The validation report conducts a number of tests with the device in three operating modes (charging the handset, handset connected to probe, handset connected to PC) to ensure the expected operation of the device relative to the modified, updated software for the InTone Control Unit and the PC Clinician Application (Revision 1.02). No revision is made to the Stimulation Unit (Version 1.00).

  Note: The lead reviewer should determine what the changes in software are relative to what was previously reviewed for this file and determine whether these are important comparison features to the predicate for the conditions the device is intended to treat. Based on how the information is presented, it appears that the deficiency responses concern changes, but it is unknown whether this is relative

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to the initial review of the file or relative the prior 510(k) supplement.

The Thursday, February 16, 2012, email requested the firm clarify the changes and when they were implemented. Based on the information provided by the firm, the modifications to the software described in Supplement 2 have all been adequately validated.

Validation of InTone Control Unit Revision 1.02

1. **Audio and Reboot** - Verify that audio does not reboot from the volume being set too high. This test confirmed this expected performance.

2. **Logarithmic Display** - Stimulation Unit streams the current pressure exerted on it via a pressure sensor to the handset. This stream of data is a pressure waveform. The bar graph now displays in a logarithmic fashion verses a linear scaling fashion. logarithmic scaling of log base 1.37. The bar graph is confirmed to now display in a logarithmic fashion verses a linear scaling fashion.

3. **Abbreviated Display -** Visually verify that when pressure is applied to the Stim Unit each of the 8 LED window segments on the Control Unit's bar graph illuminates from a low brightness to a high brightness before the next segment is illuminated. Function confirmed.

4. (b)(4) TS [redacted]

5. **3-Second Delay** – Verify that there is a three second delay after the stimulation is increased or decreased prior to the simulation being applied. Operation confirmed.

6. **Change Stimulation** – Confirm display flash after setting changes through all 20 stimulation levels.

7. **Audio Alignment** – Patient audio prompts confirmed to coincide with the same timing as recording and displaying patient contraction pressure. The audio prompts occurred within 0.2 seconds of the measured events.

8. **Watchdog Reboot** – Confirm that Control Unit software version 1.02 prevents an intermitted reboot during power down which occurred in a third of the tested units under software version 1.01. The new software did not reboot with 25 tests.

9. **Manufacturer Monitor** – Preliminary, confirmatory test of a function for a future software version (Version 102T is not part of the official

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software version 1.02 updates). Real time output of the control unit outputs with an active stimulation signal to constantly read pressure data and outputs pressure on the LED bar graph when connected to a Stimulation Unit (no calibration intended as part of this preliminary functionality check). This is used as a spot check the Stimulation Unit pressure sensor and stimulation generation system. The operation of this function was confirmed while the stimulation unit was disconnected and reconnected to the control unit.

10. **Completion Confirmation** – Confirm that those treatments which were interrupted due to power failure are recorded by the software as partially completed and those which finished properly are merely tallied. This occurred as expected during each of the 10 tests with 3 control units.

11. **Name Length –** Confirm the patient name field stores up to 31 characters and names in excess of those unrecorded. Confirmed.

12. **Session Maximum** – Maximum session the Control unit can produce is raised from (b)(4) to make treatment sessions over that limit not recordable. Tests confirmed that the device continued to work but memory limits stop the ability of the device to record more treatment sessions.

13. **Data Storage** – Modify how data is stored to enable manual erase of the data from 15 treatment sessions. The deletion capabilities were confirmed by this test.

14. **Voltage Check** – Software added in Control Unit software Version 1.02 but not activated (until following firmware update) to check the voltage during power initialization. This feature was not tests nor implemented.

InTone PC Clinician Application Revision 1.02

15. **Year Assignment** – Affirm the software now stores the correct year based on the system clock year. The bug is now fixed as proven by the test.

16. **Data Export –** Perform 10 patient treatment session with the stimulation unit and the control unit to ensure that the export data feature of the PC Clinical Application can store in a file the data from the control unit used for those treatment sessions.

    While the data export and storage functions worked, the results noted that the exported file failed to display the proper digits if the whole value ended with a zero. This was attributed to setting an incorrect

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Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Microsoft Excel format.

17. **Averages Skipped** – Version 1.02 of the PC Clinician Application includes an average function for the individual pressure recordings. This test was to confirm that the averaging program skips the data where only a partial reading was obtained. The test verified that the that the pressure averages (minus the partial rows) correctly adds up to the "Weekly Averaged" pressure displayed on the bottom of each row from the stored data. The exclusion of partial data was confirmed by this test.

18. **Name Storage** – Confirm that a name entered in the PC Clinician Application remains stored in the control unit. Name storage was confirmed up to 31 characters.

19. **Crash Fixes** – Verify that the PC Clinician application does not crash when the control unit is randomly connected and disconnected while the PC Clinician application is restarted. Reports were that version 1.01 crashed 20% of the time when the application was open and the control unit USB was attached. The test confirmed crashes when two PC Clinician applications are open and the control unit is connected. This programming bug is confirmed and noted by this test.

20. **Full Partial** – Data records that are entirely made of partial recordings are not averaged. No weekly average was displayed for this type of data set.

Software Validation Report vl03 (Document 010, 6 pages)

This version of software adds a stepped up stimulation feature and a low battery check.

21. **Three Step** – The stimulation is initiated 3 levels lower and fully ramps to the pre-set level. The first pulse is 3 stimulation settings lower; with each pulse increasing by 1 level until the programmed amplitude is fully achieved by the forth pulse. Oscilloscope tracings confirm this new feature.

22. **Low Battery** – Confirm that the device will not start when battery power is 2.3 VDC but will start with a minimum 2.4 VDC. Confirmed.

Software Validation Report v104 (Document 011, 6 pages)

23. **Prevent Maximum** – Prevent a stimulation jump to maximum when the stimulation unit is disconnected and reconnected to the control unit as had occurred with Revision 1 of the software for the Stimulation unit. The test of this condition both in patient treatment mode and setup mode confirmed that the software inhibit all tested conditions

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Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

which previously created an unexpected output maximum. The software does this by shutting down when the stimulation unit id disconnected or reconnected to the Control Unit. The firm for the next software revision is investigating how to also allow "hot swap" conditions without causing the previously experienced maximum stimulation.

InTone Abnormal Usage test report (Document 012, 11 pages) -

The conditions which cause an unacceptable operation mode are investigated in this report. Some of these are addresses by the software updates discussed above.

24. **Auto Max** – Disconnecting or reconnecting the stimulation and control units creates a maximum, full power (level 20) output. This bug is addressed by Control Unit software Version 1.04.

25. **Weak Battery** – The device ceases to operate when the battery drops during a patient session.

26. **Charging Indicator** – An LED light was not properly illuminating during recharge. This anamoly was noted.

27. **Keypad Response** – While charging, confirmed that no keypad buttons create any device behavior at all.

28. **Setup Response** – No response observed when device is in setup mode and charging.

29. **PC Response** – Crashes in PC Clinician application confirmed when USB was connected and disconnected.

30. **Control Response** – The control unit switches from the powered patient session state to the PC data communication state when the control unit is turned off.

c. a revision history log that provides release version numbers and dates; and

The revision histories for the PC application and embedded firmware for the hand-held control unit are included. Each history starts with the first release candidate. See revision histories in documents 013 and 014.

The revisions for the Intone Control Unit are provided in Document 13 and the revisions for the InTone Clinical Unit are provided in Document 14. This adequately addresses the deficiency.

d. a list of unresolved software anomalies, bugs, or defects that remain with an explanation of its impact on the usage of your device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The list of unresolved anomalies for the PC application and control unit firmware are included. The list includes a description of each, its potential impact on the user, and the current disposition. See the document 015 software Problem Report (SPR) List. The list adequately addresses the deficiency.

Recommendation

The deficiency responses adequately address all components of deficiency 2.

James C. Seiler
Reviewer

2/16/2012
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Seiler, Jim

From: mjleigh@wi.rr.com
Sent: Thursday, February 16, 2012 2:07 PM
To: Valdes, Thelma
Cc: Seiler, Jim; Chan, Dulciana
Subject: Re: K110179 In Control - Software

Ms. Valdes,

There are two revision history documents included in the latest update; one for the Control Unit's embedded firmware, and one for the clinical PC application. These each summarize the changes made. The histories primarily cover the period from the first release candidate last January through January of this year. These changes are the result of continuing development to improve the product based on design team (and their consultants') feedback. This evening, I can provide the specific document numbers, if necessary. If the summary is not adequate, we can provide the specific code with "was" and "is" comparisons. Do you wish the analyze the actual code changes?

The test records included in this update reference the versions that were tested. They are also dated (as is the updates in the revision histories. Each test is planned based on its objectives and the changes made since the previous test pass. The set of tests records provided in the most recent update includes the most recent examples in each area of testing.

Michael Leigh

---- "Valdes wrote:
> Mr. Leigh,
>
> We continue to review your submission, and some questions have come up on the Software validation.
>
> Could you please provide a table, or bullet list for us (or let us know where in the submission we can find it) listing :
>
> * The specific changes you have made to the software in this submission and
> * The location of these changes in the validation report
>
> Having this information readily available to us, will expedite our continuing review process.
> If you could provide to me as soon as possible, I would greatly appreciate it.
>
>
> Thank you,
> Thelma
>
>
>
> ---
> Thelma Valdes, Ph.D.
> Biomedical Engineer
> The Food and Drug Administration
> Center for Devices and Radiological Health
> Office of Device Evaluation
> Division of Reproductive, Gastro-Renal, and Urological Devices
> Urology and Lithotripsy Devices Branch
> WO66 Room G274
> 10903 New Hampshire Ave.
> Silver Spring, MD 20993-0002
> tel. (301) 796-9621
> thelma.valdes@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Dulciana D. Chan

Subject: 510(k) Number K110179/S1

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		n/a	
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			☒
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X

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Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	**Class***	**Product Code**
21 CFR 876.5320	II	KPI

(*If unclassified, see 510(k) Staff)

Additional Product Codes: HCC

Review: _____ VLDB 11/4/2011
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K110179/S1

Date: November 03, 2011
To: The Record
From: Dulciana D. Chan

Office: ODE
Division: DRGUD

510(k) Holder: InControl Medical, LLC
Device Name: InControl InTone
Contact: Michael J. Leigh
Phone: 262-957-6797
Email: mike-leigh@earthlink.net

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the InControl InTone into interstate commerce. The sponsor submitted amendments on April 1, 2011 and August 23, 2011.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: **Prescription** or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form #3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf		X	
Clinical Trials Form http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf			X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?	X		
Are "cleaning" instructions included for the end user?	X		

The device includes 2 parts; an inflatable balloon for intra-vaginal use and external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. Other components include the external monitor, AC charger and PC cable.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The control unit is a display device used to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. Other features include:

- select and lock in the correct amount of current necessary to stimulate pelvic floor contraction
- provide biofeedback program to measure and record pressure generated by patient pelvic floor
- exercises
- display contraction force (as pressure)
- allow downloading of data to personal computer through custom USB cable and allow graphing in commercially available software (e.g. Excel)
- provide verbal exercise session coaching
- provide single button stop to discontinue electrical pulses if necessary

The Insert unit is an inflatable balloon for intra-vaginal use. The balloon is attached to a hand pump bulb with release knob. The balloon has a semi-rigid core to allow insertion. The core also carries inflation air and electrical conductors. The insertion unit connects to the control unit through a flexible connection.

The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulated pelvic floor contraction.

The AC charger is used to recharge the control unit battery. The unit cannot be used while it is being charged.

The PC Cable allows the Control Unit to be connected to the USB port of a personal computer. This connection allows the transfer of data to the PC. The unit cannot be used while it is being connected.

It is not clear whether the external monitor or hand pump bulb is included with the device.

IV. Indications for Use

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Predicate K080350
As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions:

- Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles

As a biofeedback device the STIWELL med4 is indicated for the following conditions:

- Biofeedback, relaxation and muscle re-education purposes

Predicate K053434

The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the

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Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

abdominal or gluteal muscles.

The MyoTrac Infiniti system is also indicated for the ongoing treatment of the following conditions: Relaxation of Muscle Spasms, Prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion and Stroke Rehab by Muscle re-education. It is also used for Biofeedback, Relaxation & Muscle Re-Education purposes.

Predicate K050483

The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary and fecal (electromyographic biofeedback) incontinence.

The indications for use of the subject device is equivalent to the predicates. The indication does not changes the intended therapeutic effect of the device.

V. Predicate Device Comparison

	InControl (subject device)	Otto Bock STIWELL med4 K080950	MyoTrac Infiniti K053434	Hollister evadri K050483
Power Source	2 AA Batteries Nickel metal hydride battery	Battery pack Li-ion 1V	4 AAA 1.5V Alkaline or rechargeable NiMH batter pack 6VDC-15W power adapter (class II)	?
Method of line current isolation	n/a (battery)	n/a (battery)	?	?
Patient leakage current	n/a (battery)	n/a (battery)	?	?
# output modes Feedback	1	1 0	?	?
# output channels Feedback	1	1 0	?	?
Regulated current or voltage Feedback	Regulated voltage	Regulated current n/a	?	?
Firmware controlled	Yes	Yes	?	?
Automatic Overload Trip	Yes	Yes	?	?
Automatic No-load trip	Yes	Yes	?	?
Automatic shut off	Yes	Yes (10 min.)	?	?
Indicator Display **On/Off Status** **Low Battery** **Volt/Curr Level**	 Yes Yes Yes	 Yes Yes Yes	?	?
Waveform, shape	(b)(4) TS [redacted]	Biphasic symmetrical	Asymmetrical balanced pulsed	Biphasic, balanced

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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	(b)(4) TS	rectangular	current	
Frequency Stress Urge Mixed Feedback		35 Hz 10 Hz 5-60 Hz n/a	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz
Pulse Width Stress Urge Mixed Feedback		300 µs 500 µs 350-500 µs n/a	0.2 ms	0.3 ms
Time Stress On Off Urge On Off Mixed On Off Feedback		9-12 secs 7-8 secs 13 secs 3 secs 9-11 secs 3-6 secs n/a	2-20 s 2-50 s	Urinary incontinence 1-80 s 0-80 s
Total session time		5-25 min	1-120 min	1-30 min
Max output voltage 500 Ω 2 kΩ 10 kΩ		50 V 115 V n/a	?	?
Max output current 500 Ω 2 kΩ 10 kΩ		100 mA 58 mA n/a	100 mA	?
Max phase charge (500 Ω) Stress Urge Mixed Feedback		30 µC 50 µC 50 µC n/a	60µC	?
Electrode surface area		21.2 cm^2	7.4 cm^2 x 2(St-Cloud) 10.5 cm^2 x 2 (Femelex)	?
Max current density (500Ω)		4.7 mA/cm^2	6.76 mA/cm^2 (St-Cloud) 4.76 mA/cm^2 (Femelex)	?
Max power density (500 Ω) Stress		105 $\mu W/cm^2$	22.84 mW/cm^2 (St-Cloud) 11.32 mW/cm^2	?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Urge Mixed Feedback	(b)(4) TS	23.5 μW/cm^2 42 mW/cm^2 n/a	(Femelex)	
Biofeedback			?	Air pressure
Sterile	No		No	?
Biocompatibility	No	Applicators yes	Applicators yes	?
Patient Override Control	yes	Yes	?	?
Net Charge μC/pulse (500Ω)		0 μC	?	?
Burst Mode		n/a	?	?
Probes	Vaginal	Vaginal electrode – EMG	Vaginal Anal Vaginal-EMG	Vaginal anal

The maximum power density, net charge, and whether there is a burst mode should be provided.

Battery

Two AA batteries, nickel metal hydride
Battery pack size – 1.75" x 1.145" x 0.57".
Battery capacity – 1200mAh
Battery voltage – 2.4 V
Charge voltage – 6 VDC
Charge current – 0.24 A
Discharge current – (b)(4)
Charging time – 5 hours
Charging frequency – defined by the user, up to 8 hours use

VI. Labeling

A user manual which includes instructions for use and an appropriate prescription statement as required by 21 CFR 801.109(b). was provided.

A sample back label of the control unit was provided in Appendix F.

A label for the insertion unit was not provided.

The user manual erroneously states stress and urge incontinence and improvement of urethral closure on page 5 of 22. The pulse width is erroneously labeled as (b)(4) in the user manual on page 20 of 22.

EMC tables are needed in the user manual.

(b)(4) TS

The user manual should be updated to show how to connect the hand pump bulb to the insertion unit for proper inflation.

VII. Sterilization/Shelf Life/Reuse

The device is not sterile.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The insertion unit has an expiration date of 1 year since the silicone material used in the insertion date has shelf life of 18 months.

On page 7 of 22 of the user manual, it states that the insertion unit is reusable. It is assumed that the control unit is reusable.

On page 20 of 22 of the user manual, it states the insertion unit for a single patient.

Cleaning instructions as follows were included in the manual and are adequate:

On page 10-11 of 22 you state that the device can be cleaned with common, commercially available cleaners. On page 13 of 22 of the user manual, you state that the insertion unit can be wiped with alcohol or other antiseptic in accordance with the care provider's infection control procedures.

On page 13 of 22 of the user manual,
Wash the outside of the Insertion Unit with warm soapy water. Do not soak.
The control unit can be wiped with antiseptic or a damp cloth. Do not immerse or spray.

Approved Antiseptics
The following cleaners can be used with the InTone Insertion Unit. This list is based on material compatibility.
isopropyl alcohol
hydrogen peroxide, <10%
sodium hypochlorite, <10%

This is adequate.

VIII. Biocompatibility

	Control Unit enclosure	Insertion Unit outer surface	Electrodes	Connector assembly outer surface	Insertion unit
Chemical Name	ABS, acrylonitrile, butadiene, styrene	Liquid Rubber Silicone	(b)(4) stainless steel	PVC, poly vinyl chloride	(b)(4) CCI
Supplier	(b)(4) CCI				
Supplier trade name					
Polymer formulation					
Processing description					
Processing materials					

The insertion unit has mucosal membrane surface contact for a limited duration (<24 hours).

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Cytotoxicity, sensitization, irritation or intracutaneous reactivity information was provided for the different materials.

The control unit and connector assembly have skin surface contact for a limited duration (<24 hours). Since contact is on hand (thick skin) no biocompatibility testing is necessary.

See biocompatibility Checklist.

IX. Software

Version:		
Level of Concern: Moderate This level is appropriate because there is a small risk of thermal injury if the device delivers too much energy to the body as a result of a software failure.		
	Yes	**No**
Software description: (See S1/Appendix C)	X	
Device Hazard Analysis: Hardware and software hazards, including severity assessment and mitigation were provided in S1/Appendix B.	X	
Software Requirements Specifications: The software requirements were provided in S1/Appendix C.	X	
Architecture Design Chart: (See Data Flow Diagram and Thread of Control document sent via email)	X	
Design Specifications: The design specifications are listed in section 11.	X	
Traceability Analysis/Matrix: Traceability among requirements, specifications, identified hazards and mitigation(s), and Verification and Validation testing was provided in S1/Appendix B.		X
Development: (see S1/Appendix C)	X	
Verification & Validation Testing: Validation testing in Appendix G.		X
Revision level history:		X
Unresolved anomalies:		X

No traceability analysis, verification testing, revision level history, or unresolved anomalies were provided.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The submission states that electrode lead wires and patient cables comply with 21 CFR Part 898.

Electrical safety test results were provided in Appendix H in accordance with:
IEC60601-1:1995, Medical Electrical Equipment - Part 1: General Requirements for Safety

This includes thermal safety, mechanical strength, leakage current, and dielectric strength testing.

IEC 60601-1-1:2000 Medical electrical equipment Part 1-1: General requirements for safety - Safety requirements for medical electrical systems

This is adequate.

EMC Testing:
EMC testing results were provided in Appendix I in accordance with

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

ISO 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).

According to CISPR 11: 2003+A1:2004, *Industrial, Scientific and Medical radio-frequency equipment – Electromagnetic disturbance characteristics – limits and methods of measurement*, the device is classified as Group 1, Class A.(intentional RF energy in a non domestic establishment).

Equipment Limits: Conduction emissions		
Frequency band (MHz)	Quasi-peak dB(μV)	Average dB(μV)
0.15-0.5	100	90
0.5-5	86	76
5-30	70→90	60→80
Device	Pass 0.15-30 MHz	Pass 0.15-30 MHz

Testing was only performed in Charging Mode.

Immunity to electrostatic discharges (ESD)			
	Test level	Compliance level	Humidity
IEC 60601-1-2	± 6 kV contact ± 8 kV air		≥ 30%
Device	2, 4, 6 kV contact 2, 4, 8 kV air	Pass	53 %

There were testing failures in Stimulation (operation) mode.

Immunity to radiated radio frequency interference in the 80-2500 MHz range at 3 V/m at 2 and 3 m Pass in all modes

Equipment Limits: Radiation disturbance (CISPR 11 table 3)(Emissions)		
Frequency band (MHz)	Quasi-peak dB(μV)	
30-230	40 at 10 m	
230-1000	47 at 10 m	
Subject Devices	Pass 30-1000 MHz	All modes *Testing was performed at 20% and 80% stimulation output.*

Immunity to Electrical Fast Transients/Bursts		
	Test level	Compliance level
IEC 60601-1-2	± 2 kV power supply lines	
Device	± 2 kV	Pass *Testing was only performed in Charging Mode.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Immunity to Surge Transients		
	Test level	Compliance level
IEC 60601-1-2	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode
Device	0.5, 1 kV differential mode 0.5, 1 2 kV common mode	Pass *Testing was only performed in Charging Mode and differential model.* -

Immunity to Voltage Dips and Interruptions			
	Test level	Compliance level	Duration
IEC 60601-1-2 Voltage Dip	<5% 40% 70%	>95% 60% 30%	0.5 periods 5 periods 25 periods
Device	Pass *Testing was only performed in Charging Mode.*		
IEC 60601-1-2 Interruption	<5%	>95%	5 sec
Device	Pass *Testing was only performed in Charging Mode.*		

Immunity to Power Frequency Magnetic Field		
	Test level	Compliance level
IEC 60601-1-2	3 A/m	3A/m
Subject device	Power frequency (50,60 Hz)	Not susceptible at 3 A/m in all modes

Harmonic Emissions

Done in accordance with EN 61000-3-2-2006: "Electromagnetic Compatibility – Part 3-2: Limits – Limits for Harmonic Current Emissions (Equipment Input Current ≤ 16 Amps Per Phase).

Testing was only performed in Charging Mode.

Voltage Fluctuations/flicker emissions

Done in accordance with EN 61000-3-3-2008: "Electromagnetic Compatibility – Part 3-3: Limits – Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems for Equipment with Rated Current ≤ 16 Amps Per Phase and not Subject to Conditional Connection + Amendment A1: 2001.

Testing was only performed in Charging Mode.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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XI. Performance Testing – Bench

(b)(4) TS

[redacted]

XII. Performance Testing – Animal – n/a

XIII. Performance Testing – Clinical –n/a

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		X	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		X	If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: n/a
2. Explain why there is or is not a new effect or safety or effectiveness issue: n/a
3. Describe the new technological characteristics: The new characteristic is the inflatable insertion unit. This allows an adjustable fit for each patient.
4. Explain how new characteristics could or could not affect safety or effectiveness: The inflatable insertion unit could not affect safety or effectiveness because the insertion unit will still provide stimulation to the vaginal wall without inflation. The inflation is just for it is

5. Explain how descriptive characteristics are not precise enough: n/a
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used: n/a
8. Explain what performance data is needed: n/a
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: n/a

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

XV. Deficiencies from the original 510(k)

The following deficiencies (in bold) were sent to the sponsor in our February 25, 2011 additional information letter. The sponsors' responses are below each deficiency.

1. **You provided an indications for use that is different from your predicate devices. Your intended use includes "improvement of urethral sphincter closure" which is not contained in any known predicates and changes the intended therapeutic effect of your device. Please remove this or provide scientific evidence of improvement of urethral sphincter closure.**

   The improvement of urethral sphincter closure has been removed. The indication for use has been revised to be the following:
   The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

   This is adequate.

2. **You provided a device description, however some key elements are missing. The configuration of your electrodes is not provided and the biofeedback feature of your device is not explained. Please clarify the description of your device to include, the following for all components of your device:**
   a. **Device specifications;**
   b. **Any new features of the device;**
   c. **Identification of the relevant dimensions and weight of the device and accessories;**
   d. **A description of all user controls, displays, and functions;**
   e. **A description of how the device interconnects with other components;**
   f. **Engineering drawings and/or photographs of the device; and**
   g. **Length, construction, material, and connections between the stimulator device and the electrodes.**

   The device specifications, features, dimensions, functions, engineering drawings, photographs, and electrode specifications were provided. The connection with the hand pump bulb is necessary. This is inadequate.

3. **You provided output characteristics of your device. However, it is unclear whether there are separate parameters for the treatment of stress, urge, and mixed urinary incontinence and the biofeedback setting. Please clarify the parameters for all three possible stimulation settings and the biofeedback setting including but not limited to time, maximum phase charge, maximum power density, and net charge. For example, you did not provide the frequency and pulse width for the mixed urinary incontinency setting.**

   The sponsor removed the treatment of stress and urge incontinence from the device. The output characteristics of the mixed incontinence treatments were provided. This is adequate.

4. **You state that your device will use a Li ion battery. However you did not provide enough information about the battery. Please provide the size, capacity, voltage, charge and discharge currents, and estimate how long it will take to recharge the battery and the frequency of charging intervals.**

   The battery information was provided and is adequate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

5. **On page 7 of 25 in your user manual, you state that the insertion unit is reusable. In order to ensure the safety of your device, please indicate which components of your device are reusable and whether the components are reusable for a single patient only and if they can be reusable for multiple patients.**

   The sponsor has stated that the insertion unit is for single patient use only on page 20 of 22 of the user manual. This is adequate.

6. **You state that the outer material of the insertion unit is silicone and that the control unit is made with plastics. However, you do not provide complete information about the materials used in the components of your device (insertion unit, electrodes, control unit). Please provide the following material information for your device:**

   a. **Table identifying all of the generic materials by chemical name, supplier trade name, supplier name, and device component location;**
   b. **Polymer component formulations (to include generic chemical component names and amounts specified as weight or volume percentages); and**
   c. **Sufficient processing information to include any processing materials (and amounts) that could impact on biocompatibility.**

   The sponsor provided material information in section D of the August 23, 2011 response. This is adequate.

7. **You state that there are no biocompatibility issues for your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility testing. In order to ensure the safety of your device, please provide complete cytotoxicity, sensitization, and irritation or intracutaneous reactivity testing on your final device.**

   Biocompatibility testing on the final device was not provided. This is inadequate.

8. **You did not provide any electrical testing. In order to ensure the safety and efficacy of your device, please provide electrical testing preferably in accordance with an FDA recognized standard such as IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-1:2000 Medical electrical equipment Part 1-1: General requirements for safety - Safety requirements for medical electrical systems or provide an adequate justification for why this testing is not necessary. Other potentially useful standards are IEC 60601-2-10:2001 Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators and IEC 60601-1-4:2000 Medical electrical equipment Part 1-4: General requirements for safety –Programmable electrical medical systems.**

   Electrical safety test results were provided in Appendix H in accordance with IEC6061-1:1995, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance by an independent lab, Underwriter's Laboratory. This is adequate.

9. **You did not provide electromagnetic compatibility testing for your device. In order to review the safety and efficacy of your device please provide electromagnetic compatibility testing preferably in accordance with an FDA recognized standard such as ISO 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).**

   The EMC testing was provided but is not adequate.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

10. **You provided information about the software used in your device. However, your software description was not detailed and some elements were missing. In order to complete the review of your device, please provide software design specifications, a development plan, verification and validation testing, a revision level history, and unresolved anomalies. These elements are necessary for the review of your device and are consistent with the required information necessary for software with a moderate level of concern. For further information please refer to the Guidance for the Content of Premarket Submission for Software contained in Medical Devices located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf and General Principles of Software Validation; Final Guidance for Industry and FDA Staff located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf**

    The software documentation is inadequate.

11. **You provided waveform representations of maximum voltage output but did not provide representations of each stimulation setting (urge, stress, and mixed urinary incontinence). In order to review the safety and efficacy of your device, please provide waveform representations of each of your stimulation settings.**

(b)(4) TS

[redacted]

12. **You state that there is no expiration date for your device. The vaginal probes and electrodes used with the predicate devices identified in your submission that are similar to your insertion unit have shelf life dates. In order to ensure the safety and efficacy of your device, please provide an expiration date and the results from your device aging data or a justification for why this data is not necessary.**

    The insertion unit has an expiration date of 1 year since the silicone material used in the insertion date has shelf life of 18 months. This is adequate.

13. **You provide a user manual in your submission. To adequately inform users, your manual requires additional information including:**

    a. **A description of all features, functions, output modalities, and specifications;**
       The user manual has been updated and is adequate.
    b. **A description of all user-accessible controls;**
       The user manual has been updated and is adequate.
    c. **Indicators, markings, and/or labels on the device which provide information regarding the function or meaning of each control, display, output jack, etc.;**
       The user manual has been updated and is adequate.
    d. **A description of the size and type of electrodes to be used with the device;**
       Electrode information has been provided and is adequate.
    e. **Cleaning and/or maintenance instructions. Please be aware that cleaning instructions are required in your user manual for reusable components. A mucosal contacting device, such as your insertion unit, must be thoroughly cleaned and undergo a high level of disinfection including subjection to a germicidal process with a broad spectrum of activity. Please be sure that your instructions are understandable, comprehensive and include disinfection and rinsing steps.**
       Cleaning instructions were added and are adequate.
    f. **A warning statement indicating that the long-term effects of chronic electrical stimulation are unknown.**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

This was added to the user manual and is adequate.

g. **A statement indicating caution should be used for patients with suspected or diagnosed heart problems.**
This was added to the user manual and is adequate.

h. **A statement indicating caution should be used for patients with suspected or diagnosed epilepsy.**
This was added to the user manual and is adequate.

i. **A statement indicating caution should be used when there is a tendency to hemorrhage following acute trauma or fracture;**
This was added to the user manual and is adequate.

j. **A statement indicating that electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.**
This was added to the user manual and is adequate.

k. **A statement indicating that patients with a total / partial prolapse of the uterus / vagina must be stimulated with extreme caution;**
This was added to the user manual and is adequate.

l. **A statement indicating that for patients with urethritis, the disease must be treated before commencing stimulation;**
This was added to the user manual and is adequate.

m. **A statement indicating that worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they are applied;**
This was added to the user manual and is adequate.

n. **An adverse reaction statement indicating that skin irritation and burns beneath the electrodes have been reported with the use of powered stimulators;**
This was added to the user manual and is adequate.

o. **A contraindication for patients with extra-urethra incontinence (syrinx, ectopic urethra);**
This was added to the user manual and is adequate.

p. **A contraindication for patients with overflow incontinence caused by evacuation problems;**
This was added to the user manual and is adequate.

q. **A contraindication for patients with severe urine retention in the upper urethras;**
This was added to the user manual and is adequate.

r. **A contraindication for patients with complete peripheral denervation of the pelvic floor;**
This was added to the user manual and is adequate.

s. **A contraindication for patients with an intestinal clamp; and**
This was added to the user manual and is adequate.

t. **The removal of fast twitch and slow twitch muscle stimulation. (For example, these terms are located in page 9 of 25 of your user manual.)**
These terms were removed and are adequate.

14. **You did not provide sample labeling to show the information as required by 21 CFR 801.109. In order for the Agency to complete its review, please provide sample labeling for your device as well as all available promotional and advertising materials. You may find additional guidance for labeling using the following:**

    a. **ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991**
    http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm

    b. **Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers**
    http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070801.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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c. **Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)** **http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf**

A label for the control unit was provided.. It contained symbols without wording. This is inadequate..

15. **You provide a 510(k) Summary in your submission. However, several of the sections are incomplete. Please revise your 510(k) Summary to be in accordance with 21 CFR 807.92.**

The 510(k) Summary still contains some erroneous information that should be revised. This is inadequate.

XVI. Contact History

I called Mr. Leigh on October 31, 2011 to ask for software documentation (InTone SRS document, InTone Flow Diagram and Thread of Control document, and the InTone Traceability Matrix) that was not included in the submission and left a voice mail. He returned my call on November 1, 2011 and it was agreed that he would send me software documentation via email by November 3, 2011. He stated that the SRS document was Appendix A which was named the System Requirements Specifications. On November 2, 2011 Mr. Leigh emailed me the InTone Flow Diagram and Thread of Control document and the InTone Traceability Matrix (attached).

XVII. Deficiencies to S1

1. You provided a device description. However, some information remains unclear. In order for the Agency to complete its review, please indicate whether the external monitor and hand pump bulb are included with the device.

2. You provided software documentation in Appendix C and via email. However, some requirement elements necessary for software with a moderate level of concern are not complete. In order to complete the review of your device, please provide the following:

    a. a complete traceability analysis which links requirements, specifications, identified hazards and mitigation, and verification and validation testing;

    b. a more detailed verification testing report. This report should document how specified requirements have been fulfilled;

    c. a revision history log that provides release version numbers and dates; and

    d. a list of unresolved software anomalies, bugs, or defects that remain with an explanation of its impact on the usage of your device.

3. You reduced your stimulation settings to be for mixed urinary incontinence and provided most output characteristics for your device. However, there are several characteristics that were not provided. In order to accurately describe your device, please provide the maximum power density, net charge, and indicate whether there is a burst mode and if so, the output characteristics of burst mode.

4. You provided EMC testing, however some of the testing was incomplete. In order to ensure the safety of your device, please provide the following testing:

    a. emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

fluctuations/flicker missions testing in stimulation and data transfer mode. These tests were performed only with the device in charging mode;

b. radiation emission testing on your device in stimulation mode at 100% stimulation or provide an adequate justification for the lower stimulation output. Your testing was performed in stimulation mode at 20% and 80% stimulation output; and

c. repeated immunity to electrostatic discharges testing or an adequate justification for the behavior of your device during testing. During testing in stimulation mode, treatment stops on a few sides of the device. The report stated that it is intended for the device to interrupt treatment when abnormal conditions are detected. However, treatment does not stop at all areas of the device.

5. You provided biocompatibility information and the processing description for the raw materials used in your device. It is inadequate to determine the biocompatibility of your device only based on the provided description of processing for the raw materials used in your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility evaluation for cytotoxicity, irritation, and sensitization per ISO 10993-1:2009 and the FDA blue book memo #G95-1. In lieu of biocompatibility testing of the final device, biocompatibility evaluation may be acceptable based on proper chemical analysis of leachables from your final device and adequate toxicity risk assessment with existing toxicity data of each chemical identified from the chemical analysis using principles outlined in ISO 10993-17:2002. Therefore, to determine the biocompatibility of your device, please provide biocompatibility testing on the final insertion unit or assessment of the insertion unit as suggested above.

6. You provided a user manual in your submission. However, there is a mistake and several omissions in the manual. To adequately inform users, please revise the following:

   a. an explanation for the connection of the hand pump bulb to the insertion unit for proper inflation;

   b. (b)(4) TS [redacted]

   c. EMC tables to your user manual. You stated conformance with EMC testing required by ISO 60601-1-2. However, you did not include the EMC tables required by ISO 60601-1-2. (Annex C of ISO 60601-1-2 provides examples of properly completed tables.)

7. You provided a 510(k) Summary in your submission. However, there are several mistakes in your output characteristics. In order to accurately describe your device, please revise the frequency and pulse width in the 510(k) Summary.

8. You provided a label for the control unit. However you did not provide labeling for the insertion unit. Also, symbols on your label were not accompanied by a description on the product label. In order for the Agency to complete its review, please provide sample labeling for the insertion unit and revise the control unit label to describe the symbols used. You may find additional guidance for labeling using the following:

   a. ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm

   b. Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

XVIII. Recommendation

Regulation Number: 21 CFR 876.5320
Regulation Name: Stimulator, Electrical, Non-implantable, for incontinence
Regulatory Class: Class II
Product Code: KPI, HCC – biofeedback device

There is inadequate information to determine substantial equivalence. Additional information is requested via additional information letter.

Reviewer — 11/03/2011 Date

Branch Chief — Date

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Summary Review Checklist: Biocompatibility Evaluation of Medical Devices

Device: InControl InTone_____
File Number: K110179/S1_____

Patient-Contacting Materials: (this list may be obtained from submission.) See Table 1.

Table 1. Component Materials - List of patient-contacting materials in the device

Component	Material(s)	Patient Contact Potential (direct, indirect,)	Previous Device Using Same Material with Similar Body Contact*
Insertion unit cover	(b)(4) CCI	Direct - mucosal membrane	
Insertion unit cover		Direct - mucosal membrane	
Hand held control unit enclosure		Direct - skin	
Electrodes		Direct - mucosal membrane	
Connector assembly (outer surface)	PVC	Direct - skin	

*Description of how used in previous device (e.g., tissue contact, duration, etc.)

Type of Tissue Contact: (check one) For non patient-contact, no biocompatibility evaluation necessary.

__X__ Surface device: skin
__X__ Surface device: mucosal membrane
_____ Surface device: breached or compromised surfaces
_____ External communicating device: blood path, indirect
_____ External communicating device: tissue/bone/dentin
_____ External communicating device: circulating blood
_____ Implant device: tissue/bone
_____ Implant device: blood

Duration of Contact: (check one)

__x__ < 24 hours
_____ > 24 hours, but less than 30 days
_____ > 30 days
_____ potential for repeat exposure (If so, please explain)

Biocompatibility Testing Submitted: (See Table 2.) For suggested Biocompatibility Testing for Devices, see Attachments for specific biocompatibility tests.

Table 2. Biocompatibility Testing Submitted

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Biocompatibility Test	FDA Recommended See Attached	Firm Provided Elastosil	Loctite	Firm Should Provide
Cytotoxicity	X	X	X	
Sensitization	X	X		
Irritation or intracutaneous reactivity	X	X	X	
Acute systemic toxicity			X	
Material mediated pyrogenicity				
Hemocompatibility			X	
Hemolysis		X	X	
Complement activation				
Thrombogenicity				
For tests listed below, check with Division Focal Point				
Implantation		X	X	
Genotoxicity				
Gene mutations in bacteria				
Gene mutations in mammalian cells				
Clastogenicity in mammalian cells				
Sub-chronic toxicity				
Chronic toxicity				
Carcinogenicity				
Reproductive/developmental				
Biodegradation				

*Per ISO 10993-3 genotoxicity testing should be performed using methods outlined in option

Summary of tests reviewed using checklists: (See Table 3.)

Table 3. Summary of Tests Reviewed Using Checklists

Test Name	Methods	Results	Outstanding Issues
(List tests conducted)	Acceptable per checklist: □ Yes □ No	Acceptable per checklist: □ Yes □ No	See note below.

Summary of tests reviewed by Biocompatibility Focal Point: (See Table 4.)

Table 4. Tests Reviewed by Biocompatibility Focal Point

Test Name	Methods	Results	Outstanding Issues
(List tests conducted)	(Insert summary of method)	(Insert results)	
	Acceptable per Focal Point: □ Yes □ No	Acceptable per Focal Point: □ Yes □ No	

Outstanding questions/issues for applicant:

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

510(k) SUMMARY REQUIREMENTS – 21 CFR 807.92

All 510(k) summaries shall contain the following information [807.92]:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared [807.92(a)(1)]	✓		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name [807.92(a)(2)]	✓		
3	An identification of the legally marketed device to which the submitter claims equivalence. [807.92(a)(3)]	✓		
4	A description of the device that is the subject of the premarket notification submission, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties) [807.92(a)(4)]	✓		
5	A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. Or, if the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled [807.92(a)(5)]	✓		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. Or,-if the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section[807.92(a)(6)]	✓		
510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence [807.92(b)(1)]	✓		
8	A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence [807.92(b)(2)]			✓
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section[807.92(b)(3)]	✓		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Chan, Dulciana

From: Mike Leigh [mike-leigh@earthlink.net]
Sent: Wednesday, November 02, 2011 6:49 PM
To: Chan, Dulciana
Subject: K110179

Hello Ms Chan,

This message is follow-up to our conversation yesterday, 1Nov. Attached are the two documents referenced in the software requirements specification; the Data Flow Diagram and Flow Control, and the Traceability Matrix.

If you have any other questions, I am happy to help. Thank you.

Sincerely,
Michael Leigh
262-957-6797

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) CCI/TS

(b)(4) CCI/TS

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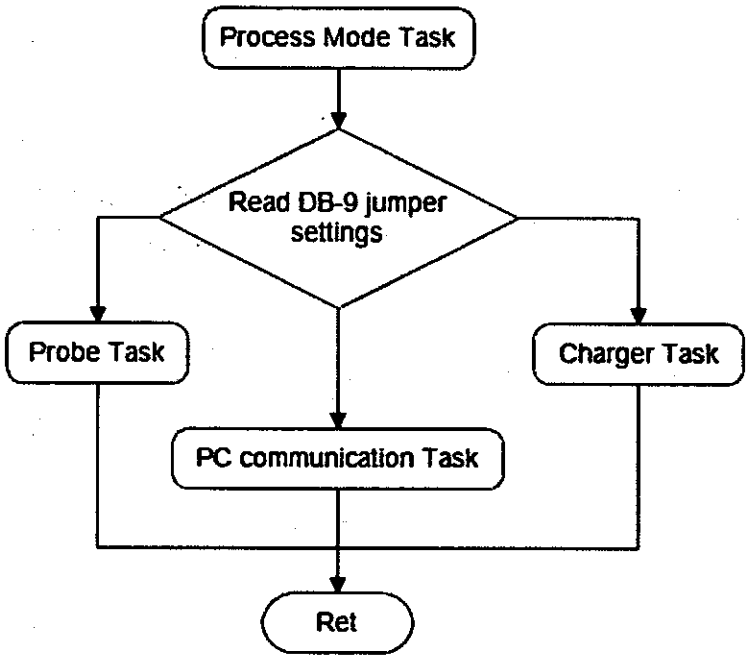
Process Mode Task

This task reads connector jumpers, and can branch into one of the three possible tasks:

- Probe task – normal stimulation activity
- PC communication task, if communication cable is plugged in
- Charger task, if charger cable is plugged in

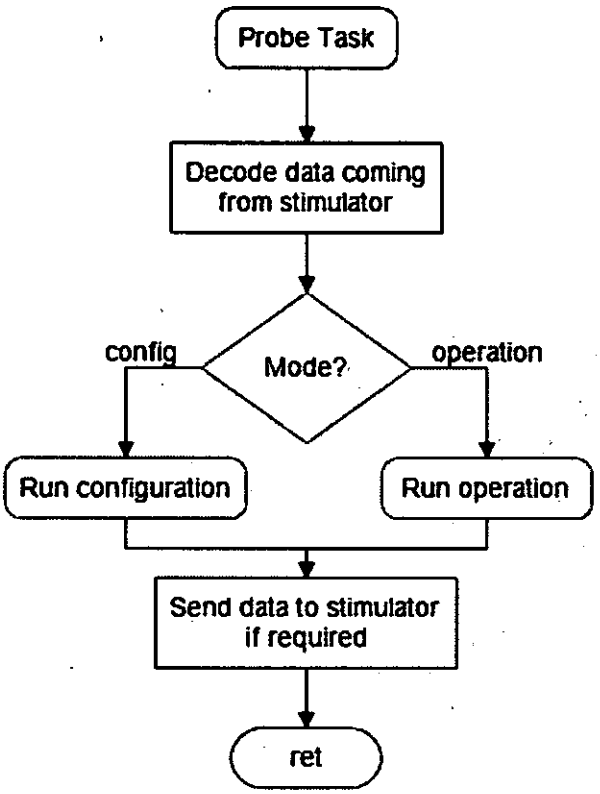


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Probe Task

In this task (b) receives pressure reading and other data from the stimulator. Then depending in the mode, this task either supports PC configuration mode, or runs normal stimulation session, implementing a set of prompts to the patient.
Then, if some commands are needed to be sent to the stimulator, they are sent before return from this task.

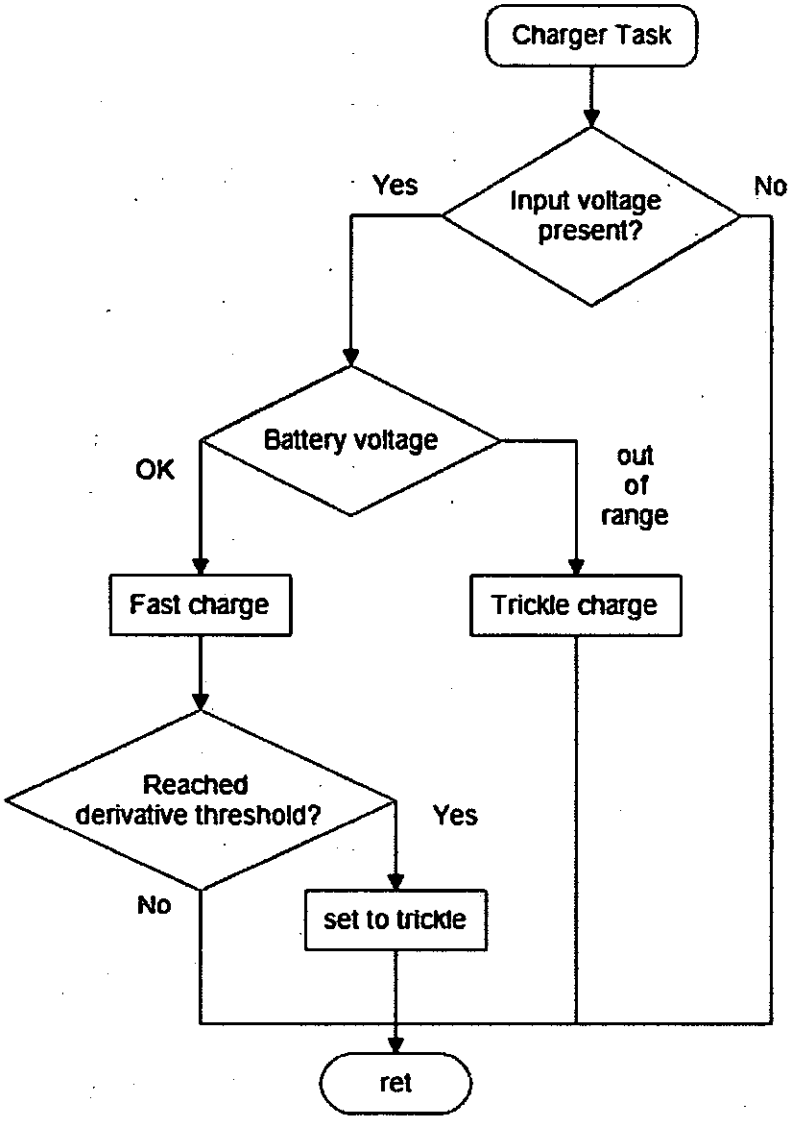


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Charger Task

This task is run if power cord is plugged into the unit. (b) checks if input voltage is present (power supply is plugged into the wall), and if so, it checks the battery voltage. If battery voltage is in range, it runs a fast charge algorithm. Otherwise, it waits in the trickle mode. The end of fast charging mode is detected when derivative of the voltage per time becomes less or equal to zero.

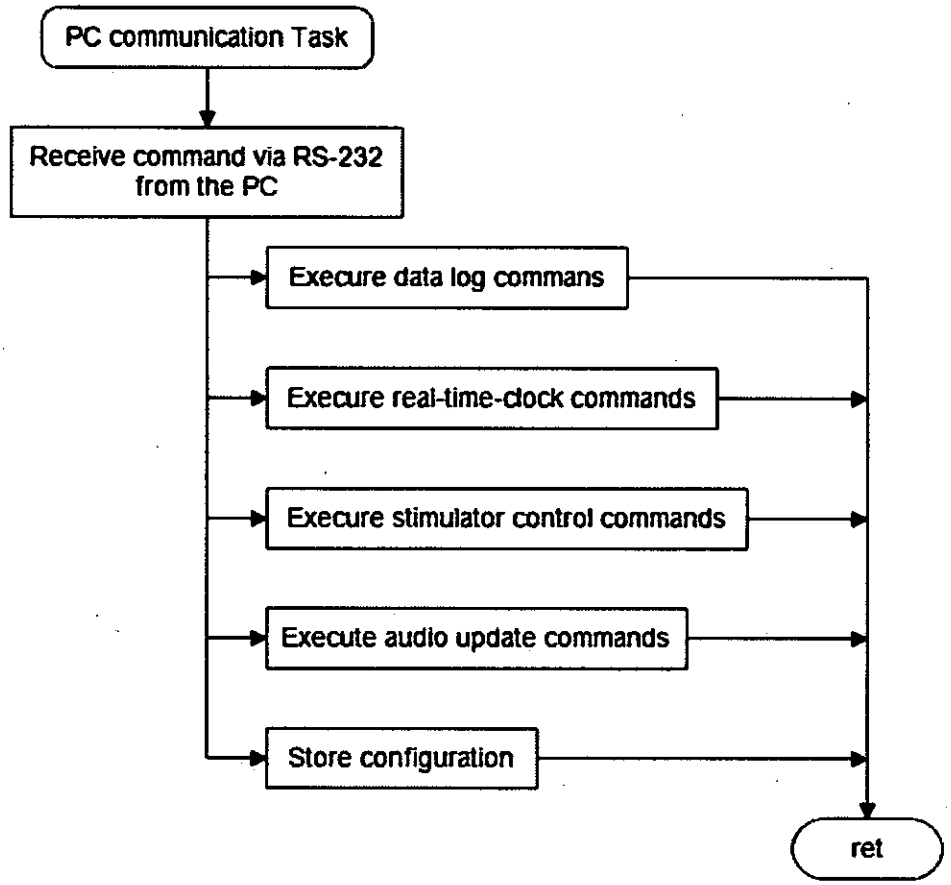


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

PC Communication Task

This task receives and processes commands from PC, as shown on the chart below:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8419.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SRS Item	SRS Requirement	How addressed
3.1	Power On/Off button functionality	Software module Keypad.cpp
	Start button functionality	Software module Mode_Probe.cpp
	Volume up and down keys	Software module Audio.cpp
	Pause button	Software module Mode_Probe.cpp
3.2	Timer display	Software module Mode_Probe.cpp
	Pressure bar graph	Software module Mode_Probe.cpp
	USB communication LED	Software module Mode_PC.cpp
	Battery LED	Software module Mode_Charger.cpp
	Speaker	Software module Audio.cpp
4.0	Computer connection	Software module Mode_PC.cpp
5.0	Battery	Software module Mode_Charger.cpp
6.5	Treatment duration	Software module Mode_Probe.cpp
	Frequency	Electronics
	Pulse width	Electronics
	On / Off time	Software module Mode_Probe.cpp
	Intensity	Electronics
		Software module Mode_Probe.cpp
	Maximum current	Electronics
	Air pressure	Software module Mode_Probe.cpp

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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V&V	Result
Page 8, "Proper handling of the software controlled power"	passed
Page 9, "Proper handling of patient session"	passed
Page 9, "Proper handling of audio volume controls"	passed
Page 12, "Proper handling of pausing and resuming a session"	passed
Page 12, "Proper handling of pausing and resuming a session"	passed
Page 10, "Proper display of real time pressure"	passed
Page 7, "Proper operation of the USB indicator"	passed
Page 9, "Proper handling of low battery"	passed
Page 9, "Proper handling of patient session"	passed
Page 4, "Handset Connected to PC", multiple tests	passed
Page 7, "Handset Connected to Battery Charger", multiple tests	passed
Battery charge/discharge duration test	passed
Page 9, "Proper handling of patient session"	passed
Verified with a scope	passed
Verified with a scope	passed
Page 9, "Proper handling of patient session"	passed
Verified with a scope	passed
Page 13, "Patient Setup"	passed
Verified with a scope	passed
Page 10, "Proper display of real time pressure"	passed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Chan, Dulciana

From: Chan, Dulciana
ent: Monday, April 11, 2011 4:57 PM
.o: 'Mike-leigh@earthlink.net'
Subject: K110179/S1

Dear Mr. Leigh,

I have received your submission. You are granted an extension. All additional information requests are permitted to be on hold for up to a maximum of 180 days from the date of the additional information request. I am also emailing to inform you that I have not reviewed the information you submitted in supplement 1 (dated March 28, 2011) since it was an incomplete response. Please submit a full response to our additional information letter dated February 25, 2011 as only complete responses are reviewed. If you have any further questions, please contact me (information below).

Sincerely,

Dulciana D. Chan

Dulciana D. Chan
Biomedical Engineer
FDA/CDRH/ODE/DRGUD/ULDB
phone: 301-796-2592
fax: 301-796-9927

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Dulciana D. Chan

Subject: 510(k) Number K110179

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

X Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ ULOB 2/25/2011
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K110179

Date: February 22, 2011
To: The Record
From: Dulciana D. Chan

Office: ODE
Division: DRGUD

510(k) Holder: InControl Medical, LLC
Device Name: InControl
Contact: Michael J. Leigh
Phone: 262-957-6797
Email: mike-leigh@earthlink.net

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the InControl into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: **Prescription** or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form		X	

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X	X	

The device includes 2 parts; an inflatable balloon for intra-vaginal use and external control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulated pelvic floor contraction.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The control unit is a display device used to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises.

The Insert unit is an inflatable balloon for intra-vaginal use. The balloon is attached to a hand pump bulb with release knob. The balloon has a semi-rigid core to allow insertion. The core also carries inflation air and electrical conductors. The core is surrounded by an inflatable balloon that carries the electrodes. The insertion unit connects to the control unit through a flexible connection.

The AC charger is used to recharge the control unit battery. The unit cannot be used while it is being charged.

An accurate device description is not provided. The electrode configuration is not shown and the only device design is images provided are diagrams from the instructions for use manual. The biofeedback feature is not described.

IV. Indications for Use

The InControl device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral sphincter closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Predicate K080350
As a nonimplanted electrical continence device the STIWELL med4 is indicated for the following conditions:

- Acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscles through reflexive mechanisms and strengthening of pelvic floor muscles
- Incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal and the gluteus muscles

As a biofeedback device the STIWELL med4 is indicated for the following conditions:

- Biofeedback, relaxation and muscle re-education purposes

Predicate K053434

The MyoTrac Infiniti system is indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles.

The MyoTrac Infiniti system is also indicated for the ongoing treatment of the following conditions: Relaxation of Muscle Spasms, Prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion and Stroke Rehab by Muscle re-education. It is also used for Biofeedback, Relaxation & Muscle Re-Education purposes.

Predicate K050483

The evadri Bladder Control System is intended to provide electrical stimulation or electromyographic or pressure biofeedback for the treatment of urinary and fecal (electromyographic biofeedback) incontinence.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The difference in indications for use is that the subject device also has an intended result of improvement of urethral sphincter closure which is not contained in the predicates. This changes the intended therapeutic effect of the device.

V. Predicate Device Comparison

	InControl (subject device)	Otto Bock STIWELL med4 K080950	MyoTrac Infiniti K053434	Hollister evadri K050483
Power Source	Li-Ion battery	Battery pack Li-ion 1V	4 AAA 1.5V Alkaline or rechargeable NiMH batter pack 6VDC-15W power adapter (class II)	
Method of line current isolation	n/a (battery)	n/a (battery)		
Patient leakage current	n/a (battery)	n/a (battery)		
# output modes Feedback	1	1 0		
# output channels Feedback	1	1 0		
Regulated current or voltage Feedback	Regulated current	Regulated current n/a		
Firmware controlled	Yes	Yes		
Automatic Overload Trip	Yes	Yes		
Automatic No-load trip	Yes	Yes		
Automatic shut off	Yes	Yes (10 min.)		
Indicator Display **On/Off Status** **Low Battery** **Volt/Curr Level**	 Yes Yes Yes	 Yes Yes Yes		
Waveform, shape	(b)(4) TS	Biphasic symmetrical, rectangular	Asymmetrical balanced pulsed current	
Frequency Stress Urge Mixed Feedback		 35 Hz 10 Hz 5-60 Hz n/a	12.5, 50, 100, 200 Hz	
Pulse Width Stress Urge Mixed Feedback		 300 µs 500 µs 350-500 µs n/a	0.2 ms	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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	(b)(4) TS			
Time Stress On Off Urge On Off Mixed On Off Feedback		9-12 secs 7-8 secs 13 secs 3 secs 9-11 secs 3-6 secs n/a	2-20 s 2-50 s	
Total session time		5-25 min	1-120 min	
Max output voltage 500 Ω 2 kΩ 10 kΩ		50 V 115 V n/a		
Max output current 500 Ω 2 kΩ 10 kΩ		100 mA 58 mA n/a	100 mA	
Max phase charge (500 Ω) Stress Urge Mixed Feedback		30 µC 50 µC 50 µC n/a	60µC	
Electrode surface area		21.2 cm^2	7.4 cm^2 x 2(St-Cloud) 10.5 cm^2 x 2 (Femelex)	
Max current density (500Ω)		4.7 mA/cm^2	6.76 mA/cm^2 (St-Cloud) 4.76 mA/cm^2 (Femelex)	
Max power density (500 Ω) Stress Urge Mixed Feedback		105 $\mu W/cm^2$ 23.5 $\mu W/cm^2$ .42 mW/cm^2 n/a	22.84 mW/cm^2 (St-Cloud) 11.32 mW/cm^2 (Femelex)	
Biofeedback				
Insertion material	Silicone, plastics			
Sterile	No		No	
Biocompatibility	No	Applicators yes	Applicators yes	
Patient Override Control		Yes		
Net Charge µC/pulse (500Ω)		0 µC		
Burst Mode		n/a		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

No information about mixed urinary incontinence setting was provided.

VI. Labeling

A user manual which includes instructions for use and an appropriate prescription statement as required by 21 CFR 801.109(b). was provided.

No sample labeling has been provided.
No cleaning instructions were provided in the instructions for use.

Predicate K080950 has the following contraindications for urological programs:

- Patients with extra-urethra incontinence (syrinx, ectopic urethra);
- Patients with overflow incontinence caused by evacuation problems;
- Patients with severe urine retention in the upper urethras;
- Patients with complete peripheral denervation of the pelvic floor; and
- Patients with an intestinal clamp.

Cautions

- Patients with a total / partial prolapse of the uterus / vagina must be stimulated with extreme caution (applies to urological programs);
- For patients with urethritis, the disease must be treated before commencing electrostimulation with the urological programs of the electrostimulation device;
- Worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they applied.

VII. Sterilization/Shelf Life/Reuse

The device is not sterile.

The sponsor states that there is no expiration date and that the predicates did not have expiration dates.

The vaginal probes used with the predicates had shelf life dates. There should be a shelf life date and data for the insertion unit.

On page 7 of 25 of the user manual, it states that the insertion unit is reusable. It is assumed that the control unit is reusable.

It is not indicated whether the insertion unit is reusable for a single patient or whether it can be reused on multiple patients. There are no cleaning instructions.

VIII. Biocompatibility

The insertion unit has mucosal membrane surface contract for a limited duration (<24 hours).
The sponsor states that the outer material of the insertion unit is silicone and that the control unit is made with plastics. They also state that there are no biocompatibility issues for the device.

Cytotoxicity, sensitization, irritation or intracutaneous reactivity testing as well as material information for the insertion unit and electrodes should be provided.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

IX. Software

Version:		
Level of Concern: Moderate This level is appropriate because there is a small risk of thermal injury if the device delivers too much energy to the body as a result of a software failure.		
	Yes	**No**
Software description:	X	
Device Hazard Analysis: Hardware and software hazards, including severity assessment and mitigation were provided in section 12.	X	
Software Requirements Specifications: The specific requirements of the software are listed in section 11.	X	
Architecture Design Chart:	X	
Design Specifications:		X
Traceability Analysis/Matrix: Traceability among requirements, specifications, identified hazards and mitigation(s), and Verification and Validation testing was provided in section 12.	X	
Development:		X
Verification & Validation Testing:		X
Revision level history:		X
Unresolved anomalies:		X

No Software Design Specifications, development plan, verification and validation testing, revision level history, or unresolved anomalies were provided.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

No electrical safety or EMC testing was provided. This is deficient.

The submission states that electrode lead wires and patient cables complies with 21 CFR Part 898.

Predicate K080950 provided the following testing:
IEC 60601-1:1995 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
IEC 60601-1-1:2000 Medical electrical equipment Part 1-1: General requirements for safety - Safety requirements for medical electrical systems
IEC 60601-2-10:2001 Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
IEC 60601-1-4:2000 Medical electrical equipment Part 1-4: General requirements for safety – Programmable electrical medical systems
ISO 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).

XI. Performance Testing – Bench

The predicate devices provided waveform representations of maximum current and voltage outputs.

(b)(4) TS [redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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were provided with pulses of 50μS-500μS.

Sample waveforms for each stimulation setting is required.

XII. Performance Testing – Animal – n/a

XIII. Performance Testing – Clinical –n/a

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		X	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	X		If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: The difference in indications for use is that the subject device also has an intended result of improvement of urethral sphincter closure which is not contained in the predicates. This changes the intended therapeutic effect of the device.

2. Explain why there is or is not a new effect or safety or effectiveness issue: An improvement of urethral sphincter closure changes the intended therapeutic effect of the device.

3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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XV. Deficiencies

1. You provided an indications for use that is different from your predicate devices. Your intended use includes "improvement of urethral sphincter closure" which is not contained in any known predicates and changes the intended therapeutic effect of your device. Please remove this or provide scientific evidence of improvement of urethral sphincter closure.

2. You provided a device description, however some key elements are missing. The configuration of your electrodes is not provided and the biofeedback feature of your device is not explained. Please clarify the description of your device to include, the following for all components of your device:
    a. Device specifications;
    b. Any new features of the device;
    c. Identification of the relevant dimensions and weight of the device and accessories;
    d. A description of all user controls, displays, and functions;
    e. A description of how the device interconnects with other components;
    f. Engineering drawings and/or photographs of the device; and
    g. Length, construction, material, and connections between the stimulator device and the electrodes.

3. You provided output characteristics of your device. However, it is unclear whether there are separate parameters for the treatment of stress, urge, and mixed urinary incontinence and the biofeedback setting. Please clarify the parameters for all three possible stimulation settings and the biofeedback setting including but not limited to time, maximum phase charge, maximum power density, and net charge. For example, you did not provide the frequency and pulse width for the mixed urinary incontinency setting.

4. You state that your device will use a Li ion battery. However you did not provide enough information about the battery. Please provide the size, capacity, voltage, charge and discharge currents, and estimate how long it will take to recharge the battery and the frequency of charging intervals.

5. On page 7 of 25 in your user manual, you state that the insertion unit is reusable. In order to ensure the safety of your device, please indicate which components of your device are reusable and whether the components are reusable for a single patient only and if they can be reusable for multiple patients.

6. You state that the outer material of the insertion unit is silicone and that the control unit is made with plastics. However, you do not provide complete information about the materials used in the components of your device (insertion unit, electrodes, control unit). Please provide the following material information for your device:

    a. Table identifying all of the generic materials by chemical name, supplier trade name, supplier name, and device component location;
    b. Polymer component formulations (to include generic chemical component names and amounts specified as weight or volume percentages); and
    c. Sufficient processing information to include any processing materials (and amounts) that could impact on biocompatibility.

7. You state that there are no biocompatibility issues for your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility testing. In order to ensure the safety of your device, please provide complete cytotoxicity, sensitization, and irritation or intracutaneous reactivity testing on your final device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

8. You did not provide any electrical testing. In order to ensure the safety and efficacy of your device, please provide electrical testing preferably in accordance with an FDA recognized standard such as IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance and IEC 60601-1-1:2000 Medical electrical equipment Part 1-1: General requirements for safety - Safety requirements for medical electrical systems or provide an adequate justification for why this testing is not necessary. Other potentially useful standards are IEC 60601-2-10:2001 Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators and IEC 60601-1-4:2000 Medical electrical equipment Part 1-4: General requirements for safety –Programmable electrical medical systems.

9. You did not provide electromagnetic compatibility testing for your device. In order to review the safety and efficacy of your device please provide electromagnetic compatibility testing preferably in accordance with an FDA recognized standard such as ISO 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).

10. You provided information about the software used in your device. However, your software description was not detailed and some elements were missing. In order to complete the review of your device, please provide software design specifications, a development plan, verification and validation testing, a revision level history, and unresolved anomalies. These elements are necessary for the review of your device and are consistent with the required information necessary for software with a moderate level of concern. For further information please refer to the Guidance for the Content of Premarket Submission for Software contained in Medical Devices located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf and General Principles of Software Validation; Final Guidance for Industry and FDA Staff located at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf

11. You provided waveform representations of maximum voltage output but did not provide representations of each stimulation setting (urge, stress, and mixed urinary incontinence). In order to review the safety and efficacy of your device, please provide waveform representations of each of your stimulation settings.

12. You state that there is no expiration date for your device. The vaginal probes and electrodes used with the predicate devices identified in your submission that are similar to your insertion unit have shelf life dates. In order to ensure the safety and efficacy of your device, please provide an expiration date and the results from your device aging data or a justification for why this data is not necessary.

13. You provide a user manual in your submission. To adequately inform users, your manual requires additional information including:

    a. A description of all features, functions, output modalities, and specifications;
    b. A description of all user-accessible controls;
    c. Indicators, markings, and/or labels on the device which provide information regarding the function or meaning of each control, display, output jack, etc.;
    d. A description of the size and type of electrodes to be used with the device;
    e. Cleaning and/or maintenance instructions. Please be aware that cleaning instructions are required in your user manual for reusable components. A mucosal contacting device, such as your insertion unit, must be thoroughly cleaned and undergo a high level of disinfection including subjection to a germicidal process with a broad spectrum of activity.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Please be sure that your instructions are understandable, comprehensive and include disinfection and rinsing steps.

f. A warning statement indicating that the long-term effects of chronic electrical stimulation are unknown.
g. A statement indicating caution should be used for patients with suspected or diagnosed heart problems.
h. A statement indicating caution should be used for patients with suspected or diagnosed epilepsy.
i. A statement indicating caution should be used when there is a tendency to hemorrhage following acute trauma or fracture;
j. A statement indicating that electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
k. A statement indicating that patients with a total / partial prolapse of the uterus / vagina must be stimulated with extreme caution;
l. A statement indicating that for patients with urethritis, the disease must be treated before commencing stimulation;
m. A statement indicating that worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they are applied;
n. An adverse reaction statement indicating that skin irritation and burns beneath the electrodes have been reported with the use of powered stimulators;
o. A contraindication for patients with extra-urethra incontinence (syrinx, ectopic urethra);
p. A contraindication for patients with overflow incontinence caused by evacuation problems;
q. A contraindication for patients with severe urine retention in the upper urethras;
r. A contraindication for patients with complete peripheral denervation of the pelvic floor;
s. A contraindication for patients with an intestinal clamp; and
t. The removal of fast twitch and slow twitch muscle stimulation. (For example, these terms are located in page 9 of 25 of your user manual.)

14. You did not provide sample labeling to show the information as required by 21 CFR 801.109. In order for the Agency to complete its review, please provide sample labeling for your device as well as all available promotional and advertising materials. You may find additional guidance for labeling using the following:

    a. ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm

    b. Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070801.pdf

    c. Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf

15. You provide a 510(k) Summary in your submission. However, several of the sections are incomplete. Please revise your 510(k) Summary to be in accordance with 21 CFR 807.92.

XVI. Contact History-n/a

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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XVII. Recommendation

Regulation Number: 21 CFR 876.5320
Regulation Name: Stimulator, Electrical, Non-implantable, for incontinence
Regulatory Class: Class II
Product Code: KPI, HCC – biofeedback device

There is inadequate information to determine substantial equivalence. Additional information is requested via additional information letter. The potentially NSE letter is being used due to new intended use

Dulcenia D. Chan
Reviewer

02/22/2011
Date

Branch Chief

2/25/2011
Date

587

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

510(k) SUMMARY REQUIREMENTS – 21 CFR 807.92

All 510(k) summaries shall contain the following information [807.92]:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared [807.92(a)(1)]	✓		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name [807.92(a)(2)]	✓		
3	An identification of the legally marketed device to which the submitter claims equivalence. [807.92(a)(3)]	✓		
4	A description of the device that is the subject of the premarket notification submission, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties) [807.92(a)(4)]		✓	
5	A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. Or, if the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled [807.92(a)(5)]	✓		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. Or, if the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section[807.92(a)(6)]		✓	
510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence [807.92(b)(1)]		✓	
8	A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence [807.92(b)(2)]			✓
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section[807.92(b)(3)]		✓	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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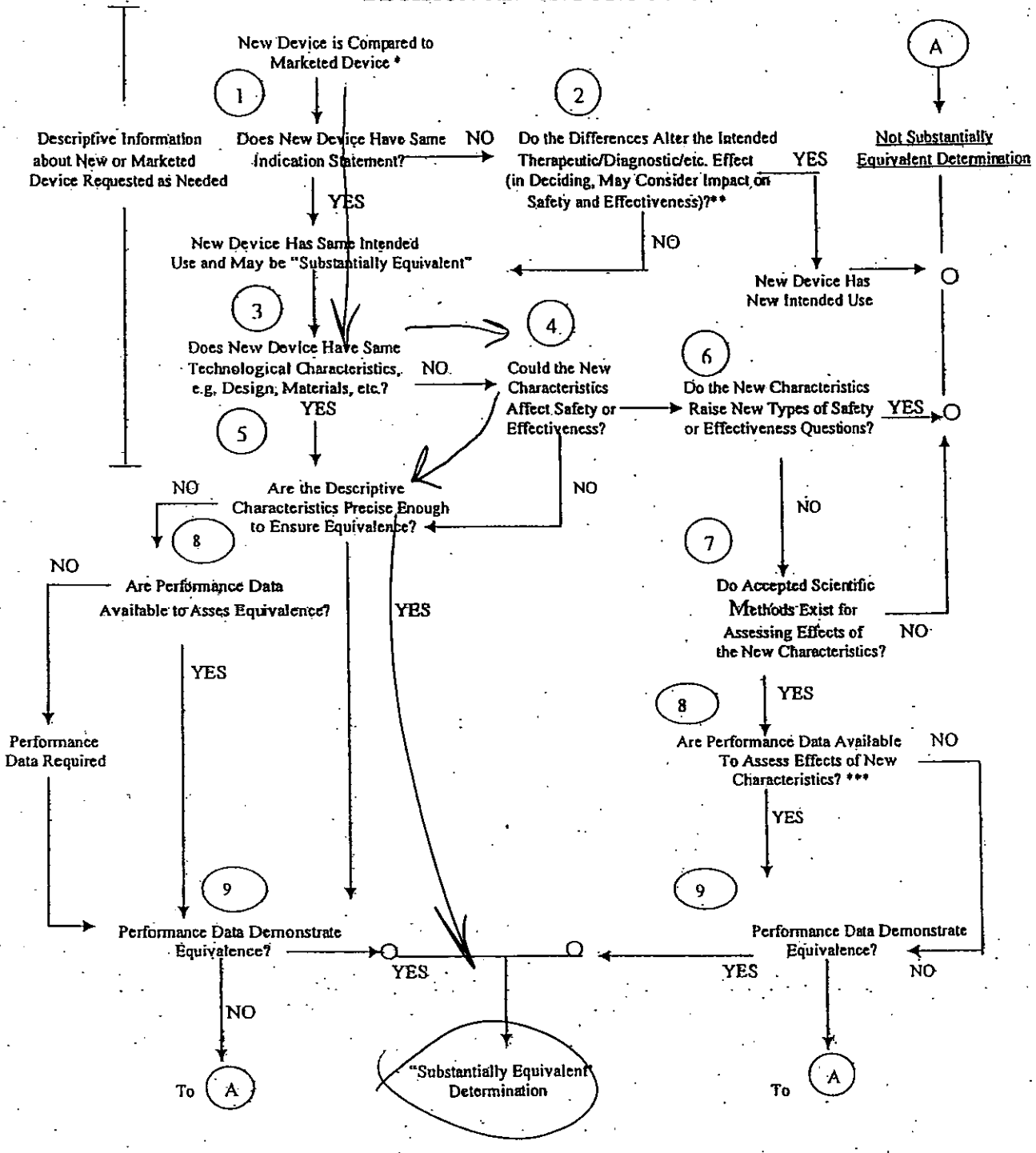
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Records processed under FOIA Request #2015-664, Released by CDRH on 04-11-2016. GWDRGWD K110179/S2

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC
JAN 31 2012
RECEIVED K5

Re: K110179
Trade Name: InControl InTone

January 24, 2011

Dear Ms. Morris:

This letter is in response to your letter stamped "Oct 04, 2011" and received November 7. The letter references your receipt of "October 7, 2011." Listed below are the numbered requests for more information along with the response for each. Supporting documentation is referenced and attached. An electronic copy of the response is being provided. It is an exact duplicate of the paper copy.

1. *You provided a device description. However, some information remains unclear. In order for the Agency to complete its review, please indicate whether the external monitor and hand pump are included with the device.*

The device set includes the Insertion Unit with integral hand pump, hand-held Control Unit, and clinician PC software. The device description has been updated to clarify the complete device. See updated device description in document 002 Information on New Device.

2. *You provided software documentation in Appendix C and via email. However, some requirement elements necessary for software with a moderate level of concern are not complete. In order to complete the review of your device, please provide the following:*

    a. *a complete traceability analysis which links requirements, specifications, identified hazards and mitigation, and verification and validation testing;*

The traceability analysis has been updated to include reference to requirements, specifications and design features, identified hazards and mitigations, and verification and validation testing. See the traceability analysis in document 003.

    b. *a more detailed verification testing report. This report should document how specified requirements have been fulfilled;*

Previously provided test reports included the system waveform verification report, EMC report, electrical safety (IEC60601-1) report, and the system verification/validation report. Additional verification and validation reports are included in this update. They include;

Physical Dimensions and Inflation report
Battery test report
Short Circuit test report
Air Pressure test report
Audio Volume test report
Software Validation Report v102
Software Validation Report v103

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Software Validation Report v104
InTone Abnormal Usage test report

See the additional verification test reports in documents 004 through 012.

c. a revision history log that provides release numbers and dates; and

The revision histories for the PC application and embedded firmware for the hand-held control unit are included. Each history starts with the first release candidate. See revision histories in documents 013 and 014.

d. a list of unresolved software anomalies, bugs, or defects that remain with an explanation of its impact on the usage of the device.

The list of unresolved anomalies for the PC application and control unit firmware are included. The list includes a description of each, its potential impact on the user, and the current disposition. See the document 015 SPR List.

3. *You reduced your stimulation settings to be for mixed urinary incontinence and provided most output characteristics for your device. However, there are several characteristics that are not provided. In order to accurately describer your device, please provide the maximum power density, net charge, and indicate whether there is a burst mode and if so, the output characteristics of burst mode.*

The maximum power density at (b)(4) TS [redacted]. The net charge (maximum phase) at (b)(4) TS [redacted]. These have been included in the 510(k) Summary and predicate device comparison table. It has now been added to the manual as well. See the updated manual, document 022.

There is no burst mode in the InTone device.

4. *You provided EMC testing, however, some of the testing was incomplete. In order to ensure the safety of your device, please provide the following testing:*

a. emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker missions testing in stimulation and data transfer mode. These tests were performed only with the device in charging mode;

The device was tested in three modes; charging mode, use mode, and data transfer mode. The charging mode is the only mode in which the device is connected to mains power and thus potentially exposed to electrical fast transients/bursts, surge transients, voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker. In the other two modes, the unit is not connected to mains power and operates on battery. See the attached email from the UL test engineer, document 016.

b. radiation emission testing on your device in stimulation mode at 100% stimulation or provide adequate justification for the lower stimulation output. Your testing was performed in stimulation mode at 20% and 80% stimulation output; and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The UL test engineer reported that preliminary scans were made at 100%. Full testing was conducted at 20% and 80% because these lower levels showed more noise than the 100% level, however there was little difference between them. Since no significant difference in emissions was measured, testing was completed at these levels. See the attached email from UL test engineer, document 017.

c. *repeated immunity to electrostatic discharges testing or an adequate justification for the behavior of your device during testing. During testing in stimulation mode, treatment stops on a few sides of the device. The report stated that it is intended for the device to interrupt treatment when abnormal conditions are detected. However, treatment does not stop at all areas of the device.*

The impact of electrostatic discharge may be different in different orientations or test points. The InTone processor will stop treatment if it detects abnormal conditions. The same discharge may not create abnormal conditions in the processor in every orientation. Some orientations may be parallel to the field and other perpendicular. Treatment was able to continue normally in some orientations. See the attached email from UL test engineer, document 017.

5. *You provided biocompatibility information and the processing description for the raw materials used in your device. It is inadequate to determine biocompatibility of your device only based on the provided description of processing for the raw materials used in your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility evaluation for cytotoxicity, irritation, and sensitization per ISO 10993-1:2009 and the FDA blue book memo #G95-1. In lieu of biocompatibility testing of the final device, biocompatibility evaluation may be acceptable based on proper chemical analysis of leachables from your final device and adequate toxicity risk assessment with existing toxicity data of each chemical identified from the chemical analysis using principles outlined in ISO 10993-17:2002. Therefore, to determine the biocompatibility of your device, please provide biocompatibility testing on the final insertion unit or assessment of the insertion unit as suggested above.*

Biocompatibility testing of the finished insertion unit has been completed. It included cytotoxicity, irritation, and sensitization testing per ISO10993-1:2009. All testing met the requirements of that standard series. The reports are included as documents 018 through 021.

6. *You provided a user manual in your submission. However, there is a mistake a several omissions in the manual. To adequately inform users, please provide the following:*

a. *an explanation of the connection of the hand pump bulb to the insertion unit for proper inflation;*

The hand pump bulb was incorporated into the insertion unit between the original submittal in January and the update in August 2011. The bulb cannot be connected, disconnected, or otherwise removed. The instructions for inflation and deflation have been expanded in the Manual. An updated Manual is included as document 022.

b. (b)(4) TS [redacted]

The pulse width in the Manual was corrected to (b)(4) [redacted] The updated Manual is document 022.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

c. *EMC tables to your user manual. You stated conformance with EMC testing required by ISO 60601-1-2. However, you did not include the EMC tables required by ISO 60601-1-2. (Annex C of ISO 60601-1-2 provides examples of properly completed tables.)*

EMC tables were added to the updated manual. The Manual now includes tables 201, 204, and 206, as required by the standard. See the updated Manual, document 022.

7. *You provided a 510(k) Summary in your submission. However, there are several mistakes in your output characteristics. In order to accurately describe your device, please revise the frequency and pulse width in the 510(k) Summary.*

The output characteristics in 510(k) Summary were corrected to ensure they match the Manual and other documents. An updated Summary is included as documents 024 and 024.

8. *You provided a label for the control unit. However, you did not provide labeling for the insertion unit. Also, symbols on your label were not accompanied by a description on the product label. In order for the Agency to complete its review, please provide sample labeling for the insertion unit and revise the control unit label to describe the symbols used. you may find additional guidance for labeling using the following:*

   a. *ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991*

   b. *Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)*

"InTone" is molded into the Insertion Unit. To further identify it and the manufacturer, a label has been added to the unit's cable. The cable cannot be removed from the unit. Descriptions of each of the symbols used have been added to Insertion Unit and Control Unit labels. The Insertion Unit cord label is document 025. The updated Control Unit back label is document 026.

If you have any questions regarding the additional information provided in this submittal, please don't hesitate to contact me. InControl Medical and I hope that we have answered all of your questions adequately. Thank you for your time and consideration.

Sincerely,

Michael J. Leigh
consultant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K110179
Trade Name: InControl InTone

January 24, 2011

Dear Ms. Morris:

This letter is in response to your letter stamped "Oct 04, 2011" and received November 7. The letter references your receipt of "October 7, 2011." Listed below are the numbered requests for more information along with the response for each. Supporting documentation is referenced and attached. An electronic copy of the response is being provided. It is an exact duplicate of the paper copy.

1. *You provided a device description. However, some information remains unclear. In order for the Agency to complete its review, please indicate whether the external monitor and hand pump are included with the device.*

The device set includes the Insertion Unit with integral hand pump, hand-held Control Unit, and clinician PC software. The device description has been updated to clarify the complete device. See updated device description in document 002 Information on New Device.

2. *You provided software documentation in Appendix C and via email. However, some requirement elements necessary for software with a moderate level of concern are not complete. In order to complete the review of your device, please provide the following:*

    a. *a complete traceability analysis which links requirements, specifications, identified hazards and mitigation, and verification and validation testing;*

The traceability analysis has been updated to include reference to requirements, specifications and design features, identified hazards and mitigations, and verification and validation testing. See the traceability analysis in document 003.

    b. *a more detailed verification testing report. This report should document how specified requirements have been fulfilled;*

Previously provided test reports included the system waveform verification report, EMC report, electrical safety (IEC60601-1) report, and the system verification/validation report. Additional verification and validation reports are included in this update. They include;

Physical Dimensions and Inflation report
Battery test report
Short Circuit test report
Air Pressure test report
Audio Volume test report
Software Validation Report v102
Software Validation Report v103

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Software Validation Report v104
InTone Abnormal Usage test report

See the additional verification test reports in documents 004 through 012.

c. *a revision history log that provides release numbers and dates; and*

The revision histories for the PC application and embedded firmware for the hand-held control unit are included. Each history starts with the first release candidate. See revision histories in documents 013 and 014.

d. *a list of unresolved software anomalies, bugs, or defects that remain with an explanation of its impact on the usage of the device.*

The list of unresolved anomalies for the PC application and control unit firmware are included. The list includes a description of each, its potential impact on the user, and the current disposition. See the document 015 SPR List.

3. *You reduced your stimulation settings to be for mixed urinary incontinence and provided most output characteristics for your device. However, there are several characteristics that are not provided. In order to accurately describer your device, please provide the maximum power density, net charge, and indicate whether there is a burst mode and if so, the output characteristics of burst mode.*

The maximum power density at [redacted] (b) [redacted] The net charge (maximum phase) at (b) [redacted] (b) These have been included in the 510(k) Summary and predicate device comparison table. It has now been added to the manual as well. See the updated manual, document 022.

There is no burst mode in the InTone device.

4. *You provided EMC testing, however, some of the testing was incomplete. In order to ensure the safety of your device, please provide the following testing:*

a. *emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker missions testing in stimulation and data transfer mode. These tests were performed only with the device in charging mode;*

The device was tested in three modes; charging mode, use mode, and data transfer mode. The charging mode is the only mode in which the device is connected to mains power and thus potentially exposed to electrical fast transients/bursts, surge transients, voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker. In the other two modes, the unit is not connected to mains power and operates on battery. See the attached email from the UL test engineer, document 016.

b. *radiation emission testing on your device in stimulation mode at 100% stimulation or provide adequate justification for the lower stimulation output. Your testing was performed in stimulation mode at 20% and 80% stimulation output; and*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The UL test engineer reported that preliminary scans were made at 100%. Full testing was conducted at 20% and 80% because these lower levels showed more noise than the 100% level, however there was little difference between them. Since no significant difference in emissions was measured, testing was completed at these levels. See the attached email from UL test engineer, document 017.

c. *repeated immunity to electrostatic discharges testing or an adequate justification for the behavior of your device during testing. During testing in stimulation mode, treatment stops on a few sides of the device. The report stated that it is intended for the device to interrupt treatment when abnormal conditions are detected. However, treatment does not stop at all areas of the device.*

The impact of electrostatic discharge may be different in different orientations or test points. The InTone processor will stop treatment if it detects abnormal conditions. The same discharge may not create abnormal conditions in the processor in every orientation. Some orientations may be parallel to the field and other perpendicular. Treatment was able to continue normally in some orientations. See the attached email from UL test engineer, document 017.

5. *You provided biocompatibility information and the processing description for the raw materials used in your device. It is inadequate to determine biocompatibility of your device only based on the provided description of processing for the raw materials used in your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility evaluation for cytotoxicity, irritation, and sensitization per ISO 10993-1:2009 and the FDA blue book memo #G95-1. In lieu of biocompatibility testing of the final device, biocompatibility evaluation may be acceptable based on proper chemical analysis of leachables from your final device and adequate toxicity risk assessment with existing toxicity data of each chemical identified from the chemical analysis using principles outlined in ISO 10993-17:2002. Therefore, to determine the biocompatibility of your device, please provide biocompatibility testing on the final insertion unit or assessment of the insertion unit as suggested above.*

Biocompatibility testing of the finished insertion unit has been completed. It included cytotoxicity, irritation, and sensitization testing per ISO10993-1:2009. All testing met the requirements of that standard series. The reports are included as documents 018 through 021.

6. *You provided a user manual in your submission. However, there is a mistake a several omissions in the manual. To adequately inform users, please provide the following:*

a. *an explanation of the connection of the hand pump bulb to the insertion unit for proper inflation;*

The hand pump bulb was incorporated into the insertion unit between the original submittal in January and the update in August 2011. The bulb cannot be connected, disconnected, or otherwise removed. The instructions for inflation and deflation have been expanded in the Manual. An updated Manual is included as document 022.

b. (b)(4) TS [redacted]

The pulse width in the Manual was corrected to (b)(4) [redacted]. The updated Manual is document 022.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

c. *EMC tables to your user manual. You stated conformance with EMC testing required by ISO 60601-1-2. However, you did not include the EMC tables required by ISO 60601-1-2. (Annex C of ISO 60601-1-2 provides examples of properly completed tables.)*

EMC tables were added to the updated manual. The Manual now includes tables 201, 204, and 206, as required by the standard. See the updated Manual, document 022.

7. *You provided a 510(k) Summary in your submission. However, there are several mistakes in your output characteristics. In order to accurately describe your device, please revise the frequency and pulse width in the 510(k) Summary.*

The output characteristics in 510(k) Summary were corrected to ensure they match the Manual and other documents. An updated Summary is included as documents 024 and 024.

8. *You provided a label for the control unit. However, you did not provide labeling for the insertion unit. Also, symbols on your label were not accompanied by a description on the product label. In order for the Agency to complete its review, please provide sample labeling for the insertion unit and revise the control unit label to describe the symbols used. you may find additional guidance for labeling using the following:*

   a. *ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991*

   b. *Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)*

"InTone" is molded into the Insertion Unit. To further identify it and the manufacturer, a label has been added to the unit's cable. The cable cannot be removed from the unit. Descriptions of each of the symbols used have been added to Insertion Unit and Control Unit labels. The Insertion Unit cord label is document 025. The updated Control Unit back label is document 026.

If you have any questions regarding the additional information provided in this submittal, please don't hesitate to contact me. InControl Medical and I hope that we have answered all of your questions adequately. Thank you for your time and consideration.

Sincerely,

Michael J. Leigh
consultant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SECTION 7B: INFORMATION ON NEW DEVICE

Device Description

The general description of the InTone device, including required features, functionality and interface, user options, and packaging, is equivalent to that of the predicate devices, Otto Bock STIWELL med 4, MyoTrac Infiniti, and Hollister evadri devices.

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: strengthening of pelvic floor muscles, and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

The device includes an insertion unit with inflatable balloon for intra-vaginal use, an external hand-held control unit to initiate and control treatment sessions, record and store results of electro-stimulation and patient generated pelvic floor exercises, and a PC-based software application to program the hand-held unit and store and display the results of electro-stimulation and patient generated pelvic floor exercises. The application allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. The insertion unit includes an integral inflation bulb and valve to provide a custom fit for the inflatable balloon.

Comparison to Predicate

The principle difference between the InControl InTone device and the predicates is that the InTone device includes an inflatable insertion unit. The unit is manually inflated by the patient after insertion. This provides a better fit for the patient population. The electrical parameters and controls are similar to the predicate devices. There are no differences in the intended use or indications for use.

The following comparison information illustrates differences and similarities between the legally marketed predicate prescription devices, Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), Hollister evadri (K050483), and the InControl device, including intended use and functional characteristics.

The FDA guidance documents used to prepare this comparison as well as this 510(k) are:

FDA Guidance Title	Revision Date
Format for Traditional and Abbreviated 510(k)s	November 17, 2005
Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence	September 19, 2008
Software Contained in Medical Devices	May 11, 2005
Labeling - Regulatory Requirements for Medical Devices	August 1989
ODE Bluebook Memo G91-1, "Device Labeling Guidance"	March 8, 1991
Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing	May 1, 1995

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Statement of Substantial Equivalence

The proposed device, InControl InTone continence device, is substantially equivalent to the Otto Bock STIWELL med4 (K080950), MyoTrac Infiniti (K053434), and Hollister evadri (K050483). When compared to the predicate devices:

- The changes are not due to a recall or corrective action.
- The indications for use are the same. There are no changes in contraindications.
- The user's manual provides equivalent instructions for use, along with equivalent warnings.
- There are no significant differences in features, fundamental technology, or functionality.

The InControl InTone device and the predicate devices all provide pulsed biphasic current to stimulate the pelvic floor muscles. Each includes provision for biofeedback. The InTone device is not significantly different from the predicates. The InTone device does not raise new safety or effectiveness issues. It has the same intended use and basic functions.

Intended Use

The intended use InControl InTone is the same as the predicates.

> The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control: improvement of urethral closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

The intended use and indications of the device, as described in its labeling are the same as the intended use and indications for the predicate devices.

Labeling

User Manual

The InControl InTone *User Manual* uses text and graphics to lead the user through hardware setup and use. Each piece of equipment appears in a list with a brief description illustrating each step for ease of use.

Safety and Product Information

The document also provides maintenance, troubleshooting, repair, warranty, and customer service information. The *User Manual*, provides comprehensive safety information, product specifications and guidelines. The document can be found in "Attachment A" of this 510(k) submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Notes on Guidance and Information Labeling:

The manual provides the concepts and instructions needed to install, program, use, and maintain the InControl InTone device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

SRS Item	SRS Requirement	How addressed	V&V	Result
3.1	Power On/Off button functionality	Software module Keypad.cpp	Validation test, page 8, "Proper handling of the software controlled power"	passed
	Start button functionality	Software module Mode_Probe.cpp	Validation test, page 10, "Proper handling of patient session"	passed
	Volume up and down keys	Software module Audio.cpp	Validation test, page 9, "Proper handling of audio volume controls"	passed
			Volume Test	
	Pause button	Software module Mode_Probe.cpp	Validation test, page 12, "Proper handling of pausing and resuming a session"	passed
3.2	Timer display	Software module Mode_Probe.cpp	Validation test, page 12, "Proper handling of pausing and resuming a session"	passed
	Pressure bar graph	Software module Mode_Probe.cpp	Validation test, page 11, "Proper display of real time pressure"	passed
			Air Pressure Test	
	USB communication LED	Software module Mode_PC.cpp	Validation test, page 7, "Proper operation of the USB indicator"	passed
	Battery LED	Software module Mode_Charger.cpp	Validation test, page 9, "Proper handling of low battery"	passed
	Speaker	Software module Audio.cpp	Validation test, page 10, "Proper handling of patient session"	passed
4.0	Computer connection	Software module Mode_PC.cpp	Validation test, page 3, "Handset Connected to PC", multiple tests pgs 3 - 7	passed
	USB Link			
	Charging	charging circuit	Battery Test	
	Connetion with the insertion device		Valdiation test, multiple tests pgs 8 - 14	
5.0	Battery	Software module Mode_Charger.cpp	Validation test, page 8, "Handset Connected to Battery Charger", multiple tests pgs 7 - 8	passed
			Battery charge/discharge duration test	passed
6.0	Insertion Unit			
	Dimensions		Physical Dimensions test	
6.5	Treatment duration	Software module Mode_Probe.cpp	Valdiation test, page 9, "Proper handling of patient session"	passed
	Frequency	Electronic circuit design	Output Waveforms verification	passed
	Pulse width	Electronic circuit design	Output Waveforms verification	passed
	On / Off time	Software module Mode_Probe.cpp	Validation test, page 9, "Proper handling of patient session"	passed
	Intensity	Electronic circuit design	Output Waveforms verification	passed
		Software module Mode_Probe.cpp	Validation test, page 14, "Patient Setup"	passed
	Maximum current	Electronic circuit design	Output Waveforms verification	passed
	Air pressure	Software module Mode_Probe.cpp	Validation test, page 11, "Proper display of real time pressure"	passed

Risk number	Identified Risks	How addressed	V&V	Result
1	shock due to leakage current	low voltage battery	IEC60601-1 test	passed
2	shock due ot current overload	battery power, circuil includes overload trip	IEC60601-1 test	passed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

		3	shock due to engergizing with no load	inflable design improves fi, decreases likelihood	Inflation test	passed
		4	shock due ot lack of isolation, charger	design allows only one connection at a time, unit disabled when charger is connected	Validation test	passed
		5	shock due ot lack of isolation, USB	design allows only one connection at a time, unit disabled when USB is connected	Validation test	passed
		6	overinflation	manual inflation	Inflation test	passed
					Physical Dimensions test	
		7	burn from arcing	inflatable insertion unit decreases likelihood	Inflation test	passed
		8	muscle strain due to too strong signal	manual stop, adjustable level accessible only by clinician, defined electrical characteristics	Valdiation test	passed
		9	shock due to damaged electrical connector	rugged mechanical design	IEC60601-1 test	passed
		10	biocompatability with materials	use materials compliant with USP, ISO10993	material certifications	passed
					ISO 10993 biocompatibility testing	passed
		11	biofeedback incorrect	level only accessible by clinician, pressure indicates difference only	Air pressure test	passed
		12	unintended change in treatment due to ESD or interference	circuit design	EMC test report	passed
		13	burn from hot surface	circuit design	IEC60601-1 test report	passed

See Revision History and SPR records for traceability to SPR testing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Physical Dimension and Inflation Report

A record of the testing and results for the InTone system.

Intone: **1.00**

Revision History

Rev	Date	Who Changed	Description
1	2011-12-22	J. Lemke	Document Created

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Purpose

This test procedure was created and executed to verify the physical dimensions of the InTone hand-held Control Unit and Insertion Unit.

Dimensional Test

Measure dimensions and weight of first production run of Control Unit and Insertion Unit.

Table of measurements:

Parameter	*Results*	*Status*
Dimensions (hand-held)	Actual measurements: Length: 4.88” Width: 2.38” Height: 1.07”	Pass
Dimensions (insertion unit)	Actual measurements: Length: 12.2" Width: 2.5" at widest point of handle Height: 4.0"	Pass
Weight (hand-held)	Actual weight 5.7 oz	Pass
Weight (insertion unit)	Actual weight 9.9 oz	Pass

Inflation Test

The Insertion Unit is 1.2" wide when deflated.

The Insertion unit was pumped to full size. After six pumps of the inflation bulb, the Insertion Unit was 1.5" wide

The release valve allows the Unit to deflate in 1.5 seconds.

Conclusion

The manufactured sample units met the specified dimensions. Six pumps allows fine increases between minimum and maximum size. The deflation time is short enough to not cause unnecessary delay or inconvenience.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Battery Validation Report

A record of the testing and results for the InTone system.

Intone: **1.00**

Revision History

Rev	Date	Who Changed	Description
1	2011-12-18	E. Palatnei	Document Created

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Purpose

This test procedure was created and executed to validate the Control Unit's battery function, expected life, and charging system.

Test

Battery Parameters

1.1 Battery Pack Parameters

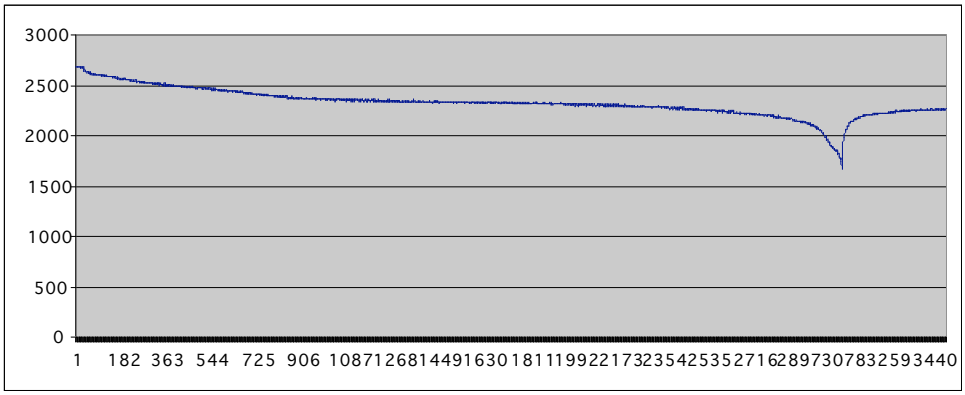
* Size 1.76” x 1.1” x 0.57”
* Capacity 1200mAh

1.2 Battery Pack Voltage Profile

The test was done to verify the battery voltage profile, and software settings for the low and dead battery. The USB data trending voltmeter was connected to the battery, which was powering the device under normal operating conditions. Data have been collected into Excel spread sheet file (see file discharge.xls).

From this file the following data points were defined:
* Maximum (open circuit) battery voltage is 2.68VDC.
* “Dead battery” voltage, when the device turns itself off is 1.66V, which corresponds to 1.7V of the software setting (considering accuracy of the measurement under fluctuating load).
* Low battery threshold is set in software to 1.9V, which corresponds to the beginning of the steep drop in the battery voltage on the curve, thus this setting is correct.
* Average working voltage is 2.3VDC

The graph below shows the curve:



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The X coordinate indicates intervals in 10 sec increments; the Y coordinate indicates voltage in mV.

The total time of discharge was 3081 * 10 sec = 30810 sec = 8.55 hours. At 140mA discharge current, it corresponds to 1197mAh, which is the capacity of the battery pack.

1.3 Charging current

Charging current was measured to be 236mA

1.4 Charger voltage

Charger is powered by the linear wall plug supply, which is rated to 6VDC, 300mA

1.5 Discharge current

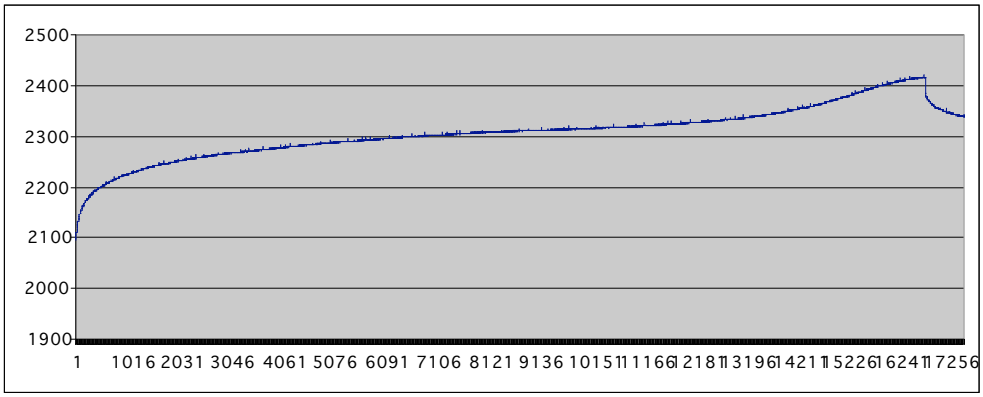
Discharge current was measured by the integrating analog current meter at normal operation load. The average current was (b)(4) .

1.6 Charging time and charging profile

The test was conducted to verify the charging time and charging profile. The battery is considered fully charged when the first derivative of the charging voltage changes sign from positive to zero. The software was modified to serially report battery voltage while charger is operational; the data points were recorded into Excel sheet file “charge.xls”.

The battery was fully discharged before the test.

The charging profile is shown on the graph below:



The X coordinate indicates time in seconds, the Y coordinate voltage in mV.
It is clear from the curve that the charging was complete when the curve became “flat” (derivative is zero). The total charging time was 16833 seconds, or 4.67 hours.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Conclusion

The test unit discharge and charging times met the specified requirements and expectations of sample users.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Short Circuit Verification Report

A record of the testing and results for the InTone system.

Intone: **1.00**

Revision History

Rev	Date	Who Changed	Description
1	2011-12-18	E. Palatnei	Document Created

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

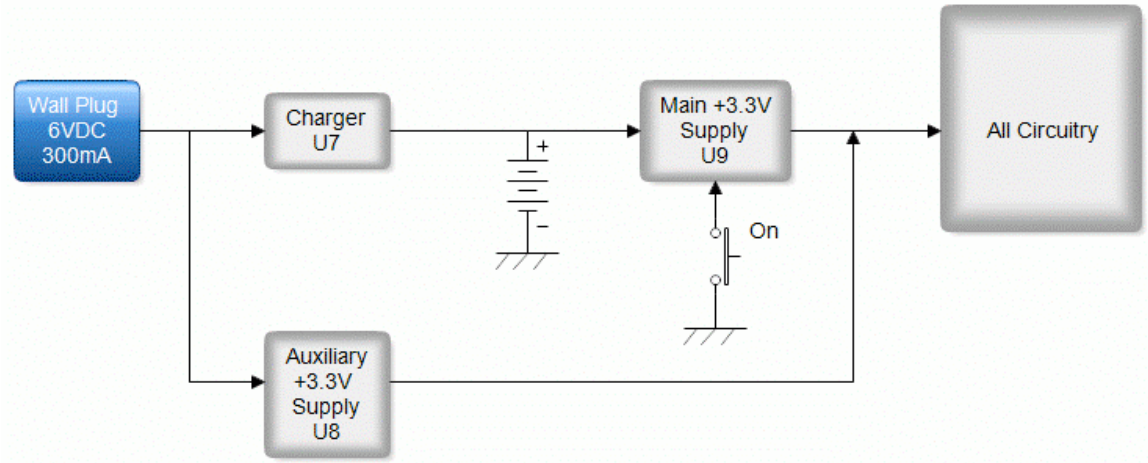
Purpose

This test procedure was created and executed to verify the Control Unit's reaction to short circuit conditions.

Test

Short Circuit Test

The power diagram of the device is shown below:



The Wall Plug power supply delivers 6VDC to the device. The power line is connected to the charger U7, and to the Auxiliary +3.3V Supply U8, which supplies power to the circuitry when battery is being charged.
When the unit operates on the battery, then the Main +3.3V Supply U9 delivers +3.3V to the circuitry.

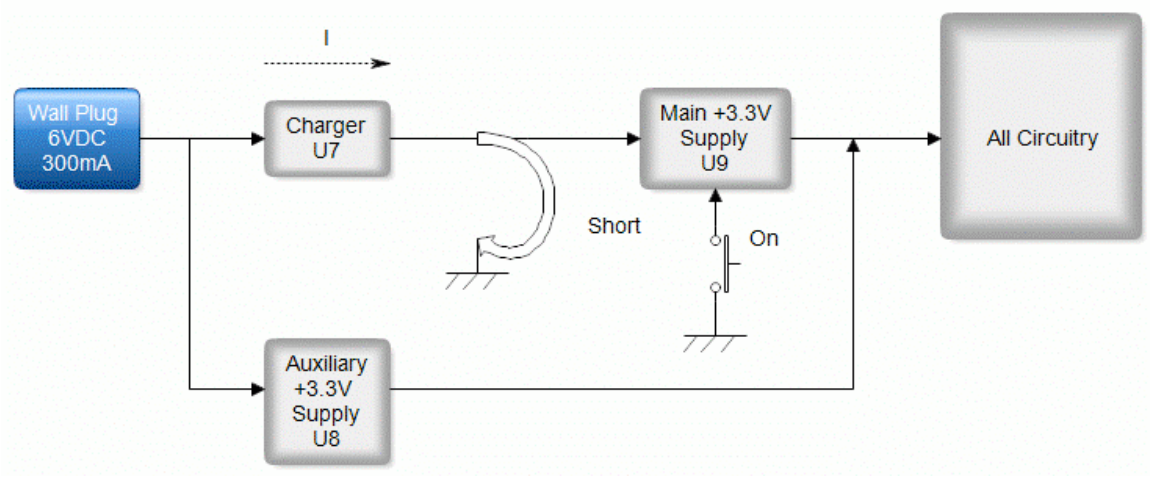
The test was conducted to introduce short circuit conditions and measure the short circuit current.

Condition 1. Charger U7 is shorted.

The diagram of such failure condition is shown below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

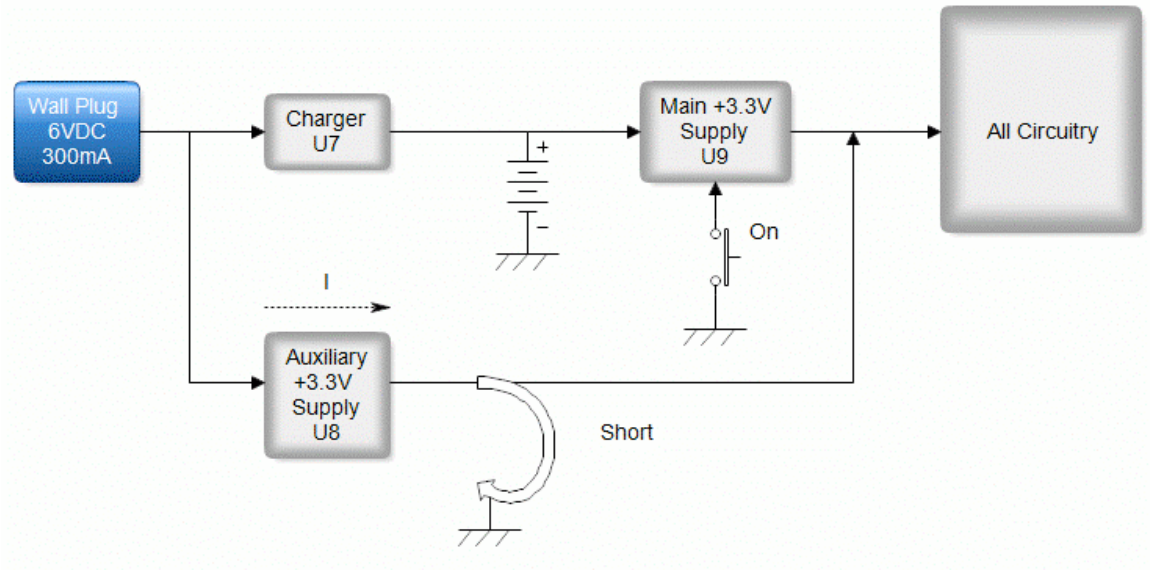
Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



This condition simulates short in the battery when the unit is being charged. The measured current was 250mA (limited by U7), which does not exceed the nominal rating 300mA of the Wall Plug Supply.

Condition 2. Auxiliary +3.3V Supply U8 is shorted.

The diagram of such failure condition is shown below:



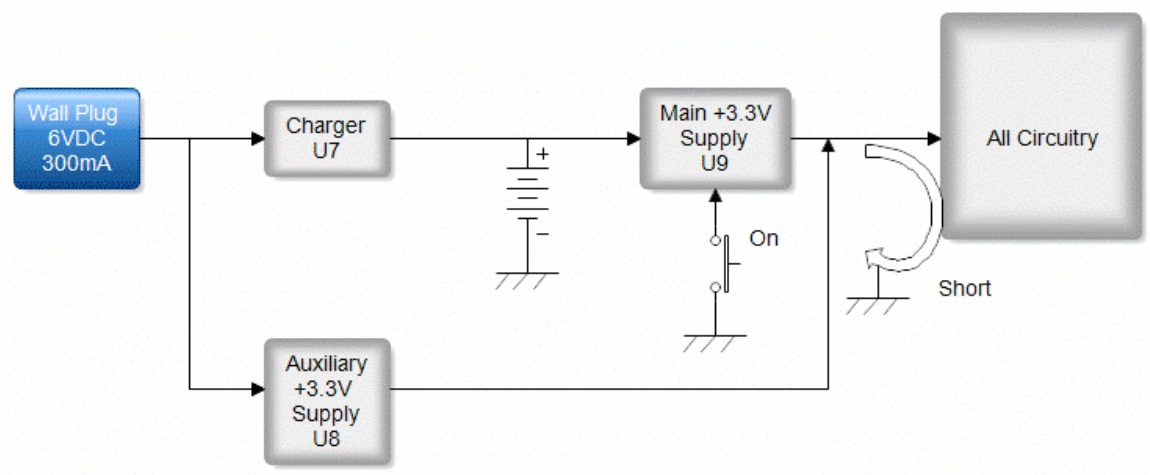
This condition simulates failure in the circuitry while unit is being charged. The measured current was 216mA (limited by U8), which does not exceed the nominal rating 300mA of the Wall Plug Supply.

Condition 3. Main +3.3V Supply U9 is shorted.

The diagram of such failure condition is shown below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.



This condition simulates failure in the circuitry while the unit is powered from the battery. The current was zero, since the power ON circuitry does not latch in the "on" condition if the output is shorted. To latch the "on" condition, the processor must start and latch it; but since the power on the processor was zero, processor never started and never confirmed "on" condition; thus unit stayed off.

Conclusion

The test unit functioned safely in all short circuit conditions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Air Pressure Verification Report

A record of the testing and results for the InTone system.

Intone: **1.00**

Revision History

Rev	Date	Who Changed	Description
1	2011-12-18	E. Palatnei	Document Created

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Purpose

This test procedure was created and executed to verify the function of the Insertion Unit's air pressure measurement and interface with the Control Unit.

Test

Pressure test

The following pressure test was conducted. Using T adapter, a calibrated digital manometer HHP-3200 was inserted into the pneumatic circuit. See the picture below:

(b)(4) TS

Using the inTone pump, the pneumatic circuit was pressurized to the maximum value, when all 8 segments of the bar graph were lit to the full intensity.

(b)(4) TS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

To verify linearity, pressure was verified at several points:

Level	*Bars*	*Pressure* (b)(4) TS
Deflated	None	
25%	Two bright	
50%	Four bright	
75%	Six bright	
100%	All bright	

Conclusion

The test unit's indicator light span met the specified air pressure range. The light indicators were shown to correlate linearly with air pressure.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Volume Report

A record of the testing and results for the InTone system.

Intone: **1.00**

Revision History

Rev	Date	Who Changed	Description
1	2011-12-24	J. Lemke	Document Created

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Purpose

This test procedure was created and executed to verify the adjustable volume of the InTone hand-held Control Unit.

Equipment and Setup

- Extech Sound Level Meter Model Number 407730.
- The sound meter was place at 1 foot from InTone Control Unit. Both the meter and the InTone Control Unit where standing upright for the sound level recordings.
- The average ambient sound lever of the test environment was recorded at 44dB

Test

Measure average minimum, maximum, and sound level per volume increment of a sample InTone Control Unit.

The sample unit produced an average of 85 dB at the maximum. The minimum was 52 dB.

There are 20 increments available to adjust volume from minimum to maximum. The volume adjusts in a linear fashion. Each increment is approximately a 1.7 dB increase.

Level	*Increment*	*Volume*
Mute	0	0 dB
lowest	+1	52 dB
25%	+5	60 dB
50%	+10	67 dB
75%	+15	77 dB
highest	+20	85 dB

Conclusion

The manufactured sample unit was found to produce acceptable sound quality and volume. The adjustments are linear enough for predictable adjustment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Software Validation Report for Intone Control Unit and Clinician PC Application Software

A record of the testing and results for the InTone system utilizing the following software versions:

Intone Control Unit: **1.02**
Clinician PC Tools: **1.02**
Stimulation unit: **1.00**

Date	Author	Description
1-9-2012	Jason Lemke	Software Validation Report for InTone System

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

InTone Urinary Incontinence Solution

Purpose

This test record was created and executed to test the fundamental and critical operation of the InTone system. The InTone system software consists of a PC application the clinician will use to interact with the InTone Control Unit, the InTone Control Unit firmware, and the Stimulation Unit firmware. Except in the case of setting up the correct stimulation level on the probe, each of the three configurations (charging the handset, handset connected to probe, handset connected to PC) was tested independently.

This software validation concentrates on validating both the InTone Control Unit and PC Clinician application that have both been updated from rev 1.01 to 1.02. The Stimulation Unit remains at the initially released version of 1.00.

Terms used and defined

The following is a listing of some of the terminology used in this report and their respective definitions:

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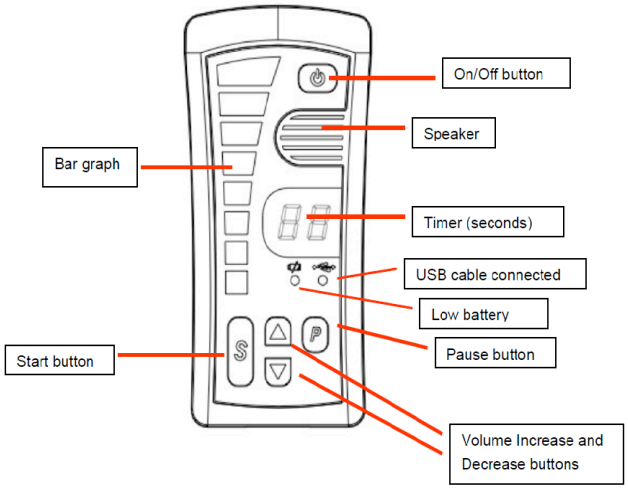
Stimulation level or amplitude:

The power level of electrical stimulation used during the stimulation portion of a session.

Handset or device:

The actual InTone module which may be connected to an insertion probe, PC using USB, or battery charger.



InTone Control Unit or 'Handset' features

Session data or log entry:

The data recorded on the InTone which contains patient performance metrics of a session.

InTone PC Clinician Application

Stimulation or Stim Unit:

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The actual module which a patient vaginally inserts. This will provide stimulation as well as measure a patient's performance.

InTone Stimulation or Stim Unit

Charge state:

Either in a charging mode or a trickle charge mode when the battery is full.

Pressure waveform:

The Stimulation Unit streams the current pressure exerted on it via a pressure sensor to the handset. This stream of data is a pressure waveform.

Setup level:

Is a temporary stimulation level which is only used during the setup of the InTone under the guidance of a clinician.

Balloon, or inflated balloon:

This the vaginally inserted portion of the Stimulation Unit. The balloon is inflated by the pumping of the pump in the heel of the Stim Unit.

Inflatable Balloon on the InTone Stimulation Unit

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Validation of InTone Control Unit Revision 1.02

****Limit audio to a level which should prevent reboot**

Procedure:

Verify that audio does not reboot from the volume being set too high. This will be done with three different Control Units, all with batteries at full charge to promote conditions to create the highest current drawing audio tone. The highest sound pressure level(s) that the Control Unit can produce are to be captured with a sound level meter (Extech model 407730) and revisited by all three Control Units for this test

Expected Results:

Exercising the devices with full battery charge and maximum volume does not initiate a reboot to the device.

Results Obtained:

There were no reboots on any of the three test Control Units at the maximum sound pressure levels on any of the three Control Units. This test was repeated several times with each unit, all of which failed to produce a reboot condition.

****The bar graph is now logarithmic in relation to pressure**

Procedure:

Verify that the bar graph now displays in a logarithmic fashion verses a linear scaling fashion. The Control Unit will be given pressure data from a pressure stimulator. The pressures from the stimulator will start low and be slowly increased. The pressure on the stimulator will be recorded after each new level of bar graph illumination has incremented. The intent is to capture the pressure at the very moment the pressure increments the display's intensity.

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After the pressure data is obtained, it will be calculated to ascertain whether the logarithmic scaling of log base 1.37 is present.

Expected Results:

The LED bar graph scales to fit the logarithmic scaling. The bar graph will be fast to illuminate for an increasingly consistent amount of applied pressure unit well within the mid to upper higher pressure ranges where the LEDs will start to illuminate at a much slower pace with the same consistently increasing pressure.

Results Obtained:

The LED bar graph scaled true to its claimed logarithmic function. The low to mid pressure levels were quick to illuminate the display as expected. Not until the upper to high pressures did the bar graph illuminate ¾ to full in its scale. This is consistent with the said logarithmic scaling.

****The bar graph now has 2 steps per bar instead of 4**

Procedure:

Visually verify that when pressure is applied to the Stim Unit each of the 8 LED window segments on the Control Unit's bar graph illuminates from a low brightness to a high brightness before the next segment is illuminated.

Expected Results:

The bar graph segments illuminate from a low to a high or 2 levels of illumination before proceeding to the next segment.

Results Obtained:

It was visually confirmed that the bar graph did in fact illuminate twice per segment before starting to illuminate the next segment. This was confirmed on all 8 LED window segments. No anomalies where found or noted.

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****Setup mode stimulation now pulses the stimulation rather than providing a non-interrupted 'always on' stimulation**

Procedure:

The pulsed stimulation will be verified via a stimulation test tool which will be used to visually show the stimulation that is being applied as well as physically feeling the stimulation via holding the Stim Unit in the hand. The Control Unit will be inserted into a USB cable connected to a PC, the Clinician application revision 1.02 will (b)(4) TS

(b)(4) TS

Verify that the stimulation test tool's LED is not constantly illuminated, but rather shows a pulsed pattern that cycles the LED's illumination between on and off.

Expected Results:

While in setup mode the stimulation is visually and physically confirmed to pulse at (b)(4) TS or cycles per second, just the same as a treatment session, and not stimulated in a constant non interrupted fashion.

Results Obtained:

The stimulation was visibly verified to be the same pulsed frequency as a normal treatment session. When holding the Stim Unit in the hand the results were also confirmed, the pulsing pattern of (b)(4) TS was in fact present during the setup mode.

****Stimulation will disable for 3 seconds when the amplitude is changed in setup mode**

Procedure:

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(b)(4) TS

[redacted]

Increment up all 20 simulation levels and verify the 3 second delay on each increment, also verify the same with 20 decrements.

Verify with the increment/decrement routine outline above with three different Control Units

Expected Results:

Upon incrementing/decrementing the stimulation level, the simulation test tool's LED will show a 3 second delay from the time the stimulation level is changed to the time the stimulation is applied on the electrodes.

Results Obtained:

The three second delay is in fact present on all three Control Units tested. The delay was present on all 20 increments and decrements.

****The seven segment LED numeric display on the Control Unit that indicates stimulation level during setup mode flashes after incrementing/decrementing the stimulation level during the 3 second disabled time period prior to stimulation being applied**

Procedure:

(b)(4) TS

[redacted]

Increment up all 20 simulation levels and verify that the numeric display flashes the current stimulation level during the 3 second delay on every increment, also verify the same with 20 decrements.

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Verify with the increment/decrement routine outline above with three different Control Units

Expected Results:

Upon incrementing/decrementing, the simulation test tool's LED will show a 3 second delay from the time the stimulation level is changed to the time the stimulation is applied on the electrodes. During this 3 second period the numeric display on the Control Unit will flash the current stimulation value. After the three seconds expire the stimulation with be applied and the numeric display with immediately transition from flashing state to a solid on or non-flashing state.

Results Obtained:

During the setup mode after the stimulation was incremented/decremented the Control Unit's numeric display flashed as expected during the 3 second delay prior to the stimulation being applied. This result was consistent with all three Control Units tested and throughout the range of 20 stimulation increment and decrements for each unit.

****Changed timing to match up with the new audio prompts so that the audio matches up with the actual start and end of the recorded contractions.**

Procedure:

This test will be validated by running through a patient session and verifying the audio that prompts the patient to contract starts and ends at the same time the recording contraction pressure occurs.

This test will be performed by connecting the Control Unit to a Stim Unit and running through a treatment session. Prior to the audible prompting of the contractions the inflated balloon on the stim unit will depressed to ensure maximum pressure and full illumination of the bar graph. At the moment the Control Unit audibly prompts the patient to contract the bar graph with illuminate. The timing between the two events will be viewed and noted.

The activation of the bar graph coincides with the recording event of the pressure sensor data; when one is active the other is as well.

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The timing is verified by the audible arrival of the prompts with the visual timing of the bar graph illumination.

Expected Results:

The audible prompting for the patient to contract should start at the exact time that the LED bar graph illuminates due the balloon being pre-inflated to maximum pressure prior to the prompting event. The two events should start at the same time.

Results Obtained:

The result of the test confirms that the timing is adequate. The timing has a slight offset, as measured was averaging 0.20 seconds from when the audible prompts started to when the bar graph illumination appears.

****Reboot from a shutdown attempt caused by the watchdog reset**

Procedure:

The reboot from a power down initiation with Control Unit firmware (v1.01) was evident by the unit powering back on immediately after the unit was powered down. This is difficult item to test other than by power cycling a unit to identify any power on states after power down has been initiated.

A series of power cycling with the old version 1.01 and with 1.02 will be conducted on three units. After 25 cycles with each, the amount times the units power back on will be recorded to evaluate the effectiveness of the test.

Expected Results:

The results of the version 1.01 Control Units to stay powered down after the power down has been initiated should be significantly more than the version 1.02 Control Unit. There should be no version 1.02 Control Units that power back on after the being powered down.

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Results Obtained:

After the test was concluded the rev 1.01 Control Unit powered back on an average of 32% of the power down attempts. The version 1.02 did not have a single one Control Units power back on during all 3 Control Unit's 25 power down events.

****Added a manufactures test build to the code base**

Procedure:

This test is stretching the boundaries of testing/validating v1.02 firmware. The code has been added to the code base, but activating a switch within the code base to enable the manufactures test changes the functionality of the version 1.02 Control Unit.

With that being said, we will briefly verify that the manufactures test code functions as planned, even though there is no contribution to validating the version 1.02 code base. This manufacturing test code will be validated in a future validation report prior to manufacturing the InTone devices.

When enabling the manufactures' code in version 1.02 and recompiling the code in what we will call 1.02T, the Control unit simply outputs an active stimulation signal and constantly reads pressure data and outputs the pressure to the LED bar graph from a connected Stimulation Unit.

The test operator will be able to start the stimulation by pressing the "S" button and increment/decrement the stimulation level with the up and down arrow keys. The pressure on the balloon is displayed on the bar graph in real time. The test will verify the stimulation starts, increments, decrement, and that any pressure on the Stimulation Unit is output on the bar graph. The stimulation will be verified with the stimulation test tool.

This tool is to verify or spot check the Stim Unit's pressure sensor and stimulation generation system, to verify these two items function properly after being assembled.

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Expected Results:

With the Stimulation and Control Unit connected, the Control Unit should read any pressures exhibited on the Stim Unit's balloon in real time from the moment of power up. With a press of the "S" button on the control unit the stimulation should be activated and the stimulation level able to be incremented/decremented with the current stimulation level displayed in the numeric display.

Results Obtained:

With a control unit flashed with revision 1.02T manufacturing test firmware the bar graph properly translated and displayed any pressures exerted onto the balloon. (The accuracy of the pressure was not verified as the sensor is never calibrated; just a relative pressure is used base on a zeroed base pressure.) When the "S" button was pressed the stimulation activated and the output was correctly verified when incremented/decremented. The stimulation turns off when the "S" button is pressed a second time.

The Stimulation Unit is able to be hot swapped and the control unit will still work properly, that is, a Stimulation Unit is able to be disconnected from the powered Control Unit and then connected again and the Stim Unit will start communicating properly to the Control Unit upon being re-connected.

****Records whether a session was completed or not**

Procedure:

With a Stim and Control Unit connected, power will be applied and a complete patient session exercised. After the session is complete the Control Unit will be powered cycled and another patient session started, but this time the session will be terminated or the Control unit power cycled before completing the whole patient session.

This will be repeated on three Control Units that will record 10 patient sessions each, 5 complete and 5 incomplete sessions.

Verification will be based upon what appears in the "Session Number" column within the Session Data tab in the PC Clinician

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application (ver 1.02). An assigned session number indicates a complete patient session occurred. However, the partial or incomplete sessions will be indicated by the Session Number having the word “Partial” leading the number. Upon verification the data will be erased and Control Unit disconnect from the PC.

(b)(4) TS

[redacted]

Expected Results:

The completed patient sessions will be indicated with a number within the “Session Number” column. The session that are not completed, but rather powered down during the session will have the word “Partial” lead the session number in the “Session Column” within the PC Clinician Application. This should be consistent will all 10 readings on all three Control Units.

Results Obtained:

The units followed the test protocol correctly. The Control Unit sessions that were fully completed indicated so by recording a whole number in the “Session Number” data column. The sessions that were terminated prematurely recorded the word “Partial” leading the session number in the “Session Number” column.

It is noted that the earliest a session is able to be recorded as a partial session is after the initial “Start Pressure” has been recorded.

****Allows a name (up to 31 characters) to be stored**

Procedure:

(b)(4) TS

[redacted]

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"Patient Name". Verify that the entered characters tunicate the characters above the 31 character limit.

Disconnect the Control Unit from the PC and terminate the PC Clinician application window. Open the PC Clinician application v1.02 again and connect the Control Unit used in the prior step via the USB PC cable. With the Control Unit connected click on the "Device Information" tab and verify that the name set in the prior step is displayed in the "Patient Name" row.

Expected Results:

Any characters that were entered in addition to the first 31 characters will not appear in the "patient name" box upon reconnecting the Control Unit. Any names that are entered with 31 characters or less will appear.

Results Obtained:

The Control Unit properly recorded Patient names that were of varying length up to the 31 character limit. Any additional characters past the 31 allowed were cut off and not displayed in the name.

All characters are able to be used, small case, large case, numbers, and special characters.

****Raised the maximum amount of sessions from** (b)(4) TS

Procedure:

Enter (b)(4) patient sessions to determine if (b)(4) sessions can be entered and if the Control Unit will prevent any more than (b)(4) sessions.

Expected Results:

Up to (b)(4) patient sessions will be stored and retained. The (b)(4) TS session will not be able to be recorded.

Results Obtained:

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After many patient session recordings (b)(4) session where reached. The Control Unit stopped recording patient sessions after (b)(4) readings were stored. The device continued to work and function properly, the device simply did not record any additional session data into memory.

****Refactored Data Storage**

Procedure:

This change restructured the way the Control Unit stores data to memory. The best method to exercise this new data storage function is to write and erase data to memory and note any anomalies.

The prior test that recorded (b)(4) patient sessions will be referenced for the data recording exercise. That test proved plenty sufficient to consider the data writes to be solid.

The more scrutinized function is the writing of data to memory. As such the erasing function will not call out such enormous effort; it will consist of three Control Units that will have 15 patient sessions recorded with the erasing of each session after every write.

After recording a patient session connect the Control Unit to the PC via the USB cable. Under “Device” heading choose “Clear Log Data” to erase the recorded patient session. A dialog box asking to “Clear all log data from device?” will appear, choose “Yes”. The patient data will now be cleared from the Session Data log. Repeat this routine for 15 times on all three Control Units.

Expected Results:

All 15 patient data sessions for all three Control Units should successfully appear in the PC Clinician Application in the Session Data log. All 15 logged patient sessions for all three Control Units should be able to be cleared.

Results Obtained:

All data on all three Control Units was properly deleted when the data was cleared. Never once did any data remain in the logged session data after clearing the logged data.

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****Prepared for power on voltage check**

Procedure:

This code structure was add in Control Unit Version 1.02, but the functionality of the power on voltage check has not yet been implemented and will be on the next firmware release.

At this point no testing can nor will be performed for this code feature

Expected Results: N/A

Results Obtained: N/A

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Validation of InTone PC Clinician Application Revision 1.02

****Fixed a problem assigning the year when setting the Control Unit's clock.**

Procedure:

If the test PC's system date is prior to 2012 go into the test PC's BIOS and change the system time to a date in 2012. If the date is 2012 proceed with the next step.

Connect a Control Unit (version 1.02) to the PC via the USB cable and execute the PC Clinician Application. Once the Control Unit is recognized by the application click "Device" on the menu bar and choose "Set Time". A pop up box will appear named "Ready to set time", choose "Yes" to set the time on the device with the current time on your PC.

Follow this procedure with 3 different Control Units.

Expected Results:

The bug that should be fixed locked the date to 2011, even when the system date was 2012. Upon finishing with the procedure listed above the "Device Clock" under the system tab should list the year as 2012 on all three Control Units. The system clock must still be set to 2012 to verify.

Results Obtained:

With the system clock set to 2012 the "Device Clock" listed under the "Device Information" tab was correctly displaying the year as 2012 on all three Control Units.

****Data export is supported**

Procedure:

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With a Control and Stim Unit record data by completing 10 patient sessions, both with partial and complete sessions. Complete this with task with three different Control Units.

Open the PC Clinician Application version 1.02 and connect a Control Unit with the 10 patient sessions via the USB cable. Within the app click “Data” on the menu bar and choose “Export Data”. A “Save As” window will appear. Choose a name for the file and location to save the file and click “Save”. The data will now be exported to the PC.

Open the location that was specified to save the .CSV data export file. Open the .CSV data file and verify that the data within the file matches the 10 patient session’s that were taken and listed within the PC app under the “Session Data” tab.

Expected Results:

The Data within the generated file should match the 10 patient sessions that were recorded exactly for all three Control Units.

Results Obtained:

The exported data successfully matched the 10 patient sessions for all three Control units. No significant anomalies were noted between the on screen PC Clinician app data and the .CSV exported data.

The only minor anomaly that could be found was that the exported file didn’t display the proper significant digit value if the recorded data numeric ended in a ‘0’; it simply omitted the zero. This can be attributed to an improper Microsoft Excel format setup.

****Skip averaging of partial readings**

Procedure:

With a Control and Stim Unit record data by completing 10 patient sessions, both with partial and complete sessions. Complete this with task with three different Control Units.

Open PC Clinician Application version 1.02 and connect a Control Unit with the 10 patient sessions via the USB cable. Within the

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application click on the tab titled “Session Data”. This will display the recorded patient data for all 10 recorded patient sessions.

For every data column that records pressure manually average all individual pressure **excluding** the partial reading rows. Verify that the pressure averages (minus the partial rows) correctly adds up to the “Weekly Averaged” pressure displayed on the bottom of each row.

Repeat this procedure for all three Control Units.

Expected Results:

The manually tabulated averages confirmed the displayed averages for every column on every Control Unit. The partial sessions are confirmed to not be included in the averaging total on the “Start Pressure” or any pressure averaging column.

****Added ability to store a name on an InTone**

Procedure:

A Control Unit will be connected to the PC via a USB cable and the Clinician Tool application v1.02 ran. Under the “Device Information” tab on the bottom there will be a box to enter text. This is where names are entered. Enter a name that has more than 31 characters. After the name is entered press the “Set New Name” button to the left of the text box. After the button is pressed the characters entered will appear in the data box row named “Patient Name”. Verify that the entered characters tunicate the characters above the 31 character limit.

Disconnect the Control Unit from the PC and terminate the PC Clinician application window. Open the PC Clinician application v1.02 again and connect the Control Unit used in the prior step via the USB PC cable. With the Control Unit connected click on the “Device Information” tab and verify that the name set in the prior step is displayed in the “Patient Name” row.

Expected Results:

Any characters that were entered in addition to the first 31 characters will not appear in the “patient name” box upon

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reconnecting the Control Unit. Any names that are entered with 31 characters or less will appear.

Results Obtained:

The Control Unit properly recorded Patient names that were of varying length up to the 31 character limit. Any additional characters pass the 31 allowed were cut off and not displayed in the name.

All characters are able to be used, small case, large case, numbers, and special characters.

****Fixed a problem with some crashes**

Procedure:

Open the PC Clinician application v1.02. Connect a Control Unit to the PC via the PC USB cable. Click on the Device Information tab and verify that the Control Unit's information populates.

Disconnect the Control unit from the USB cable, the information unit "Device Information" should depopulate. (Verify no PC Clinician app crash)

With the PC Clinician application still open, reconnect the Control unit to the USB cable. (Verify no PC Clinician app crash

With the Control Unit still connected close the PC Clinician application. (Verify no PC Clinician app crash while the application shuts down)

With the Control Unit still connected open another instance of the PC Clinician application and verify Device Information populates. (Verify no PC Clinician app crash while the app opens)

Expected Results:

No PC Clinician application crashes are to be reported at any time.

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Results Obtained:

The PC Clinician application had shown a crash rate of 20% upon the PC app being open and the Control Unit inserted. This will be written up as a SPR. Different combinations of PC UBS cables and were used but didn't prove to be immune to the few PC app crashes. At this point it is not known whether these crashes stem from a hardware or software problem. The risk is low as the users can reopen the application and no data is being lost; it is just an inconvenience.

There was a crash that was noted when there are two PC Clinician applications open and a Control Unit is connected to the PC the PC app that has focus will terminate or crash.

This specific crash does not occur if the active focus is removed from both apps and placed on another PC window when the Control Unit is connected to the PC. With the Control Unit connected and both apps running in the back ground the focus can be brought back to one of the two running apps and it will successfully establish communication with Control Unit. This bug has been reported in the SPR list.

****Average records are not created for periods of time where all the readings are partial reading.**

Procedure:

With a Control and Stim Unit record data by completing 10 patient sessions, all of which are partial sessions. Complete this task with three different Control Units.

Upon completion, open the PC Clinician application ver.1.02 and click the Session Data tab to view the 10 partially recorded patient data session.

Expected Results:

No "Weekly Average" row will appear because all of the patient sessions were recorded at partials.

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Results Obtained:

With all three Control Units the “Weekly Average” row was absent in the Session Data.

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Software Validation Report for Intone Control Unit and Clinician PC Application Software

A record of the testing and results for the InTone system utilizing the following software versions:

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Clinician PC Tools: **1.02**
Stimulation unit: **1.00**

Date	Author	Description
1-21-2012	Jason Lemke	Software Validation Report for InTone System

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This software validation concentrates on validating the InTone Control Unit version 1.03. The Stimulation Unit and PC application remains at the initially released version of 1.00 and 1.02 respectively.

Terms used and defined

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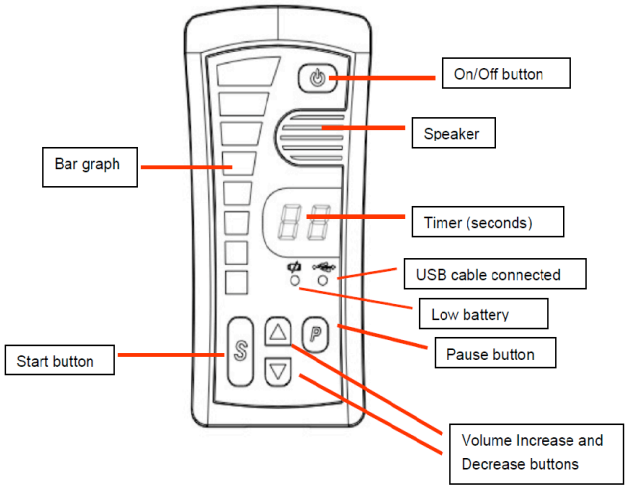
Handset or device:

The actual InTone module which may be connected to an insertion probe, PC using USB, or battery charger.



InTone Control Unit or 'Handset' features

Session data or log entry:

The data recorded on the InTone which contains patient performance metrics of a session.

InTone PC Clinician Application

Stimulation or Stim Unit:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The actual module which a patient vaginally inserts. This will provide stimulation as well as measure a patient's performance.

InTone Stimulation or Stim Unit

Charge state:

Either in a charging mode or a trickle charge mode when the battery is full.

Pressure waveform:

The Stimulation Unit streams the current pressure exerted on it via a pressure sensor to the handset. This stream of data is a pressure waveform.

Setup level:

Is a temporary stimulation level which is only used during the setup of the InTone under the guidance of a clinician.

Balloon, or inflated balloon:

This the vaginally inserted portion of the Stimulation Unit. The balloon is inflated by the pumping of the pump in the heel of the Stim Unit.

Inflatable Balloon on the InTone Stimulation Unit

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Validation of InTone Control Unit Revision 1.03

****During the beginning of the stimulation the stimulation is initiated 3 levels lower and fully ramps to the pre-set level. The first pulse is 3 stimulation settings lower; with each pulse increasing by 1 level until the programmed amplitude is fully achieved by the forth pulse**

Procedure:

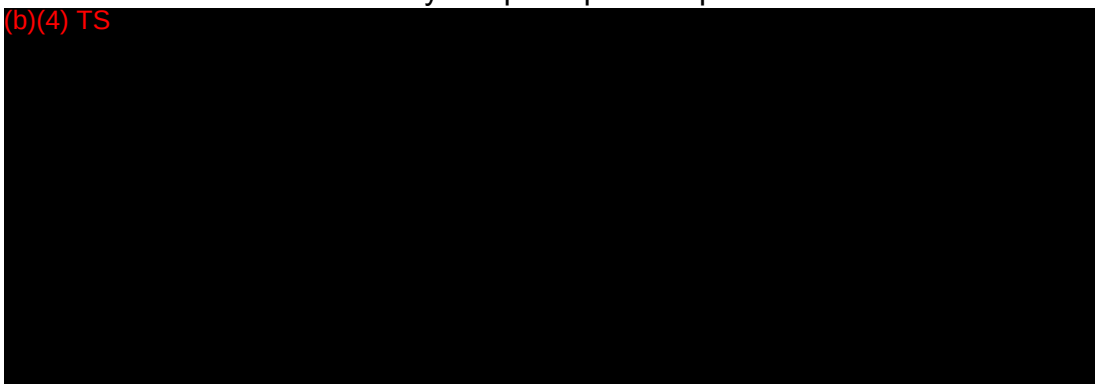
With an oscilloscope measure the beginning stimulation waveform during a patient stimulation session. Verify that the waveform ramps three levels higher to the pre-set stimulation level after the first initial waveform.

Expected Results:

The stimulation starts three levels lower than the pre-set level and increments one stimulation level every cycle until the stimulation pre-set level is reached. The stimulation level will not ramp higher than the pre-set stimulation level.

Results Obtained:

The first 5 waveforms of a patient session where recorded. As the waveforms that were recorded from this session show (below), the patient session did start 3 stimulation levels lower than the pre-set stimulation level and fully ramped up to the pre-set stimulation level



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

****Low battery detection added. The device will not operate at all if the battery level is not at a sufficient level. The battery check is skipped if the battery charger or PC cable is detected**

Procedure:

Connect a power supply up the control unit's battery connection terminal. The low battery detect activation occurs at 2.4VDC. Apply 2.4VDC to the battery terminal with the variable power supply and attempt to power up the Control Unit, observe the results.
Apply 2.3VDC from the power supply to the Control Unit and power the unit and observe.

Expected Results:

The Control unit should power up when the input voltage is set to l 2.4VDC or greater.

When the input voltage provided to the Control Unit is set to 2.3VDC or less (less than 2.4VDC) the Control Unit should not power up, this would confirm that the battery detection implemented in v1.03 is preventing the device from power up.

Results Obtained:

When the input voltage was increased above the low battery voltage detection threshold (2.4VDC or greater) the device did start up and operate properly; the voltage was set to 2.4VDC.

With the input voltage set to 2.3VDC the Control Unit failed to power up. This verified that the low battery detection was preventing this startup properly and the threshold is set properly.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Software Validation Report for Intone Control Unit and Clinician PC Application Software

A record of the testing and results for the InTone system utilizing the following software versions:

Intone Control Unit: **1.04**
Clinician PC Tools: **1.02**
Stimulation unit: **1.00**

Date	Author	Description
1-24-2012	Jason Lemke	Software Validation Report for InTone System

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

InTone Urinary Incontinence Solution

Purpose

This test record was created and executed to test the fundamental and critical operation of the InTone system. The InTone system software consists of a PC application the clinician will use to interact with the InTone Control Unit, the InTone Control Unit firmware, and the Stimulation Unit firmware. Except in the case of setting up the correct stimulation level on the probe, each of the three configurations (charging the handset, handset connected to probe, handset connected to PC) was tested independently.

This software validation concentrates on validating the InTone Control Unit version 1.04. The Stimulation Unit and PC application remains at the initially released version of 1.00 and 1.02 respectively.

Terms used and defined

The following is a listing of some of the terminology used in this report and their respective definitions:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

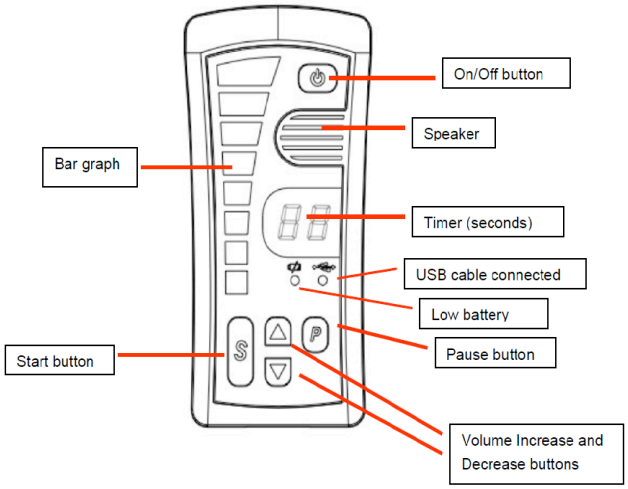
Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Stimulation level or amplitude:

The power level of electrical stimulation used during the stimulation portion of a session.

Handset or device:

The actual InTone module which may be connected to an insertion probe, PC using USB, or battery charger.



InTone Control Unit or 'Handset' features

Session data or log entry:

The data recorded on the InTone which contains patient performance metrics of a session.

InTone PC Clinician Application

Stimulation or Stim Unit:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The actual module which a patient vaginally inserts. This will provide stimulation as well as measure a patient's performance.

InTone Stimulation or Stim Unit

Charge state:

Either in a charging mode or a trickle charge mode when the battery is full.

Pressure waveform:

The Stimulation Unit streams the current pressure exerted on it via a pressure sensor to the handset. This stream of data is a pressure waveform.

Setup level:

Is a temporary stimulation level which is only used during the setup of the InTone under the guidance of a clinician.

Balloon, or inflated balloon:

This the vaginally inserted portion of the Stimulation Unit. The balloon is inflated by the pumping of the pump in the heel of the Stim Unit.

Inflatable Balloon on the InTone Stimulation Unit

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Validation of InTone Control Unit Revision 1.04

**** Added a fix that prevented the stimulation to jump to maximum (level 20) when the Stimulation Unit is disconnected and reconnected to the Control Unit during a patient or setup session. (Prior InTone Control Unit SPR #42)**

Procedure:

Connect a Control Unit (rev1.04) to a Stim Unit start a patient session. With the Stimulation Unit (rev1.00) active during the patient stimulation session disconnect the Stimulation Unit from the Control Unit and immediately reconnect the Stimulation Unit to the Control Unit. Observe the results.

Connect a Control Unit (rev1.04) to a PC USB cable and with the PC Clinician Application (rev1.02) set the Control Unit into setup Mode. Connect the Control Unit that is in Setup Mode to a Stimulation Unit, initiate stimulation by pressing “S”, and increment to level 3 of 20 stimulation output. Connect a stimulation test tool across the electrodes and verify the low intensity (level 3 of 20) stimulation on the LED indicator (the LED will be dimly lit). Disconnect and immediately reconnect the Stimulation Unit from the Control Unit. Observe the results.

Expected Results:

In the first case (patient session test), the Control Unit will immediately terminate its patient session and shut down preventing any possibility of reintroducing level 20 of 20 stimulation level output upon reconnection to the Control Unit.

In the second case (setup mode), the Control Unit will terminate the stimulation output and restart at level 0, or off. The ‘Timer’ or numeric display on the Control Unit will read dashes indicating stim output is not active.

Results Obtained:

In the first case, when the Stim Unit is disconnected from the Control Unit the Control Unit does immediately power down. The patient would have to restart the session. This event was recorded

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as a partial session on the PC Clinician application under the Session Data information.

This behavior removes any risk that the patient would receive maximum stimulation by the Stimulation Unit being disconnected during a patient session. It is a bit of an inconvenience and a SPR has been added to investigate changing the behavior of the Stimulation Unit's code to allow the disconnect/reconnect of the Stimulation Unit from the Control Unit while in a stimulation session and have the Stimulation Unit return to the same pre-set stimulation level and continue the session.

During the second test (setup mode), upon disconnecting/reconnecting the Stimulation Unit from the Control Unit the Control Unit stopped the stimulation and did display dashed lines on the 'Timer' display indicating the stimulation was off. Pressing the "S" button to restart the stimulation made the stimulation activate once again at the proper level where it had last been, level 3. The stimulation level never jumped up to maximum.

The 'setup mode' was further tested by starting level 3 stimulation output, pausing the control unit, disconnecting/reconnecting the Stimulation Unit, and pressing the pause button to reactivate the stimulation output once again. The results were such that the Control Unit was not able to return to the level 3 stimulation. Rather the Control Unit was once again set to a 'no output' state, or off. Pressing the "S" button would again initiate the stimulation and the user would need to up arrow/increment to the desired stimulation output level.

The test concludes that the setup mode is not able to be placed into maximum stimulation by disconnecting the Stimulation Unit from the Control Unit.

In both tests the version 1.04 Control Unit firmware inhibits the Stimulation Unit from outputting maximum stimulation by disconnect/reconnect of the Stim Unit as noted by SPR #42. It will be noted again that an SPR has been added to investigate a code enhancement that allows the Stimulation Unit to disconnect/reconnect from the Control Unit while not shutting down the patient session. This would be an added convenience to the patient using the InTone system.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

InTone Abnormal Usage Testing

Author	**Jason Lemke**
Date	**1-10-12**
Control Unit Version	**1.02**
PC Clinician Application Version	**1.02**

Purpose:

This test is designed to subject the InTone urinary incontinence device to various abnormal usage scenarios in order to observe and report the resulting behavior. It's through these tests that a more complete picture of the behavior of the system will be found and documented.

It is this documents intent that any abnormalities found will be noted in the software SPR list. Likewise, the same will follow with any hardware related issues. Through these tests a more solid understanding of how the software and hardware interact will be shown.

Terms used and defined

The following is a listing of some of the terminology used in this report and their respective definitions:

Stimulation level or amplitude:

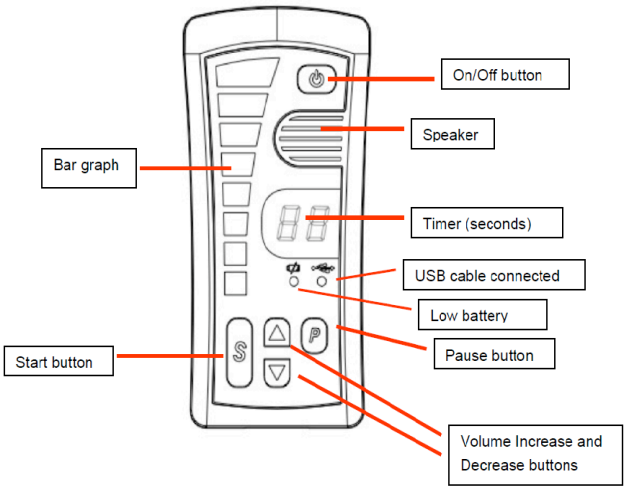
The power level of electrical stimulation used during the stimulation portion of a session.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Handset or device:

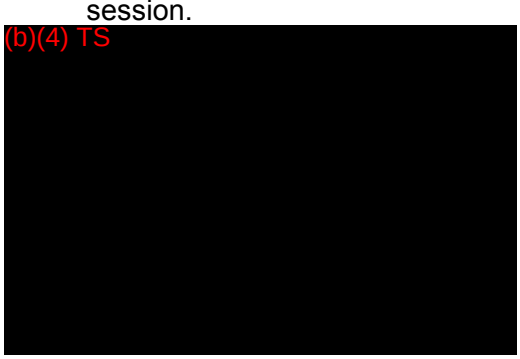
The actual InTone module which may be connected to an insertion probe, PC using USB, or battery charger.



InTone Control Unit or 'Handset' features

Session data or log entry:

The data recorded on the InTone which contains patient performance metrics of a session.



InTone PC Clinician Application

Stimulation or Stim Unit:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

The actual module which a patient vaginally inserts. This will provide stimulation as well as measure a patient's performance.

InTone Stimulation or Stim Unit

Charge state:

Either in a charging mode or a trickle charge mode when the battery is full.

Pressure waveform:

The Stimulation Unit streams the current pressure exerted on it via a pressure sensor to the handset. This stream of data is a pressure waveform.

Setup level:

Is a temporary stimulation level which is only used during the setup of the InTone under the guidance of a clinician.

Balloon, or inflated balloon:

This the vaginally inserted portion of the Stimulation Unit. The balloon is inflated by the pumping of the pump in the heel of the Stim Unit.

Inflatable Balloon on the InTone Stimulation Unit

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

**__Abnormal Test__: During Patient Session, disconnect Stimulation Unit during a base pressure reading

Procedure:

With the Stimulation and Control unit connected start a patient session. During the base pressure recording disconnect the stimulation Unit and reconnect after the base pressure is finished being recorded. Finish patient session.

Results Observed:

The Stim Unit was disconnected from the Control unit half way through the base pressure recording. The Session data showed no signs of anomalies.

(b)(4) TS

Additional Comments:

The reason for data appearing in the 'Start Pressure' column even while the Stim Unit was disconnected is because the Control Unit averaged what pressure data it was able to record before the Stim Unit was disconnected.

**__Abnormal Test__: During a Patient Session, disconnect the Stimulation Unit during a prompted contraction

Procedure:

With the Stimulation and Control unit connected start a patient session. During the first prompted contraction disconnect the Stimulation Unit and reconnect after the 3 second contraction period is concluded.

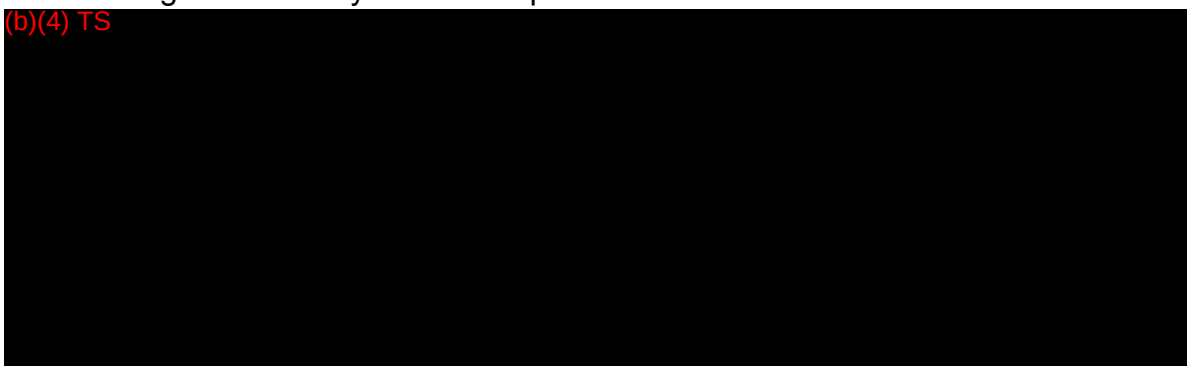
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Results Observed:

After the Stim Unit was disconnected half way through the first 3 second short contractions the remainder of the patient session was allowed to continue and complete. The session data populated the short contraction average without any noticeable problem.

(b)(4) TS



Additional Comments:

Stimulation level was not set prior to the test, thus the zero in the 'Stimulation level' column.

****<u>Abnormal Test</u>: During a Patient Session, disconnect Stimulation Unit during the stimulation session**

Procedure:

With the Stimulation and Control unit connected start a patient session. During the 5m stimulation session disconnect and reconnect the Stim Unit.

Results Observed:

The stimulation continued without interruption after the Stim Unit was reconnected to the device. All pressure averages correctly populated in their respective columns.

However, there is a noticeable bug that appears after the Stim Unit is reconnected, the stimulation output returns at level 20 (full power).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

(b)(4) TS

Additional Comments:

This bug has been submitted to the software SPR list. Note that the pressure increase on the screen capture was due to the pump being inflated with handling the Stim Unit.

****<u>Abnormal Test</u>: During a patient session, the battery drops too low to continue Control Unit operation and shuts down during the session.**

Procedure:

With the battery charged just enough to start a patient session, but not charged enough to finish said session, record as much of the patient session and evaluate.

Results Observed:

The test conducted had the battery drop out at during the patient stimulation session. The Control Unit powered off without notice and the session was terminated.

When the Control Unit was hooked up to the PC Clinician application the 'Session Data' showed zeros in the columns that had yet to finish and record. The recording session was properly labeled "Partial" due to the premature termination of the session.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

(b)(4) TS

[redacted]

Additional Comments:

This is an expected behavior

****<u>Abnormal Test</u>: The wall charger is connected to the Control Unit and while connected together plugged into the wall outlet to charge.**

Procedure:

Connect the Control Unit to the wall charger. When connected insert the wall charger/Control Unit into the wall outlet and observer any anomalies.

Results Observed:

When the charger is inserted in the wall outlet the Control Unit starts to charge as expected, the charging indicator LED starts to pulse.

One anomaly that was observed was being able to keep the charging/low battery indicator LED illuminated while the Control Unit was still connected to the wall charger but after the wall charger was disconnected from the wall outlet.

If the Control Unit was connected to the wall charger and the wall charger connected to the wall outlet, disconnecting the wall charger from the wall at the very moment the charging/low battery LED was illuminated retains the illuminated state of the LED Indicator in a ‘solid on’ or non-pulsing fashion. The charging/low battery LED will stay illuminated as long as the Control Unit is connected to the wall charger. Once the two are disconnected from each other the charging/low battery LED extinguishes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Additional Comments:

The anomaly described above has been added to the InTone Control Unit SPR list.

****<u>Abnormal Test</u>: While Control Unit is being charged with a wall charger press all keypad buttons and evaluate**

Procedure:

Connect a Control Unit to a wall charger that is connected to a wall outlet. Press all keypad buttons and observe any anomalies.

Results Observed:

The keypad buttons are non-responsive and do not invoke any anomalies or strange behavior, no matter what combination, repeat strike speed, or both are applied.

Additional Comments:

None

****<u>Abnormal Test</u>: With a Control Unit in 'Setup Mode' connect Control Unit to a wall charger that is connected to a wall outlet and evaluate**

Procedure:

Connect a Control Unit to a PC via PC USB cable. Open the PC Clinician application v1.02 and from the menu bar click on "Setup" to place the Control Unit in Setup Mode.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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With the Control Unit in Setup Mode connect the Control Unit to a wall charger that is connected to a wall outlet and observer any anomalies.

Results Observed:

Upon connection to the wall charger the Control Unit immediately switches from Setup Mode state to a charging state. No anomalies are noted.

Additional Comments:

None

****<u>Abnormal Test</u>: With the PC Clinician Application v1.02 open and a PC USB cable connected to a Control Unit, connect/disconnect the Control Unit/USB cable as a whole to/from the PC and observe**

Procedure:

With the PC Clinician Application v1.02 open and a PC USB cable connected to a Control Unit, connect the Control Unit/USB cable into the PC and observe

Results Obtained:

Upon connection to the PC the Control Unit was recognized by the PC Clinician application, this was successfully repeated several times.

It was noted that the removal of the USB cable and Control Unit as a whole crashed the PC Clinician application. This was able to be continuously repeated. The following error screen was invoked:

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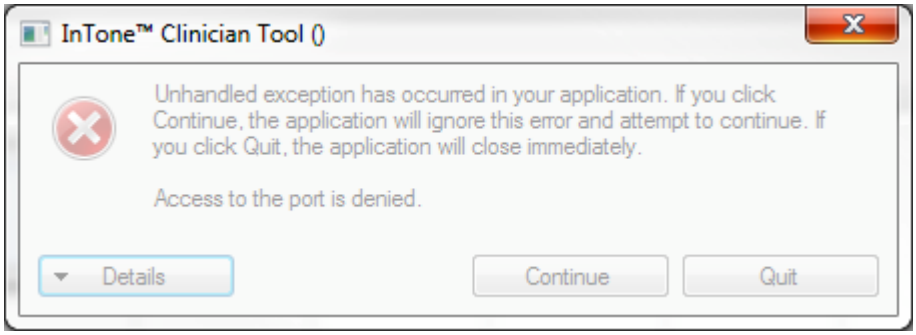

Additional Comments:

The bug where the application crashes when the USB Cable and Control unit are removed as a whole from the PC has been added to the SPR list.

There was a minor anomaly noted, the USB and Charging LEDs stay illuminated when the PC USB cable is removed from the PC with the Control Unit still connected. If the USB is then disconnected from the Control Unit the USB and charging LEDs extinguish. Likewise, a power cycle to the Control Unit will remove the hanging LEDs. This anomaly has been added to the SPR list.

****<u>Abnormal Test</u>: With the PC application running, power a Control Unit and then proceed to connect to the PC with the PC USB cable, observe the results.**

Procedure:

With the PC Clinician application connected to the PC, power the Control Unit and connect to the PC via the PC USB cable, observe the results.

Results Obtained:

There were no anomalies that were to be noted. After several connections to the PC USB cable with the powered Control Unit, the Control Unit simply switched from the powered patient session state to the PC data communication state and established communication with PC Clinician Application.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Additional Comments:

None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

1.04 2012-01-24
*Added a fix that prevented the stimulation to jump to maximum (level 20) when the Stimulation Unit is disconnected and reconnected to the Control Unit during a patient or setup session. (Prior InTone Control Unit SPR #42)

1.03 2012-01-21
*During a stimulation session, the stimulation is initiated 4 levels lower and ramps to the pre-set level. The first pulse is 4 stimulation settings lower; with each pulse increasing by 1 level until the programmed amplitude is achieved
*There is an immediately power on low battery detection. The device will not operate at all if the battery level is not at a sufficient level. The battery check is skipped if the battery charger or PC cable is detected

1.02 2012-01-05
*Limit audio to a level which should prevent reboot (20 total levels and rescaled volume to fit linearly within the 20 increments)
*The bar graph is now logarithmic using a Log base of 1.37.
*The bar graph now has 2 steps per bar instead of 4.
*Setup mode stimulation now pulses on and off like a stimulation session
*The stimulation will disable for 3 seconds when the amplitude is changed in setup mode
*The numbers displaying the stimulation amplitude flash while disabled in setup mode.
*Changed timing to match up with the new audio prompts so the audio should match up with the actual start and end of recorded contractions.
*Fixed a reboot from a shutdown attempt caused by the watchdog reset being set too short (changed from 100mS to 500ms).
*Added a Manufacture test build to the code base
*Records whether a session was completed or not
*Allows a name (up to 31 characters) to be stored.
*Raised the maximum amount of sessions from 256 to 800.
*Refactored data storage
*Prepared for power on voltage check

1.01 2011-11-17
*Fixed the bar graph scaling for setup mode.
*Added extra status reporting needed for the clinician tool auto connection and setup mode handling.
*Fixed a bug where the stimulation countdown would go from 2 to 0.
*Fixed a problem where the wrong prompt was played after stimulation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

*Added a one second pause after prompting the start of a contraction and when the display starts the countdown.
*Added a half second pause after the countdown reaches zero and the prompting the end of a contraction.
*The stimulation counts down in minutes.
*The patient is instructed about the baseline and it is taken as an average of 3 seconds.
*The graph for the contractions is zeroed at the baseline.
*The bars on the graph phase in and out in four steps with each step representing 0.05 PSI for a fully lit bar representing 0.20 PSI allowing a range of 1.6 PSI on the entire graph.
*Many prompts have been changed.
*Improvement to Low battery detection
*Fix a bug where the InTone would reset when uploading more than 12 sessions or so from a watchdog reset.
*Started to add extra prompt delays in a patient session.
*Immediately terminate audio and session if the PC or charger cable is inserted or the power is pressed. (Before if a PC or charger cable was inserted the audio would continue to play and the session completed so far would not be recorded. The audio prompt would continue to play about 1 second after power off as well.)
*Added a workaround for a bug in the stimulation board. The stimulation board should still be fixed.
*Added pulsing to the stimulation during a session.
*Fixed a bug where you could adjust the simulation level when in configuration mode even when the stimulation was off and the device displayed dashes. This would let you hold the up arrow and raise it to 20 then hit start and shock yourself.
*The when entering configuration mode, the stimulation level always starts at zero, before it would start at zero the first time but would then start at the last value used until power cycled.
*Fixed the problem when first plugged into charger and the device does not charge.
*Added stimulation level to a session record.
*Start pressure properly recorded.
*Added watchdog to reboot the system if locked up.
*Fixed a battery charger problem
*probe baud rate changed to 115200

1.00 2011-7-21
*Initial internal release version

2011-1-14
*Final development version

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Clinician Tool 1.02 2012-01-06
*Fixed a problem assigning the year when setting the InTone clock.
*Data export is supported.
*Skip averaging of partial readings
*Added ability to store a name on an InTone.
*Fixed a problem with some crashes.
*Average records are not created for periods of time where all the readings are partial readings.

Clinician Tool 1.01 2011-11-17
*Added auto connection
*Added auto disconnection
*Added new setup procedure mode with multiple prompts
*Moved menu items around
*Added a demo build

Clinician Tool 1.00 2011-8-25
*Initial internal release version

Clinician Tool 2011-1-14
* Final development version

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Open SPR Report

product	SPR	description	impact	current disposition
PC software	61	When exporting data the 'save as' window pops up. Default file name is patient's name. Suggestion to make default "InTone" instead of the patient's name.	potential preference	defer
PC software	62	Provide export data options; be able to export data in a more graphically appealing forms.	Opinion was that the .cvs Excel output file's format was is unsightly, unorganized, and the titles too long. A few more options that consist of a polished and 'ready to use' format has been requested.	defer
PC Software	63	Suggestion to allow user to save the number of pumps required for comfortably snug fitment, then display said numeric value on the Control Unit during session start.	potentially useful	defer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

PC Software	64	When there are two PC Clinician app open and a Control Unit is then connected to the PC, the actively focused PC app will crash. This app crash will not occur if the active focus is removed from both apps (placed on another PC window) when the Control Unit is connected to the PC. With the Control Unit connected and both apps running in the back ground the focus can be brought back to one of the two running apps and it will successfully establish communication with the Control Unit.	PC application reliability and robustness gain. No changes or data loss.	defer
PC Software	65	With the PC application up, and a Control Unit connected to a USB Cable, connecting the Control Unit/USB cable as a whole into the PC causing the PC Clinician application to crash.	Reliability improvement in case of unintended connection sequence. No changes or data loss.	defer
PC Software	66	PC App still randomly crashing when the Control Unit is Connected to an already connected PC USB cable.	Reliability improvement. No changes or data loss.	defer
InTone control unit	35	Stimulation session ramp-up. It may be preferred to ramp up the pulses to programmed strength starting 4 levels lower and ramp up to programmed strength on the 4th pulse	provide more gentle start to session, currently ramps up in 3 steps to programmed level	defer

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InTone control unit	36	Sometimes starts up at full volume. The volume will inconsistently reset to max level after a power cycle.	volume may be louder than desired and require adjustment	defer
InTone control unit	37	Battery light does not turn on when it should.	may have late indication of low battery possibly causing delay or interruption	defer
InTone control Unit	38	During trickle charge mode, threshold to extinguish pulsating charge LED indicator needs adjustment, the LED never stops pulsing on/off, even with several hours (10+) of charge time.	Unintended operation of device, no impact on charging or use	defer
InTone control unit	39	Allow the pause to work at startup	convenience if patient decides not ready to start yet	defer
InTone control unit	40	Improve low power handling at startup. The system should check the power level at start up and disallow if power too low.	session may be interrupted if battery too low	defer
InTone control unit	41	Boot loader added to allow the software to be reprogrammed through the serial port on the InTone so the PCB does not need to be removed from enclosure to update firmware.	manufacturing convenience if software revision required	defer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

InTone control unit	43	If the Control Unit was connected to the wall charger and the wall charger connected to the wall outlet, disconnecting the wall charger from the wall at the very moment the charging/low battery LED was illuminated retains the illuminated state of the LED Indicator in a 'solid on' or non-pulsing fashion. The charging/low battery LED will stay illuminated as long as the Control Unit is connected to the wall charger. Once the two are disconnected from each other the charging/low battery LED extinguishes	unintended operation of device, unlikely combination of events, no impact, indication corrects after disconnection required for any other use	defer
InTone control unit	44	The USB and Charging LEDs stay illuminated when the PC USB cable is removed from the PC with the Control Unit still connected. If the USB is then disconnected from the Control Unit the USB and charging LEDs extinguish.	unintended operation of device, no impact, indication corrects after disconnection required for any other use	defer
InTone control unit	45	Allow the stimulation unit to disconnect/reconnect to the control unit without terminating the patient session	convenience to the patient, enhancement	defer

InTone Stimulation Unit	7	Allow the stimulation unit to disconnect/reconnect to the control unit without terminating the patient session	convenience to the patient, enhancement	defer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

From: Jason Lemke <jlemke@gmail.com>
Date: January 9, 2012 9:29:45 AM CST
To: "Michael J. Leigh" <michaeljamesleigh62@gmail.com>, Eugene Palatnik <epalatn@itecengineering.com>
Subject: Fwd: Order Request for INCONTROL MEDICAL L L C - Order # 6187628 - Project # 11CA38346 - PRE-COMPLIANCE RE & RFI ON STIMULATION DEVICE.

The answer to questions a. is below. If there is anything in addition that needs to be clarified let me know and I'll coordinate an answer.

Thanks,
Jason

---------- Forwarded message ----------
From: **Mucha, Bartlomiej** <Bartlomiej.Mucha@ul.com>
Date: Mon, Jan 9, 2012 at 9:25 AM
Subject: RE: Order Request for INCONTROL MEDICAL L L C - Order # 6187628 - Project # 11CA38346 - PRE-COMPLIANCE RE & RFI ON STIMULATION DEVICE.
To: Jason Lemke <jlemke@gmail.com>

Jason,

Where they are asking for emissions I suspect they mean conducted emissions. And the reason these were done in charging only mode is because this is the only mode where the EUT connects to mains supply. For all other modes the EUT is used on battery power.

Bartlomiej Mucha
UL Verification Services, WiSE Business Segment
Wireless, **I**nteroperability, payment **S**ecurity, & **E**MC

333 Pfingsten Rd.
Northbrook, IL 60062
Phone: 847-664-1216
Fax: 847-407-1216

From: Jason Lemke [mailto:jlemke@gmail.com]
Sent: Monday, January 09, 2012 9:06 AM

To: Mucha, Bartlomiej
Subject: Re: Order Request for INCONTROL MEDICAL L L C - Order # 6187628 - Project # 11CA38346 - PRE-COMPLIANCE RE & RFI ON STIMULATION DEVICE.

Good Morning Bart,

Hope the Holidays and new year has you well! If you can remember the InTone project we are to be concluded this week with the biological testing and then the project can be sent back the the FDA for (hopefully) approval. There was on final (hopefully:) question that our regulatory consultant requested from you just to have on document. I hope it's not too much to dig up an answer from ya. Thanks in advance for your help!

Jason

a. Why were emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker tested in charging mode only?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

On Sun, Nov 20, 2011 at 7:49 PM, Jason Lemke <jlemke@gmail.com> wrote:

Hi Bart,

Sorry again for the late reply, I've been in Northern WI since Thursday. I appreciate the reply and will forward it to our regulatory consultant and see what he says. From what I see there should be no issues and your summary will be sufficient. If I have any further questions I'll let you know, otherwise thanks again for taking the time to reply to our questions.

Jason

On Wed, Nov 16, 2011 at 6:20 PM, Mucha, Bartlomiej <Bartlomiej.Mucha@ul.com> wrote:

Jason,

For the first one – when we did preliminary testing we used 100% output. After you guys came back to do the final measurements we started with 80% and 20% and when we looked at the data we found that 80% and 20% has more noise than 100% did. We also found that there was not much difference between 80% and 20%.

For the second one – because of how the board is placed in the device the EUT will react different to the field at different positions. At one position the board could be parallel to the field and in others could be cross-polarized.

Hope that this helps.

Bartlomiej Mucha
UL Verification Services, WiSE Business Segment
Wireless, **I**nteroperability, payment **S**ecurity, & **E**MC

333 Pfingsten Rd.
Northbrook, IL 60062
Phone: 847-664-1216
Fax: 847-407-1216

From: Jason Lemke [mailto:jlemke@gmail.com]
Sent: Wednesday, November 16, 2011 3:30 PM
To: Mucha, Bartlomiej

Subject: Re: Order Request for INCONTROL MEDICAL L L C - Order # 6187628 - Project # 11CA38346 - PRE-COMPLIANCE RE & RFI ON STIMULATION DEVICE.

Thanks for reminding me Bart! I've been loaded down today. See below:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

I explained what you noted, if you could email something very similar it would be great (that there where no differences between 20 and 80 percent, so no need to test any further.)

Do you know why the radiation emission testing in stimulation mode was performed at 20% and 80% level (and not 100%)? The standard does not require reporting all levels tested, but I don't see why these were the ones reported. Were they the peak levels for radiation emissions? Is it possible to get an email from your contact at the lab stating why those are the two levels reported?

Also there is the question of the following nature, any insight would be great.

With the ESD testing during stimulation mode, we had treatment stop on a couple of the sides, but not all. The note in the report says that we said it should stop if abnormal conditions are detected. That is fine, but it stops on some sides and not others. My explanation would be that the conditions are abnormal if they find their way to the processor so they are detected. If the conditions are not detected by the processor they are not abnormal enough to affect the device. This is dependent on the strength of the static and the side that it hits. That may not be a great explanation. Do you remember the discussion at the time with the test lab folks?

Thanks for any comments Bart!

Jason

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Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

From: Jason Lemke <jlemke@gmail.com>
Date: January 9, 2012 9:02:54 AM CST
To: "Michael J. Leigh" <michaeljamesleigh62@gmail.com>, Eugene Palatnik <epalatn@execpc.com>
Subject: Fwd: Order Request for INCONTROL MEDICAL L L C - Order # 6187628 - Project # 11CA38346 - PRE-COMPLIANCE RE & RFI ON STIMULATION DEVICE.

Hi Mike,

Below are the answers to questions b. and c. on from your email Sunday. I will ask Bart question a. as I haven't posed that question to him.

I will have sound data for you today as well. I will be testing average decibel between volume increments as well as max volumn decibel reading. If there are any other sound level senerios that you may need please suggest what they may be and I've provide.

Thanks,
Jason

---------- Forwarded message ----------
From: **Mucha, Bartlomiej** <Bartlomiej.Mucha@ul.com>
Date: Wed, Nov 16, 2011 at 6:20 PM
Subject: RE: Order Request for INCONTROL MEDICAL L L C - Order # 6187628 - Project # 11CA38346 - PRE-COMPLIANCE RE & RFI ON STIMULATION DEVICE.
To: Jason Lemke <jlemke@gmail.com>

Jason,

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Hope that this helps.

Bartlomiej Mucha
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Wireless, **I**nteroperability, payment **S**ecurity, & **E**MC

333 Pfingsten Rd.
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Phone: 847-664-1216
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From: Jason Lemke [mailto:jlemke@gmail.com]
Sent: Wednesday, November 16, 2011 3:30 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

To: Mucha, Bartlomiej

Subject: Re: Order Request for INCONTROL MEDICAL L L C - Order # 6187628 - Project # 11CA38346 - PRE-COMPLIANCE RE & RFI ON STIMULATION DEVICE.

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I explained what you noted, if you could email something very similar it would be great (that there where no differences between 20 and 80 percent, so no need to test any further.)

Do you know why the radiation emission testing in stimulation mode was performed at 20% and 80% level (and not 100%)? The standard does not require reporting all levels tested, but I don't see why these were the ones reported. Were they the peak levels for radiation emissions? Is it possible to get an email from your contact at the lab stating why those are the two levels reported?

Also there is the question of the following nature, any insight would be great.

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Thanks for any comments Bart!

Jason

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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InTone™ User Manual

PN: xxxxxx-E | **Draft Date: 1/13/12**

Users must read this Guide before using the Product

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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InControl Medical, LLC
Brookfield, WI 53045 USA
www.incontrolmedical.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Preface

Overview

The In Control InTone™ device includes three parts; an inflatable balloon for intra-vaginal use, a hand-held control and display device to record, store and display the results of electro-stimulation and patient generated pelvic floor exercises, and a PC application to program the hand-held device and store and display the results of electro-stimulation and patient generated pelvic floor exercises. The external monitor allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

This guide provides procedures for setting up and using the InControl InTone™ incontinence device.

Intended Use

The InControl InTone™ device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of stress, urge, and mixed urinary incontinence where the following results may improve urinary control: improvement of urethral closure, strengthening of pelvic floor muscles, inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

Intended Audience

The InTone™ User Manual is intended for users of the system, including care providers and patients. The product is intended to be used under the direction of the care provider.

Contact Information

For more information about InControl products, go to www.incontrolmedical.com. For technical support, questions or comments about documentation, contact (800) xxx-xxxx or (262) xxx-xxxx.

Product Warranty

Product Warranty information can be found with your original system proposal and invoice.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Symbols Used

The following symbols are used in this manual or on the product.

Attention! Please follow the instructions in the User Manual.

Type BF applied part. Internally powered.

The Control Unit can be damaged by ElectroStatic Discharge. The pins of the Control Unit connectors should not be touched unless ESD precautions are taken.

Warnings and Notes

Warnings and Notes are used in this manual. A Warning is used when failure to follow the instructions may result in injury or device damage. Notes are used to provide clarification or advice. The following Warnings are used in this manual.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Warning: Electro-Stimulation is one part of a total therapy program. It is meant to be used in conjunction with counseling and feedback. Do not undertake therapy without the advice of a care provider.

Warning: Do Not use a charger other than supplied by InControl Medical LLC for the InTone system. The incorrect charger can result in damage to the unit.

Warning: Remove battery pack if the equipment is not to be used for an extended period of time.

Warning: Read all instructions prior to use. Failure to follow these directions may result in personal injury or damage to the equipment.

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⚠ **Warning:** Only use approved antiseptics that leave no residue.

⚠ **Warning:** The InTone system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

⚠ **Warning:** Therapy is defined on an individual basis, dependent on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

⚠ **Warning:** Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

⚠ **Warning:** Do not operate device within 10 feet of operating televisions, arc welders, radio thermal treatment equipment, X-ray machines, MRI machines, or any other equipment that produces magnetic fields, sparks, or radio transmissions. RF communications equipment can affect this device

⚠ **Warning:** The reusable Insertion Unit presents a potential risk of cross-infection, particularly if used on broken skin.

⚠ **Warning:** Explosion hazard: Do not use in the presence of flammable anesthetics, nitrous oxide, or oxygen enriched environments.

⚠ **Warning:** Take care in arranging patient and cables to avoid risk of entanglement, tripping, or strangulation.

⚠ **Warning:** Use of any equipment should be discontinued upon any signs of treatment related stress or discomfort.

⚠ **Warning:** The device should not be used while walking, driving, operating machinery, or any other activity in which involuntary muscle contraction may put the user at risk.

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⚠ **Warning:** Do not use the device while in the bath, swimming, or otherwise submerged.

⚠ **Warning:** The long-term effects of chronic electrical stimulation are unknown.

⚠ **Caution:** Caution should be used for patients with suspected or diagnosed heart problems.

⚠ **Caution:** Caution should be used for patients with suspected or diagnosed epilepsy.

⚠ **Caution:** Caution should be used when there is a tendency to hemorrhage following acute trauma or fracture.

⚠ **Caution:** Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

⚠ **Caution:** Patients with a total/partial prolapse of the uterus/vagina must be stimulated with extreme caution.

⚠ **Caution:** Patients with urethritis must be treated before commencing stimulation.

⚠ **Caution:** Worn electrodes can result in increased current densities; therefore, the condition of the electrodes should be checked before they are applied.

⚠ **Caution:** Adverse reactions have been reported. Skin irritations and burns beneath the electrodes have been reported with the use of powered stimulators.

Contraindications

- This device is not intended for diagnostic purposes or critical patient monitoring.
- The device is not defibrillator proof.
- The device should not be used on patients with cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Do not use if patient has a history of rate or conductive disturbance.
- Do not use if patient has symptoms of an active urinary tract infection.
- Do not use if the patient has vaginal infections, localized lesions, or other undiagnosed symptoms.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

- Do not use if patient has undiagnosed pain.
- Do not use if patient has a neurological deficiency that does not permit proper sensory perception or stimulation.
- Do not use if patient has diminished mental capacity or physical competence that limits use of the device or interaction with the care provider regarding the device settings.
- Do not use if patient is currently pregnant or attempting to get pregnant.
- Do not use if patient has anatomical vaginal structures that do not permit proper and complete placement of the Insertion Unit.
- Do not use if the patient has irregular menstrual bleeding cycles.
- Do not use if the patient has a history or symptoms of urinary retention.
- Do not use if the patient has extra-urethra incontinence, (i.e. syrinx, ectopic, urethra).
- Do not use if the patient has overflow incontinence caused by evacuation problems.
- Do not use if the patient has severe urine retention in the upper urethra.
- Do not use if the patient has complete peripheral denervation of the pelvic floor.
- Do not use if the patient has an intestinal clamp.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Chapter 1

Equipment Overview

This chapter provides an overview of the equipment included in the InControl InTone System. The InTone System includes three parts.

- hand-held Control Unit
- inflatable Insertion Unit
- PC-based software application

Control Unit

The Control Unit is a display device used to initiate and control treatment sessions, record and store results of electro-stimulation and patient generated pelvic floor exercises. It can either be connected to the insertion unit or an external PC, but not both at the same time. The PC-based software application allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. It also stores and displays the results of prior sessions.

The Control Unit has the following features and functions.

- select and lock in the correct amount of current necessary to stimulate pelvic floor contraction
- provide biofeedback program to measure and record pressure generated by patient pelvic floor exercises
- display contraction force (as pressure)
- allow downloading of data to personal computer through custom USB cable and allow graphing in commercially available software (e.g. Excel)
- provide verbal exercise session coaching
- provide single button stop to discontinue electrical pulses if necessary
- ability to clean with common, commercially available cleaners

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Insertion Unit

The Insertion Unit is an inflatable balloon for intra-vaginal use. The unit has a semi-rigid core to allow insertion. The core also carries inflation air and electrical conductors. The core is surrounded by an inflatable balloon that carries the electrodes. The handle portion of the Unit includes an integral inflation bulb and relief valve to customize the fit. The insertion unit connects to the control unit through a flexible connection.

The Insertion Unit has the following features and functions.

- for self or clinician insertion in the patient's vagina
- provide manual inflation of balloon to fill the vagina to a comfortable level
- when inflated, provide full contact of electrodes to vaginal wall
- provide programmed electro-stimulation of pelvic floor muscles
- ability to clean with common, commercially available cleaners.

PC Cable

The PC Cable allows the Control Unit to be connected to the USB port of a personal computer. This connection allows the transfer of data to the PC. The unit cannot be used while it is connected to the PC.

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Chapter 2

Setting up the Components

This chapter provides procedures on how to set up the InTone units for use.

The components in the InTone system are provided as a kit, consisting of assembled units and parts. These kits should be kept together until you are ready to use them.

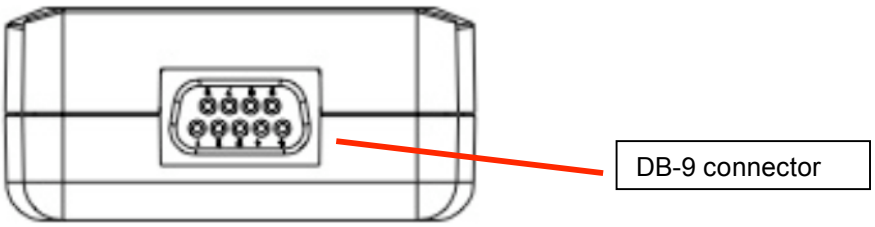
⚠ **Warning:** Read all instructions prior to use. Failure to follow these directions may result in personal injury or damage to the equipment.

⚠ **Caution:** Federal law restricts this device to sale by or on the order of a physician.

⚠ **Warning:** Electro-Stimulation is one part of a total therapy program. It is meant to be used in conjunction with counseling and feedback. Do not undertake therapy without the advice of a care provider.

Connecting the Insertion Unit to the Control Unit

1. Align the connectors of the Insertion and Control Units. The DB-9 connector is on the bottom of the control unit.



Gently press the connector into place.

Disconnecting the Insertion Unit from the Control Unit

1. Gently pull the DB-9 connectors apart.

ⓘ **Tip:** Do not touch the conductors in the connector. This could cause damage to the pins or control unit.

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Charging the Battery

The battery should be charged when the low battery indicator is shown, or if charging will not be available for a time.

1. Disconnect the Insertion Unit.
2. Connect the wall charger to the Control Unit.
3. When charging is complete, unplug the cable from the Control Unit.

ⓘ **Tip:** Ensure battery is charged prior to use. Control unit cannot be used when the USB cable is connected.

⚠ **Warning:** Do Not attempt to use a charger other than supplied by InControl Medical LLC for the InTone system. The incorrect charger can result in damage to the unit.

Cleaning the Insertion Unit

Following use, the Insertion Unit should be cleaned.

1. Turn **off** the Control Unit.
2. Disconnect the Insertion Unit from the Control Unit.
3. Inflate the balloon. Wipe the Insertion Unit clean with warm soapy water. Do not soak.
4. Rinse thoroughly.

ⓘ **Tip:** Do not attempt to fill the Insertion Unit with water or any other liquid. If water enters the Unit, thoroughly dry prior to re-use.

5. The outside of the Insertion Unit may be wiped with alcohol or other antiseptic in accordance with the care provider's infection control procedures.

⚠ **Warning:** Only use approved antiseptics that leave no residue. Do NOT soak.

6. Allow Unit to air dry.
7. The control unit can be wiped with antiseptic or a damp cloth. Do not immerse or spray.

Approved Antiseptics

The following cleaners can be used with the InTone Insertion Unit. This list is based on material compatibility.

- isopropyl alcohol
- hydrogen peroxide, <10%
- sodium hypochlorite, <10%

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Chapter 3

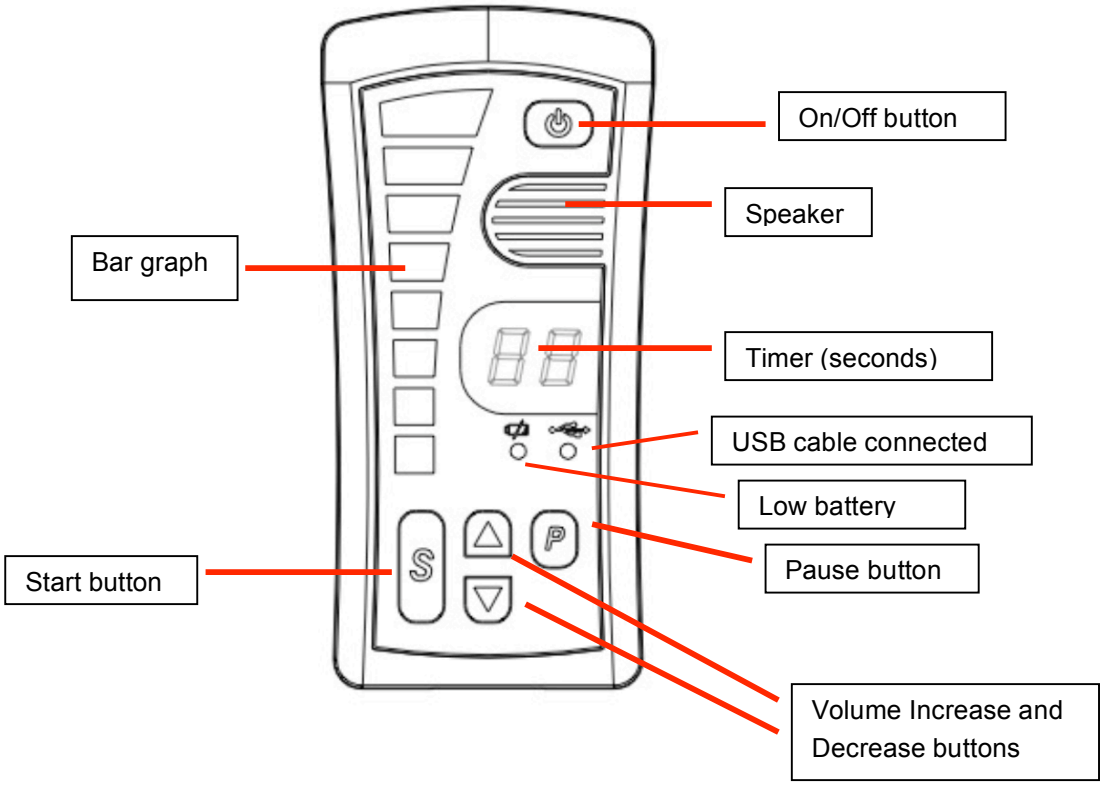
Programming the System

Introduction

This chapter provides procedures on how to program the InControl Control Unit. The system must be programmed before it is used by patients. It is programmed for one patient at a time.

Programming - Clinician Only

The front panel of the Control Unit provides information on the status of the system and its operation.



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How to Program the Control Unit

During a scheduled office visit, you will program the InTone device for your patient by accessing the

(b)(4) TS

(b)(4) TS

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(b)(4) TS

Reviewing Patient Session Data

(b)(4) TS

Export Data

(b)(4) TS

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Clearing Logged Data

(b)(4) TS

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Chapter 4

Using the System

This chapter provides instructions for using the system. It includes both therapeutic treatment and biofeedback use instructions.

⚠ **Warning:** The InTone system is intended for indoor use only. Exposure of the Control Unit to liquids may cause personal injury or equipment damage.

Electro-stimulation and biofeedback are treatments used to train and strengthen the pelvic floor muscles in a controlled manner. Electro-stimulation is used to strengthen muscles. In particular, it improves the ability of muscles to hold a contraction of an extended period of time. It is a treatment for urinary incontinence in conjunction with coaching and biofeedback. During a session, electrical impulses are delivered to specific muscles to stimulate their contraction. This contraction exercises the muscles and also helps the patient recognize which muscles to condition.

Biofeedback provides visual confirmation of the patient's voluntary muscle contractions.

⚠ **Warning:** Therapy is defined on an individual basis, dependant on the patient's symptoms and condition. Do not undertake or alter therapy recommendations without the advice of the care provider.

⚠ **Warning:** If tissue irritation occurs, discontinue treatment immediately. Ask your care provider for advice before continuing further treatment.

Patient Use

A quiet, private place is recommended to aid relaxation. Many women prefer to do their sessions while in bed.

1. The patient lies in a semi-reclined position with knees slightly bent. The legs should be upright and tilted out slightly.
2. Press the On/Off button and follow the voice guided instructions
3. Insert InTone gently into your vagina to the base of the balloon, after insertion, press bulb and inflate balloon until comfortably snug as instructed by your clinician, when ready to begin session press the “start key”. Continue to follow audio prompts.
4. The bar graph reflects contraction force. The display reflects the timing of contractions relative to the voice commands

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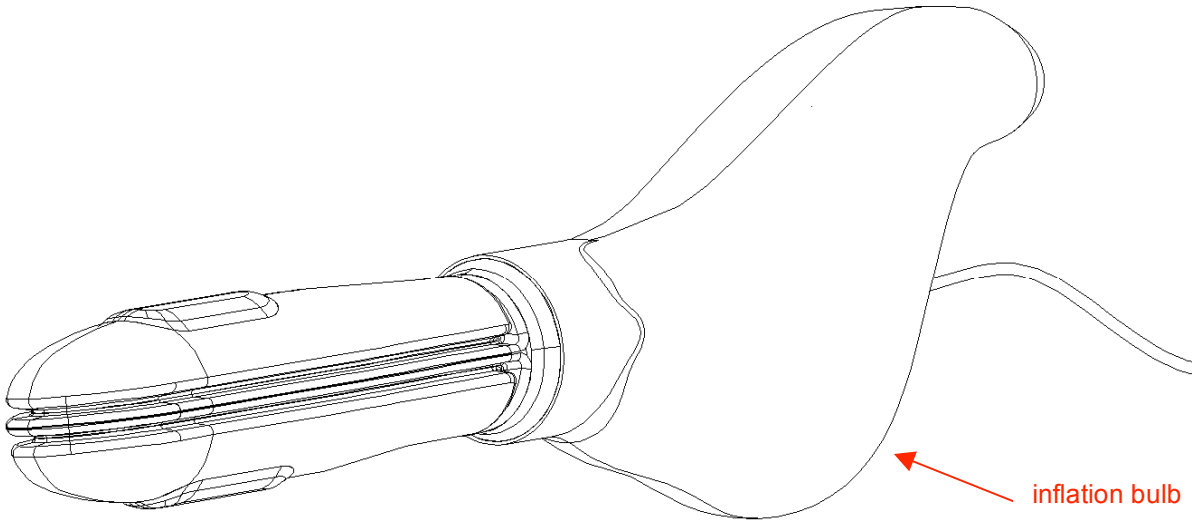
5. When the session is complete, use the air release valve to deflate the insertion unit and remove from your vagina.
6. Wash the Insertion Unit and allow to air dry.

ⓘ **Tip:** Treatment can be stopped at any time by pressing the **P** (pause) button. The interrupted sessions data can be restarted by pressing the pause key again. If the session is not restarted within five minutes, the device will turn off.



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Chapter 5

Testing and Servicing the System

This chapter provides procedures to test the InTone system prior to use. It is important to test the overall functionality of each component prior to putting the system into service. Additionally, it is important to periodically verify the continuing proper operation of each component.

ⓘ **Tip:** You should test all of the system components prior to use to verify proper operation.

⚠ **Warning:** Do not use an Insertion Unit or Control Unit that appears to be damaged. Using a damaged device may result in personal injury.

1. Visually inspect the Insertion Unit, Control Unit, and connectors for damage.
2. Connect the Insertion Unit to the Control Unit.
3. Turn on the Control Unit.
4. An error will be displayed if the connection is not complete.

Replacing a Control Unit Battery

The Control Unit battery pack can be replaced. Use only battery packs supplied by InTone. Properly maintaining the batteries' charge will extend life.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Chapter 6

Troubleshooting the System

This chapter provides procedures on how to service and troubleshoot the InTone System. If you have consistent issues with the system, please contact InControl Technical Support at 1-800-xxx-xxxx.

Troubleshooting the Insertion and Control Unit

Prior to use or any troubleshooting,

1. Verify that the Control Unit battery is charged. If the low battery indicator is shown, recharge the battery.
2. Inspect the Insertion Unit for damage. If the silicone covering or any cables appear damaged, the Unit must be replaced.
3. Disconnect the Insertion Unit from the Control Unit. Inspect the connectors for damage. If the pins are not straight, or otherwise appear damaged, the Unit must be replaced.
4. Carefully reconnect the Insertion Unit to the Control Unit.
5. If the assembled Units still do not function correctly, contact InControl Technical Support.

Patient cannot feel pelvic contractions

1. Check that InTone control unit is on and the batteries are charged.
2. Have patient use electrode gel prior to insertion.
3. Reinsert the Insertion unit and re-inflate to ensure electrodes are in full contact with the muscle wall.

Patient complains of painful insertion of the unit

1. Have patient use a water-based lubricant prior to insertion.
2. Check patient for vaginal irritation or infection.
3. Ensure the unit is not partially inflated.

Patient complains of pain in rectum with pelvic contractions

1. Tell patient not to insert the unit as deep into the vagina.
2. Instruct patient not to dangle her legs or feet during a session: lie in a reclined position with both feet evenly placed in front of her.
3. Tilt the insertion unit slightly anteriorly.

Patient stops feeling contractions during a session

1. Have patient manually reposition the unit until pelvic contractions are perceivable again.
2. Instruct patient not to stand or move about during a session.
3. Check that device is on and the batteries are charged.

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Chapter 7

Specifications

This chapter provides specifications for the InControl InTone system components. The InTone system is a class II medical device with internal power. It must only be used indoors.

Control Unit

Size:	4.83” x 2.4” x 1.1”
Weight:	5 oz
Enclosure:	ABS

Battery:
Battery pack size – 4/5 AA rechargeable nickel metal hydride
Battery capacity – 1200mAh
Battery voltage – 2.4V nominal
Discharge current – (b)(4)
Charge current – 240 mA
Charging time – 5 hours, charge complete will be displayed
typically 6 to 8 hours use between charges, user determines

Low Battery: Shown on display approximately 15 minutes before unit shuts down and is indicated by a the green battery LED illuminating while not connected to the AC charger

Full battery: Full battery is indicated by a solid illuminating battery LED while connected to the AC charger

Audio Volume: adjustable, approximately 85dB max volume

PC interface: USB, 1.1 and 2.0 compatible

Waveform: low-frequency, dual-phase, direct current, rectangular pulses

Program for Mixed Incontinence Treatments:
- Treatment Duration (b)(4) TS
- Frequency:
- Pulse Width:
- Voltage:
- Maximum Current: (b)(4) TS
- Maximum Phase Charge: (b)(4) TS
- Maximum Power Density:

Biofeedback:
- Air Pressure: (b)(4) TS
- Response Time:

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Insertion Unit

Single Patient Use

Size:	5 inches long 1.25 inch diameter, uninflated up to 2.5 inches diameter, inflated
Method of Inflation:	Hand pump bulb, with release knob
Outer Material:	silicone
Electrode Size:	two stainless steel, rigid, semi-tubular, each approximately 2” x 0.75”
Shelf Life:	one year

Computer Connection

via USB 2.0, Type A plug

AC Charger

Input Voltage:	120 VAC
Input Frequency:	60Hz
Input Current Draw:	up to 300 mA
Output:	6 VDC

Environmental Conditions

Operating Conditions:

Temperature:	10 to 40C
Relative Humidity:	10% - 90%, non-condensing

Storage and Transportation Conditions:

Temperature:	10 to 40C
Relative Humidity:	10% to 90%, non-condensing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Guidance and manufacturer's declaration - electromagnetic emissions		
The InTone is intended for use in the electromagnetic environment specified below. The customer or the user of InTone should assure that it is used in such and environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The InTone uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The InTone is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The InTone is intended for use in the electromagnetic environment specified below. The customer or the user of the InTone should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycles 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	< 5% U_T (>95% dip in U_T) for 0.5 cycles 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration - electromagnetic immunity			
The InTone is intended for use in the electromagnetic environment specified below. The customer or the user of the InTone should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test standard**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the InTone, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHZ to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in with the InTone is used exceeds the applicable RF compliance level above, the InTone should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the InTone.			
[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than xxx V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the InTone			
The InTone is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the InTone can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the InTone as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation application to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 - At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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510(k) Summary for InControl InTone

Submitter: InControl Medical, LLC

Address: 3225 Gateway Road, Suite 250
Brookfield, Wisconsin 53045

Corporate Contact: Herschel Peddicord, President
InControl Medical, LLC

Telephone: Ph: (414) 429-2625

Establishment Registration #: to be registered following 510(k)

Submission Contact: Michael J. Leigh, consultant
12715 Falcon Drive
Brookfield, Wisconsin 53005
Ph: (262) 957-6797

Trade Name: InControl InTone

Predicate Device: Otto Bock STIWELL med, K080950
MyoTrac Infiniti, K053434
Hollister evadri, K050483

Common Name: Stimulator, Electrical, Non-Implantable, for Incontinence

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
870.5320	KPI	Non-implanted electrical continence device	II

Device Description:

The device includes three parts; an insertion probe and a hand-held control unit. The insertion probe features an inflatable balloon that provides more adaptable fit for intra-vaginal use. The probe includes stainless steel electrodes to deliver electro-stimulation. The hand-held control and display device records, stores, and displays the results of electro-stimulation and patient generated pelvic floor exercises. It allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction. It also stores data on contraction pressure for later review. The PC application allows the clinician to select and lock in the correct amount of current necessary to stimulate pelvic floor contraction.

Intended Use:

The InControl InTone device is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures. It is intended for acute and ongoing treatment of mixed urinary incontinence where the following results may improve urinary control strengthening of pelvic floor muscles and inhibition of the detrusor muscle through reflexive mechanisms. The biofeedback feature can be used for muscle re-education purposes.

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Performance Data:

Complete EMC, electrical, mechanical, safety (operator and patient), temperature/humidity, and software testing demonstrate compliance with applicable standards. The results demonstrate that the InControl InTone device is in compliance with the guidelines and standards referenced in the FDA reviewer's guides, and that it performed within its specifications and functional requirements for the device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with FDA requirements.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Feature/ Function	InControl InTone (new device)	Otto Bock STIWELL med4 (K080950)	MyoTrac Infiniti (K053434)	Hollister evadri (K050483)	Comparison
Technology, Engineering, and Performance					
Environmental Specifications	For indoor use only	For indoor use only	For indoor use only	For indoor use only	Identical (to all)
Power Source	Nickel metal hydride battery	Li-Ion battery	Four AAA 1.5V alkaline batteries	AC power supply	Equivalent
Number of output modes	1	1	1	1	Identical (to all)
Number of output channels	1	1	1	1	Identical (to all)
Regulated current of voltage?	Regulated voltage	Regulated current	Unknown	Unknown	Equivalent
Firmware controlled?	Yes	Yes	Yes	Yes	Identical (to all)
Automatic Overload Trip?	Yes	Yes	Unknown	Unknown	Identical (to Otto Bock)
Automatic Shut Off?	Yes	Yes	Unknown	unknown	Identical (to Otto Bock)
Indicator Display **On/Off Status** **Low Battery**	 Yes Yes	 Yes Yes	 Yes Yes	unknown	Identical (to Otto Bock, MyoTrac)
Waveform, shape	(b)(4) TS	Biphasic symmetrical rectangular	asymmetric, balanced pulse	Balanced biphasic	Identical (to Otto Bock, Hollister)
Frequency **Mixed** **Stress** **Urge**		 35 Hz 10 Hz	12.5, 50, 100, 200 Hz	10, 12.5, 20, 50, 100, 200 Hz	Identical (to MyoTrac, Hollister)
Pulse width **Mixed** **Stress** **Urge**		 300 μs/phase 500 μs/phase	0.2 ms	0.3 or 1 ms	Within range
Time **On** **Off**		 9 - 12 s for Stress, 13 s for Urge 7 - 9 s for Stress, 3 s for Urge	 2 - 20 secs 2 - 50 secs	 1 - 80 secs 0 - 80 secs	Within range
Total Session Time		5 - 25 mins	0 - 120 mins	1 - 30 mins	Within range
Max output voltage (500Ω)		50 Vdc	30 Vdc	30 Vdc	Identical (to Otto Bock)
Max output current (500Ω)		100 mA	100 mA	100 mA	Identical
Maximum phase charge (500Ω)		50 μC	60 μC	Unknown	Identical (to Otto Bock)
Electrode surface area		21.2 cm^2	Various, 1.53 cm^2 to 10.5 cm^2	unknown	Equivalent
Max current density		4.7 mA/ cm^2	Various, 4.7 mA/ cm^2 to 32 mA/ cm^2		Identical
Maximum power density (500Ω)		23.5 μW/ cm^2	Various, 11.32 μW/ cm^2 to 22.84 μW/ cm^2	Unknown	Equivalent
Biofeedback		EMG	EMG	EMG pressure, 0 - 350 cm H_2O or combination	Equivalent (to Hollister)

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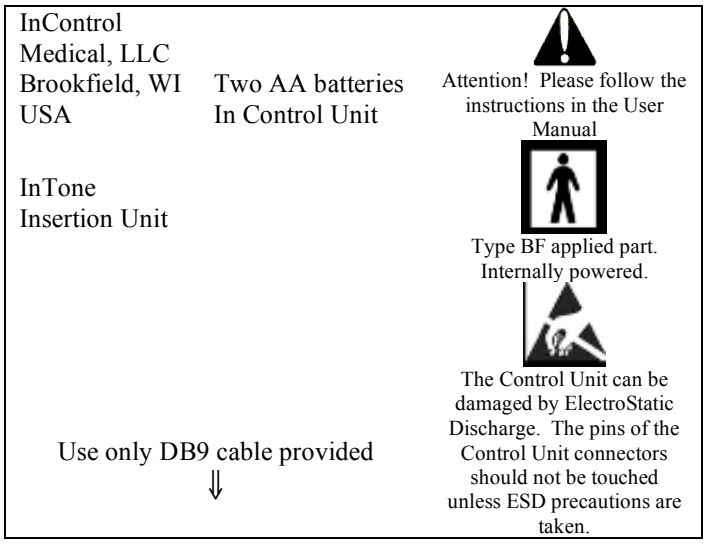

Insertion Unit cord label, rev A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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InControl
Medical, LLC
Brookfield, WI
USA

InTone
Control Unit

Two AA batteries

120 VAC 60Hz
input
6 VDC output, up
to 300mA

Use only DB9 cable provided
⇓

Attention! Please follow the instructions in the User Manual

Type BF applied part.
Internally powered.

The Control Unit can be damaged by ElectroStatic Discharge. The pins of the Control Unit connectors should not be touched unless ESD precautions are taken.

Control Unit back label, rev B

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 07, 2011

INCONTROL MEDICAL, LLC
12715 FALCON DRIVE
BROOKFIELD, WISCONSIN 53005
ATTN: MICHAEL LEIGH

510k Number: K110179

Product: INCONTROL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8116

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Grayson, Giovanna *

From: Microsoft Exchange
To: 'mike-leigh@earthlink.net'
Sent: Friday, October 07, 2011 2:08 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'mike-leigh@earthlink.net'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8718

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Friday, October 07, 2011 2:08 PM
To: 'mike-leigh@earthlink.net'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 07, 2011
LEIGH
MICHAEL
INCONTROL MEDICAL, LLC
12715 FALCON DRIVE
BROOKFIELD, WISCONSIN 53005
ATTN: MICHAEL LEIGH

510k Number: K110179

Product: INCONTROL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510 (k).

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Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

K110179/81

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC
OCT 7 2011
RECEIVED

K-34

Re: K110179

September 14, 2011

Dear Ms. Valdes,

This letter is in response to our email correspondence between September 2 and 8. Per your request, enclosed are three disks, each containing exact copies of the original InControl premarket notification from January 2011 and the updated notification from August 2011. All three disks are exact copies of these submittals.

You also requested additional information regarding the protocols and results related to biocompatibility testing. These are included in the August update volume, VOL_002 in the App D files, documents 029 through 043. The pages not included in the August paper copy are also included on paper in this mailing.

To facilitate your review

- each submittal is in its own volume
- all files are in pdf format produced using Adobe
- each file name begins with a sequential number and underscore so that its sort order matches the paper copies
- after the sequential number, the file name is descriptive and matches the paper document
- the volumes do not contain any folders
- all individual files sizes are less than 50MB
- there are no index files, embedded files, or links on the disks

If you have any questions regarding the additional information provided in this submittal, please don't hesitate to contact me. Thank you for your time and consideration.

Sincerely,

Michael J. Leigh
consultant

127

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K110179

August 18, 2011

Dear Ms. Morris

This letter is in response to your letter dated February 25, 2011 received March 4. The response includes an update to the premarket notification, 510(k). The location of updates is referenced for each item below.

1. This term has been removed. It was an inadvertent editing error from an earlier draft. See new Intended Use.
2. The original submittal included requirements specifications. This update includes additional design specifications and drawings. Specifically,
   a. See Appendices.
   b. The principle new feature of the device is the inflatable insertion unit. This allows an adjustable fit for each patient. All other features of the device are meant to parallel similar products on the market.
   c. Dimensions and weights are included in the specification in the Appendix.
   d. Descriptions of the user controls, displays, and functions are included in the specification in the Appendix. These have been expanded in the User Manual update.
   e. The control unit has a DB-9 connector. This connector has three purposes, but only one can be employed at a time. It is the connection to the insertion unit, providing control during a session. It can also be used with a custom cable to connect to a personal computer via a type A USB port. When connected to a computer, data can be downloaded to an Excel file. The port is also used to connect an AC charger to recharge the battery pack. See the Appendix for drawings of the control unit, insertion unit, and their connection.
   f. See drawings in the Appendix.
   g. The connection between the control and insertion units are described, with specifications, in the specification in the Appendix. The Appendix also includes drawings of the connector assembly.
3. Information regarding the settings was originally in the User Manual. It has now been expanded in the Section 6 of the specification in the Appendix. Further, the options have been limited to a single mode for mixed incontinence and one treatment time, 12 minutes. The only parameter that can be adjusted is the voltage. It can only be adjusted by the clinician.
4. Battery specifications have been included in section 5 of the specification in the Appendix.
5. The insertion unit is reusable but intended for single patient use only. This has been clarified in the User Manual.
6. The following table identifies the materials used in the control unit, insertion unit, electrodes, and cable. Material data sheets are included in the Appendix.

	Control Unit enclosure	**Insertion Unit outer surface**	**Electrodes**	**Connector assembly outer**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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	surface
Chemical Name	(b)(4) CCI [redacted]
Supplier	
Supplier trade name	
Polymer formulation	(b)(4) CCI [redacted]
Processing description	
Processing materials	

7. The entire outside surface of the insertion unit is molded of Wacker Elastosil LR silicone. This material has complete cytotoxicity, sensitization, and irritation testing as shown in the Appendix. Where adhesive is required, on inner surfaces, Loctite 4061 Prism Medical Device adhesive is used. This material also has complete cytotoxicity, sensitization, and irritation testing as shown in the Appendix.
8. Electrical safety test results are included in the Appendix. Evaluation to IEC6061-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance by an independent lab, Underwriter's Laboratory.
9. Electromagnetic compatibility test results are included in the Appendix. Evaluation to IEC6061-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility by an independent lab, Underwriter's Laboratory.
10. The information on software has been expanded. See the Software Specifications in the Appendix.
11. The waveforms included in the Appendix show the limits of the adjustment. Only one mode is now available.
12. The silicone material has an 18-month usable life. A one year shelf life has been defined for the insertion unit. This has been added to the User Manual.
13. The User Manual has been updated with the following specific items. This revision also includes updates to the user instructions.
    a. The User Manual describes all features, functions, output modalities, and specifications. See the Appendix.
    b. The User Manual includes expanded descriptions of the updated controls. These will be further updated and expanded in the subsequent response.
    c. The front panel and a draft back label are included in the Appendix. The indicators are described in the User Manual.
    d. The size and type of electrodes are described in the Specifications section of the User Manual.
    e. The User Manual includes a section for cleaning. No other maintenance is required.
    f. The warning statement has been added to the User Manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

g. The caution statement has been added to the User Manual.
h. The caution statement has been added to the User Manual.
i. The caution statement has been added to the User Manual.
j. The statement has been added to the User Manual.
k. The caution statement has been added to the User Manual.
l. The statement has been added to the User Manual.
m. The statement has been added to the User Manual.
n. The adverse reaction statement has been added to the User Manual.
o. The contraindication has been added to the User Manual.
p. The contraindication has been added to the User Manual.
q. The contraindication has been added to the User Manual.
r. The contraindication has been added to the User Manual.
s. The contraindication has been added to the User Manual.
t. The statement has been removed.

14. Device labeling includes the User Manual and back label of the control unit. Promotional and advertising materials are not available at this time. See the Appendix for the control unit front panel and back label.
15. The 510(k) Summary has been updated.

If you have any questions regarding the additional information provided in this submittal, please don't hesitate to contact me. Thank you for your time and consideration.

Sincerely,

Michael J. Leigh
consultant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) CCI

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC
JAN 31 2012
RECEIVED K5

Re: K110179
Trade Name: InControl InTone

January 24, 2011

Dear Ms. Morris:

This letter is in response to your letter stamped "Oct 04, 2011" and received November 7. The letter references your receipt of "October 7, 2011." Listed below are the numbered requests for more information along with the response for each. Supporting documentation is referenced and attached. An electronic copy of the response is being provided. It is an exact duplicate of the paper copy.

1. *You provided a device description. However, some information remains unclear. In order for the Agency to complete its review, please indicate whether the external monitor and hand pump are included with the device.*

The device set includes the Insertion Unit with integral hand pump, hand-held Control Unit, and clinician PC software. The device description has been updated to clarify the complete device. See updated device description in document 002 Information on New Device.

2. *You provided software documentation in Appendix C and via email. However, some requirement elements necessary for software with a moderate level of concern are not complete. In order to complete the review of your device, please provide the following:*

    a. *a complete traceability analysis which links requirements, specifications, identified hazards and mitigation, and verification and validation testing;*

The traceability analysis has been updated to include reference to requirements, specifications and design features, identified hazards and mitigations, and verification and validation testing. See the traceability analysis in document 003.

    b. *a more detailed verification testing report. This report should document how specified requirements have been fulfilled;*

Previously provided test reports included the system waveform verification report, EMC report, electrical safety (IEC60601-1) report, and the system verification/validation report. Additional verification and validation reports are included in this update. They include;

Physical Dimensions and Inflation report
Battery test report
Short Circuit test report
Air Pressure test report
Audio Volume test report
Software Validation Report v102
Software Validation Report v103

Records processed under FOIA Request #2015-664; Released by CDRH on 04-11-2016.

Software Validation Report v104
InTone Abnormal Usage test report

See the additional verification test reports in documents 004 through 012.

c. a revision history log that provides release numbers and dates; and

The revision histories for the PC application and embedded firmware for the hand-held control unit are included. Each history starts with the first release candidate. See revision histories in documents 013 and 014.

d. a list of unresolved software anomalies, bugs, or defects that remain with an explanation of its impact on the usage of the device.

The list of unresolved anomalies for the PC application and control unit firmware are included. The list includes a description of each, its potential impact on the user, and the current disposition. See the document 015 SPR List.

3. *You reduced your stimulation settings to be for mixed urinary incontinence and provided most output characteristics for your device. However, there are several characteristics that are not provided. In order to accurately describer your device, please provide the maximum power density, net charge, and indicate whether there is a burst mode and if so, the output characteristics of burst mode.*

The maximum power density at (b) (2) (b)(4) TS The net charge (maximum phase) at (b) (b) (b)(4) These have been included in the 510(k) Summary and predicate device comparison table. It has now been added to the manual as well. See the updated manual, document 022.

There is no burst mode in the InTone device.

4. *You provided EMC testing, however, some of the testing was incomplete. In order to ensure the safety of your device, please provide the following testing:*

a. emissions, immunity to electrical fast transients/bursts, immunity to surge transients, immunity to voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker missions testing in stimulation and data transfer mode. These tests were performed only with the device in charging mode;

The device was tested in three modes; charging mode, use mode, and data transfer mode. The charging mode is the only mode in which the device is connected to mains power and thus potentially exposed to electrical fast transients/bursts, surge transients, voltage dips and interruptions, harmonic emissions, and voltage fluctuations/flicker. In the other two modes, the unit is not connected to mains power and operates on battery. See the attached email from the UL test engineer, document 016.

b. radiation emission testing on your device in stimulation mode at 100% stimulation or provide adequate justification for the lower stimulation output. Your testing was performed in stimulation mode at 20% and 80% stimulation output; and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8180.

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The UL test engineer reported that preliminary scans were made at 100%. Full testing was conducted at 20% and 80% because these lower levels showed more noise than the 100% level, however there was little difference between them. Since no significant difference in emissions was measured, testing was completed at these levels. See the attached email from UL test engineer, document 017.

c. *repeated immunity to electrostatic discharges testing or an adequate justification for the behavior of your device during testing. During testing in stimulation mode, treatment stops on a few sides of the device. The report stated that it is intended for the device to interrupt treatment when abnormal conditions are detected. However, treatment does not stop at all areas of the device.*

The impact of electrostatic discharge may be different in different orientations or test points. The InTone processor will stop treatment if it detects abnormal conditions. The same discharge may not create abnormal conditions in the processor in every orientation. Some orientations may be parallel to the field and other perpendicular. Treatment was able to continue normally in some orientations. See the attached email from UL test engineer, document 017.

5. *You provided biocompatibility information and the processing description for the raw materials used in your device. It is inadequate to determine biocompatibility of your device only based on the provided description of processing for the raw materials used in your device. Your insertion unit contacts mucosal membrane surfaces and therefore requires biocompatibility evaluation for cytotoxicity, irritation, and sensitization per ISO 10993-1:2009 and the FDA blue book memo #G95-1. In lieu of biocompatibility testing of the final device, biocompatibility evaluation may be acceptable based on proper chemical analysis of leachables from your final device and adequate toxicity risk assessment with existing toxicity data of each chemical identified from the chemical analysis using principles outlined in ISO 10993-17:2002. Therefore, to determine the biocompatibility of your device, please provide biocompatibility testing on the final insertion unit or assessment of the insertion unit as suggested above.*

Biocompatibility testing of the finished insertion unit has been completed. It included cytotoxicity, irritation, and sensitization testing per ISO10993-1:2009. All testing met the requirements of that standard series. The reports are included as documents 018 through 021.

6. *You provided a user manual in your submission. However, there is a mistake a several omissions in the manual. To adequately inform users, please provide the following:*

a. *an explanation of the connection of the hand pump bulb to the insertion unit for proper inflation;*

The hand pump bulb was incorporated into the insertion unit between the original submittal in January and the update in August 2011. The bulb cannot be connected, disconnected, or otherwise removed. The instructions for inflation and deflation have been expanded in the Manual. An updated Manual is included as document 022.

b. (b)(4) TS [redacted]

(b)(4) TS [redacted] The updated Manual is document 022.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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c. *EMC tables to your user manual. You stated conformance with EMC testing required by ISO 60601-1-2. However, you did not include the EMC tables required by ISO 60601-1-2. (Annex C of ISO 60601-1-2 provides examples of properly completed tables.)*

EMC tables were added to the updated manual. The Manual now includes tables 201, 204, and 206, as required by the standard. See the updated Manual, document 022.

7. *You provided a 510(k) Summary in your submission. However, there are several mistakes in your output characteristics. In order to accurately describe your device, please revise the frequency and pulse width in the 510(k) Summary.*

The output characteristics in 510(k) Summary were corrected to ensure they match the Manual and other documents. An updated Summary is included as documents 024 and 024.

8. *You provided a label for the control unit. However, you did not provide labeling for the insertion unit. Also, symbols on your label were not accompanied by a description on the product label. In order for the Agency to complete its review, please provide sample labeling for the insertion unit and revise the control unit label to describe the symbols used. you may find additional guidance for labeling using the following:*

   a. *ODE Bluebook Memo G91-1, "Device Labeling Guidance," dated March 8, 1991*

   b. *Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203)*

"InTone" is molded into the Insertion Unit. To further identify it and the manufacturer, a label has been added to the unit's cable. The cable cannot be removed from the unit. Descriptions of each of the symbols used have been added to Insertion Unit and Control Unit labels. The Insertion Unit cord label is document 025. The updated Control Unit back label is document 026.

If you have any questions regarding the additional information provided in this submittal, please don't hesitate to contact me. InControl Medical and I hope that we have answered all of your questions adequately. Thank you for your time and consideration.

Sincerely,

Michael J. Leigh
consultant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.