October 27, 2023

inomed Medizintechnik GmbH
Shuofei Cheng, Ph.D.
Regulatory Affairs
Im Hausgruen 29
Emmendingen, Baden-Wuerttemberg 79312
Germany

Re: K233292
Trade/Device Name: ISIS Headboxes, ISIS Neurostimulator, ISIS Xpert Plus, ISIS Xpert, ISIS Xpress
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: Class II
Product Code: GWF, GWJ, GWQ, ETN, IKN
Dated: September 29, 2023
Received: September 29, 2023

Dear Shuofei Cheng:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FDA Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological

and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233292

Device Name
ISIS Headbox and ISIS Neurostimulator
(ISIS IOM Systems: ISIS Xpert®, ISIS Xpert®Plus, ISIS Xpress)

Indications for Use *(Describe)*
The product is used for intraoperative monitoring and testing during surgical procedures
• to examine neuronal tissue (central and peripheral nervous system) by recording and stimulation
The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations:

• Measurement:
o Auditory evoked potentials (AEP)
o Electroencephalography (EEG)
o Electrocorticography (ECoG)
o Electromyography (EMG)
o Somatosensory evoked potentials (SSEP)
o Motor evoked potentials (MEP)
o Train of Four (TOF)

• Stimulation:
o Transcranial electrical stimulation (TES)
o Direct cortical and subcortical stimulation (DCS)
o Direct nerve stimulation (DNS)
o Transcutaneous intraoperative nerve stimulation (TINS)
o Direct muscle stimulation (DMS)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PRAStaff@fda.hhs.gov

"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 number."

510(k) Summary

Submission Date:	29 September 2023
510(k) Holder:	inomed Medizintechnik GmbH Im Hausgrün 29 79312 Emmendingen, Germany
Submitter and Application Correspondent:	Tomasz Moszkowski, Ph.D. Phone: +49 7641 6414 583 Email: t.moszkowski@inomed.com
Manufacturing Site:	inomed Medizintechnik GmbH Im Hausgrün 29 79312 Emmendingen, Germany
Trade Name:	ISIS Headbox 5042XX and ISIS Neurostimulator (ISIS IOM Systems: ISIS Xpert®, ISIS Xpert®Plus, ISIS Xpress)
Common and Classification Name:	Evoked response stimulator and intraoperative monitor
Classification Regulation:	21 CFR §882.1870
Product Code:	GWF
Subsequent Product Codes:	GWJ, GWQ, ETN, IKN
Regulation Medical Specialty:	Neurology

Substantially Equivalent Devices:	Predicate 510(k) Number	Predicate Manufacturer/ Model
Predicate Device:	K212166	inomed medizintechnik GmbH / ISIS Headbox 5042XX and ISIS Neurostimulator

(ISIS IOM Systems: ISIS Xpert®, ISIS Xpert®Plus, ISIS Xpress)

Device Description:

The ISIS Headboxes and the ISIS Neurostimulator constitute multimodal intraoperative neuromonitoring systems called ISIS IOM Systems. These systems consist of custom stimulation and recording hardware, a standard laptop or desktop personal computer running an off-the-shelf operating system, and operating software called NeuroExplorer. As an option, these systems mount on device carriers or housings tailored for intraoperative use.

The ISIS IOM Systems support the following measurement modalities:

- Auditory Evoked Potentials
- Transcranial and cortical Motor Evoked Potentials
- Somatosensory Evoked Potentials
- Free-running and triggered Electromyography
- Electroencephalography
- Train of Four

Intended Use and Indications for Use:

The product is used for intraoperative monitoring and testing during surgical procedures:

- to examine neuronal tissue (central and peripheral nervous system) by recording and stimulation

The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations:

- Measurement:
  - Auditory evoked potentials (AEP)
  - Electroencephalography (EEG)
  - Electrocorticography (ECoG)
  - Electromyography (EMG)
  - Somatosensory evoked potentials (SSEP)
  - Motor evoked potentials (MEP)
  - Train of Four (TOF)
- Stimulation:
  - Transcranial electrical stimulation (TES)
  - Direct cortical and subcortical stimulation (DCS)
  - Direct nerve stimulation (DNS)
  - Transcutaneous intraoperative nerve stimulation (TINS)
  - Direct muscle stimulation (DMS)

Comparison of Intended Use and Indications for Use:

The ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpert®Plus, ISIS Xpert®, ISIS Xpress) are equal in terms of intended use and indications for use to the predicate device compared to the predicate device. The subject device employs the same technological characteristics as the predicate device.

	Subject devices	Predicate device	Claimed Equivalence
System	ISIS Headbox 5042XX and ISIS Neurostimulator with NeuroExplorer 8	ISIS Headbox 5042XX and ISIS Neurostimulator with NeuroExplorer 7	-
Manufacturer	inomed Medizintechnik GmbH	inomed Medizintechnik GmbH	-
Picture			-
510(k) Number	K233292	K212166	-
Device Class	II	II	Equal
Product Code	GWF	GWF	Equal
Subsequent Product Codes	GWJ, GWQ, ETN, IKN	GWJ, GWQ, ETN, IKN	GWJ – Equal GWQ – Equal ETN – Equal IKN – Equal
Main function, site of usage, intended user group			
Main function	"The product is used for intraoperative monitoring and testing during surgical procedures to examine neuronal tissue (central and peripheral nervous system) by recording and stimulation"	ISIS Headboxes 5042XX: "The products are intended for use in the operating room to measure and display the electrical signals generated by muscle, peripheral nerves and the central nervous system."	Equal Both the predicate and subject devices can acquire, display and store physiologic data from peripheral nerves, muscles, and the central nervous system. The statements use different wording, but do not differ in terms of the clinical aspects.
Site of usage	"The product is used for intraoperative monitoring and testing during surgical procedures. (…)"	ISIS Headboxes 5042XX: "The products are intended for	Equal The predicate and the subject device are intended for use during surgical procedures.

	"The product can be used during surgical procedures (…)"	intraoperative neuromonitoring" "The products are intended for use in the operating room (…)"	
Intended user group	Neurophysiologists (clinical neurophysiologists, neurosurgeons, neurologists or medical technical assistants for functional diagnostics)	Neurophysiologists (clinical neurophysiologists, neurosurgeons, neurologists or medical technical assistants for functional diagnostics)	Equal
Indended Use and Indications for Use			
Intended use	The product is used for intraoperative monitoring and testing during surgical procedures - to examine neuronal tissue (central and peripheral nervous system) by recording and stimulation	ISIS Headbox 5042XX: "The products are intended for intraoperative neuromonitoring; for the recording of electrophysiological signals and stimulating of nerve and muscle tissues. (…)" ISIS Neurostimulator 504180: "The ISIS Neurostimulator is intended for the provision of neurophysiological stimulation when used in surgical procedures and for diagnostics. (…)"	Equal Both the subject and predicate device are intended for the recording of electrophysiological signals and stimulation of neuronal tissue during intraoperative neuromonitoring.
Indications for use	"The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations: • Measurement: - Auditory evoked potentials (AEP) (…) • Stimulation: - Transcranial electrical stimulation (TES) - Direct cortical and subcortical stimulation (DCS) - Direct nerve stimulation (DNS) - Transcutaneous intraoperative nerve stimulation (TINS) - Direct muscle stimulation (DMS)" -	ISIS Headbox 5042XX: "The products support the clinical application of (…) Auditory Evoked Potentials (AEP) (…)" ISIS Neurostimulator 504180: The ISIS Neurostimulator is intended for the provision of neurophysiological stimulation (…). It is suitable for continuous operation and can be used in the following fields: - Transcranial electrical stimulation (TES) - Direct cortical stimulation (DCS) - Direct nerve stimulation (DNS)	Equal AEP: Equal TES: Equal DCS: Equal DNS: Equal TINS and TNS: Equal, the statement was reformulated from transcutaneous electrical nerve stimulation to transcutaneous intraoperative nerve stimulation to highlight the non-therapeutic aspect. DMS: Equal Both the subject and predicate device are indicated for use during surgical procedures that justify the use of aforementioned monitoring modalities.

		- Transcutaneous electrical nerve stimulation (TNS) - Direct muscle stimulation (DMS)	
	"The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities (…) • Measurement: (…) Electroencephalography (EEG)"	ISIS Headbox 5042XX: "The products support the clinical application of Electroencephalography (EEG)"	Equal Both the subject and predicate devices are intended for electroencephalography (EEG).
	"The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities (…) • Measurement: (…) Electromyography (EMG)."	ISIS Headbox 5042XX: "The products support the clinical application of (…) Electromyography (EMG)."	Equal Both the subject and predicate devices are intended for electromyography (EMG).
	"The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations: • Measurement: (…) Motor Evoked Potentials (MEP). (…) • Stimulation: (…) transcranial electrical stimulation (TES)."	ISIS Headbox 5042XX: "The products support the clinical application of (…) Motor Evoked Potentials (MEP)." ISIS Neurostimulator 504180: "It is suitable for continuous operation and can be used in the following fields: (…) transcranial electrical stimulation (TES)."	Equal Both devices can deliver transcranial stimulation via dedicated outputs. The ISIS Headbox is capable of recording MEP signals during transcranial electrical stimulation provided by the ISIS Neurostimulator.
	"The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities (…) • Stimulation: (…) direct cortical stimulation (DCS)."	ISIS Neurostimulator 504180: "It is suitable for continuous operation and can be used in the following fields: (…) direct cortical stimulation (DCS)."	Equal Both devices can deliver electrical current for direct cortical stimulation.
	"The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations:	ISIS Headbox 5042XX: "The products support the clinical application of (…) Electromyography (EMG)." ISIS Neurostimulator 504180:	Equal Both devices can measure triggered EMG signals. The subject devices achieve this by combining the EMG measurement using the ISIS Headboxes and direct nerve

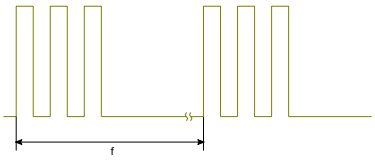
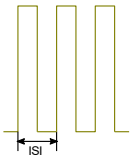
	• Measurement: (…) Electromyography (EMG)." • Stimulation: (…) direct nerve stimulation (DNS)."	"It is suitable for continuous operation and can be used in the following fields: (…) direct nerve stimulation (DNS)."	stimulation (DNS) using the ISIS Neurostimulator.
	"The product can be used during surgical procedures that justify non-therapeutic clinical use of the following modalities or their combinations: combinations: • Measurement: (…) Train of Four (TOF) • Stimulation: (…) Transcutaneous intraoperative nerve stimulation (TINS)."	ISIS Headboxes 5042XX: "The products support the clinical application of (…) Electromyography (EMG)." ISIS Neurostimulator 504180: "The ISIS Neurostimulator is intended for the provision of neurophysiological stimulation (…) in the following fields: (…) transcutaneous electrical nerve stimulation (TNS)."	Equal Both products can be used for performing twitch tests to measure the level of muscle relaxation due to muscular blockers. This measurement is performed by employing a simultaneous transcutaneous electrical nerve stimulation and EMG measurement.
	"The products are not intended for monitoring life-sustaining functions."	ISIS Headbox 5042XX: "The products are not intended for monitoring life-sustaining functions."	Equal Both products are not intended for monitoring of life-sustaining function.

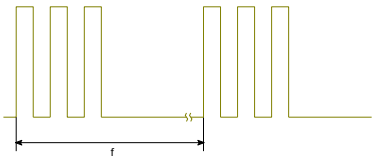
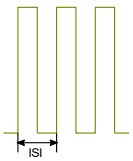
Technology Comparison:

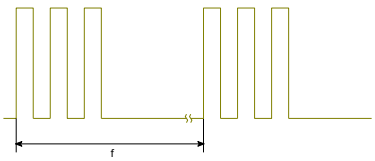
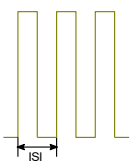
The ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpert®Plus, ISIS Xpert®, ISIS Xpress) exhibit technological characteristics equivalent to those of the predicate device.

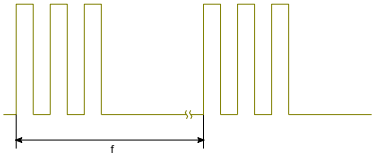
	Subject device	Predicate device
System	ISIS Headbox 5042XX and ISIS Neurostimulator With NeuroExplorer 8	ISIS Headbox 5042XX and ISIS Neurostimulator With NeuroExplorer 7
Manufacturer	inomed Medizintechnik GmbH	inomed Medizintechnik GmbH
Technical aspects		
Protection against electrical shock	Class I protection	Class I protection
Protection against	Device type BF (Body Floating)	Device type BF (Body Floating)

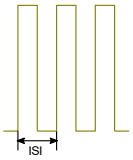
<table>
<tr><td>electrical shock of patient leads</td><td></td><td></td></tr>
<tr><td>System configuration</td><td>Computer-based equipment with dedicated hardware and software components</td><td>Computer-based equipment with dedicated hardware and software components</td></tr>
<tr><td colspan="3">Signal recording</td></tr>
<tr><td>Measurement principle</td><td>Amplifiers based on differential (bipolar) and referential (unipolar) type of recording</td><td>Amplifiers based on differential (bipolar) and referential (unipolar) type of recording</td></tr>
<tr><td>Amplifier components</td><td>Desired combination of ISIS Headboxes with a total of 64 channels</td><td>Desired combination of ISIS Headboxes with a total of 64 channels</td></tr>
<tr><td>Number of amplifier channels</td><td>Up to 64:<table><tr><th>Module</th><th>Channels</th></tr><tr><td>ISIS Headbox 16 Ch. REF (504261)</td><td>Unipolar: 16
Bipolar: 0</td></tr><tr><td>ISIS Headbox 16 Ch. DIF (504271)</td><td>Unipolar: 0
Bipolar: 16</td></tr><tr><td>ISIS Headbox 16 Ch. REF – AEP (504281)</td><td>Unipolar: 16
Bipolar: 0</td></tr><tr><td>ISIS Headbox 8 Ch. DIF – 8 Ch. REF – AEP (504285)</td><td>Unipolar: 8
Bipolar: 8</td></tr></table></td><td>Up to 64:<table><tr><th>Module</th><th>Channels</th></tr><tr><td>ISIS Headbox 16 Ch. REF (504261)</td><td>Unipolar: 16
Bipolar: 0</td></tr><tr><td>ISIS Headbox 16 Ch. DIF (504271)</td><td>Unipolar: 0
Bipolar: 16</td></tr><tr><td>ISIS Headbox 16 Ch. REF – AEP (504281)</td><td>Unipolar: 16
Bipolar: 0</td></tr><tr><td>ISIS Headbox 8 Ch. DIF – 8 Ch. REF – AEP (504285)</td><td>Unipolar: 8
Bipolar: 8</td></tr></table></td></tr>
<tr><td>A/D resolution</td><td>16-bit</td><td>16-bit</td></tr>
<tr><td>Hardware bandpass</td><td>Hardware high-pass filter:
0.5-120 Hz on all modules
Hardware low-pass filter:
2500, 5000 Hz on all modules</td><td>Hardware high-pass filter:
0.5-120 Hz on all modules
Hardware low-pass filter:
2500, 5000 Hz on all modules</td></tr>
<tr><td>Sampling frequency</td><td>20 kHz</td><td>20 kHz</td></tr>
<tr><td>Notch filter</td><td>50, 60 Hz</td><td>50, 60 Hz</td></tr>
<tr><td>Common-mode rejection ratio (CMRR)</td><td>> 100 dB
Conformant with IEC 80601-2-26:2019, clause 201.12.1.106 Common mode rejection.</td><td>> 100 dB
Conformant with IEC 80601-2-26:2019, clause 201.12.1.106 Common mode rejection.</td></tr>
<tr><td>Amplifier noise</td><td>Conformant with IEC 80601-2-26:2019, clause 201.12.1.104 Input noise</td><td>Conformant with IEC 80601-2-26:2019, clause 201.12.1.104 Input noise</td></tr>
<tr><td colspan="3">Stimulation</td></tr>
<tr><td>TcMEP stimulation</td><td>Realized by High Current Stimulator (HC) in transcranial stimulation mode</td><td>Realized by High Current Stimulator (HC) in transcranial stimulation mode</td></tr>
<tr><td>Stimulator type</td><td>Current controlled</td><td>Current controlled</td></tr>
<tr><td>No. of outputs</td><td>12</td><td>12</td></tr>
</table>

Stimulation intensity (I) and pulse width (PW)		
	Current controlled: up to 250 mA (voltage limit of 410 V) Voltage controlled: n/a 0.05 – 2 ms	Current controlled: up to 250 mA (voltage limit of 410 V) Voltage controlled: n/a 0.05 – 2 ms
Intensity step	Constant current: 0.1 mA Constant voltage: n/a	Constant current: 0.1 mA Constant voltage: n/a
No. of stimulus pulses	1-9	1-9
Stimulation frequency (f) range		
	Up to 500 Hz	Up to 500 Hz
Limitation of stimulation frequency	1/10 pulse width to stimulation period ratio	1/10 pulse width to stimulation period ratio
Limitation of inter-stimulus interval		
	Limited to ½ pulse width to ISI	Limited to ½ pulse width to ISI
Absolute minimum inter-stimulus interval	0.1 ms	0.1 ms
Maximum charge per phase	189.66 µC	189.66 µC
Maximum RMS stimulation intensity	30 mA RMS	30 mA RMS
Minimum electrode size	n/a	0.39 cm²
Maximum current density	90,8 mA/cm²	76.92 mA/cm²
Maximum charge density	61.5 µC/cm²	61.5 µC/cm²

Maximum power density	160 W/cm²	160 W/cm²
Power limitation	≤50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	≤50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.
High-current stimulator for SEP and TOF	Realized by High Current Stimulator (HC) in subcutaneous stimulation (SEP, TOF) mode	Realized by High Current Stimulator (HC) in subcutaneous stimulation (SEP, TOF) mode
Stimulator type	Constant current	Constant current
No. of outputs	12	12
Stimulation intensity (I)		
	Accessory-dependent	Up to 75 mA
Intensity step	0.1 mA	0.1 mA
Pulse width (PW)	0.05 – 2 ms	0.05 – 2 ms
No. of stimulus pulses	1-9	1-9
Stimulation frequency (f) range		
	SEP: Up to 500 Hz TOF: 2 Hz (fixed)	SEP: Up to 500 Hz TOF: 2 Hz (fixed)
Limitation of stimulation frequency	1/10 pulse width to stimulation period ratio	1/10 pulse width to stimulation period ratio
Limitation of inter-stimulus interval		
	Limited to ½ pulse width to ISI	Limited to ½ pulse width to ISI
Absolute minimum inter-stimulus interval	0.1 ms	0.1 ms
Maximum charge per phase	150 µC	150 µC
Maximum RMS	Accessory-dependent	23.7 mA RMS

stimulation intensity		
Minimum electrode size	n/a	0.272 cm²
Maximum current density	90.8 mA/cm²	87.1 mA/cm²
Maximum charge density	150.0 µC/cm²	150.0 µC/cm²
Maximum power density	20.7 W/cm²	20.7 W/cm²
Power limitation	≤50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	≤50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.
Low-current stimulator for direct cortical stimulation:	Realized by High Current Stimulator (HC) in direct cortical stimulation mode	Realized by High Current Stimulator (HC) in direct cortical stimulation mode
Stimulator type	Constant current	Constant current
Stimulation intensity (I)		
	Accessory-dependent	Up to 30 mA
Intensity step	0.01 mA	0.01 mA
Pulse width (PW)	0.05 – 2 ms	0.05 – 2 ms
No. of stimulus pulses	1 – 9	1 – 9
Stimulation frequency (f) range		
	Up to 500 Hz	Up to 500 Hz
Limitation of stimulation frequency	1/10 pulse width to stimulation period ratio	1/10 pulse width to stimulation period ratio
Limitation of inter-stimulus interval		
	Limited to ½ pulse width to ISI	Limited to ½ pulse width to ISI

Absolute minimum inter-stimulus interval	0.1 ms	0.1 ms
Maximum charge per pulse	60 µC	60 µC
Maximum RMS stimulation intensity	Accessory-dependent	9.5 mA RMS
Minimum electrode size	n/a	0.126 cm²
Maximum current density	90.8 mA/cm²	75.29 mA/cm²
Maximum charge density	150.8 µC/cm²	150.8 µC/cm²
Maximum power density	7.1 W/cm²	7.1 W/cm²
Power limitation	≤50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	≤50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.
Low-current stimulator for direct nerve stimulation:	Realized by Direct Nerve Stimulator (DNS) in direct nerve stimulation mode	Realized by Direct Nerve Stimulator (DNS) in direct nerve stimulation mode
Stimulator type	Constant current	Constant current
No. of outputs	1	1
Stimulation intensity (I)		
	Accessory-dependent	Up to 5 mA
Intensity step	0.01 mA	0.01 mA
Pulse width (PW)	0.05 – 2 ms	0.05 – 2 ms
No. of stimulus pulses	1 – 9	1 – 9
Stimulation frequency (f) range		
	Up to 500 Hz	Up to 500 Hz

Limitation of stimulation frequency	1/10 pulse width to stimulation period ratio	1/10 pulse width to stimulation period ratio
Limitation of inter-stimulus interval		
	Limited to ½ pulse width to ISI	Limited to ½ pulse width to ISI
Absolute minimum inter-stimulus interval	0.1 ms	0.1 ms
Maximum charge per pulse	10 µC	10 µC
Maximum RMS stimulation intensity	Accessory-dependent	1.58 mA RMS
Minimum electrode size	n/a	0.020 cm²
Maximum current density	90.8 mA/cm²	79 mA/cm²
Maximum charge density	158 µC/cm²	158 µC/cm²
Maximum power density	1.25 W/cm²	1.25 W/cm²
Power limitation	≤50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.	≤50 mJ/pulse Conformant to IEC 60601-2-40:2016, clause 201.12.4.103.

Summary of Performance Testing:

Biocompatibility: The ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpert®Plus, ISIS Xpert®, ISIS Xpress) have no patient contact materials, and therefore this section does not apply.

Software: The Documentation Level of inomed NeuroExplorer Software is ENHANCED DOCUMENTATION. The software was designed and developed according to a rigorous development process, including software verification and validation. Software information is provided in accordance with internal requirements and the following guidance documents and standards:

- FDA Guidance: Content of Premarket Submissions for Device Software Functions, Jun 14, 2023
- FDA guidance: Off-the-shelf software use in medical devices, August 11, 2023
- FDA guidance: General principles of software validation: Final guidance for industry and FDA staff, Jan 02, 2002
- FDA guidance: Content of premarket submissions for management of cybersecurity in medical devices, Oct 02, 2014
- IEC 62304:2006/AMD1:2015, Medical device software — Software life cycle processes

Test results demonstrate that the inomed NeuroExplorer software complies with its predetermined specifications, the applicable guidance documents, and standards.

Electrical Safety: The ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpert®Plus, ISIS Xpert®, ISIS Xpress) were tested according to the following standards:

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 80601-2-26:2019, Medical electrical equipments – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- IEC 60601-2-40:2016, Medical electrical equipments – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

Test results demonstrate that the products comply with the applicable standards.

Electromagnetic Compatibility: The ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpert®Plus, ISIS Xpert®, ISIS Xpress) were tested according to the following standards:

- IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests.

Test results demonstrate that the products comply with the applicable standards.

Performance Testing – Bench

The essential performance and safety of the ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpert®Plus, ISIS Xpert®, ISIS Xpress) were tested for performance in accordance with internal requirements. The devices including their accessories and corresponding intended combinations with further products have been designed according to requirement specifications formulated at the following levels:

- Requirements for electrical medical systems
- Requirements for the system carrier
- Requirements for the amplifier (ISIS Headboxes) and stimulator (ISIS Neurostimulator) modules
- Requirements for the operating software (NeuroExplorer) incl. ISIS Headbox and ISIS Neurostimulator firmware
- ISIS Headbox and ISIS Neurostimulator accessories (adaptor boxes)
- Custom Microsoft® Windows 10 image

The products successfully underwent the bench testing to confirm the fulfillment of the requirements at these levels as part of the verification and validation process.

Moreover, the testing of the influence of human factors on the devices demonstrates that the products are safe to use and that no further improvement of the user interface design relating to safety is necessary.

The non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicate.

Performance Testing – Clinical

No additional clinical testing was performed for the ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpert®Plus, ISIS Xpert®, ISIS Xpress). Therefore, this section does not apply.

Conclusion

In order to establish the performance and safety characteristics, the ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpert®Plus, ISIS Xpert®, ISIS Xpress) underwent successful testing in terms of the device software, electrical safety, electromagnetic compatibility, bench testing, and human factors engineering. The results of these activities demonstrate that the devices are as safe, effective and perform as well as or better than the predicate device.

Therefore, the ISIS Headboxes and ISIS Neurostimulator including accessories as part of ISIS IOM Systems (ISIS Xpert®Plus, ISIS

Xpert®, ISIS Xpress) are considered substantially equivalent to the predicate device.