Table of Contents

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2001

Lifelines, Ltd.
c/o Christina Smith
Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

Re: K010460
Trade/Device Name: Lifelines Trackit Recorder
Regulation Number: 882.1400
Regulatory Class: II
Product Code: GWQ
Dated: February 16, 2001
Received: February 16, 2001

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010460

Device Name: Lifelines Trackit Recorder

Classification Panel: GWQ

Indications for Use:

The Lifelines Trackit Recorder is a 36 channel ambulatory electroencephalograph that is designed for use in a variety of monitoring applications, to record physiological data for EEG and Sleep Studies.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010460

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over the Counter Use** _____

DUPLICATE K010460/A1

Smith

~ FDA CONSULTANTS ~

Specializing in Regulatory Affairs

Food and Drug Administration
Document Control Center
9200 Corporate Blvd.
Rockville, Maryland 20850

April 3, 2001

RE: K010460
Trade Name: Lifelines TrackIt EEG Recorder

Dear Mr. Yen:

Following is the response to your letter dated March 29, 2001.

1. Trackit is a 36 channel ambulatory EEG system with 24 EEG channels, 8 polygraphic channels, and 4 Hi level inputs (or Hi level Aux). Please provide design descriptions of these 4 Hi level inputs, the purposes or functions, and relation to EEG recording.

See a description of the Hi level inputs in the TrackIt specification detail attached (Exhibit 1 of the response).

2. On page 20, you stated that the system has been certified and complies with EN60601-1-2, EMC requirement. Please provide summary test results including pass/fail criteria for the applicable standards.

Please reference EMC summary (Exhibit 2 of the response).

3. Please provide a copy of your software requirement specifications (SRS) and summary from your validation/verification testing that describes each tested functions or requirements, pass/fail criteria used, and test results.

Please reference Trackit SRS (Exhibit 3 of the response), Validation V2 (Exhibit 4 of the response), and TrackIt Prod Test (Exhibit 5 of the response)

4. Please clarify that there are no recording electrodes included in this submission.

There are no recording electrodes included in this 510(k) submission.

P.O. Box 4341 • Crofton, Maryland 21114
PHONE: (888) 729-9674 • **FAX:** (410) 793-0448
WEB SITE: www.fdaconsultants.com • **E-MAIL:** ESmith9746@aol.com

1

5. In Appendix 2, please provide the following additional product specifications:

a) **Input impedance (in megaohms)**
b) **Amplifier design and frequency response over the frequency spectrum of interest.**
c) **Filter characteristics**

Input impedance is 100 megaohms
Differential input impedance is 20 megaohms
Amplifier frequency spectrum is 0.16 - 70Hz (-6dB) or DC - 70Hz (-6dB) when in DC mode.

Please reference TrackIt specifications for all details on this information (Exhibit 1 of the response). Please reference TrackIt Block Design for a design overview (Exhibit 6 of the response).

6. In your promotional materials, please address the following:

a) **In what sense is your device the "worlds first ambulatory EEG recorder"?**
b) **Do you intend to market different configurations of the system (e.g., TrackIt 36, TrackIt 24, and TrackIt 12)?**

The TrackIt device is the worlds first ambulatory system where the user can swap disks and batteries without stopping the recording. The term Lifelines has coined for this is continuous data recording.

Lifelines intend to market the 36, 24, and 12 channel EEG recorders. They are identical systems with fewer channels.

If any further information is required please feel free to contact me by telephone (410) 451-0639 or by Fax (410) 793-0448.

Sincerely,

Christina Smith

Smith & Associates
P.O. Box 4341 • Crofton, Maryland 21114
PHONE: (888) 729-9674 • **FAX:** (410) 793-0448
WEB SITE: www.rdaconsultants.com • **E-MAIL:** DSmith9746@aol.com

2

Exhibit 1
TrackIt Specification Detail

IEC801-4:1988, Fast Transient Bursts.
IEC801-5:1989, Surge Immunity.

- For degree of protection against electrical shock (when connected to Host system) : Type BF
- Type of protection against electrical shock: Internally Powered or Class II (when connected to Host system)
- For degree of protection against harmful ingress of water: Ordinary (no protection).
- For the mode of operation: Continuous.
- For the degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Not suitable

* Note: Lifelines reserves the right to change the product specification at any time without notice. This is in-line with the company's policy of continual product development.

4

Exhibit 2
EMC Summary

[redacted] **Intertek Testing Services**
ETL SEMKO

EMC TEST REPORT

COMPANY: Lifelines Limited
PRODUCT: EEG Ambulatory Recorder

REPORT NO. EM00002654

WRITTEN BY:	**M N Larke**	
APPROVED BY:	**J A Beerpark**	
TEST ENGINEER:	**M N Larke**	
ISSUE: 1	**DATE: 29th August 2000**	**TOTAL PAGES: 29**

Opinions and interpretations based on test results are outside our scope of NAMAS Accreditation.

ITS Testing & Certification Ltd
ITS House, Cleeve Road, Leatherhead, Surrey KT22 7SB
Tel: +44 (0)1372 376600 Fax: +44 (0)1372 376600
Registered No. 3775001 Registered office: 25 Savile Row, London W1X 1AA
For terms and conditions please see reverse

[redacted]

6

2. TEST SUMMARY

2.1. NAMAS Accredited Test

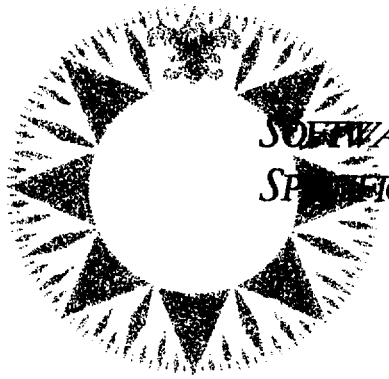
EN60601-1-2:1993	EN55011:1991, Group 1, Class B Conducted Emissions	Pass
	EN55011:1991, Group 1, Class B Radiated Emissions	Pass
	IEC801-2:1991, Electrostatic Discharge	Pass
	IEC801-3:1984, RF Electromagnetic Field	Pass
	IEC801-4:1988, Fast Burst Transients	Pass
	IEC801-5:Draft, Surge Immunity	Pass

Where comments other than "pass" are entered in the comments column, further details may be found in the **TEST RESULTS** section.

Exhibit 3
Software Requirement Specifications (SRS)

LIFELINES

The Trackit Recorder



SOFTWARE REQUIREMENT SPECIFICATION

Version: 2

Revision date: 17th August 2000

LIFELINES LTD, 7 CLARENDON COURT, OVER WALLOP, NR STOCKBRIDGE
HAMPSHIRE, UK SO208HU
WWW.LLINES.COM

(b)(4) Pages 15 through 20 removed

[redacted] 1

(b)(4) Pages 22 through 105 removed

Lifelines Ltd
Trackit Ambulatory Recorder System
Software Verification V2.0

101

(b)(4) Pages 107 through 110 removed

Exhibit 5
TrackIt Prod Test

(b)(4) Pages 112 through 122 removed

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over the Counter Use** _____

3

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service, Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) DWIGHT YEN

Subject: 510(k) Number K010460

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

- ☐ A 510(k) summary OR ☑ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☑ The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☑ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 84 GWZ Class II 882.1400

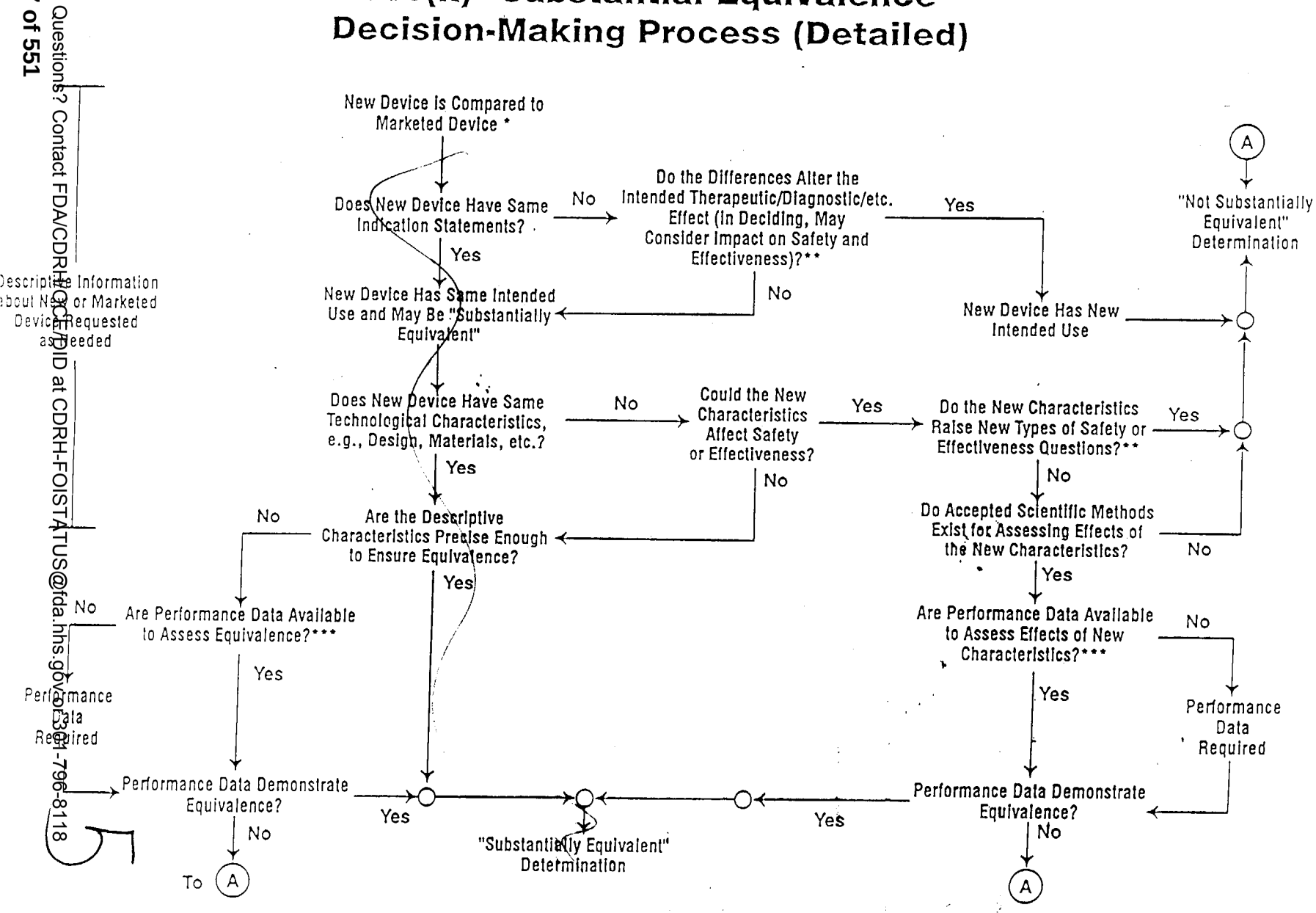
Additional Product Code(s) with panel (optional):

Review: Neil R P Ogden (Branch Chief) GSDS (Branch Code) 5/14/01 (Date)

Final Review: for CDRH (Division Director) 6/14/01 (Date)

4

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Inform[illegible] If the Relationship Between Marketed and "Predicate" (Pre-Amendment. [illegible]eclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testi[illegible]ormation is Sometimes Required.

*** Data May Be [illegible] 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

510K Memo Record

Date: 10 May 2001

To: The record K010460
From: Dwight Yen, Electronics Engineer (HFZ 410)

Subject: Premarket notification from Lifelines Ltd. For the Lifelines Trackit Recorder

Contact: c/o Christina Smith, Smith Associates (410) 451-0639

Description: The Trackit Recorder is a 36-channel ambulatory (portable) EEG system. The system is comprised of the following components:

1. A 24 channel EEG amplifier acquisition board,
2. An 8 channel polygraphic acquisition board,
3. 4 Hi level Aux? Describe relation to actual EEG recording (see below).
4. Control board with all the I/O interface for serial and patient communication,
5. Electrode connector block for standard 1.5 mm touchproof EEG recording electrodes,
6. Host isolator box,
7. DC power supply module,
8. 3 PP3 disposable alkaline batteries,
9. ATA Flash disk to store the EEG data, and
10. Trackit Set-up Software that runs under MS windows 95/98 on the host PC.

The sponsor was asked for additional information on the submission. Their initial response dated 4/3/2001 was lost after it arrived at FDA Document Mail Center as Amendment 1. A second copy was sent and received on 5/1/2001 as Amendment 2. The sponsor clarified that the device will be available in the following configurations: Trackit 36, Trackit 24 and Trackit 12 corresponding to the 36, 24 and 12 channels. There are no recording electrodes included in this submission. The system is compatible with currently marketed EEG electrodes. In Amendment 3, the sponsor explains that the Hi level Aux inputs are used for connecting devices such as light meters, body position (motion) sensors, respiration transducers and other patient event markers to complement the ambulatory EEG system. Software documentations are provided in accordance to FDA guidance and finally, EMC test results and pass/fail criteria are provided to show the device meets with IEC 601 standard.

Intended Use: The device is use in a variety of monitoring applications to record physiological data for EEG and Sleep Studies. This intended use is SE to predicates (K961642).

Predicates: The Medelec MR 95 (K961642) is a 17-channel ambulatory EEG recorder. Other than having more channels (36 versus 17), the subject device is SE to predicate in technology and intended use. There are other EEG systems currently on the market with similar numbers of channels. The additional channels do not raise new issues of safety or effectiveness.

Labeling: Draft labels and instructions for use are provided.

Sterility: The device does not need to be sterilized in normal use.

Manufacture: The sponsor states that the device meets the IEC 60601-1 standard and UL 2601-1 for electrical safety for an electrical medical device. Bench test results by Intertek Testing Services are provided. The sponsor has provided summary of test results and pass/fail criteria used for the IEC 60601-1-2, EMC, tests.

The sponsor defines the level of concern at moderate. Predicate EEG systems with the same intended use are considered minor level of concern. The following software documentations for a minor level of concern are provided. A device hazard analysis and a software architecture flow chart. The sponsor has provided a copy of their software requirement specification and summary of their validation and verification testing that describe functions tested, pass/fail criteria and test results.

Materials: The only patient contact material of concerns for EEG systems are the electrodes. The sponsor clarifies that there are no recording electrodes included in this 510(k). The system is compatible to electrodes that are already on the market.

Technical: Technical specifications provided include noise level <2uV peak to peak, CMRR >100 dB. Amplifier input impedance is 100 Mohms, differential input impedance is 20 Mohms, frequency response spectrum is 0 to 70 Hz.

An Indication for use, a 510K Statement, a Truthful and Accurate Statement are provided.

RECOMMENDATION: SE to predicates, 84 GWQ Class II 882.1400.

5/14/12

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name:	K
Submitter (Company):	

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA SPECIALS YES	NA SPECIALS NO	YES ABBREVIATED YES	YES ABBREVIATED NO	NO TRADITIONAL YES	NO TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				✓		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*					NA		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					✓		
i) Labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) ***STATEMENT - INTENDED USE AND INDICATIONS***			* If no - STOP not a special	

requirements or deviations noted below						
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed						
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device						
v) A specification of any deviations from each applicable standard that were applied						
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference						
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations						
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards						

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:					✓		
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:					✓		
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:					✓		
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No**
Date: 5/10/21

Reviewer: Dwight Y
Concurrence by Review Branch: Mel

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 010460

Reviewer: DWIGHT YEN

Division/Branch: DGRND / GSDB

Device Name: TRACKit Recorder

Product To Which Compared (510(K) Number If Known): K961642

	YES	NO	
1. Is Product A Device	✓		If **NO** = Stop
2. Is Device Subject To 510(k)?	✓		If **NO** = Stop
3. Same Indication Statement?	✓		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?	✓		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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Prescription Use ✓ **or** **Over the Counter Use** _____

3

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service, Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) DWIGHT YEN

Subject: 510(k) Number K010460

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

- ☐ A 510(k) summary OR ☑ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☑ The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☑ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 84 GWZ Class II 882.1400

Additional Product Code(s) with panel (optional):

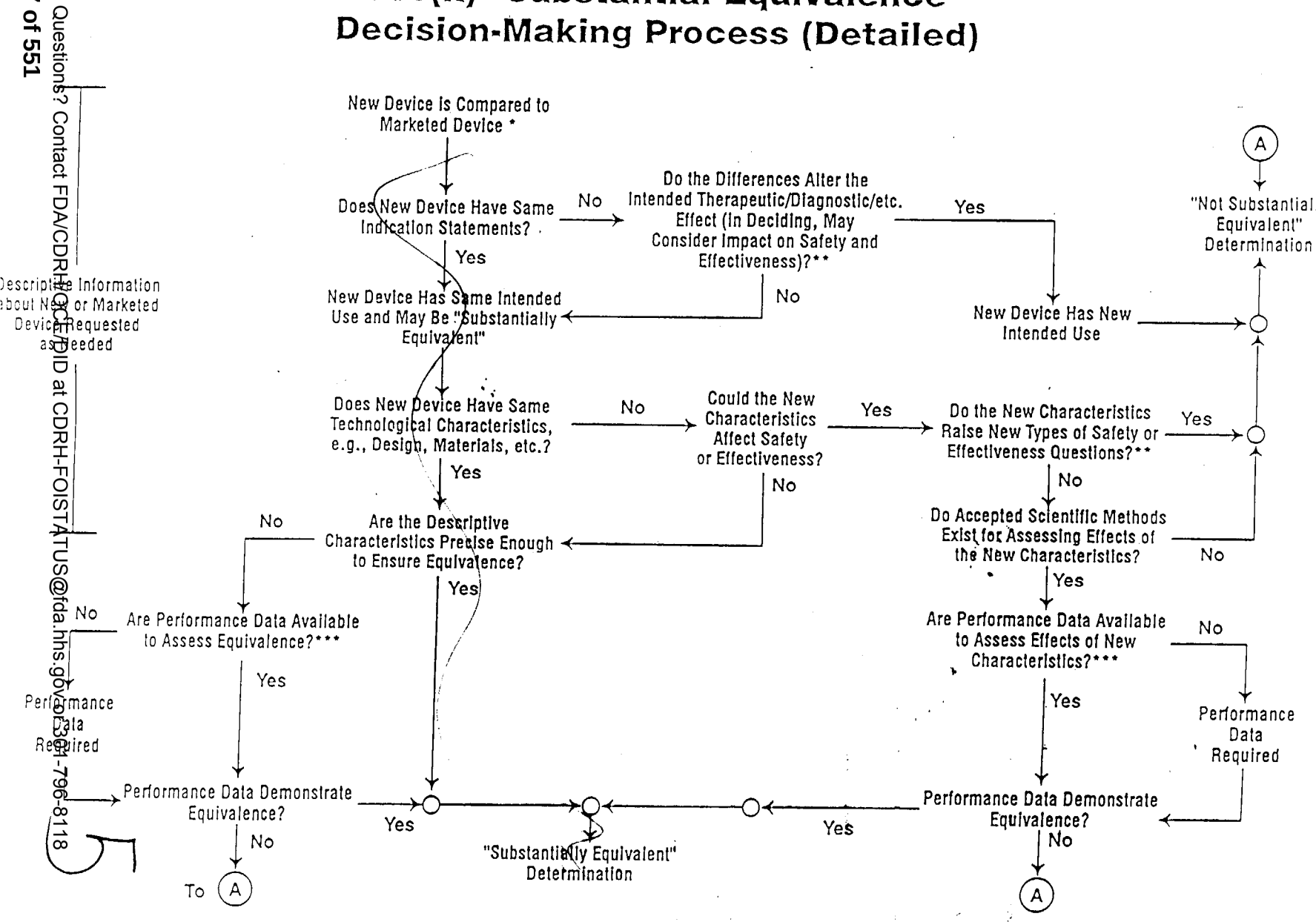
Review: Neil R P Ogden (Branch Chief) GSDB (Branch Code) 5/14/01 (Date)

Final Review: for CDRH (Division Director) 6/14/01 (Date)

4

Revised: 8/17/99

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Inform[illegible] If the Relationship Between Marketed and "Predicate" (Pre-Amendment. [illegible]eclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testi[illegible]ormation is Sometimes Required.

*** Data May Be [illegible] 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

510K Memo Record

Date: 10 May 2001

To: The record K010460
From: Dwight Yen, Electronics Engineer (HFZ 410)

Subject: Premarket notification from Lifelines Ltd. For the Lifelines Trackit Recorder

Contact: c/o Christina Smith, Smith Associates (410) 451-0639

Description: The Trackit Recorder is a 36-channel ambulatory (portable) EEG system. The system is comprised of the following components:

1. A 24 channel EEG amplifier acquisition board,
2. An 8 channel polygraphic acquisition board,
3. 4 Hi level Aux? Describe relation to actual EEG recording (see below).
4. Control board with all the I/O interface for serial and patient communication,
5. Electrode connector block for standard 1.5 mm touchproof EEG recording electrodes,
6. Host isolator box,
7. DC power supply module,
8. 3 PP3 disposable alkaline batteries,
9. ATA Flash disk to store the EEG data, and
10. Trackit Set-up Software that runs under MS windows 95/98 on the host PC.

The sponsor was asked for additional information on the submission. Their initial response dated 4/3/2001 was lost after it arrived at FDA Document Mail Center as Amendment 1. A second copy was sent and received on 5/1/2001 as Amendment 2. The sponsor clarified that the device will be available in the following configurations: Trackit 36, Trackit 24 and Trackit 12 corresponding to the 36, 24 and 12 channels. There are no recording electrodes included in this submission. The system is compatible with currently marketed EEG electrodes. In Amendment 3, the sponsor explains that the Hi level Aux inputs are used for connecting devices such as light meters, body position (motion) sensors, respiration transducers and other patient event markers to complement the ambulatory EEG system. Software documentations are provided in accordance to FDA guidance and finally, EMC test results and pass/fail criteria are provided to show the device meets with IEC 601 standard.

Intended Use: The device is use in a variety of monitoring applications to record physiological data for EEG and Sleep Studies. This intended use is SE to predicates (K961642).

Predicates: The Medelec MR 95 (K961642) is a 17-channel ambulatory EEG recorder. Other than having more channels (36 versus 17), the subject device is SE to predicate in technology and intended use. There are other EEG systems currently on the market with similar numbers of channels. The additional channels do not raise new issues of safety or effectiveness.

Labeling: Draft labels and instructions for use are provided.

Sterility: The device does not need to be sterilized in normal use.

Manufacture: The sponsor states that the device meets the IEC 60601-1 standard and UL 2601-1 for electrical safety for an electrical medical device. Bench test results by Intertek Testing Services are provided. The sponsor has provided summary of test results and pass/fail criteria used for the IEC 60601-1-2, EMC, tests.

The sponsor defines the level of concern at moderate. Predicate EEG systems with the same intended use are considered minor level of concern. The following software documentations for a minor level of concern are provided. A device hazard analysis and a software architecture flow chart. The sponsor has provided a copy of their software requirement specification and summary of their validation and verification testing that describe functions tested, pass/fail criteria and test results.

Materials: The only patient contact material of concerns for EEG systems are the electrodes. The sponsor clarifies that there are no recording electrodes included in this 510(k). The system is compatible to electrodes that are already on the market.

Technical: Technical specifications provided include noise level <2uV peak to peak, CMRR >100 dB. Amplifier input impedance is 100 Mohms, differential input impedance is 20 Mohms, frequency response spectrum is 0 to 70 Hz.

An Indication for use, a 510K Statement, a Truthful and Accurate Statement are provided.

RECOMMENDATION: SE to predicates, 84 GWQ Class II 882.1400.

5/14/12

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name:	K
Submitter (Company):	

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA SPECIALS YES	NA SPECIALS NO	YES ABBREVIATED YES	YES ABBREVIATED NO	NO TRADITIONAL YES	NO TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				✓		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*					NA		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					✓		
i) Labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) ***STATEMENT - INTENDED USE AND INDICATIONS***			* If no - STOP not a special	

requirements or deviations noted below						
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed						
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device						
v) A specification of any deviations from each applicable standard that were applied						
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference						
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations						
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards						

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:					✓		
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:					✓		
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:					✓		
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No**
Date: 5/10/21

Reviewer: Dwight Y
Concurrence by Review Branch: Mel

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 010460

Reviewer: DWIGHT YEN

Division/Branch: DGRND / GSDB

Device Name: TRACKit Recorder

Product To Which Compared (510(K) Number If Known): K961642

	YES	NO	
1. Is Product A Device	✓		If **NO** = Stop
2. Is Device Subject To 510(k)?	✓		If **NO** = Stop
3. Same Indication Statement?	✓		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?	✓		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Smith
DA CONSULTANTS ~
Specializing in Regulatory Affairs

Food and Drug Administration
9200 Corporate Blvd
Rockville, Maryland 20850

May 8, 2001

RE: K010460
Trade Name: Lifelines Trackit EEG Recorder

Dear Mr. Yen:

Enclosed please find the response regarding the Lifelines Trackit EEG Recorder. If you have any further questions please feel free to contact me at 410-451-0639 or by fax 410-793-0448.

Thank you,

Christina Smith

P.O. Box 4341 • Crofton, Maryland 21114
PHONE: (888) 729-9674 • FAX: (410) 793-0448
WEB SITE: www.fdaconsultants.com • E-MAIL: ESmith9746@aol.com

1. **Please give a more detailed description of the 4 high level inputs and what their function is in relation to EEG. If there is a predicate product with these same features please reference that product.**

Exhibit 1 contains the predicate device information that has the same set-up as our system except that they have 16 isolated auxiliary DC (Hi level DC) inputs see section C6 of the spec sheet from Compumedics user manual. The 510(k) information is also attached.

2. **Please submit the EMC Test Criteria Used.**

Exhibit 2 contains the test criteria used for the EMC testing.

Exhibit 1

C Technical Description

C.1 System Environmental Requirements

C.1.1 Transport and Storage Conditions:

- -20°C (4°F) to +50°C (122°F),
- 30-95% RH non- condensing conditions

C.1.2 Operating Temperature

- Ambient operating temperature range: 0°C - 45°C (32°F - 113°F)

C.1.3 Altitude

- Less than 50,000 feet

C.2 Recording Unit

Part Number:	8007-0001-01
Classification:	Type CF, IEC 60601-1
Power Input:	External Power Supply / Battery Charger (refer C.3); or Ni-MH Battery Pack (P/N 0300-0009-00) or 4 x AA Alkaline
Fuses:	There are no user-replaceable fuses.
Service:	There are no user-serviceable parts inside the Siesta Recording Unit. Repairs to any component of the Siesta System must be made at a Compumedics authorised repair centre.

If you require a replacement or additional NiMH battery, contact Compumedics or your authorised representative. The internal battery charger function will only charge the NiMH Battery Pack (P/N 0300-0009-00).

The NiMH Battery Pack can be replaced with alkaline AA batteries if desired. The Siesta will not attempt to charge alkaline batteries.

C.2.1 Features

A stable, low noise, high gain, high input impedance, software programmable amplifier/data acquisition system, providing state of the art in amplification and digitization of physiological signals from electrodes, sensors and transducers. Features up to 32 isolated high-frequency (4 DC coupled) channels, and up to 32 high-level DC inputs (through external DC modules). External devices are interfaced via 4-channel DC modules, which may be replaced with signal specific modules to measure pressure (via nasal cannula, esophageal balloon or CPAP mask) or oximetry.

C.2.2 Patient Safety Standards

- Complies with IEC601-1 specifications for medical electrical equipment
- Complies with IEC601-1-2 specifications for electromagnetic compatibility

C.2.3 Inputs

32 user defined, AC, fully isolated, referential (4 DC coupled)

C.2.4 Input Impedance

10 MΩ

C.2.5 Input Current

Typically 10nA, 100nA max

C.2.6 Input Noise

Typically 2μVp-p

C.2.7 Input Range

500μV to 500mV set in six steps

- 500μVp-p
- 2mVp-p
- 10mVp-p
- 25mVp-p
- 100mVp-p
- 500mVp-p

C.2.8 CMRR

> 100dB

C.2.9 Frequency Response

- 0.15 to 210 Hz for all channels when in AC mode;
- 0.05 to 210 Hz for channels 29 to 32 when in extended mode;
- DC to 210 Hz for channels 1 to 4 when in DC mode

C.2.10 High Pass Filter

- Standard 0.15 Hz,
- Channels 29-32 have extended HP filter of 0.046Hz for support of respiratory sourced signals.
- Software based display filtering of 0-12Hz in 0.05Hz steps.

C.2.11 Low Pass Filter

- four pole anti-aliasing low-pass filter, -3dB of 210Hz.
- Software based display filtering of 0Hz to half the sampling rate.

C.2.12 Notch Filter

Software based display filtering of 50Hz, 60Hz, or off

C.2.13 Sampling Rate

The signals for each of the units is sampled and stored from 4 to 512Hz with true 16-bit digital resolution

C.2.14 Data Storage

The Siesta provides built-in storage using an industry standard removable Compact Flash card. The current maximum size available is 194MB. The Siesta is supplied with a 128MB CF card.

C.2.15 Isolation

Siesta has no inherent patient isolation as it operates from batteries. When operating from an external supply, the supply has 1500Vrms isolation from ground and 4000Vrms isolation from mains

C.2.16 Dimensions

- 5.5in x 3inx 1.5in
- 139.7mm x 76.2mm x 38.1mm

C.2.17 Weight

- 9.6 ounces
- 300 grams

C.3 Power Supply / Battery Charger

Part Number: 8007-0006-01
Classification: Class I, Type CF, IEC 60601-1

Mains Supply: 100-240V~ 50/60Hz
Power Input: 55VA
Output: 10V ⎓ 1.0A
Fuses: There are no user-replaceable fuses. The Recording Unit contains self-resettable fuses.
Service: There are no user-serviceable parts inside the Siesta Power Supply / Battery Charger. Repairs to any component of the Siesta System must be made at a Compumedics authorised repair centre.

WARNINGS

- Only connect the Siesta Power Supply / Battery Charger to the Siesta Recording Unit. Other third party power supplies **MUST NOT** be used.
- The Battery Charger/Power Supply will only charge the NiMH Battery Pack (P/N 0300-0009-00).

C.3.1 Battery Charge Time

2.5 hours

Where battery power is to be used, the battery should be fully charged within 24 hours prior to operation. To fully charge the battery, allow for a charging period of 2.5 hours.

The battery is good for up to 500 charge/discharge cycles. Replace with the type specified in Appendix A.

C.4 Radio LAN Communication

The Siesta was designed to operate in a TCP/IP wireless and wired network environment using a commercial Spread Spectrum Radio network device. The circuitry and antenna are inside the case. The unit is fully IP compliant with a routable IP address. The wireless nature of the connection allows for subject mobility and roaming within the range of the host computer. Use of bridge devices can extend the range of subject mobility to areas in excess of 1000 feet from the host computer. Nominal transmission distance between the Siesta unit and a host PC with a 6-8dB gain antenna is 30 to 50 meters, though RF transmission is affected by environmental and architectural factors.

C.5 IrDA Port

The IrDA standard infrared serial port built into the Siesta Recording Unit provides a communication link with a computer equipped with an external IrDA port attached to a serial port. The port is used primarily for changing control settings in the Siesta, for troubleshooting and for short-term data transmission. As is the case with most IrDA devices, the port operates in line-of sight, with a range of about 1 to 1.5 meters.

C.6 DC Input Modules

2 expansion ports with up to 16 high-level DC inputs *(±1V or ±10V)* each

Each Module provides 4 isolated, DC inputs, up to 4 DC Modules can be daisy-chained for a total of 16 inputs per expansion port.

C.6.1 DC Input Range

±1V or ±10V

C.6.2 Sampling Rate

1-64 Hz per input

DEC 2 7 2000

K003775

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Compumedics Pty Ltd. summary for the Compumedics Siesta System.

SUBMITTER'S NAME:	Compumedics Telemed Pty Ltd
ADDRESS:	1 Marine Parade, Abbotsford, Victoria, 3067 Australia
CONTACT PERSON:	Constance Bundy, C.G. Bundy Associates, Inc.
TELEPHONE NUMBER:	612-574-1976
FAX NUMBER:	612-571-2437
DATE OF SUBMISSION:	October 6, 2000

1. Identification of device

Proprietary Name: Compumedics Siesta System
Common Name: Electroencephalograph
Classification Status: Class II per regulations 882.1400
Product Codes: GWQ

2. Equivalent devices

Compumedics believes the Compumedics Siesta System is substantially equivalent to the Compumedics Sleep Monitoring System, *510(k) No:* K955841 and Compumedics E-Series EEG System, *510(k) No:* K000068.

3. Description of the Device

The Compumedics Siesta System is a multi-functional ambulatory recording device. The system is used for the recording, monitoring, storage and transfer of up to 32 biophysical parameters such as brain, heart and muscle activity, eye movement, blood pressure, breathing, and body movements. In addition it has an Oximeter interface for heart rate and oxygen saturation as well as supporting up to 16 serial ports for the connection of external devices such as pH meters.

Electrodes and sensors from the patient are connected to adaptors, which are in turn connected to the Siesta Recording Unit.

Patient Studies recorded using the Siesta and ProFusion PSG Software allow the user to view, print, summarize, analyze and create Patient Study reports.

The Siesta Recording Unit has a built in Compact Flash Disk interface for storage and convenient transfer to review workstations. There is no proprietary hardware required to transfer the study data.

20

A built in wireless Radio LAN module allows the Siesta Recording Unit to remotely monitor study parameters.

Battery power can be used to power the unit for up to 24 hours of continuous operation, depending upon use of Radio LAN and configuration of study. The unit supports both rechargeable and non-rechargeable batteries as well as an external main powered combination power supply/battery charger.

4. **Intended use**

The Siesta System is intended for use in the recording, displaying, monitoring, printing and storage of biophysical parameters for the purpose of assisting in the diagnosis of neurological and sleep disorders.

The Siesta System unit is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

The Siesta System is only to be used under the direction and supervision of a physician, EEG technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.

5. **Technological characteristics, comparison to predicate device.**

Like the predicate devices, the Compumedics Siesta System is intended to detect physiological signals from various points on the patient's body, individually or as a signal measured between selected electrodes, and to record those signals in accordance with preset parameters (in a montage) for analysis by a clinician.

Comparison Table:

Characteristic	*Compumedics Sleep Monitoring System (P-Series)*	*Compumedics Siesta System*	*Compumedics E-Series System*
Intended Use	For use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of neurological and sleep disorders	Same	Same
Configuration	Waist belt or desktop	Waist belt or desktop	Desktop
Number of patients can monitor simultaneously	1 per Unit	1 per Unit	1 per Unit
Portable Design	Yes	Yes	No
Data Collection	Yes	Yes	Yes
Data Analysis	Optional	Optional	Optional
Report Generation	Optional	Optional	Optional
Capable of Data Transfer for Analysis and Report Generation	Yes	Yes	Yes
Channels	16 or 24	32	44 or 64
Data Input Types	ECG, Neurological, Respiratory	ECG, Neurological, Respiratory	ECG, Neurological, Respiratory
Remote Capability to Monitor Lead Quality	Yes	Yes	Yes
Remote Capability to Monitor Recording Parameters	Yes	Yes	Yes
Electrode Imped. Check	Yes	Yes	Yes
Calibration Check	Yes	Yes	Yes
Selectable Montage Configuration	Yes	Yes	Yes
Annotations on study	Yes	Yes	Yes
Raw data storage	Flashcard	Hard disk, Flashcard	Hard disk
Study Modes	Polysomnography Recording, Long Term Monitoring, Retrieval and Replay	Polysomnography Recording, Long Term Monitoring, Retrieval and Replay	Polysomnography Recording, Long Term Monitoring, Retrieval and Replay
Optional Equipment	Time Sync Video/Digital Video/Printer	Digital Video/Printer	Time Sync Video/Digital Video/Printer
Radio LAN Capabilities	No	Yes	No

6. **Discussion of performance testing.**

An extensive collection of tests has been conducted and successfully completed, including safety, performance and comparative tests.

7. **Conclusion**

It is the conclusion of Compumedics that the Siesta System is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

22

B. INDICATIONS FOR USE

510(k) Number K003175

Device Name: Siesta System

Indications for Use:

The Siesta System is intended for use in the recording, displaying, monitoring, printing and storage of biophysical parameters for the purpose of assisting in the diagnosis of neurological and sleep disorders.

The Siesta System is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

The Siesta System is only to be used under the direction and supervision of a physician, EEG technologist or clinician. It will not prevent or restore the interruption of loss of any physiological system.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003175

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

23

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2000

Compumedics Telemed Pty, Ltd.
c/o Ms. Constance G. Bundy
C.G. Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, Minnesota 55432

Re: K003175
Trade Name: Compumedics Siesta System
Regulatory Class: II
Product Code: GWQ
Dated: October 6, 2000
Received: October 10, 2000

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for ~~the indications for~~ use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

24

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of ~~General~~, Restorative
and Neurological Devices
~~Office of Device~~ Evaluation
Center for Devices and
~~Radiological Health~~

Enclosure

25

Exhibit 2

(b)(4) Pages 159 through 170 removed

Smith
FDA CONSULTANTS ~
Specializing in Regulatory Affairs

K010460-A2

Food and Drug Administration
Document Control Center
9200 Corporate Blvd.
Rockville, Maryland 20850

April 3, 2001

RE: K010460
Trade Name: Lifelines TrackIt EEG Recorder

Dear Mr. Yen:

Following is the response to your letter dated March 29, 2001.

1. Trackit is a 36 channel ambulatory EEG system with 24 EEG channels, 8 polygraphic channels, and 4 Hi level inputs (or Hi level Aux). Please provide design descriptions of these 4 Hi level inputs, the purposes or functions, and relation to EEG recording.

See a description of the Hi level inputs in the TrackIt specification detail attached (Exhibit 1 of the response).

2. On page 20, you stated that the system has been certified and complies with EN60601-1-2, EMC requirement. Please provide summary test results including pass/fail criteria for the applicable standards.

Please reference EMC summary (Exhibit 2 of the response).

3. Please provide a copy of your software requirement specifications (SRS) and summary from your validation/verification testing that describes each tested functions or requirements, pass/fail criteria used, and test results.

Please reference Trackit SRS (Exhibit 3 of the response), Validation V2 (Exhibit 4 of the response), and TrackIt Prod Test (Exhibit 5 of the response)

4. Please clarify that there are no recording electrodes included in this submission.

There are no recording electrodes included in this 510(k) submission.

P.O. Box 4341 • Crofton, Maryland 21114
PHONE: (888) 729-9674 • FAX: (410) 793-0448

5. In Appendix 2, please provide the following additional product specifications:

a) Input impedance (in megaohms)

b) Amplifier design and frequency response over the frequency spectrum of interest.

c) Filter characteristics

Input impedance is 100 megaohms
Differential input impedance is 20 megaohms
Amplifier frequency spectrum is 0.16 - 70Hz (-6dB) or DC - 70Hz (-6dB) when in DC mode.

Please reference TrackIt specifications for all details on this information (Exhibit 1 of the response). Please reference TrackIt Block Design for a design overview (Exhibit 6 of the response).

6. In your promotional materials, please address the following:

a) In what sense is your device the "worlds first ambulatory EEG recorder"?

b) Do you intend to market different configurations of the system (e.g., TrackIt 36, TrackIt 24, and TrackIt 12)?

The TrackIt device is the worlds first ambulatory system where the user can swap disks and batteries without stopping the recording. The term Lifelines has coined for this is continuous data recording.

Lifelines intend to market the 36, 24, and 12 channel EEG recorders. They are identical systems with fewer channels.

If any further information is required please feel free to contact me by telephone (410) 451-0639 or by Fax (410) 793-0448.

Sincerely,

Christina Smith

Exhibit 1
TrackIt Specification Detail

41

TRACKIT SPECIFICATIONS *

EEG inputs:

Number of EEG channels: 24 monopolar touchproof inputs
ADC Resolution: 16 bits
Sampling: 1 to 256Hz rate, simultaneous sampling all channels
Differential Input impedance: >20 Mohms
Common mode input impedance: >100 Mohms
Common Mode Rejection Ratio: >110 dB @ 0.16Hz to 70Hz with active ground connected.
Equivalent input noise: <3uV pk-pk @ 0.16Hz to 70Hz
Hardware gain: 1000 ±2%
Max differential AC input before clipping: 10 mV pk-pk
Max operational DC input voltage (electrode offset): ±500mV
Bandwidth: 0.16 - 70 Hz (-6dB)
Max common mode input voltage: 2V pk-pk
Input bias current: < ±25nA

Polygraphy inputs

Number of Polygraphy inputs: 8 bipolar touchproof inputs
ADC Resolution: 16 bits
Sampling: 1 to 256Hz rate, simultaneous sampling all channels
Differential Input impedance: >20 Mohms
Common mode input impedance: >100 Mohms
Common Mode Rejection Ratio: >110 dB @ 0.16Hz to 70Hz with active ground connected.
Equivalent input noise: <3uV pk-pk @ 0.16Hz to 70Hz
Hardware gain, AC setting: 1000 ±2%
Max differential AC input before clipping: 10mV pk-pk
Max operational DC input voltage (electrode offset), AC setting: ±500mV
Hardware gain, DC setting: 20.2 ±2%
Max differential input before clipping, DC setting: ±250mV
Bandwidth: 0.16 - 70 Hz (-6dB) or DC - 70 Hz
Max common mode input voltage: 2V pk-pk
Input bias current: < ±25nA

Aux. High-level DC Inputs

Number of Aux channels: 4 on Aux. connector
ADC Resolution: 16 bits
Sampling: 1 to 256Hz rate, simultaneous sampling all channels
Input impedance: 47 Kohms
Hardware gain: 2 ±2%
Max input before clipping: ±2.5 V
Bandwidth: DC - 70 Hz (-6dB)

Modes of operation

Impedance: < 2 to > 90 KOhm, measured with 0.075uAp-p,10Hz signal. Measurement accuracy ±15%.
Calibration: 1mVpp square wave @ 1Hz at ADC input. Amplitude accuracy ±5%.

42

Connections, Ports and Controls

Patient Connection Unit: connector for touch-proof Patient Connection Unit (PCU)
Front-panel push-buttons:
1 On/Off push-button
2 General-purpose push-buttons (for stand-alone time/date adjustment)
Any 1 of 3 Patient Event during record
Aux. Connector 1:
- ✓ 1 RS232 Host communication port operating at 115kBaud
- ✓ 1 spare RS232 Host communication port
- ✓ External power input

Aux. Connector 2:
- ✓ As for Aux. Connector 1 (repeated)
- ✓ External Patient Event input
- ✓ 4 Aux. High-level DC inputs

PCMCIA port: 1 TypeII socket
Batteries: 3 type PP3/MN1604 sockets
Internal beeper sounds when:
- ✓ door open
- ✓ battery low
- ✓ disk storage low
- ✓ Patient Event
- ✓ Battery polarity reversal

Back-light Display

Current Time and Date
Recording Time
Battery Life remaining
Disk Storage remaining
Door open warning

Recording Format

Native European Data Format (EDF)
Native MSDOS/Windows disk data structure

Physical Characteristics

Weight: 700g including disk and batteries
Size: 15cm x 10.5cm x 3.2cm

Safety and EMC Standards

EN60601-1:1990 European standard for medical electrical equipment, general requirements. Amendments 1:1991, 2:1995, 11 & 12:1993, 13:1996. Including Part 2-26.

UL2601:1997 USA standard for medical electrical equipment, general requirements.

CAN/CSA 22.2 No 601.1 M90 inc. S1-94. Canadian standard for medical electrical equipment, general requirements.

EN60601-1-2:1993 European standard for medical electrical equipment, EMC requirements. Calling:
EN55011:1991, Conducted Emissions.
EN55011:1991, Radiated Emissions.
IEC801-2:1991, Electrostatic Discharges.
IEC801-3:1984, Radiated RF Field Susceptibility.

IEC801-4:1988, Fast Transient Bursts.
IEC801-5:1989, Surge Immunity.

- For degree of protection against electrical shock (when connected to Host system) : Type BF
- Type of protection against electrical shock: Internally Powered or Class II (when connected to Host system)
- For degree of protection against harmful ingress of water: Ordinary (no protection).
- For the mode of operation: Continuous.
- For the degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Not suitable

* Note: Lifelines reserves the right to change the product specification at any time without notice. This is in-line with the company's policy of continual product development.

Exhibit 2
EMC Summary

(b)(4) Pages 178 through 287 removed

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 16, 2001

LIFELINES LTD.
C/O SMITH ASSOCIATES
PO BOX 4341
CROFTON, MD 21114
ATTN: CRHISTINA SMITH

510(k) Number: K010460
Received: 16-FEB-2001
Product: LIFELINES TRACKIT

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

156

1C010460

Lifelines Ltd.
7 Clarendon Court
Over Wallop, Near Stockbridge
Hants., SO20 8HU UK

Food and Drug Administration
Office of Medical Devices
Document Control Center
9200 Corporate Blvd.
Rockville, MD 20850

Attention: Document Mail Clerk

This is to notify you of the intention, by Lifelines Ltd, to manufacture and market the following device.

Classification Name:	Electroencephalograph
Common/Usual Name:	EEG
Proprietary Name:	Lifelines Trackit
Establishment Registration Number:	
Classification:	Class II
Classification Panel:	GWQ

Labeling/Product Information/Promotional Material:

Indications for Use/Labeling:	Reference Appendix 1
Product Design & Product Specifications:	Reference Appendix 2
Electrical and Environmental Testing:	Reference Appendix 3
Software Hazard Analysis:	Reference Appendix 4
Promotional Information:	Reference Appendix 5

SE
P507
SK 11

Comparison of Predicate Devices: Reference Appendix 6

Company	Product	510(k)#
Oxford Instruments	Medilog MR95	K961642

Mrs. Christina Smith –consultant-of Smith Associates, is authorized to represent Lifelines Ltd. in connection with this notification. Her contact details are as follows:

Smith Associates
PO Box 4341
Crofton, Maryland, 21114
Tel: (410)-451-0639
Fax: (410)-793-0448

Please contact Mrs. Smith with regard to any additional information, which may be required.

Sincerely,

Christina Smith

E.J. Smith
Yolanda Smith

Appended Statements:

Indications for Use Form: 21CFR801.109
Premarket Notification 510(k) Statement
Premarket Notification Truthful and Accurate Statement

158

510(k) Number (if known):

Device Name: Lifelines Trackit Recorder

Classification Panel: GWQ

Indications for Use:

The Lifelines Trackit Recorder is a 36 channel ambulatory electroencephalograph that is designed for use in a variety of monitoring applications, to record physiological data for EEG and Sleep Studies.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or Over the Counter Use**_____

159

PREMARKET NOTIFICATION
510(K) STATEMENT
(As required by 21 CFR 807.81)

I certify that, as Director of Regulatory Affairs for Lifelines Ltd, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secrets and confidential commercial information, as defined in 21 CFR 20.61

(Signature)

Steven Walters
(Typed Name)

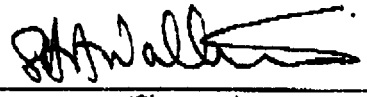
03/02/01 3rd Feb 2001
(Date)

(Premarket Notification 510(k) Number)

160

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR 807.81 (j)]

I certify that as Director of Regulatory Affairs for Lifelines Ltd, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Steven Walters
(Typed Name)

03/02/01 3rd FEB 2001
(Date)

(Premarket Notification 510(k) Number)

181

TABLE OF CONTENTS

APPENDIX 1: INDICATION FOR USE

1.1 Indications for Use:

The Lifelines Trackit Recorder is a 36 channel ambulatory electroencephalograph that is designed for use in a variety of monitoring applications, to record physiological data for EEG and Sleep Studies.

1.2 Description:

The Trackit Recorder is a 36 channel ambulatory electroencephalograph that is designed for use in a variety of monitoring applications, including those concerned with neurological and sleep disorders.

The Trackit Recorder is comprised of the following components:

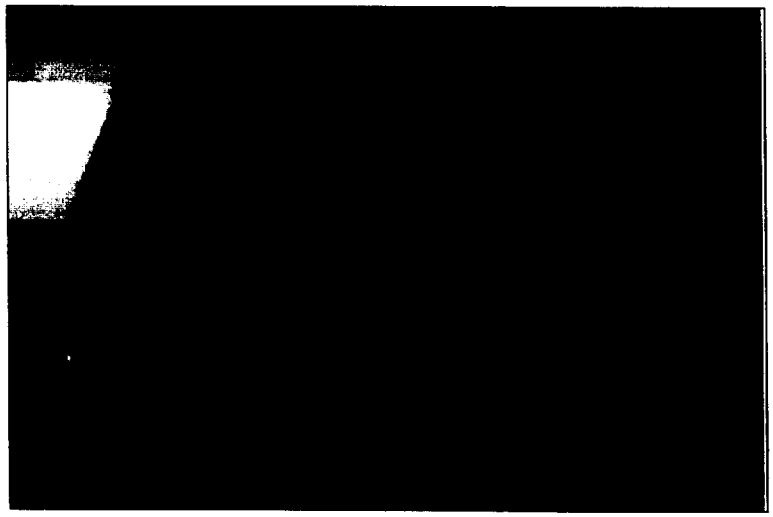


Figure 1.1

The Trackit Recorder: The Trackit Recorder is a multi channel recording device that is designed to be used for recording a patients EEG signals. It comprises a 24 channel EEG amplifier acquisition board, an 8 channel polygraphic acquisition board and control board with all the I/O interface for serial and patient communication. The device may be powered either by batteries or from a medically isolated DC source via the Trackit Isolator. Storage of the patients EEG data is onto an internal ATA flash card (b) (4)

(b) (4)

[redacted]

Electrode Connector Block: The electrode connector block connects the standard 1.5 mm touchproof EEG recording electrodes from the Trackit unit to the patient. It is a block of moulded plastic with 1.5 mm touchproof sockets connected to the Trackit unit via a shielded cable. It connects to a miniature 50-way connector on the side of the unit. There is a label to allow each electrode to be assigned a position.

Host Isolator Box: The host isolator box provides power, isolation and serial communication to the Trackit unit when it is connected to a Host PC. The isolator box is itself powered by the medical grade DC power module supplied with the Trackit unit. The isolator provides the isolation between the DC input and the Recorder. When connected to the Trackit, it is designed to charge the internal backup batteries. It can also power the Trackit itself in all operating modes and acts as a battery eliminator if no batteries are in the unit. The main purpose of this device is to provide optical isolation when a patient is being prepared in the hospital prior to the monitoring session. In this situation a qualified EEG technician will attach the electrodes to the patient and make sure that the signals obtained are of a suitable clarity by monitoring them on the PC using the host application software provided.

Medical Grade DC Power Supply Module: The medical grade mains DC power supply provides DC power to the host isolator box and Trackit recorder when connected to a host PC during system set up.

Batteries: 3 PP3 disposable alkaline batteries are supplied as standard with the Trackit recorder.

ATA Flash Disk: An ATA flash disk is used to store the EEG data recorded by Trackit. Different capacity storage disks are available in the PCMCIA type II format.

The Trackit Set-Up Software: The Trackit software runs under Microsoft Windows 95/98 on the host PC and is used to program the Trackit Recorder for an ambulatory recording session. The Trackit recorder is connected to the PC via the isolator box, the recording setup/montage, and patient information/ID is downloaded tot he device, and a short review is made to verify that all the electrodes have been attached correctly. The patient with the Trackit recorder is then disconnected from the isolator box and the ambulatory recording is then started

Functions of the starter program:

(b) (4)

(b) (4) [redacted]

A recording includes:

2-36 Channels of EEG/polygraphic signal ambulatory recording

Over a period usually not less than 24 hours

(b) (4) [redacted]

trackit's LCD display

Data and results stored to disk for future evaluation

(b) (4) [redacted]

1.3 Labeling Information:

Reference Figure 1.2 Trackit Recorder Front Panel Label

Reference Figure 1.3 Trackit Recorder Rear Panel Label

Reference Figure 1.4 Trackit Isolator Front Panel Label

Reference Figure 1.5 Trackit Isolator Rear Panel Label

1.3.1 Labeling Information: User Manual Reference Exhibit 1.1

166

(b)(4) Pages 299 through 303 removed

Trackit
User Manual

Lifelines Ltd.
7 Clarendon Court
Over Wallop, Near Stockbridge
Hants., SO20 8HU
UK

Tel/Fax 01264 782226
www.Llines.com
sales@Llines.com

Disclaimers & Warranties

The information in this section is subject to change without notice.

Except as stated below, Lifelines Ltd makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Lifelines shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance or use of the material

Lifelines shall warrant its products against all defects in material and workmanship for one year from the date of delivery.

Misuse, accident, modification, unsuitable physical or operating environment, improper maintenance or damage caused by a product for which Lifelines is not responsible will void the warranty.

Lifelines does not warrant uninterrupted or error-free operation of its products.

Lifelines or its authorized agents will repair or replace any products which prove to be defective during the warranty period, provided that these products are used as prescribed in the operating instructions in the user's and service manuals.

No other party is authorized to make any warranty to assume liability for Lifelines products. Lifelines will not recognize any other warranty, either implied or in writing. In addition, services performed by someone other than Lifelines or its authorized agents or ant technical modification or changes of products without Lifelines prior, written consent may be cause for voiding this warranty.

Defective products or parts must be returned to Lifelines or its authorized agents, along with an explanation of the failure. Shipping costs must be prepaid.

Lifelines manufacturers hardware and software to be used on or with standard PC-compatible computers and operating software. Lifelines, however, assumes no responsibility for the use or reliability of its software or hardware with equipment that is not furnished by third-party manufacturers accepted by Lifelines at the date of the purchase.

All warranties for third-party products used within the Trackit system are the responsibility of the relevant manufacturer. Please refer to the relevant documentation on each product for further details.

Microsoft, Windows and Windows NT are registered trademarks of the Microsoft Corporation.

All other trademarks and product names are the property of their relevant owners.

Responsibility of Manufacturer

The manufacturer and distributor consider themselves responsible for the equipment's safety, reliability and performance only if:

- ✓ Trackit may be used with peripheral equipment from third-party providers recommended by the manufacturer;
- ✓ Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorised by the manufacturer;
- ✓ The electrical installation of the relevant room complies with the appropriate requirements;
- ✓ The equipment is used in accordance with the instructions for use.

Note: The manufacturer has a policy of continual product improvement; hence the equipment specifications are subject to change without notice.

MB

174

175

(b)(4) Pages 308 through 323 removed

APPENDIX 1: INDICATION FOR USE

1.1 Indications for Use:

The Lifelines Trackit Recorder is a 36 channel ambulatory electroencephalograph that is designed for use in a variety of monitoring applications, to record physiological data for EEG and Sleep Studies.

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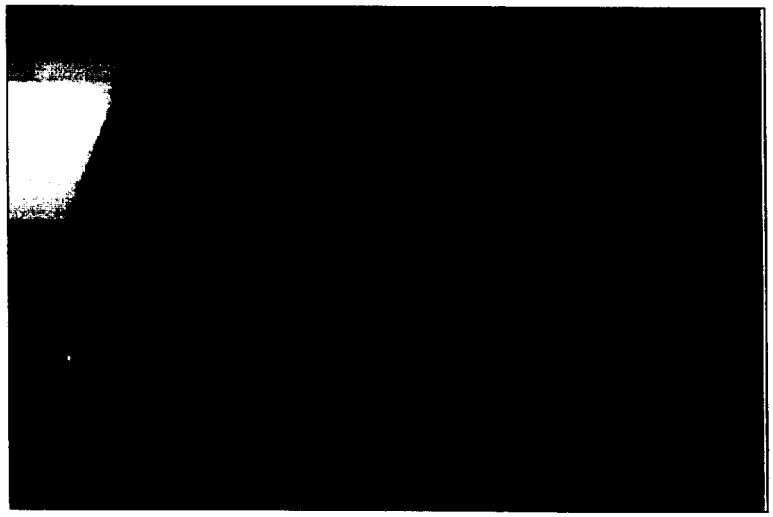

Figure 1.1

The Trackit Recorder: The Trackit Recorder is a multi channel recording device that is designed to be used for recording a patients EEG signals. It comprises a 24 channel EEG amplifier acquisition board, an 8 channel polygraphic acquisition board and control board with all the I/O interface for serial and patient communication. The device may be powered either by batteries or from a medically isolated DC source via the T(b) (4)
Isolator. Storage of the patients EEG data is onto an internal ATA flash card

(b) (4)

184

Electrode Connector Block: The electrode connector block connects the standard 1.5 mm touchproof EEG recording electrodes from the Trackit unit to the patient. It is a block of moulded plastic with 1.5 mm touchproof sockets connected to the Trackit unit via a shielded cable. It connects to a miniature 50-way connector on the side of the unit. There is a label to allow each electrode to be assigned a position.

Host Isolator Box: The host isolator box provides power, isolation and serial communication to the Trackit unit when it is connected to a Host PC. The isolator box is itself powered by the medical grade DC power module supplied with the Trackit unit. The isolator provides the isolation between the DC input and the Recorder. When connected to the Trackit, it is designed to charge the internal backup batteries. It can also power the Trackit itself in all operating modes and acts as a battery eliminator if no batteries are in the unit. The main purpose of this device is to provide optical isolation when a patient is being prepared in the hospital prior to the monitoring session. In this situation a qualified EEG technician will attach the electrodes to the patient and make sure that the signals obtained are of a suitable clarity by monitoring them on the PC using the host application software provided.

Medical Grade DC Power Supply Module: The medical grade mains DC power supply provides DC power to the host isolator box and Trackit recorder when connected to a host PC during system set up.

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The Trackit Set-Up Software: The Trackit software runs under Microsoft Windows 95/98 on the host PC and is used to program the Trackit Recorder for an ambulatory recording session. The Trackit recorder is connected to the PC via the isolator box, the recording setup/montage, and patient information/ID is downloaded tot he device, and a short review is made to verify that all the electrodes have been attached correctly. The patient with the Trackit recorder is then disconnected from the isolator box and the ambulatory recording is then started

Functions of the starter program:

(b) (4)

[redacted]

(b) (4) [redacted]

A recording includes:

2-36 Channels of EEG/polygraphic signal ambulatory recording

Over a period usually not less than 24 hours

Patient event markers correlated in time with the real time clock displayed on the trackit's LCD display

Data and results stored to disk for future evaluation

(b) (4) [redacted]

1.3 Labeling Information:

Reference Figure 1.2 Trackit Recorder Front Panel Label

Reference Figure 1.3 Trackit Recorder Rear Panel Label

Reference Figure 1.4 Trackit Isolator Front Panel Label

Reference Figure 1.5 Trackit Isolator Rear Panel Label

1.3.1 Labeling Information: User Manual Reference Exhibit 1.1

166

APPENDIX 2: PRODUCT SPECIFICATIONS AND PRODUCT DESIGN

192

APPENDIX 2: PRODUCT SPECIFICATIONS AND PRODUCT DESIGN

2.1 Product Specifications:

Hardware	**Max AC input voltage**
Control Board:	10mV AC
4 x DC Hi level inputs	1 volt
Event marker	**Input Bias current**
O2 Saturation input for Nonin XPOD	Not more than 25nA
Amp board:	**Noise Characteristics**
24 AC EEG (uni-polar inputs)	<2uV peak-peak
Poly boards:	**CMRR**
8 AC/DC EEG/poly (bipolar inputs)	>100dB-driven neutral
PCMCIA ports	**Input impedance**
For storage or transmission of data	In built in the device but only viewable from the host
1 x type II PCMCIA	**CAL**
Connections	Internal Calibration
Battery eliminator	**Event markers**
RS2321- to the host	In built button as well as a port for an external event marker
Event port for external event marker	Warnings
1 x type II PCMCIA	Turned on
4 DC Hi level inputs on RS23211 (0 to +5V)	Disk on
High density mini SCSI connector to patient connector with 1.5mm touch proofs	Current time and elapsed time
Infra red	Time left on the disk
Digital Characteristics	Time left on the battery
Sampled rates: 1-256Hz or 25-200Hz on any channel independent or ganged	Beepers-low battery and low disk
Sampling skew compensation: Sample and hold on every channel	Models of operation
Resolution: 16bits	Set up from the host
Electrical characteristics	View from the host online or off the disk
Electrode offset	Go/Stop and record to disk
1 volt on EEG and poly inputs (excluding Aux inputs)	Impedance check Calibration

193

Set time and date	Host software
Store to disk and view remotely	Trackit setup software includes impedance check, online trace view, recording setup and CAL
Timed recordings	Lifelines recommends the following EEG/Sleep review programs for use with Trackit data:
Triggered recordings, via event button	Nervus/profile EEG Editor/Reader http://www.nervus.is (Taugagreining HF)
Communications	Persyst Insight EEG suite http://www.eeg-persyst.com
Serial 115K BAUD in to the host or via modem	Physical Characteristics
Via modem for event log and online traces.	Weight: 700grams, including 3 PP3 batteries and disk
Wireless COMMS via PCMCIA	Dimensions: 14cm x 9.5cm – L x W x D
Power	Construction: All metal alloy box
3 x Internal disposable PP3 9V batteries	Conformance
Internal battery plus external DC power from isolator box	**The entire system complies with IEC601-1, the international standard for Medical electrical equipment**
External power only	• For type of protection against electrical shock: Class 1
Battery backup will allow hot swapping of batteries with a backup time of not less than 2 minutes	• For degree of protection against electrical shock: Type BF
Data	• For degree of protection against harmful ingress of water: Ordinary (no protection)
Data format	• For the mode of operation: Continuous
European data format EDF	• For the degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Not suitable
Data security	Lifelines reserves the right to change the specifications of this product without notice inline with the companies policy of continual product development
System is able to produce a FAT map so it knows where to write the data	Continuous Data Recording™ (CDR) is a registered trademark of lifelines Ltd
Data is secure and fault tolerant. A bad sector on the disk or any form of environmental interference only destroys one block of data and not the whole file.	Windows™ is a registered trademark of Microsoft Corporation

Data rates	
Depends on the sample rate and number of channels stored. Typically 16channels at 128Hz will require a 336Mb disk or flash card for a 24 hour recording	

2.2 Product Design: Reference Exhibit 2.1

195

Exhibit 2.1
Product Design

(b)(4) Pages 358 through 376 removed

APPENDIX 3: ELECTRICAL SAFETY AND ENVIRONMENTAL SAFETY

APPENDIX 3: ELECTRICAL SAFETY TESTING AND ENVIRONMENTAL TESTING

3.1 EN60601-1: Reference Exhibit 3.1

3.2 UL 2601-1: Reference Exhibit 3.2

Exhibit 3.1
EN60601-1

Intertek Testing Services
ETL SEMKO

1 November 2000

Mr D K Hulin
Lifelines Ltd
7 Claredon Court
Over Wallop, Nr. Stockbridge
Hampshire
SO20 8HU

Dear Mr Hulin,

RE: **'Trackit' EEG ambulatory recorder**
REPORT NO: **00002655**

We have completed the testing on the above product and enclose your copy of report number 00002655.

I trust that you will find this satisfactory.

Yours sincerely

G Dubois
Senior Engineer

Encs

ITS Testing & Certification Ltd
ITS House, Cleeve Road, Leatherhead, Surrey KT22 7SB
Tel: +44 (0)1372 370900 Fax: +44 (0)1372 370999
http://www.itsglobal.com
Registered No. 3272281 Registered office: 25 Savile Row, London W1X 1AA

219

Intertek Testing Services
ETL SEMKO

Listing Report

REPORT NO:00002655 Date: 01 November 2000

INSPECTION, TESTS AND EVALUATION

OF AN EEG AMBULATORY RECORDER

RENDERED TO

LIFELINES Ltd

GENERAL:

This report gives the results of the inspection, tests and evaluations of the 'Trackit' EEG ambulatory recorder for compliance with applicable requirements of the Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety (UL 2601-1 2nd edition 1997) and Medical Electrical Equipment, Part 1: General Requirements for Safety; (CAN/CSA-C22.2 No 601.1-M90 1994 including S1-94).

This investigation was authorised by: Mr D K Hulin, Purchase Order No: 273200, Dated: 08/08/00.

The investigation was begun on the 27/09/00.

The sample was provided by the client and tested at ITS Testing & Certification Ltd facility.

Participant: Lifelines Ltd
7 Claredon Court
Over Wallop, Nr. Stockbridge
Hampshire
SO20 8HU

Contact Name: Mr D K Hulin Tel: +44 (0)1264 782226 Fax: +44 (0)1264 782088

Manufacturer: As above

Contact Name:

220

CONSTRUCTION

PRODUCT COVERED:

Trackit

PRODUCT DESCRIPTION:

The product covered by this report is a multi channel recording device that is designed to be used for recording a patient's EEG signals and an isolator for connection to a computer using an RS232 link. The recorder comprises a 24 channel EEG amplifier acquisition board, an 8 channel polygraphic acquisition board and a control board with I/O interfaces for serial and patient communication. The recorder is powered by batteries (in normal use) or from the isolator (when downloading the data). The isolator is powered by an approved mains power supply. Storage of the patient's EEG data is onto an internal ATA flash card.

ELECTRICAL RATINGS:

Product	Voltage	Amperage	Frequency
Isolator	12 Vdc	0.5 A	dc
Recorder	9 Vdc Nominal		dc

TEST PERFORMANCE

A representative sample of the product was tested in accordance with the Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety (UL 2601-1 2nd edition 1997) and Medical Electrical Equipment, Part 1: General Requirements for Safety; (CAN/CSA-C22.2 No 601.1-M90 1994 including S1-94).

The following tests were performed:

Description	Clause
Identification, marking and documentation	6
Power input	7
Limitation of voltage and/or energy	15
Continuous leakage currents and patient auxiliary currents	19
Dielectric strength	20
Mechanical strength	21
Excessive temperatures	42

Results for the tests indicate the specimens conform to applicable test criteria.

CONCLUSION

A representative sample of the 'Trackit' EEG ambulatory recorder has been evaluated and found to comply with the applicable requirements of the Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety (UL 2601-1 2nd edition 1997) and Medical Electrical Equipment, Part 1: General Requirements for Safety; (CAN/CSA-C22.2 No 601.1-M90 1994 including S1-94).

Report Reviewed by:

A Cuthbert
Manager
Consumer products

In charge of tests:

G Dubois
Test Engineer

GENERAL INFORMATION

The participant and manufacturer have agreed to produce, test, and label ETL listed products in accordance with the requirements of this procedural guide. The manufacturer has also agreed to notify ETL and to request authorization prior to using alternate parts, components, or materials.

COMPONENTS:

Components used shall be those listed in the ITS report covering the products specified in the index including any amendments and/or revisions.

LISTING MARK:

The ETL listing mark applied to the products shall either be separable in form, such as labels purchased from ITS, or on a product nameplate or other media only as specifically authorized by ETL. Use of the listing mark is subject to the control of ETL.

MANUFACTURING AND PRODUCTION TESTS:

Manufacturing and production tests shall be performed as required in this procedural guide.

FOLLOW-UP SERVICE:

Periodic unannounced audits of the manufacturing facility shall be scheduled by ITS. An audit report shall be issued after each visit. Special attention will be given to the following:

1. Conformance of the manufactured product to the descriptions in this report.
2. Conformance of the use of the ETL mark with the requirements of this report and the Listing, Labelling, and Follow-up Service Agreement.
3. In-plant quality control procedures and personnel.
4. Manufacturing changes.
5. Performance of specified manufacturing and production tests.

In the event that the ITS representative identifies non-conformance(s) to any provision of this Report, the Applicant shall take one or more of the following actions:

1. Correct the non-conformance.
2. Remove the ETL Listing Mark from non-conforming product.
3. Contact the issuing product safety evaluation centre for instructions.

224

GENERAL REQUIREMENTS AND DEFINITIONS

Recognized - Identifies any component, part or subassembly covered under the recognition service of an NRTL (US) or a CO (Canada) and intended for use in ETL Listed, ETL Classified, or ETL Recognized products.

Listed - Identifies any product covered under the Listing or Certification service of an NRTL (US) or CO (Canada).

Construction Details - For specific construction details, reference should be made to the following photographs and descriptions. All dimensions are approximate unless otherwise specified as exact or within tolerance. In addition to the specific construction details described in this report, the following general requirements also apply.

1. Spacings - A minimum clearance in air of 2.5 mm and a creepage over surfaces of insulating material of 4.0 mm are maintained between patient circuits and dead metal parts and between patient circuits and SELV circuits.

2. Mechanical Assembly - Components such as switches, fuseholders, connectors, wiring terminals, and display lamps are reliably mounted and prevented from shifting or rotating by lockwashers, starwashers, use of multiple screws or bolts, or other mounting means.

3. Corrosion Protection - All ferrous metal parts are suitably protected against corrosion by painting, plating or the equivalent.

4. Internal Wiring - Internal wiring is reliably routed away from sharp or moving parts. Internal wiring leads terminating in soldered connections are made mechanically secure prior to soldering. Separable (quick disconnect) connectors of the positive detent type, closed loop connectors, or other types specifically described in the text of this report are also acceptable as internal wiring terminals. At points where internal wiring passes through metal walls or partitions, the wiring insulation is protected against abrasion or damage by plastic bushings or grommets. All wiring has a minimum rating of 300V 105°C.

5. Accessibility of Live Parts - All uninsulated live parts in primary circuitry are housed within a metal/plastic enclosure constructed such that any openings are not penetrable by the probe specified in the above referenced Standard.

6. Markings - The unit is marked with the manufacturer's name, model number, electrical ratings, date of manufacture and cautionary markings where required. Products for end-use in Canada may be required to have markings in both French and English. It is the responsibility of the Applicant to determine any such requirement and provide bilingual markings, where applicable, in accordance with the Provincial Regulatory Authorities.

7. Installation and Operating Instructions: - Instructions for the proper installation and safe use of this product are provided by the manufacturer.

225

CORRELATION PAGE

MULTIPLE LISTING

The following products which are identical to those identified in the index except for model number and participant name, are authorized to bear the ETL label under provisions of the ETL Multiple Listing Program.

MULTIPLE LISTING (name)

BASIC LISTEE (name)

Lifelines Ltd

MANUFACTURER (name)

Lifelines Ltd

PRODUCT

Trackit EEG recorder and isolator

MULTIPLE LISTEE MODEL NO	BASIC LISTEE MODEL NO	BASIC LISTEE REPORT NO	BASIC LISTEE ORDER NO
N/A	Trackit	00002655	273200

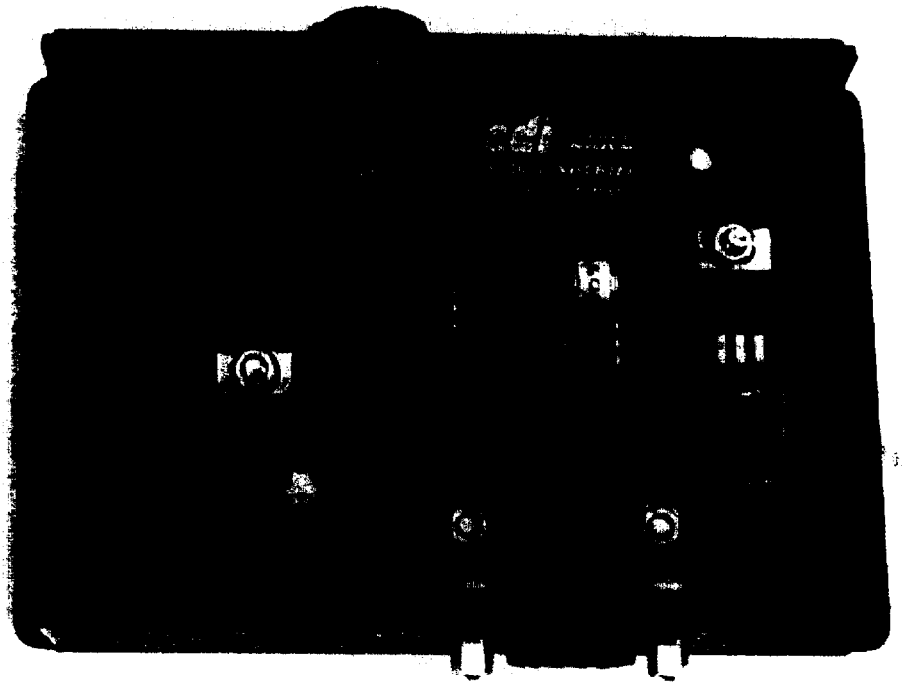
Photograph 1

Shows the system with:
- the isolator's connections to the power supply, the RS232 port and the recorder
- the recorder's connections to the isolator and the electrode connectors
- the electrode connectors' connections to the electrodes.

The power supply provided with the 'Trackit' is not defined.
It must be listed and certified to UL2601 and CSA 601, 120 Vac input, 12 Vdc, 1.25 A output.

Photgraph 2

Shows inside the isolator.



Item 1. Opto-isolators (U1, U2). Component/certified. Hewlet Packard HCPL2211.

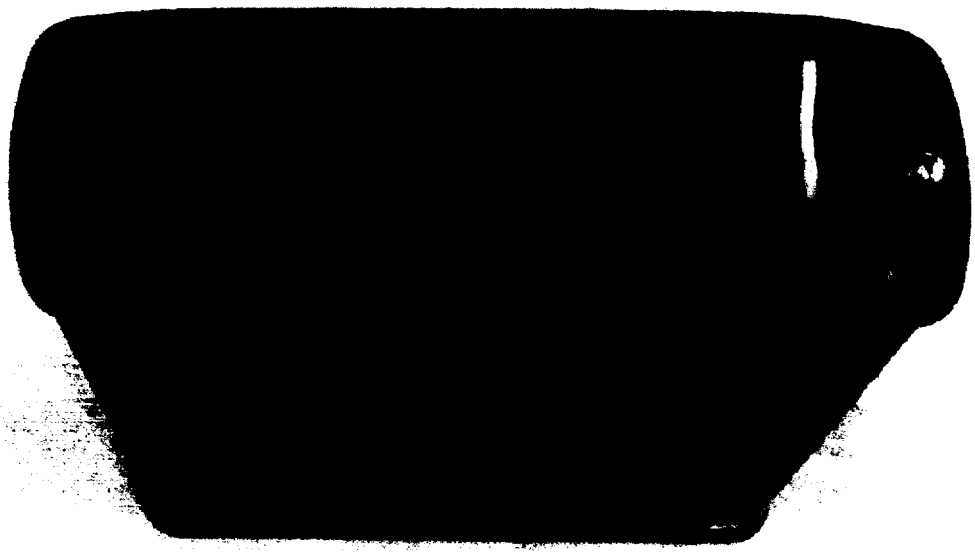
Item 2. DC-DC converter (U3). Unlisted, Conversion Devices Inc., 105D5VFI, 5Vdc input, +/-5 Vdc output

Item 3. Spark gap (UG1). Unlisted. EPCOS, EC600, 600 Vdc spark, 1300 V impulse

Item 4. PTC (FS2). Unlisted, Raychem RXE050, 0.5 A.

Photograph 3

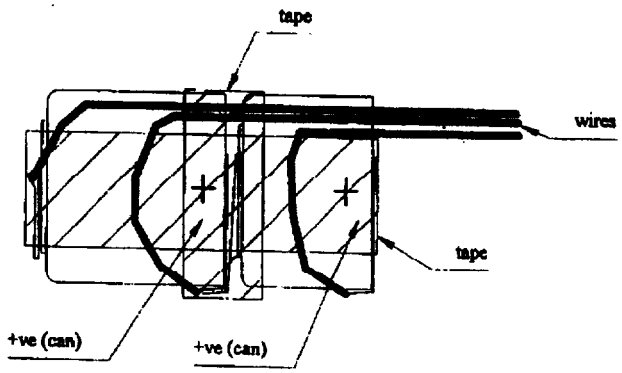
Shows the inside of the recorder, at the battery end.



Battery assembly

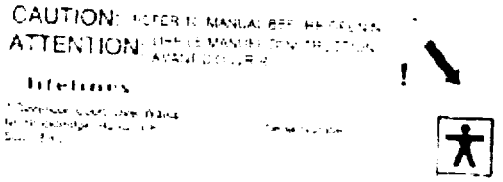
NOTES:

1. Bend battery tabs as shown before soldering connecting wires.
2. Apply PVC tape as shown to retain wires.
3. Apply 35mm length (unshrunk) of 20mm diameter heat-shrink sleeving over entire assembly.

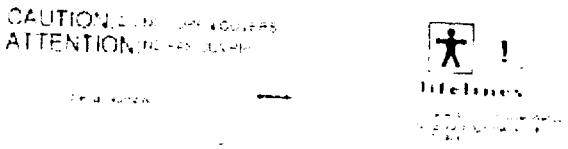


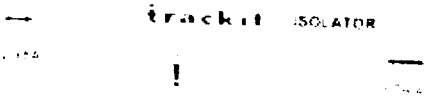
Copy of marking plates

Recorder



Isolator





231

Safety instructions

See pages 1, 5, 7, 8 and 9 of the Trackit User Manual attached.

232

(b)(4) Pages 394 through 398 removed

Exhibit 3.2
UL 2601-1

ITS Intertek Testing Services
ETL SEMKO

7 November 2000

Mr Dave Hulin
Lifelines Ltd
7 Clarendon Court, Over Wallop,
Nr Stockbridge,
Hants,
SO20 8HU, UK

Dear Mr Hulin,

RE: **Trackit Ambulatory recorder**
REPORT NO: **00002655**

We have completed the testing on the above product and enclose your copy of report number 00002655.
I trust that you will find this satisfactory.

Yours sincerely

Guy Dubois
Senior Engineer

Encs

ITS Testing & Certification Ltd
ITS House, Cleeve Road, Leatherhead, Surrey KT22 7SB
Tel: +44 (0)1372 370900 Fax: +44 (0)1372 370999
http://www.itsglobal.com
Registered No. 3272281 Registered office: 25 Savile Row, London W1X 1AA

Intertek Testing Services
ETL SEMKO

Certificate of Compliance

Issued to:	*Lifelines Ltd*
Item:	*Ambulatory recorder*
Type Reference:	*Trackit*
Rated Voltage:	*12 Vdc, 0.5 A*
Protection Classification:	*Class III*

This is to certify that a sample of the equipment defined above has been tested by ITS Testing & Certification Ltd and found to comply with the following requirements:

EN60601-1:1990 + corr. 1994, A1: 1993 + corr 1994, A12:1993 + corr 1994, A2: 1995, A13:1996

IEC 60601-1, Second edition, 1988 with Amendment 1, 1991 and Amendment 2, 1995

Medical Electrical Equipment *Part 1: General requirements for Safety.*

Full details are given in Report No. 00002655

Certificate approved by: *G A Hines*
Principal Engineer
Consumer Products Department

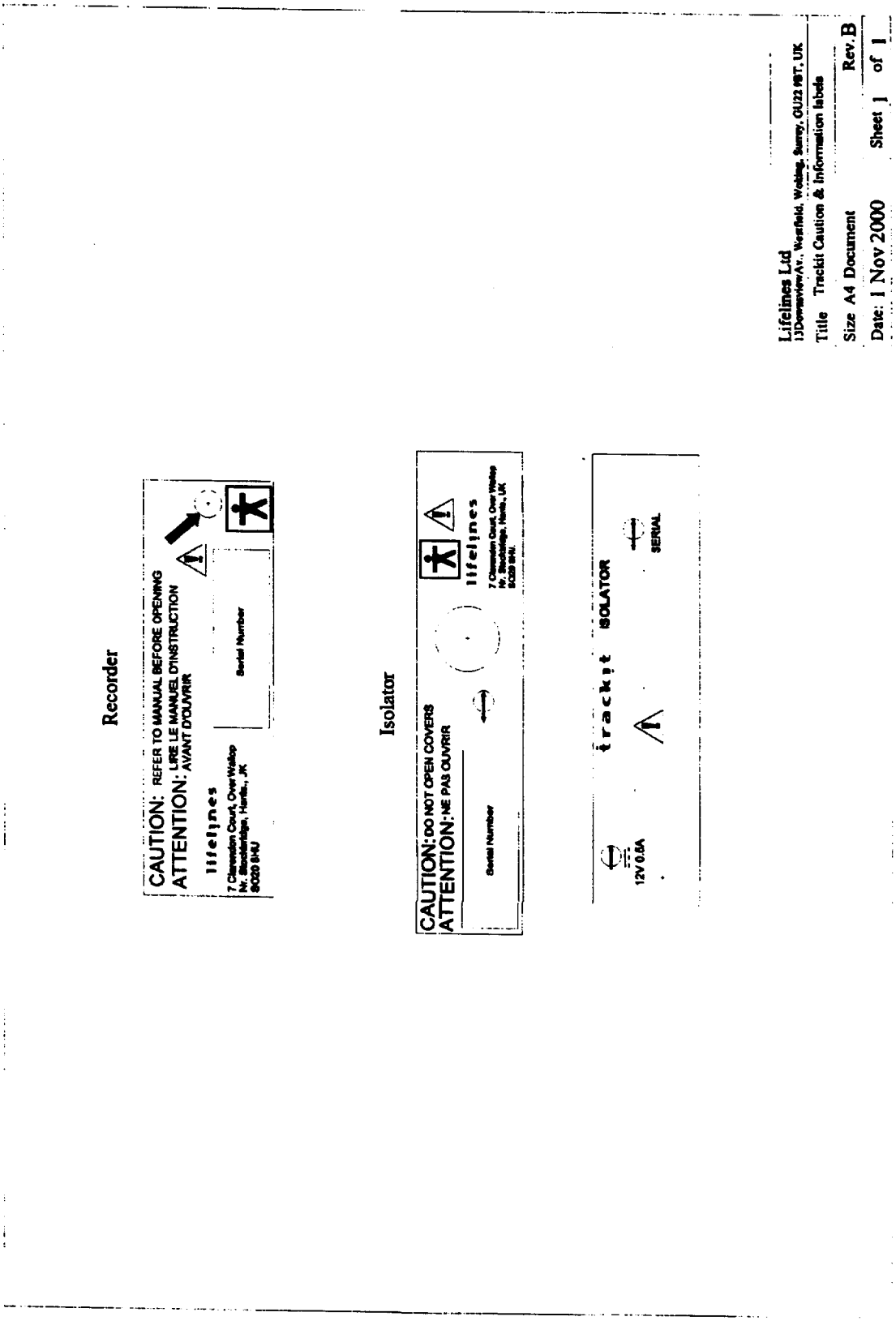
Certificate No *16052*
This certificate is dated: *7 November 2000*

ITS Testing & Certification Ltd
ITS House, Cleeve Road, Leatherhead, Surrey KT22 7SB
Tel: +44 (0)1372 370900 Fax: +44 (0)1372 370999
Registered No. 3272261 Registered office: 25 Savile Row, London W1X 1AA

Intertek Testing Services
ETL SEMKO

TEST REPORT
EN60601-1:1990 + corr. 1994, A1: 1993 + corr 1994, A12:1993 + corr 1994, A2: 1995, A13:1996 & IEC 60601-1, Second edition, 1988 with Amendment 1, 1991 and Amendment 2, 1995
Medical electrical equipment
Part 1: General requirements for safety

Report reference No ..... :	00002655
Compiled by (+ signature) ..... :	*G Dubois*
Reviewed by (+ signature) ..... :	G A Hines
Date of issue ..... :	25 October 2000
Testing laboratory ..... :	ITS Testing & Certification Ltd.
Address ..... :	ITS House, Cleeve Road, Leatherhead, Surrey, KT22 7SB
Testing location ..... :	As above
Applicant ..... :	Lifelines Ltd
Address ..... :	7 Clarendon Court, Over Wallop, Nr Stockbridge, Hants, SO20 8HU, UK
Copyright blank test report ..... :	the bodies participating in the Committee of Certification Bodies (CCB). This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator.
Test procedure ..... :	This Test Report is not valid as a CB Test Report unless signed by a CB Testing Laboratory and appended to a CB Test Certificate.
Procedure deviation ..... :	None
Non-standard test method ..... :	None
Type of test object ..... :	Ambulatory recorder
Trademark ..... :	-
Model/type reference ..... :	trackit
Manufacturer ..... :	Lifelines Ltd
Rating ..... :	Battery powered and 12 Vdc, 0.5 A via an approved power supply



242

GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use:	Isolator is class III Recorder is battery powered
Supply connection:	Via a power supply provided by Lifelines
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:	Pass
- test object does not meet the requirement:	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

General remarks:

"(see Attachment #)" 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.
The tests 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 testing laboratory.
List of test equipment must be kept on file and available for review.
Summary of contents provided on the last page of this report.

General product information and considerations:

The 'trackit' is a battery operated patient-worn 36-channel EEG recorder. Download of the information to a computer is via an isolator and the serial port. The isolator must be connected to the mains supply by a power supply meeting the requirements of EN60/IEC601-1.

US

248

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
3	**GENERAL REQUIREMENTS**		
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.)		P
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
5	**CLASSIFICATION**		
5.1	Type of protection against electric shock		
	Class I equipment		N
	Class II equipment		N
	Internally powered equipment		P
5.2	Degree of protection against electric shock		
	Type B applied part		N
	Type BF applied part		P
	Type CF applied part		N
	Not classified - no applied parts		N
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)..... :	No protection	N
5.4	Methods of sterilization or disinfection	None specified	N
5.5	Equipment not suitable for use in the presence of flammable mixtures		P
	Category AP equipment		N
	Category APG equipment		N
5.6	Mode of operation:		
	-continuous operation		P
	-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:..... :		—

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
6	IDENTIFICATION, MARKING AND DOCUMENTS		
6.1	Marking on the outside of equipment or equipment parts		
6.1 c	Markings of the specific power supply affixed		N
6.1 d	If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N
6.1 e	Name and/or trademark of the manufacturer or supplier ..... :	Isolator: Lifelines Recorder: Lifelines	P
6.1 f	Model or type reference ..... :	Isolator: trackit isolator Recorder: trackit	P
6.1 g	Rated supply voltages or voltage range(s)	Isolator: 12 V	P
	Number of phases ..... :		N
	Type of current..... :	Isolator: dc symbol (4 of T DI)	P
6.1 h	Rated frequency or rated frequency range(s) (Hz). :		N
6.1 j	Rated power input (VA, W or A)..... :	Isolator: 0.5 A	P
6.1 k	Power output of auxiliary mains socket-outlets	No mains socket outlet	N
6.1 l	Class II symbol		N
	Symbol for degree of protection against ingress of water provided ..... :	No protection	N
	Symbol for protection against electric shock ..... :	Isolator: BF Recorder: BF	P
	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
	Symbol for protection of defibrillation-proof applied parts		N
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N
6.1 m	Mode of operation (if no marking, suitable for continuous operation)	No marking	N
6.1 n	Types and rating of external accessible fuses..... :	No external fuses	N
6.1 p	Ratings of external output ..... :		N
6.1 q	Symbol for physiological effect(s):	No physiological effects	N
	- attention, consult accompanying documents		N
	- non-ionising radiation, or symbols as adopted by ISO or IEC 417		N
6.1 r	Anaesthetic-proof symbol: AP or APG..... :	Not anaesthetic proof	N
6.1 s	Dangerous voltage symbol		N

TUV

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
6.1 t	Special cooling requirements		N
6.1 u	Limited mechanical stability		N
6.1 v	Protective packing requirement(s)		N
	- Marking(s) for unpacking safety hazard(s)		N
	- Equipment or accessories supplied sterile, marked as sterile		N
6.1 y	Potential equalization terminal		N
	- Functional earth terminal		N
6.1 z	Removable protective means		N
	Durability of marking test	See appended table	P
6.2	Marking on the inside of equipment or equipment parts		
6.2 a	Nominal voltage of permanently installed equipment		N
6.2 b	Maximum power loading for heating elements or holders for heating lamps		N
6.2 c	Dangerous voltage symbol		N
6.2 d	Type of battery and mode of insertion	Refer to manual warning	P
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator	Tool provided and type and explanations in the manual	P
6.2 e	Fuses accessible with a tool identified either by type and rating or by a reference to diagram		N
6.2 f	Protective earth terminal		N
6.2 g	Functional earth terminal		N
6.2 h	Supply neutral conductor in permanently installed equipment (N)		N
6.2 j	Markings required in 6.2 f), h), k) ,and l) remain vialble after connection and are not affixed to parts which have to be removed		N
	- Markings comply with IEC 445		N
6.2 k	For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N
6.2 l	Statement for suitable wiring materials at temperatures over 75 °C		N
6.2 n	Capacitors and/or circuit parts marked as required in Sub-clause 15c		N
6.3	Marking of controls and instruments		
6.3 a	Mains switch clearly identified		N

246

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light		P
6.3 b	Indication of different positions of control devices and switches		P
6.3 c	*Indication of the direction in which the magnitude of* the function changes, or an indicating device		N
6.3 f	The functions of operator controls and indicators are identified		P
6.3 g	Numeric indications of parameters are in SI units except for units listed in Am. 2		P
6.4	Symbols		P
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)		P
6.5	Colours of the insulation of conductors		
6.5 a	Protective earth conductor has green/yellow insulation		N
6.5 b	All insulations of internal protective earth *conductors are green/yellow at least at their* terminations		N
6.5 c	Only protective or functional earthing, or potential equalization conductors are green/yellow		N
6.5 d	Colour of neutral conductor ..... :		N
6.5 e	Colours of phase conductor(s) ..... :		N
	- Compliance with IEC 227 and IEC 245		N
6.5 f	Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N
6.6	Medical gas cylinders and connections		N
6.6 a	In accordance with ISO ISO/R 32		N
6.6 b	Identification of connection point		N
6.7	Indicator lights and push-buttons		
6.7 a	Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		N
	- Yellow used to indicate caution or attention required		N
	- Green used to indicate ready for action		P
6.7 b	Colour red used only for push-buttons by which a function is interrupted in case of emergency		N
6.8	Accompanying documents		

ETS

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
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		P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description		P
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		N
	Warning statements and the explanation of warning symbols provided in the accompanying documents		P
6.8.2	Instructions for use		
6.8.2 a	General information provided in instructions for use		
	- state the function and intended application of the equipment		P
	- include an explanation of the function of controls, displays and signals		P
	- the sequence of operation		P
	- the connection and disconnection of detachable parts and accessories		P
	- the replacement of material which is consumed during operation		P
	- information regarding potential electromagnetic or other interference and advice regarding avoidance		P
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		P
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance		P
	General information provided in instructions:		
	- information for the safe performance or routine maintenance		P
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied		P
	- explanation of figures, symbols, warning statements and abbreviations on the equipment		P
6.8.2 c	Signal output or signal input parts intended only for connection to specified equipment described		P
6.8.2 d	Details about acceptable cleaning, disinfection or sterilization methods included		P

248

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
6.8.2 e	Warning statement for mains operated equipment with additional power source		N
6.8.2 f	A warning to remove primary batteries if equipment is not likely to be used for some time		P
6.8.2 g	Instructions to ensure safe use and adequate maintenance of rechargeable batteries		N
6.8.2 h	Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1		P
6.8.2 j	Identification of any risks associated with the disposal of waste products, residues, etc.		P
	- Advice in minimizing these risks		P
6.8.3	Technical description		
6.8.3 a	All characteristics essential for safe operation provided		P
6.8.3 b	Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use		P
6.8.3 c	Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		P
6.8.3 d	Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		P
7	POWER INPUT		
	Power Input Measurements		P

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
10	**ENVIRONMENTAL CONDITIONS**		
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer		P
10.2.1	Ambient temperature range of +10 to +40 °C		P
	Relative humidity range of 25 to 95 %	(mod. -2-26)	P
	Atmospheric pressure range of 700 to 1060 hPA		P
	Temperature of water at the inlet of water-cooled equipment not higher than 25 °C		N
10.2.2 a	Rated voltage not exceeding 250 V for hand-held equipment		P
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA		P
	Rated voltage not exceeding 500 V for all other equipment		N
	Rated input frequency not more than 1kHz		P
10.2.2 b	Internal replaceable electrical power source specified		P
14	**REQUIREMENTS RELATED TO CLASSIFICATION**		
14.1	Class I Equipment		N
14.2 a	Class II equipment		N
14.4 a	Class I and Class II equipment in addition to basic insulation provided with an additional protection		N
14.4 b	Equipment supplied from external dc source of reverse polarity results in no safety hazard		P
14.5 b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected		P
14.6 c	Applied parts intended for direct cardiac application are of type CF		N

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
15	**LIMITATION OF VOLTAGE AND/OR ENERGY**		
15 b	Voltage measured one sec after disconnection of the mains plug does not exceed 60 V		N
15 c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ		N
	Marking provided for manual discharging		N
16	**ENCLOSURES AND PROTECTIVE COVERS**		
16 a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)		P
	Insertion or removal of lamps - protection against contact with live parts provided		N
16 b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented		P
16 c	Conductive parts accessible after the removal of handles, knobs, levers		P
	- have a resistance of not more than 0.2 Ω		N
	- separated from live parts by one of the means described in Sub-clause 17g	Accessible parts are separated from live parts by double or reinforced insulation	P
16 d	Parts with voltage exceeding 25 Vac or 60 Vdc which cannot be disconnected by external mains switch or plug protected against contact		N
16 e	Removable enclosures protecting against contact with live parts		
	- Removal possible only with the aid of a tool		P
	- Use of automatic device making parts not live when the enclosure is opened or removed		N
	- Exception 16e applied to the following parts .....:		N
16 f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts		N

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
17	**SEPARATION**		
17 a	Separation method of the applied part from live parts:		
	1) basic insulation: applied part earthed		N
	2) by protectively earthed conductive part (e.g. screen)		N
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N
	4) by double or reinforced insulation		P
	5) by protective impedances limiting current to applied part		N
	- Additional leakage current test in single fault conditions		P
17 c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		P
17 d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		N
17 g	Separation method of accessible parts other than applied parts from live parts:		
	1) basic insulation: accessible part earthed		N
	2) by protectively earthed conductive part (e.g. screen)		N
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N
	4) by double or reinforced insulation	In the power supply	P
	5) by protective impedances limiting current to accessible part		N
	- Additional leakage current test in single fault conditions		P
17 h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator		N
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		N
18	**PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION**		N
	This is a Class III device. This section has been deleted		

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
19	**CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS**		
19.1 b	Leakage currents		
	- earth leakage current		N
	- enclosure leakage current		P
	- patient leakage current		P
	- patient auxiliary current		N
20	**DIELECTRIC STRENGTH**		
	Overall compliance with Clause 20		P
21	**MECHANICAL STRENGTH**		
21 a	Sufficient rigidity of an enclosure tested by: force of 45 N		P
21 b	Sufficient strength of an enclosure tested by: impact hammer		P
21 c	On portable equipment carrying handles or grips withstand the requirements of the loading test		N
21.3	No damage to parts of patient support and/or immobilization system after the loading test		N
21.5	Hand held equipment or equipment parts are safe after drop test	Not hand held	N
21.6	Portable and mobile equipment is able to withstand rough handling		P
22	**MOVING PARTS**		N
	There is no moving part. This section has been deleted		
23	**SURFACES, CORNERS AND EDGES**		
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered		P

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
24	**STABILITY IN NORMAL USE** (see appended table 24)		
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°		P
24.3	Equipment overbalances when tilted through an angle of 10°		N
	- does not overbalance when tilted through an angle of 5° in any position excluding transport		N
	- carry a warning notice stating that transport should only be undertaken in a certain position		N
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N
24.6 a	Equipment or its parts with a mass of more than 20 kg is provided with:		N
	- suitable handling devices (grips etc.), or		N
	- instructions for lifting and handling during assembly		N
24.6 b	On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		N
25	**EXPELLED PARTS**		
25.1	Protective means are provided where expelled parts of the equipment could be a hazard		N
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N
28	**SUSPENDED MASSES**		N
	There is no suspended mass. This section has been deleted		
29	**X-RADIATION**		
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)		P
36	**ELECTROMAGNETIC COMPATIBILITY**		
	Equipment complies with IEC 601-1-2	Not assessed	-
37	**COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT**		

ITS

254

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Requirements for category AP and APG equipment (Cl. 37 - 41)		N
42	**EXCESSIVE TEMPERATURES**		
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		P
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient		P
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		P
42.5	Guards to prevent contact with hot surfaces removable only with a tool		N
43	**FIRE PREVENTION**		
	Strength and rigidity necessary to avoid a fire hazard		P
44	**OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION**		
44.2	Equipment contain a liquid reservoir:		N
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min		N
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favourable direction(s) (if necessary with refilling)		N
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		N
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		N
44.5	Equipment sufficiently protected against the effects of humidity		
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		N
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions		P

ITS

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
45	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		N
	There is no pressure vessel nor part subjected to pressure. This section has been deleted		
48	BIOCOMPATIBILITY		
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	Not assessed	-
49	INTERRUPTION OF THE POWER SUPPLY		
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard		N
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		P
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure		N
51	PROTECTION AGAINST HAZARDOUS OUTPUT		
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally		N
52	ABNORMAL OPERATION AND FAULT CONDITIONS		
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 13)		P
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	Not assessed	-
52.5.2	Failure of thermostats presents no safety hazards		N
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard		N

ITS

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5 °C		N
52.5.6	Locking of moving parts presents no safety hazard		N
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard		N
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N
52.5.9	Failure of one component at a time presents no safety hazard		P
52.5.10	Overload of heating elements presents no safety hazard		N
52.5.10 f	Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N
52.5.10 h	Equipment with three-phase motors can safely operate with one phase disconnected		N
56	**COMPONENTS AND GENERAL ASSEMBLY**		
	List of critical components	See appended table	P
56 1 b	Ratings of components not in conflict with the conditions of use in equipment		P
	Ratings of mains components are identified	Approved power supply	P
56.1 d	Components, movements of which could result in a safety hazard mounted securely		N
56.1 f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		P
56.3 a	Connectors provide separation required by Sub-clause 17g		P
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment		P
	Medical gas connections not interchangeable		N
56.3 b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken		P
56.3 c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		P

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
56.4	Connections of capacitors		
	Not connected between live parts and non-protectively earthed accessible parts		N
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14		N
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		N
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		P
56.6	Temperature and overload control devices		
56.6 a	Thermal cut-outs which have to be reset by a soldering not fitted in equipment		N
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		N
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N
	Non-self resetting over-current releases operated 10 times		N
56.6 b	Thermostats with varying temperature settings clearly indicated		N
	Operating temperature of thermal cut-outs indicated		N
56.7	Batteries		
56.7 a	Battery compartments:		
	- adequately ventilated		N
	- accidentally short-circuiting is prevented	By electronic circuit	P
56.7 b	Incorrect polarity of connection prevented	By electronic circuit	P
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (colour see 6.7):		

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- to indicate that equipment is energized	Display on trackit Green LED on isolator	P
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N
	- to indicate when output exists if a safety hazard could result		N
	- charging mode indicator provided	On display	P
56.10	Actuating parts of controls	(see appended table 56.10)	
56.10 b	Actuating parts are adequately secured to prevent them from working loose during normal use		P
	Controls are secured to prevent the movement relative to scale marking (safety related only)		N
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N
56.10 c	Stops are provided on rotating controls:		N
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N
	- to prevent damage to wiring		N
56.11	Cord-connected hand-held and foot-operated control devices		N
56.11 a	Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g		N
56.11 b	Hand-held control devices comply with the requirement and test of Sub-clause 21.5		N
	- Foot-operated control devices designed to support the weight of an adult human being		N
56.11 c	Devices not change their setting when inadvertently placed		N
56.11 d	Foot-operated control devices are at least IPX 1		N
	- For surgical use, electrical switching parts are IPX 8		N
56.11 e	Adequate strain relief at the cord entry provided		N

57	**MAINS PARTS, COMPONENTS AND LAYOUT**		
57.1	Isolation from supply mains		P
	Note: The equipment is supplied with an approved power supply providing the required isolation. The power supply is not assessed in this project.		
57.1 a	Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously		N

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	Isolation is by unplugging the power supply from the isolator box.	P
57.1 d	Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328		N
57.1 f	Mains switches not incorporated in a power supply cord		N
57.1 h	Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		N
57.1 m	Fuses and semiconductor devices not used as isolating devices		P
57.2	Mains connectors and appliance inlets		N
	Section deleted		
57.3	Power supply cords		N
	Section deleted		
57.4	Connection of power supply cords		N
	Section deleted		
57.5	Mains terminal devices and wiring of mains part		N
	Section deleted		
57.6	Mains fuses and over-current releases		N
	Section deleted		
57.8	Wiring of the mains part		N
	Section deleted		
57.9	Mains supply transformers		N
	Section deleted		
57.10	Creepage distances and air clearances		
57.10 a	Values: compliance with at least the values of Table XVI	See appended table	P
	Creepage distances for slot insulation of motors at least 50% of the specified values		N
57.10 b	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
57.10 c	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts		N

IEC 601 + Am. 1 and 2			
Clause	Requirement + Test	Result - Remark	Verdict
58	**PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS**		N
	This is a Class II device. This section has been deleted		
59	**CONSTRUCTION AND LAYOUT**		
59.1	Internal wiring		
59.1 a	Cables and wiring protected against contact with a moving part		P
	Wiring having basic insulation only protected by additional fixed sleeving		N
	Components are not likely to be damaged in the normal assembly or replacement of covers		P
59.1 b	Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N
59.1 c	Insulating sleeving adequately secured		P
	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		N
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N
59.1 d	Aluminium wires of less than 16 mm^2 cross-section not used		P
59.1 f	Connecting cords between equipment parts considered as belonging to the equipment		P
59.2	Insulation		
59.2 b	Mechanical strength and resistance to heat and fires retained by all types of insulation		P
59.2 c	Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		P
	Parts of rubber resistant to ageing		N
59.3	Excessive current and voltage protection		
	Internal electrical power source provided with device for protection against fire hazard		P
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		N
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		P
59.4	Oil containers		N

ITS

6.1	TABLE: marking durability	
Marking tested	Remarks	
Recorder (isolator marking is of the same type)		P

7	TABLE: power input					P
Operating condition	Voltage	Frequency	Current	Power	Remarks	
Normal	264 V	50 Hz	36 mA	4 W	Measurement taken with equipment connected to a computer and to a mains power supply	

19	TABLE: leakage current			P
Type of leakage current and test condition (including single faults)	Supply voltage	Supply frequency	Measured max. value	Remarks
- patient leakage current: Current measured between applied parts at mains reference and 1) enclosure 2) isolator in/output	12 V	dc	13 µA	
(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).				

20	TABLE: dielectric strength			P
Insulation under test (area from insulation diagram)	Insulation type:	Reference voltage (V)	Test voltage (V)	Remarks
Pre humidity treatment				
'trackit' enclosure - applied parts	BI	250	1500	
Isolator SIP/SOP – patient circuit	BI	250	1500	
Post humidity treatment				
'trackit' enclosure - applied parts	BI	250	1500	
Isolator SIP/SOP – patient circuit	BI	250	1500	
Insulation type: OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced				

42	TABLE: normal temperature			P
Supply voltage: 12 Vdc	Test Condition: Normal			
Location	Temperatures			x✓
	Measured (°C)	At 40 °C (°C)	Limit	
Regulator heatsink in isolator	77.5	98.1	110	✓
Enclosure	38.0	58.6	85.0	✓
Lab ambient	19.4	40.0		
COR - indicates measurements taken using change-of-resistance method				

52	TABLE: abnormal operation	
Test type, condition and clause reference	Observed results	Remarks
Isolator: - SC D2, C5 or output of U5 - SC output of U3 - SC output of U6, or D4	FS2 operates U3 shuts down (reduced input current) U3 controls output current	FS2 reaches 90 °C in ambient of 22.5 °C FS1 does not operate
Recorder: - Back-up battery		

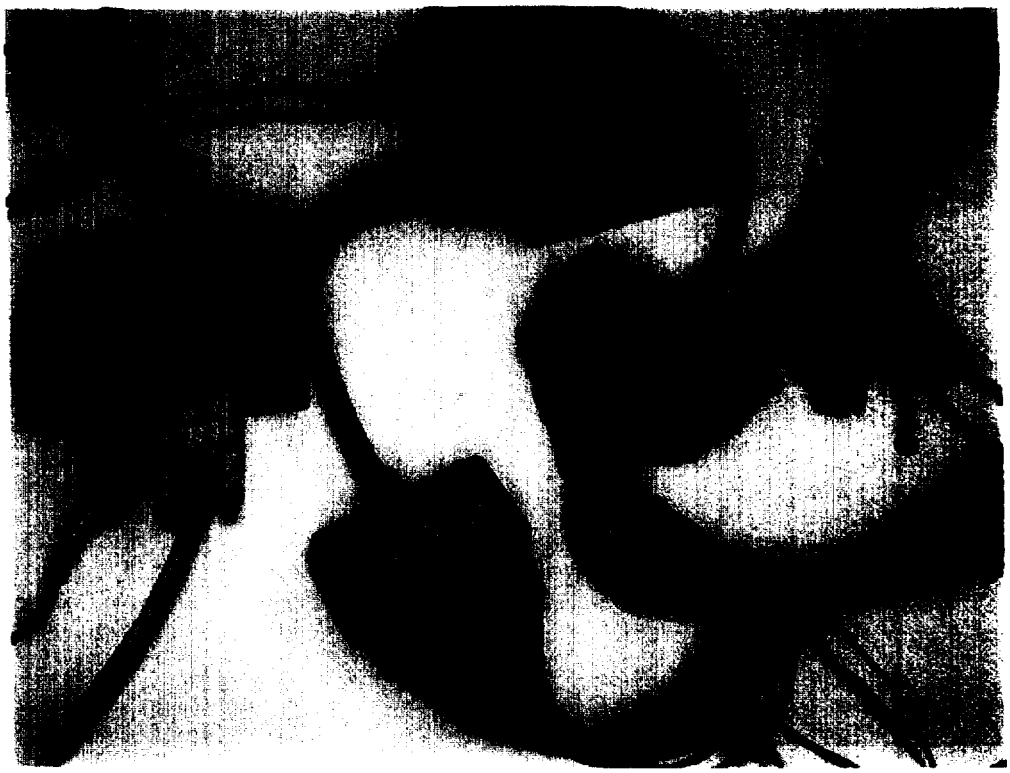
ITS

56.1	TABLE: lists of critical component parts				P
Object / part No	Manufacturer / trademark	Type / model	Technical data	Standard	Mark(s) of conformity[1])
Isolator:					
U1, U2	Hewlet Packard	HCPL2211	Optocoupler	This report	
U3	Conversion Devices Inc.	105D5VFI	5 Vin, +/-5 Vout	This report	
FS2	Raychem	RXE050	0.5 A	This report	
UG1	EPCOS	EC600	600 Vdc spark 1300 V Impulse	This report	
Recorder:					
Back-up batteries	GP Batteries	GP70BVH	Rechargeable nicket metal hydride cells	This report	
[1]) an asterisk indicates a mark which assures the agreed level of surveillance					

57.10	TABLE: Creepage distance and clearance measurements					P
Insulation under test (area from insulation diagram)	Insulation type:	Reference voltage (V)	Measured Cr (mm)	Limit Cr (mm)	Measured Cl (mm)	Limit Cl (mm)
Isolator						
Under U3	BI	250	16.0	4.0	16.0	2.5
Under U1 & U2	BI	250	6.3	4.0	4.0	2.5
Between U2 & SK1, via screw	BI	250	6.5	4.0	6.5	2.5
Patient circuit to enclosure fixing screw	BI	250	6.8	4.0	6.1	2.5
Spark gap	BI	250	4.4	4.0	2.0	NA
Recorder						
Display end panel	BI	250	>4.0	4.0	>2.5	2.5
Electronic assembly to enclosure	BI	250	>4.0	4.0	>2.5	2.5
Insulation type: OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced						

ITS

264



APPENDIX 4: SOFTWARE ANALYSIS

4.1 Hazard Analysis: Reference Exhibit 4.1

Exhibit 4.1
Software Hazard Analysis

(b)(4) Pages 420 through 518 removed

APPENDIX 5: PROMOTIONAL MATERIAL

5.1 Sales Claims: Reference Exhibit 5.1

Small Size

Flexible recording inputs

Data and recording flexibility

A robust design

A wide range of sampling rates

Signal integrity

A safe recording medium

Long battery life

24-hour recordings

A completely open data format

Ease of operation and set-up

Easy Annotation of patient events

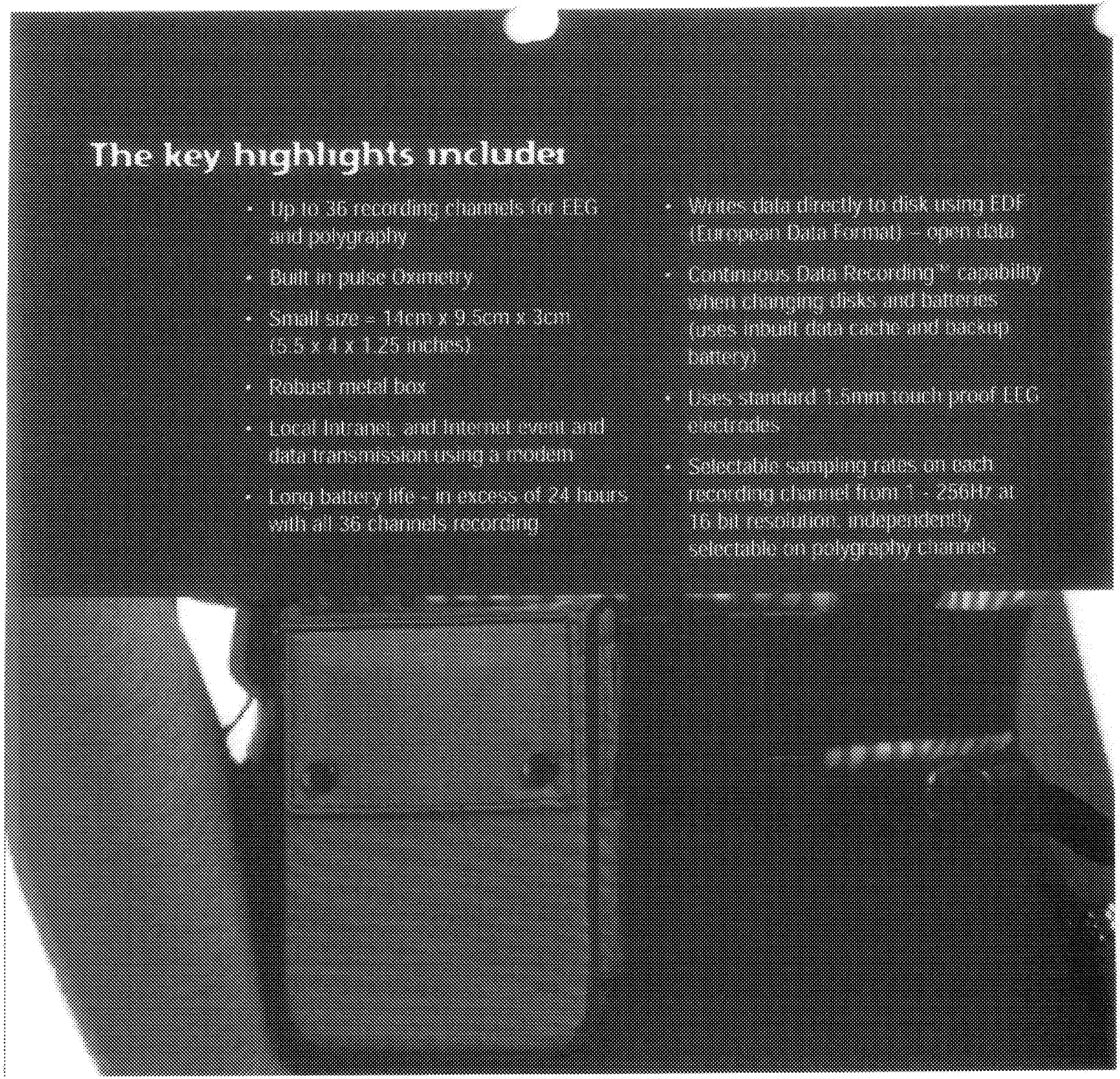
Convenience

359

Exhibit 5.1
Promotional Literature

360

361


The key highlights include:
• Up to 36 recording channels for EEG and polygraphy
• Built in pulse Oximetry
• Small size = 14cm x 9.5cm x 3cm (5.5 x 4 x 1.25 inches)
• Robust metal box
• Local Intranet, and Internet event and data transmission using a modem
• Long battery life – in excess of 24 hours with all 36 channels recording
• Writes data directly to disk using EDF (European Data Format) – open data
• Continuous Data Recording™ capability when changing disks and batteries (uses inbuilt data cache and backup battery)
• Uses standard 1.5mm touch proof EEG electrodes
• Selectable sampling rates on each recording channel from 1 - 256Hz at 16 bit resolution, independently selectable on polygraphy channels

trackit

Key highlights include:

- Unrivalled size
- Unrivalled flexibility
- Unrivalled signal quality
- Unrivalled battery life
- Unrivalled data access

The design philosophy behind Trackit is that size really does matter

365

The key benefits include:

Small size
Trackit is by far the smallest Ambulatory EEG recorder available. The product can be worn unobtrusively for ambulatory EEG recordings ensuring complete patient acceptance – size does matter!

Flexible recording inputs
Flexible recording inputs with 4 high level DC, 8 bipolar DC polygraphy, and 24 mono-polar EEG ensures that a wide range of monitoring requirements can be addressed.

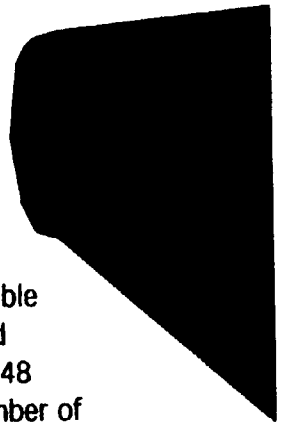
Data and recording flexibility
Trackits unique architecture allows the system to be configured either as an ambulatory recorder with local storage, a headbox with serial communication to a host computer, or as telemetry device using a wireless network adapter. It is even possible to connect Trackit to a telephone modem so that selected segments of data can be sent back to the hospital for online investigation.

A robust design
Built out of solid aluminium ensures maximum protection against Radio Frequency Interference (RFI)

A wide range of sampling rates
from 1 - 256Hz with independent sampling on selected channels (Poly and AUX only) ensures application flexibility especially when monitoring patients with sleep disorders.

Signal integrity
The use of a driven screened patient connector means that Trackit is perfectly at home in the harshest of recording environments.

A safe recording medium
The use of flash disks ensures complete data integrity for long 24-hour recordings. Flash disks are more reliable than hard disks; they consume less power resulting in longer recording times and are the technology of the future ensuring a safe investment.



Long Battery life
Low power consumption means that Trackit only uses 1 to 3 PP3 batteries (disposable or rechargeable) for extended recording times in excess of 48 hours, depending on the number of channels used.

24-hour recordings
Trackit has been designed at the outset as a 24-hour recorder with the maximum number of EEG channels selected at EEG sampling rates <256Hz.

A completely open data format
Trackit stores and transmits data in European Data Format (EDF). As a consequence data generated by Trackit is compatible with any commercially available EDF file, including the most popular EEG and Sleep analysis software on the market today.

Ease of operation and set-up
Trackit has been designed at the outset with ease of operation and set-up in mind. A simple user interface with LCD display allows parameters such as time, battery and disk life to be monitored by the technician or patient. A Microsoft Windows™ set-up program allows recording parameters to be configured and loaded onto the device and recordings to be made while connected to the host computer.

Easy annotation of patient events
An event button is available for the patient to time stamp points of interest during the recording, allowing faster data reduction and review by the physician.

Convenience
A built in impedance check and calibration means that no extra hardware is needed when setting up the device. It is also possible to interrogate impedance values from the device during a recording.

365

Specifications

Trackit 36 - 36 channels
(24 AC EEG, 8 DC/AC Bipolar Poly, 4 Hi level AUX)

Trackit 24 - 24 channels
(16 AC EEG, 8 DC/AC Bipolar Poly)

Trackit 12 - 12 channels
(8 DC/AC Bipolar Poly, 4 Hi level AUX)

Nonin XPOD Pulse Oximeter built in

1 - 256Hz sampling rate, independently selectable on poly channels. (1-256Hz or 25-200Hz)

16 bit A to D converter with sample and hold on every channel

3 PP3 batteries giving >24 hours life with 36 channels recording

Up to 5 minute inbuilt battery backup (continue recording while changing batteries)

PCMCIA type II cards for data storage

Up to 3 minutes of data buffer whilst changing disks

Use Standard 1.5 mm touch proof electrodes

Small size at only 14cm x 9.5cm x 3cm (5.5 x 4 x 1.25 inches) (L x W x D)

lifelines ltd

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APPENDIX 6: COMPARISON OF PREDICATE PRODUCT

APPENDIX 6: COMPARISON OF PREDICATE DEVICES

6.1 Indications for Use:

The Lifelines Trackit Recorder is a 36 channel ambulatory electroencephalograph that is designed for use in a variety of monitoring applications, to record physiological data for EEG and Sleep Studies.

6.2 Description:

The Trackit Recorder is a 36 channel ambulatory electroencephalograph that is designed for use in a variety of monitoring applications, including those concerned with neurological and sleep disorders.

The Trackit Recorder is comprised of the following components:

The Trackit Recorder: The Trackit Recorder is a multi channel recording device that is designed to be used for recording a patients EEG signals. It comprises a 24 channel EEG amplifier acquisition board, an 8 channel polygraphic acquisition board and control board with all the I/O interface for serial and patient communication. The device may be powered either by batteries or from a medically isolated DC source via the Trackit Isolator. Storage of the patients EEG data is onto an internal ATA flash card. The data format is native European Data Format (EDF) thus allowing the EEG files to be reviewed by any EDF compatible EEG reader.

Electrode Connector Block: The electrode connector block connects the standard 1.5 mm touchproof EEG recording electrodes from the Trackit unit to the patient. It is a block of moulded plastic with 1.5 mm touchproof sockets connected to the Trackit unit via a shielded cable. It connects to a miniature 50-way connector on the side of the unit. There is a label to allow each electrode to be assigned a position.

Host Isolator Box: The host isolator box provides power, isolation and serial communication to the Trackit unit when it is connected to a Host PC. The isolator box is itself powered by the medical grade DC power module supplied with the Trackit unit. The isolator provides the isolation between the DC input and the Recorder. When connected to the Trackit, it is designed to charge the internal backup batteries. It can also power the Trackit itself in all operating modes and acts as a battery eliminator if no batteries are in the unit. The main purpose of this device is to provide optical isolation when a patient is being prepared in the hospital prior to the monitoring session. In this situation a qualified EEG technician will attach the electrodes to the patient and make sure that the signals obtained are of a suitable clarity by monitoring them on the PC using the host application software provided.

368

Medical Grade DC Power Supply Module: The medical grade mains DC power supply provides DC power to the host isolator box and Trackit recorder when connected to a host PC during system set up.

Batteries: 3 PP3 disposable alkaline batteries are supplied as standard with the Trackit recorder.

ATA Flash Disk: An ATA flash disk is used to store the EEG data recorded by Trackit. Different capacity storage disks are available in the PCMCIA type II format.

The Trackit Set-Up Software: The Trackit software runs under Microsoft Windows 95/98 on the host PC and is used to program the Trackit Recorder for an ambulatory recording session. The Trackit recorder is connected to the PC via the isolator box, the recording setup/montage, and patient information/ID is downloaded to the device, and a short review is made to verify that all the electrodes have been attached correctly. The patient with the Trackit recorder is then disconnected from the isolator box and the ambulatory recording is then started

6.3 Predicate Products:

Company	Product	510(k)#
Oxford Instruments	MR95	K961642 See Exhibit 6.1

We our comparing the Trackit Recorder to the Medelec MR95, Please Reference Exhibit 6.1 for the Predicate Product Information and Specifications.

Nonin Medical	Xpod	See Exhibit 6.2

The Trackit Recorder comes equipped with built in Pulse Oximetry. Please Reference Exhibit 6.2 for Product information on the Nonin Medical SpO_2.

Ultralife Batteries Inc.	U9VL Lithium Primary Prismatic Batteries	See Exhibit 6.3
Duracell Ultra	Duracell Ultra Batteries	See Exhibit 6.4
Simple Technology	640MB ATA Flash Disk	See Exhibit 6.5

369

Parameter	Lifelines	Medelec
510(k) Number:		K961642
Proprietary Name:	Trackit EEG Recorder	Medelec MR95
Indications for Use:	The Lifelines Trackit Recorder is a 36 channel ambulatory electroencephalograph that is designed for use in a variety of monitoring applications, to record physiological data for EEG and sleep studies.	The Medelec MR95 is a 17 channel Ambulatory EEG Recorder
Dimensions:	14cm x 9.5cm	154 x 118 x 39 mm
Weight:	700 g (including batteries)	694g (including batteries)
Channels:	36 channels	17 channels
Power Supply:	Battery Powered	Battery Powered
Software supported by:	Microsoft Windows	Microsoft Windows

Please Reference Exhibit 6.1 for Medelec Product Information and Specifications.

370

Exhibit 6.1
Medelec Product Information

371

Device Classification Name	ELECTROENCEPHALOGRAPH
Regulation Number	882.1400
510(k) Number	K961642
Device Name	MEDILOG MR95
Applicant	OXFORD INSTRUMENTS, PLC. 11526 53RD STREET N. CLEARWATER, FL 34620
Contact	CHARLES HOLZ
Product Code	GWQ
Date Received	04/29/1996
Decision Date	01/17/1997
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Statement/Summary/Purged Status	Statement only
Type	Traditional

Premarket Approval Page

372

Medelec MR95 - text for 4pp brochure

Medelec (TECA) MR95
Ambulatory EEG Recorder

Combining the lightweight, compact flexibility of the Medelec MR95 recorder with sophisticated, multilingual* Medelec Profile review software, Oxford Instruments has developed a high quality ambulatory EEG recording package that will give you the results and versatility you need.

Main photo: see layout

Compact Without Compromise

The Medelec MR95 ambulatory EEG recorder gives you maximum capability in a single box. Weighing just 694g (including batteries and disk) the water and acetone resistant Medelec MR95 is an adaptable and practical unit for all ambulatory EEG recordings.

Powered by rechargeable batteries and recording digitally to removable memory cards, the Medelec MR95 recorder is a true 17 channel, 24-hour recorder. By providing 4 sampling rates, 2 storage rates and a dedicated ECG channel, users have an extensive choice of configuration. High sampling rates and data resolution ensure the widest possible recording range and flexibility.

Flexibility and Freedom
photo: see layout

The Medelec MR95 recorder is set-up with a Psion handheld computer for ultimate flexibility. Rapid patient hook-up can be performed with ease in any location, not just confined to the hospital. The Psion is small and light enough to fit in your pocket, enabling transportation to other locations such as the patient's own home.

The Medelec MR95 ambulatory recorder includes the invaluable feature of built-in calibration and impedance measurement, possible at any time by reconnection to the Psion. By using anti-microphonic electrode leads, you can rely on high quality recordings with little or no movement artifact; the Medelec MR95 ambulatory recorder can provide the quality of signal and recording that you would expect from routine, clinical EEG.

Rapid Replay
screen grab: audio playback, fast paging

Using new features integrated into Medelec Profile reader software, the Medelec MR95 features faster EEG review. Powerful PC hardware and specially developed software enables paging speeds of up to 80 times real time, whilst 'audio' playback is an invaluable tool for highlighting seizure activity and permitting prolonged high-speed review. Traces and audio signals can be reviewed simultaneously, and a delay feature can be configured to automatically allow for individual reaction times, rapidly pinpointing areas of interest.

Achieving Results
Screen grab: referential/remontaged recording and event editing

View results exactly the way you want them with the Medelec Profile flexible review system, designed to enhance quick and instinctive diagnostic analysis.

- Referential recordings permit re-montage
- Multiple review windows for effective comparison
- Fast, extensive search capabilities
- User-friendly controls
- Record 'pruning' – keep selected parts of the recording

Screen grab: comparing recordings in multiple windows

373

The recorder can buffer data for approx 15 minutes before flushing it out to disk to save power. The flushing process takes approx 15 secs. After every flush the file details will be filled in and the file closed immediately so that there is always a valid recording on the disk. Whenever batteries are exchanged or a disk changed there will always be 15 mins of data in memory which must be flushed.
PCMCIA slots - Two PCMCIA Rev 2.01 sockets with an ejector lever will be fitted, allowing up to 2 Type 1 or II cards, or a single Type III card up to 10.5mm thick to be inserted. Max number of insertion/ removal cycles = 3000
Storage capacity requirements - 24 hours with 17ch at 256Hz sampling, 13 bits, and 2.3:1 compression will require a 253Mb disk. Lower sampling rates will result in longer storage times and or smaller disks eg 24 hours with 17ch at 208Hz sampling will require 158Mb of disk storage. The level of compression between off an 2.3:1, number of channels, sampling rate, resolution etc. can all be adjusted for optimal recordings.
Extended recordings:- For recordings beyond 48 hours the disk will have to be changed. Simply done by unlocking the key, and changing the disk. The processor will assume that if the disk is changed without first turning the recorder off that the user is performing an extended recording.

Program storage
The program code is resident on internal EPROM and not the PCMCIA card.

Timecode
The real time clock has an accuracy of <1sec/day. Storage accuracy will support storage and retrieval of data on 1 second boundaries.

User events
Stored to a 1 second accuracy

Impedance checking
Fitted internally and able to measure a range of 1kΩ - 250kΩ

Calibration
A calibration signal will be generated that drives the input amplifiers to test the quality of the complete recording chain. It will run from the PC via the serial port and optionally when the recorder starts and stops a recording.

Isolation
RS232 compatible serial input/output: 1500V rms continuous withstand. All other I/O connections patient referenced. No exposed metal work.

Interconnections
Serial to PC - RS232 isolated 2400 - 115200 baud. The port will only be powered when something is connected to it.
Analogue - Provided for all channels plus master/slave for connecting to another recorder for more channels to be stored.

Power source
Cell choice - Six AA cells or NiMH which are re chargeable.
Capacity - 24 hours at 25Hz sampling for 17 channels
Extended recordings - can be made by removing one set of batteries and fitting another
Charge indicator - will be indicated during set up

Enclosure
Complies with UL544 and MDD for flame retardency etc.
Size - Lighter and smaller than the MR90 tape recorder
Waterproofing - It is drip proof to IEC 529 when inside its pouch and splash proof to withstand bedwetting etc.

374

Shock resistance
Can withstand being dropped without damage onto a vinyl coated concrete floor from 0.8 metres operating and outside pouch, and 1.5 metres operating when in its pouch. Operating assumes data is being written to disk.

Safety standards
Complies with IEC 601-1, Type BF, internal electrical power source, UL544, European directive on medical devices. EMC compliance is to CE (IEC 601-1-2)

Operation
The MR95 will be setup either via Psion organiser when in the field, or by the PCMCIA disk which will have had setups loaded by the PC. The RS232 interface will allow connection to the NERVUS recorder to allow monitoring of the signals after the patient has been connected, in effect like the headbox. The Nervus Reader will have a PCMCIA reader which will allow the download of the file onto the hard disk, this will take approx 20 mins for a 24hr recording 17 channels etc. Review will be via the Nervus Editor program with the addition of sound.

Standard package
The recorder will be sold as standard with a pouch, straps, a PCMCIA type III card, batteries, and a full set of electrode leads.

375

Specifications for the MR95 solid state ambulatory recorder

No of channels
17 (1 ECG, 2 DC or common reference inputs, 2 Bipolar or common reference, remaining channels are common reference only)

Leads
all leads use a driven screen terminated with a gold or plated silver/silver chloride electrode. Special pre gelled stick on electrodes for ECG, and EOG are available. The lifetime of the leads is 251 months to a 0.1% confidence level.
A Connector block will accept all the leads, with the ability to unclip and remove individual leads.

Electrical Specification
Sensitivity -2.5mV pk - pk fixed EEG, 12.5mV pk - pk ECG, ±2.5V DC channels
Sampling quantisation -0.305 uV/bit EEG, 1.53 uV/bit ECG, 0.61 mV/bit DC
Frequency response - 0.5-35Hz -3dB (104/128Hz sampling), 0.5-70Hz (208/256Hz sampling)
Noise level - 2uV pk - pk EEG, 5uV pk - pk ECG
Common mode input impedance - >100MΩ, 10MΩ DC channels
CMRR - >80dB, balanced input
Antialiasing filters - 3rd order Butterworth at 35 and 70Hz. 400Hz attenuation with 70Hz bandwidth: -46dB
Dynamic range - 78dB
Sampling resolution - 13 bit linear, signed
Sampling rates - 104, 128, 208, 256Hz. All channels the same. A factory set link will enable a 512Hz sampling rate in the future. Skew will be <600uS total for all channels
Signal to noise ratio - >60dB rms

Controls
On/Off button - Held down for 2 seconds switches the recorder off or on
Record button - Switches the recorder on if it is already off and puts it into record mode.
Patient event button - self explanatory
Clock mode button - Sets the time by cycling through date, hour, mins, secs.
PCMCIA and battery compartment doors - The door in front of the PCMCIA disk is lockable with a key and is waterproof. The lock will also operate a line to the processor to ensure that the recorder has turned itself off gracefully before the cards are removed. All recorders will use the same key to allow them to replaced easily if they are lost.

Indicators
Clock LCD - same as the 9000-II recorder
Power - The clock display will indicate whether power is on or off.
Record - A green record LED will indicate when the recorder is recording.
Low battery - Indicates when the battery is low at the end of a recording, an internal buzzer can be optionally made to sound. Battery low indication can also indicate low battery at power up.
Disk full - Lights up when the PCMCIA card is full either during a recording or at power up, an internal buzzer can be optionally made to sound.
Slave - The recorder will detect when the master/slave lead has been plugged in and will switch to the appropriate mode automatically.
Disk activity - Indicates that it is not safe to remove the PCMCIA card or batteries due to calibration or disk writing being in progress. The indicator is near the PCMCIA slot.
Error - An Error LED will light up when recording can not continue due to incorrect operation or a hardware or software fault. Reasons for errors will include: Low batteries at the start of a recording, A full disk or no disk loaded, other system errors.

Data Storage

376

Exceptional Demands, Exceptional Solutions

Designed specifically for the Microsoft Windows environment, the user-friendly Profile system creates reports using Word and Excel with results automatically incorporated into the network database. Sophisticated yet simple to use, Profile's advanced reporting capability is the solution for the ever-increasing demands of your work environment.

(in shaded box)

Configuration

Channel 1	Bipolar or common reference EEG
Channel 2	Bipolar or common reference EEG or thermocouple input for airflow
Channel 3-4	Common reference EEG or DC input
Channel 5-16	Common reference EEG
Channel 17	Bipolar ECG

Physical

Dimensions: 154 x 118 x 39 mm (6.06" x 4.65" x 1.54")
Weight: 694g (1.53 lb) with batteries and disk

Power Supply

Battery powered
Six NiMH rechargeable AA cells (for hard disk or Flash disk PC Cards) or Six AA Alkaline primary cells (for Flash disk PC Cards only)

Optional Accessories

Medelec XC95 battery holder and charger

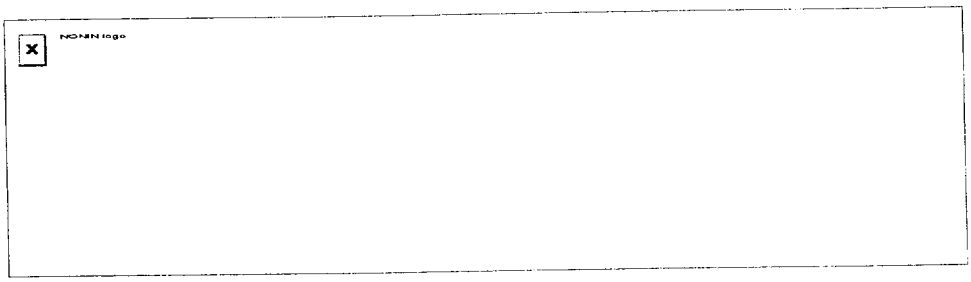
***Languages**

Medelec Profile software is available as English, French, German, Spanish, Portuguese and Italian language versions for use with corresponding Microsoft Windows / Office. The Psion computer and XS95 recorder set-up software are also available as English, French, German, Spanish, Portuguese and Italian language versions.

377

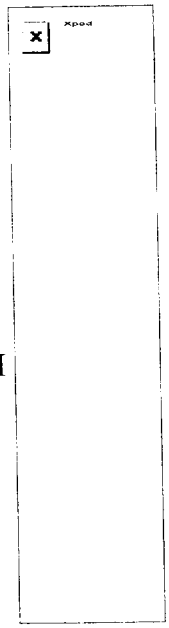
Exhibit 6.2
Nonin Product Information

378



SpO_2

SIMPLIFIED



Now...A thumb-sized pulse oximeter

No need to take precious space in your multifunctional monitor... Xpod™ is contained within the patient cable. Simply plug in our OEM, in-line pulse oximeter and reap these benefits:

- Full performance pulse oximeter
- Low power draw - 60mW @ 3-6 volts DC
- Convenient 3 wire interface
- Environmentally sealed
- Money saved through lower over-all cost
- Private labeling and custom interface options
- Sensor Options--Reusable and Disposable

Xpod OEM Pule Oximeter Specifications:

Oxygen Saturation Range
0 to 100%
Pulse Rate Range
18 to 300 pulses per minute
Measurement Wavelengths
Red - 660 Nanometers
Infrared - 910 Nanometers
Accuracy
SpO2 (±1 Standard Deviation)*
70 - 100% ±2 digits for adults using the Finger Clip Sensor
70 - 95% ±3 digits for neonates using infant or neonatal sensors
70 - 100% ±3 digits for adults using Flex or Reflectance Sensors

379

70 - 100% ±4 digits using Ear Clip Sensor
Below 70% is not specified for all sensors

Rate

±3% ±1 digit

Temperature

Operating 0 C to +50 C
Non Operating -20 C to +50 C

Humidity

Operating 10 to 90% Non Condensing
Non Operating 10 to 95% Non Condensing

Power Draw

60 mW - typical operation
250 mW - maximum at start up

Voltage Input

2 to 6 volts dc.

Output Digital Signals

0 - 5 volts (nominally)

Patient Isolation

Greater than 12 megohm

Leakage Current

Not applicable

Dimensions

2.1" x 0.8" x0.6"
53mm x 20mm x 15mm

Weight

60g (including 6' (1.8m) of cable and connector)

Fluid Spill Resistance

Immersable per IEC 68-2-16 section 6

Ruggedness

Shock per IEC 68-2-27
Vibration per Mil-standard 810C, method 514-2

Sensors

Designed to use Nonin sensors only
(Accuracy not assured when used with sensors other than Nonin)

*Standard Deviation is a statistical measure: up to 32% of the readings may fall outside these limits.

| Home | OEM | Sensors |

Prices and specifications are subject to change without notice.
Always read product labeling/inserts for complete instructions, warnings and restrictions.

You may contact us at oem@nonin.com

Nonin Medical, Inc.
2605 Fernbrook Lane North
Plymouth MN 55447-4755
USA

380

(800) 356 8874 (USA and Canada only)
(612) 553 9968
1 612 553 7807 (Fax)

Last updated 19 August 1998

381

Exhibit 6.3
Ultralife Product Information

ULTRALIFE BATTERIES INC.

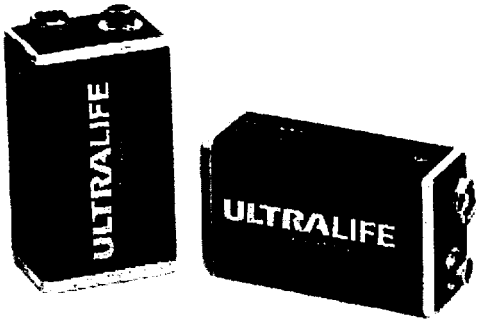
Product Data

U9VL 9V Lithium Primary Prismatic Batteries

Price in batches of 100, £4.66 per battery (1200mAh)

Contact in UK "All Batteries" tel: +44 (0)1923 770044

Web: http://www.ultralifebatteries.com/u9vl.html



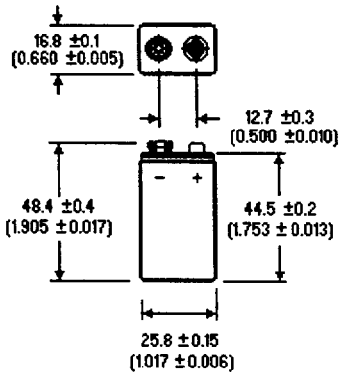
The consumer-replaceable lithium U9VL lasts up to 4 times longer than alkaline 9V batteries, 10 times longer than carbon-zinc. This primary battery has the highest energy-density, flattest discharge voltage curve, longest shelf life, widest operating temperature range, and lightest weight of any comparable 9-volt battery. The UL-recognized U9VL also has a patented safety mechanism and is environmentally friendly.

U9VL: 9-Volt Size Battery * U9VL-J: 9-Volt Size Battery with Metal Jacket

U9VL: 9-Volt Size Battery

383

Dimensions: mm (in)

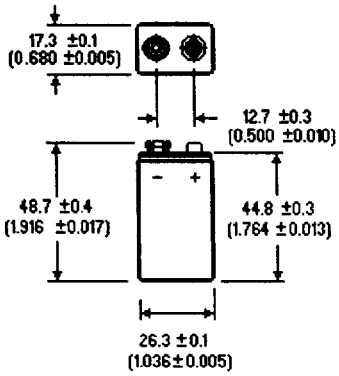


System:
Lithium/Manganese Dioxide, Li/MnO2
Designation:
NEDA 1604LC
Nominal Voltage:
9.0 Volts
Rated Capacity:
1,200 mAh at 900 Ohms to 5.4 Volts
Maximum Discharge:
120 mA Continuous
Temperature Range:
-40 C to 60 C (-40 F to 140 F)
Weight:
34.4 Grams (1.22 oz)
Volume:
21.40 cm^3 (1.3 in^3)
Terminals:
Miniature Snap
Jacket:
Non-Magnetic Plastic Housing/Label
Notes:
1. UL-recognized
2. Available in sealed foil pouch: model U9VL-FP

U9VL-J: 9-Volt Size Battery with Metal Jacket

384

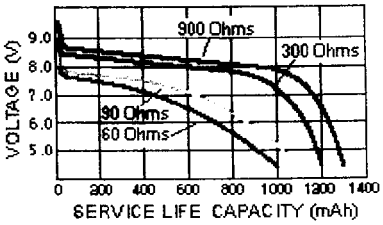
Dimensions: mm (in)



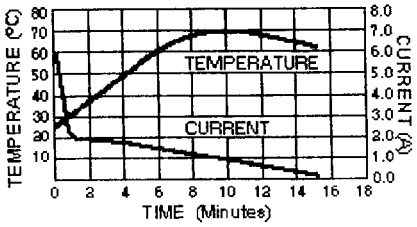
System:
Lithium/Manganese Dioxide, Li/MnO2
Designation:
NEDA 1604LC
Nominal Voltage:
9.0 Volts
Rated Capacity:
1,200 mAh at 900 Ohms to 5.4 Volts
Maximum Discharge:
120 mA Continuous
Temperature Range:
-40 C to 60 C (-40 F to 140 F)
Weight:
37.4 Grams (1.32 oz)
Volume:
22.69 cm^3 (1.38 in^3)
Terminals:
Miniature Snap
Jacket:
Aluminum/Label
Notes:
UL-recognized

385

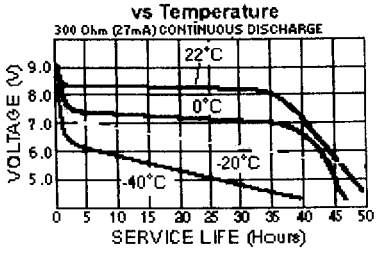
Typical Continuous Discharge Capacity



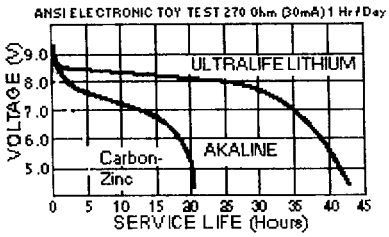
Typical Short Circuit Temperature & Current Characteristics



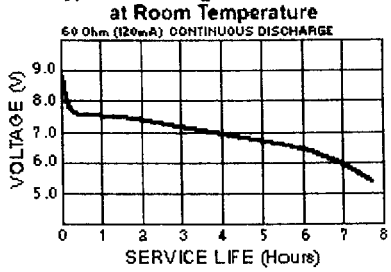
Typical Discharge Characteristics vs Temperature



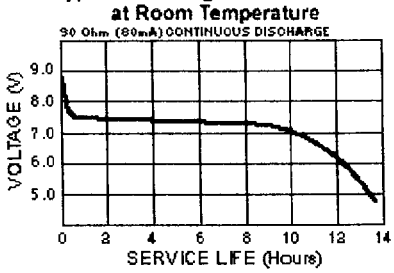
Typical Discharge Characteristics



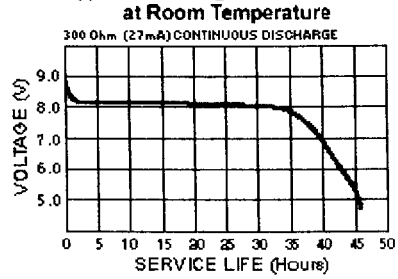
Typical Discharge Characteristics at Room Temperature



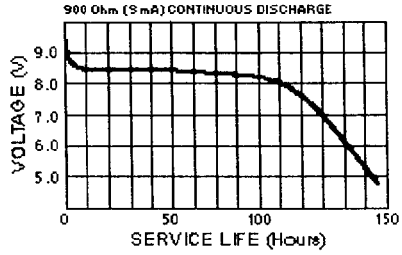
Typical Discharge Characteristics at Room Temperature



Typical Discharge Characteristics at Room Temperature



Typical Discharge Characteristics at Room Temperature



386

Exhibit 6.4
Duracell Ultra Product Information

387

Disks and batteries

Batteries (9V PP3):

We have tested trackit with Duracell Ultra batteries recording onto a 512MB flash card, and can report the following recording times:
1 x battery with 16ch's at 128Hz - 14 hours of recording time
3 x batteries with 16ch's at 200Hz - 36 hours of recording time

Lithium Manganese Dioxide (Lithium Ultralife) batteries are rated at 1.2Ah, almost 3 times the capacity of standard alkaline Duracell batteries, so in theory these should give nearly 90 hours of recording time with 16ch's at 200Hz onto flash disk.

A rule of thumb: (*Information corroborated by trial site*) An alkaline battery has a capacity of around 0.45Ah, a single Lithium Ultralife battery has a capacity of 1.2Ah. A Trackit recording with 20 channels at 200Hz will consume current at an hourly rate of 40 mA for flash and 56.6 mA for the IBM Microdrive. A 24-hour recording will therefore need batteries with a capacity of 0.96Ah for flash disks and 1.36Ah for the Microdrive.

The Microdrive may be problematic when the batteries get below 25% charge since the peak draw when writing data can be more than the battery is able to provide. Don't forget that the figures above are averaged out over the entire recording.

The prices here in the UK for Lithium Ultralife batteries are £4.66 per battery when purchasing in batches of 100. This is pretty much the same price as a Duracell Ultra Alkaline battery, which costs around £4.50/battery.

Shelf life for Lithium batteries is also considerably longer than their alkaline alternatives making it more attractive to bulk purchase.

Disks and flash cards

From testing to date we recommend the following flash cards for use with Trackit:

288

Exhibit 6.5
Simple Technology Product Information

389

Simple Technology 640MB ATA flash disk. Price £853 GBP

Simple Technology 800Mb ATA flash disk. Price £1049 GBP

These prices are available from Simple Technology in the UK. You can call the following number and quote lifelines to get the same prices if you cannot get them cheaper yourselves - Contact name Jim Watkin (Distribution Manager Europe),Tel: +44 (0)1355 57 28 54 (Direct) or + 44 (0)1355 57 28 50 (Main Line)

See Hitachi Pretec attachment below for prices of the Pretec 700MB flash card from Jactron in the UK. This card needs testing before we can promote its use with Trackit

IBM 1 GB Microdrive - Price in UK £403 GBP

IBM 340MB Microdrive - Price in UK £194 GBP

Supplier in the UK for these drives is Jactron on +44 (0)1303 891414. We are uncertain at this time about the long-term reliability of the Microdrive, but will keep you advised after further testing.

USB flash card reader This excellent device can be purchased from Jactron in the UK - see the attachment below on USB dual slot readers. The device is now supported in Windows 2000/ME.

390