Descriptive Report and Test Results

MASTER CONTRACT: 262528
REPORT: 2788070
PROJECT: 2788070

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PRODUCTS

CLASS 8780 01 - MEDICAL ELECTRICAL EQUIPMENT (Canadian adopted IEC 60601-1 3rd edition)
CLASS 8780 81 - MEDICAL ELECTRICAL EQUIPMENT (US Adopted IEC 60601-1 3rd edition)

Medical Electrical Equipment: Heating Mat, Model: BIO-BELT,
Cord-connected: Non-detachable cord, Transportable, Rated: 120 Vac, 60 Hz, 50 W.

1. Medical device protection against electric shock: Class II
2. Applied Part protection against electric shock: Type BF
3. Degree of protection against ingress of water or particulate matter: No degree of protection
4. Method of Sterilization: None
5. Suitability for use in an Oxygen Rich Environment: Medical device not intended to be used in an Oxygen Rich Environment
6. Suitability to use Medical device in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Medical device not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
7. Mode of operation: Continuous
8. Environmental Conditions: Normal: 5-40 °C, 15-93 % RH, 700-1 060 hPa

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 No. 60601-1:14	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA-C22.2 No. 60601-1-6:11	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral standard: Usability
CAN/CSA-C22.2 No. 60601-1-11:11	Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
CAN/CSA-IEC 62366:14	Medical devices – Application of usability engineering to medical devices

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005 / (R)2012, AND A1:2012, C1:2009 / (R)2012 AND A2:2010 / (R)2012 (Consolidated text - edition 3.1)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD).
ANSI/AAMI HA60601-1-11:2011	Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Subject to the following qualifications:

(1) This report describes the certification of the Medical Electrical Equipment with a North American Certified power supply cord set as indicated in the CSA description report.
(2) The user replaceable mains (line) fuse must be an approved type acceptable to the authorities where the equipment is sold.
(3) Evaluated to CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2012 excluding (Not Evaluated) requirements for Biocompatibility (Clause 11.7), Electromagnetic compatibility (Clause 17).
(4) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.
(5) Safety Risk Management: A risk management process complying with the requirements of standard ISO 14971 was inspected during the evaluation of this medical device and/or additional considerations were taken into account since the subject legacy medical device was evaluated to the previous edition of this standard. During the evaluation of this medical device, the risk management decisions affecting the test requirements have been taken into consideration. Changes/Updates in risk management documents that affect the safety of this medical device during its lifecycle shall be communicated to the CSA Group as a condition for continued certification.

MARKINGS

The manufacturer is required to apply the following markings:

- Products shall be marked with the markings specified by the particular product standard.
- Products certified for Canada shall have all Caution and Warning markings in both English and French.

Additional bilingual markings not covered by the product standard(s) may be required by the Authorities Having Jurisdiction. It is the responsibility of the manufacturer to provide and apply these additional markings, where applicable, in accordance with the requirements of those authorities.

The products listed are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US (indicating that products have been manufactured to the requirements of both Canadian and U.S. Standards) or with adjacent indicator 'US' for US only or without either indicator for Canada only.

On the Equipment Exterior:
Equipment is plainly marked in a permanent manner in a place where the details will be readily visible after installation with the following:

- The CSA applicable mark / / with optional reference to Standard, CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 AND A2:2010(R)2012 as per adopted IEC 60601-1:2005 3rd edition
- Manufacturer's identification: Name and/or CSA file number on the same label as the CSA Mark. The name and/or trademark should appear elsewhere on the equipment if only the file number is used on this label.
- Catalogue/Model/Type designation.
- Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture. (Not related to date of sale).
- Marking on the unit that indicates the manufacturing location if the equipment is manufactured at more than one factory location.
- Complete electrical ratings; in volts (V), hertz (Hz), and amperes (A), Volt-amperes (VA) or Watts (W) with the IEC 60417-5032 alternating current symbol adjacent to the marked AC voltage and dc current symbol IEC 60417-5031 marked adjacent to DC input rating for each model.
- The IEC 60417-5840/5333/5335 "Type B / BF / CF" or IEC 60417-5841/5334/5336 "Type B / BF / CF defibrillation-proof" symbol for degree of protection against electric shock; If there is more than one applied part with different degrees of protection, the relevant symbols shall be clearly marked on such applied parts or on or near relevant outlets.
- Interchangeable fuses accessible only with the aid of a tool shall be identified either by (voltage, current, operating speed, and breaking capacity) next to the fuse, or by at least a reference traceable in the Technical Manual.
- The "CAUTION" symbol ISO 7000-0434A on the nameplate, and/or on each or near each output, prefacing CAUTION labels and adjacent to SIP/SOPs.
- The IEC 60417-5008 and 60417-5007 symbols (I and O) adjacent to the mains power switch indicating "ON and OFF" positions.
- The IEC 417-5172 symbol for Class II equipment.

The following General Symbols (Table D.1) shall be applied as indicated

Indicate X in column if used	Symbol	Standard Reference	Title	Indicate X in column if used	Symbol	Standard Reference	Title
X		IEC 60417-5032	Alternating current			IEC 60417-5010	"ON" / "OFF" (push-push)
		IEC 60417-5032-1	Three-phase alternating current			IEC 60417-5011	"ON" / "OFF" (push button)
		IEC 60417-5032-2	Three-phase alternating current with neutral conductor			IEC 60417-5264	"ON" for part of the EQUIPMENT
		IEC 60417-5031	Direct current			IEC 60417-5265	"OFF" for part of the EQUIPMENT
		IEC 60417-5033	Both direct and alternating current			IEC 60417-5638	Emergency stop
		IEC 60417-5019	Protective earth (ground)			IEC 60417-5840	TYPE B APPLIED PART
		IEC 60417-5017	Earth (ground)	**X**		IEC 60417-5333	TYPE BF APPLIED PART
		IEC 60417-5021	Equipotentiality			IEC 60417-5335	TYPE CF APPLIED PART
X		IEC 60417-5172	CLASS II equipment			IEC 60417-5841	Defibrillation-proof TYPE B APPLIED PART
X		ISO 7000-0434A	Caution In case of application as a safety sign, the rules according to ISO 3864-1 are to be adhered to. See safety sign ISO 7010-W001 (Table			IEC 60417-5334	Defibrillation-proof TYPE BF APPLIED PART
		ISO 7000-1641	Operating Instructions			IEC 60417-5336	Defibrillation-proof TYPE CF APPLIED PART
		IEC 60417-5007	"ON" (power)	**X**		IEC 60417-5009	Stand-by
		IEC 60417-5008	"OFF" (power)			ISO 7000-1051	Do not reuse
		IEC 60417-5016 *	Fuse			IEC 60417-5041*	Caution , hot surface

* Note: Not part of the TABLE D.1

The following Safety Signs (Table D.2) shall be applied as indicated

Indicate X in column if used	Safety Sign	Standard Reference	Title	Indicate X in column if used	Safety Sign	Standard Reference	Title
X		ISO 7010-W001	General warning sign			ISO 7010-M001	General mandatory action sign
		ISO 7010-W012	Warning, electricity			IEC 60878 Safety 01	Follow operating instructions
		ISO 7010-P017	Pushing prohibited	X		ISO 7010-M002	Refer to instruction manual/ booklet
		ISO 7010-P018	Sitting prohibited			Figure 14 of IEC 60825-1*	Warning label - Hazard symbol Radiation of laser apparatus
		ISO 7010-P019	Stepping prohibited				

* Note: Not part of the TABLE D.2

On the Equipment Interior:

- Fuse rating, Volts, Amps, type, and breaking capacity adjacent to fuse-holders;

Marking Method: The above markings are made via silk screening, die stamping, moulding or on CSA certified or UL recognized adhesive nameplate material compatible with the surface used, or other equivalent permanent means that can pass the label rub test as per 7.1.3

Nameplate adhesive label material approval information:

Marking and labelling system	Avery Dennison Korea Ltd.	PET TC3	Material type: PET Dimensions:40 x 53 mm Color: Silver Impression type: Pressure-sensitive systems	CSA 0.15 UL 969	UR (MH26285)

ACCOMPANYING DOCUMENTS

ME EQUIPMENT shall be accompanied by documents containing at least the instructions for use and a technical description. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME EQUIPMENT.

The ACCOMPANYING DOCUMENTS shall identify the ME EQUIPMENT by including, as applicable, the following:

- name or trade-name of the MANUFACTURER and an address to which the RESPONSIBLE ORGANIZATION can refer;
- MODEL OR TYPE REFERENCE

The ACCOMPANYING DOCUMENTS shall specify any special skills, training and knowledge required of the intended OPERATOR or the RESPONSIBLE ORGANIZATION and any restrictions on locations or environments in which the ME EQUIPMENT can be used.

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

As per CAN/CSA-C22.2 No. 60601-1 (where applicable)

Clause	Description of requirement
7.9.1	Instruction for use
7.9.1	Technical description
7.9.1	Regarded as a part of the ME Equipment
7.9.1	Name or trade-name of the Manufacturer
7.9.1	Contact information to which the responsible organization can refer
7.9.1	Model or Type reference (see clause 7.2.2)
7.9.1	Any special skills, training and knowledge required of the intended operator or responsible organization
7.9.1	Any restrictions on locations or environments in which the ME equipment can be used
7.9.1	Level consistent with the education, training and any special needs of the person(s) for whom they are intended
7.9.2.1	The use of the ME Equipment as intended by the Manufacturer
7.9.2.1	The frequently used functions
7.9.2.1	Any known contraindication(s) to the use of the ME Equipment
7.9.2.1	Those parts of the ME Equipment that shall not be serviced or maintained while in use with a patient
7.9.2.1	Where the Patient is an intended Operator, the instructions for use shall indicate:
	The Patient is an intended Operator
	A warning against servicing and maintenance while the ME Equipment is in use
	Which functions the Patient can safety use and, where applicable, which functions the Patient cannot safely use
	Which maintenance the Patient can perform (e.g. changing batteries)
7.9.2.1	The instructions for use shall indicate:
	The name or trademark and address of the Manufacturer
	The Model or Type Reference
7.9.2.1	All applicable classifications specified in Clause 6
7.9.2.1	All markings specified in 7.2
7.9.2.1	The explanation of safety signs and symbols (marked on the ME Equipment)
7.9.2.2	All warning and safety notices

Clause	Description of requirement
7.9.2.2	Warnings regarding any significant RISKS of reciprocal interference posed by the presence of the ME EQUIPMENT during specific investigations or treatments
7.9.2.2	Information regarding potential electromagnetic or other interference between the ME EQUIPMENT and other devices advice on ways to avoid or minimize such interference
7.9.2.5	A brief description of the ME EQUIPMENT
7.9.2.5	How the ME EQUIPMENT functions
7.9.2.5	The significant physical and performance characteristics of the ME EQUIPMENT
7.9.2.5	Indicate any APPLIED PART
7.9.2.6	If installation of the ME EQUIPMENT or its parts is required a reference to where the installation instructions are to be found or
7.9.2.8	the necessary information for the OPERATOR to bring the ME EQUIPMENT into operation including such items as any initial control settings, connection to or positioning of the PATIENT, etc
7.9.2.8	detail any treatment or handling needed before the ME EQUIPMENT, its parts, or ACCESSORIES can be used
7.9.2.9	all information necessary to operate the ME EQUIPMENT in accordance with its specification
	explanation of the functions of controls
	displays and signals
	the sequence of operation
	connection and disconnection of detachable parts and ACCESSORIES
7.9.2.9	The meanings of figures, symbols, warning statements, abbreviations and indicator lights on ME EQUIPMENT
7.9.2.10	list all system messages, error messages and fault messages that are generated, unless these messages are self-explanatory
7.9.2.10	The list shall include an explanation of messages including important causes, and possible action(s) by the OPERATOR, if any, that are necessary to resolve the situation indicated by the message
7.9.2.11	contain the necessary information for the OPERATOR to safely terminate the operation of the ME EQUIPMENT
7.9.2.12	For ME EQUIPMENT parts or ACCESSORIES that can become contaminated through contact with the PATIENT or with body fluids or expired gases during NORMAL USE
	details about cleaning and disinfection or sterilization methods that may be used and;
	list the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT parts or ACCESSORIES can tolerate
7.9.2.13	instruct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance
7.9.2.13	information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the ME EQUIPMENT
7.9.2.14	List of ACCESSORIES, detachable parts and materials
7.9.2.15	Provide advice on the proper disposal of waste products, residues, etc. and of the ME Equipment and Accessories at the end of their Expected Service Life
7.9.2.16	the information specified in 7.9.3 or a reference to where the material specified in 7.9.3 is to be found
7.9.2.19	The instructions for use shall contain a unique version identifier such as its date of issue.
7.9.3.1	essential for safe operation, transport and storage
	measures or conditions necessary for installing the ME EQUIPMENT
	preparing it for use
	the information required in 7.2;
	the permissible environmental conditions of use including conditions for transport and storage
	all characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found;

Clause	Description of requirement
7.9.3.1	a warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT, e.g. a statement to the effect: • "WARNING: Do not modify this equipment without authorization of the manufacturer." or • "WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment." • "WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment."
	Information pertaining to Essential Performance and any necessary recurrent Essential Performance and Basic Safety testing including details of the means, methods and recommended frequency.
7.9.3.1	The MANUFACTURER may designate the minimum qualifications for SERVICE PERSONNEL
7.9.3.4	clearly identify any means used to comply with the requirements of 8.11.1

As per CAN/CSA-C22.2 No. 60601-1-6 (where applicable)

Clause	Description of requirement
5	Include a brief description of the ME Equipment, its physical operating principles and significant physical and performance characteristics relevant to its Usability.
5	The instructions for use shall contain a summary of the application specification

As per CAN/CSA-C22.2 No. 60601-1-11 (where applicable)

Clause	Description of requirement
7.3.1	The Accompanying Documents shall indicate that the Lay Operator or Lay Responsible Organization should contact the Manufacturer or the Manufacturer's representative: - for assistance, if needed, in setting up, using or maintaining the ME Equipment or ME System; or - to report unexpected operation or events
7.3.1	The ACCOMPANYING DOCUMENTS shall include a postal address and either a telephone number or web address through which the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION can contact the MANUFACTURER or the MANUFACTURER'S representative
7.3.2	The ACCOMPANYING DOCUMENTS shall include the details necessary for the healthcare professional to brief the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION on any known contraindication(s) to the use of the ME EQUIPMENT or ME SYSTEM and any precautions to be taken. This shall include:
	- precautions to be taken in the event of changes in the performance of the ME EQUIPMENT or ME SYSTEM
	- precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions (e.g. to magnetic fields, electromagnetic fields, external electrical influences, ELECTROSTATIC DISCHARGE, pressure or variations in pressure, acceleration, thermal ignition sources)
7.4.1	for each warning and safety sign, the instructions for use shall describe the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK.
7.4.1	If applicable, the instructions for use shall address the issues of:
	– strangulation due to cables and hoses, particularly due to excessive length.
	– potential allergic reactions to accessible materials used in the ME EQUIPMENT.
	– contact injuries.
7.4.1	If applicable, the instructions for use shall include warnings to the effect that it can be unsafe to:
	– use ACCESSORIES, detachable parts and materials not described in the instructions for use (see 7.9.2.14 of the general standard).
	– interconnect this equipment with other equipment not described in the instructions for use (see 16.2 c) indent 9) of the general standard).
	– modify the equipment

Clause	Description of requirement
7.4.3	the instructions for use shall include easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate ME EQUIPMENT including all controls, visual INFORMATION SIGNALS, and indicators provided with the ME EQUIPMENT (see 7.1)
7.4.4	The instructions for use shall include:
	- easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment (see 7.1)
7.4.5	The instructions for use shall include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT and the steps that can be taken by the LAY OPERATOR to identify and resolve these conditions, and shall include, where applicable, at least the following issues
	- the effects of lint, dust, light (including sunlight), etc
	- a list of known devices or other sources that can potentially cause interference problems
	- the effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems
	- the effects caused by pets, pests or children
7.4.6	The instructions for use shall include a troubleshooting guide for use when there are indications of a ME Equipment malfunction during start-up or operation.
7.4.6	The troubleshooting guide shall disclose the necessary steps to be taken in the event of an Alarm Condition
7.4.7	For ME EQUIPMENT, ME SYSTEMS, their parts or ACCESSORIES that are intended for other than single use and that can become contaminated through contact with the PATIENT or with body fluids or expired gases during INTENDED USE, the instructions for use shall:
	- indicate the frequency of cleaning, cleaning and disinfection or cleaning and sterilization, as appropriate, of the ME EQUIPMENT, ME SYSTEMS, parts or ACCESSORIES used on the same PATIENT including methods for rinsing, drying, handling and storage between uses (see 8.1 and 8.2); and
	- if intended for multiple PATIENT use, indicate that it is necessary to clean and disinfect or clean and sterilize the ME EQUIPMENT, ME SYSTEMS, parts or ACCESSORIES between uses on different PATIENTS, including methods for rinsing, drying, handling and storage until re-use (see 8.1 and 8.2) **or**
7.4.8	The instructions for use shall include:
	- the EXPECTED SERVICE LIFE of the ME EQUIPMENT
	- the EXPECTED SERVICE LIFE of parts or ACCESSORIES shipped with the ME EQUIPMENT
7.4.9	The instructions for use shall include:
	- information concerning the proper disposal of the ME EQUIPMENT, its parts or ACCESSORIES (see IEC 60601-1-9)

As per CAN/CSA-IEC 62366:14 (where applicable)

Clause	Description of requirement
6	If provided, the Accompanying Document shall include a summary of the Medical Device application specification (See 5.1)
6	If provided, the Accompanying Document shall include a concise description of the Medical Device which includes, where relevant to its use: - operating principle - significant physical characteristics - significant performance characteristics - intended User Profile
6	If provided, the Accompanying Document shall be written at a level consistent with the User Profile
6	The Accompanying Document may be provided electronically. If the Accompanying Document is provided electronically, the Usability Engineering Process shall include consideration of which information also needs to be provided as hard copy or as markings on the Medical Device

ALTERATIONS

1. The units are marked as noted under "**MARKINGS**" above.

FACTORY TESTS

The equipment at the conclusion of manufacture, before shipment, shall be subjected to the following tests which may be made at room temperature.

Applicable Factory Test (indicate by X)	Type of Factory Test
	Ground Continuity: **For Grounded Units:** Each machine shall be tested for ground continuity, as follows: Each appliance that has provision for grounding by fixed wiring means or has a power-supply cord having a grounding conductor shall be tested, as a routine production-line test, to determine grounding continuity is provided between the point of connection of the equipment grounding means (grounding blade of the attachment plug in the case of a portable appliance) and the accessible dead metal parts of the appliance that are likely to become energized. Only a single test need be made if the accessible metal selected is conductively connected to all other accessible metal. Any indicating device (an ohmmeter, a battery-an-buzzer combination or the like) may be used to determine compliance.
X	**Dielectric Strength:** **Transformers Connected to Vac Supply**: This Mains Transformer is not considered as a MOP. **For Double Insulated Units (Class II) Not Having Exposed Metal Parts:** The equipment at the conclusion of manufacture, before shipment, shall withstand for one minute, without breakdown, the application of : 3000 Vac between live parts and metal foil in contact with plastic enclosure. (Based on 120 V rated units for MOPP) 3000 Vac between live parts and metal foil in contact with applied parts. (Based on 120 V rated units for MOPP) Note: Although ac voltages are quoted above, coupling components within the product may require the tests be conducted using dc voltages or peak voltages. Where dc voltages are used, the test values are increased by 1.414 times the ac voltages. The test period may be shortened by using a potential 20 percent higher for one second. Warning: The factory test(s) specified may present a hazard of injury to personnel and/or property and should only be performed by persons knowledgeable of such hazards and under conditions designed to minimize the possibility of injury.

Applicable Factory Test (indicate by X)	Type of Factory Test
X	**Leakage Current:** Measurement of the EARTH and/or TOUCH leakage currents in Normal Condition and Single Fault shall be conducted at ambient temperature without a moisture preconditioning treatment. In cases where the number of settings of parameters of the equipment or of switches of the measuring supply circuit or of the application of a metal foil (Class II) or the application of the measuring device, to be performed during the test would be unacceptable and the results of certain tests would indicate the highest value(s), then the routine tests may be restricted to the setting(s) provoking these highest values. Warning: The factory test(s) specified may present a hazard of injury to personnel and/or property and should only be performed by persons knowledgeable of such hazards and under conditions designed to minimize the possibility of injury. Note: Manufacturers may also opt to conduct additional PATIENT and AUXILIARY leakage currents as part of their factory tests. Particular attention is made that these setups may be very complex and could be very time consuming to perform. Follow-Up services shall limit their activities to the factory process as indicated/documented by the manufacturer. When considering use of tests described in the IEC 60601-1 standard as factory tests, see Annex K of the IEC/TR 62354 or see IEC 62353 (recurrent tests) for alternative factory tests methods. Alternative factory tests methods can only be used when reviewed and accepted by CSA through a written approval.

SPECIAL INSTRUCTIONS FOR FIELD SERVICES

1. Component descriptions marked with either the "(INT)" or "(INT*)" identifiers may be substituted with other components providing the requirements specified under the notes in the "Description" are complied with.

2. The medical device shall be marked with a fixed warning notice stating that transport may be undertaken only in a certain position which is clearly described in the instructions for use or illustrated by inscription on the equipment.

3. The supply cord, if hard-wired into the unit, shall have the following colour coded wires:
Neutral - white or natural grey; supply - black, or red. Exceptionally the following colours can be accepted, Neutral - blue, supply - brown when identified in the user/installation manual.

4. The operator's manual shall contain instructions for replacement of parts subject to deterioration.

5. A correctly rated fuse link shall be fitted in each supply lead, except for PERMANENTLY INSTALLED Medical Electrical Equipment; the neutral conductor shall not be fused.

6. There shall be no indicator lights that are red in color except to indicate a warning of danger or need for urgent action.

7. The shipping package shall be marked with the prescribed transport and storage environmental conditions such as humidity range, atmospheric pressure range and temperature range. The range of environmental conditions for shipping shall be disclosed by the manufacturer and indicated in the user manual. The units shall be as per the ISO 31 or ISO 80000-1 standard (metric units) and units outside the SI unit system as indicated in TABLE 1 of the IEC 60601-1:2005 or other types of units (Imperial units) can be used as long as the metric units are included Example: Celsius and Fahrenheit, Meters and Feet...

Environmental Conditions for Shipping	Environmental Conditions for Storage
Temperature: -25 to +70 °C	Temperature: -25 to +70°C
Relative Humidity: 15 to 93 % RH	Relative Humidity: 15 to 93 %RH
Altitude: 700 to 1060 atmospheric pressure hPa	Altitude: 700 to 1060 atmospheric pressure hPa

8. The accompanying documents include a glossary of symbols used on the product and in accompanying documents. The symbols or safety signs applied to the medical device shall be explained in the accompanying documents. Examples include: Alternating Current, Protective Earth, Type B, On, Off, Caution and Safety symbols and signs, Equipotentiality.

9. All markings, symbols and warning statements appearing on the equipment appear in each of the accompanying documents.

10. For medical device that may be serviced by the RESPONSIBLE ORGANIZATION, the technical description includes a statement that the supplier will make available on request circuit diagrams, component part lists, etc.

11. Internal wiring is CSA certified, secured and routed away from sharp edges and surfaces of pcb's.

12. Safety Risk Management / ISO14971:
When safety risk management documents which are updated/modified that would affect the safety of the medical device, the certification report must be reviewed to remain in compliance

INTRODUCTION

A representative sample of the subject product was examined and is described in the body of this report. Unless specifically stated otherwise, the following general definitions, terminology and construction details apply:

Nomenclature of Critical Components:

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
1: [N1], Object					[N2] , [N3]

[N1] Code: **[INT] [CT]**

The term "(INT)", following the component name, denotes a certified component that can be replaced by one from another certified source (approved by OSHA/SCC accredited body for the same application) provided that it has an equivalent rating, configuration (size, orientation, mounting) and that applicable minimum creepage and clearance distances are maintained from live parts to bonded metal parts and secondary parts.
The term "(CT)", following the component name, denotes a component that is subject to periodic re-testing unless evidence of re-testing equivalent to the CSA program is available.

[N2] Code: Agency Approvals Logos/Marks

"CSA or  **"** = CSA Certified for Canada only

"CSAus or  **"** CSA Certified for USA only

"cCSAus or  **"** CSA Certified for Canada and USA

"UR or  **"** = UL Recognized for USA only, **"cUR or**  **"** = UL Recognized for Canada only,
"cURus or  = UL Recognized for Canada and USA

"UL or  **"** = UL Listed for USA only, **"cUL or**  **"** = UL Listed for Canada only, **"cULus or** **"** = UL Listed for Canada and USA.

Note: Other Agency approval Logos/marks can also be used.

#: Pound Sign: The "#" the pound denotes that the used Monogram does not appear on the component. A pound behind any other test house's logo/mark denotes that their monogram does not appear on the component.

Accepted: The Accepted word means tested in end-product to applicable standard of that end-product. That component meets all the requirements of the end equipment or system.

[N3] Code: CSA Master Contract number (123456) or UL or UR Licence number (E123456).

Other Definitions

Mechanical Construction: Unless otherwise specified, all mechanical parts are provided with lock washers or other equivalent means to prevent separation of mechanical parts. Screws between metal parts, covers, etc. employ star washers or masked screw heads and prevents paint build up to insure good electrical continuity between parts. All accessible dead metal parts, including covers, screen, brackets, and fan guards are readily connected with bolts, straps, or wires to the housing or frame. Fuse holders and rotational switches are prevented from rotation by a positive means such as keying, the use of lock washers or other equivalent means.

All exposed edges, projections and corners of the enclosure, frame, guards and the like are smooth, well rounded and free from burrs. All surfaces in contact with moving internal wiring or cables are smoothed to prevent abrasion of insulation. All ferrous metal parts are painted, plated, or protected by equivalent means to prevent corrosion, except for bearing and latching surfaces.

Solder Connections: All connections are made mechanically secure prior to soldering.

Dimensions: All dimensions specified are approximations only, and shown in millimetres (mm).

Internal Wiring: All primary and grounding circuit conductors are Certified and UL Recognized, rated min 80ºC, 300 V ac. All wiring is suitably routed and secured away from sharp edges and moving parts to prevent chafing of the insulation. Alternatively, additional insulation is provided where the wiring passes over sharp edges and through holes. All mains circuit wiring shall be doubly secured at all connection points.

Crimp Connectors: All crimp-type connectors used in primary and grounding circuits are  or  appropriately sized for the gauge of conductors used, vinyl insulated (optional for grounding), rated min 90ºC, 250 Vac.

Connectors: All connectors used in primary circuits are  or , appropriately sized for the number and gauge of conductors used, rated min 250 Vac.

Printed Circuit Boards (PC-B): All PC-B's are made of paper phenolic, paper epoxy or glass epoxy, min 1.6 mm thick, unless circuit is limited to less than 15 W.

COMPONENT SPECIAL PICKUP

1. Component descriptions marked with the identifier "(CT)" are subject to annual pickup and Conformity Testing.

DESCRIPTION

Notes:

1. Component Substitution
   a) Critical components (those identified by mfr name, cat no), which are NOT identified with either "INT" or "INT*" are not eligible for substitution without evaluation and report updating
   b) The term "INT" means a "Certified" and/or "Listed" (or a "Recognized" and/or "Accepted") component may be replaced by one "Certified" and/or "Listed" by another certification organization accredited by the appropriate accreditation body or scheme requirements to the correct standard, for the same application; providing the applicable country identifiers are included and requirements in item "d" below are complied with.
   c) The Term "INT*" means a "Recognized" and/or "Accepted" component may be replaced by one "Recognized" and/or "Accepted" by another certification organization accredited by the appropriate accreditation body or scheme requirements to the correct standard, for the same application, providing the applicable country identifiers are included, the component is **also** CSA Certified, the requirements in item "d" below are complied with and any "conditions of suitability" for the component (as recorded in this descriptive report) are complied with.
   d) Components which have been substituted, must be of an equivalent rating, configuration (size, orientation, mounting) and the applicable minimum creepage and clearance distances are to be maintained from live parts to bonded metal parts and secondary parts.
   e) Substitution of a "Certified" and/or "Listed" component with a component that is "Recognized" or "Accepted" is not permitted without evaluation and report updating.

General: This equipment is indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis; the temporary relief of muscle spasms, minor sprains and strains, and minor muscular back pain; the relaxation of muscles; and the temporary increase of local circulation where applied. This equipment is intended for use in home healthcare environment.

LIST OF CRITICAL COMPONENTS
ALL critical components and accessories included in this critical component list have been evaluated as part of the medical device

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
1: Main Enclosure of Controller	LG Chem Ltd.	AF312C	Type: Transportable Overall Dimensions: 120 x 60 x 28 mm by 2.5 mm thick Material: ABS (V-0) Color: Black, White Weight: 0.04 kg	CSA 0.17 UL 746C UL 94	UL (E67171)
2: Marking and labelling system	Avery Dennison Korea Ltd.	PET TC3	Material type: PET Dimensions:59 x 34 mm Color: Silver Impression type: Pressure-sensitive systems	CSA 0.15 UL 969	UR (MH26285)
3: Power Cord Set (INT)	Korea KDK Co., Ltd.	KKP-11W with SJT Flexible cord	- Power plug: 125 V~; 15 A - Power cord: Seize of wire: 18 AWG; 300 V; 60 ºC Type: SJT (Non-detachable type)	CSA 21 UL 817	UL (E58075)
4: Main Fuse (FUSE)	Cooper Bussmann LLC	SS-5	250 V~; 3.15 A Interrupting rating: 35 A Type: T3.15AL Dimension: 8.6 x 4.3 x 8.4 mm	CSA 248-1 CSA 248-14 UL 248-1 UL 248-14	UR (E19180)
5: Surge protective device (TNR1)	Thinking Electronic Industrial Co., Ltd.	TVR10471	Varistor voltage: 470 V; Max. operating voltage: 300 V~; Max. surge current: 2 500 A	CSA 516 UL 1449	UR (E314979)
6: X2 Capacitor (C1)	Carli Electronics Co., Ltd.	MPX	1.0 µF; 275 V~; X2	CSA E60384-1 CSA E60384-14 UL 60384-14	UR (E120045)
7: X2 Capacitor (C8 & C9)	Carli Electronics Co., Ltd.	MPX	0.01 µF; 275 V~; X2	CSA E60384-1 CSA E60384-14 UL 60384-14	UR (E120045)
8: Optical Isolators / Couplers (PC1)	Fairchild Semiconductor Corp.	MOC3041	Isolation: 3 750 V~ Creepage: 7 mm	CSA Notice No. 5 UL 1577	UR (E90700)
9: PC-Board (Only material can be interchanged, due to layout and traces)	Shanghai Nanya Copper Clad Laminates Co., Ltd.	NY1140	Material: FR-4.0 Dimensions: 100.17 x 48.5 x 1.75 mm by 1.6 mm thick Inflammability rating: V-0; 130 ºC	UL 746E UL 796 IEC 60695-11-10	UR (E108706)

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
10: Front panel sheet	Mianyang Longhua Film Co., Ltd.	PC-1811A	Dimensions: 94.5 x 49 x 1 mm by 1.0 mm thick Inflammability rating: V-2; 80 ºC	UL 746 UL 94 CSA 0.17.92	UR (E254551)
11: Plastic of control switch	LG Chem Ltd.	AF312C	Inflammability rating: V-0; 80 ºC	UL 746 UL 94 CSA 0.17.92	UR (E67171)
12: Output Cord	Kwang Il Electric Wire Co., Ltd.	2464	18 AWG; 300 V; 80 ºC; VW-1 Type	CSA 127 UL 758	UR (150633)
13: Plastic enclosure of Output Connector (INT)	Samsung SDI Co., Ltd.	EN-1052(+)	Dimensions: 48 x 51.17 x 16.63 mm by 2.5 mm thick Inflammability rating: V-0; 130 ºC	UL 746 UL 94 CSA 0.17.92	UR (E115797)
Heating Mat					
1: Main Enclosure of Heating mat	R&L Co., Ltd.	BIO-BELT	Type: Transportable Overall Dimensions: 460 x 210 x 24 mm Weight: 1.3 kg	CSA 60601-1 ANSI 60601-1	Accepted
2: Plastic enclosure of Output Connector of Heating mat (INT)	Samsung SDI Co., Ltd.	EN-1052(+)	Dimensions: 66 x 77.13 x 32.49 mm by 2.5 mm thick Inflammability rating: V-0; 130 ºC	UL 746 UL 94 CSA 0.17.92	UR (E115797)
3: Output Terminal Block of Heating mat (INT)	Sunmoon Industrial Co.	103S	300 V; 6 A Heat resistance: 200 ºC Deflection temperature: 170 ºC	CSA 60601-1 ANSI 60601-1	Accepted
4: Heating Wire	Hyun Electronics Co.	-	120 V; 50 W	CSA 60601-1 ANSI 60601-1	Accepted
5: Temperature Sensor	International Sensor Co.	D203JCW-C2000M (Black)	10 kΩ	CSA 60601-1 ANSI 60601-1	Accepted
6: Thermostats	Seki Controls Co., Ltd.	ST-22	90 ºC	CSA 24 UL 873	UR (E162183)
7: Flame-resisting material (Thermal protection layer)	B & B	Thermal protection layer	Dimensions: 420 x 180 mm by 3 mm thick Inflammability rating: 200 ºC	CSA 60601-1 ANSI 60601-1	Accepted
8: Flame-resisting material (Thermal preservation layer)	Hyun Electronics Co.	Thermal preservation layer	Dimensions: 460 x 210 mm by 0.6 mm thick Inflammability rating: 210 ºC	CSA 60601-1 ANSI 60601-1	Accepted

Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
9: Flame-resisting material (Aluminum insulation layer)	Hansung Hanalon Co., Ltd.	Aluminum insulation layer	Dimensions: 420 x 180 mm by 2 mm thick Inflammability rating: 90 ºC	CSA 60601-1 ANSI 60601-1	Accepted
10: Flame-resisting material (Fiber-grass layer)	GS	Fiber-grass layer	Dimensions: 420 x 180 mm by 0.3 mm thick Inflammability rating: 120 ºC	CSA 60601-1 ANSI 60601-1	Accepted

TEST HISTORY

Project 2788070

Test Location: Witness Test Location (WMTC)

DT&C Co., Ltd.
42, Yurim-ro 154 beon-gil, Cheoin-gu, Yougin-si, Gyeonggi-do, Korea 449-935

HCT Co., Ltd.
74, Seoicheon-ro 578 beon-gil, Majang-myeon, Icheon-si, Gyeonggi-do, 467-811 Korea

The following tests were performed on a sample model: BIO-BELT, configured for the worst-case conditions according to the CAN/CSA-C22.2 NO. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012, AND C1:2009 AND A2:2010(R)2012 as per adopted IEC 60601-1 edition 3.0 and/or 3.0 + amendment 1 (edition3.1), including the applicable risk management process decisions. The risk management process for legacy medical devices evaluated to the previous edition of this standard are covered as required by the technical requirements otherwise the worst-case conditions of the current and previous editions of the standards. Records of these decisions are documented in the Manufacturer's RM Documents as referenced in the appropriate IECEE TRF IEC 60601-1 version.

Note: All risk management documents shall be referenced as attachments. (Supporting objective evidence)

SUMMARY OF TESTS and RISK MANAGEMENT
(Edition 3.0 + amendment 1) – TRF version i

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
4	**General requirements**	---	---
4.11	Power Input	---	P
5	**General requirements for testing MEE**	---	---
5.7	Humidity preconditioning treatment	---	P
5.9.2	Determination of APPLIED parts and ACCESSIBLE parts	---	P
7	**ME EQUIPMENT identification, marking, and documents**	---	---
7.1.2	Legibility of markings	---	P
7.1.3	Durability of marking test	---	P
7.2.18	External pressure source	---	N/A
7.2.20	Removable protective means	---	N/A
7.2.21	Mass of MOBILE ME equipment (SWL in Kilograms)	---	N/A
7.3.8	Temperature of supply terminals	---	N/A
8	**Protection against electrical HAZARDS from ME EQUIPMENT**	---	---
8.1a,b (8.9.2)	Application of normal and single-fault conditions	---	P
*8.2.2	Connection to an external d.c. power source (wrong polarity)	---	N/A
8.4.2 (8.5.1.3)	Accessible parts and applied parts	---	P
8.4.3	ME equipment intended to be connected to a power source by a plug	---	P
8.4.4	Internal capacitive circuits	---	N/A

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
8.5.1.2 (8.8.3 and 8.10)	MEANS OF PATIENT PROTECTION (MOPP)	---	P
8.5.1.3 (8.8.3 and 8.10)	MEANS OF OPERATOR PROTECTION (MOOP - 60950-1)	---	P
8.5.2.1 (8.7 and 8.8.3)	F-TYPE APPLIED PARTS	---	N/A
8.5.2.2	Type B applied parts	---	N/A
*8.5.2.3	PATIENT Leads	N/A	N/A
8.5.4	WORKING VOLTAGE (Insulation diagram and Insulation Table)	---	P
8.5.5.1 a)	Defibrillation-proof applied parts – Common-mode differential-mode tests (Figs 9 and 10)	---	N/A
8.5.5.1 b)	Defibrillation-proof applied parts – Recovery time	---	N/A
8.5.5.2	Defibrillation-proof applied parts - Energy reduction test	---	N/A
8.6.2 (8.11.4.3)	PROTECTIVE EARTH TERMINAL	---	N/A
8.6.4	Impedance and current-carrying capability of protective earth connections	---	N/A
8.7.4 (8.4.2 a)	Measurement of PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT from, to, or between PATIENT CONNECTIONS	---	P
8.7.4 (8.4.2 b)	Measurement of LEAKAGE CURRENT from, to, or between ACCESSIBLE PARTS other than PATIENT CONNECTIONS	---	P
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT (Fig. 13) using MD	---	N/A
8.7.4.5	Measurement of the EARTH LEAKAGE CURRENT (Fig. 13) using 1 KΩ non-inductive resistor	---	N/A
8.7.4.6	Measurement of the TOUCH CURRENT (Fig. 14) using MD	---	P
8.7.4.6	Measurement of the TOUCH CURRENT (Fig. 14) using 1 KΩ non-inductive resistor	---	P
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT (Figs. 15 to 19) using MD	---	P
8.7.4.7	Measurement of the PATIENT LEAKAGE CURRENT (Figs. 15 to 19) using 1 KΩ non-inductive resistor	---	P
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT (Fig. 19) using MD	---	N/A
8.7.4.8	Measurement of the PATIENT AUXILIARY CURRENT (Fig. 19) using 1 KΩ non-inductive resistor	---	N/A
8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS using MD	---	N/A
8.7.4.9	ME EQUIPMENT with multiple PATIENT CONNECTIONS using 1 KΩ non-inductive resistor	---	N/A
8.8.2 (8.8.3)	Distance through solid insulation or use of thin sheet material	---	N/A

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
8.8.3	Dielectric strength test of solid insulating materials with safety function – Means of operator protection (MOOP) or patient protection (MOPP) - 1 min duration	---	P
8.8.4.1	Mechanical strength and resistance to heat of insulations – ball-pressure test	P	P
*8.8.4.2	Resistance to environmental stress – ageing in oxygen	---	N/A
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES – Values – General (Insulation Diagram and Insulation Table)	---	P
8.9.2	Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4	---	P
8.9.3.2	Thermal cycling tests - Insulating compound forming solid insulation between conductive parts	---	N/A
8.9.3.3	Reliability of the joint - Insulating compound forming a cemented joint with other insulating parts	---	N/A
8.9.3.4	Thermal cycling tests on one sample of cemented joint (see 8.9.3.2 and 8.9.3.3)	---	N/A
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES (2 N and 30 N)	---	N/A
8.10.3 (5.9.2)	Connections between different parts of ME equipment	---	P
8.10.4	Cord-connected hand-held and foot-operated control devices	---	N/A
8.10.7	Insulation of internal wiring (temperature measurement)	---	N/A
8.11.1 (8.10)	Isolation from the Supply Mains	---	N/A
8.11.3.2 (8.10)	POWER SUPPLY CORDS - Types	---	P
8.11.3.4 (8.11.4.4)	Appliance Couplers	---	N/A
8.11.3.5 (8.10.4.2)	Cord anchorage - power supply cord (hand-held or foot-operated controls)	---	P
8.11.3.6 (8.10.4.2)	Cord guards - power supply cord (hand-held or foot-operated controls)	---	P
*8.11.4.2 e)	MAINS TERMINAL DEVICES – Loose strand	---	N/A
*8.11.4.3	Fixing of mains terminals - means for clamping the conductors	---	N/A
8.11.5 (8.10)	Mains fuses and OVER-CURRENT RELEASES	---	P
*8.11.6	Short-circuit singe-fault condition - cross-sectional area of other wiring in the MAINS PART and the sizes of tracks on printed wiring circuits	---	P
9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**	---	---
9.2.2.2	Measurement of gap “a” according to Table 20 (ISO 13857:2008)	---	N/A

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
9.2.2.3	Safe Distances (ISO 13857:2008)	---	N/A
9.2.2.4.1 (15.3)	GUARDS and protective other RISK CONTROL measures - Access to TRAPPING ZONES	---	N/A
9.2.3	Other mechanical hazards associated with moving parts	---	N/A
9.2.3.2	Overtravel end stops	---	N/A
9.2.4	Emergency stopping device	N/A	N/A
9.2.5	Release of patient	N/A	N/A
9.4.2.1	Instability in transport position	---	P
9.4.2.2	Instability excluding transport	---	P
9.4.2.3	Instability from horizontal and vertical forces	---	P
9.4.2.4.2	Castors and wheels – Force for propulsion	---	N/A
9.4.2.4.3	Castors and wheels – Movement over a threshold	---	N/A
9.4.3.1	Instability from unwanted lateral movement (including sliding) in transport	---	N/A
9.4.3.2	Instability from unwanted lateral movement (including sliding) excluding transport	---	N/A
9.4.4	Grips and other handling devices	---	N/A
*9.6.2.1	Audible acoustic energy	---	N/A
*9.6.3	Hand-transmitted vibration (ISO 5349-1)	---	N/A
9.7.5	Pressure vessels	---	N/A
*9.8.2	TENSILE SAFETY FACTOR	N/A	N/A
9.8.3.2 a), b)	Static forces due to loading from persons	---	N/A
9.8.3.3	Dynamic forces due to loading from persons	---	N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended for single activation	---	N/A
10	**Protection against unwanted and excessive radiation HAZARDS**	---	---
10.1.1	Measurement of X–radiation - MEE not producing therapeutic/diagnostic X-radiation but producing ionizing radiation	---	N/A
10.1.2	ME Equipment intended to produce diagnostic or therapeutic X-radiation	N/A	N/A
10.1.3	Measurement of microwave radiation	---	N/A
10.3*	Microwave radiation	---	N/A
11	**Protection against excessive temperatures and other HAZARDS**	---	---
11.1.1 / 11.1.3	Measurements - Excessive temperatures in ME EQUIPMENT (Tables 22 to 24)	---	P
11.1.3	Measurements - Temperature of windings by change-of-resistance method	P	P
11.2.2.1	Risk of fire in an oxygen rich environment - alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source	N/A	N/A
11.2.2.1	Risk of fire in an oxygen rich environment - alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source	---	N/A

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
*11.2.2.1 b)1)	Calculation of power, energy and temperature values in NORMAL CONDITION and SINGLE FAULT CONDITION (as identified in 11.2.3)	---	N/A
*11.2.2.1 b)2)	Measurement of oxygen concentration in compartments that contain parts or components that can be a source of ignition only under SINGLE FAULT CONDITION and that can be penetrated by oxygen (e.g. because of an undetected leak)	---	N/A
*11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS	---	N/A
*11.3	Constructional requirements for fire enclosures of ME equipment (IEC 60695-11-10, FV-1 test)	N/A	P
11.6.2	Overflow in ME Equipment	---	N/A
11.6.3	Spillage on ME Equipment and ME System	---	N/A
11.6.5	Ingress of water particulate maater into ME Equipment and ME system (IEC 60529)	---	N/A
11.6.6	Cleaning and disinfection of ME Equipment and ME systems	---	P
11.6.7	Sterilization of ME equipment and ME system	N/A	N/A
11.7	Biocompatibility of ME Equipment and ME system (ISO 10993)	---	N/E
*11. 8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	---	P
12	**Accuracy of controls and instruments and protection against hazardous outputs**	---	---
12.4.5.2	Diagnostic X-ray equipment - (IEC 60601-1-3)	---	N/A
13	**HAZARDOUS SITUATIONS and fault conditions for ME Equipment**	---	---
13.1.2	Measurement of 15 W / 900 J power dissipation limits (to justify waiving of the tests of 4.7, 8.1 b), 8.7.2, and 13.2.2)	---	P
13.2.1	SINGLE FAULT CONDITIONS - General	P	P
13.2.2	Electrical single fault conditions according to 8.1	---	P
13.2.3	Overheating of transformers according to 15.5	---	N/A
13.2.4	Failure of thermostats according to 13.2.13 & 15.4.2, overloading - thermostats short circuited or interrupted, the less favorable of the two	---	N/A
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, thermostats short circuited or interrupted, the less favorable of the two:	---	P
13.2.6	Leakage of liquid - risk management file examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	N/A	N/A
13.2.7	Impairment of cooling that could result in a hazard using test method of 11.1:	---	N/A
	Single ventilation fans locked consecutively	---	N/A

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
	Ventilation openings on top and sides impaired by covering openings on top of enclosure or positioning of ME equipment against walls	---	N/A
	Simulated blocking of filters	---	N/A
	Flow of a cooling agent interrupted	---	N/A
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below	---	N/A
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	---	N/A
13.2.10 a to d	Additional test criteria for motor operated ME equipment in 13.2.8 &13.2.9:	---	N/A
	For every test in single fault condition of 13.2.8 and 13.2.9, motor-operated equipment stared from cold condition at rated voltage or at the upper limit of rated voltage range for specified time:	---	N/A
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, thermal cut-outs, motor protective devices	---	N/A
	Temperatures measured as specified in 11.1.3 d)	---	N/A
	Temperatures did not exceed limits of Table 26	---	N/A
13.2.11	Failures of components in ME equipment used in conjunction with oxygen rich environments:	---	N/A
13.2.12	Failure of parts that might result in a mechanical hazard (See Clauses 9 & 15.3):	---	P
*13.2.13.1	General overload test conditions	---	P
*13.2.13.2	ME EQUIPMENT with heating elements	---	P
*13.2.13.3	ME EQUIPMENT with motors	---	N/A
*13.2.13.4	ME EQUIPMENT RATED for non-CONTINUOUS OPERATION	---	N/A
15	**Construction of ME EQUIPMENT**	---	---
15.3.2	Push test	---	P
15.3.3	Impact test	---	P
15.3.4.1	Drop test - HAND-HELD ME EQUIPMENT	---	P
15.3.4.2	Drop test - Portable ME equipment	---	N/A
15.3.5	Rough handling test	---	N/A
15.3.6	Mould stress relief test	---	P
15.4.1	Construction of connectors	P	N/A
15.4.2.1 b)	THERMAL CUT-OUTS with a safety function	---	N/A
*15.4.2.1 f)	Use of a THERMAL CUT-OUT or OVER-CURRENT RELEASE	---	N/A
*15.4.2.1 g)	Test with fluid-filled containers of heating equipment emptied	---	N/A
15.4.3.4	Lithium battery packs (tests of IEC 60086-4 or IEC 61233)	---	N/A
15.4.3.5	Short-circuit of INTERNAL ELECTRICAL POWER SOURCE output connectors	---	N/A
15.4.6.1	Fixing, prevention of maladjustment – torque and axial pull tests	---	N/A

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
15.4.6.2	Limitation of movement	---	N/A
15.4.7.1 b)	Mechanical strength - Foot-operated control device supported an actuating force of 1350 N for 1 min	---	N/A
*15.4.7.2	Accidental operation of ME EQUIPMENT - Control device of hand-held and Foot-Operated	---	N/A
*15.4.7.3 b)	Cord-connected HAND-HELD and foot-operated control devices (Entry of liquids tests of IEC 60529)	---	N/A
15.4.9	Oil containers – leakage test	---	N/A
15.5.1.2	Overheating Transformer short circuit test - short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION	---	N/A
15.5.1.3	Transformer overload test – conducted only when protective device under short-circuit test operated	---	N/A
15.5.2	Dielectric strength – Transformer (after humidity preconditioning as per clause 5.7)	---	N/A
16	**ME SYSTEM**	---	---
*16.5	Separation Device (tests of 8.8 and 8.9)	---	N/A
*16.6.1	TOUCH CURRENT measurements from or between parts of the ME SYSTEM within the PATIENT ENVIRONMENT	---	N/A
*16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of an ME SYSTEM in NORMAL CONDITION	---	N/A
*16.8	Interruption of the power supply to parts of an ME SYSTEM	---	N/A
17	**Electromagnetic compatibility**	---	---
17	Electromagnetic compatibility of ME equipment and ME systems (IEC 60601-1-2)	N/E	N/E

*** NOTE: When a clause is preceded with a star (*) in the above table, there is no corresponding test results tables in the TRF. Use Test Results table SP at the end of the TRF.**

* N/E can only be used for clauses: 11.7 (Bio-Compatibility), 7.1.1 and 12.2 (Usability) and 17 (Electromagnetic Compatibility) for ME Equipment and ME System

** N/E can be used for some risk management clauses concerning the component type SMPS this ensuring that RM clauses will be addressed through additional engineering judgement or other means

SUMMARY OF TESTS (IEC 60601-1-11 Standard)

CSA / ANSI/AAMI / IEC CLAUSE	CLAUSE INFORMATION	VERDICT (P, F, N/A or N/E)	
		Risk Management	Testing
4	**General requirements**	---	---
4.2.1	Permissible environmental conditions of transport and storage	N/A	P
4.2.2	Permissible environmental conditions under normal use	N/A	P
4.2.3	Environmental operating conditions than indicated in 4.2.2	---	N/A
7	**ME Equipment identification, marking and documents**	---	---
7.4.1	Additional requirements for warning and safety notices	P	---
7.4.5	Additional requirements for operating instructions	P	---
8	**Protection against excessive temperatures and other hazards**	---	---
8.4	Additional requirements for interruption of power supply / supply mains to ME Equipment and ME Systems	N/A	---
10	**Construction of ME Equipment**	---	---
10.1.2 a	Shock test (IEC 60068-2-27:2008), using the following conditions	---	P
10.1.2 b	Broad-band random vibration test (IEC 60068-2-64:2008) using the following conditions	---	P
10.1.3 a 1	Shock test (IEC 60068-2-27:2008) for other than HAND-HELD EQUIPMENT, parts, and mounting ACCESSORIES under the following conditions (Test Type 1)	---	N/A
10.1.3 a 2	Shock test (IEC 60068-2-27:2008) on other than HAND-HELD ME EQUIPMENT, parts, and mounting ACCESSORIES under the following conditions (Test Type 2)	---	N/A
10.1.3 b 1	Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 1)	---	N/A
10.1.3 b 2	Shock test (IEC 60068-2-27:2008) on HAND-HELD ME EQUIPMENT parts, and mounting ACCESSORIES using the following conditions (Test Type 2)	---	N/A
10.1.3 c	Broad-band random vibration test (IEC 60068-2-64:2008) on ME EQUIPMENT, parts, and mounting ACCESSORIES using the following conditions	---	N/A
10.1.3 d	Free fall test (IEC 60068-2-31:2008), using PROCEDURE 1, on PORTABLE and MOBILE ME EQUIPMENT, parts, and mounting ACCESSORIES (with carrying case if intended), under the following conditions	---	N/A
11	**Protection against strangulation or asphyxiation**	---	---
11.0	PROTECTION AGAINST STRANGULATION AND ASPHYXIATION	P	---

---End of Report---