



IEC 60601-1
TEST REPORT
Medical Electrical Equipment

Master Contract-Report: 245877
Project: 2134719

TABLE OF CONTENTS
This Report includes the following parts:

	Content Summary of this document (Index 2) of CSA/IEC 60601-1 (A1+A 2): PART I - Test-Reports Forms (TRF)	Pages
	Document Control Content	1 to 8

Index	Subject	Total pages
1	CB Test Certificate	-- pages
2	CSA/IEC 60601-1 (A1+A 2): PART I - Test-Reports Forms (TRF)	46 pages
3	IEC 60601-1 PART I: National Deviation Checklist - CB Bulletin 112A	-- pages
4	IEC 60601-1-X PART I: Collaterals - Test-Reports Forms (TRF)	-- pages
5	IEC 60601-2-X PART 2 Test Reports Forms (TRF)	-- pages
6	IEC 60601-2-X PART 2: National Deviation Checklist - CB Bulletin 109A	-- pages
7	Photographs	4 pages
8	Electrical Schematics / Drawings and Illustrations	18 pages
9	CSA Certification and Description Report	-- pages
10	Operation Manual / Service manual	61 pages
11	Approval Licences/Certificates and Component Specifications	-- pages
12	Additional Information	-- pages
*13	Original Test Data	-- pages
*14	Obsolete pages	-- pages

Note: * These documents are kept internally at CSA International.

History Record

<p>Edition 1: February 27, 2009; CSA Project 2134719 Issued by Dennis Smith; Reviewed by M. Brossoit</p> <p><u>Brief Summary:</u> Custom testing to only the part 1 standard. No CSA Certification to be issued</p>	
CB Testing Laboratory.....	CSA INTERNATIONAL
Address	2912 Kraft St., Suite 10, Arlington TX 76010
Testing location	INTERTest Systems
Testing location/procedure....	CBTL <input type="checkbox"/> RMT <input type="checkbox"/> SMT <input type="checkbox"/> WMT <input checked="" type="checkbox"/> TMP <input type="checkbox"/>
Testing location/Address....	1490 Garden of the Gods, Colorado Springs, CO

Classification Summary			
Subject		Type/Degree/Mode	Comments
1-	Type of protection against electric shock of Equipment:	Class II	--
2-	Degree of protection against electric shock of Applied Part:	B	Applies to all parts
3-	Degree of protection against harmful ingress of water:	Not rated	
4-	Protection of Ignition of Flammable Anaesthetic Mixtures: Category AP/APG equipment - Equipment which is suitable for use in a Flammable Anaesthetic Mixtures with Air, Oxygen or Nitrous Oxide:	--	Not rated
5-	Mode of operation:	Continuous	--
6-	Environmental Conditions:(Normal:10-40°C, 30-75% rH, 700-1060hPa) or Special)	Normal	--

Summary of applicable standards*/clauses* to evaluated product			
Subject		Information	
The product was investigated to the following applicable clauses or collateral standards:		Applicable to product (Yes/No)	Part of this evaluation/report (Yes/No)
1-	Biocompatibility (Clause 48) as per ISO 10993-1	Yes	No
2-	Medical Electrical Systems as per IEC 60601-1-1	No	--
3-	Electromagnetic Compatibility (Clause 36) as per IEC 60601-1-2	Yes	No
4-	Radiation Protection in Diagnostic X-ray Equipment as per IEC 60601-1-3	No	--
5-	Programmable Electrical Medical Systems (Clause 52.1) as per IEC 60601-1-4	Yes	No
6-	Usability as per IEC 60601-1-6	Yes	No
7-	Alarm Systems in Electrical Medical Equipment/Systems as per IEC 60601-1-8	No	--
The product was investigated to the following additional particular standards:			
8-	Particular requirements of Electrical Medical Equipment as per IEC 60601-2-X		
	a) --	--	--
	b) --	--	--
9-	Other applicable standards		
	a) IEC 60950	--	--

Note *: It is to the responsibility of the submitter of this product to ensure that all applicable standards to his product shall be performed as indicated in the above guidance document entitled Summary of applicable standards/clauses to evaluated product.

Additional Considerations: (Delete accordingly if not applicable)	
1-	The above units are evaluated or use with the submitter's products only, where the suitability of each combination is to be determined by the Accepting NCB.
2-	The product was tested in a branch circuit protected by a 20/15 A circuit breaker. Additional evaluation shall be conducted if a higher protector is to be used in the end system.
3-	CSA cannot be held liable or responsible for standards/clauses which were applicable to the product but were not mandated by the submitter to be evaluated by CSA. Refer to Summary of applicable standards*/clauses* to evaluated product.
Summary of compliance with additional National Differences:	
No national differences were evaluated	


TEST EQUIPMENT LIST

Test Equipment	Manufacturer/Model	Asset Number	Calibration date		Comments
			Last ¹	Due	
Digital multi-meter	Wavetek, 27XT	E-045	3-2008	March 4,2009	
Digital multi-meter	Tektronix, TX3	E-137	6-2008	June 2, 2009	
Current clamp	Unitest, CHB35	E-101	12-08	Dec. 2009	
601 leakage circuit	--	--	--	--	
Datalogger	Omega, MDS41-TC	E-126	3-2008	March 4, 2009	
Dielectric withstand tester	Associate Research, 3565D	E-008	10-2008	Oct. 3,2009	
Force gauge	Shimpo, FGE-100	M-002	3-2008	March 6, 2009	
Impact hammer	ED&D	M-009	12-2008	Dec.10, 2009	
1) or interval between calibrations.					

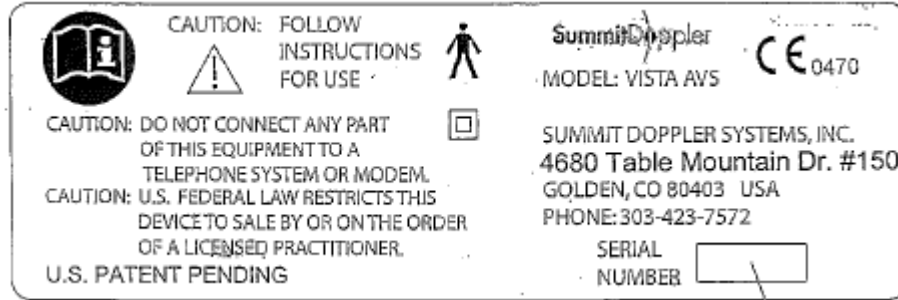
SUMMARY OF TESTS

CSA / UL / IEC CLAUSE	CLAUSE INFORMATION	TEST VERDICT		
		P	F	N/A
6.1	Label Rub Test for External Labels	X		
7	Power Input	X		
15 b)	Limitation of Voltage and / or Energy			X
15 c)	Internal Capacitor Discharge Test			X
16 a)	Enclosure Test			X
18	Protective Earthing (Ac Power supply)			X
19	Leakage Current	X		
20	Dielectric Strength	X		
21 a) b) c)	Rigidity, Impact, Handle Loading	X		
21.3	Weight Application to an Immobilization or Patient Support Unit			X
21.5	Hand Held Drop Test (Applied parts)	X		
21.6	Rough Handling of Portable and Mobile Equipment	X		
24.1-24.3	Stability Test (10 degree Tip or alternative under 24.3)	X		
28	Suspended Masses			X
29	X-Radiation			X
42	Excessive Temperatures	X		
44.2	Overflow of Liquid Reservoir			X
44.3	Spillage, for Equipment Using or Handling Liquids			X
44.4	Leakage, for Equipment Using or Handling Liquids			X
44.5	Humidity	X		
44.6	Ingress of Liquids as per IEC 60529			X
44.7	Cleaning, Sterilization, Disinfection			X
45.2	Pressure			X
45.7	Pressure Relief Device Test			X
49.1	Cut-Outs / Overprotection in Power Supply			X
49.2	Safe Operation During Power Interruption	X		
52.5	Abnormal Operation			X
52.5.1	Overloading of Mains transformer in Equipment			X
52.5.2	Failure of Thermostats			X
52.5.3	Short-Circuit of part of Double Insulation.			X

CSA / UL / IEC CLAUSE	CLAUSE INFORMATION	TEST VERDICT		
		P	F	N/A
52.5.4	Interruption of Protective Earth Conductor (CI 19.4)			X
52.5.5	Impairment of Cooling			X
52.5.6	Locking of Moving Parts			X
52.5.7	Short-Circuiting of Motor capacitors			X
52.5.8	Additional Test for Motor Operated Equipment			X
52.5.9	Failure of Components			X
52.5.10 a)	Overload - Having Heating Elements			X
52.5.10 b)	Overload - Motors			X
55	Enclosures: Conductive Coating			X
	Flammability Test			X
	Mold Stress Relief Distortion Test (UL 746C)			X
	Impact and Drop (see also CI 21)			X
56.6	Temperature & Overload Control Devices			X
56.10 b) c)	Prevention of Maladjustment of Controls and Knobs			X
56.11 a)	Hand-Held or Foot Operated Devices	X		
56.11 b)	Foot-Controls withstand 1350N for 1 Min			X
57.4 a)	Strain Relief Test	X		
57.4 b)	Bending Cord Test			X
57.9 a)	Transformer Short Circuit Tests			X
57.9 b)	Transformer Overload Tests			X
57.9.2	Induced Dielectric Strength Test for Transformer			X
57.9.4 e)	Dielectric Strength for Double or Reinforced Transformer			X
59.2 b) (1) or (2)	Enclosure Ball Pressure Test			X
59.2 c)	Rubber Insulation Aging Test			X
60DV.1.2.3	Direct Plug-In Power Supply (UL 1310)			X
Test Case Verdict :				
N/A (Not applicable) - Test case does not apply to the test object				
P (Pass) - Test item does meet the requirements				
F (Fail) - Test item does not meet the requirements				

TEST REPORT IEC 60601-1 Medical electrical equipment Part 1: General requirements for safety	
Report reference No.:	245877-2134719 (Project 2134719)
Compiled by (+ signature).....:	Dennis Smith 
Reviewed by (+ signature)	Michel Brossoit <i>M. Brossoit</i>
Approved by (+ signature).....:	N/A
Date of issue	February 27, 2009
Testing laboratory	CSA International
Address	2912 Kraft St., Suite 10, Arlington TX 76010
Testing location	INTERTest Systems 1490 Garden of the Gods, Colorado Springs, CO
Applicant	Summit Doppler Systems, Inc.
Address	4680 Table Mountain Dr., #150, Golden CO 80403
Standard.....	IEC 601-1:1988 + A1:1991 + A2:1995
Test Report Form No.:	I601-1_C/97-04
TRF Originator	Underwriters Laboratories Inc.
Master TRF	dated 97-04
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	CB Scheme
Procedure deviation	(applicable countries)
Non-standard test method	(other standard apart from the IEC 60601-1 series standards)
Type of test object.....:	Arterial examination system
Trademark.....:	--
Model/type reference	VISTA AVS
Manufacturer	Summit Doppler
Address	As above
Rating.....:	External adaptor rated 100-240 Vac, 50-60 Hz, 1.2 A; output 7 Vdc, 5.0 A

Copy of marking plate:



GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use	: mobile
Supply connection	: Cord connected (ac adaptor)
Accessories and detachable parts included in the evaluation :	Handpiece part no.SD8B Pendant remote Blood pressure cuff, part no. CUF0004, with hose ASY0008 PPG part no. SPPG
Options included	: None
Possible test case verdicts:	
- test case does not apply to the test object	: (N/ A) N/A
- test object does meet the requirement	: (Pass) P
- test object does not meet the requirement	: (Fail) F
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:	
<p>"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IEC 60601-1-2".</p> <p>"(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 shall be part of this document or can be kept on file and available for review. Summary of contents provided in the first pages of this report.</p>	
<p>General product information and considerations: The device is for detection of blood flow in veins and arteries using bi-directional Doppler ultrasound, arterial photoplethysmograph, and a pressure system. The system is powered by an external adaptor, and consists of a plastic enclosure housing various printed wiring boards, battery, etc, all mounted on a five leg pole.</p> <p>Enclosure dimensions: 10" H x 12" W x 3.6"D, 4.75 lbs, stand 47" H</p> <p>Only part 1 of the standard was considered during this investigation.</p>	

IEC 60601 + Am1& 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.)	No	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	No alternative construction	N/A
5	CLASSIFICATION		---
5.1	Type of protection against electric shock		P
	Class I equipment		N/A
	Class II equipment		P
	Internally powered equipment		N/A
5.2	Degree of protection against electric shock		P
	Type B applied part		P
	Type BF applied part		N/A
	Type CF applied part		N/A
	Not classified - no applied parts		N/A
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)	Unit is IPX0	N/A
5.4	Methods of sterilization or disinfection	Manual page 38	P
5.5	Equipment not suitable for use in the presence of flammable mixtures	Not suitable for use with flammable mixtures	N/A
	Category AP equipment		N/A
	Category APG equipment		N/A
5.6	Mode of operation:		P
	-continuous operation	Continuous use	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		—

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	permissible loading/rest time		

INSULATION DIAGRAM

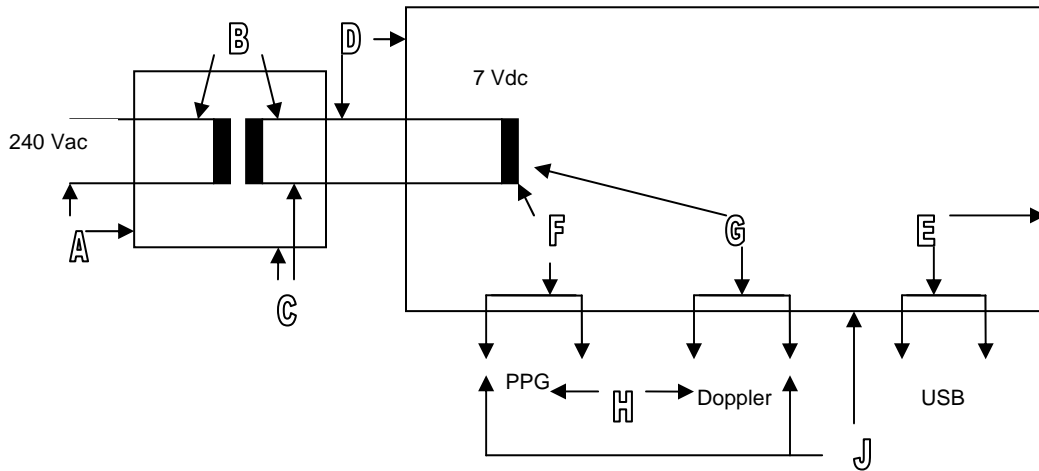


Table: to insulation diagram							P
Area	Insulation type: basic / supplementary / double / reinforced	Reference voltage (V)	Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
A	BI	240	3	1.6	--	--	Certified external adaptor
B	RI	240	8	5	--	--	Certified external adaptor
C	BI	7	4	2.5	--	--	Certified external adaptor
D	BI	7	1.7	0.8	4	2	
E	BI	7	1.7	0.8	5	2	
F	BI	7	1.7	0.8	1.8	--	
G	BI	7	1.7	0.8	1.8	--	
H	BI	7	1.7	0.8	2.0	1.0	
J	BI	7	1.7	0.8	2.0	--	

NOTES:

- As no particular standards were considered for this evaluation insulation between applied parts (B-b) was evaluated as basic.

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM CONVENTIONS

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

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

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

6	IDENTIFICATION, MARKING AND DOCUMENTS		---
6.1	Marking on the outside of equipment or equipment parts		P
	c) Markings of the specific power supply affixed	Powered from mains	N/A
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		P
	e) Name and/or trademark of the manufacturer or supplier.....:	SummitDoppler	P
	f) Model or type reference	VISTA AVS	P
	g) Rated supply voltages or voltage range(s)	Marked on external adaptor	P
	Number of phases	Single phase	N/A
	Type of current.....:		N/A
	h) Rated frequency or rated frequency range(s) (Hz)		P
	j) Rated power input (VA, W or A).....:		P
	k) Power output of auxiliary mains socket-outlets	None	N/A
	l) Class II symbol	Provided	P
	Symbol for degree of protection against ingress of water provided	Not required for IPXO	P
	Symbol for protection against electric shock	Type B	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	All applied parts have same rating	N/A
	Symbol for protection of defibrillation-proof applied parts	Not defibrillation proof	N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
	m) Mode of operation (if no marking, suitable for continuous operation)	Continuous	N/A
	n) Types and rating of external accessible fuses ...:	None	N/A
	p) Ratings of external output	Function of all connections marked	N/A
	q) Symbol for physiological effect(s):		N/A
	- attention, consult accompanying documents		N/A
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	r) Anaesthetic-proof symbol: AP or APG		N/A
	s) Dangerous voltage symbol		N/A
	t) Special cooling requirements		N/A
	u) Limited mechanical stability		N/A
	v) Protective packing requirement(s)		N/A
	- Marking(s) for unpacking safety hazard(s)		N/A
	- Equipment or accessories supplied sterile, marked as sterile		N/A
	y) Potential equalization terminal		N/A
	- Functional earth terminal		N/A
	z) Removable protective means		N/A
	Durability of marking test	(see appended table 6)	P
6.2	Marking on the inside of equipment or equipment parts		P
	a) Nominal voltage of permanently installed equipment	Cord connected	N/A
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements	N/A
	c) Dangerous voltage symbol		N/A
	d) Type of battery and mode of insertion	Doppler type B200	P
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator	May be changed by user	N/A
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram		N/A
	f) Protective earth terminal		N/A
	g) Functional earth terminal		N/A
	h) Supply neutral conductor in permanently installed equipment (N)		N/A
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed		N/A
	- Markings comply with IEC 445		N/A
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)		N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	l) Statement for suitable wiring materials at temperatures over 75 °C		N/A
	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c		N/A
6.3	Marking of controls and instruments		P
	a) Mains switch clearly identified		P
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light	ON/OFF symbol IEC 60417-5010 used	P
	b) Indication of different positions of control devices and switches	Volume knob is only control	P
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device		P
	f) The functions of operator controls and indicators are identified		P
	g) Numeric indications of parameters are in SI units except for units listed in Am. 2	None provided	N/A
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	Colors of the insulation of conductors		P
	a) Protective earth conductor has green/yellow insulation	Internal to external adaptor	P
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		P
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		P
	d) Color of neutral conductor	Blue	P
	e) Colors of phase conductor(s)	Brown	P
	- Compliance with IEC 227 and IEC 245		P
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N/A
6.6	Medical gas cylinders and connections		N/A
	a) In accordance with ISO ISO/R 32	No gasses used	N/A
	b) Identification of connection point		N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
6.7	Indicator lights and push-buttons		P
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	No red indicators	N/A
	- Yellow used to indicate caution or attention required	Battery charging and low battery indicators	P
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency	No such push-buttons	N/A
6.8	ACCOMPANYING DOCUMENTS		P
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	User's Manual provided	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		P
	Warning statements and the explanation of warning symbols provided in the accompanying documents		P
6.8.2	Instructions for use		P
	a) General information provided in instructions for use		P
	- state the function and intended application of the equipment	Page 3, 7	P
	- include an explanation of: the function of controls, displays and signals	Section 5	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	No consumables	N/A
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	None stated	N/A
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety		P

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance		P
	General information provided in instructions:		P
	- 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	Section 13	P
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	Pages 43 and 44	P
	c) Signal output or signal input parts intended only for connection to specified equipment described	USB port described, page 44 and 45	P
	d) Details about acceptable cleaning, disinfection or sterilization methods included	Section 13	P
	e) Warning statement for mains operated equipment with additional power source	Battery is maintained in a charged state	N/A
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	No primary batteries, rechargeable type used	N/A
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	Page 40 and 41	P
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	Doppler, type B200	P
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	Page 41	P
	- Advice in minimizing these risks	Refer to local regulations	P
6.8.3	Technical description		P
	a) All characteristics essential for safe operation provided		P
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N/A
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	Parts do not typically deteriorate	N/A
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	Parts of accessories and contact info provided	P

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		P

7	POWER INPUT		---
	Power Input Measurements	(see appended table 7)	P

10	ENVIRONMENTAL CONDITIONS		---
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	No special requirements	P
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment	Not hand held	N/A
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA		N/A
	Rated voltage not exceeding 500 V for all other equipment		N/A
	Rated input frequency not more than 1kHz		N/A
10.2.2b	Internal replaceable electrical power source specified		P

14	REQUIREMENTS RELATED TO CLASSIFICATION		---
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection	Double insulated	P
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard		N/A
14.5b	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	Enclosure is equivalent to reinforced insulation	P
14.6c	Applied parts intended for direct cardiac application are of type CF	No type CF parts	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
15	LIMITATION OF VOLTAGE AND/OR ENERGY		---
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	(see appended table 15b)	P
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ	(see appended table 15c)	N/A
	Marking provided for manual discharging		N/A

16	ENCLOSURES AND PROTECTIVE COVERS		---
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	Fully enclosed with no openings. Tool required to access battery	P
	Insertion or removal of lamps - protection against contact with live parts provided	No lamps	N/A
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	No openings	N/A
16c	Conductive parts accessible after the removal of handles, knobs, levers		N/A
	- have a resistance of not more than 0.2 Ω	(see appended table 18)	N/A
	- separated from live parts by one of the means described in Sub-clause 17g	No handles knobs or levers	N/A
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact		N/A
16e	Removable enclosures protecting against contact with live parts		P
	- Removal possible only with the aid of a tool	Tool required to open	P
	- Use of automatic device making parts not live when the enclosure is opened or removed		N/A
	- Exception 16e applied to the following parts :		N/A
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No such adjustments	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
17	SEPARATION		---
17a	Separation method of the applied part from live parts:		P
	1) basic insulation: applied part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N/A
	4) by double or reinforced insulation	AC adaptor provide RI	P
	5) by protective impedances limiting current to applied part		N/A
	- Additional leakage current test in single fault conditions	(see appended table 19)	N/A
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		P
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)	No such shafts	N/A
17g	Separation method of accessible parts other than applied parts from live parts:		P
	1) basic insulation: accessible part earthed		N/A
	2) by protectively earthed conductive part (e.g. screen)		N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N/A
	4) by double or reinforced insulation		P
	5) by protective impedances limiting current to accessible part		N/A
	- Additional leakage current test in single fault conditions	(see appended table 19)	N/A
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:		N/A
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator	(see appended table 17h1)	N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function	(see appended table 17h2)	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
18	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		---
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	No earthing in the device	N/A
18b	Protective earth terminals suitable for connection to the protective earth conductor		N/A
18e	Potential equalization conductor		N/A
	- Readily accessible		N/A
	- Accidental disconnection prevented in normal use		N/A
	- Conductor detachable without the use of a tool		N/A
	- Power supply cord does not incorporate a potential equalization conductor		N/A
	- Connection means marked with Symbol 9, Table DI		N/A
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1 \Omega$	(see appended table 18)	N/A
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \Omega$	(see appended table 18)	N/A
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2 \Omega$	(see appended table 18)	N/A
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition	(see appended table 18 and 19)	N/A
18k	Functional earth terminal not used to provide protective earthing		N/A
18l	Class II equipment with isolated internal screens		N/A
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N/A
	- functional earth terminal clearly marked		N/A
	- explanation of functional earth terminal provided in the accompanying documents		N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

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

20	DIELECTRIC STRENGTH		---
	Overall compliance with Clause 20	(see appended table 20)	P

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

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

22	MOVING PARTS		---
22.2a	Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	No moving parts	N/A
22.2b	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation		N/A
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N/A
	Guides or other safeguards are removable only with a tool		N/A
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N/A
22.6	Parts of equipment subject to mechanical wear are accessible for inspection		N/A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N/A
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard		N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N/A
	Means for stopping of movements operate as a result of one single action		N/A

23	SURFACES, CORNERS AND EDGES		---
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	All edges smooth and rounded	P

IEC 60601 + Am1& 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/A
	- does not overbalance when tilted through an angle of 5° in any position excluding transport		N/A
	- carry a warning notice stating that transport should only be undertaken in a certain position		N/A
	- in the position specified for transport does not overbalance when tilted to an angle of 10°		N/A
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:		N/A
	- suitable handling devices (grips etc.), or		N/A
	- instructions for lifting and handling during assembly		N/A
24.6b	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/A

25	EXPELLED PARTS		---
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	No CRTs, etc.	N/A
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

28	SUSPENDED MASSES		---
28.3	Suspension system with safety device		N/A
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with Sub-clause 28.4		N/A
	Safety device has safety factors complying with Sub-clause 28.4.2		N/A
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N/A
28.4	Suspension systems of metal without safety devices		N/A
	1) Total load does not exceed the safe working load		N/A
	2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N/A
	3) Safety factors not less than 8 where impairment is expected		N/A
	4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		N/A
	5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		N/A

29	X-RADIATION		---
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)	(see appended table 29)	N/A

36	ELECTROMAGNETIC COMPATIBILITY		---
	Equipment complies with IEC 601-1-2	(see Attachment #) Not evaluated	N/A

37	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		---
	Requirements for category AP and APG equipment (Cl. 37 - 41)	(see Attachment #)	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

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	(see appended table 42)	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	No hot surfaces	N/A

43	FIRE PREVENTION		---
	Strength and rigidity necessary to avoid a fire hazard	Refer to tests of clause 21	P

44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION		---
44.2	Equipment contain a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overflow steadily over a period of 1 min	(see appended table 44)	N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)	(see appended table 44)	N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)	(see appended table 44)	N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard	(see appended table 44)	N/A
44.5	Equipment sufficiently protected against the effects of humidity	(see appended table 44)	P
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	(see appended table 44)	N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	(see appended table 44)	P

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

45	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		---
45.2	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure	(see appended table 45)	N/A
45.3	Maximum pressure does not exceed the maximum permissible working pressure for individual parts		N/A
45.7	Unless excessive pressure can not occur, pressure-relief device provided		N/A
45.7a	Pressure-relief device connected as close as possible to the pressure vessel		N/A
45.7b	Readily accessible for inspection		N/A
45.7c	Not capable of being adjusted or rendered inoperative without a tool		N/A
45.7d	Discharge opening located that the released material is not directed towards person		N/A
45.7e	Discharge opening located that operation will not deposit material which may cause a safety hazard		N/A
45.7f	Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure		N/A
45.7g	No shut-off valve between a pressure-relief device and the parts intended to be protected		N/A
45.7h	Minimum number of cycles of operation: 100.000	(see appended table 45)	N/A

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	(see Attachment #) Not evaluated	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

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	No hazard from loss of function	P
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/A

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	Multiple intensity outputs not provided	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
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 Cl. 13)	(see appended table 52)	N/A
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	(see Attachment #)	N/A
52.5.2	Failure of thermostats presents no safety hazards	(see appended table 52)	N/A
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard	(see appended table 19)	N/A
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	(see appended table 52)	N/A
52.5.6	Locking of moving parts presents no safety hazard	(see appended table 52)	N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	(see appended table 52)	N/A
52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8		N/A
52.5.9	Failure of one component at a time presents no safety hazard	(see appended table 52)	N/A
52.5.10	Overload of heating elements presents no safety hazard	(see appended table 52)	N/A
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection		N/A
	h) Equipment with three-phase motors can safely operate with one phase disconnected	(see appended table 52)	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
56	COMPONENTS AND GENERAL ASSEMBLY		---
	List of critical components	(see appended table 56)	P
56.1b	Ratings of components not in conflict with the conditions of use in equipment	AC adaptor is approved for medical use	P
	Ratings of mains components are identified		P
56.1d	Components, movements of which could result in a safety hazard mounted securely	All components soldered to PWB or mounted with screws	P
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		P
56.3a	Connectors provide separation required by Sub-clause 17g	All connectors in SELV circuits	P
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	Doppler and PPG connectors are interchangeable. Dielectric and leakage repeated with connectors swapped	P
	Medical gas connections not interchangeable	No gas used	N/A
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	All are in SELV circuits	P
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	No conductive patient connections	N/A
56.4	Connections of capacitors		P
	Not connected between live parts and non-protectively earthed accessible parts	No such capacitors	N/A
	If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14		N/A
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts	In approved AC adaptor	P
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs		N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	No such devices used	P

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
56.6	Temperature and overload control devices		N/A
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment	None provided	N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		N/A
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N/A
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		N/A
	Non-self resetting over-current releases operated 10 times		N/A
56.6b	Thermostats with varying temperature settings clearly indicated		N/A
	Operating temperature of thermal cut-outs indicated		N/A
56.7	Batteries		P
	a) Battery compartments:		P
	- adequately ventilated	Sealed batteries used	N/A
	- accidentally short-circuiting is prevented		P
	b) Incorrect polarity of connection prevented	Keyed connector used	P
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):		P
	- to indicate that equipment is energized	On and Charging indicators	P
	- to indicate the operation of non-luminous heaters if a safety hazard could result		N/A
	- to indicate when output exists if a safety hazard could result		N/A
	- charging mode indicator provided		P
56.10	Actuating parts of controls	(see appended table 56.10)	P
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use	Volume control is in an SELV circuit	P
	Controls are secured to prevent the movement relative to scale marking (safety related only)		P

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Detachable indicating devices are prevented from incorrect connection without the use of tool		P
56.10c	Stops are provided on rotating controls:		P
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard	Potentiometer used for volume control	P
	- to prevent damage to wiring		P
56.11	Cord-connected hand-held and foot-operated control devices		P
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g	Pendant is in SELV circuit	P
	b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5		P
	- Foot-operated control devices designed to support the weight of an adult human being	(see appended table 56.11b)	N/A
	c) Devices not change their setting when inadvertently placed		P
	d) Foot-operated control devices are at least IPX 1	(see appended table 44)	N/A
	- For surgical use, electrical switching parts are IPX 8		N/A
	e) Adequate strain relief at the cord entry provided	(see appended table 57.4)	P

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
57	MAINS PARTS, COMPONENTS AND LAYOUT		---
57.1	Isolation from supply mains		P
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Cord connected	P
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		P
	d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328	Switches not used for disconnection	N/A
	f) Mains switches not incorporated in a power supply cord		P
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		P
	m) Fuses and semiconductor devices not used as isolating devices		P
57.2	Mains connectors and appliance inlets		P
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug	No auxiliary outlets	N/A
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment	Power supply is considered class I	P
57.3	Power supply cords		P
	a) Not more than one connection to a particular supply mains		P
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously		N/A
	The mains plug has only one power supply cord		P
	Non-permanently connected equipment provided with power supply cord or appliance inlet		P
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		P
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C	Temperatures do not exceed 75°C	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		P
	d) Stranded conductors not soldered if fixed by any clamping means		P
57.4	Connection of power supply cords		N/A
57.4a	Cord anchorages		N/A
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	(see appended table 57.4) Adaptor has appliance inlet	N/A
	Tying the cord into a knot or tying the ends with string not used		N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N/A
	Cord anchorages made of metal provided with an insulating lining		N/A
	Clamping screws do not bear directly on the cord insulation		N/A
	Screws associated with cable replacement are not used to secure other components		N/A
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals		N/A
57.4b	Power supply cord protected against excessive bending	(see appended table 57.4b)	N/A
57.4c	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		N/A
57.5	Mains terminal devices and wiring of mains part		N/A
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws, nuts or equally effective methods	Not permanently connected	N/A
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		N/A
	Screws and nuts which clamp external conductors not serve to fix any other component		N/A
	b) Terminals closely grouped with any protective earth terminal		N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	Mains terminal devices accessible only with use of a tool		N/A
	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact		N/A
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N/A
	d) Cord terminals not require special preparation of the conductor		N/A
57.6	Mains fuses and overcurrent releases		P
	Fuses or over-current releases provided accordingly for Class I and Class II	Part of external adaptor	P
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		P
	Protective earth conductor not fused		P
	Neutral conductor not fused for permanently installed equipment		N/A
57.8	Wiring of the mains part		P
	a) Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 227 or 245, treated as bare conductor		P
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply cord		P
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits sufficient to prevent any fire hazard		P
57.9	Mains supply transformers		N/A
57.9.1	Overheating		N/A
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative	Part of external adaptor	N/A
57.9.1a	Short-circuit of secondary windings not caused excessive temperature	(see appended table 57.9.1a)	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
57.9.1b	Overload of secondary windings not caused excessive temperature	(see appended table 57.9.1b)	N/A
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	(see appended table 57.9.2)	N/A
57.9.4	Construction		N/A
	a) Separation of primary and secondary windings		N/A
	- separate bobbins or formers		N/A
	- one bobbin with insulating partition		N/A
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		N/A
	- concentrically wound on one bobbin with windings separated by double insulation		N/A
	c) Means provided to prevent displacement of end turns		N/A
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		N/A
	e) Insulation between the primary and secondary in transformers with double insulation		N/A
	- 1 insulation layer with thickness of at least 1 mm		N/A
	- at least 2 insulation layers with a total thickness of at least 0.3 mm		N/A
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation		N/A
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding		N/A
57.10	Creepage distances and air clearances		P
	a) Values: compliance with at least the values of Table XVI	(see table for insulation diagram)	P
	Creepage distances for slot insulation of motors at least 50% of the specified values		N/A
	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	(see appended table 52)	N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts		N/A
58	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		---
58.1	Clamping means of the protective earth terminal		N/A
	Not be able to loosen without the aid of a tool		N/A
	Screws for internal earth connections are covered or protected against loosening from outside		N/A
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal		N/A
58.8	The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing		N/A
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting		N/A

59	CONSTRUCTION AND LAYOUT		---
59.1	Internal wiring		N/A
	a) Cables and wiring protected against contact with a moving part	Part of external adaptor, wiring in unit is SELV	N/A
	Wiring having basic insulation only protected by additional fixed sleeving		N/A
	Components are not likely to be damaged in the normal assembly or replacement of covers		N/A
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead		N/A
	c) Insulating sleeving adequately secured		N/A
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test	(see appended table 20)	N/A
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N/A
	d) Aluminium wires of less than 16 mm ² cross-section not used		N/A
	f) Connecting cords between equipment parts considered as belonging to the equipment		N/A

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

59.2	Insulation		N/A
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	No insulation used	N/A
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		N/A
	Parts of rubber resistant to ageing		N/A
59.3	Excessive current and voltage protection		P
	Internal electrical power source provided with device for protection against fire hazard	PTC and thermistor are integral to battery pack	P
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder	No external fuses	N/A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.	None provided	N/A
59.4	Oil containers		N/A
	Oil containers adequately sealed		N/A
	Container allow for the expansion of the oil		N/A
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

6.1	TABLE: marking durability			P	
Marking tested		Remarks			
Nameplate		No smearing, curling or peeling			
Supplementary information: Lexsaver Overlaminat, vinyl 0.002 thickness					
Ambient Temperature (°C)	22	Relative Humidity (rH%)	46	Atmospheric Pressure (hPA)	980

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

7	TABLE: power input					P
Operating condition	Voltage	Frequency	Current	Power	Remarks	
Unit off, battery charging	7.35	DC	1.22	--		
Unit on, discharged battery	7.35	DC	0.35	--		
Unit on, printing	7.35	DC	0.72	--		
Supplementary information:						
Ambient Temperature (°C)	22	Relative Humidity (rH%)	46	Atmospheric Pressure (hPA)	980	

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

15b	TABLE: residual voltage in attachment plug										N/A
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
supply pins (pin 1 & pin 2)											
line pin 1 and enclosure											
line pin 2 and enclosure											
pin 1 and earth pin											
pin 2 and earth pin											
Supplementary information: Approved AC adaptor											
Ambient Temperature (°C)				Relative Humidity (rH%)				Atmospheric Pressure (hPA)			

15c	TABLE: residual voltage or energy in capacitors					N/A					
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (µF)	Residual energy (mJ)	Remarks						
Supplementary information:											
Ambient Temperature (°C)				Relative Humidity (rH%)				Atmospheric Pressure (hPA)			

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

18	TABLE: protective earthing				N/A
Test location	Test current (A)	Measured voltage (V)	Resistance (ohms)	Remarks	
Supplementary information: Device is not earthed					
Ambient Temperature (°C)		Relative Humidity (rH%)		Atmospheric Pressure (hPA)	

19	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)	Supply voltage	Supply frequency	Measured max. value	Remarks	
EN, B, S5-1, S-1	264	60	2.0		
EN, B, S5-1, S-0	264	60	2.7		
EN, B, S5-0, S-1	264	60	1.6		
EN, B, S5-0, S-0	264	60	2.7		
EN, B, S5-1, S-1, pendant control	264	60	1.4		
EN, B, S5-1, S-0, pendant control	264	60	2.1		
EN, B, S5-0, S-1, pendant control	264	60	1.3		
EN, B, S5-0, S-0, pendant control	264	60	2.1		
P, B, S5-1, S-1, Doppler	264	60	1.4		
P, B, S5-1, S-0, Doppler	264	60	2.0		
P, B, S5-0, S-1, Doppler	264	60	1.2		
P, B, S5-0, S-0, Doppler connected to PPG	264	60	1.9		
P, B, S5-1, S-1, Doppler connected to PPG	264	60	1.4	See 56.3a	
P, B, S5-1, S-0, Doppler connected to PPG	264	60	2.0	See 56.3a	
P, B, S5-0, S-1, Doppler connected to PPG	264	60	1.2	See 56.3a	
P, B, S5-0, S-0, Doppler	264	60	1.9	See 56.3a	
P, B, S5-1, S-1, PPG	264	60	1.4		
P, B, S5-1, S-0, PPG	264	60	2.4		

IEC 60601 + Am1& 2					
Clause	Requirement + Test			Result - Remark	Verdict
P, B, S5-0, S-1, PPG	264	60	1.1		
P, B, S5-0, S-0, PPG	264	60	1.8		
P, B, S5-1, S-1, PPG connected to Doppler	264	60	1.4		See 56.3a
P, B, S5-1, S-0, PPG connected to Doppler	264	60	2.4		See 56.3a
P, B, S5-0, S-1, PPG connected to Doppler	264	60	1.1		See 56.3a
P, B, S5-0, S-0, PPG connected to Doppler	264	60	1.8		See 56.3a
(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).					
<u>Abbreviations used:</u>					
ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA -Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device			A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition		
Ambient Temperature (°C)	22	Relative Humidity (rH%)	46	Atmospheric Pressure (hPA)	980

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

21	TABLE: mechanical strength				P
Part under test	Test (impact, drop, force, handle, rough handling, mobile)		Remarks		
Enclosure	Force (45 N)		Pass		
Enclosure	Impact (0.5 J impact hammer)		Pass		
Doppler	Drop (1 M)		Pass		
PPG	Drop (1 M)		Pass		
Unit on stand	Rough handling (20 mm step, 20 times)		Pass		
Supplementary information:					
Ambient Temperature (°C)	22	Relative Humidity (rH%)	46	Atmospheric Pressure (hPA)	980

24	TABLE: - stability				P
Part under test	Test condition		Remarks		
Unit on stand	Tilt all directions		Does not overturn		
Supplementary information:					
Ambient Temperature (°C)	22	Relative Humidity (rH%)	46	Atmospheric Pressure (hPA)	980

29	TABLE: X - radiation			N/A
Part under test	Test condition	Measured radiation (mR)	Remarks	
Supplementary information: None developed				
Ambient Temperature (°C)		Relative Humidity (rH%)		Atmospheric Pressure (hPA)

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

42	TABLE: normal temperature			F	
Supply voltage: 90 V, 60 Hz Ambient temperature: 20°C		Test Condition: See below			
Measuring location	Measured temperature [°C]	Compensated Temperature at 40 °C	Remarks		
Power supply case	30	50	Charging mode		
Battery	30	50	Charging mode		
Enclosure, top	27	47	Charging mode		
Doppler applied part	23	43	Charging mode		
PPG applied part	23	43	Charging mode		
Power supply case	30	50	Normal operation		
Battery	29	49	Normal operation		
Enclosure, top	26	46	Normal operation		
Doppler applied part	37	57**	Normal operation		
PPG applied part	24	44	Normal operation		
Supplementary information: **Procedures for temperature testing of ultrasound applied parts are found in IEC 60601-2-37 and should be noted					
Ambient Temperature (°C)	22	Relative Humidity (rH%)	46	Atmospheric Pressure (hPA)	980

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection			P	
Test type and condition		Part under test	Remarks		
Humidity		Entire unit	93% RH, 22 C, applied parts detached. See leakage and electric strength results		
Supplementary information: No reservoirs, or liquids used					
Ambient Temperature (°C)	22	Relative Humidity (rH%)	46	Atmospheric Pressure (hPA)	980

45	TABLE: hydrostatic pressure and pressure-relief device cycling test			N/A	
Test type and condition		Part under test	Test pressure	Remarks	
Supplementary information: No pressure vessels					
Ambient Temperature (°C)		Relative Humidity (rH%)		Atmospheric Pressure (hPA)	

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

56.1	TABLE: lists of critical component parts				P
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity ¹⁾
1: Enclosure	Summit Doppler	MPH0040 or MPH0041	<u>Type:</u> Stationary, Bench, Transportable, Mobile <u>Overall Dimensions:</u> 254 H x 305 W x 91 mm <u>Color:</u> Tan <u>Weight:</u> 2.2 (kg) <u>Vent Openings:</u> None	--	None
1.1 Plastic	Bayer	Bayblend FR110	V-2 minimum, minimum 1 mm thickness		UR
1.2 Rollout stand	Summit Doppler	K270	119 cm H with five 29 mm long wheeled legs		None
2: External adaptor	Ault	MW160	In: 100-240 Vac, 50-60 Hz, 1.2 A Out: 7 Vdc, 5.0 A Medical grade, SELV		cURus E145177 TUV CE
3. Printed wiring board	Sierra Midwest	PCB0017	Material: FR4 Dimensions:225 x 190 mm, 1.6 mm thick Flammability V-1 or V-0		UR Material
3.3 Pressure cuff pump	Oken Seiko Co.	P22DO1R	5 Vdc	--	Accepted
3.4 Solenoid	Pneutronics	910-000101- 008	3 Vdc,	--	Accepted
4: Display	APLUS Products	AG3224A-SMI	Dimensions: 160 x 109 x 13 mm 5 V 0.14 A STN NegativeType	--	Accepted
5. Battery	Energy Sales	ES3179	7.2 V, 2.15 Ah, NiMH rechargeable, overcurrent Raychem,	--	None

IEC 60601 + Am1& 2					
Clause	Requirement + Test			Result - Remark	Verdict
				LR4-550.	
Printer	Fujitsu	FTP-628MCL401	5 Vdc, 2 inch	--	Accepted
Pendant	Summit Doppler	FDX0021	Located in SELV circuit	--	Accepted
Doppler handpiece	Summit Doppler	SD8B, or SD5B	Type B, 5 MHz or MHz ultrasound probe	--	Accepted
PPG handpiece	Summit Doppler	SPPG	Type B	--	Accepted
Pressure Cuff	Summit Doppler	CUF000X, where X is 2, 3, 4, 5, 8, or 9	Non-electrical, blood pressure cuff	--	Accepted
¹⁾ an asterisk indicates a mark which assures the agreed level of surveillance					

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

56.10	TABLE: actuating parts and controls			N/A
Part under test	Torque applied		Remarks	
Supplementary information: Volume adjust is in SELV circuit				
Ambient Temperature (°C)		Relative Humidity (rH%)		Atmospheric Pressure (hPA)

56.11b	TABLE: foot operated control devices-loading			N/A
Part under test	Observed results		Remarks	
Supplementary information: None provided				
Ambient Temperature (°C)		Relative Humidity (rH%)		Atmospheric Pressure (hPA)

57.4	TABLE: cord anchorages					P
Cord under test	Mass of equipment	Pull	Torque	Remarks	Verdict	
Pendant control	0.5 kg	30 N	0.1 N-m	Per 56.11	Pass	
Supplementary information:						
Ambient Temperature (°C)	22	Relative Humidity (rH%)	46	Atmospheric Pressure (hPA)	980	

IEC 60601 + Am1& 2			
Clause	Requirement + Test	Result - Remark	Verdict

57.4b	TABLE: cord bending				N/A
Cord under test	Test mass	Measured curvature	Remarks		
Supplementary information: Mains connection is to appliance inlet in external adaptor					
Ambient Temperature (°C)		Relative Humidity (rH%)		Atmospheric Pressure (hPA)	

57.9.1a	TABLE: transformer short circuit					N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
Supplementary information: Part of external adaptor						
Ambient Temperature (°C)		Relative Humidity (rH%)		Atmospheric Pressure (hPA)		

57.9.1b	TABLE: overload						N/A
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cutout temp.	Remarks
		Primary	Secondary	Ambient			
Supplementary information: Part of external adaptor							
Ambient Temperature (°C)		Relative Humidity (rH%)		Atmospheric Pressure (hPA)			

IEC 60601 + Am1& 2					
Clause	Requirement + Test			Result - Remark	Verdict
57.9.2	TABLE: transformer dielectric strength				N/A
	Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks
Supplementary information:					
	Ambient Temperature (°C)		Relative Humidity (rH%)		Atmospheric Pressure (hPA)

TABLE: additional tests				N/A
Clause	Test type and condition	Remarks and observed results	Remarks	
Supplementary information:				
	Ambient Temperature (°C)		Relative Humidity (rH%)	Atmospheric Pressure (hPA)