



Test Report issued under the responsibility of:



Electrical &
Electronics

TEST REPORT

IEC 60601-1-12

Medical electrical equipment-

**Part 1-12: General requirements for basic safety and essential performance – Collateral Standard:
Requirements for medical electrical equipment and medical electrical systems intended for use in the
emergency medical services environment**

Report Number.....: EFSH26030113-IE-01-L04

Date of issue.....: 2026-09-09

Total number of pages.....: 31

Name of Testing Laboratory preparing the Report.....: Eurofins Electrical Testing Service (Shanghai) Co., Ltd

Applicant's name.....: GlobTek, Inc.

Address.....: 186 Veterans Dr. Northvale, NJ 07647 USA

Test specification:

Standard.....: IEC 60601-1-12:2014, AMD1:2020
for use in conjunction with IEC 60601-1:2005, AMD1:2012,
AMD2:2020

Test procedure.....: CB Scheme

Non-standard test method.....: N/A

TRF template used.....: IECEE OD-2020-F1:2020, Ed.1.3

Test Report Form No.: IEC60601_1_12B

Test Report Form(s) Originator: TÜV SÜD Product Service GmbH

Master TRF.....: 2020-10-15

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Test item description :	DC/DC Converter
Trade Mark(s)	
Manufacturer	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA
Model/Type reference :	GTD9X1002-****, GTD9X1003-****, 8016-000102 The 1st * can be “001” to “100”, denotes the rated output wattage designation from 1W to 100W, with a step of 1, which denotes 1W. The 2nd * can be “12” to “54” or “12.0” to “54.0”, denotes the standard rated output voltage designation from 12.0V to 54.0Vdc, with a step of 0.1, which denotes 0.1V. The 3th * denotes the input structure, =-TW denotes input with wires, =-TWC denotes input with wires and a cigarette lighter plug installed The last * denotes any six characters, which can be 0-9 or A-Z or ()[] or – or blank for marketing purposes.
Ratings :	For GTD9X1002-****, GTD9X1003-**** Input: 12-28Vdc, 12.0A Output: 12.0-54.0VDC, Max. 8.33A, Max. 100W For 8016-000102 Input: 12-28Vdc, 12.0A Output: 15.0VDC, 4.0A, 120W(Peak)

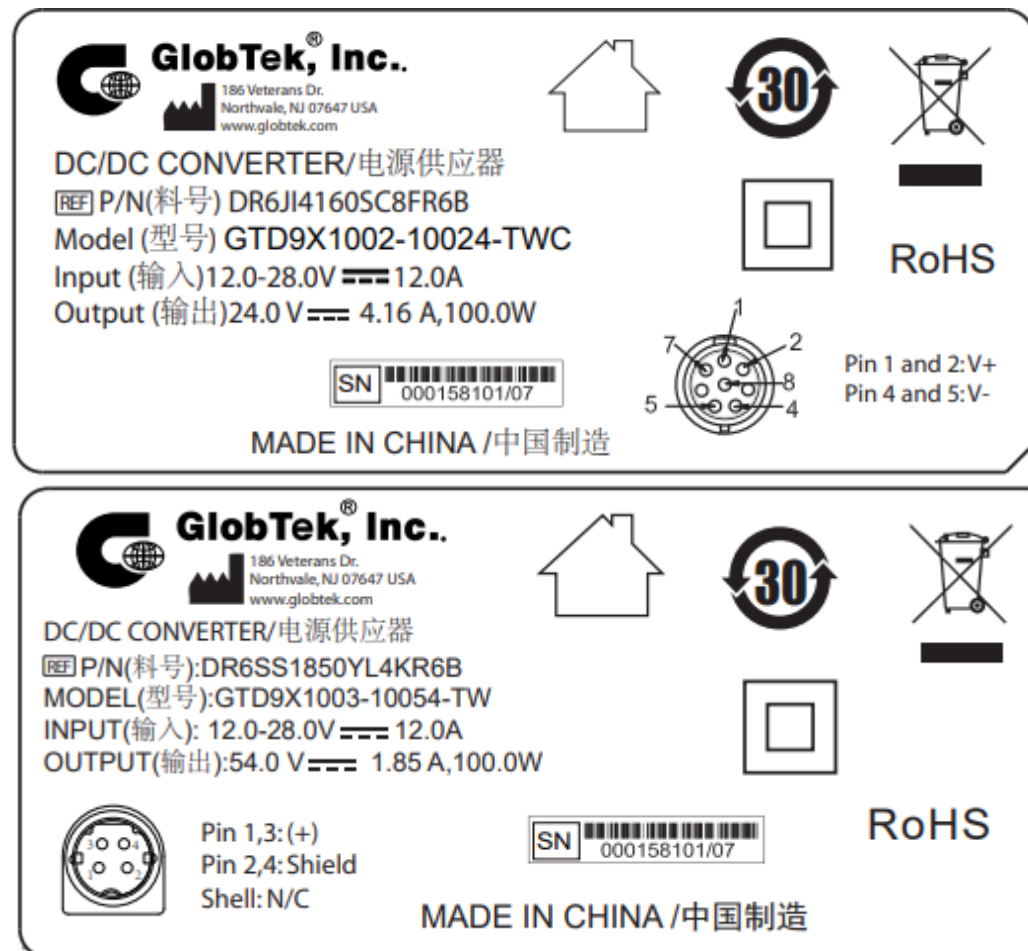
Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):		
☒	CB Testing Laboratory:	Eurofins Electrical Testing Service (Shanghai) Co., Ltd
Testing location/ address		Room 102/501/502, Building 18, No. 2168 Chenhong Highway, Minhang District, Shanghai, China
Tested by (name, function, signature).....		Jack Gan Project Manager 
Approved by (name, function, signature) ..		Jackie Zhao Reviewer 
☐	Testing procedure: CTF Stage 1:	N/A
Testing location/ address		N/A
Tested by (name, function, signature).....		N/A
Approved by (name, function, signature) ..		N/A
☐	Testing procedure: CTF Stage 2:	N/A
Testing location/ address		N/A
Tested by (name + signature)		N/A
Witnessed by (name, function, signature) .		N/A
Approved by (name, function, signature) ..		N/A
☐	Testing procedure: CTF Stage 3:	N/A
☐	Testing procedure: CTF Stage 4:	N/A
Testing location/ address		N/A
Tested by (name, function, signature).....		N/A
Witnessed by (name, function, signature) .		N/A
Approved by (name, function, signature) ..		N/A
Supervised by (name, function, signature) :		N/A

List of Attachments (including a total number of pages in each attachment): N/A	
Summary of testing:	
Tests performed (name of test and test clause): All applicable tests.	Testing location: Eurofins Electrical Testing Service (Shanghai) Co., Ltd Room 102/501/502, Building 18, No. 2168 Chenhang Highway, Minhang District, Shanghai, China
Summary of compliance with National Differences (List of countries addressed): EU Group, Switzerland (CH): no national differences. US (United States of America), Canada (CA), Japan (JP): no national differences in IECEE website. ☒ The product fulfils the requirements of <u>EN 60601-1-12: 2015+A1:2020, SN EN 60601-1-11:2015</u>	
Statement concerning the uncertainty of the measurement systems used for the tests (may be required by the product standard or client) ☐ Internal procedure used for type testing through which traceability of the measuring uncertainty has been established: Procedure number, issue date and title: Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing. ☒ Statement not required by the standard used for type testing (Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)	

Copy of marking plate:

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

(Typical)

**Note:**

1, Markings of other models are similar as above except model name and made in nation.

Test item particulars..... :	
Classification of installation and use..... : transportable	
Supply Connection : DC connector :	
Possible test case verdicts: - test case does not apply to the test object..... : N/A - test object does meet the requirement..... : P (Pass) - test object does not meet the requirement..... : F (Fail)	
Testing..... : Date of receipt of test item : 2026-03-09 Date (s) of performance of tests : 2026-03-09 to 2026-06-11	
General remarks: "(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. Throughout this report a ☐ comma / ☐ point is used as the decimal separator. This report is only valid in conjunction with IEC 60601-1 test report EFSH26030113-IE-01-L01.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC 60601-1:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided	☒ Yes ☐ Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) : 1. GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA 2. GlobTek (Suzhou) Co., Ltd. Building 4, No. 76 JinLing East Road, Suzhou Industrial Park, Suzhou, JiangSu, 215021, China 3. AMETEK Reynosa TSE, Inc Avenida Los Encinos Manzana #1, Lot 3, Parque Industrial Villa Florida, Reynosa, Tamaulipas C.P. 88730 Mexico	
General product information and other remarks: Refer to IEC 60601-1 test report EFSH26030113-IE-01-L01.	

IEC 60601-1-12			
Clause	Requirement - Test	Result - Remark	Verdict
4	GENERAL REQUIREMENTS		-
4.1	Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS		P
	Characteristics of SUPPLY MAINS specified in 4.10.2 of Part 1 applied, except ME EQUIPMENT or ME SYSTEMS intended for EMS ENVIRONMENT complies with the following:		P
	– SUPPLY MAINS in the EMS ENVIRONMENT did not exceed 110 % or was not below 85 % of NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (% V)..... :	10.2-30.8 V	P
	- RATED range of NOMINAL voltage did include at least 12.4 V to 15.1 V for operation from a 12 V dc supply mains		P
	- RATED range of NOMINAL voltage did include at least 24.8 V to 30.3 V for operation from a 24 V dc supply mains		N/A
	The equipment maintained BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 10 V from a 12 V dc SUPPLY MAINS		P
	The equipment maintained BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 20 V from a 24 V dc SUPPLY MAINS		P
	- For ME EQUIPMENT or ME SYSTEMS intended to be powered from an aircraft, the SUPPLY MAINS shall comply with Section 16 of either EUROCAE ED-14G or RTCA DO-160G.		N/A
4.2.1	Environmental conditions of transport and storage between uses		P
	Permissible environmental conditions of transport and storage of ME EQUIPMENT indicated in Instructions for use		P
	temperature range: -40 °C to + 5 °C		N/A
	temperature range: +5 °C to +35 °C at a non-condensing relative humidity up to 90%		N/A
	temperature range: >35 °C to 70 °C at a water vapour pressure up to 50 hPa		N/A
	For more restricted range of environmental transport and storage conditions between uses, the environmental conditions are specified		P
	– Justified in the RISK MANAGEMENT FILE	See RISK MANAGEMENT Table 4.2.1	P
	– Marked on the ME EQUIPMENT		P
	When not practicable, the more restricted range is disclosed in the instructions for use		P

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Clause	Requirement - Test	Result - Remark	Verdict
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses		N/A
	Symbol 5.3.5 (ISO 7000-0534), 5.3.6 (ISO 7000-0533), or 5.3.7 (ISO 7000-0632) of ISO 15223-1:2012 used to mark temperature range		P
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 used to mark humidity range		P
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 used to mark atmospheric pressure range		P
	Where ME EQUIPMENT used different marking for conditions of transport and storage between uses, continuous operating conditions and transient operating conditions, markings accompanied by supplementary markings except where the respective applicability was obvious		N/A
	Environmental transport and storage test		P
	a) ME EQUIPMENT prepared for transportation or storage according to instructions for use		P
	b) ME EQUIPMENT exposed to its lowest specified environmental transport and storage conditions (temperature 0_{-4}°C) ($^{\circ}\text{C}$)..... :	-40	P
	– For at least 16 h or, ensure ME EQUIPMENT reached THERMAL STABILITY for at least 2 h		P
	c) Then ME EQUIPMENT exposed to $34^{\circ}\text{C} \pm 4^{\circ}\text{C}$ and 93% $\pm 3\%$ relative humidity until the test chamber reached equilibrium and held for at least 2 hours. The transition from low to high temperature was made slowly enough to provide a non-condensing environment.		P
	d) ME EQUIPMENT exposed to its highest specified environmental transport and storage conditions, not requiring a water vapour pressure greater than 50 hPa (temperature 4_0°C); ($^{\circ}\text{C}$, $\pm\%$)..... :	80	P
	– For at least 16 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h		P
	e) At the end of this conditioning period, ME EQUIPMENT allowed to return and stabilize at the operating conditions of NORMAL USE		P
	f) ME EQUIPMENT evaluated to its specifications and ensured it provides BASIC SAFETY and ESSENTIAL PERFORMANCE		P
4.2.2.1	Environmental operating conditions - Continuous operating conditions		P

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Clause	Requirement - Test	Result - Remark	Verdict
	Instructions for use indicate the permissible continuous environmental operating conditions of the ME EQUIPMENT.	Indicated in the IFU: -10 – 40°C, 0 - 95%, 54 kPa – 106 kPa	P
	ME EQUIPMENT complied with its specifications and all requirements of the standard when operated in NORMAL USE within temperature 0 °C to +40 °C,		N/A
	Relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and		N/A
	An atmospheric pressure range of 620 hPa to 1060 hPa		N/A
	For more restricted range of environmental operating conditions:		P
	- justified in the risk management file;	See RISK MANAGEMENT Table 4.2.2.1	P
	-marked on the equipment; or were not practical in the instructions for use.....:	In the instructions for use	P
	– Marked on the carrying case when the instructions for use indicate the ME EQUIPMENT is intended to be operated in a carrying case		N/A
	Symbol 5.3.5 (ISO 7000-0534), 5.3.6 (ISO 7000-0533), or 5.3.7 (ISO 7000-0632) of ISO 15223-1:2012 used to mark temperature range		P
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 used to mark humidity range		P
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 used to mark atmospheric pressure range		P
	Where ME EQUIPMENT used different marking for conditions of continuous operating conditions and transient operating conditions, markings accompanied by supplementary markings		N/A
	If readings or performance vary when operated in NORMAL USE under the specified environmental operating conditions:		N/A
	Table of correcting values disclosed in the instructions for use		P
	Table indicates the extent of the variation		P
	Environmental operating conditions test		P
	a) ME EQUIPMENT was set up for operation according to INTENDED USE		P
	b) ME EQUIPMENT exposed to 20 °C ± 4 °C for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h, (h)..... :	6 h	P

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Clause	Requirement - Test	Result - Remark	Verdict
	c) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	d) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE while at the lowest specified atmospheric pressure.		P
	e) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE while at the highest specified atmospheric pressure.		P
	f) Pressure in chamber relieved		P
	g) ME EQUIPMENT cooled to its lowest specified environmental operating conditions (temperature 0_{-4}°C and relative humidity $\leq 15\%$)		P
	h) ME EQUIPMENT held at lowest specified environmental operating conditions for at least 6 h or, ensured the ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	6 h	P
	i) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	j) ME EQUIPMENT warmed to its highest specified continuous environmental operating conditions (temperature 4_0°C)		P
	k) ME EQUIPMENT held the conditions of j) for at least 6 h or, ensured the ME EQUIPMENT reached THERMAL STABILITY for at least 2 h	6 h	P
	l) ME EQUIPMENT met its specifications and BASIC SAFETY and ESSENTIAL PERFORMANCE		P
4.2.2.2	Transient operating conditions		P
	Instructions for use indicate permissible transient environmental operating conditions of EMS ENVIRONMENT ME EQUIPMENT		P
	ME EQUIPMENT complied with its specifications and all requirements of the standard when operated in NORMAL USE for at least 20 min within temperature -20°C to $+50^{\circ}\text{C}$,		P
	Relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and		P
	For more restricted range of environmental operating conditions		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	- justified in the risk management file;	See RISK MANAGEMENT Table 4.2.2.2	N/A
	-marked on the equipment; or were not practical in the instructions for use.....:		N/A
	Symbol 5.3.5 (ISO 7000-0534), 5.3.6 (ISO 7000-0533), or 5.3.7 (ISO 7000-0632) of ISO 15223-1:2012 used to mark temperature range		N/A
	Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 used to mark humidity range		N/A
	Symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 used to mark atmospheric pressure range		N/A
	Where ME EQUIPMENT used different marking for conditions of continuous operating conditions and transient operating conditions, markings accompanied by supplementary markings		N/A
	Transient operating conditions test		P
	a) ME EQUIPMENT exposed to $20\text{ }^{\circ}\text{C} \pm 4\text{ }^{\circ}\text{C}$ for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h, (h).....:	6 h	P
	b) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE		P
	c) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE for 20 min while at the lowest specified transient environmental operating conditions (temperature $0_{-4}\text{ }^{\circ}\text{C}$ and relative humidity $\leq 15\%$)		P
	d) ME EQUIPMENT exposed to $20\text{ }^{\circ}\text{C} \pm 4\text{ }^{\circ}\text{C}$ for at least 6 h or, ensured ME EQUIPMENT reached THERMAL STABILITY for at least 2 h, (h).....:	2 h	P
	e) ME EQUIPMENT evaluated to its specifications and ensured it continued to provide BASIC SAFETY and ESSENTIAL PERFORMANCE for 20 min while at the highest specified transient environmental operating conditions (temperature $4_0\text{ }^{\circ}\text{C}$)		P

5	CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS		-
	TRANSPORTABLE ME EQUIPMENT intended for EMS ENVIRONMENT classified as follows:		P
	– CLASS II or INTERNALLY POWERED	For Class II models	P
	– Not provided with a FUNCTIONAL EARTH TERMINAL		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	– When equipped with APPLIED PARTS, they are TYPE BF or CF		N/A

6	ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS		-
6.1	Additional requirements for legibility of markings		P
	Markings, controls and displays on the outside of the ME EQUIPMENT necessary for operation of the ME EQUIPMENT clearly legible in twilight and full daylight :	See Appended Table 6.1	P
6.2	Additional requirements for marking of IP classification		N/A
	In addition to requirements of 7.2.9 of the general standard, the carrying case provided some or all of the ingress protection against water or particulate matter, The ENCLOSURE is marked with the safety sign ISO 7010-W001 and “keep dry” or		N/A
	Symbol ISO 15223-1:2012, 5.3.4 (ISO 7000-0626)		N/A
	A carrying case marked with degree of protection		N/A
	Carrying case inspected, and tests and criteria of 7.1.2 and 7.1.3 of Part 1 applied.....	See IEC 60601-1 Test report, Sub-clauses 7.1.2 and 7.1.3	N/A
6.3	Instructions for use		P
6.3.1	Additional general requirements		N/A
	– intended medical indication	Power supply, to be evaluated in the final installation	N/A
	– intended PATIENT population		N/A
	– intended part of the body or type of tissue applied to or interacted with		N/A
	– intended OPERATOR PROFILE		N/A
	– intended conditions of use; including		N/A
	1) Whether ME EQUIPMENT is to be FIXED, PERMANENTLY INSTALLED or TRANSPORTABLE.....		N/A
	2) The type of ambulance for which the ME EQUIPMENT is intended		N/A
6.3.2	Additional requirements for an electrical power source		N/A
	When BASIC SAFETY or ESSENTIAL PERFORMANCE depends on the INTERNAL ELECTRICAL POWER SOURCE, the instructions for use describes the following:	No INTERNAL ELECTRICAL POWER SOURCE	N/A
	– Typical operation time or number of procedures....		N/A
	– Typical service life of the INTERNAL ELECTRICAL POWER SOURCE; and		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	– Behaviour of ME EQUIPMENT while the rechargeable INTERNAL ELECTRICAL POWER SOURCE is charging		N/A
6.3.3	Additional requirements for ME EQUIPMENT start-up PROCEDURE		P
	– Understandable diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment		P
	– the time from switching “ON” until the ME EQUIPMENT is ready for NORMAL USE, when it exceeds 15 s (see 15.4.4 of Part 1) (s)		N/A
	-the time required for ME EQUIPMENT to warm from the minimum storage temperature between uses until it is ready for intended use; and	To be evaluated in end-product	N/A
	-the time required for ME EQUIPMENT to cool from the maximum storage temperature between uses until it is ready for intended use; and	To be evaluated in end-product	N/A
6.3.4	Additional requirements for operating instructions		P
	Instructions for use include a description of generally known conditions in the EMS ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT		P
	The steps that can be taken by the OPERATOR to identify and resolve the above conditions		P
	- The effects of lint, dust, light (including sunlight), etc.		P
	- A list of known devices or other sources that can potentially cause interference problems		P
	- The effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems		P
	The instructions for use explain the meaning of the IP classification marked on the ME EQUIPMENT, and on any carrying case provided with the ME EQUIPMENT as applicable	See RISK MANAGEMENT Table 6.3.4	P
6.3.5	Additional requirements for ME EQUIPMENT messages		P
	Instructions for use include a troubleshooting guide for use when there are indications of a ME EQUIPMENT malfunction during start-up or operation		P
	Troubleshooting guide discloses the necessary steps in the event of a TECHNICAL ALARM CONDITION		P
6.4	Technical description – FIXED or PERMANENTLY INSTALLED CLASS I ME EQUIPMENT		N/A
	The technical description for FIXED or PERMANENTLY INSTALLED CLASS I ME EQUIPMENT includes:	Not CLASS I ME EQUIPMENT	N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	– A warning indicating the ME EQUIPMENT installation, including a correct PROTECTIVE EARTH CONNECTION, must only be carried out by qualified SERVICE PERSONNEL		N/A
	– Specifications of the PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR		N/A
	– A warning to verify the integrity of the external protective earthing system		N/A
	– A warning to connect and verify that the PROTECTIVE EARTH TERMINAL of the FIXED or PERMANENTLY INSTALLED ME EQUIPMENT is connected to the external protective earthing system		N/A

7	PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT		-
	ME EQUIPMENT intended for the EMS ENVIRONMENT other than PERMANENTLY INSTALLED or FIXED, the pollution degree classification of insulation for MEANS OF OPERATOR PROTECTION within ME EQUIPMENT is pollution degree 3, or	Pollution degree 2 (Enclosure IP54)	P
	The ENCLOSURE of insulation relied upon provides IP54 ingress protection	IP54	P

8	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS		-
8.1	Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		P
8.1.1	Ingress of water or particulate matter into ME EQUIPMENT		P
	TRANSPORTABLE ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529 for at least IP 33 ..		P
	For PORTABLE ME EQUIPMENT intended to be used only while in a carrying case, IP33 met with the ME EQUIPMENT in its the carrying case		N/A
	FIXED or PERMANENTLY INSTALLED ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529 for at least IP 22	IP54	P
	Maintenance of BASIC SAFETY and ESSENTIAL PERFORMANCE VERIFIED		P
8.1.2	Ingress of water or particulate matter into ME SYSTEMS		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	ENCLOSURES of the non-ME EQUIPMENT parts of the ME SYSTEMS provide the degree of protection against harmful ingress of water or particulate matter equivalent to equipment complying with their respective IEC or ISO safety standards	Not ME SYSTEM	N/A
	Tests of IEC 60529:1989 conducted with the equipment placed in the least favourable position of NORMAL USE and the ENCLOSURES inspected		N/A
8.2	Additional requirements for interruption of the power supply to ME EQUIPMENT and ME SYSTEM		N/A
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT maintained its ESSENTIAL PERFORMANCE for a sufficient time or for a sufficient number of PROCEDURES when loss or failure of SUPPLY MAINS or near depletion INTERNAL ELECTRICAL POWER SOURCE occurred	to be evaluated in the final installation	N/A
	The time or number of PROCEDURES remaining allowed alternative life-supporting methods to be employed		N/A
	Optionally, an INTERNAL ELECTRICAL POWER SOURCE was used to maintain ESSENTIAL PERFORMANCE		N/A
	Optionally, independent means were used to provide ESSENTIAL PERFORMANCE		N/A
	Instructions for use disclose the time or number of procedures available following a loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE		N/A
	Instructions for use describes the alternative life-supporting methods to be employed		N/A
	The technical description describes methods that can be employed for longer periods		N/A
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT with no INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION indicating power failure		N/A
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an automatic switchover from the SUPPLY MAINS to INTERNAL ELECTRICAL POWER SOURCE		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT with an INTERNAL ELECTRICAL POWER SOURCE is equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION indicating the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for operation		N/A
	TECHNICAL ALARM CONDITION provides sufficient time or sufficient number of procedures for a LAY OPERATOR to act		N/A
	A TECHNICAL ALARM CONDITION of at least LOW PRIORITY remained active until the INTERNAL ELECTRICAL POWER SOURCE returned to a level above the ALARM LIMIT or until depleted		N/A
	It was not possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION		N/A
	Functional tests conducted, and the RISK MANAGEMENT FILE inspected	See RISK MANAGEMENT Table 8.2	N/A
8.3	Additional requirements for INTERNAL ELECTRICAL POWER SOURCE for ME EQUIPMENT		N/A
	ME EQUIPMENT other than FIXED or PERMANENTLY INSTALLED is capable of being powered in its INTENDED USE for at least 20 min from an INTERNAL ELECTRICAL POWER SOURCE..... :	No INTERNAL ELECTRICAL POWER SOURCE	N/A
	ME EQUIPMENT provided with a means for the OPERATOR to determine state of the INTERNAL ELECTRICAL POWER SOURCE when the is essential for BASIC SAFETY or ESSENTIAL PERFORMANCE or to control risks associated with loss of ESSENTIAL PERFORMANCE		N/A
	State of INTERNAL ELECTRICAL POWER SOURCE indicated by:		N/A
	- number of PROCEDURES remaining;		N/A
	- remaining operating time;		N/A
	- percentage of the remaining operating time or energy; or		N/A
	- "fuel" gauge		N/A
	Instructions described method to determine state of INTERNAL ELECTRICAL POWER SOURCE		N/A
9	Accuracy of controls and instruments and protection against hazardous outputs		-

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Clause	Requirement - Test	Result - Remark	Verdict
	The risks associated with usability in the EMS ENVIRONMENT include at least the following considerations:		P
	– changes of controls		N/A
	– unexpected movement		P
	– potential for misconnection		P
	– potential for improper operation, or unsafe use		P
	– potential for confusion as to current operational mode		N/A
	– need for an indication to ensure that state of a control is correctly perceived by the OPERATOR		N/A
	– exposure to environmental conditions specified in this standard		P
	– change in the transfer of energy or substance, and		N/A
	– exposure to biological materials		N/A
	Particular emphasis placed on the situational urgency of the EMS ENVIRONMENT.		P
	Usability engineering file inspected for compliance..... :		P

10	CONSTRUCTION OF ME EQUIPMENT		-
10.1	Additional requirements for mechanical strength of ME EQUIPMENT intended for the EMS ENVIRONMENT		P
10.1.1	General requirements for mechanical strength		P
	Table 1 shows the relationship between the mechanical strength test of the general standard and this standard.		P
	For the purposes of the tests of Clause 10, HAND-HELD ME EQUIPMENT shall be considered TRANSPORTABLE ME EQUIPMENT.		N/A
10.1.2	Requirements for mechanical strength for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT intended for use in a road ambulance		N/A
	FIXED or PERMANENTLY INSTALLED ME EQUIPMENT, its parts, and mounting ACCESSORIES and mounting ACCESSORIES in a road ambulance displayed adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact and rough handling	Not for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT	N/A
	Requirement also applies to the means to permit the attachment of mounting ACCESSORIES of TRANSPORTABLE ME EQUIPMENT.		N/A
	ME EQUIPMENT and mounting ACCESSORIES maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008		N/A
	1) Test type: Type 1..... :	See Appended Table 10.1.2a1	N/A
	2) Test type: Type 2..... :	See Appended Table 10.1.2a2	N/A
	b) Broad-band random vibration tests conducted in accordance with IEC 60068-2-64:2008	See Appended Table 10.1.2b	N/A
10.1.3	Requirements for mechanical strength for TRANSPORTABLE ME EQUIPMENT		P
	TRANSPORTABLE ME EQUIPMENT and its parts, including mounting ACCESSORIES displayed adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling during transportation.		P
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		P
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008		P
	1) Test type: Type 1..... :	See Appended Table 10.1.3a1	P
	2) Test type: Type 2..... :	See Appended Table 10.1.3a2	N/A
	b) Broad-band random vibration tests conducted in accordance with IEC 60068-2-64:2008	See Appended Table 10.1.3b	P
	c) Free fall tests conducted in accordance with IEC 60068-2-31:2008, using PROCEDURE 1	See Appended Table 10.1.3c	P
	BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained		P
10.1.4	Requirements for mechanical strength for ME EQUIPMENT intended for airborne use		N/A
	ME EQUIPMENT and its parts, including mounting ACCESSORIES displayed adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling.	to be evaluated in the final installation	N/A
	Technical description disclosed the type of aircraft for which the ME EQUIPMENT has been qualified		N/A
	ME EQUIPMENT maintained BASIC SAFETY and ESSENTIAL PERFORMANCE after mechanical tests		N/A
	a) Shock tests conducted in accordance with IEC 60068-2-27:2008		N/A
	1) Test type: Type 1..... :	See Appended Table 10.1.4a1	N/A
	2) Test type: Type 2..... :	See Appended Table 10.1.4a2	N/A

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Clause	Requirement - Test	Result - Remark	Verdict
	b) Vibration tests in accordance with Section 8, Table 8-1, of either EUROCAE ED-14G or RTCA DO-160G (Category S for fixed wing or Category U for rotary wing)..... :	Component power supply, to be evaluated in the final installation	N/A
	BASIC SAFETY and ESSENTIAL PERFORMANCE were maintained		N/A
10.2	Requirements for mounting of ME EQUIPMENT		N/A
	ME EQUIPMENT, other than HAND-HELD or BODY-WORN ME EQUIPMENT equipped with means to permit the attachment of mounting ACCESSORIES.		N/A

11	Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS		-
	ME EQUIPMENT and ME SYSTEMS intended for EMS ENVIRONMENT are Class B according to CISPR 11:2009..... :		N/E
	Me equipment and me systems intended for aircraft use comply with Section 21, Category M of EUROCAE ED-14G or RTCA DO-160G for ELECTROMAGNETIC EMISSIONS..... :		N/E

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Clause	Requirement - Test	Result - Remark	Verdict

4.2.1	RM RESULTS TABLE: Permissible environmental conditions of transport and storage, between uses, indicated in instructions for use		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
5.2	GT-RM2026-001 & 5	Intended operating conditions are recorded	P
5.3	GT-RM2026-001 & 6.2.3	Environmental hazards and contributory factors	P
5.4	GT-RM2026-001 & 6.3	Estimation of the risk(s) for each hazardous situation, No. 12	P
5.5	GT-RM2026-001 & 6.4	Estimation of the risk situation	P
Supplementary information:			

4.2.2.1	RM RESULTS TABLE: Environmental operating conditions - Continuous operating conditions		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
5.2	GT-RM2026-001 & 5	Intended storage and transportation conditions are recorded	P
5.3	GT-RM2026-001 & 6.2.3	Environmental hazards and contributory factors	P
5.4	GT-RM2026-001 & 6.3	Estimation of the risk(s) for each hazardous situation, No. 12	P
5.5	GT-RM2026-001 & 6.4	Estimation of the risk situation	P
Supplementary information:			

4.2.2.2	RM RESULTS TABLE: Environmental operating conditions - Transient operating conditions		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2	GT-RM2026-001 & 2	Evaluation team member qualification	P
4.3	GT-RM2026-001 & 2	Evaluation team member qualification	P
4.4	GT-RM2026-001 & 3	Risk management process	P
Supplementary information:			

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Clause	Requirement - Test	Result - Remark	Verdict

6.1	TABLE: Additional requirements for legibility of markings		P
Marking tested		Ambient illuminance (lx)	Remarks
Outside Markings..... :		10-10000	Legible
Controls & Displays :		--	--
Supplementary information:			
Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 10 lx to 10.000 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.			

6.3.4	RM RESULTS TABLE: Additional requirements for operating instructions		P
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
5.2	GT-RM2026-001 & 5	Intended use	P
5.3	GT-RM2026-001 & 6.1.29	Questionnaires according to intended use	P
5.4	GT-RM2026-001 & 6.3	Estimation of the risk(s) for each hazardous situation	P
5.5	GT-RM2026-001 & 6.4	Estimation of the risk situation	P
6	GT-RM2026-001 & 7	Risk evaluation	P
7.2	GT-RM2026-001 & 8.1	Risk reduction analysis	P
7.3	GT-RM2026-001 & 8.2	Residual risk evaluation	P
7.4	GT-RM2026-001 & 8.3	Risk/benefit analysis	P
7.5	GT-RM2026-001 & 8.1	Risk reduction analysis	P
7.6	GT-RM2026-001 & 10	Risk Management Conclusion	P
Supplementary information:			

8.2	RM RESULTS TABLE: Additional requirements for interruption of the power supply to ME EQUIPMENT and ME SYSTEM		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			

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Clause	Requirement - Test	Result - Remark	Verdict
8.2	RM RESULTS TABLE: Additional requirements for interruption of the power supply to ME EQUIPMENT and ME SYSTEM		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result – Remarks	Verdict
6.3			
6.4			
6.5			
6.6			
6.7			
Supplementary information:			

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Clause	Requirement - Test	Result - Remark	Verdict

[illegible]

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Clause	Requirement - Test	Result - Remark	Verdict

10.1.2a2	TABLE: Shock test (IEC 60068-2-27:2008) for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT and mounting ACCESSORIES intended for use in a road ambulance under the following conditions (Test Type 2):		N/A
	Peak acceleration	300 m/s ² (30 g)	
	Duration.....	6 ms	
	Pulse shape	half-sine	
	Number of shocks.....	3 shocks per direction per axis (18 total)	
Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
Supplementary information:			

IEC 60601-1-12			
Clause	Requirement - Test	Result - Remark	Verdict
10.1.2b	TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT and mounting ACCESSORIES intended for use in a road ambulance under the following conditions*:		N/A
1	Acceleration amplitude	10 Hz to 100 Hz: 1,0 (m/s ²) ² /Hz	
2	Acceleration amplitude	100 Hz to 200 Hz: - 3 dB per octave	
3	Acceleration amplitude	200 Hz to 2 000 Hz: 0,5 (m/s ²) ² /Hz	
	Duration.....	30 min per perpendicular axis (3 total)	
Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
1			
2			
3			
1			
2			
3			
1			
2			
3			
Supplementary information: *(NOTE 2 This represents Class 7M2 as described in IEC/TR 60721-4-7:2001)			

IEC 60601-1-12			
Clause	Requirement - Test	Result - Remark	Verdict

10.1.3a1	TABLE: Shock test (IEC 60068-2-27:2008) for TRANSPORTABLE ME EQUIPMENT and its parts, including mounting ACCESSORIES under the following conditions* (Test Type 1):		P
	Peak acceleration	300 m/s ² (30 g)	
	Duration.....	11 ms	
	Pulse shape	half-sine	
	Number of shocks.....	3 shocks per direction per axis (18 total)	
Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
+	X	Yes	3 shocks
-	X	Yes	3 shocks
+	Y	Yes	3 shocks
-	Y	Yes	3 shocks
+	Z	Yes	3 shocks
-	Z	Yes	3 shocks
Supplementary information: *(NOTE 2 This represents Class 7M3 as described in IEC/TR 60721-4-7:2001 [6])			

IEC 60601-1-12			
Clause	Requirement - Test	Result - Remark	Verdict

10.1.3a2	TABLE: Shock test (IEC 60068-2-27:2008) for TRANSPORTABLE ME EQUIPMENT and its parts, including mounting ACCESSORIES under the following conditions (Test Type 2):		N/A
	Peak acceleration	1000 m/s ² (100 g)	
	Duration.....	6 ms	
	Pulse shape	half-sine	
	Number of shocks.....	3 shocks per direction per axis (18 total)	
Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
Supplementary information:			

IEC 60601-1-12			
Clause	Requirement - Test	Result - Remark	Verdict
10.1.3b	TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) for TRANSPORTABLE ME EQUIPMENT and its parts, including mounting ACCESSORIES under the following conditions*:		P
1	Acceleration amplitude	10 Hz to 100 Hz: 5,0 (m/s ²) ² /Hz	
2	Acceleration amplitude	100 Hz to 200 Hz: - 7 dB per octave	
3	Acceleration amplitude	200 Hz to 2 000 Hz: 1,0 (m/s ²) ² /Hz	
	Duration.....	30 min per perpendicular axis (3 total)	
Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
1	1	Yes	
1	2	Yes	
1	3	Yes	
2	1	Yes	
2	2	Yes	
2	3	Yes	
3	1	Yes	
3	2	Yes	
3	3	Yes	
Supplementary information: *(NOTE 3 This represents Class 7M3 as described in IEC/TR 60721-4-7:2001)			

IEC 60601-1-12			
Clause	Requirement - Test	Result - Remark	Verdict

10.1.3c	TABLE: Free fall test (IEC 60068-2-31:2008), using PROCEDURE 1, for TRANSPORTABLE ME EQUIPMENT and its parts, including mounting ACCESSORIES (for PORTABLE ME EQUIPMENT with carrying case if intended), under the following conditions*:			P
1	Fall height for mass ≤ 1 kg	1,0 m		
2	Fall height for mass > 1 kg and ≤ 10 Kg	0,5 m		
3	Fall height for mass > 10 kg and ≤ 50 Kg	0,25 m		
4	Fall height for mass > 50 kg	0,1 m		
Specified altitude (m)	Mass (Kg)	Fall No.	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
1,0	≤ 1	1	Yes	
1,0	≤ 1	2	Yes	
0,5	> 1 & ≤ 10	1	--	
0,5	> 1 & ≤ 10	2	--	
0,25	> 10 & ≤ 50	1	--	
0,25	> 10 & ≤ 50	2	--	
0,1	> 50	1	--	
0,1	> 50	2	--	
Supplementary information: *(NOTE 4 This represents Class 7M3 as described in IEC/TR 60721-4-7:2001)				

IEC 60601-1-12			
Clause	Requirement - Test	Result - Remark	Verdict

10.1.4a1	TABLE: Shock test (IEC 60068-2-27:2008) for ME EQUIPMENT intended for airborne use and its parts, including mounting ACCESSORIES under the following conditions* (Test Type 1):			N/A
	Peak acceleration	:	300 m/s ² (30 g)	
	Duration.....	:	11 ms	
	Pulse shape	:	half-sine	
	Number of shocks.....	:	3 shocks per direction per axis (18 total)	
Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks	

Supplementary information:

*(NOTE 2 This represents Class 7M3 as described in IEC/TR 60721-4-7:2001 [6])

IEC 60601-1-12			
Clause	Requirement - Test	Result - Remark	Verdict

10.1.4a2	TABLE: Shock test (IEC 60068-2-27:2008) for ME EQUIPMENT intended for airborne use and its parts, including mounting ACCESSORIES under the following conditions (Test Type 2):		N/A
	Peak acceleration	1000 m/s ² (100 g)	
	Duration.....	6 ms	
	Pulse shape	half-sine	
	Number of shocks.....	3 shocks per direction per axis (18 total)	
Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
Supplementary information:			