Cerpass Technology Corporation

Conformity of Compliance

No. T0909202-600

Type of equipment:	**Medical Station**
License holder:	**AAEON Technology Inc.**
Trade mark:	**AAEON Technology Inc.**
Type designation:	**xxxxxONYX-1922DTy-xxxxxxxx, xxxxxONYX-192DTy-xxxxxxxx (where y = T or blank; x = 0-9, A-Z, "-" or blank for marketing purpose)**
Technical data:	**Input: DC 24V, 5A**

Standard(s) used for showing compliance with the essential requirements:

Standard(s):	*Test report(s):*	*Issued by:*	*Date(s):*
IEC 60601-1:1988+A1:1991 +A2:1995+corrigendum1995, mod. EN60601-1:1990+A1,A11, A12:1993+A2:1995+A13: 1996	**T0909202-600**	**Cerpass**	**December 30, 2009**

Edward Lin
Testing Department

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Certification Department

TEST REPORT
IEC 60601-1/EN 60601-1
Medical electric equipment
Part 1: General requirements for safety

Report

Reference No.	T0909202-600
Compiled by (+ signature)	Cash Peng
Approved by (+ signature)	Stephen Lin
Date of issue	December 30, 2009
Contents	86 pages

Testing laboratory

Name	Cerpass Technology Corp.
Address	9F, No. 200, Gangcian Rd., Neihu District, Taipei City 114, Taiwan
Testing location	Same as above

Client

Name	AAEON Technology Inc.
Address	5F, No.135, Lane 235, Pao Chiao Rd., Hsin-Tien City, Taipei, Taiwan

Test specification

Standard	IEC 60601-1:1988 + A1:1991 + A2:1995 + corrigendum 1995, mod. EN 60601-1: 1990 + A1, A11, A12:1993 + A2:1995 + A13: 1996
Test procedure	Test Report
Procedure deviation	N.A.
Non-standard test method	N.A.

Test item

Description	Medical Station
Trademark	**AAEON Technology Inc.**
Model and/or type reference	xxxxxONYX-1922DTy-xxxxxxxx, xxxxxONYX-192DTy-xxxxxxxx (where y = T or blank; x = 0-9, A-Z, "-" or blank for marketing purpose)
Manufacturer	Same as Client
Factory	Same as Client
Rating(s)	Input: DC 24V, 5A

Particulars: test item vs. test requirements	
Classification of installation and use ..... :	Portable equipment
Supply connection..... :	Power Adaptor
Test case verdicts	
Test case does not apply to the test object..... :	N/A
Test item does meet the requirement ..... :	P(ass)
Test item does not meet the requirement ..... :	F(ail)
..... :	
Testing	
Date of receipt of test item ..... :	November 23, 2009
Date(s) of performance of test..... :	November 23, 2009 - December 25, 2009

General remarks:

This test report shall not be reproduced except in full without the written approval of the testing laboratory.

The test results presented in this report relate only to the item tested.
"(see remark #)" refers to a remark 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.

Brief description of device under test:

The subject product, Medical Station, consists of HDD, LCD panel, battery pack and main board, enclosed in plastic enclosure, supplied by external power source, for use in the Medical System, intended to diagnose, treat or monitor the Patient.

Model xxxxxONYX-1922DTy-xxxxxxxx is different from model xxxxxONYX-192DTy-xxxxxxxx except for enclosure shape, opening dimension, DC/AC Inverter, LCD panel and arm base.

The equipment is specified to derive power from external power adaptor (Manufacturer: FSP Group Inc. / Type: PMP120-14-yyy), which has been approved by TÜV Rheinland according to IEC/EN 60601-1 and a non-approved battery pack (Manufacturer: AAEON / Type: AAE-123).

Please see following specification of battery pack for details.

Nominal voltage (V)	11.1 V
Rated capacity (mAh)	4107 mAh
Maximum charging voltage (V)	12.65 V
Maximum charging current (A)	2.5 A
Maximum discharging current (A)	6.67 A
End-of-discharge voltage (V)	9 V
Number of series connected cells	3 S (Series), 2 P (Parallel)
Weight of battery (kg)	0.29 kg

Maximum charging voltage 12.7 Vdc is considered as the worst case condition to be used.

The equipment is evaluated for maximum ambient temperature of 40°C.

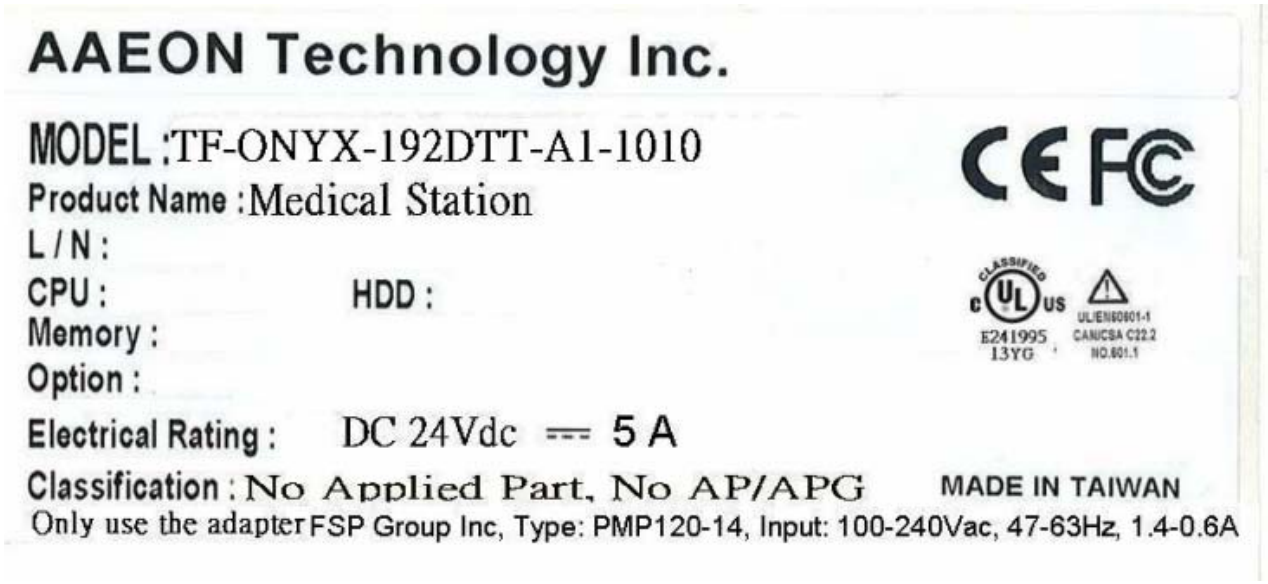
Mass of equipment is: 6.2 kg (For model xxxxxONYX-192DTy-xxxxxxxx without arm base)
6.3 kg (For model xxxxxONYX-1922DTy-xxxxxxxx without arm base)

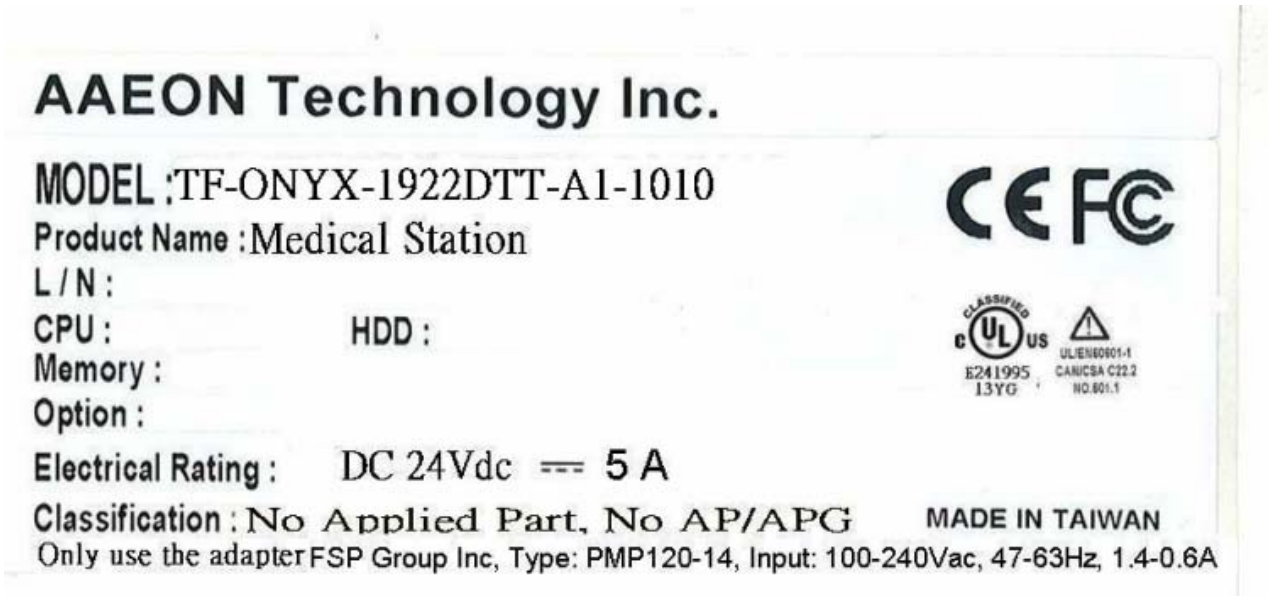
This label drawing is a draft of an artwork for marking plates pending approval by National Certification Bodies and it shall not be affixed to products prior to such an approval.

The test samples were preproduction without serial number.

Copy of the marking plate(s):

(Representative)





IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
3.	GENERAL REQUIREMENTS		**P**
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.)	The equipment causes no hazards when used according the manufacturers instructions.	**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		**P**
5.1	Type of protection against electric shock		**P**
	Class I equipment	EQUIPMENT energized from a class I external power adaptor.	**P**
	Class II equipment		**N/A**
	Internally powered equipment		**N/A**
5.2	Degree of protection against electric shock		**P**
	Type B applied part		**N/A**
	Type BF applied part		**N/A**
	Type CF applied part		**N/A**
	Not classified, no applied parts	No applied parts.	**P**
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) ..... :	Ordinary protection: IPX0	**N/A**
5.4	Methods of sterilization or disinfection	Not required.	**N/A**
5.5	Equipment not suitable for use in the presence of flammable mixtures	The equipment is not classified as category AP or APG.	**N/A**
	Category AP equipment		**N/A**
	Category APG equipment		**N/A**
5.6	Mode of operation:		**P**
	continuous operation	The equipment is designed for continuous operation.	**P**
	short-time operation, specified operation; period .. :		**N/A**

IEC 60601-1/EN 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	intermittent operation, specified operation; rest period ..... :		**N/A**
	continuous operation with short-time, stated permissible loading time ..... :		**N/A**
	continuous operation with intermittent, stated permissible loading/rest time ..... :		**N/A**
	Table: insulation diagram		
	Protection against electric shock - Block diagram of system		
INSULATION DIAGRAM			
Not provided due to operation insulation is provided in the EUT [1)].			

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict

	Table: to insulation diagram						**N/A**
area	insulation type: operational/basic/ supplementary/ double/reinforced	reference voltage (V)	required creepage (mm)	required clearance (mm)	measured creepage (mm)	measured clearance (mm)	remarks

Note:

1. The equipment does not have direct mains connection and is supplied from EN 60601-1 approved external power adaptor. Voltages measured inside the Medical Station are all below 25Vac and 60Vdc, except for the DC/AC inverter.
   Additional evaluation is applied to DC/AC inverter. See appended table 19 for details.

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, optical isolators, 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 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
6.	IDENTIFICATION, MARKING AND DOCUMENTS		**P**
6.1	Marking on the outside of equipment or equipment parts		**P**
	c) Markings of the specific power supply are affixed	The information (manufacturer, model name) of approved external power adaptor was provided on the label and in the accompany document as well.	**P**
	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 ..... :	**AAEON Technology Inc.**	**P**
	f) Model or type reference ..... :	xxxxxONYX-1922DTy-xxxxxxxx, xxxxxONYX-192DTy-xxxxxxxx (where y = T or blank; x = 0-9, A-Z, "-" or blank for marketing purpose)	**P**
	g) Rated supply voltages or voltage range(s)	Rating is not required.	**N/A**
	Number of phases ..... :		**N/A**
	Type of current ..... :	DC	**N/A**
	h) Rated frequency or rated frequency range(s) (Hz) ..... :		**N/A**
	j) Rated power input (VA, W or A) ..... :	Rating is not required.	**N/A**
	k) Power output of auxiliary mains socket-outlets	No mains socket-outlet provided.	**N/A**
	l) Class II symbol	Powered by Class I external power adaptor.	**N/A**
	Symbol for degree of protection against ingress of water provided ..... :	IPX0 marked in Instruction Manual.	**N/A**
	Symbol for protection against electric shock :	No applied part.	**N/A**
	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	No applied part.	**N/A**
	Symbol for protection of defibrillation-proof applied parts ..... :	No applied part.	**N/A**
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable	No patient cable.	**N/A**

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	m) Mode of operation (if no marking, suitable for continuous operation	Optional, continuous operation.	**P**
	n) Types and rating of external accessible fuses .. :	No external accessible fuses.	**N/A**
	p) Ratings of external output ..... :	Not applicable.	**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**
	r) Anaesthetic-proof symbol: AP or APG ..... :	The equipment is not classified as category AP or APG.	**N/A**
	s) Dangerous voltage symbol	No dangerous voltage.	**N/A**
	t) Special cooling requirements	No special cooling requirements.	**N/A**
	u) Limited mechanical stability		**N/A**
	v) Protective packing requirement(s)	No special measures have to be taken during transport or storage.	**N/A**
	Marking(s) for unpacking safety hazard(s)		**N/A**
	Equipment or accessories supplied sterile, marked as sterile		**N/A**
	y) Potential equalisation terminal	No such terminal provided.	**N/A**
	Functional earth terminal	No such terminal provided.	**N/A**
	z) Removable protective means	No such means.	**N/A**
	Durability of marking test	(see appended table 6.1)	**P**
6.2	Marking on the inside of equipment or equipment parts		**P**
	a) Nominal voltage of permanently installed equipment	Not permanently installed equipment.	**N/A**
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements or heating lamps.	**N/A**
	c) Dangerous voltage symbol	No such voltages generated.	**N/A**
	d) Type of battery and mode of insertion	RTC battery and battery pack provided.	**P**
	Marking referring to accompanying documents used for battery not intended to be changed by the operator	An identifying marking for battery pack referring to information stated in the Instruction manual.	**P**

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	Fuses provided inside the approved external power adaptor and DC/AC inverter. Reference to diagram provided.	**P**
	f) Protective earth terminal	Appliance inlet is provided on external power adaptor.	**N/A**
	g) Functional earth terminal	Ditto.	**N/A**
	h) Supply neutral conductor in permanently installed equipment (N)	Not permanently installed equipment.	**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	No such marking required.	**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)	Not permanently installed equipment.	**N/A**
	l) Statement for suitable wiring materials at temperatures over 75 °C	Not permanently installed equipment.	**N/A**
	n) Capacitors and/or circuit parts are marked as required in Cl. 15. c)	No such capacitor and circuit parts.	**N/A**
6.3	Marking of controls and instruments		**P**
	a) Mains switch clearly identified	No direct mains connection.	**N/A**
	ON and OFF positions marked according to Symbols 15 and 16 of Table D1 or indicated by an adjacent indicator light		**N/A**
	b) Indications of different positions of control devices and switches		**P**
	c) Indication of the direction in which the magnitude of the function changes, or an indicting device	No such controls.	**N/A**
	f) The functions of operator controls and indicators are identified	Provided in the accompanying document.	**P**
	g) Numeric indications of parameters are in SI units except for units listed in A2	No numeric indication used for control.	**N/A**
6.4	Symbols		**P**
	Symbols used comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	In accordance with Appendix D.	**P**

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
6.5	Colours of insulation of conductors		**N/A**
	a) Protective earth conductor has green/yellow insulation		**N/A**
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		**N/A**
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		**N/A**
	d) Colour of neutral conductor ..... :	No direct mains connection.	**N/A**
	e) Colours of phase conductors ..... :	No direct mains connection.	**N/A**
	Compliance with IEC 227 and IEC 245		**N/A**
	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/R 32		**N/A**
	b) Identification of connection point		**N/A**
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	The indicator for the operation mode is with green or orange color.	**P**
	Yellow used to indicate caution or attention required	Ditto.	**P**
	Green used to indicate ready for action	Ditto.	**P**
	b) Colour red used only for push-buttons by which a function is interrupted in case of emergency	No used.	**N/A**
6.8	Accompanying documents		**P**
6.8.1	Equipment is accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Provided in Instruction Manual.	**P**
	Classifications specified in Cl. 5. are included in both the instructions for use and the technical description	Ditto.	**P**
	Markings specified in 6.1 included in the accompanying documents if they have not been permanently affixed to equipment		**N/A**

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	Warning statements and the explanation of warning symbols provided in the accompanying documents	Provided in Instruction Manual.	**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	Provided in Instruction Manual.	**P**
	- include an explanation of: the function of controls, displays and signals	Ditto.	**P**
	- the sequence of operation	Ditto.	**P**
	- the connection and disconnection of detachable parts and accessories	Ditto.	**P**
	- the replacement of material which is consumed during operation	No such materials.	**N/A**
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	Shall be evaluated when submitted to national approval.	**N/A**
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	User shall only use the approved external power adaptor specified by the manufacturer. All necessary information was provided on label and Instruction Manual.	**P**
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	Provided in Instruction Manual.	**P**
	General information provided in instructions:		**P**
	- information for the safe performance or routine maintenance	Provided in Instruction Manual.	**P**
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	Ditto.	**P**
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	Ditto.	**P**
	c) Signal output or signal input parts intended only for connection to specified equipment described	Ditto.	**P**
	d) Details about acceptable cleaning, disinfection or sterilization methods included	Ditto.	**P**
	e) Warning statement for mains operated equipment with additional power source	No additional power source.	**N/A**

IEC 60601-1/EN 60601-1			
Clause	Requirement – Test	Result – Remark	Verdict
	f) A warning to remove primary batteries if equipment is not likely to be used for some time		**N/A**
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	Provided in Instruction Manual.	**P**
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	Provided on label and Instruction Manual.	**P**
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	Provided in Instruction Manual.	**P**
	Advice in minimizing these risks	Ditto.	**P**
6.8.3	Technical description		**P**
	a) All characteristics essential for safe operation provided	The Instruction Manual is well written and contains all necessary information required.	**P**
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	Not permanently installed equipment.	**N/A**
	Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	No such parts.	**N/A**
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	There are no particular parts designated as repairable.	**N/A**
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	Provided in Instruction Manual.	**P**
7.	POWER INPUT		**P**
	Power input measurements	Refer to appended table 7.	**P**
10.	ENVIRONMENTAL CONDITIONS		**P**
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	Provided in Instruction Manual.	**P**
10.2.2	a) Rated voltage not exceeding 250 V for hand-held equipment	No hand-held equipment.	**N/A**

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4 kVA	Equipment rated 24Vdc. Approved external power adaptor rated 100-240Vac.	**P**
	Rated voltage not exceeding 500 V for all other equipment		**N/A**
	Rated input frequency not more than 1 kHz	DC power source.	**P**
	b) Internal replaceable electric power source specified	No internal power source.	**N/A**
14.	REQUIREMENTS RELATED TO CLASSIFICATION		**P**
14.4	a) Class I and Class II equipment in addition to basic insulation provided with an additional protection	Equipment not having direct main connection and supplied by external power adaptor classified as Class I equipment.	**N/A**
	b) Equipment supplied from external d.c. source of reverse polarity results in no safety hazard	No hazards.	**P**
14.5	b) Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected	Equipment not having direct main connection and supplied by external power adaptor classified as Class I equipment.	**N/A**
14.6	c) Applied parts intended for direct cardiac application are of type CF	No applied parts.	**N/A**
15.	LIMITATION OF VOLTAGE AND/OR ENERGY		**N/A**
	b) Voltage measured one sec after disconnection of the mains plug does not exceed 60 V	The unit is supplied from external power adaptor, which is in compliance with IEC/EN 60601-1.	**N/A**
	c) For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceeds 2 mJ	No such parts.	**N/A**
	Marking provided for manual discharging		**N/A**
16.	ENCLOSURES AND PROTECTIVE COVERS		**P**
	a) Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	The equipment is provided with protective plastic enclosure.	**P**

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	Insertion or removal of lamps: protection against contact with live parts provided		**N/A**
	b) Opening in a top cover so positioned that accessibility of live parts by a test rod is prevented	No top openings provided. Numerous openings provided on left and right side. Each measured approx. maximum 2.1 x 52.5mm and cover an area approx. 52.5 x 206mm.	**P**
	c) Conductive parts accessible after the removal of handles, knobs, levers:		**N/A**
	- have a resistance of not more than 0,2	No such removable parts.	**N/A**
	- separated from live parts by one of the means described in Cl. 17. g)	Ditto.	**N/A**
	d) Parts with voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected by external mains switch or plug protected against contact	Not applicable.	**N/A**
	e) Removable enclosures protecting against contact with live parts		**P**
	Removal possible only with the aid of a tool	Two parts of enclosure are fixed by screws which can be removed by tool only.	**P**
	Use of automatic device making parts not live when the enclosure is opened or removed	Not applicable.	**N/A**
	Exception 16 e) applied to the following parts ..... :	Not applicable.	**N/A**
	f) Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No such openings.	**N/A**

17.	SEPARATION *The separation from the mains supply has been evaluated during the approval of the external switching power supply source.*		**P**
	a) Separation method of the applied part from live parts:		**N/A**
	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		**N/A**

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
	5) by protective impedances limiting current to applied part		**N/A**
	Additional leakage current test in single fault conditions		**N/A**
	c) There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed		**N/A**
	d) Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)		**N/A**
	g) 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		**N/A**
	5) by protective impedances limiting current to accessible part		**N/A**
	Additional leakage current test in single fault conditions	CREEPAGE DISTANCE and/or AIR CLEARANCE between an ACCESSIBLE PART and LIVE parts which does not comply with the requirements of Sub-clause 57.10 are short-circuited. The ENCLOSURE LEAKAGE CURRENT is subsequently measured as described in Sub-clause 19.4. Refer to appended table 19.	**P**
	h) 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		**N/A**
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function		**N/A**

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
18.	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION *Unit is supplied by IEC/ EN 60601-1 approved external power adaptor providing voltage: 24Vdc.*		**N/A**
	a) Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		**N/A**
	b) Protective earth terminals suitable for connection to the protective earth conductor		**N/A**
	e) 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**
	f) For equipment without power supply cord, impedance between protective earth terminal and accessible metal part 0,1		**N/A**
	For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part 0,1		**N/A**
	For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part 0,2		**N/A**
	g) If the impedance of protective earth connections other than in Cl. 18. f) exceeds 0,1 , the allowable value of the enclosure leakage current is not exceeded in single fault condition		**N/A**
	k) Functional earth terminal not used to provide protective earthing		**N/A**
	l) 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**

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Clause	Requirement – Test	Result – Remark	Verdict
	- functional earth terminal clearly marked		**N/A**
	- explanation of functional earth terminal provided in the accompanying documents		**N/A**
19.	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		**P**
19.1	b) Leakage currents	See below.	**P**
	Earth leakage current	Refer to appended table 19.	**P**
	Enclosure leakage current	Refer to appended table 19.	**P**
	Patient leakage current	No patient circuits.	**N/A**
	Patient auxiliary current	Ditto.	**N/A**
20.	DIELECTRIC STRENGTH AT OPERATING TEMPERATURE *The separation from the mains supply has been evaluated during the approval of the external switching power supply source.*		**P**
	Overall compliance with Cl. 20.	Refer to appended table 20.	**P**
21.	MECHANICAL STRENGTH		**P**
	a) Sufficient rigidity of enclosure tested by: force of 45 N	Tests applied and passed. Refer to appended table 21.	**P**
	b) Sufficient strength of an enclosure tested by: impact hammer	Ditto.	**P**
	c) Portable equipment carrying handles or grips withstand the requirements of the loading test		**N/A**
21.3	No damage to parts of patient support and/or immobilization system after the loading test	No patient support.	**N/A**
21.5	Hand-held equipment or equipment parts are safe after drop test	Not hand-held equipment.	**N/A**
21.6	Portable and mobile equipment is able to withstand rough handling	Refer to appended table 21.	**P**
22.	MOVING PARTS		**N/A**
22.2	a) Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	No moving parts.	**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
	b) 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 of the control 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, taken 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		**P**
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	The enclosure edges are smooth and cannot cause an injury.	**P**
24.	STABILITY IN NORMAL USE *The equipment, Medical Station, is intended to be fixed on arm base during its normal operation.*		**N/A**
24.1	Equipment does not overbalance during normal use when tilted trough an angle of 10		**N/A**
24.3	Equipment overbalances when tilted through an angle of 10 :		**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
	- 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**
24.6	a) 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**
	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		**N/A**
25.1	Protective means are provided where expelled parts of the equipment could be a hazard		**N/A**
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		**N/A**
28.	SUSPENDED MASSES		**P**
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 28.4		**N/A**
	Safety device has safety factors complying with 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:		**P**
	1) the 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**

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Clause	Requirement Test	Result – Remark	Verdict
	3) safety factors not less than 8 where impairment is expected	xxxxxONYX-1922DTy-xxxxxxxx: A force (74.4 kg) including the equipment is applied downward the arm base. xxxxxONYX-192DTy-xxxxxxxx: A force (73.6kg) including the equipment is applied downward the arm base. No any breaking on arm base means.	**P**
	4) safety factors multiplied by 1,5 for metal having an elongation at break of less than 5%		**N/A**
	5) sheaves, sprockets, bandwheels and guides so constructed that the safety factors shall be maintained till replacement		**N/A**
29.	X-RADIATION		**N/A**
29.2	Equipment not intended to produce X-radiation produces an exposure 130 nC/kg (0,5 mR)		**N/A**
36.	ELECTROMAGNETIC COMPATIBILITY		**N/A**
	Equipment complies wit IEC 601-1-2	Shall be evaluated when submitted to national approval.	**N/A**
37.	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		**N/A**
	Requirements for category AP and APG equipment (Cl. 37. - 41.)	Equipment not classified as category AP and APG.	**N/A**
42.	EXCESSIVE TEMPERATURES		**P**
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures specified in 10.2.1	Refer to appended table 42.	**P**
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25 °C ambient	Ditto.	**P**
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41 °C	No applied part.	**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
42.5	Guards to prevent contact with hot surfaces removable only with a tool	No hot accessible surface.	**N/A**
43.	FIRE PREVENTION		**P**
	Strength and rigidity necessary to avoid a fire hazard	The equipment is well constructed with regard to avoid fire hazard. Refer to clause 21.	**P**
44.	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION AND COMPATLBILITY		**P**
44.2	If equipment contains a liquid reservoir:		**N/A**
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min		**N/A**
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favourable direction(s) (if necessary with refilling)		**N/A**
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)		**N/A**
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		**N/A**
44.5	Equipment sufficiently protected against the effects of humidity	Refer to appended table 44.	**P**
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529		**N/A**
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	Refer to appended table 44.	**P**
45.	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE *No pressure vessels and parts used.*		**N/A**
45.2	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure		**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
45.3	The maximum pressure does not exceed the maximum permissible working pressure for individual parts		**N/A**
45.7	Unless excessive pressure cannot occur, pressure-relief device provided		**N/A**
	a) Pressure-relief device connected as close as possible to the pressure vessel		**N/A**
	b) Readily accessible for inspection		**N/A**
	c) Not capable of being adjusted or rendered inoperative without a tool		**N/A**
	d) Discharge opening so located that the released material is not directed towards any person		**N/A**
	e) Discharge opening so located that operation will not deposit material which may cause a safety hazard		**N/A**
	f) Adequate discharge capacity to ensure that pressure does not exceed the maximum permissible working pressure		**N/A**
	g) No shut-off valve between the pressure-relief device and the parts intended to be protected		**N/A**
	h) Minimum number of cycles of operation is 100 000		**N/A**
48.	BIOCOMPATIBILITY		**N/A**
	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	No such parts.	**N/A**
49.	INTERRUPTION OF THE POWER SUPPLY		**P**
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may give a safety hazard	Not such components provided.	**N/A**
49.2	Interruption and restoration of the power supply shall not result in a safety hazard other than interruption of its intended function	Interruption and restoration of the power supply will not result in a safety hazard.	**P**
49.3	Means are provided for removal of mechanical constraints on a patient in case of a supply mains failure	Not applicable.	**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
51.	PROTECTION AGAINST HAZARDOUS OUTPUT		**N/A**
51.4	Equipment providing both low-intensity and high-intensity outputs provided with means minimizing the possibility of a high-intensity output being selected accidentally	No such outputs.	**N/A**
52.	ABNORMAL OPERATION AND FAULT CONDITIONS		**P**
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 below.	**P**
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	Incorporated software not relevant for the safety concept of the EUT.	**N/A**
52.5.2	Failure of thermostat presents no safety hazard	No thermostats provided.	**N/A**
52.5.3	Short-circuiting of either constituent part of double insulation presents no safety hazard	Tested accordingly during the approval of the external power adaptor.	**P**
52.5.5	Impairment of cooling: temperatures not exceeding 1,7 times the values of Cl. 42. minus 17,5 °C	Refer to appended table 52.	**P**
52.5.6	Locking of moving parts presents no safety hazard	No moving parts.	**N/A**
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	No such components used.	**N/A**
52.5.8	Duration of motors locked rotor test in compliance with 52.5.8	No such components used.	**N/A**
52.5.9	Failure of one component at a time presents no safety hazard	Tested accordingly for the approved external power adaptor. For other components inside the equipment, refer to appended table 19.	**P**
52.5.10	Overload of heating elements presents no safety hazard	No heating elements.	**N/A**
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	Not applicable.	**N/A**
	h) Equipment with three-phase motors can safely operate with one phase disconnected	No such device.	**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
56.	COMPONENTS AND GENERAL ASSEMBLY		**P**
	List of critical components	Refer to appended table 56.	**P**
56.1	b) Ratings of components not in conflict with the conditions of use in equipment	All components rated accordingly.	**P**
	Ratings of mains components are identified	No direct mains connection. EN 60601-1 approved external power adaptor used. Refer to appended table 56.	**N/A**
	d) Components, movements of which could result in a safety hazard mounted securely	The movement of components is prevented.	**P**
	f) Conductors and connectors are secured and/or insulated to prevent accidental detachment resulting in a safety hazard	Conductors and connectors are adequately secured and insulated. Accidental detachment will not result in a safety hazard.	**P**
56.3	a) Connectors provide separation required by Cl. 17. g)	No such components provided.	**N/A**
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No patient circuit.	**N/A**
	Medical gas connections not interchangeable	No such connections.	**N/A**
	b) Accessible metal parts cannot become live when detachable interconnection cord between different parts of equipment is loosened or broken	No such cord.	**N/A**
	c) Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages		**N/A**
56.4	Connections of capacitors		**N/A**
	Not connected between live parts and non-protectively earthed accessible parts	No direct mains connection.	**N/A**
	If connected between mains part and protectively earthed metal parts, comply with IEC 384-14	Ditto.	**N/A**
	Enclosure of capacitors connected to mains part and providing only basic insulation is not secured to non-protectively earthed metal parts	Ditto.	**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
	Capacitors or other spark-suppression devices are not connected between the contacts of thermal cut-outs	No such components used.	**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.	**N/A**
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		**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**
	b) Thermostats with varying temperature settings clearly indicated		**N/A**
	Operating temperature of cut-outs is clearly indicated		**N/A**
56.7	Batteries		**P**
	a) Battery compartments are:		**N/A**
	- adequately ventilated		**N/A**
	- accidentally short-circuiting is prevented		**N/A**
	b) Incorrect polarity of connection prevented	Refer to appended table for additional tests.	**P**
56.8	Indicators, unless indication is provided by other means (from the normal operation position), indicator lights are used (colour see 6.7)		**P**
	- to indicate that equipment is energized	Green LED used.	**P**
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No heater.	**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
	- to indicate when output exists if a safety hazard could result		**N/A**
	- charging mode indicator is provided		**N/A**
56.10	Actuating parts of controls	No actuating part.	**N/A**
	b) Actuating parts are adequately secured to prevent them from working loose during normal use	Ditto.	**N/A**
	Controls are secured to prevent the movement relative to scale marking (safety related only)	Ditto.	**N/A**
	Detachable indicating devices are prevented from incorrect connection without the use of a tool	Ditto.	**N/A**
	c) Stops are provided on rotating controls:		**N/A**
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		**N/A**
	- to prevent damage to wiring		**N/A**
56.11	Cord-connected hand-held and foot-operated control devices		**N/A**
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17. G)		**N/A**
	b) Hand-held devices comply with the requirement and test of 21.5		**N/A**
	Foot-operated control devices designed to support the weight of an adult human being		**N/A**
	c) Devices shall not change their setting when inadvertently placed		**N/A**
	d) Foot-operated control devices are at least IPX1		**N/A**
	For surgical use, electrical switching parts are IPX8		**N/A**
	e) Adequate strain relief at the cord entry provided		**N/A**

57.	MAINS PARTS, COMPONENTS AND LAYOUT		**P**
57.1	Isolation from supply mains		**P**
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	No directly mains connection. EN 60601-1 approved power supply with appliance inlet used.	**P**

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Clause	Requirement Test	Result – Remark	Verdict
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	Ditto.	**N/A**
	d) Switches used to comply with 57.1 a) comply with the creepage distances and air clearances as specified in IEC 328	Ditto.	**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 57.1 a)	See 57.1 a)	**P**
	m) Fuses and semiconductor devices are not used as isolating devices	Not used.	**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 mains socket-outlet provided.	**N/A**
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment		**P**
57.3	Power supply cords		**P**
	a) Not more than one connection to a particular supply mains	No direct mains connection. The external power adaptor had single appliance inlet for mains connection.	**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	Complied.	**P**
	Non-permanently connected equipment provided with power supply cord or appliance inlet	Appliance inlet provided in the external power adaptor.	**P**
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53		**N/A**
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75 °C		**N/A**
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV		**N/A**
	d) Stranded conductors not soldered if fixed by any clamping means		**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
57.4	Connection of power supply cords		**N/A**
	a) Cord anchorages:		**N/A**
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	Appliance inlet provided in external power adaptor for connection of a detachable power supply cord.	**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 so 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**
	b) Power supply cord protected against excessive bending		**N/A**
	c) 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**
	a) Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts or equally effective methods		**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 shall not serve to fix any other component		**N/A**
	b) Terminals closely grouped with any protective earth terminal		**N/A**
	Mains terminal devices accessible only with use of a tool		**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
	Mains terminal devices located or shielded so 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 shall not require special preparation of the conductor		**N/A**
57.6	Mains fuses and over-current releases		**N/A**
	Fuses or over-current releases provided accordingly for Class I and Class II	Provided in the approved external power adaptor.	**N/A**
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current	Ditto.	**N/A**
	Protective earth conductor not fused		**N/A**
	Neutral conductor not fused for permanently installed equipment	Not permanently installed equipment.	**N/A**
57.8	Wiring of mains part		**N/A**
	a) Individual conductors 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 IEC 245, treated as bare conductor ..... :		**N/A**
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply		**N/A**
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits are sufficient to prevent any fire hazard		**N/A**
57.9	Mains supply transformers *Mains supply transformers provided in the approved external switching power supply.*		**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		**N/A**
	a) Short-circuit of secondary windings not caused excessive temperature		**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
	b) Overload of secondary windings not caused excessive temperature		**N/A**
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		**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 earth screen has only one turn		**N/A**
	e) Insulation between the primary and secondary winding in transformers with double insulation:		**N/A**
	- 1 insulation layer having a 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**
	- 3 layers provided that each combination of 2 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 a total thickness at least 0,3 mm extending at least 20 mm outside the winding		**N/A**
57.10	Creepage distances and air clearances		**N/A**
	a) Values: compliance with at least the values of Table XVI	Safety separations were evaluated during the approval of the external power adaptor.	**N/A**
	Creepage distances for slot insulation of motors are at least 50% of the specified values		**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
	b) Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard		**N/A**
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No such parts.	**N/A**

58.	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		**N/A**
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 is 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		**P**
59.1	Internal wiring		**P**
	a) Cables and wiring protected against contact with a moving part	No moving parts.	**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		**P**
	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 strength test		**N/A**

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Clause	Requirement Test	Result – Remark	Verdict
	Conductors subjected to temperatures exceeding 70 °C, have an insulation of heat-resistant material	All internal wiring is suitably rated.	**P**
	d) Aluminium wires of less than 16 mm² cross-section not used		**N/A**
	f) Connecting cords between equipment parts considered as belonging to the equipment	No such cords provided.	**N/A**
59.2	Insulation		**P**
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	Insulation with adequate prorerties is used. Refer to appended table additional tests.	**P**
	c) Insulation not likely to be impaired by deposition of dirt or dust resulting from wear of parts	No such parts.	**N/A**
	Parts of rubber resistant to ageing	No such parts.	**N/A**
59.3	Excessive current and voltage protection		**N/A**
	Internal electrical power source provided with device for protection against fire hazard		**N/A**
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		**N/A**
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		**N/A**
59.4	Oil containers		**N/A**
	Oil containers adequately sealed	No oil container used	**N/A**
	Container design shall 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**

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Clause	Requirement Test	Result – Remark	Verdict

6.1	TABLE: marking durability	**P**
marking tested		remarks
Product rating label		Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit at ambient temperature and then for 15 s with a cloth rag soaked with isopropyl alcohol.
supplementary information:		

7.	TABLE: power input					**P**
Operating condition	Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks	
For model xxxxxONYX-1922DTy-xxxxxxxx						
Measured at Power Adaptor: FSP Group Inc. / PMP120-14-yyy						
Normal operation	90Vac	47	0.95	84	--	
Ditto.	90Vac	63	0.95	85	--	
Ditto.	100Vac	47	0.84	84	Rated input: 1.4A	
Ditto.	100Vac	63	0.84	87	Rated input: 1.4A	
Ditto.	240Vac	47	0.37	86	Rated input: 0.6A	
Ditto.	240Vac	63	0.39	85	Rated input: 0.6A	
Ditto.	264Vac	47	0.41	86	--	
Ditto.	264Vac	63	0.43	87	--	
Measured at Medical Station						
Normal operation	24Vdc	--	2.6	62.4	Rated input of Medical Computer: 5A	
For model xxxxxONYX-192DTy-xxxxxxxx						
Measured at Power Adaptor: FSP Group Inc. / PMP120-14-yyy						
Normal operation	90Vac	47	0.77	69	--	
Ditto.	90Vac	63	0.79	69	--	
Ditto.	100Vac	47	0.69	69	Rated input: 1.4A	
Ditto.	100Vac	63	0.68	68	Rated input: 1.4A	

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Clause	Requirement Test	Result – Remark	Verdict

Ditto.	240Vac	47	0.30	69	Rated input: 0.6A
Ditto.	240Vac	63	0.31	69	Rated input: 0.6A
Ditto.	264Vac	47	0.34	69	--
Ditto.	264Vac	63	0.35	69	--
Measured at Medical Station					
Normal operation	24Vdc	--	2.5	60	Rated input of Medical Computer: 5A
supplementary information: Maximum normal load was defined as follows: HDD plays continuously, LCD panel with maximum contrast / brightness, the dummy load of 2.5W is applied in each USB ports and empty battery pack(for model xxxxxONYX-1922DTy-xxxxxxxx).					

15. b)	TABLE: residual voltage in attachment plugs										**N/A**
voltage measured between:	measurements (V)										remarks
	1	2	3	4	5	6	7	8	9	10	
supplementary information:											

15. c)	TABLE: residual voltage or energy in capacitors				**N/A**
capacitor and its location	residual voltage (V)	time after disconnection (s)	capacitance value (F)	residual energy (mJ)	remarks
supplementary information:					

17. h1)	TABLE: defibrillation-proof applied parts				**N/A**
test condition: fig. 50 or 51	accessible part of measurement:	applied part with test voltage	test voltage polarity	measured voltage between Y1 and Y2 (mV)	remarks
supplementary information:					

17. h2)	TABLE: defibrillation-proof recovery time			**N/A**
applied part with test voltage	test voltage polarity	recovery time from accompanying document(s)	measured recovery time (s)	remarks

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Clause	Requirement Test	Result – Remark	Verdict

supplementary information:				

18.	TABLE: protective earthing			**N/A**
test location	test current (A)	measured voltage (V)	resistance ( )	remarks
supplementary information:				

19.	TABLE: leakage current			**P**
type of leakage current and test condition (including single faults)	supply voltage (V)	supply frequency (Hz)	measured max. value (uA)	remarks
For model xxxxxONYX-1922DTy-xxxxxxxx				
Measured at Power Adaptor: FSP Group Inc. / PMP120-14-yyy				
Figure 17, Earth leakage current	**--**	**--**	**B / A**	**--**
ER, NC, S1 = 1, S5 = N, S2 =1, S3 =1	264	63	127.7 / 130.2	**MD1 between plastic enclosure of adaptor and earth.**
ER, NC, S1 = 1, S5 = R, S2 =1, S3 =1	264	63	131.1 / 133.2	Ditto.
ER, SFC, S1 = 1, S5 = N, S2 =1, S3 =0	264	63	122.5 / 124.9	Ditto.
ER, SFC, S1 = 1, S5 = R, S2 =1, S3 =0	264	63	124.2 / 126.5	Ditto.
ER, SFC, S1 = 1, S5 = N, S2 =0, S3 =1	264	63	123.1 / 125.3	Ditto.
ER, SFC, S1 = 1, S5 = R, S2 =0, S3 =1	264	63	124.5 / 126.6	Ditto.
ER, SFC, S1 = 0, S5 = N, S2 =1, S3 =1	264	63	240.0 / 243.0	Ditto.
ER, SFC, S1 = 0, S5 = R, S2 =1, S3 =1	264	63	240.3 / 243.1	Ditto.
Figure 19, Enclosure leakage current	**--**	**--**	**B / A**	**--**
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	4.6 / 6.7	**MD1 between plastic enclosure of adaptor and earth.**

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Clause	Requirement Test	Result – Remark		Verdict

EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	4.7 / 6.6	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	3.6 / 5.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	3.6 / 5.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	3.6 / 5.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	3.6 / 5.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	5.2 / 7.4	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	5.0 / 7.1	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	5.7 / 7.6	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.7 / 7.6	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.1 / 2.5	**MD2 between plastic enclosure of adaptor and plastic enclosure of adaptor.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.7 / 1.4	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	0.9 / 1.7	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.4 / 1.4	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	0.9 / 1.7	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.4 / 1.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	1.1 / 2.3	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	1.1 / 2.3	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.6 / 1.5	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.6 / 1.5	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	2.4 / 5.5	**MD3 between plastic enclosure of unit and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	2.5 / 5.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	2.0 / 4.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	2.0 / 4.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	2.0 / 4.0	Ditto.

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Clause	Requirement Test	Result – Remark		Verdict

EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	2.0 / 4.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	5.6 / 7.4	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	4.9 / 7.0	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	2.8 / 5.1	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	2.9 / 5.1	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	87.8 / 89.2	**MD3 between metallic enclosure of unit and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	95.8 / 96.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	68.4 / 70.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	69.9 / 70.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	69.6 / 71.7	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	69.8 / 71.7	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	122.1 / 124.4	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	128.8 / 130.9	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	108.4 / 110.7	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	108.4 / 110.7	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	14.0 / 16.2	**MD4 between metallic enclosure of unit and plastic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.9 / 8.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	9.7 / 12.1	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	3.6 / 5.7	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	9.7 / 11.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	3.7 / 5.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	11.7 / 13.8	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	10.0 / 11.9	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	5.8 / 6.9	Ditto.

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Clause	Requirement – Test	Result – Remark	Verdict

EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.8 / 6.9	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.1 / 2.1	**MD4 between plastic enclosure of unit and plastic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.61 / 1.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	1.0 / 2.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.5 / 1.4	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	0.91 / 1.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.4 / 1.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	1.2 / 1.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	1.2 / 1.9	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.8 / 1.7	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.8 / 1.7	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.7 / 1.7	**MD4 between metallic enclosure of unit and metallic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.4 / 0.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	0.5 / 1.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.2 / 0.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	0.5 / 1.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.2 / 0.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	0.7 / 1.6	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	0.6 / 1.6	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.0	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.0	Ditto.
DC/AC inverter; Output connector P2, Pin1 (High Voltage) - Metallic chassis, s-c				
Figure 19, Enclosure leakage current	**--**	**--**	**B / A**	**--**

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Clause	Requirement Test	Result – Remark	Verdict

EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	5.4 / 7.5	**MD1 between plastic enclosure of adaptor and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	6.1 / 8.2	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	4.1 / 6.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	4.2 / 6.3	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	4.1 / 6.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	4.2 / 6.2	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	6.0 / 7.7	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	6.0 / 7.7	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	6.6 / 8.7	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	6. / 8.7	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	5.4 / 7.9	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	6.0 / 8.2	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.5 / 2.8	**MD2 between plastic enclosure of adaptor and plastic enclosure of adaptor.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	1.4 / 2.7	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	1.4 / 2.7	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	1.0 / 2.3	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	1.4 / 2.5	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	1.0 / 2.3	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	1.6 / 2.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	1.6 / 2.9	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.6 / 2.9	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	1.5 / 2.8	Ditto.

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Clause	Requirement Test	Result – Remark	Verdict

EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.6 / 3.1	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	1.4 / 3.1	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	2.8 / 5.1	**MD3 between plastic enclosure of unit and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	3.1 / 5.7	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	2.3 / 4.6	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	2.3 / 4.6	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	2.4 / 4.7	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	2.4 / 4.7	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	6.0 / 8.1	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	6.1 / 8.3	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	3.5 / 5.6	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	3.5 / 5.6	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	2.8 / 5.2	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	3.2 / 5.8	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	84.7 / 86.8	**MD3 between metallic enclosure of unit and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	72.8 / 74.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	67.2 / 69.4	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	68.7 / 70.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	67.6 / 69.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	68.0 / 69.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	122.5 / 124.5	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	123.2 / 125.3	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	107.3 / 109.4	Ditto.

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Clause	Requirement Test	Result – Remark		Verdict

EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	107.3 / 109.4	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	85.3 / 87.7	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	93.0 / 95.1	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	10.9 / 13.2	**MD4 between metallic enclosure of unit and plastic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.5 / 7.7	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	10.1 / 13.1	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	3.7 / 5.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	10.1 / 12.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	3.7 / 5.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	10.8 / 13.3	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	11.0 / 13.5	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	6.0 / 8.2	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	6.0 / 8.2	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	10.9 / 13.3	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.6 / 7.8	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.0 / 2.1	**MD4 between plastic enclosure of unit and plastic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.5 / 0.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	1.0 / 2.1	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.4 / 0.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	0.9 / 1.9	Ditto.

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict

EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.4 / 0.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	1.0 / 2.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	1.0 / 2.0	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.7 / 1.4	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.7 / 1.4	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.0 / 2.1	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.4 / 0.9	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.6 / 1.5	**MD4 between metallic enclosure of unit and metallic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.4 / 0.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	0.5 / 1.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.2 / 0.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	0.5 / 1.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.2 / 0.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	0.6 / 1.1	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	0.6 / 1.1	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.6 / 1.1	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.1	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.2	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.3 / 0.7	Ditto.
For model xxxxxONYX-192DTy-xxxxxxxx				
Measured at Power Adaptor: FSP Group Inc. / PMP120-14-yyy				
Figure 17, Earth leakage current	**--**	**--**	**B / A**	**--**

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict

ER, NC, S1 = 1, S5 = N, S2 =1, S3 =1	264	63	130.4 / 133.2	**MD1 between plastic enclosure of adaptor and earth.**
ER, NC, S1 = 1, S5 = R, S2 =1, S3 =1	264	63	134.1 / 136.2	Ditto.
ER, SFC, S1 = 1, S5 = N, S2 =1, S3 =0	264	63	123.3 / 124.9	Ditto.
ER, SFC, S1 = 1, S5 = R, S2 =1, S3 =0	264	63	125.1 / 126.8	Ditto.
ER, SFC, S1 = 1, S5 = N, S2 =0, S3 =1	264	63	123.0 / 125.5	Ditto.
ER, SFC, S1 = 1, S5 = R, S2 =0, S3 =1	264	63	124.8 / 126.8	Ditto.
ER, SFC, S1 = 0, S5 = N, S2 =1, S3 =1	264	63	241.6 / 243.7	Ditto.
ER, SFC, S1 = 0, S5 = R, S2 =1, S3 =1	264	63	241.6 / 243.7	Ditto.
Figure 19, Enclosure leakage current	**--**	**--**	**B / A**	**--**
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	5.3 / 7.4	**MD1 between plastic enclosure of adaptor and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	6.1 / 8.2	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	4.0 / 6.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	4.0 / 6.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	4.1 / 6.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	4.1 / 6.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	6.6 / 7.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	5.5 / 6.6	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	6.3 / 7.8	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	6.4 / 7.8	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.0 / 1.8	**MD2 between plastic enclosure of adaptor and plastic enclosure of adaptor.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.8 / 1.6	Ditto.

IEC 60601-1/EN 60601-1				
Clause	Requirement Test	Result – Remark		Verdict

EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	0.8 / 1.6	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.3 / 0.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	0.8 / 1.6	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.3 / 0.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	1.0 / 2.4	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	0.9 / 2.0	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.5 / 0.9	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.5 / 0.9	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	2.3 / 5.8	**MD3 between plastic enclosure of unit and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	2.5 / 5.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	1.9 / 3.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	1.9 / 3.2	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	1.9 / 3.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	1.9 / 3.2	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	4.8 / 7.1	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	4.9 / 7.1	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	2.6 / 6.0	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	2.7 / 6.0	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	85.3 / 87.4	**MD3 between metallic enclosure of unit and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	92.5 / 94.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	67.2 / 69.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	68.6 / 69.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	66.9 / 67.5	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	67.4 / 69.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	118.8 / 120.1	Ditto.

IEC 60601-1/EN 60601-1				
Clause	Requirement Test	Result – Remark		Verdict

EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	122.2 / 124.2	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	106.2 / 108.3	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	106.2 / 108.3	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	11.5 / 14.1	**MD4 between metallic enclosure of unit and plastic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.8 / 7.1	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	10.6 / 12.7	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	4.0 / 5.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	10.6 / 12.7	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	4.0 / 5.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	11.5 / 13.8	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	11.7 / 13.8	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	6.4 / 8.5	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	6.3 / 8.4	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	11.7 / 13.9	**MD4 between plastic enclosure of unit and plastic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.9 / 8.1	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	10.8 / 12.8	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	4.0 / 6.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	10.8 / 12.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	4.0 / 6.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	11.6 / 14.6	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	15.1 / 17.2	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	6.4 / 8.1	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	6.4 / 8.1	Ditto.

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict

EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.0	**MD4 between metallic enclosure of unit and metallic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.3 / 0.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	0.4 / 0.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.2 / 0.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	0.5 / 0.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.2 / 0.7	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	0.5 / 0.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	0.5 / 0.9	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.1	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.0	Ditto.
DC/AC inverter; Output connector P2, Pin1 (High Voltage) - Metallic chassis, s-c				
Figure 19, Enclosure leakage current	**--**	**--**	**B / A**	**--**
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	4.8 / 7.2	**MD1 between plastic enclosure of adaptor and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.4 / 7.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	3.7 / 6.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	3.8 / 6.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	3.7 / 7.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	3.8 / 7.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	5.3 / 7.4	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	5.4 / 7.4	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	5.9 / 7.8	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.9 / 7.7	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	4.9 / 7.2	Ditto.

IEC 60601-1/EN 60601-1				
Clause	Requirement Test	Result – Remark		Verdict

EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.4 / 7.2	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.1 / 1.9	**MD2 between plastic enclosure of adaptor and plastic enclosure of adaptor.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.8 / 1.4	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	1.0 / 2.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.5 / 1.3	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	1.0 / 2.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.5 / 1.3	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	1.1 / 1.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	1.2 / 2.1	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.9 / 1.7	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.9 / 1.7	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.2 / 2.0	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.8 / 1.4	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	2.5 / 4.8	**MD3 between plastic enclosure of unit and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	2.7 / 5.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	2.1 / 4.5	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	2.2 / 4.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	2.1 / 4.5	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	2.2 / 4.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	5.0 / 7.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	5.4 / 7.3	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	3.0 / 5.2	Ditto.

IEC 60601-1/EN 60601-1				
Clause	Requirement Test	Result – Remark		Verdict

EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	3.0 / 5.2	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	2.5 / 5.1	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	2.7 / 5.1	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	84.0 / 87.0	**MD3 between metallic enclosure of unit and earth.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	91.1 / 93.3	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	66.7 / 68.8	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	68.4 / 69.8	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	67.0 / 69.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	67.2 / 69.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	122.1 / 125.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	117.7 / 119.7	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	105.8 / 107.8	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	105.8 / 107.8	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	85.4 / 88.1	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	92.4 / 95.5	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	11.1 / 13.5	**MD4 between metallic enclosure of unit and plastic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.6 / 7.7	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	10.3 / 12.5	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	3.8 / 5.9	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	10.3 / 12.5	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	3.8 / 5.9	Ditto.

IEC 60601-1/EN 60601-1				
Clause	Requirement Test	Result – Remark		Verdict

EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	11.1 / 13.0	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	11.3 / 13.1	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	6.0 / 7.7	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	6.1 / 7.8	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	11.0 / 13.5	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	5.7 / 8.1	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.2 / 3.4	**MD4 between plastic enclosure of unit and plastic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	1.2 / 3.4	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.5 / 1.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	1.1 / 3.4	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.5 / 1.0	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	1.2 / 2.9	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	1.2 / 2.9	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.8 / 1.5	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.8 / 1.5	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	1.2 / 3.0	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.6 / 1.5	Ditto.
EN, NC, S1 = 1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.2	**MD4 between metallic enclosure of unit and metallic enclosure of unit.**
EN, NC, S1 = 1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.4 / 1.0	Ditto.

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Clause	Requirement Test	Result – Remark	Verdict

EN, SFC, S1=1, S5 = N, S8 =1, S2 =1, S3 =0	264	63	0.5 / 1.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =1, S3 =0	264	63	0.2 / 0.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =1, S2 =0, S3 =1	264	63	0.5 / 1.2	Ditto.
EN, SFC, S1=1, S5 = R, S8 =1, S2 =0, S3 =1	264	63	0.2 / 0.5	Ditto.
EN, SFC, S1=1, S5 = N, S8 =0, S2 =1, S3 =1	264	63	0.5 / 1.1	Ditto.
EN, SFC, S1=1, S5 = R, S8 =0, S2 =1, S3 =1	264	63	0.5 / 1.1	Ditto.
EN, SFC, S1=0, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.1	Ditto.
EN, SFC, S1=0, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.1	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = N, S8 =1, S2 =1, S3 =1	264	63	0.5 / 1.3	Ditto.
EN, SFC, (Q2; C-E, s-c), S1=1, S5 = R, S8 =1, S2 =1, S3 =1	264	63	0.3 / 0.6	Ditto.

(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).

Supplementary information:

1. For power supply adaptor, the leakage currents were measured during the adaptor's approval.
2. Additional tests were performed for the DC/AC inverter under normal and single fault condition for evaluation of compliance according to sub-clause 17g).
   The leakage current measured all below the limit for both normal (0.1mA) and single fault conditions (0.5mA).
   Following single faults were conducted before tests:
   - Output connector P2, Pin1 (High Voltage) - Metallic chassis, s-c
   (where "s-c" stands for short-circuit)

Abbreviations used: 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 IEC 601-1	MD - Measuring device A - After humidity conditioning B - Before humidity condtioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition

20.	TABLE: dielectric strength			**P**
insulation under test (area from insulation diagram)	insulation type: (OP-operational/BI-basic/ SI-supplementary/DI-double/ RI-reinforced	reference voltage (V)	test voltage (V)	Remarks

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Clause	Requirement Test	Result – Remark	Verdict

Before humidity conditioning				
L / N of adaptor to metallic enclosure of Medical Station	Double / Reinforced insulation	250	5656Vdc	No breakdown
L / N of adaptor to plastic enclosure of Medical Station	Double / Reinforced insulation	250	5656Vdc	No breakdown
L / N of adaptor to SIP/SOP of Medical Station	Double / Reinforced insulation	250	5656Vdc	No breakdown
After humidity conditioning				
L / N of adaptor to metallic enclosure of Medical Station	Double / Reinforced insulation	250	5656Vdc	No breakdown
L / N of adaptor to plastic enclosure of Medical Station	Double / Reinforced insulation	250	5656Vdc	No breakdown
L / N of adaptor to SIP/SOP of Medical Station	Double / Reinforced insulation	250	5656Vdc	No breakdown
supplementary information: 1. Tests were conducted with power adaptor (FSP Group Inc. / PMP120-14-yyy). 2. Tests were conducted on models xxxxxONYX-1922DTy-xxxxxxxx and xxxxxONYX-192DTy-xxxxxxxx.				

21.	TABLE: mechanical strength		P
part under test	test (impact, drop, force, handle, rough handling, mobile)	Remarks	
Whole unit	Force of 45N applied over surface of 625mm^2	Tested all over the plastic / metallic enclosure. No damage.	
Whole unit	Impact with 0.5J	Tested all over the plastic / metallic enclosure. No damage.	
Whole unit	Rough Handling - Drop test	Height: 5cm, three times. No damage.	
supplementary information: Tests were conducted on models xxxxxONYX-1922DTy-xxxxxxxx and xxxxxONYX-192DTy-xxxxxxxx.			

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Clause	Requirement Test	Result – Remark	Verdict

24.	TABLE: stability		**N/A**
part under test	test condition	Remarks	
supplementary information:			

29.	TABLE: X-radiation			**N/A**
part under test	test condition	measured radiation (mR)	Remarks	
supplementary information:				

42	TABLE: normal temperature						**P**
Supply voltage……..…..: --	Test Condition: A) Normal operation: Horizontal (90Vac) B) Normal operation: Horizontal (264Vac) C) Normal operation: Vertical (90Vac) D) Normal operation: Vertical (264Vac) E) All openings blocked : Horizontal (240Vac) F) Normal operation: Horizontal Discharge(from battery pack) G) Battery pack with charging mode (Charge voltage: 12.7Vdc / Charge current: 2.5A) H) Battery pack with discharging mode (Discharge current: 6.67A)						
Ambient temperature °C ..……...: --							
Measuring location	Measured temperature [°C]						Remarks (allowed Tmax [°C])
For model xxxxxONYX-192DTy-xxxxxxxx							
Test Condition:	A)	B)	C)	D)	--	--	
For power adaptor:							
T1 coil	86.5	86.1	87.8	85.9	--	145	
T1 core	77.8	77.8	79.2	77.8	--	145	
Enclosure outside (plastic), near T1	58.2	59.3	59.6	59.5	--	85	
For D/A inverter:							
PCB near IC1	84.4	85.8	60.4	59.4	--	105	
L2 coil	85.4	86.7	65.9	64.7	--	105	

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Clause	Requirement Test	Result – Remark	Verdict

T1 coil	81.2	83.2	62.2	61.6	--	105
For other board (near HDD)						
PCB near U1	94.5	95.2	86.8	81.0	--	105
For DC board:						
PCB near Q1	100.9	100.8	99.1	98.5	--	105
L1 coil	100.7	100.8	103.4	103.8	--	105
PCB near U1	95.7	95.8	100.7	100.3	--	105
PCB near U2	88.3	88.1	82.1	81.7	--	105
L3 coil	103.7	103.1	91.7	91.1	--	105
For main board (near DC board):						
PCB near U1	75.1	75.0	64.5	64.1	--	105
For CPU board:						
PCB near U4	84.3	84.6	82.5	81.6	--	105
PCB near U8	80.0	80.6	79.1	78.3	--	105
PCB near U3	73.4	75.0	69.8	69.6	--	105
RTC battery	78.4	79.9	74.5	74	--	100
For other parts:						
HDD body	61.0	61.0	60.9	59.9	--	--
Enclosure outside (heat sink), near U4	56.1	56.8	58.5	58.6	--	60
Enclosure inside (plastic), near U4	63.4	63.0	63.5	63	--	65
Enclosure outside (plastic), near U4	52.1	51.9	54.0	53.9	--	85
Enclosure outside (metal), near DC-IN jack	54.8	55.1	58.8	58.6	--	60
Enclosure inside (plastic), near heat sink	55.5	54.9	49.5	48.2	--	65
Enclosure outside (plastic), near heat sink	54.4	53.9	46.6	45.9	--	85
Tamb	26.4	25.7	25.7	25.5	--	--
Tma	40.0	40.0	40.0	40.0	--	--
Test Condition:	E)	--	--	--	--	--
For power adaptor:						
T1 coil	90.4	--	--	--	--	190
T1 core	81.8	--	--	--	--	190
Enclosure outside (plastic), near T1	62.3	--	--	--	--	--

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Clause	Requirement Test	Result – Remark	Verdict

For D/A inverter:						
PCB near IC1	96.6	--	--	--	--	150
L2 coil	97.4	--	--	--	--	--
T1 coil	97.7	--	--	--	--	--
For other board (near HDD)						
PCB near U1	106.2	--	--	--	--	150
For DC board:						
PCB near Q1	116.8	--	--	--	--	150
L1 coil	116.0	--	--	--	--	--
PCB near U1	112.3	--	--	--	--	150
PCB near U2	102.6	--	--	--	--	150
L3 coil	118.7	--	--	--	--	--
For main board (near DC board):						
PCB near U1	89.1	--	--	--	--	150
For CPU board:						
PCB near U4	97.9	--	--	--	--	150
PCB near U8	93.4	--	--	--	--	150
PCB near U3	88.9	--	--	--	--	150
RTC battery	93.6	--	--	--	--	--
For other parts:						
HDD body	71.7	--	--	--	--	--
Enclosure outside (heat sink), near U4	69.8	--	--	--	--	--
Enclosure inside (plastic), near U4	67.2	--	--	--	--	--
Enclosure outside (plastic), near U4	63.0	--	--	--	--	--
Enclosure outside (metal), near DC-IN jack	67.4	--	--	--	--	--
Enclosure inside (plastic), near heat sink	67.5	--	--	--	--	--
Enclosure outside (plastic), near heat sink	65.8	--	--	--	--	--
Tamb	23.9	--	--	--	--	--
Tma	40.0	--	--	--	--	--
For model xxxxxONYX-1922DTy-xxxxxxxx						
Test Condition:	A)	B)	C)	D)	F)	--

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Clause	Requirement Test	Result – Remark	Verdict

For power adaptor:						
T1 coil	92.9	87.7	87.4	86.9	--	145
T1 core	83.7	79.3	79.2	78.6	--	145
Enclosure outside (plastic), near T1	63.3	59.36	59.9	58.3	--	85
For D/A inverter:						
PCB near IC1	81.4	79.6	69.5	69	91.1	105
L2 coil	79.8	78.4	64.8	63.1	90.5	105
T1 coil	80.7	79.5	62.7	61.2	90.9	105
For other board (near HDD):						
PCB near U1	72.5	70.2	61.8	61	77.4	105
For DC board:						
PCB near Q1	97.7	95.9	922	91.4	103.3	105
L1 coil	103.2	103.6	98.9	98	103.4	105
PCB near U1	83.6	82	76.2	75.4	89.8	105
PCB near U2	76.4	75	67.2	66.4	82.3	105
L5 coil	77.6	76.5	66.8	65.9	83.8	105
For other board (near DC board):						
PCB near T3	82.7	77	77	82.2	84.1	105
PCB near U2	86.5	84.9	76.6	83.5	92.5	105
L1 coil	92.2	75.6	74.6	78.8	81.7	105
L2 coil	76.2	72	72.9	75	78.1	105
For CPU board:						
PCB near U4	85.9	84.5	80.6	79.9	94.1	105
PCB near U15	88.5	87.3	85.0	84.4	97.1	105
PCB near U8	92.7	91.4	90.7	89.4	100.6	105
PCB near U16	91.0	89.8	89.8	88.9	99.3	105
RTC battery	82.2	80.9	76.3	75.3	91.0	100
For other parts:						
HDD body	62.6	57.2	55.2	55.9	67.7	--
Battery cell (Battery pack)	64.2	63.2	62.3	61.5	73.9	100
Enclosure outside (heat sink), near U8	58.1	57.7	57.9	56.0	57.8	60

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Clause	Requirement Test	Result – Remark	Verdict

Enclosure inside (plastic), near U8	58.1	55.6	59	59.3	55.7	65
Enclosure outside (plastic), near U8	53.0	50.9	55.3	55.7	55.4	85
Enclosure outside (metal), near DC-IN jack	58.1	56.9	58.1	59.3	58.1	60
Enclosure inside (plastic), near heat sink	55.6	55.3	46.9	45.1	57.0	65
Enclosure outside (plastic), near heat sink	51.9	52.2	44.0	43.2	55.9	85
Tamb	24.9	24.5	23.4	23.9	24.7	--
Tma	40.0	40.0	40.0	40.0	40.0	--
Test Condition:	E)	--	--	--	--	--
For power adaptor:						
T1 coil	89.5	--	--	--	--	190
T1 core	81.1	--	--	--	--	190
Enclosure outside (plastic), near T1	62.2	--	--	--	--	--
For D/A inverter:						
PCB near IC1	94.1	--	--	--	--	150
L2 coil	93.5	--	--	--	--	--
T1 coil	93.7	--	--	--	--	--
For other board (near HDD):						
PCB near U1	81.1	--	--	--	--	150
For DC board:						
PCB near Q1	108.1	--	--	--	--	150
L1 coil	115.5	--	--	--	--	--
PCB near U1	92.7	--	--	--	--	150
PCB near U2	85.0	--	--	--	--	150
L5 coil	86.8	--	--	--	--	--
For other board (near DC board):						
PCB near T3	85.7	--	--	--	--	150
PCB near U2	95.0	--	--	--	--	150
L1 coil	83.4	--	--	--	--	--
L2 coil	79.6	--	--	--	--	--
For CPU board:						
PCB near U4	97.3	--	--	--	--	150

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Clause	Requirement Test	Result – Remark	Verdict

PCB near U15	100.2	--	--	--	--	150
PCB near U8	104.3	--	--	--	--	150
PCB near U16	102.7	--	--	--	--	150
RTC battery	93.9	--	--	--	--	--
For other parts:						
HDD body	79.1	--	--	--	--	--
Battery cell (Battery pack)	83.6	--	--	--	--	--
Enclosure outside (heat sink), near U8	66.9	--	--	--	--	--
Enclosure inside (plastic), near U8	65.1	--	--	--	--	--
Enclosure outside (plastic), near U8	59.5	--	--	--	--	--
Enclosure outside (metal), near DC-IN jack	66.2	--	--	--	--	--
Enclosure inside (plastic), near heat sink	66.6	--	--	--	--	--
Enclosure outside (plastic), near heat sink	63.3	--	--	--	--	--
Tamb	24.0	--	--	--	--	--
Tma	40.0	--	--	--	--	--
For Battery Pack (Manufacturer: AAEON / Type: AAE-123)						
	G)	H)	--	--	--	--
PCB between U1 and U2	48.1	118.2	--	--	--	130
PCB near U5	43.7	78.3	--	--	--	130
PCB near R31	45.9	93.0	--	--	--	130
Battery cell	44.4	78.7	--	--	--	100
Tma	40.0	40.0	--	--	--	--
Tamb	28.7	28.5	--	--	--	--

Supplementary information:

1. Tests were conducted with power adaptor (FSP Group Inc. / PMP120-14-yyy).
2. The maximum specified ambient temperature is 40°C.
3. Maximum normal load was defined as follows: HDD plays continuously, LCD panel with maximum contrast / brightness, the dummy load of 2.5W is applied in each USB ports and empty battery pack(for model xxxxxONYX-1922DTy-xxxxxxxx).

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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
Cleaning (44.7): Rub the unit with a piece of cloth with some water or rubbing alcohol.		Whole unit.	No dielectric breakdown.
Humidity treatment at 30°C, 93% R.H. for 48 hours		Whole unit and external power adaptor	No dielectric breakdown.
supplementary information: 1. Tests were conducted with power adaptor (FSP Group Inc. / PMP120-14-yyy). 2. Tests were conducted on models xxxxxONYX-1922DTy-xxxxxxxx and xxxxxONYX-192DTy-xxxxxxxx.			

45.	TABLE: hydrostatic pressure and pressure-relief device cycling test			**N/A**
test type and condition	part under test	test pressure	remarks	
supplementary information:				

52.	TABLE: abnormal operation		**P**
test type, condition and clause reference		observed results	Remarks
Ventilation openings all covered		No damage, no hazards. Refer to table 42 for temperature measurement.	Measured temperature all below the limit.
supplementary information: 1. Tests were conducted with power adaptor (FSP Group Inc. / PMP120-14-yyy). 2. Tests were conducted on models xxxxxONYX-1922DTy-xxxxxxxx and xxxxxONYX-192DTy-xxxxxxxx.			

56.1	TABLE: lists of critical component parts				**P**
object/part No.	manufac-turer/trademark	type/model	Technical data	standard	Mark(s) of conformity[1])
Medical Power Adaptor	FSP Group Inc.	PMP120-14-yyy (y = 0-9, A-Z or blank for marketing purpose)	I/P: AC 100-240V, 47-63Hz, 1.4-0.6A O/P: DC 24V, 5A. 40°C, Class I	EN 60601-1:1990+A1+A2+A13 IEC 60601-1:1988+A1+A2	TÜV

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Clause	Requirement Test	Result – Remark	Verdict

Enclosure	Sabic Innovative Plastics	C2800	V-0, 65°C, 3.1mm thick min.	UL 94	UL
Arm Base	--	--	Metal, Weight 2.97kg approx.	--	--
Metallic chassis	--	--	1.0mm thick min.	--	--
Speaker (Two provided)	--	--	4ohm, 2W max.	--	--
LCD Panel	Au Optronics Corporation	M190EG01 V2	19.0” TFT type	--	--
H.D.D. (Optional)	--	--	5Vdc, 0.6A max.	EN 60950-1:2001 IEC 60950-1: 2001	TUV, CB
Battery Pack (Optional)	AAEON	AAE-123	11.1Vdc, 4107mAh	--	--
- Battery Cell (Six provided) (3S2P)	Samsung SDI	ICR18650-22	Lithium-Ion type, 3.7Vdc, 2200mAh	UL 1642	UL
- Thermal Link (FUSE1)	NEC	D6X	32Vdc, 12A, 139°C	EN 60691	VDE
- MOSFET (U1, U2)	Alpha & Omega	AO4407	--	--	--
- Protective IC (U5)	Texas	BQ29312A	--	--	--
- Sensor Resister (R31)	--	--	0.01ohm, 2W	--	--
- Thermistor (TH1,TH2)	--	--	10kohm at 25°C	--	--
- PCB	--	--	Min. V-1. Min. 130°C.	UL 796	UL
RTC Battery (BAT1)	Panasonic Corporation Panasonic Corporation Of North America	CR2032	Max. abnormal charging current 10mA.	UL 1642	UL
	Hitachi Maxell Ltd.	CR2032	Max. abnormal charging current 10mA.	UL 1642	UL
	Sony Energy Devices Corp.	CR2032	Max. abnormal charging current 10mA.	UL 1642	UL

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Clause	Requirement Test	Result – Remark	Verdict

	Toshiba Home Appliances Corp.	CR2032	Max. abnormal charging current 10mA.	UL 1642	UL
	Mitsubishi Electric Corp.	CR2032	Max. abnormal charging current 10mA.	UL 1642	UL
	Sanyo Energy (U S A) Corp.	CR2032	Max. abnormal charging current 10mA.	UL 1642	UL
DC/AC Inverter	Hwa Youn C0., Ltd.	QF132V1.16(S)	I/P: 13.2Vdc max., 2050mA max. O/P: 760Vrms, 6.7mArms max.	--	--
- Transformers (T1, T2)	Hwa Youn	EFD15-TF505	Min. 105°C.	--	--
PCB	--	--	Min. V-1. Min. 105°C.	UL 796	UL
[1]) an asterisk indicates a mark which assures the agreed level of surveillance					

56.10	TABLE: actuating parts and controls		**N/A**
part under test	torque applied	remarks	
supplementary information:			

56.11 b)	TABLE: foot-operated control devices loading		**N/A**
part under test	observed results	remarks	
supplementary information:			

57.4	TABLE: cord anchorages				**N/A**
cord under test	mass of equipment	pull	torque	remarks	verdict
supplementary information:					

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Clause	Requirement Test	Result – Remark	Verdict

57.4 b)	TABLE: cord bending			**N/A**
cord under test		test mass	measured curvature	remarks
supplementary information:				

57.9.1 a)	TABLE: transformers short-circuit					**N/A**
winding under test	protection	measured temperatures (C)			test duration	remarks
		primary	secondary	ambient		
supplementary information:						

57.9.1 b)	TABLE: overload						**N/A**
winding under test	protection	measured temperatures (C)			test duration	test current or thermal cut-out temp.	remarks
		primary	secondary	ambient			
supplementary information:							

57.9.2	TABLE: transformer dielectric strength				**N/A**
transformer under test	test voltage applied to	test voltage	test frequency	remarks	
supplementary information:					

59.2	TABLE: ball pressure tests			**P**
part/material	Temperature rise of this part from TABLE 42 (°C)	Test temperature (°C)	Impression diameter(mm)	
Plastic enclosure (Sabic Innovative / C2800)	63.5	75.0	0.8	
supplementary information: Tests were conducted on models xxxxxONYX-1922DTy-xxxxxxxx and xxxxxONYX-192DTy-xxxxxxxx.				

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict

	TABLE: additional tests		**P**
Clause	Test type and condition	Remarks and observed results	Verdict
For models xxxxxONYX-1922DTy-xxxxxxxx and xxxxxONYX-192DTy-xxxxxxxx			
55 (U.S): Ball Drop Test	Height: 1.3m, No damage.	No cracking.	Pass
55 (U.S): Mold Stress Relief	Test temperature = 70°C	No cracking.	Pass
56.7: Reversed Battery Connection	CR2032, Reversed battery connection	Operated normally. No hazard.	Pass
For models xxxxxONYX-1922DTy-xxxxxxxx			
4.3.8 per EN 60950-1: Lithium Battery Reverse Current Measurement	CR2032, Lithium Battery Reverse Current Measurement	Abnormal reverse current = 3.22mA (D15; 1-2, short-circuited), that did not exceed the limit (10mA) of RTC battery.	Pass
4.3.8 per EN 60950-1: Overcharging	Battery pack (Type AAE-123), (No any single fault) Charge voltage = 12.7Vdc. Test duration = 8hrs.	Max. temp. of battery cell = 32°C. No hazard.	Pass
	Battery pack (Type AAE-123), (U2, Pin 1 to 8, short-circuited) Charge voltage = 12.7Vdc. Test duration = 7hrs.	FUSE1 opened. Unit shut down at 13.9Vdc. Max. temp. of battery cell = 28.9°C.	Pass
4.3.8 per EN 60950-1: Rapid Discharging	Battery pack (Type AAE-123), (U1, Pin 1 to 8, short-circuited) Discharge current = 6.67A. Test duration = 2hrs.	FUSE1 opened. Unit shut down. Max. temp. of battery cell = 74.7°C.	Pass
4.3.8 per EN 60950-1: Reversed charging	Battery pack (Type AAE-123), Charge voltage = 12.7Vdc. Test duration = 7hrs.	Unit shut down immediately. No damage, no hazard. Max. temp. of battery cell = 28.5°C.	Pass
4.3.8 per EN 60950-1: Output short-circuiting	Battery pack (Type AAE-123), Test duration = 10min.	Unit shut down immediately. No damage, no hazard.	Pass
56.7: Reversed	Battery pack (Type AAE-123), Reversed	Operated normally. No hazard.	Pass

IEC 60601-1/EN 60601-1			
Clause	Requirement Test	Result – Remark	Verdict
Battery Connection	battery connection		
For models xxxxxONYX-192DTy-xxxxxxxx			
4.3.8 per EN 60950-1: Lithium Battery Reverse Current Measurement	CR2032, Lithium Battery Reverse Current Measurement	Abnormal reverse current = 3.29mA (D8; 1-2, short-circuited), that did not exceed the limit (10mA) of RTC battery.	Pass
supplementary information:			

Photo(s)

For models xxxxxONYX-1922DTy-xxxxxxxx

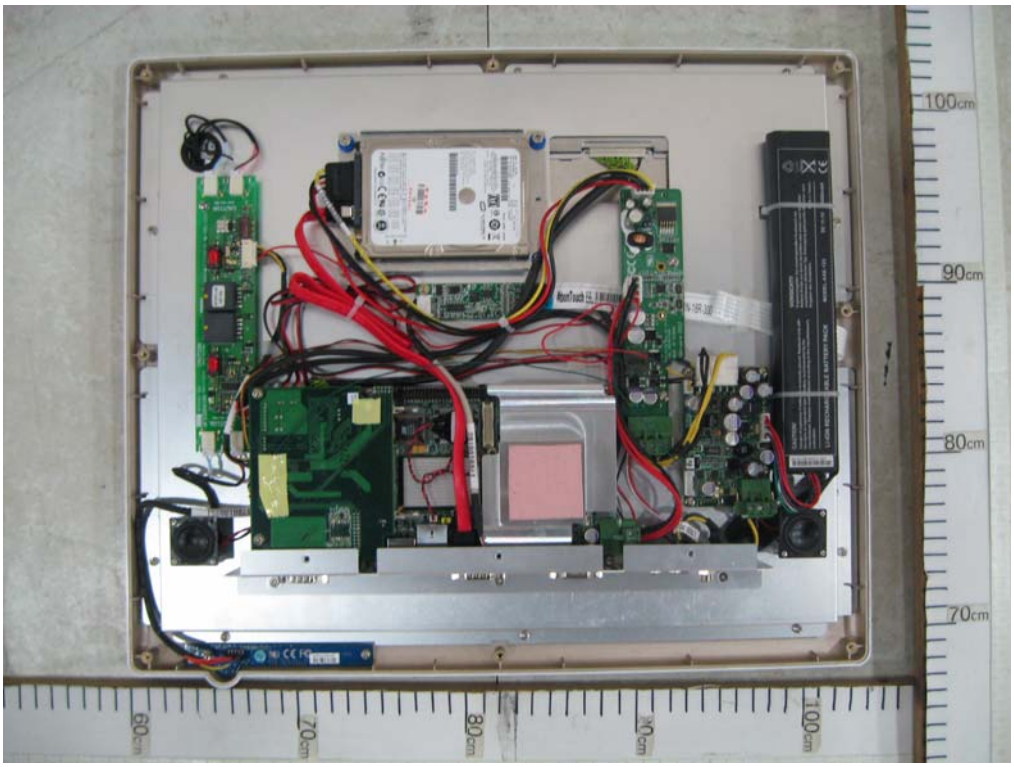
Photo(s)


50cm
40cm
30cm
20cm
10cm
30cm
50cm
60cm
70cm
80cm
90cm


100cm
90cm
80cm
70cm

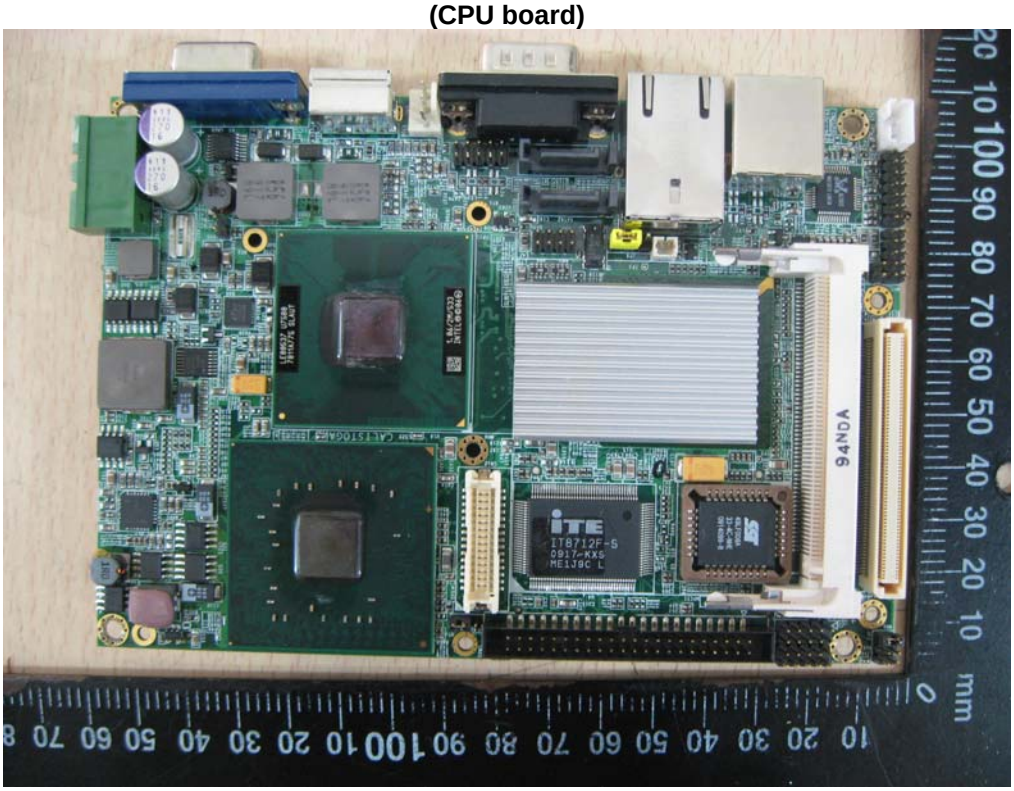
Photo(s)

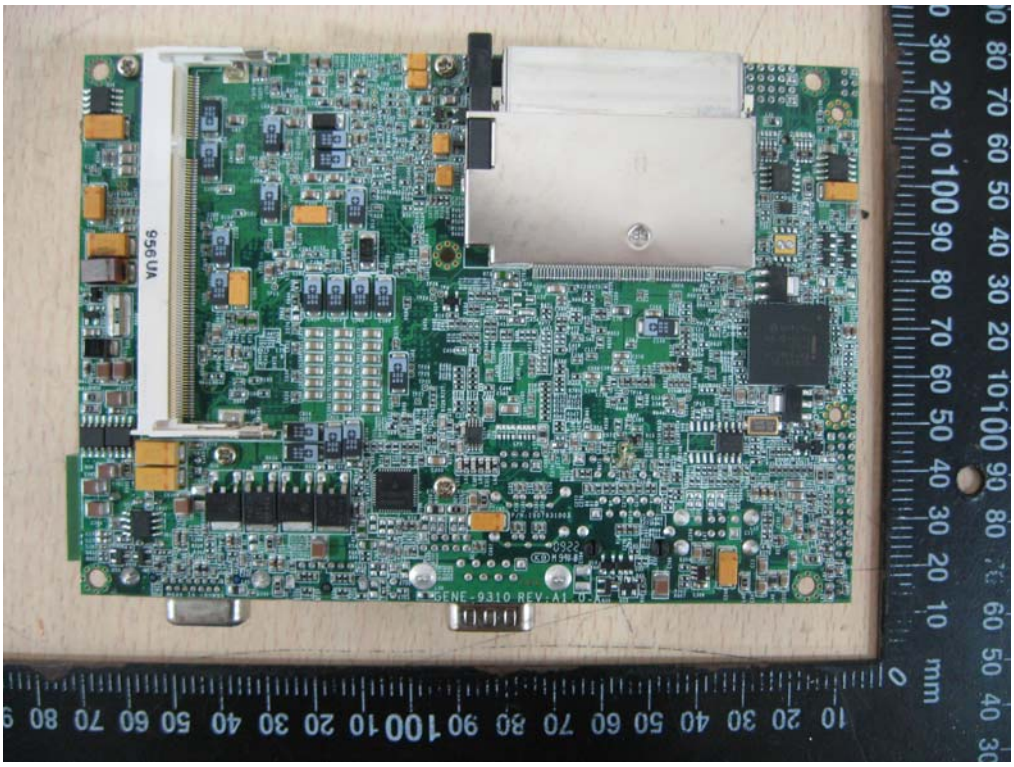
Photo(s)



Photo(s)

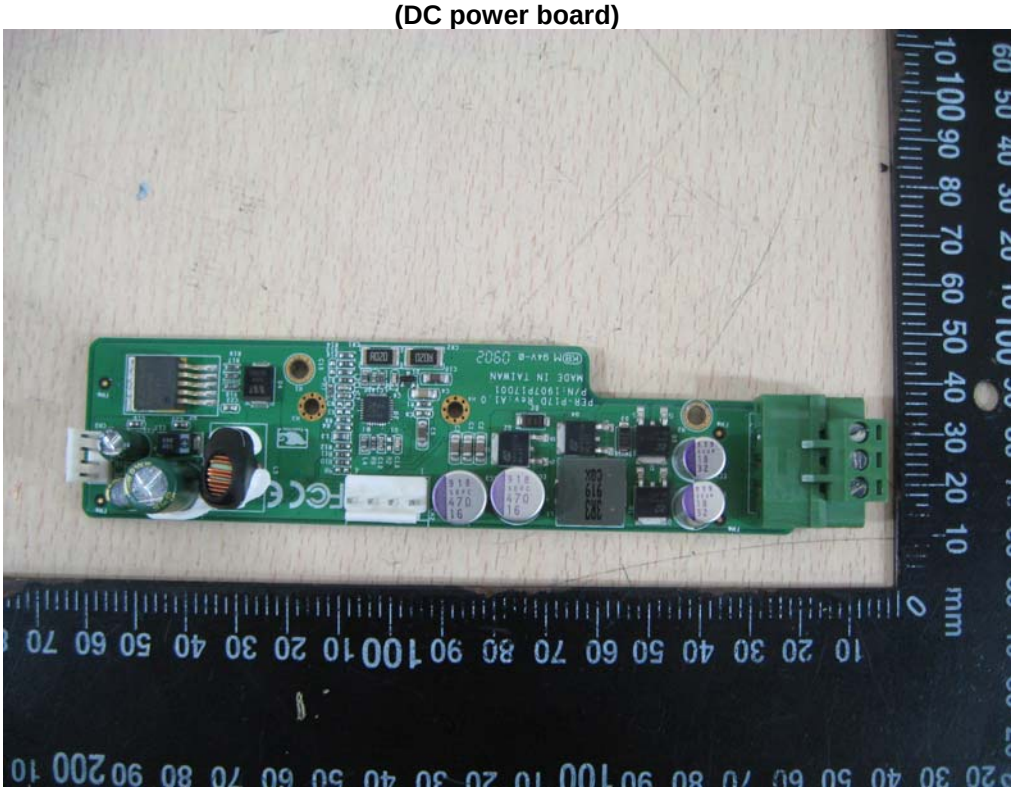
(CPU board)

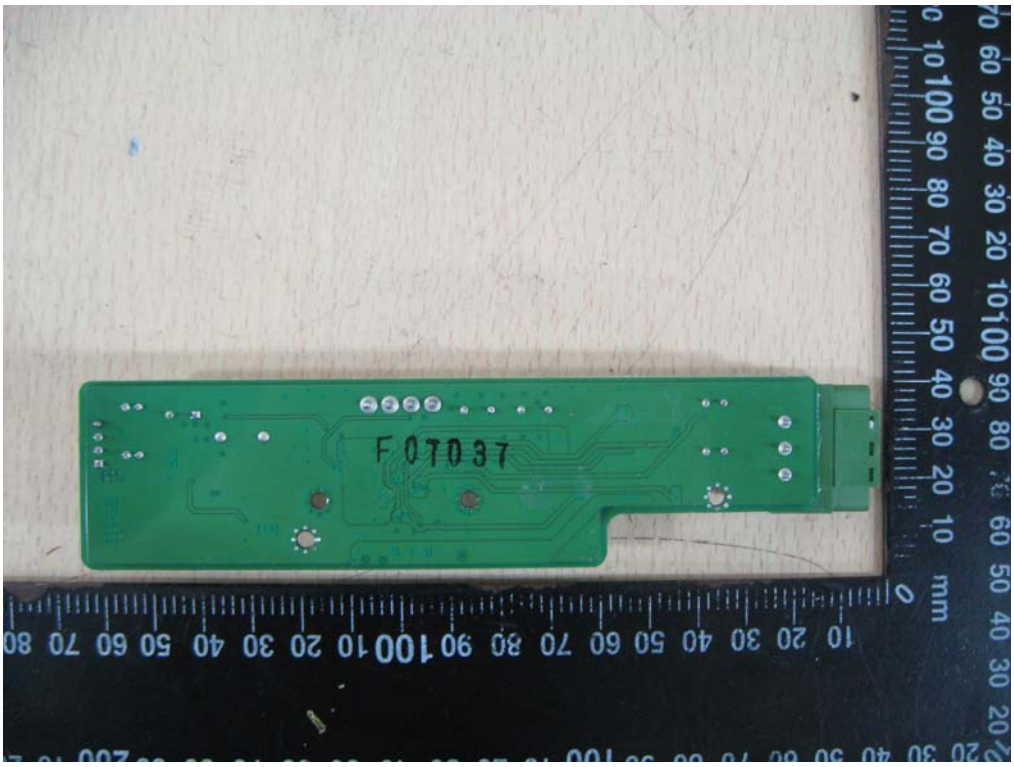




Photo(s)

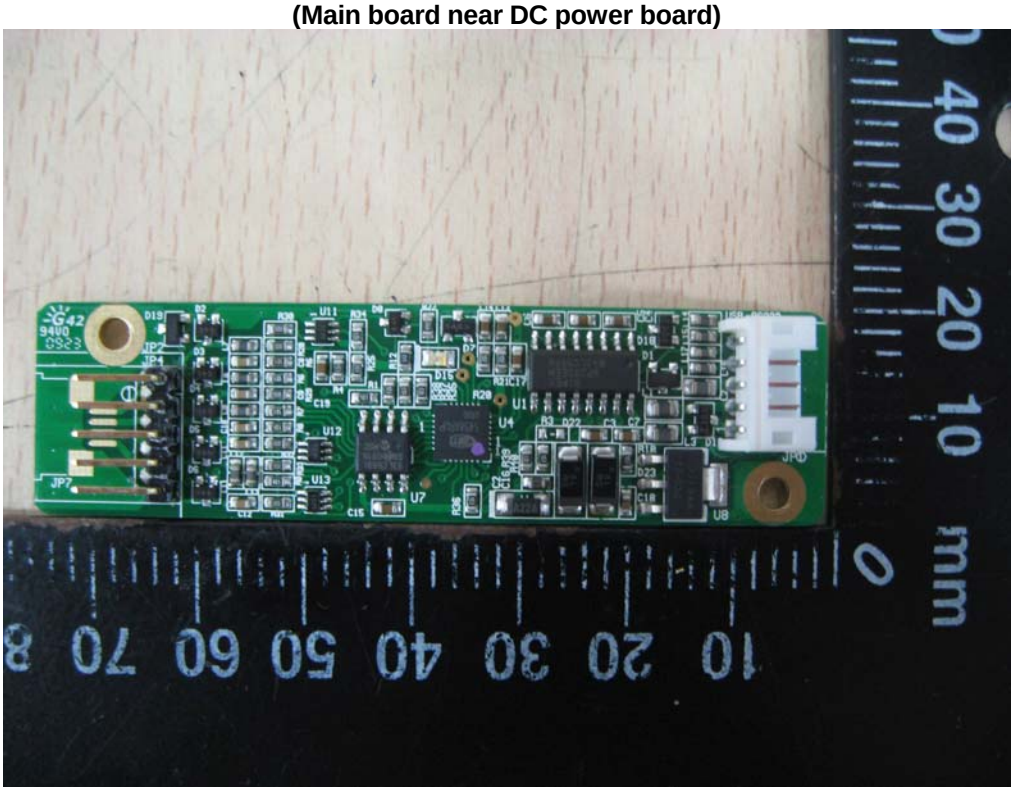
(DC power board)

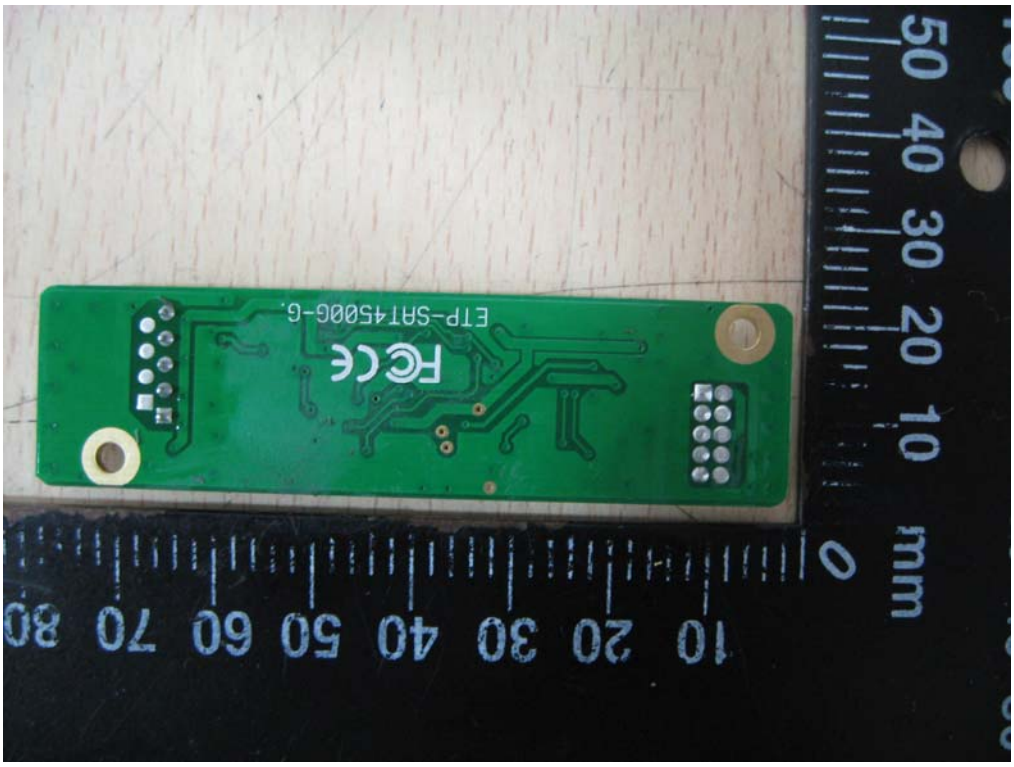




Photo(s)

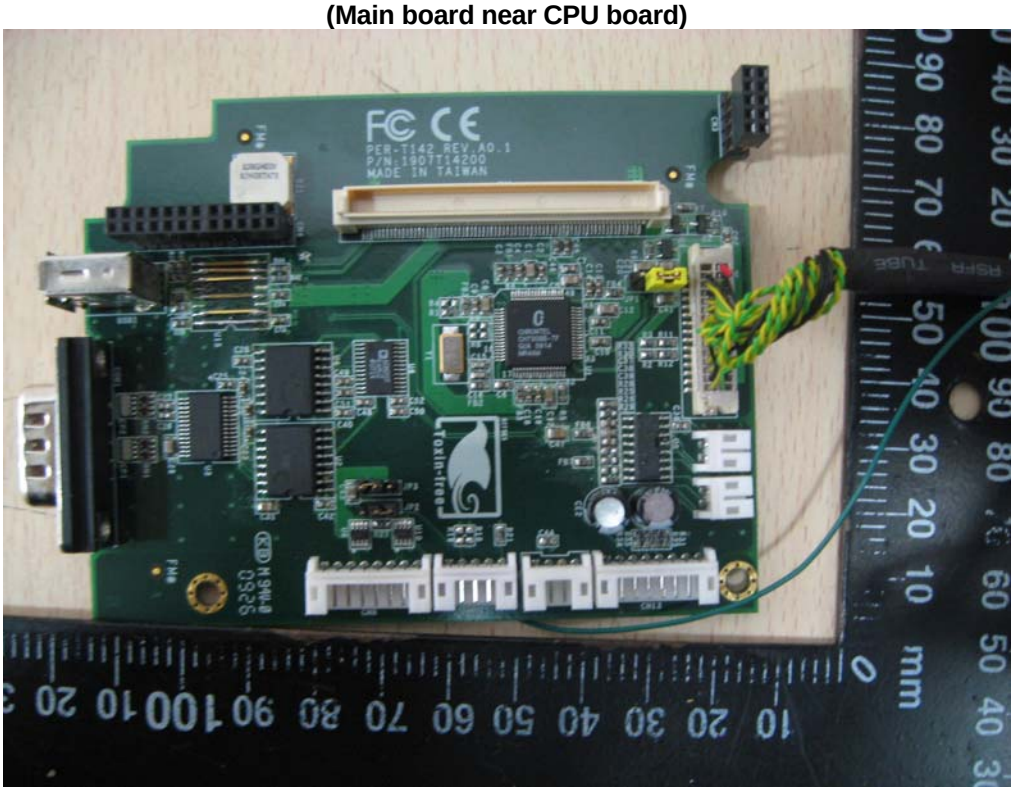
(Main board near DC power board)

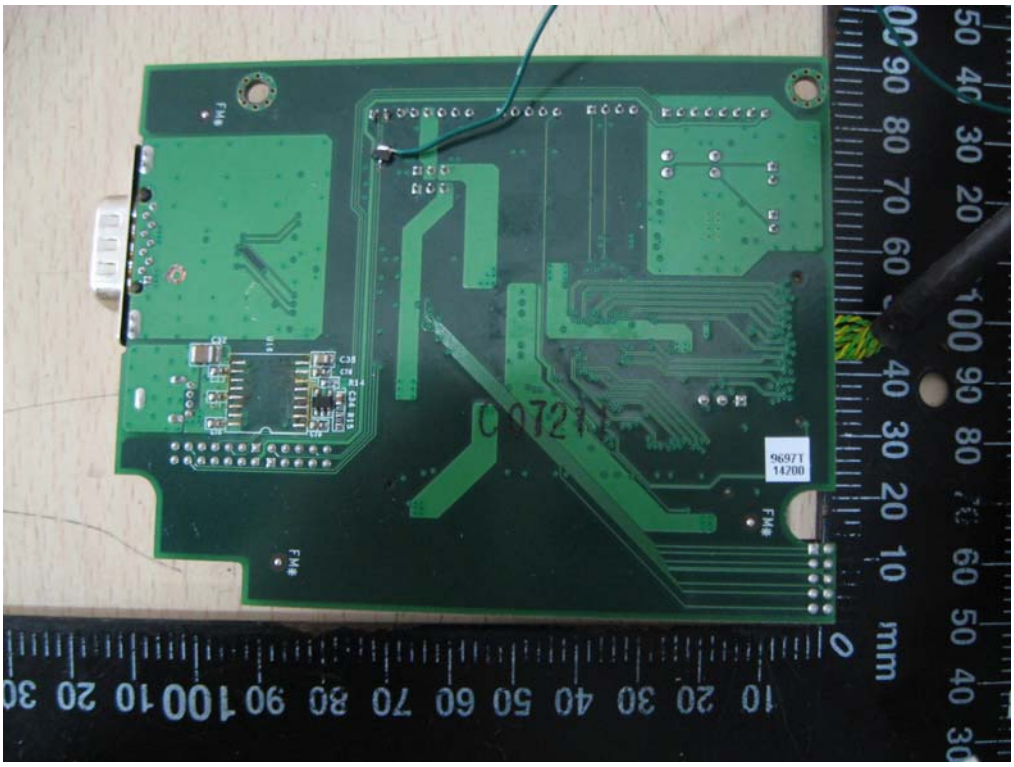




Photo(s)

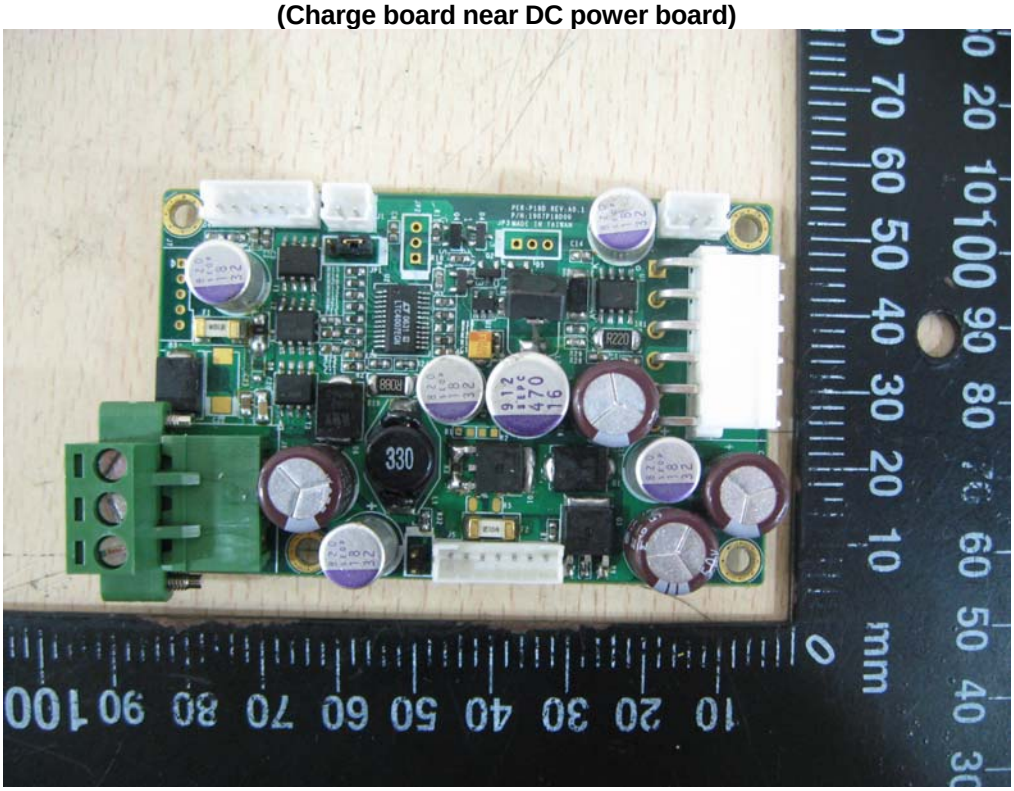
(Main board near CPU board)

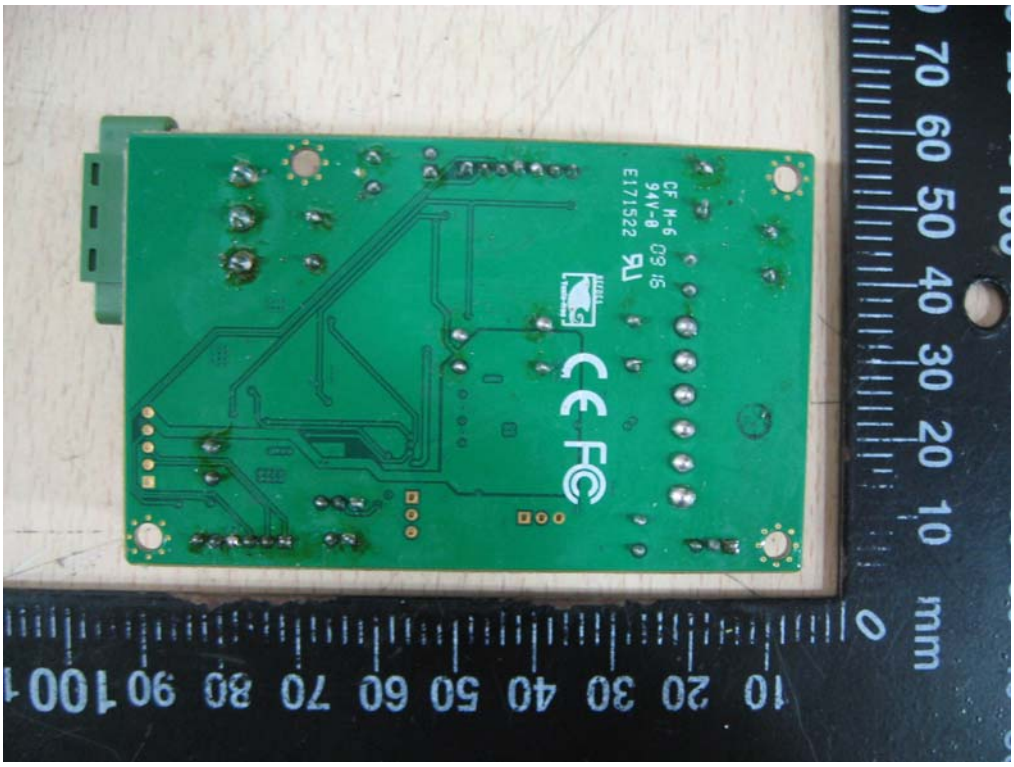




Photo(s)

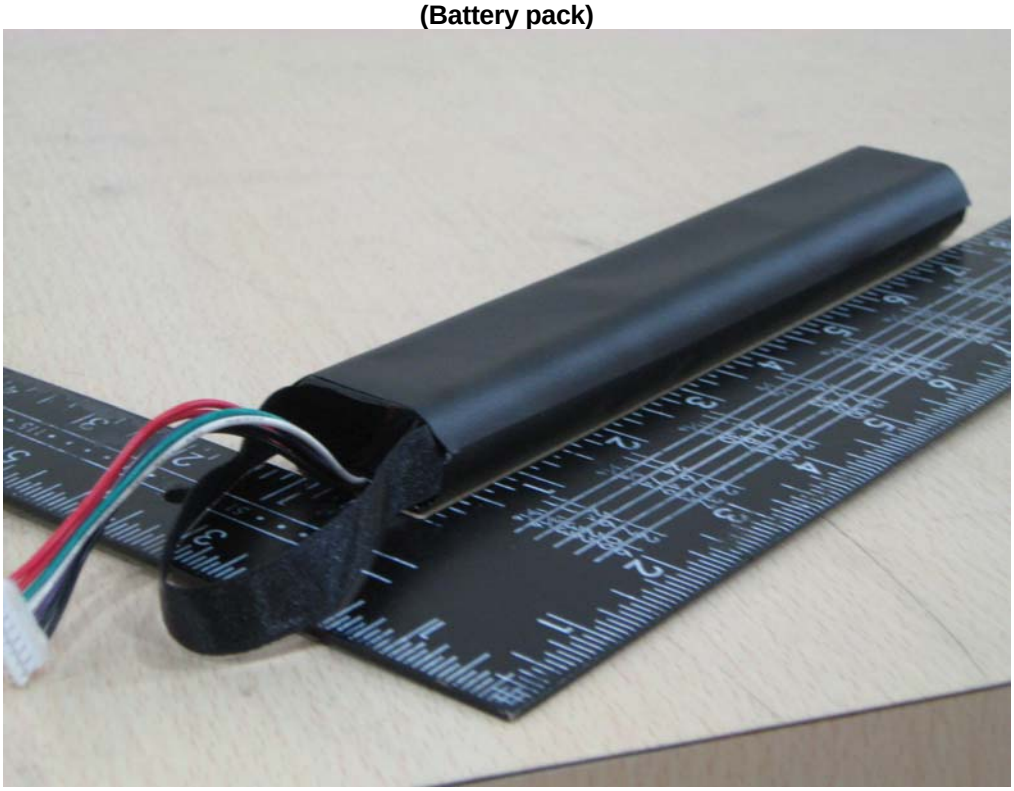
(Charge board near DC power board)





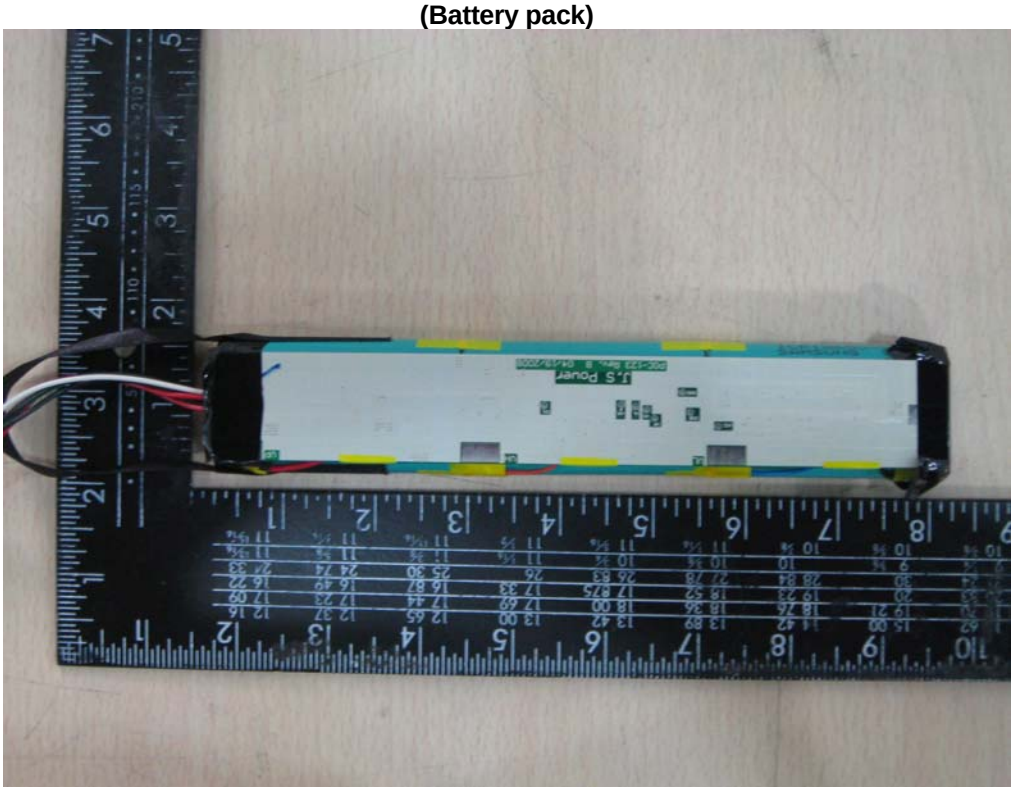
Photo(s)

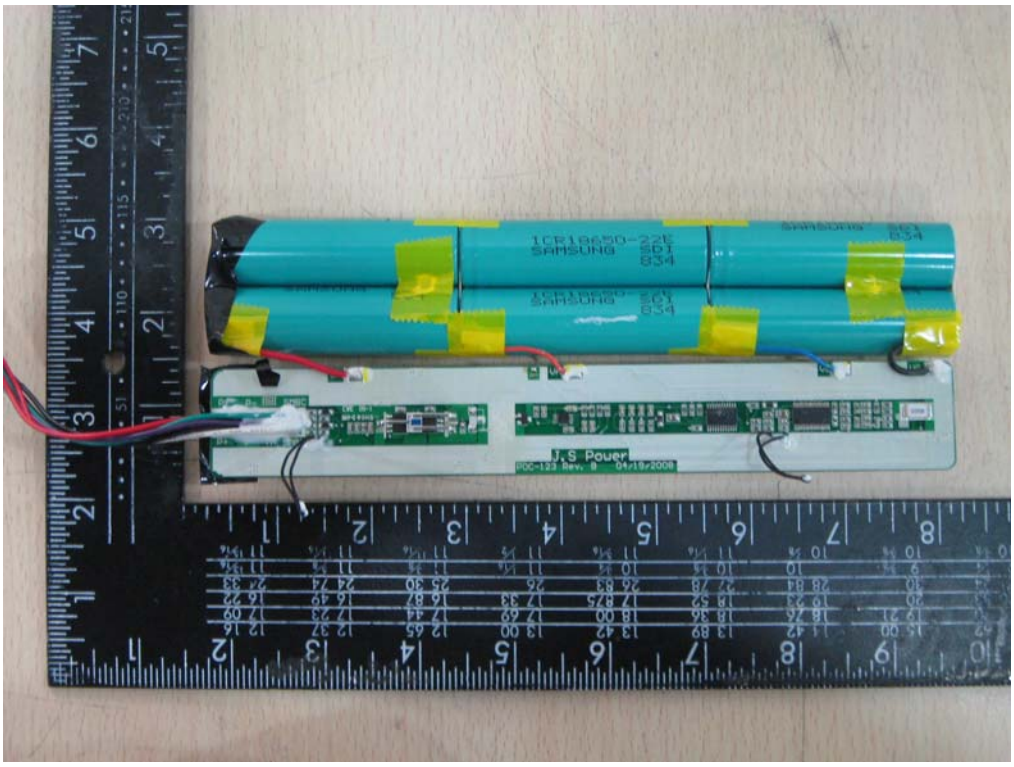
(Battery pack)



Photo(s)

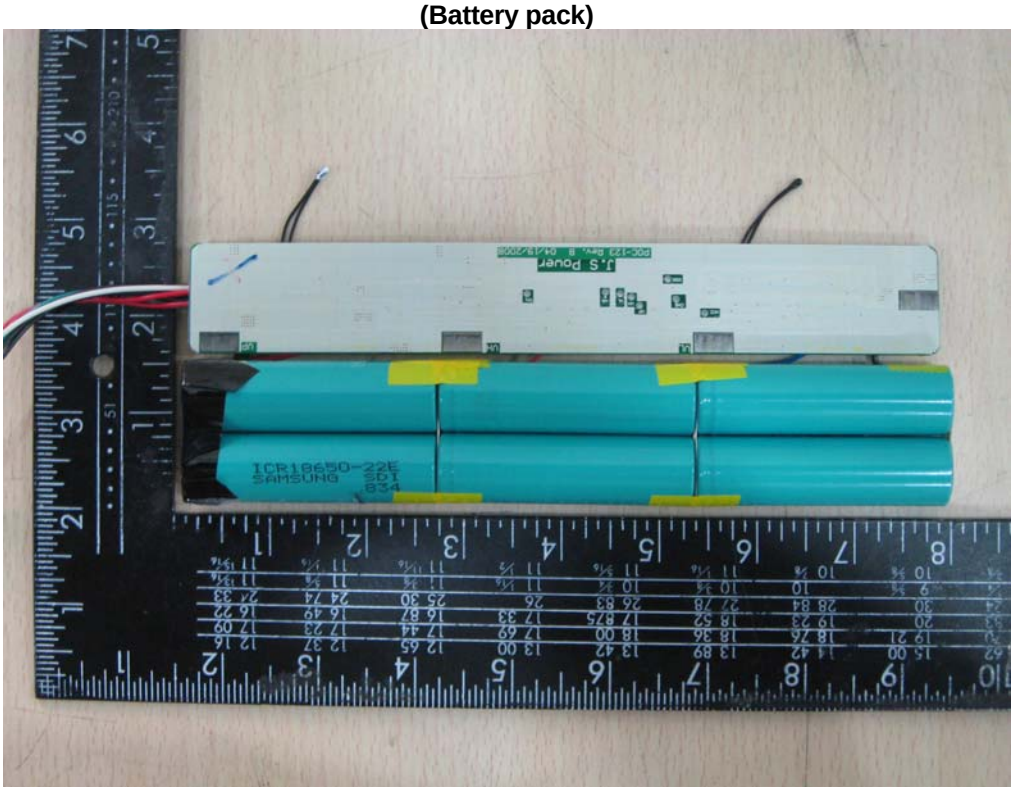
(Battery pack)





Photo(s)

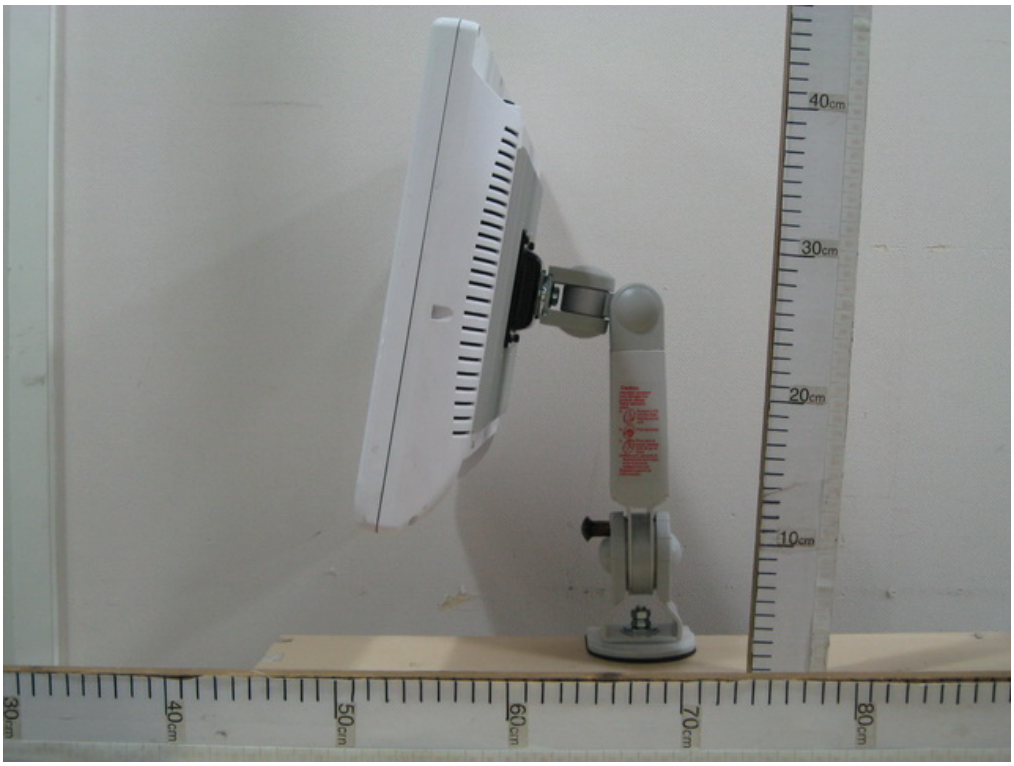
(Battery pack)



Photo(s)

For models xxxxxONYX-192DTy-xxxxxxxx

Photo(s)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70cm
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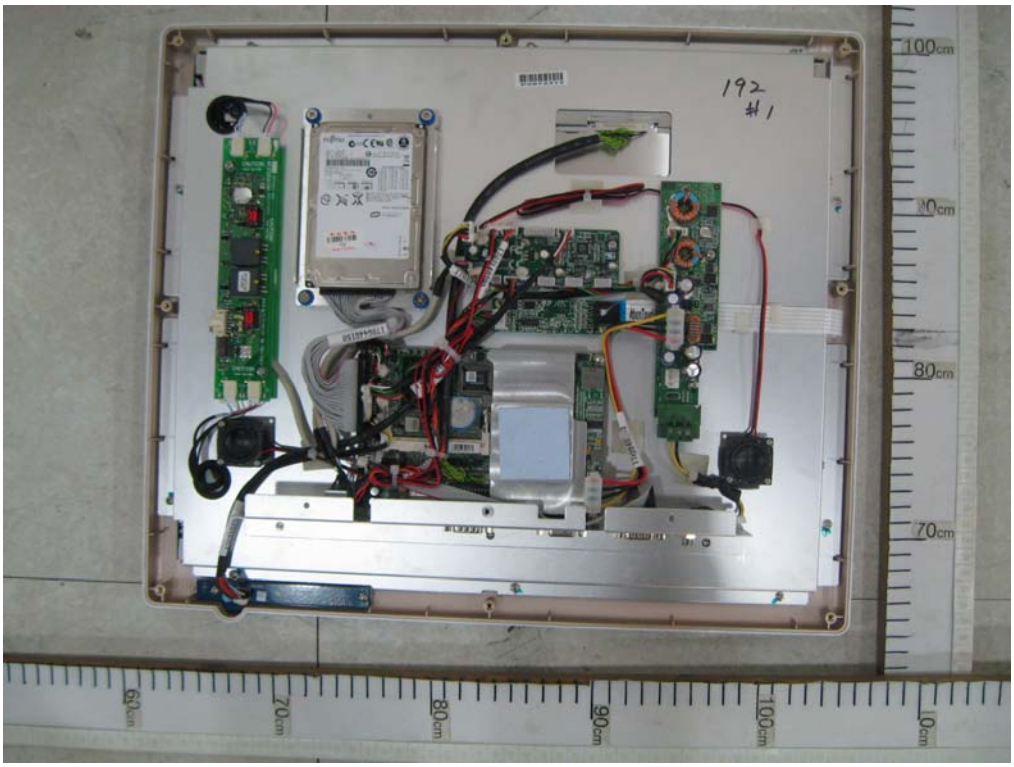
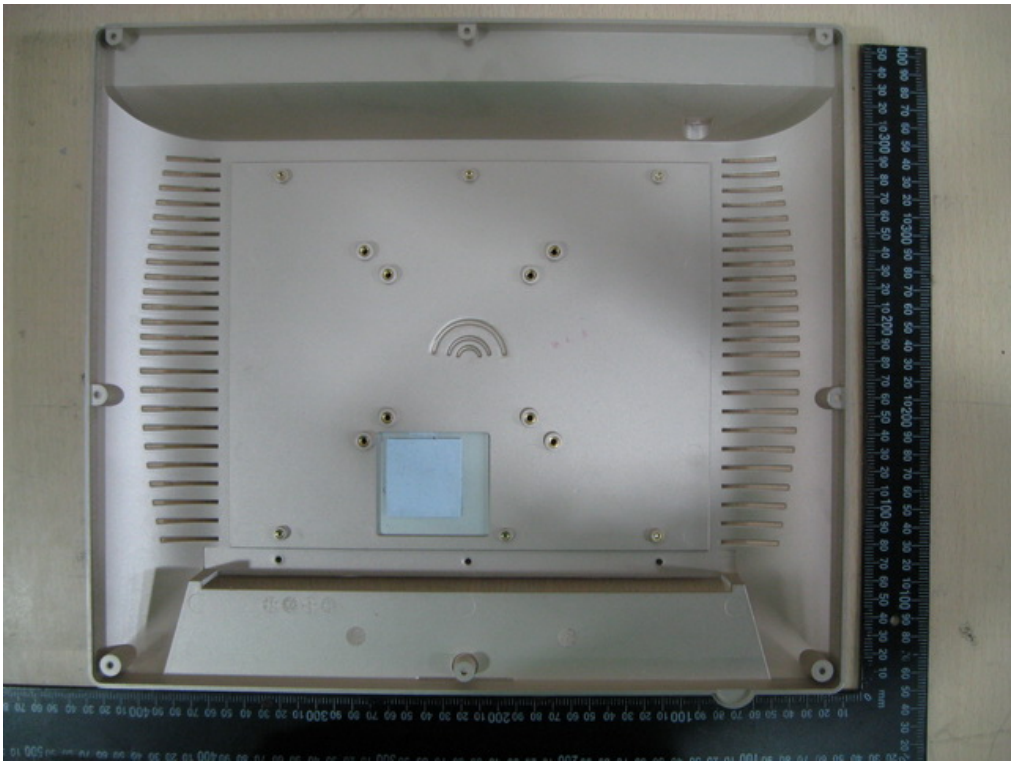
90cm
100cm

Photo(s)

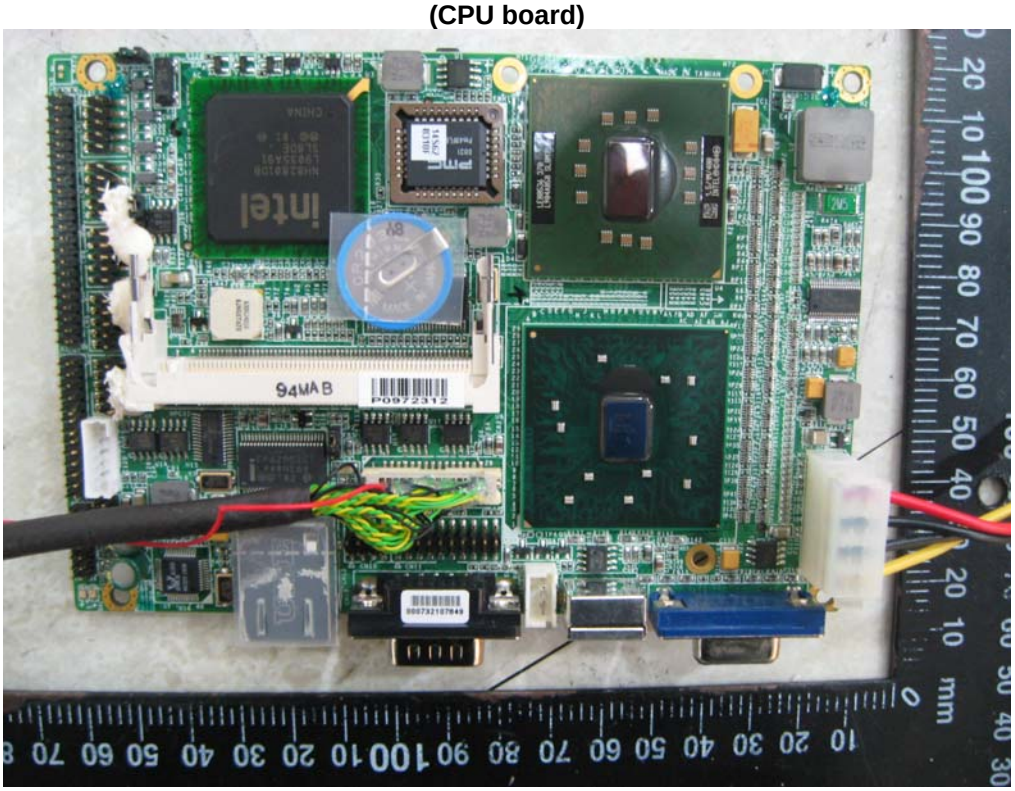
Photo(s)

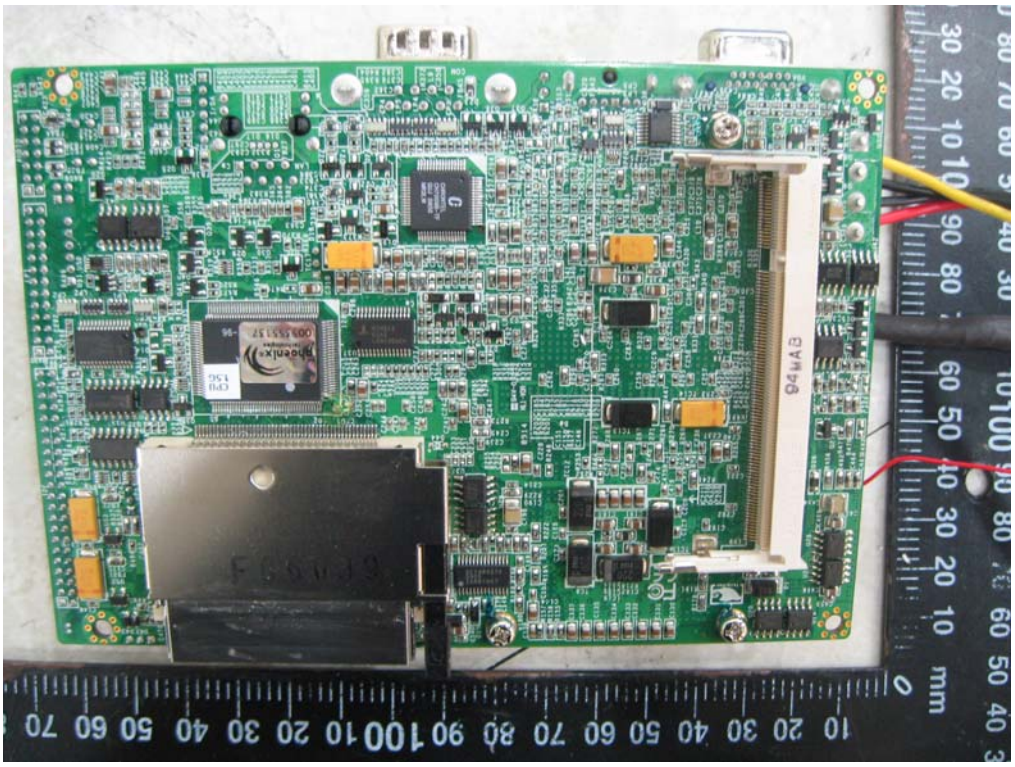




Photo(s)

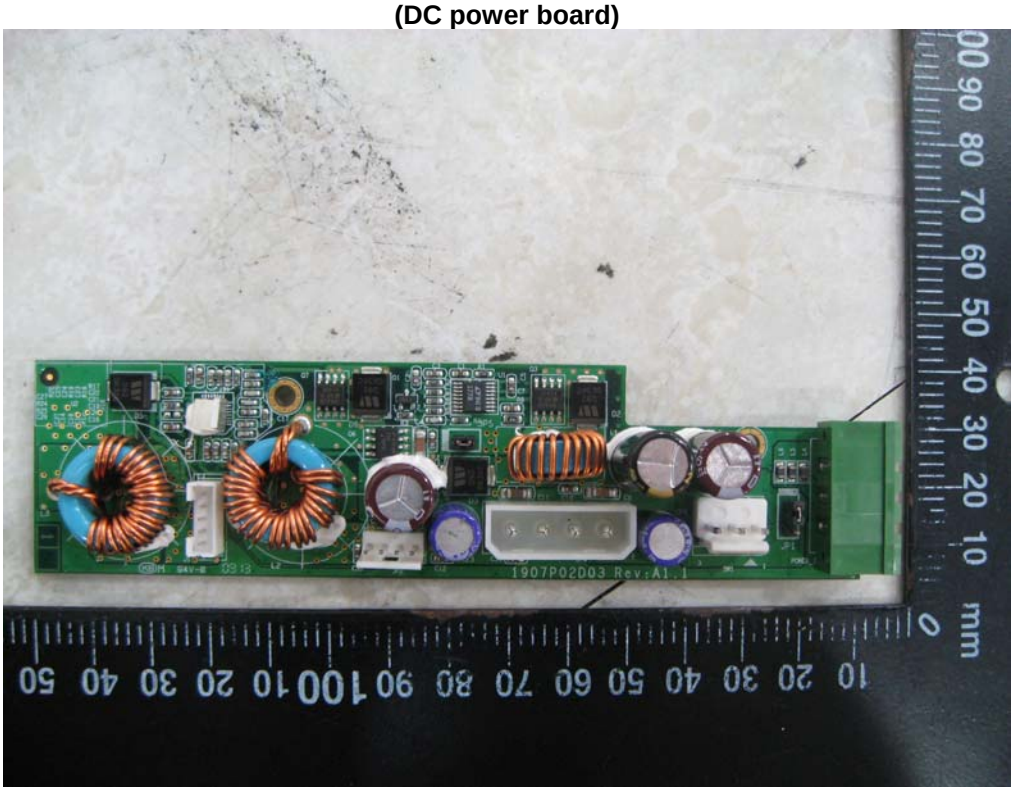
(CPU board)

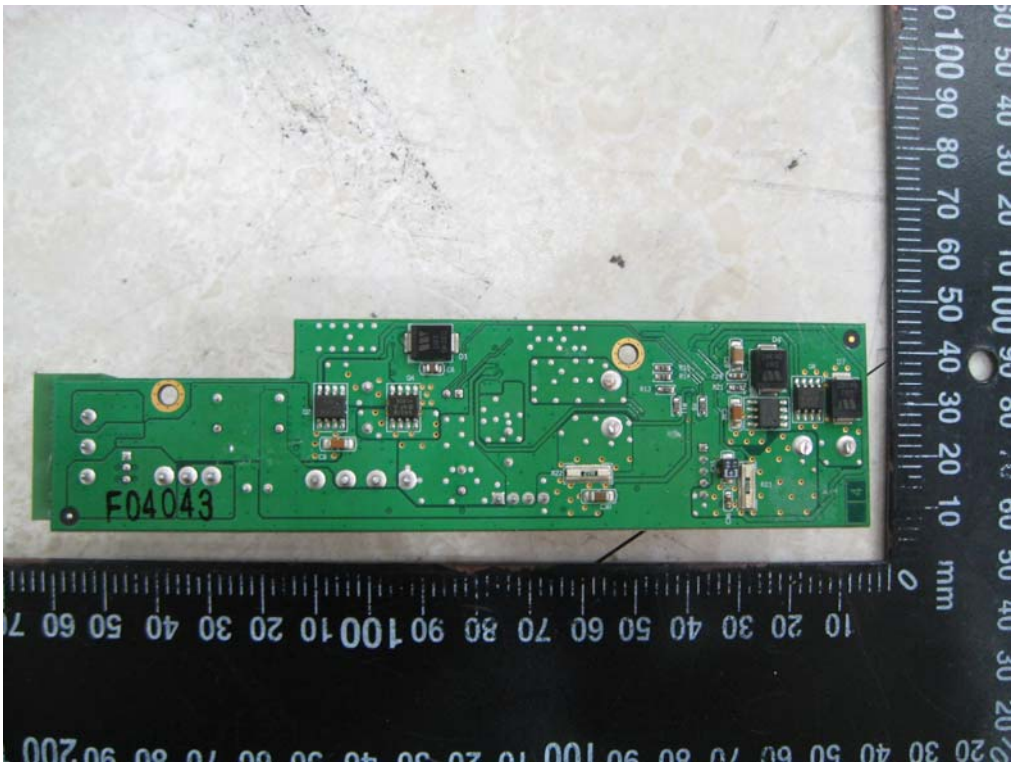




Photo(s)

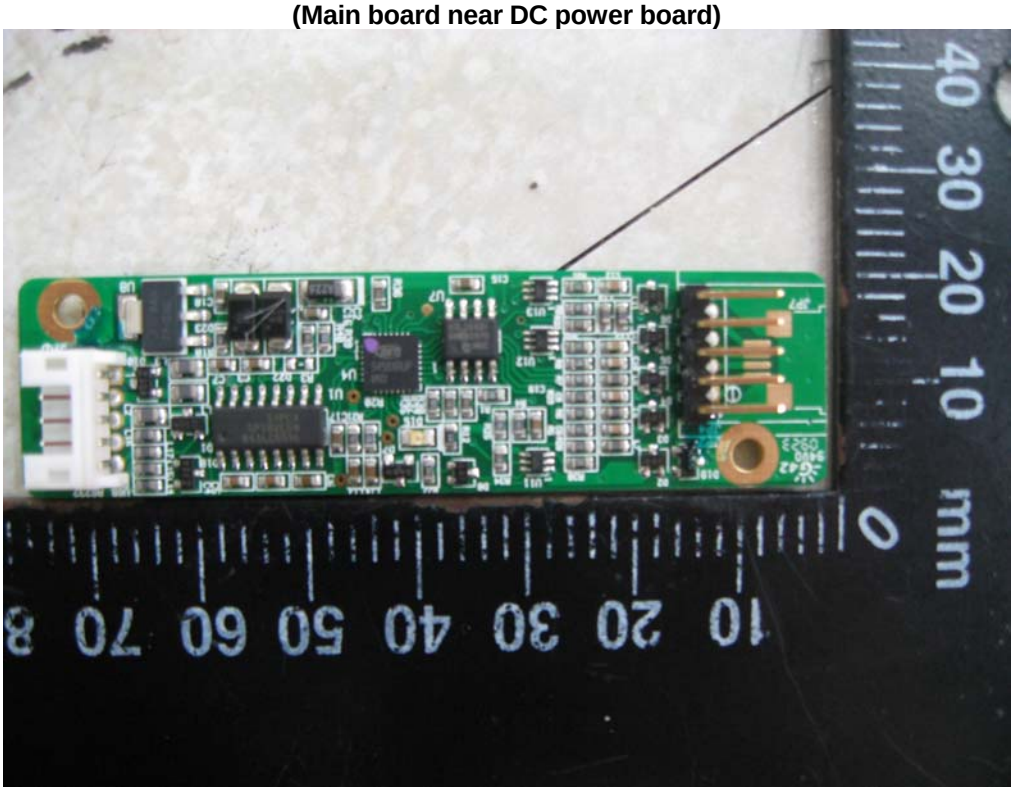
(DC power board)

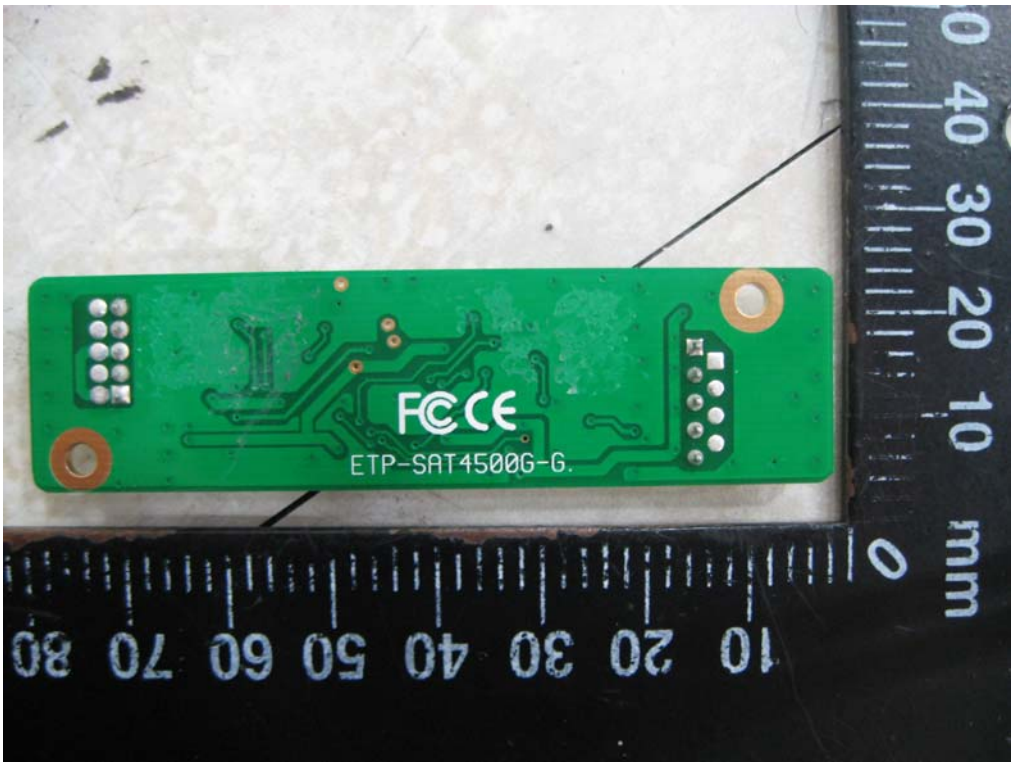




Photo(s)

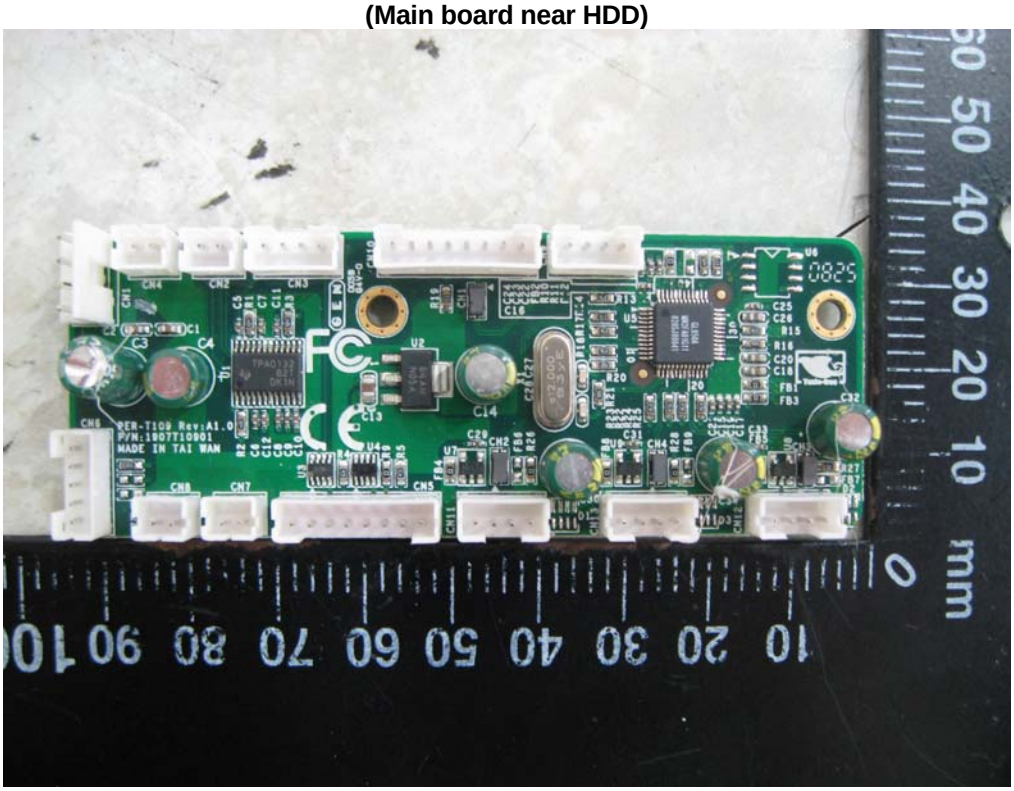
(Main board near DC power board)

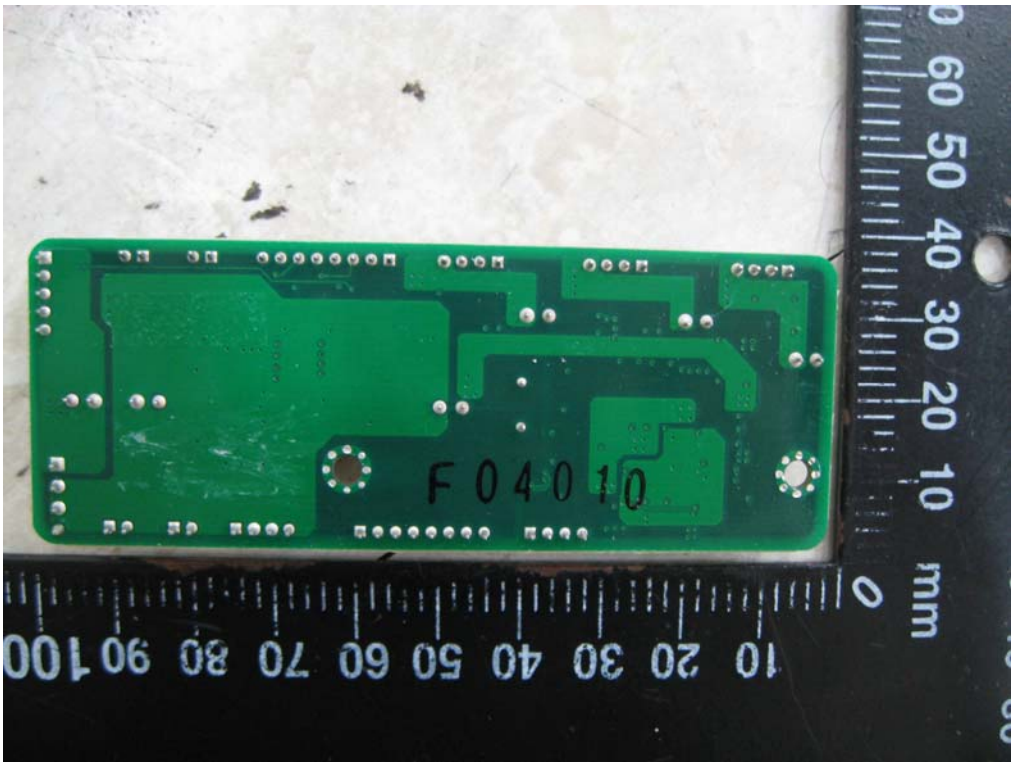




Photo(s)

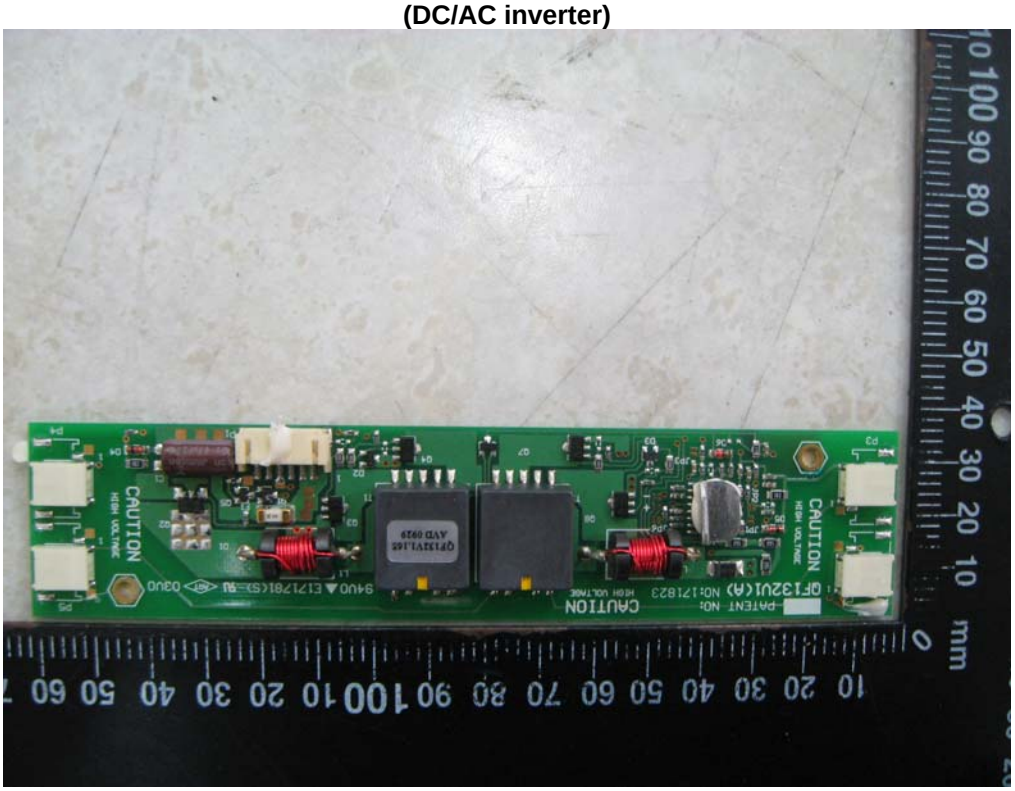
(Main board near HDD)

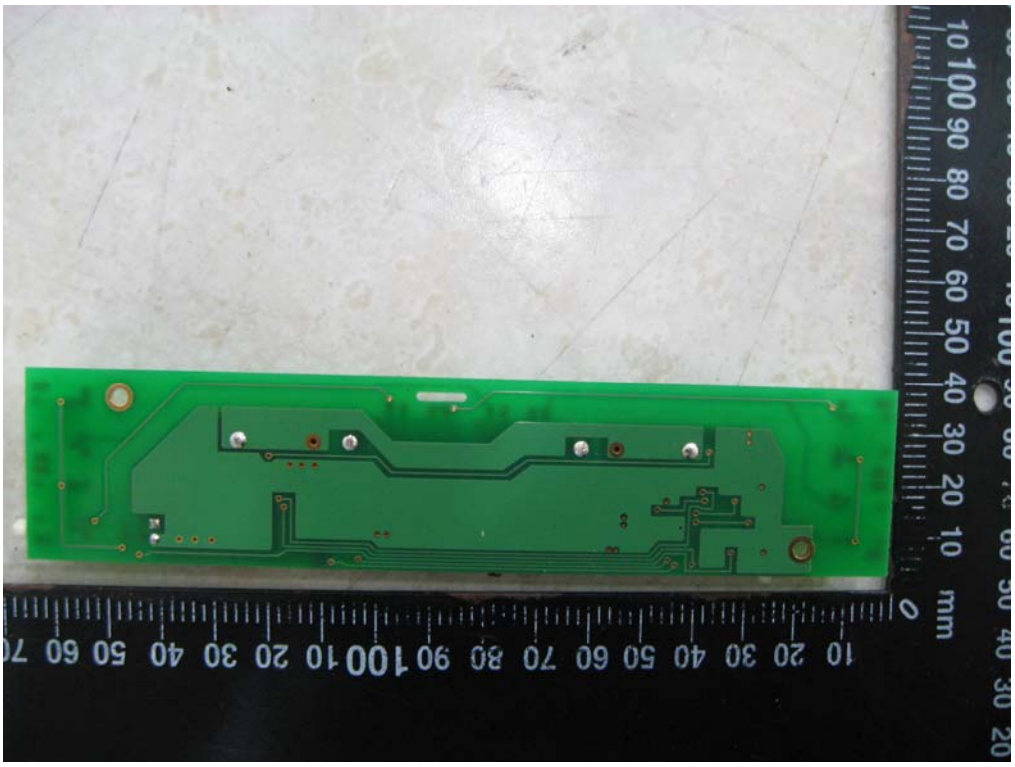




Photo(s)

(DC/AC inverter)





Photo(s)

(Arm base)