Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

TEST REPORT

IEC 61010-1/ EN 61010-1

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 1: General requirements

Report Reference No..... :	CPSZ0928781
Tested by (name and signature)..... :	Albert. Lee
Approved by (name and signature) .. :	Harry. Kwon
Date of issue..... :	2011-08-22
Contents ..... :	4 pages
Modification Test Report Reference Number ..... :	CPSA0142849
Modification to appliance..... :	Applicant address
Testing Laboratory..... :	TÜV SÜD Korea Laboratory (TKL)
Address ..... :	#315 and 316, MARIO Tower, 222-12, Guro-Dong, Guro-Gu, 152-050, Seoul, Korea
Testing location/procedure ..... :	CE-LVD
Address ..... :	Same as above
Applicant's name..... :	Boditech Med Inc.
Address ..... :	1144-2 Geoduri, Dongnaemyeon, Chuncheon, Gangwon-do, 200-883, Republic of KOREA
Test specification:	
Standard..... :	EN 61010 – 1 : 2001 (2nd Edition)
Test procedure ..... :	CE-LVD
Non-standard test method..... :	N/A
Test Report Form No..... :	IEC61010_C
TRF Originator..... :	VDE
Master TRF..... :	Dated 01-07-27

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

Test item description	:	Blood and urine analyzer
Trademark	:	Boditech
Model/Type reference	:	i-CHROMA
Rating(s)	:	12 V d.c., 3.0 A

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

Test item particulars ..... :	Blood and urine analyzer
Type of item tested ..... :	Laboratory (IVD equipment)
Description of equipment function..... :	Analyzing of blood and urine
Installation/overvoltage category..... :	N/A
Pollution degree..... :	2
Environmental rating..... :	Normal
Equipment mobility ..... :	Movable
Connection to mains supply ..... :	N/A
Operating conditions..... :	Continuous
Overall size of the equipment (L x W x H)..... :	250 mm X 185 mm X 80 mm
Mass of the equipment (kg)..... :	1.2 kg
Marked degree of protection to IEC 60529 ..... :	N/A
Accessories and detachable parts included in the evaluation ..... :	N/A
Options ..... :	N/A

Test case verdicts:

Test case does not apply to the test object..... :	N/A
Test object does meet the requirement ..... :	P(Pass)
Test object does not meet the requirement ..... :	F(Fail)

Testing ..... :	
Date of receipt of test item ..... :	N/A
Date (s) of performance of tests ..... :	N/A

General remarks:

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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

The test results presented in this report relate only to the item(s) tested.

"(see remark #)" refers to a remark appended to the report.
"(see Annex #)" refers to an annex appended to the report.
"(see Form A.#)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

Copy of marking plate:

Summary of test results (information/comments): Pass

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001, IEC/EN 61010-2-101 and IEC/EN 61010-2-081.

Product Service

TEST REPORT

IEC 61010-1/ EN 61010-1

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 1: General requirements

Report Reference No.....:	**CPSA0142849**
Tested by (name and signature).....:	Edward.Yang
Approved by (name and signature) ..:	Thomas.Kim
Date of issue.....:	2009-11-27
Contents .....:	61 Pages
Testing Laboratory.....:	TÜV SÜD Korea Laboratory (TKL)
Address .....:	#315 and 316, MARIO Tower, 222-12, Guro-Dong, Guro-Gu, 152-050, Seoul, Korea
Testing location/procedure .....:	CE-LVD
Address .....:	Same as above
Applicant's name.....:	Boditech Med Inc.
Address .....:	#3-2,Bioventure Plaza 198-60, HupyeongDong, Chuncheon, Kangwon, 200-160, Republic of Korea
Test specification:	
Standard .....:	EN 61010 – 1 : 2001 (2nd Edition)
Test procedure .....:	CE-LVD
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC61010_C
TRF Originator.....:	VDE
Master TRF.....:	Dated 01-07-27

Test item description .....:	Blood and urine analyzer
Trademark .....:	Boditech
Model/Type reference.....:	i-CHROMA
Rating(s) .....:	12 V d.c., 3.0 A

Product Service

Test item particulars ..... :	Blood and urine analyzer
Type of item tested ..... :	Laboratory (IVD equipment)
Description of equipment function..... :	Analyzing of blood and urine
Installation/overvoltage category..... :	N/A
Pollution degree..... :	2
Environmental rating..... :	Normal
Equipment mobility ..... :	Movable
Connection to mains supply ..... :	N/A
Operating conditions..... :	Continuous
Overall size of the equipment (L x W x H)..... :	250 mm X 185 mm X 80 mm
Mass of the equipment (kg)..... :	1.2 kg
Marked degree of protection to IEC 60529 ..... :	N/A
Accessories and detachable parts included in the evaluation ..... :	N/A
Options ..... :	N/A
Test case verdicts:	
Test case does not apply to the test object..... :	N/A
Test object does meet the requirement ..... :	P(Pass)
Test object does not meet the requirement ..... :	F(Fail)
Testing ..... :	
Date of receipt of test item ..... :	2009-10-26
Date (s) of performance of tests ..... :	2009-10-26 until 2009-11-20

General remarks:

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"(see Annex #)" refers to an annex appended to the report.
"(see Form A.#)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

Product Service

Copy of marking plate:

Summary of test results (information/comments): Pass

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001 and IEC/EN 61010-2-101, IEC/EN 61010-2-081
- i-CHROMA is basic model which was tested.
- For test, AC/DC adaptor model MPU50-105, manufacturerd by Sinpro electronics Co., Ltd. was used.

Product Service

	TABLE: 1 - Documents attached to this report	
Document No.	Document description	Page Numbers
Attachment	Photos	2

Product Service

	TABLE: 2 - Test equipment list				P
Item	Type	Equipment No.	Calibration date		Comments
			Last[1]	Due	
1-A	Temperature & Humidity Chamber	ER-35MHHP	2009-02-02	2010-02-02	
2-A	Temperature Chamber	EPRH-432-2T	2009-02-02	2010-02-02	
7-A	DC Power Supply	DRP305DN	2009-02-02	2010-02-02	
8-B	Temperature Recorder	DR230	2009-02-03	2010-02-03	
15-A	Dielectric Strength Tester	TOS9201	2009-02-02	2010-02-02	
23-A	DC mA Meter	2011	2009-02-02	2010-02-02	
25-A	True RMS Multi-Meter	187	2009-02-02	2010-02-02	
51-A	IEC61032 Test Probe B	P1032-B	2009-04-28	2010-04-28	
55-A	Drop Test Check Jig & Scale	IT0410	2009-04-24	2012-04-24	
59-A	Hard Wood Surface	-	2009-10-07	2010-04-07	
65-A	Stop Watch	HS-3	2009-06-10	2010-06-10	
68-B	Isopropyl alcohol	16.788.07	-	-	
35-B	Push-pull gauge	DPS-5K	2009-02-23	2010-02-23	
51-I	IEC60950-1 Fig.2C Test probe	P0330	2009-04-28	2012-04-28	

1) or interval between calibrations.

Product Service

	TABLE: 3 - List of components and circuits relied on for safety				P
Unique component reference or location (including drawing reference if required)	Application/Function	Manufacturer (NOTE 1)	Part number	RATING (NOTE 2)	Evidence of acceptance (NOTE 3)
AC/DC Adaptor	-	Sinpro electronics Co., Ltd.	MPU50-105	Input : 100-240 V~, 47-63 Hz, 1.35 A Output : 12 V d.c., 3.75 A	UL, TUV Rheinland
Power switch	-	Zhongxun	KCD11	250 V~, 3 A	TUV Rheinland
Motor	-	Saehan Electronics	4S42Q-T12034SD	12 V d.c.	Tested with appliance
Lithium battery(BT1)	-	Panasonic	CR2032	3 V d.c. Max. abnormal charging current : 10 mA	UL
LCD panel	-	Shenzhen Topway Technology co.,LTD	LMB164ACD	6 V d.c., 1.3 mA	Tested with appliance
Laser diode in measuring module	-	QSI Co., Ltd.	QL63D	-	SEMKO
Enclosure	-	BASF Corp.	GP-35	Min.thickness 2.5 mm, HB	UL
PCB	-	EUNSUNG ELECCOM.CO.LTD	1, 2	94V-0, 105 ℃, Min. thickness 1.6 mm	UL

NOTE 1 - List all manufacturers concerned.
NOTE 2 - Electrical, mechanical, flammability, etc.
NOTE 3 - Licence number, file number or other documentary evidence of acceptance

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
5	MARKING AND DOCUMENTATION		—
5.1.1	General		—
	Required equipment markings are:		P
	visible:		P
	From the exterior; or		P
	After removing a cover; or		N/A
	Opening a door		N/A
	After removal from a rack or panel		N/A
	Not put on parts which can be removed by an OPERATOR		P
	Letter symbols (IEC 60027) used		P
	Graphic symbols (IEC 61010-1: Table 1) used		P
5.1.2	Identification		—
	Equipment is identified by:		—
5.1.2a)	Manufacturer's or supplier's name or trademark	Boditech	P
5.1.2b)	Model number, name or other means	i-CHROMA	P
	Manufacturing location identified		N/A
5.1.3	Mains supply		—
	Equipment is marked as follows:		—
5.1.3a)	Nature of supply:		—
	1) a.c. RATED mains frequency or range of frequencies ..... :		N/A
	2) d.c. with symbol 1		P
5.1.3b)	RATED supply voltage(s) or range..... :	12 V d.c.	P
5.1.3c)	Max. RATED power (W or VA)or input current ..... :	3.0 A	P
	If more than one voltage range:		—
	Separate values marked; or		N/A
	Values differ by less than 20 %	(see Form A.3)	N/A
5.1.3d)	OPERATOR-set for different RATED supply voltages:	No such parts	—
	Indicates the equipment set voltage		N/A
	PORTABLE EQUIPMENT indication is visible from the exterior		N/A
	Changing the setting changes the indication		N/A
5.1.3e)	Accessory mains socket-outlets accepting standard mains plugs are marked:	No such socket-outlets	—

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	With the voltage if it is different from the mains supply voltage ..... :		N/A
	For use only with specific equipment		N/A
	If not marked for specific equipment it is marked with:		—
	The maximum RATED current or power; or		N/A
	Symbol 14 with full details in the documentation		N/A
5.1.4	Fuses		—
	OPERATOR replaceable fuse marking (see also 5.4.5) ..... :	None of replaceable fuse	N/A
5.1.5	TERMINALS, connections and operating devices		—
	Where necessary for safety, indication of purpose of TERMINALS, connectors, controls and indicators marked		N/A
	If insufficient space, symbol 14 used		N/A
5.1.5.1	TERMINALS		N/A
	Mains supply TERMINALS identified		N/A
	Other TERMINAL marking..... :		N/A
5.1.5.1a)	FUNCTIONAL EARTH TERMINALS (symbol 5 used)		N/A
5.1.5.1b)	PROTECTIVE CONDUCTOR TERMINALS:		—
	Symbol 6 is placed close to or on the TERMINAL; OR		N/A
	Part of appliance inlet		N/A
5.1.5.1c)	TERMINALS of measuring and control circuits (symbol 7 used)		N/A
5.1.5.1d)	HAZARDOUS LIVE TERMINALS supplied from the interior		—
	Standard MAINS socket outlet; or		N/A
	RATINGS marked; or		N/A
	Symbol 14 used		N/A
5.1.5.1e)	ACCESSIBLE FUNCTIONAL EARTH TERMINALS:		—
	Self-evident; or		N/A
	Indication (symbol 8 acceptable)		N/A
5.1.5.2	Measuring circuit TERMINALS		—
	For TERMINALS other than those permanently connected and not ACCESSIBLE:		—
	RATED voltage or current marked		N/A
	Unless clear indication that below limits:		—

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Maximum RATED voltage to earth is marked; or		N/A
	For specific connection to other equipment TERMINALS only, and means for identifying provided		N/A
	Appropriate measurement category marked (CAT II, CAT III or CAT IV); or		N/A
	No measurement category marked (CAT I)		N/A
	Required markings are adjacent to TERMINALS; OR		N/A
	If insufficient space:		—
	On the RATING plate or scale plate; or		N/A
	TERMINAL is marked with symbol 14		N/A
5.1.6	Switches and circuit breakers		—
	If disconnecting device, on or off position marked		N/A
5.1.7	Equipment protected by DOUBLE INSULATION or REINFORCED INSULATION		—
	Protected throughout (symbol 11 used)		N/A
	Only partially protected (symbol 11 not used)		N/A
5.1.8	Field-wiring TERMINAL boxes		—
	If TERMINAL or ENCLOSURE exceeds 60 °C:	(See Form A.21A)	—
	Cable temperature RATING marked		N/A
	Marking visible or beside TERMINAL		N/A
5.2	Warning markings		—
	Visible when ready for NORMAL USE		N/A
	Are near or on applicable parts		N/A
	Symbols and text correct dimensions and colour		N/A
	If necessary marked with symbol 14		N/A
	Statement to isolate or disconnect		N/A
5.3	Durability of markings		—
	The required markings remain clear and legible in NORMAL USE	(see Form A.4)	P
5.4	Documentation		—
5.4.1	General		—
	Equipment is accompanied by documentation which includes:		—
5.4.1a)	Intended use		P
5.4.1b)	Technical specification		P
5.4.1c)	Instructions for use		P

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.4.1d)	Name and address of manufacturer or supplier		P
5.4.1e)	Information specified in 5.4.2 to 5.4.5		—
5.4.1f)	If marking of TERMINALS required, definition of measurement category		N/A
5.4.1g)	If CAT 1:		—
	Warning		N/A
	RATINGS		N/A
	Warning statements and a clear explanation of warning symbols:		—
	Provided in the documentation; or		N/A
	Information is marked on the equipment		N/A
5.4.2	Equipment RATINGS		—
	Documentation includes:		—
5.4.2a)	Supply voltage or voltage range	(See copy of marking plate)	P
	Frequency or frequency range		N/A
	Power or current RATING	(See copy of marking plate)	P
5.4.2b)	Description of all input and output connections		P
5.4.2c)	RATING of insulation of external circuits, when such circuits are nowhere ACCESSIBLE		N/A
5.4.2d)	Statement of the range of environmental conditions		P
5.4.2e)	Degree of protection (IEC 60529)		N/A
5.4.3	Equipment installation		—
	Documentation includes instructions for:		—
5.4.3a)	Assembly, location and mounting	In manual	
5.4.3b)	Protective earthing		N/A
5.4.3c)	Connections to supply	In manual	P
5.4.3d)	PERMANENTLY CONNECTED EQUIPMENT:		—
	1) Supply wiring requirements		N/A
	2) If external switch or circuit-breaker, requirements and location recommendation		N/A
5.4.3e)	Ventilation requirements		N/A
5.4.3f)	Special services (e. g. air, cooling liquid)		N/A
5.4.3g)	Maximum sound power level		N/A
5.4.3h)	Instructions about sound pressure		N/A
5.4.3i)	Permanently connected measuring TERMINALS:		—
	Measurement category		N/A

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RATED maximum WORKING VOLTAGE or current		N/A
5.4.4	Equipment operation		—
	Instructions for use include:		—
5.4.4a)	Identification of operating controls		P
5.4.4b)	Positioning for disconnection		N/A
5.4.4c)	Interconnection		N/A
5.4.4d)	Specification of intermittent operation limits		N/A
5.4.4e)	Explanation of symbols used		N/A
5.4.4f)	Replacement of consumable materials		P
5.4.4g)	Cleaning and decontamination (see 11.2)	In manual	P
5.4.4h)	Listing of any poisonous or injurious gases and quantities		N/A
5.4.4i)	Risk-reduction procedures relating to flammable liquids		N/A
	A statement about protection impairment if used in a manner not specified by the manufacturer		P
5.4.5	Equipment maintenance		—
	Instructions include:		—
	Sufficient preventive maintenance and inspection information		P
	Replacement of hoses, etc.		N/A
	Specific battery type		N/A
	Any manufacturer specified parts		P
	RATING and characteristics of fuses		N/A
6	PROTECTION AGAINST ELECTRIC SHOCK	(see Form A.5)	—
6.1	General		—
6.1.1	Requirements		—
	ACCESSIBLE parts not HAZADOUS LIVE in NORMAL CONDITION and SINGLE FAULT CONDITION		P
	Conformity is checked by the determination of 6.2 and 6.3 followed by the tests of 6.4 to 6.11		—
6.1.2	Exceptions		—
	Capacitance test	(see Forms A.6 and A.7)	N/A
	Parts not HAZARDOUS LIVE 10 s after interruption of supply		N/A
6.2	Determination of ACCESSIBLE parts		—
6.2.1	General examination	(see Form A.6)	P

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.2.2	Openings above parts that are HAZARDOUS LIVE		N/A
6.2.3	Openings for pre-set controls		N/A
6.3	Permissible limits for ACCESSIBLE parts		—
6.3.1	Values in NORMAL CONDITION	(see Form A.7)	P
6.3.2	Values in SINGLE FAULT CONDITION	(see Form A.8)	P
6.4	Protection in NORMAL CONDITION (see 6.2, 6.3.1, 6.7, 6.8 and 8.1)		P
6.5	Protection in SINGLE FAULT CONDITION		—
	Additional protection is provided by:		—
	One or more of 6.5.1 to 6.5.3; or		N/A
	Automatic disconnection of the supply (6.5.4)		N/A
6.5.1	Protective BONDING		—
	ACCESSIBLE conductive parts:		—
	Separated by DOUBLE INSULATION or REINFORCED INSULATION; or		N/A
	Bonded to the PROTECTIVE CONDUCTOR TERMINAL; or		N/A
	Separated by screen or BARRIER bonded to PROTECTIVE CONDUCTOR TERMINAL from parts which are HAZARDOUS LIVE		N/A
6.5.1.1	Integrity of PROTECTIVE BONDING		—
6.5.1.1a)	PROTECTIVE BONDING consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses		N/A
6.5.1.1b)	Soldered connections:		—
	Independently secured		N/A
	Not used for other purposes		N/A
	Screw connections are secured		N/A
6.5.1.1c)	PROTECTIVE BONDING not interrupted		N/A
6.5.1.1d)	Any moveable connection specifically designed, and meets 6.5.1.3		N/A
6.5.1.1e)	No external metal braid of cables used		N/A
6.5.1.1f)	If MAINS supply passes through:		—
	Means provided for passing protective conductor;		N/A
	Impedance meets 6.5.1.3.		N/A
6.5.1.1g)	Protective conductors bare or insulated, if insulated, green/yellow		N/A
	Exceptions:		—

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Clause	Requirement + Test	Result - Remark	Verdict
	1) earthing braids;		N/A
	2) internal protective conductors etc.;		N/A
	Green/yellow not used for other purposes		N/A
6.5.1.1h)	TERMINAL suitable, and meets 6.5.1.2		N/A
6.5.1.2	PROTECTIVE CONDUCTOR TERMINAL		—
6.5.1.2a)	Contact surfaces are metal		N/A
6.5.1.2b)	Appliance inlet used		N/A
6.5.1.2c)	For rewireable cords and PERMANENTLY CONNECTED EQUIPMENT, PROTECTIVE CONDUCTOR TERMINAL is close to MAINS supply TERMINALS		N/A
6.5.1.2d)	If no MAINS supply is required, any PROTECTIVE CONDUCTOR TERMINAL:		—
	Is near TERMINALS of circuit for which protective earthing is necessary		N/A
	External if other TERMINALS external		N/A
6.5.1.2e)	Equivalent current-carrying capacity to MAINS supply TERMINALS	(see Form A.9)	N/A
6.5.1.2f)	If plug-in, makes first and breaks last		N/A
6.5.1.2g)	If also used for other bonding purposes, protective conductor:		—
	Applied first;		N/A
	Secured independently;		N/A
	Unlikely to be removed by servicing; or		N/A
	Warning marking requires replacement of protective conductor		N/A
6.5.1.2h)	Protective conductor of measuring circuit:		N/A
	1) Current RATING;		N/A
	2) PROTECTIVE BONDING:		—
	Not interrupted; or		N/A
	Indirect bonding used (see 6.5.1.5)		N/A
6.5.1.2i)	FUNCTIONAL EARTH TERMINALS allow independent connection		N/A
6.5.1.2j)	If a binding screw:		—
	Suitable size for bond wire		N/A
	Not smaller than M 4 (No. 6)		N/A
	At least 3 turns of screw engaged		N/A

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Contact pressure not capable of reduction by deformation of materials		N/A
	Passes tightening torque test	(see Form A.9)	N/A
6.5.1.3	Impedance of PROTECTIVE BONDING of plug-connected equipment	(see Form A.10)	N/A
6.5.1.4	Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT	(see Form A.10)	N/A
6.5.1.5	Indirect bonding for measuring and test equipment	(see Form A.11)	N/A
6.5.2	DOUBLE INSULATION and REINFORCED INSULATION (see 6.7, 6.8 and 6.9.2)		—
6.5.3	PROTECTIVE IMPEDANCE	(see Form A.12)	N/A
6.5.3a)	HIGH-INTEGRITY single component used (s. 14.6); or		N/A
6.5.3b)	A combination of components used; or		N/A
6.5.3c)	A combination of BASIC INSULATION and current- or voltage-limiting device used		N/A
	Components, wires and connections are RATED as required		N/A
6.5.4	Automatic disconnection of the supply		N/A
	If used, it meets :		—
6.5.4a)	Supplied with the equipment; or		N/A
	Specified by installation instruction		N/A
6.5.4b)	RATED disconnecting time within limit specified		N/A
6.5.4c)	RATED for maximum RATED LOAD		N/A
6.6	Connections to external circuits		—
6.6.1	General		—
	Connections do not cause ACCESSIBLE parts of the following to become HAZARDOUS LIVE in NORMAL CONDITION or SINGLE FAULT CONDITION:		—
6.6.1a)	The external circuits		N/A
6.6.1b)	The equipment		N/A
	Separation of circuits provided; or		N/A
	Short circuit of separation does not cause a Hazard		N/A
	Instructions or markings include:		—
	1) RATED conditions for TERMINAL		N/A
	2) Required RATING of external circuit insulation		N/A
6.6.2	TERMINALS for external circuits		—

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	TERMINALS which receive a charge from an internal capacito are not HAZARDOUS LIVE	(see Form A.7)	N/A
	High voltage TERMINALS energized from the interior are:		—
	Not ACCESSIBLE if connected; or		N/A
	Unmated HAZARDOUS LIVE TERMINALS not ACCESSIBLE ; or		N/A
	marked with symbol 12		N/A
6.6.3	Circuits with TERMINALS which are HAZARDOUS LIVE		—
	These circuits are:		—
	Not connected to ACCESSIBLE conductive parts; or		N/A
	Connected to ACCESSIBLE conductive parts, but are not MAINS CIRCUITS and have one TERMINAL contact at earth potential		N/A
	No ACCESSIBLE conductive parts are HAZARDOUS LIVE		N/A
6.6.4	ACCESSIBLE TERMINALS for stranded conductors		—
6.6.4a)	No risk of accidental contact because:		—
	Located or shielded		N/A
	Self-evident or marked whether connected to ACCESSIBLE conductive parts		N/A
6.6.4b)	ACCESSIBLE TERMINALS will not work loose		N/A
6.7	CLEARANCES and CREEPAGE DISTANCES	(See Form A.5 and A.13)	N/A
6.8	Procedure for dielectric strength tests	(See Form A.5 and A.14)	P
6.9	Constructional requirements for protection against electric shock		—
6.9.1	General		—
	If a failure could cause a HAZARD:		—
6.9.1a)	Security of wiring connections		N/A
6.9.1b)	Screws securing removable covers		N/A
6.9.1c)	Sccidental loosening		N/A
	Easily damaged materials not used		P
	Non-impregnated hydroscopic materials not used		P
6.9.2	ENCLOSURES of equipment with DOUBLE INSULATION or REINFORCED INSULATION		—
	ENCLOSURE surrounds all metal parts except for small metal parts which are separated		N/A
	ENCLOSURES or parts made of insulating material		N/A

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Protection for metal ENCLOSURES or parts by:		—
6.9.2a)	An insulating coating or BARRIER on the inside; or		N/A
6.9.2b)	CLEARANCES and CREEPAGE DISTANCES cannot be reduced by loosening of parts or wires		N/A
6.9.3	Over-range indication		—
	Unambiguous		N/A
6.10	Connection to MAINS supply source and connections between parts of equipment		—
6.10.1	MAINS supply cords		—
6.10.1a)	RATED for maximum equipment current (see 5.1.3c)		N/A
	Cable complies with IEC 60227 or IEC 60245		N/A
6.10.1b)	Heat-resistant if likely to contact hot parts		N/A
6.10.1c)	Temperature RATING (cord and inlet)		N/A
6.10.1d)	Green/yellow used only for connection to PROTECTIVE CONDUCTOR TERMINALS		N/A
	Detachable cords with IEC 60320 MAINS connectors:		—
	Conform to IEC 60799; or		N/A
	Have the current RATING of the MAINS connector		N/A
6.10.2	Fitting of non-detachable MAINS supply cords		—
	Non-detachable cord protection:		—
6.10.2a)	Inlet or bushing smoothly rounded; or		N/A
6.10.2b)	Insulated cord guard protruding =5D		N/A
	The protective earth conductor is the last to take the strain		N/A
6.10.2	Cord anchorages:		—
6.10.2a)	Cord is not clamped by direct pressure from a screw		N/A
6.10.2b)	Knots are not used		N/A
6.10.2c)	Cannot push the cord into the equipment to cause a hazard		N/A
6.10.2d)	No failure of cord insulation in anchorage with metal parts		N/A
6.10.2e)	compression bushing:		—
	1) Clamps all types and sizes of MAINS cords; and		N/A
	2) Is suitable:		—
	For connection to TERMINALS provided; or		N/A

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	It is designed for screened MAINS cord		N/A
6.10.2f)	Cord replacement does not cause a HAZARD and method of strain relief is clear		N/A
	Push-pull test	(see Form A.15)	N/A
6.10.3	Plugs and connectors		—
6.10.3a)	MAINS supply plugs, connectors etc., conform with relevant specifications		N/A
6.10.3b)	If equipment supplied at voltages below 6.3.2.a) or from a sole source:		—
	Plugs of supply cords do not fit MAINS sockets above RATED supply voltage		N/A
	MAINS-type plugs used only for connection to MAINS supply		N/A
6.10.3c)	Plug pins which receive a charge from an internal capacitor	(See Form A.7)	N/A
6.10.3d)	Accessory MAINS socket outlets:		—
	1) Marking if accepts a standard MAINS plug (see 5.1.3e)		N/A
	2) Input has a protective earth conductor if outlet has earth TERMINAL contact		N/A
6.11	Disconnection from supply source		—
6.11.1	General		—
	Disconnects all current carrying conductors	DC connector was used	P
6.11.1.1	Exceptions		—
6.11.1.1a)	Equipment supplied by low energy source; or		N/A
6.11.1.1b)	Equipment connected to impedance protected supply; or		N/A
6.11.1.1c)	Equipment constitues an impedance protected load		N/A
6.11.2	Requirements according to type of equipment		—
6.11.2.1	PERMANENTLY CONNECTED EQUIPMENT and multi-phase equipment		—
	Employs switch or circuit-breaker		N/A
	If switch or circuit-breaker is not part of the equipment, documentation specifies:		—
6.11.2.1a)	Switch or circuit-breaker to be included in building installation		N/A
6.11.2.1b)	Location		N/A
6.11.2.1c)	Marking		N/A
6.11.2.2	Single-phase cord-connected equipment		—

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Equipment is provided with:		—
6.11.2.2a)	Switch or circuit-breaker; or		N/A
6.11.2.2b)	Appliance coupler (disconnectable without TOOL); or		N/A
6.11.2.2c)	Separable plug (without locking device)		N/A
6.11.2.3	HAZARDS arising from function		—
	Emergency switch		N/A
	Emergency switch ≤ 1 m from the moving part		N/A
6.11.3	Disconnecting devices		—
	Electrically close to the supply		N/A
6.11.3.1	Switches and circuit-breakers		—
	When used as disconnection device:		—
	Meets IEC 60947-1 and IEC 60947-3		N/A
	Marked to indicate function		N/A
	Not incorporated in MAINS cord		N/A
	Does not interrupt protective earth conductor		N/A
	If has other contacts meets separation requirements of 6.6 and 6.7		N/A
6.11.3.2	Appliance couplers and plugs		—
	Where an appliance coupler or seperable plug is used as the disconnecting device (see 6.11.2.2):		—
	Readily identifiable and easily reached by the OPERATOR		N/A
	Single-phase PORTABLE EQUIPMENT cord length ≤ 3 m		N/A
	Protective earth conductor connected first and disconnected last		N/A
7	PROTECTION AGAINST MECHANICAL HAZARDS		—
7.1	General		—
	Conformity is checked by 7.2 to 7.6		P
7.2	Moving parts		—
	Moving parts not able to crush, etc. (see also 6.11.2.3)		N/A
	If OPERATOR access permitted:		—
7.2a)	Access requires TOOL		N/A
7.2b)	Statement about training		N/A
7.2c)	Warning markings or symbol 14		N/A

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.3	Stability		—
	Marking of non-automatic means		N/A
	Conformity tests:		—
7.3a)	10° tilt test		P
7.3b)	multi-directional force test		N/A
7.3c)	downward force test		N/A
7.4	Provisions for lifting and carrying		—
	Handles or grips withstand four times weight		N/A
	Equipment >18 kg :		—
	Has means for lifting or carrying; or		N/A
	Directions in documentation		N/A
7.5	Wall mounting		—
	Mounting brackets withstand four times weight		N/A
7.6	Expelled parts		—
	Equipment contains or limits the energy		N/A
	Protection not removable without the aid of a TOOL		N/A
8	MECHANICAL RESISTANCE TO SHOCK AND IMPACT		—
	After the tests of 8.1 to 8.2:		—
	Voltage tests	(see Form A.14)	P
	Inspections:		—
8a)	HAZARDOUS LIVE parts not accessible		N/A
8b)	ENCLOSURE shows no cracks (hazard)		P
8c)	CLEARANCES not less than their permitted values	(see Form A.13)	N/A
8d)	BARRIERS not damaged or loosened		N/A
8e)	No moving parts exposed, except permitted by 7.2		N/A
8f)	No damage which could cause spread of fire		P
9	PROTECTION AGAINST THE SPREAD OF FIRE		—
	Conformity for each source of HAZARD or area of the equipment is checked by one of the following:	(See Form A.16)	—
9a)	Fault test of 4.4; or	(See Forms A.1 and A.2)	P
9b)	Application of 9.1 (eliminating or reducing the sources of ignition); or		P
9c)	Application of 9.2 (containment of fire within the equipment)		N/A

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.1	Eliminating or reducing the sources of ignition within the equipment		—
9.1a)	1) Limited-energy circuit (see 9.3); or		P
	2) Insulation meets the requirements for BASIC INSULATION; OR	(see Form A.5 and A.14)	N/A
	Bridging the insulation does not cause ignition	(see Form A.2)	N/A
9.1b)	Surface temperature of liquids and parts (see 9.4.a)		N/A
9.1c)	No ignition in circuits designed to produce heat	(see Form A.2)	N/A
9.2	Containment of the fire within the equipment, should it occur		—
9.2a)	Energizing of the equipment is controlled by an OPERATOR held switch		N/A
9.2b)	Enclosure is conform with constructional requirements of 9.2.1; and		N/A
	Requirements of 9.4b) or c) are met		N/A
9.2.1	Constructional requirements		—
9.2.1a)	Insulated wires have flammability classification FV1 or better	(see Table 3 or Form A.17)	N/A
	Connectors and insulating material have flammability classification FV2 or better	(see Table 3 or Form A.17)	N/A
9.2.1b)	The enclosure is constructed as follows :		—
	1) Bottom constructed with:		—
	No openings; or		N/A
	Extent as specified in figure 7; or		N/A
	Baffles as specified in figure 6; or		N/A
	Perforated as specified in Table 12; or		N/A
	Metal screen with a mesh		N/A
	2) Sides have no openings as specified in figure 7		N/A
	3) Material of ENCLOSURE and any baffle or flame barrier is made of:		—
	Metal (except magnesium); or		N/A
	Non metallic materials have flammability classification FV1 or better	(see Table 3 or Form A.17)	N/A
	4) ENCLOSURE and any baffle or flame barrier have adequate rigidity		N/A
9.3	Limited-energy circuit	(see Form A.19)	—
9.3a)	Potential not more than 30 r.m.s. and 42.4 V peak, or 60 V dc	Within limits	P

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.3b)	Current limited by one of following means:	Certified AC/DC adaptor used	—
	1) Inherently or by impedance; or		N/A
	2) Overcurrent protective device; or		N/A
	3) A regulating network limits also in SINGLE FAULT CONDITION		N/A
9.3c)	Is separated by at least BASIC INSULATION		N/A
	If overcurrent protective device used:		—
	Fuse or a non adjustable electromechanical device		N/A
9.4	Requirements for equipment containing or using flammable liquids		N/A
	Flammable liquids contained in or specified for use with equipment do not cause spread of fire		N/A
	Risk is reduced to a tolerable level :	(see Form A.19)	—
9.4a)	The temperature of surface or parts in contact with flammable liquids is 25 °C below fire point		N/A
9.4b)	The quantity of liquid is limited		N/A
9.4c)	Flames are contained within the equipment		N/A
	Detailed instructions for risk-reduction provided		N/A
9.5	Overcurrent protection		N/A
	Devices not in the protective conductor		N/A
	Fuses or single-pole circuit-breakers not fitted in neutral (multi-phase)		N/A
9.5.1	PERMANENTLY CONNECTED EQUIPMENT		N/A
	Overcurrent device:		—
	Fitted within the equipment; or		N/A
	Specified in manufacturer's instructions		N/A
9.5.2	Other equipment		N/A
	Protection within the equipment		N/A
10	EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT		—
10.1	Surface temperature limits for protection against burns		—
	Easily touched surfaces within the limits	(see Form A.20A)	P
	Heated surfaces necessary for functional reasons exceeding specified values:		—
	Are recognizable as such by appearance or function; or		N/A

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Are marked with symbol 13		N/A
	Guards are not removable without TOOL		N/A
10.2	Temperatures of windings	(see Form A.20B)	N/A
	Limits not exceeded in:		—
	NORMAL CONDITION		N/A
	SINGLE FAULT CONDITION		N/A
10.3	Other temperature measurements	(see Form A.20A)	P
	Following measurements conducted if applicable:		—
10.3a)	Value of 60 °C of field-wiring TERMINAL box not exceeded		N/A
10.3b)	Surface of flammable liquids and parts in contact with this liquids		N/A
10.3c)	Surface of non-metallic ENCLOSURES		P
10.3d)	Parts made of insulating material supporting parts connected to MAINS supply		N/A
10.3e)	TERMINALS carrying a current more than 0.5 A		N/A
10.4	Conduct of temperature test	(see Form A20)	P
10.5	Resistance to heat		P
10.5.1	Integrity of CLEARANCE and CREEPAGE DISTANCES	(See Form A.13)	N/A
10.5.2	Non-metallic ENCLOSURES	(See Forms A.21)	P
	After treatment:		P
	No HAZARDOUS LIVE parts ACCESSIBLE;		N/A
	Tests of 8.1 and 8.2	(See Form A.13)	P
	In case of doubt, tests of 6.8 (without humidity preconditioning)	(See Form A.14)	P
10.5.3	Insulating material		N/A
10.5.3a)	Parts supporting parts connected to MAINS supply		N/A
10.5.3b)	TERMINALS carrying a current more than 0.5 A		N/A
	Examination of material data; or		N/A
	in case of doubt::		—
	1) Ball pressure test; or	(See Form A.22)	N/A
	2) Vicat softening testof ISO 306	(See Form A.22)	N/A
11	PROTECTION AGAINST HAZARDS FROM FLUIDS		—
11.1	General		P

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.2	Cleaning	(See Form A.23)	P
11.3	Spillage	(See Form A.23)	N/A
11.4	Overflow	(See Form A.23)	N/A
11.5	Battery electrolyte		—
	Battery electrolyte leakage presents no hazard		N/A
11.6	Specially protected equipment	(See Form A.23)	N/A
11.7	Fluid pressure and leakage		—
11.7.1	Maximum pressure		—
	Maximum pressure of any part does not exceed P_{RATED}		N/A
11.7.2	Leakage and rupture at high pressure	(See Form A.24)	N/A
	Test to IEC 60335 (refrigeration only)		N/A
11.7.3	Leakage from low-pressure parts	(See Form A.24)	N/A
11.7.4	Overpressure safety device		—
	Does not operate in NORMAL USE		N/A
	Meets ISO 4126-1; and		N/A
	It is conform with:		—
11.7.4a)	Connected as close as possible to parts intended to be protected		N/A
11.7.4b)	Easy access for inspection, maintenance and repair		N/A
11.7.4c)	Adjustment only with TOOL		N/A
11.7.4d)	No discharge towards person		N/A
11.7.4e)	No HAZARD from deposit of discharged material		N/A
11.7.4f)	Adequate discharge capacity		N/A
11.7.4g)	No shut-off valve between overpressure safety device and protected parts		N/A
12	PROTECTION AGAINST RADIATION, INCLUDING LASER SOURCES, AND AGAINST SONIC AND ULTRASONIC PRESSURE		—
12.1	General		—
	Equipment provides protection		N/A
12.2	Equipment producing ionizing radiation		N/A
12.2.1	Ionizing radiation	(See Form A.25)	N/A
12.2.2	Accelerated electrons		N/A
12.3	Ultra-violet (UV) radiation	(Conformity test under consideration)	—

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	No unintentional and HAZARDOUS escape of UV radiation		N/A
12.4	Micro-wave radiation		—
	Power density does not exceed 10 W/m^2.....:		N/A
12.5	Sonic and ultrasonic pressure		—
12.5.1	Sound level	(See Form A.26)	N/A
12.5.2	Ultrasonic pressure	(See Form A.26)	N/A
12.6	Laser sources (IEC 60825-1)		N/A
13	PROTECTION AGAINST LIBERATED GASES, EXPLOSION AND IMPLOSION		—
13.1	Poisonous and injurious gases		N/A
	Attached data/test reports demonstrate conformity		N/A
13.2	Explosion and implosion		—
13.2.1	Components		—
	Components liable to explode:		—
	Pressure release device provided; or		N/A
	Apparatus incorporates OPERATOR protection (see also 7.6)		N/A
	Pressure release device:		—
	Discharge without danger		N/A
	Cannot be obstructed		N/A
13.2.2	Batteries and battery charging		—
	If explosion or fire hazard could occur:		—
	Protection incorporated in the equipment; or		P
	Instructions specify batteries with built-in protection		N/A
	In case of wrong type of battery used:		—
	No HAZARD; or		P
	Warning by marking and within instructions		N/A
	Equipment with means to charge rechargeable batteries:	No such means	—
	Warning against the charging of non-rechargeable batteries; and		N/A
	Type of rechargeable battery indicated; or		N/A
	Symbol 14 used		N/A
	Battery compartment design		P
	Single component failure	(See Form A.27)	P

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Polarity reversal test	Not installed with polarity reversed	P
13.2.3	Implosion of cathode ray tubes		—
	If maximum face dimensions > 160 mm.....:		—
	Intrinsically protected and correctly mounted; or		N/A
	ENCLOSURE provides protection:		N/A
	If non-intrinsically protected:		—
	Screen not removable without TOOL		N/A
	If glass screen, not in contact with surface of tube		N/A
13.2.4	Equipment RATED for high pressure (See 11.7)		N/A
14	COMPONENTS		—
14.1	General		—
	Where safety is involved, components meet relevant requirements	(see Table 3)	P
14.2	Motors		—
14.2.1	Motor temperatures		—
	Does not present a HAZARD when stopped or prevented form starting; or	(See Form A.20)	P
	Protected by overtemperature or thermal protection device conform with 14.3		N/A
14.2.2	Series excitation motors		—
	Connected direct to device, if overspeeding causes a HAZARD		N/A
14.3	Overtemperature protection devices		N/A
	Devices operating in a SINGLE FAULT CONDITION	(See Form A.28)	N/A
14.3a)	Reliable function is ensured		N/A
14.3b)	RATED to interrupt maximum current and voltage		N/A
14.3c)	Does not operate in NORMAL USE		N/A
14.4	Fuse holders		N/A
	No access to HAZARDOUS LIVE parts		N/A
14.5	Mains voltage selecting devices		N/A
	Accidental change not possible		N/A
14.6	HIGH INTEGRITY components		N/A
	Used in applicable positions (see Table 3)		N/A
	Conforms with IEC publications		N/A
	Single electronic device not used		N/A

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict
14.7	Mains transformers tested outside equipment	(See Forms A.29 and A.30)	N/A
14.8	Printed circuit boards		P
	Data shows conformity with FV-1 of IEC 60707 or better; or	(See Table 3)	P
	Test shows conformity with FV-1 of IEC 60707 or better; or	(See Form A.17)	N/A
	Thin film flexible PCB with limited-energy circuit used		N/A
14.9	Circuits or components used as transient overvoltage limiting devices		—
	After test, no sign of overload or degradation		N/A
15	PROTECTION BY INTERLOCKS		—
15.1	General		—
	Interlocks are designed to remove a hazard before OPERATOR exposed		N/A
15.2	Prevention of reactivation		N/A
15.3	Reliability		—
	Single fault unlikely to occur; or		N/A
	Cannot cause a HAZARD		N/A
16	TEST AND MEASUREMENT EQUIPMENT		N/A
16.1	Current measuring circuits	(see Form A.31)	N/A
16.2	Multifunction meters and similar equipment	(see Form A.32)	N/A
	No HAZARD from:		—
	RATED input voltage combinations		N/A
	Settings of functions		N/A
	Settings of range controls		N/A
ANNEX F	ROUTINE TESTS		P
	Manufacturer's declaration		P

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.4.2	**TABLE: Summary of SINGLE FAULT CONDITIONS**			**Form A.1**	—
Subclause	Title	Does not apply	Carried out	Comments	
4.4.2.1	PROTECTIVE IMPEDANCE	X			
4.4.2.2	Protective conductor	X			
4.4.2.3	Equipment or parts for short-term or intermittent operation	X			
4.4.2.4	Motors		X		
4.4.2.5	Capacitors	X			
4.4.2.6	Mains transformers Attach drawing of MAINS Txs showing all protective devices (see Forms A.29 and A.30)	X			
4.4.2.7	Outputs	X			
4.4.2.8	Equipment for more than one supply	X			
4.4.2.9	Cooling – air holes closed – fans stopped – coolant stopped	 X X X			
4.4.2.10	Heating devices – timer overridden – temperature controller overridden – loss of cooling liquid – overfilled or empty or both	 X X X X			
4.4.2.11	Insulation between circuits and parts	X			
4.4.2.12	Interlocks	X			
List below all SINGLE FAULT CONDITIONS not covered by 4.4.2.1 to 4.4.2.12:					
13.2.2	Batteries		X		
Supplementary information: (see Form A.2 for details of tests)					

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

4.4	**TABLE: Testing in single FAULT CONDITION – Results**			**Form A.2**	**P**
Test subclause	Fault No.	Fault description	Td 4.4.3 (NOTE)	How was test terminated Comments	Meets 4.4.4
4.4.2	1	Component(EC1) short-circuited, Sample #1-1/3	30 min.	Protect circuit operated. No hazards. NB	P
4.4.2	2	Component(EC1) short-circuited, Sample #1-2/3	30 min.	Protect circuit operated. No hazards. NB	P
4.4.2	3	Component(EC1) short-circuited, Sample #1-3/3	30 min.	Protect circuit operated. No hazards. NB	P
4.4.2	4	Component(D1,1-3) short-circuited, Sample #1-1/3	30 min.	Protect circuit operated. No hazards. NB	P
4.4.2	5	Component(D1,1-3) short-circuited, Sample #1-2/3	30 min.	Protect circuit operated. No hazards. NB	P
4.4.2	6	Component(D1,1-3) short-circuited, Sample #1-3/3	30 min.	Protect circuit operated. No hazards. NB	P
4.4.2	7	Component(D1,2-4) short-circuited, Sample #1-1/3	30 min.	Protect circuit operated. No hazards. NB	P
4.4.2	8	Component(D1,2-4) short-circuited, Sample #1-2/3	30 min.	Protect circuit operated. No hazards. NB	P
4.4.2	9	Component(D1, 2-4) short-circuited, Sample #1-3/3	30 min.	Protect circuit operated. No hazards. NB	P

NOTE Td = Test duration in h:min:s
Record dielectric strength test on Form A.14 and temperature tests on Form A.20.
Record in the comments column for each test whether carried out during or after SINGLE FAULT CONDITION.

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

5.1.3c)	**TABLE: Mains supply**	**Form A.3**	**P**
	Marked rating.....:	3 V d.c.	—
	Phase..... :	N/A	—
	Frequency .....:	- Hz	—
	Current .....:	- A	—
	Power .....:	- W	—
	Power .....:	- VA	—

Test No.	Voltage V	Frequency Hz	Current A	Power in W	Power in VA	Comments
1	90	50	0.13	5.9	-	Max. Normal load
2	100	50	0.12	5.8	-	Max. Normal load
3	240	50	0.08	6.9	-	Max. Normal load
4	264	50	0.08	7.1	-	Max. Normal load
5	90	60	0.13	5.9	-	Max. Normal load
6	100	60	0.13	5.9	-	Max. Normal load
7	240	60	0.08	6.9	-	Max. Normal load
8	264	60	0.08	7.2	-	Max. Normal load
9	12 V d.c.	-	0.33	-	-	Max. Normal load, Sample #1-1/3
10	12 V d.c.	-	0.32	-	-	Max. Normal load, Sample #1-2/3
11	12 V d.c.	-	0.32	-	-	Max. Normal load, Sample #1-3/3

Note: Measurements are only required for marked ratings.

Supplementary information:

From test no.1 to 8 are for references.

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

5.3	**TABLE: Durability of markings**	**Form A.4**	**P**

Marking method (see NOTE)	Agent
1) Silk-screened	A Water
2) Printed on label by ink	B Isopropyl alcohol
3)	C Hexan 99%
4)	D (specify agent)
5)	E (specify agent)

NOTE – Where applicable include print method, label material, ink or paint type, fixing method, adhesive and surface to which marking is fixed.

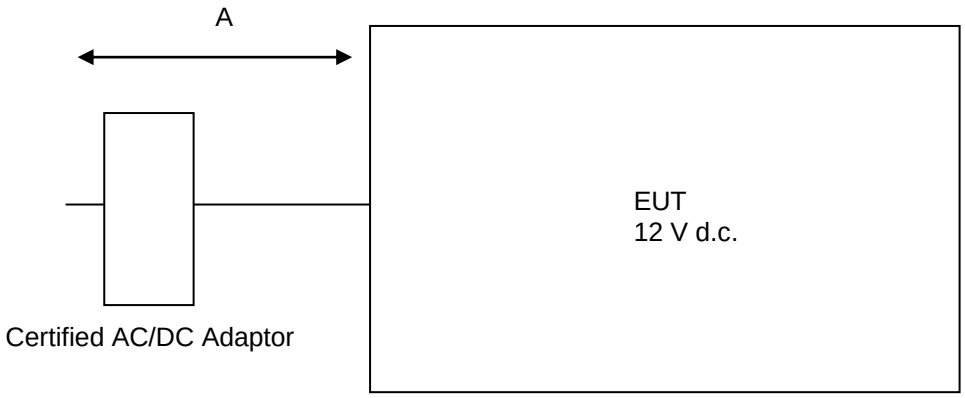
Marking location	Marking method (see above)
Identification (5.1.2)	2)
Mains supply (5.1.3)	2)
Fuses (5.1.4)	N/A
TERMINALS and operating devices (5.1.5.1)	N/A
Measuring circuit TERMINALS (5.1.5.2)	N/A
Switches and cricuit breakers (5.1.6)	N/A
DOUBLE/REINFORCED equipment (5.1.7)	N/A
Field wiring TERMINAL boxes (5.1.8)	N/A
Warning marking (5.2)	N/A
Battery charging (13.2.2)	N/A

Method	Test agent	Remains legible Verdict	Label loose Verdict	Curled edges Verdict	Comments
Rubbed	B	Yes	No	No	Sample #1-1/3
Rubbed	B	Yes	No	No	Sample #1-2/3
Rubbed	B	Yes	No	No	Sample #1-3/3

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6	**TABLE: Protection against electric shock - Block diagram of system Form A.5**	**P**



Pollution degree.....: 2

Installation category (overvoltage category) ..... : N/A

Location or description	Insulation type (NOTE 1)	Maximum working voltage (NOTE 2)	CREEPAGE DISTANCE (NOTE 3)				CLEARANCE (NOTE 3)	Test voltage (NOTE 2)	Comments
			PWB mm	CTI	Other mm	CTI	mm	V	
A	DI	240 V	-	-	-	-	-	2224 V rms	Certified AC/DC adaptor

NOTE 1 – Type of insulation:
BI = BASIC INSULATION
DI = DOUBLE INSULATION
PI = PROTECTIVE IMPEDANCE
RI = Reinforced INSULATION
SI = Supplementary INSULATION
FI = Functional Insulation

NOTE 2 - Types of voltage
Peak impulse test voltage (pulse)
r.m.s.
d.c.
peak

NOTE 3 - INSTALLATION CATEGORIES (OVERVOLTAGE CATEGORIES) or POLLUTION DEGREES which differ from these should be shown under "Comments".

Supplementary Information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6.2	**TABLE: List of ACCESSIBLE parts**	**Form A.6**	**P**
6.1.2	Exceptions		—
6.2	Determination of accessible parts		—

Item	Description	Determination method (NOTE 5)	Exception under 6.1.2 (NOTE 4)
1	Enclosure, outside (Sample #1-1/3)	Test finger	No
2	Serial port, outside (Sample #1-1/3)	Test finger	No
3	Adaptor output (Sample #1-1/3)	Test finger	No
4	Enclosure, outside (Sample #1-2/3)	Test finger	No
5	Serial port, outside (Sample #1-3/3)	Test finger	No
6	Adaptor output (Sample #1-2/3)	Test finger	No
7	Enclosure, outside (Sample #1-3/3)	Test finger	No
8	Serial port, outside (Sample #1-3/3)	Test finger	No
9	Adaptor output (Sample #1-3/3)	Test finger	No

NOTE 1 – Test fingers and pins are to be applied without force unless a force is specified (see 6.2.1)
NOTE 2 – Special consideration should be given to inadequate insulation and high voltage parts (see 6.2)
NOTE 3 – Parts are considered to be ACCESSIBLE if they could be touched in the absence of any covering which is not considered to provide suitable insulation (see note to paragraph 1 of 6.4).
NOTE 4 – Capacitor test may be required (see Form A.7).
NOTE 5 – The determination methods are: visual; rigid test finger; jointed test finger; pin 3 mm diameter; pin 4 mm diameter.

Supplementary information

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6	**TABLE: Values in NORMAL CONDITION**	**Form A.7**	**P**
6.1.1	Exceptions	11.2 Cleaning and decontamination	—
6.3.1	Values in NORMAL CONDITION (see NOTE 1)	11.3 Spillage	—
6.6.2	Terminals for external circuit	11.4 Overflow	—
6.10.3	Plugs and connections		—

Item (see Form A.6)	Voltage			Current				Capacitance		10 s test (NOTE 2)			Comments
	V r.m.s.	V peak	V d.c.	Test circuit A1/A2/A3	mA r.m.s.	mA peak	mA d.c.	µC	mJ	V	µC	mJ	
1	7.3	-	-	-	-	-	-	-	-	-	-	-	Sample # 1-1/3
2	0	-	-	-	-	-	-	-	-	-	-	-	Sample # 1-1/3
3	108	-	-	A1	0.098	-	-	0.42	-	-	-	-	Sample # 1-1/3
4	7.3	-	-	-	-	-	-	-	-	-	-	-	Sample # 1-2/3
5	0	-	-	-	-	-	-	-	-	-	-	-	Sample # 1-2/3
6	107	-	-	A1	0.099	-	-	0.42	-	-	-	-	Sample # 1-2/3
7	7.2	-	-	-	-	-	-	-	-	-	-	-	Sample # 1-3/3
8	0	-	-	-	-	-	-	-	-	-	-	-	Sample # 1-3/3
9	106	-	-	A1	0.097	-	-	0.42	-	-	-	-	Sample # 1-3/3

NOTE 1 – The requirements of 6.3.1 include drying out (if specified). For permanently connected equipment, the current values are 1,5 times the specified values.
NOTE 2 – A 5 s test is specified in 6.10.3c).

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6.3.2	**TABLE: Values in SINGLE FAULT CONDITION**											**Form A.8**	**P**
Item (See Form A.6)	Subclause and fault No. (see FormA.2)	Voltage			Transient (see NOTE)		Current				Capacitance µF (NOTE)	Comments	
		V r.m.s.	V peak	V d.c.	V	s	Test circuit A1/A2/A3	mA r.m.s.	mA peak	mA d.c.			
1	Clause 4.4.2, No.1,4,7	7.3	-	-	-	-	-	-	-	-	-	Sample # 1-1/3	
2	Clause 4.4.2, No.1,4,7	0	-	-	-	-	-	-	-	-	-	Sample # 1-1/3	
3	Clause 4.4.2, No.1,4,7	108	-	-	-	-	A1	0.098	-	-	0.42	Sample # 1-1/3	
4	Clause 4.4.2, No.2,5,8	7.3	-	-	-	-	-	-	-	-	-	Sample # 1-2/3	
5	Clause 4.4.2, No.2,5,8	0	-	-	-	-	-	-	-	-	-	Sample # 1-2/3	
6	Clause 4.4.2, No.2,5,8	107	-	-	-	-	A1	0.097	-	-	0.42	Sample # 1-2/3	
7	Clause 4.4.2, No.3,6,9	7.2	-	-	-	-	-	-	-	-	-	Sample # 1-3/3	
8	Clause 4.4.2, No.3,6,9	0	-	-	-	-	-	-	-	-	-	Sample # 1-3/3	
9	Clause 4.4.2, No.3,6,9	106	-	-	-	-	A1	0.096	-	-	0.42	Sample # 1-3/3	
NOTE – Transient voltages must be below the limits given from Figure 1 and the capacitance below the limits from figure 2 of IEC 61010-1.													

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6.5.1.1	TABLE: Cross-sectional area of bonding conductors	Form A.9	N/A
Conductor location	Cross-sectional area mm^2		Verdict
6.5.1.2	TABLE: Tighting torque test		N/A
Conductor location	Size of Screw	Tighting torque Nm	Verdict

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6.5.1.3	**TABLE: Bonding impedance of plug connected equipment**			**Form A.10**	**N/A**
ACCESSIBLE part under test		Test current A	Voltage attained after 1 min V	Calculated resistance (maximum allowed 0,1 Ω) Ω	Verdict
Supplementary information:					

6.5.1.4	**TABLE: Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT**		**N/A**
ACCESSIBLE part under test	Test current A	Voltage attained after 1 min (maximum 10 V) V	Verdict
Supplementary information:			

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6.5.1.5	**TABLE: Indirect bonding for measuring and test equipment**	**Form A.11**	**N/A**

ACCESSIBLE part under test	Voltage attained s	Time for voltage to drop to allowable levels s	Verdict
a) Voltage limiting device	—	—	—
Supplementary Information:			

ACCESSIBLE part under test	Voltage applied V	Time for device to trip s	Verdict
b) Voltage-sensitive tripping device			
Supplementary Information:			

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6.5.3	**TABLE:** PROTECTIVE IMPEDANCE	**Form A.12**	**N/A**

A high INTEGRITY single component		
Component	Location	Comments

A combination of components		
Component	Location	Comments

A combination of BASIC INSULATION and a current or voltage limiting device		
Component	Location	Comments

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6.7	**TABLE: CLEARANCES and CREEPAGE DISTANCES** **Form A.13**	**N/A**
8	Mechanical resistance to shock and impact	P
10.5.1	Integrity of CLEARANCES and CREEPAGE DISTANCES	N/A

Location (see Form A.5)	Measured (initial – 6.7)		Verdict	Mechanical tests (note)					Test at max. RATED ambient (10.5.1)	Measured after test (if required)		Verdict	Comments
	CREEPAGE DISTANCE mm	CLEARANCE mm		Applied force (6.7) N	Rigidity (8.1)		Drop (8.2)			CREEPAGE DISTANCE mm	CLEARANCE mm		
					Static	Dynamic	Normal	Hand-held/ Plug-in					
A	-	-	-	10	30 N	5 J	Corner drop	-	40	-	-	-	Sample #1-1/3 (With certified AC/DC adaptor)
A	-	-	-	10	30 N	5 J	Corner drop	-	40	-	-	-	Sample #1-2/3 (With certified AC/DC adaptor)
A	-	-	-	10	30 N	5 J	Corner drop	-	40	-	-	-	Sample #1-2/3 (With certified AC/DC adaptor)

NOTE – Refer to Form A.12 for dielectric strength tests following the above tests.

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6.8	**TABLE: Dielectric strength tests**	**Form A.14**	**P**
4.4.4.1 b)	Conformity after application of fault conditions[1]		P
6.4	Protection in NORMAL CONDITION		P
6.5.2	DOUBLE INSULATION and REINFORCED INSULATION		P
6.6.1	Connections to external circuits		N/A
6.7.3.1 c)	CLEARANCE values – General: reduced CLEARANCES for homogeneous construction		N/A
6.10.2.5	Fitting of non-detachable MAINS SUPPLY cords[1]		N/A
8	Mechanical resistance to shock and impact		P
9.1 a) 2)	Eliminating or reducing the sources of ignition within the equipment		N/A
9.3 c)	Limited-energy circuit		N/A
11.2	Cleaning[1]		P
11.3	Spillage[1]		N/A
11.4	Overflow[1]		N/A
11.6	Specially protected equipment[1]		N/A
[1] Record the fault, test or treatment applied before the dielectric strength test			
	Test site altitude .....:	250m	—
	Test voltage correction factor (see Table 10)....:	-	—

Location or references from Forms A.2 and A.5	Clause or sub-clause	Humidity Yes/No	Working voltage V	Test voltage r.m.s./peak/d.cV	Comments	Verdict
A, Sample #1-1/3	4.4.4.1 b)	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	4.4.4.1 b)	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	4.4.4.1 b)	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-1/3	6.5.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	6.5.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	6.5.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-1/3	6.4	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	6.4	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	6.4	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-1/3	11.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	11.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	11.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-1/3	8	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	8	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	8	No	240 Vrms	2224 Vrms	No breakdown	P
Supplementary information: Cut off current 10 mA						

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

6.10.2	**TABLE: Cord anchorage**				**Form A.15**	**N/A**
Location	Mass kg	Pull N	Verdict	Torque Nm	Verdict	Comment
Supplementary information:						

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

9	**TABLE: Protection against the spread of fire**		**Form A.16**	**P**
Item	Source of HAZARD or area of the equipment considered (circuit, component, liquid etc.)	Protection Method (9a, 9b or 9c)	Protection details	Verdict
1	Certified AC/DC adaptor, Sample #1-1/3	9a, 9b	Certified AC/DC adaptor which was fullfilled max. limitations	P
2	Certified AC/DC adaptor, Sample #1-2/3	9a, 9b	Certified AC/DC adaptor which was fullfilled max. limitations	P
3	Certified AC/DC adaptor, Sample #1-3/3	9a, 9b	Certified AC/DC adaptor which was fullfilled max. limitations	P
Supplementary information:				

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

9.2.1	**TABLE: Constructional requirements**	**Form A.17**	**N/A**
14.8	Printed circuit boards		N/A
Material tested .....:			—
Generic name .....:			—
Material manufacturer .....:			—
Type .....:			—
Colour .....:			—
Conditioning details.....:			—

		Sample 1	Sample 2	Sample 3
Thickness of specimen	mm			
Duration of flaming after first Application	s			
Duration of flaming plus glowing After second application	s			
Specimen burns to holding clamp	Yes/No			
Cotton ignited	Yes/No			
Sample result	Pass/Fail			
Supplementary information:				

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

9.3	**TABLE: Limited-energy circuit**					**Form A.18**	**N/A**
Item or Location (see Form A.16)	9.3 a) Maximum potential in circuit voltage r.m.s./d.c. V	9.3 b) Current and power limitation Maximum available current A	 Maximum available power VA	 Overload protection after 120 s A	9.3 c) Circuit separation	Decision Yes/No	Comments
Supplementary information:							

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

9.4	**TABLE: Requirements for equipment containing or using flammable liquids**		**Form A.19**	**N/A**
Type of liquid	9.4 Flammable liquids			Verdict
	b) quantity	c) Containment		
Supplementary information:				

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

10.	**TABLE : Temperature Measurements** **Form A.20A**	**P**
10.1	Surface temperature limits - NORMAL CONDITION and / or SIGNLE FAULT CONDITION	P
10.2	Temperature of windings- NORMAL CONDITION and / or SIGNLE FAULT CONDITION	N/A
10.3	Other temperature measurements	N/A

Operating conditions:	Max. Normal load conditions. Sample #1-1/3		
Frequency ..... :	60 Hz	Test room ambient temperature (t_a)..... :	23.2 °C
Voltage ..... :	264 V	Test duration ..... :	1 h 44 min

Part / Location	t_m °C	t_c °C	t_{max} °C	Verdict	Comments
DC input connector body	32.1	48.9	70	P	Tested with certified adaptor
D1 body	41.9	58.7	-	P	Tested with certified adaptor
J11 body	36.8	53.6	-	P	Tested with certified adaptor
PCB near U9	33.6	50.4	-	P	Tested with certified adaptor
Battery body	52.9	69.7	-	P	Tested with certified adaptor
Motor body	41.6	58.4	-	P	Tested with certified adaptor
Measuring module body	29.2	46.0	-	P	Tested with certified adaptor
LCD body	26.5	43.3	70	P	Tested with certified adaptor
Inside enclosure (top)	28.8	45.6	-	P	Tested with certified adaptor
Outside enclosure (top)	26.7	43.5	80	P	Tested with certified adaptor
Adaptor body (enclosure top)	33.4	50.2	80	P	Tested with certified adaptor
Ambient	23.2	40.0	-	P	Tested with certified adaptor

NOTE 1 - t_m = measured temperature
t_c = t_m corrected (t_m–t_a+ 40 °C or max. RATED ambient)
t_{max} = maximum permitted temperature
NOTE 2 - See also 14.1 with reference to component operating conditions
NOTE 3 - Record values for NORMAL CONDITION and / or SINGLE FAULT CONDITION in this Form use additional form if necessary
NOTE 4 - See Form A.20B for details of winding temperature measurements

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

10.	**TABLE : Temperature Measurements** **Form A.20A**	**P**
10.1	Surface temperature limits - NORMAL CONDITION and / or SIGNLE FAULT CONDITION	P
10.2	Temperature of windings- NORMAL CONDITION and / or SIGNLE FAULT CONDITION	N/A
10.3	Other temperature measurements	N/A

Operating conditions:	Max. Normal load conditions. Sample #1-2/3		
Frequency ..... :	60 Hz	Test room ambient temperature (t_a)..... :	23 °C
Voltage ..... :	264 V	Test duration ..... :	2 h 4 min

Part / Location	t_m °C	t_c °C	t_{max} °C	Verdict	Comments
DC input connector body	31.3	481	70	P	Tested with certified adaptor
D1 body	41.2	58.0	-	P	Tested with certified adaptor
J11 body	36.0	52.8	-	P	Tested with certified adaptor
PCB near U9	32.7	49.5	-	P	Tested with certified adaptor
Battery body	52.2	69.0	-	P	Tested with certified adaptor
Motor body	40.8	57.6	-	P	Tested with certified adaptor
Measuring module body	28.7	45.5	-	P	Tested with certified adaptor
LCD body	26.6	43.4	70	P	Tested with certified adaptor
Inside enclosure (top)	28.4	45.2	-	P	Tested with certified adaptor
Outside enclosure (top)	26.4	43.2	80	P	Tested with certified adaptor
Adaptor body (enclosure top)	33.6	50.4	80	P	Tested with certified adaptor
Ambient	23.2	40.0	-	P	Tested with certified adaptor

NOTE 1 - t_m = measured temperature
t_c = t_m corrected (t_m–t_a+ 40 °C or max. RATED ambient)
t_{max} = maximum permitted temperature
NOTE 2 - See also 14.1 with reference to component operating conditions
NOTE 3 - Record values for NORMAL CONDITION and / or SINGLE FAULT CONDITION in this Form use additional form if necessary
NOTE 4 - See Form A.20B for details of winding temperature measurements

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

10.	**TABLE : Temperature Measurements** **Form A.20A**	**P**
10.1	Surface temperature limits - NORMAL CONDITION and / or SIGNLE FAULT CONDITION	P
10.2	Temperature of windings- NORMAL CONDITION and / or SIGNLE FAULT CONDITION	N/A
10.3	Other temperature measurements	P

Operating conditions:	Max. Normal load conditions. Sample #1-2/3		
Frequency ..... :	60 Hz	Test room ambient temperature (t_a)..... :	22 °C
Voltage ..... :	264 V	Test duration ..... :	h 55 min

Part / Location	t_m °C	t_c °C	t_{max} °C	Verdict	Comments
DC input connector body	30.0	47.8	70	P	Tested with certified adaptor
D1 body	39.8	57.6	-	P	Tested with certified adaptor
J11 body	34.8	52.6	-	P	Tested with certified adaptor
PCB near U9	31.4	49.2	-	P	Tested with certified adaptor
Battery body	51.9	69.7	-	P	Tested with certified adaptor
Motor body	39.1	56.9	-	P	Tested with certified adaptor
Measuring module body	27.5	45.3	-	P	Tested with certified adaptor
LCD body	25.1	42.9	70	P	Tested with certified adaptor
Inside enclosure (top)	27.3	45.1	-	P	Tested with certified adaptor
Outside enclosure (top)	25.2	43.0	80	P	Tested with certified adaptor
Adaptor body (enclosure top)	31.5	49.3	80	P	Tested with certified adaptor
Ambient	22.2	40.0	-	P	Tested with certified adaptor

NOTE 1 - t_m = measured temperature
t_c = t_m corrected (t_m–t_a+ 40 °C or max. RATED ambient)
t_{max} = maximum permitted temperature
NOTE 2 - See also 14.1 with reference to component operating conditions
NOTE 3 - Record values for NORMAL CONDITION and / or SINGLE FAULT CONDITION in this Form use additional form if necessary
NOTE 4 - See Form A.20B for details of winding temperature measurements

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

10.2	**TABLE: Temperature of windings** **Form A.20B** **Resistance method Temperature Measurements**	**N/A**
4.4.2.6	MAINS Transformers	N/A
14.2.1	Motor temperatures	N/A

Operating conditions:								
Frequency ..... :	Hz	Test room ambient temperature (t_{a1}/t_{a2})... :				/	°C (initial / final)	
Voltage ..... :	V	Test duration ..... :				h	min	
Part / Designation	R_{cold} Ω	R_{warm} Ω	Current A	t_r K	t_c °C	t_{max} °C	Verdict	Comments

NOTE 1- R_{cold} = initial resistance
t_r = temperature rise
t_{max} = maximum permitted temperature
R_{warm} = final resistance
t_c = t_r corrected (t_c= t_r - { t_{a2} - t_{a1}} + [40 °C or max RATED ambient])
NOTE 2 - Indicate insulation class (IEC 85) under comments (optional)
NOTE 3 - Record values for NORMAL CONDITION and / or SINGLE FAULT CONDITION in this Form use additional form if necessary

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

10.5.2	**TABLE: Resistance to heat of non-metallic enclosures**				**P**
	Test method used:				—
	Non operative treatment..... :	[x]			P
	Empty ENCLOSURE ..... :	[ ]			N/A
	Operative treatment..... :	[ ]			N/A
	Temperature during tests ..... :	70°C			—
	ENCLOSURE samples tested were..... :				—

Description	Material	Comments	Verdict
Enclosure, Sample #1-1/3	Non-metallic	Not damaged	P
Enclosure, Sample #1-2/3	Non-metallic	Not damaged	P
Enclosure, Sample #1-3/3	Non-metallic	Not damaged	P

	Dielectric strength test (6.8) ..... :	2224	V	rms	P

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

10.5.3	**TABLE: Insulating Materials**	**Form A.22**	**N/A**
10.5.3a)	Ball pressure test		N/A
	Max. allowed impression diameter..... :	2 mm	—

Part	Test temperature °C	Impression Diameter (mm)	Verdict

Supplementary information:

10.5.3b)	Vicat softening test (ISO 306)		N/A

Part	Vicat softening temperature °C	Thickness of sample (mm)	Verdict

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

8	**TABLE: Mechanical resistance to shock and impact**	**Form A.23**	**P**
11	**Protection against hazards from fluids**		**P**

Voltage tests can be carried out once after performing the tests of clause **8** and clause **11**. However, if voltage tests are carried out separately after each set of tests, two forms can be used.

	Clause 8 tests				Clause 11 tests							
Location (see form A.5)	Static	Dynamic	Normal	Handheld Plug-in	Cleaning (11.2)	Spillage (11.3)	Overflow (11.4)	IEC 60529 (11.6)	Working voltage V	Test voltage V	Verdict	Comments
A	30 N	5 J	Corner drop	-	Isopropyl alchol	-	-	-	240 V	2224 V	P	Sample #1-1/3 (With certified AC/DC adaptor)
A	30 N	5 J	Corner drop	-	Isopropyl alchol	-	-	-	240 V	2224 V	P	Sample #1-2/3 (With certified AC/DC adaptor)
A	30 N	5 J	Corner drop	-	Isopropyl alchol	-	-	-	240 V	2224 V	P	Sample #1-3/3 (With certified AC/DC adaptor)

NOTE – Use r.m.s., d.c. or peak to indicate the used test voltage.

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

11.7.2	**TABLE: Leakage and rupture at high pressure**	**Form A.24**	**N/A**

Part	Maximum permissible working pressure MPa	Test pressure MPa	Leakage YES / NO	Burst YES / NO	Comments

Supplementary information:

11.7.3	Leakage from low-pressure parts	N/A

Part	Test pressure MPa	Leakage YES / NO	Comments

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

12.2.1	**TABLE: Ionizing radiation**		**Form A.25**	**N/A**
Locations tested	Measured values µSv/h	Verdict	Comments	
Supplementary information:				

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

12.5.1	**TABLE: Sound level**	**Form A.26**	**N/A**

Locations tested	Measured values dBA	Calculated maximum sound pressure level
At operator's normal position and at bystanders' positions		
a)		
b)		
c)		
d)		
e)		

Supplementary information:

12.5.2	Ultrasonic pressure	N/A

Locations tested	Measured values		Comments
	dB	kHz	
At OPERATOR'S normal position			
At 1 m from the ENCLOSURE			
a)			
b)			
c)			
d)			
e)			

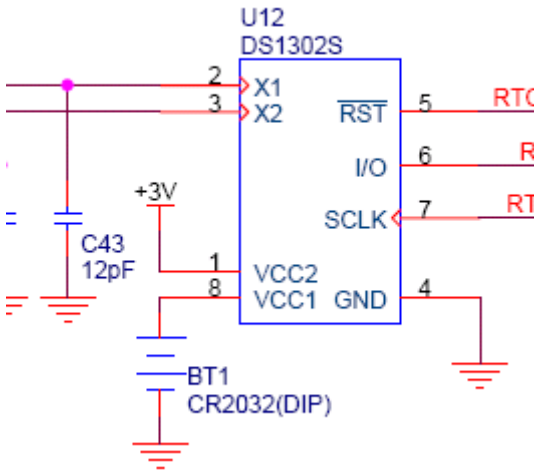
NOTE – No limit is specified at present, but a limit of 110 dB above the reference pressure value of 20 μPa is under consideration for applicable frequencies between 20 kHz and 100 kHz.

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

13.2.2	**TABLE: Batteries**	**Form A.27**	**P**
	Battery load and charging circuit diagram:		



	Battery type.....:	Lithium battery	—
	Battery manufacturer/model/catalogue No. .....:	Panasonic / CR2032	—
	Battery ratings.....:	DC 3V	—
	Reverse polarity instalment test	No hazard	P

Single component failures	Verdict	
Component	Open circuit	Short circuit
U12(6,8), Sample #-1-1/3	N/A	No hazard.
U12(6,8), Sample #-1-2/3	N/A	No hazard.
U12(6,8), Sample #-1-3/3	N/A	No hazard.

Supplementary information: No hazard

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

14.3	**TABLE: Overtemperature protection devices**	**Form A.28**	**N/A**

Reliability test

Component	Type (note)	Verdict	Comments

NOTE:
NSR = non-self-resetting (10 times)
NR = non-resetting (1 time)
SR = self-resetting (200 times)

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

4.4.2.6	**TABLE: Mains transformer**			**Form A.29**	**N/A**
4.4.2.6.1	Short circuit				N/A
14.7.1	MAINS transformers tested outside equipment				N/A
Type.....:					—
Manufacturer .....:					—
Test in equipment					
Test on bench					
Test repeated inside equipment (see 14.7)					
Optional – Insulation class (IEC 60085) of the lowest RATED winding .....:					—
Winding identification					
Type of Protector for winding (Note 1)					
Elapsed time					
Current, A primary secondary					
Winding temperature, °C primary (see Note 2) secondary					
Tissue paper / cheesecloth OK ? (Pass / Fail)					
Voltage tests (see Note 3)					
primary to secondary	_____ V ____				
primary to core	_____ V ____				
secondary to secondary	_____ V ____				
secondary to core	_____ V ____				
Verdict					

Note 1:	Primary fuse	- PF /	( )	A
	Secondary fuse	- SF /	( )	A
	Overtemperature protection	- OP /	( )	°C
	Impedance protection	- Z		

Note 2: Indicate method of measurement TC = with thermocouple
R = resistance method
If resistance method is used,record resistance in cold and warm condition in FormA.20B!

Note 3: Record the voltage applied and the type of voltage (r.m.s. / d.c. / peak) and for results use NB = no breakdown or B = breakdown

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

4.4.2.6	**TABLE: Mains transformer**			**Form A.30**	**N/A**
14.7.2	Overload tests (for mains transformers)				N/A
Type.....:					—
Manufacturer .....:					—
Test in equipment					
Test on bench					
Test repeated inside equipment (see 14.7)					
Optional – Insulation class (IEC 60085) of the lowest RATED winding .....:					—
Winding identification					
Type of Protector for winding (Note 1)					
Elapsed time					
Current, A primary secondary					
Winding temperature, °C primary (see Note 2) secondary					
Tissue paper / cheesecloth OK ? (Pass / Fail)					
Voltage tests (see Note 3)					
primary to secondary	_____ V ____				
primary to core	_____ V ____				
secondary to secondary	_____ V ____				
secondary to core	_____ V ____				
Verdict					

Note 1:	Primary fuse	- PF /	( )	A
	Secondary fuse	- SF /	( )	A
	Overtemperature protection	- OP /	( )	°C
	Impedance protection	- Z		

Note 2: Indicate method of measurement TC = with thermocouple
R = resistance method
If resistance method is used,record resistance in cold and warm condition in FormA.20B!

Note 3: Record the voltage applied and the type of voltage (r.m.s. / d.c. / peak) and for results use NB = no breakdown or B = breakdown

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

16.1	**TABLE: Current measuring circuits**	**Form A.31**	**N/A**

These tests are performed with all types and models of current transformers without internal protection, and which are specified by the manufacturer for use with the equipment

a) Current transformers

Type/Model	RATED current A	Test current A	Interrupt Yes / No	Verdict	Comments

Supplementary information:

b) Range changing switches

Type / Model	Maximum rated current of switch A	Cycling test Verdict	Comments

Supplementary information:

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

16.2	**TABLE: Multifunctional meters and similar equipment** **Form A.32**		**N/A**
	Operating conditions .....:		—
	Maximum RATED voltage applied (V)..... :		—
	Measurement category ..... :		—
	Test source limit (KVA) ..... :		—

Function	Range	Verdict

Supplementary information:

Product Service

TEST REPORT

IEC 61010-2-101 / EN 61010-2-101

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Report Reference No. ..... :	CPSZ0928781
Compiled by (+ signature) ..... :	Albert. Lee
Approved by (+ signature) ..... :	Harry. Kwon
Date of issue ..... :	2011-08-22
Contents ..... :	5 pages
Modification Test Report Reference Number ..... :	CPSA0142849
Modification to appliance ..... :	Applicant address

CB / CCA Testing Laboratory ..... :	TÜV SÜD Korea Laboratory (TKL)
Address ..... :	#315 and 316, MARIO Tower, 222-12, Guro-Dong, Guro-Gu, 152-050, Seoul, Korea
Testing location ..... :	CBTL ☒ SMT ☐ TMP ☐
Address ..... :	Same as above

Applicant's name ..... :	Boditech Med Inc.
Address ..... :	1144-2 Geoduri, Dongnaemyeon, Chuncheon, Gangwon-do, 200-883, Republic of KOREA

Test specification:	
Standard ..... :	IEC 61010-2-101: 2002 (ed.1) EN 61010-2-101: 2002 (ed.1)
Test procedure ..... :	CE-LVD
Non-standard test method ..... :	N/A

Test Report Form No ..... :	IECEN61010_2_101A
TRF Originator ..... :	VDE
Master TRF ..... :	Dated February 2004

Product Service

Test item description..... :	Blood and urine analyzer
Trade Mark .....:	Boditech
Manufacturer .....:	Same as applicant
Model/Type reference.....:	i-CHROMA
Ratings .....:	12 V d.c., 3.0 A

Product Service

Copy of marking plate:

Summary of testing: Pass

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001 and IEC/EN 61010-2-101, IEC/EN 61010-2-081

Product Service

Test item particulars	:	Blood and urine analyzer
Type of item tested	:	Laboratory (IVD)
Description of equipment function	:	Analyzing of blood and urine
Installation/overvoltage category	:	N/A
Pollution degree	:	2
Environmental rating	:	Standard
Equipment mobility	:	Movable
Connection to mains supply	:	N/A
Operating conditions	:	Continuous
Overall size of the equipment (W x D x H)	:	250 mm X 185 mm X 80 mm
Mass of the equipment (kg)	:	1.2 kg
Marked degree of protection to IEC 60529	:	IPX0
Accessories and detachable parts included	:	N/A
Other options included	:	N/A
Possible test case verdicts:		
- test case does not apply to the test object	:	N/A
- test object does meet the requirement	:	P(Pass)
- test object does not meet the requirement	:	F(Fail)

Product Service

General remarks:

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report, a point is used as the decimal separator.

List of test equipment must be kept on file and available for review.

This Test Report is intended for the investigations of laboratory equipment for in vitro diagnostic (IVD) use and shall not be used without the CB Test Report covering the evaluation of the product according to IEC 61010-1, Part 1, General Requirements.

This Test Report includes the assessment of group differences to complete the assessment according to the last valid edition the relevant EN standards. Those requirements / differences are included at the end of the test case section (main body).

General product information:

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001, IEC/EN 61010-2-101 and IEC/EN 61010-2-081.

Product Service

TEST REPORT

IEC 61010-2-101 / EN 61010-2-101

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Report Reference No. ..... :	CPSA0142849
Compiled by (+ signature) ..... :	Edward. Yang
Approved by (+ signature) ..... :	Thomas. Kim
Date of issue ..... :	2009-11-27

CB / CCA Testing Laboratory ..... :	TÜV SÜD Korea Laboratory (TKL)
Address ..... :	#315 and 316, MARIO Tower, 222-12, Guro-Dong, Guro-Gu, 152-050, Seoul, Korea
Testing location ..... :	CBTL ☒ SMT ☐ TMP ☐
Address ..... :	Same as above
Applicant's name ..... :	Boditech Med Inc.
Address ..... :	#3-2,Bioventure Plaza 198-60, HupyeongDong, Chuncheon, Kangwon, 200-160, Republic of Korea
Test specification:	
Standard ..... :	IEC 61010-2-101: 2002 (ed.1) EN 61010-2-101: 2002 (ed.1)
Test procedure ..... :	CE-LVD
Non-standard test method ..... :	N/A
Test Report Form No ..... :	IECEN61010_2_101A
TRF Originator ..... :	VDE
Master TRF ..... :	Dated February 2004

Test item description ..... :	Blood and urine analyzer
Trade Mark ..... :	Boditech
Manufacturer ..... :	Same as applicant
Model/Type reference ..... :	i-CHROMA
Ratings ..... :	12 V d.c., 3.0 A

Product Service

Copy of marking plate:

Summary of testing: Pass

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001 and IEC/EN 61010-2-101, IEC/EN 61010-2-081

Product Service

Test item particulars	:	Blood and urine analyzer
Type of item tested	:	Laboratory (IVD)
Description of equipment function	:	Analyzing of blood and urine
Installation/overvoltage category	:	N/A
Pollution degree	:	2
Environmental rating	:	Standard
Equipment mobility	:	Movable
Connection to mains supply	:	N/A
Operating conditions	:	Continuous
Overall size of the equipment (W x D x H)	:	250 mm X 185 mm X 80 mm
Mass of the equipment (kg)	:	1.2 kg
Marked degree of protection to IEC 60529	:	IPX0
Accessories and detachable parts included	:	N/A
Other options included	:	N/A
Possible test case verdicts:		
- test case does not apply to the test object	:	N/A
- test object does meet the requirement	:	P(Pass)
- test object does not meet the requirement	:	F(Fail)

Product Service

General remarks:

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(see Enclosure #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report, a point is used as the decimal separator.

List of test equipment must be kept on file and available for review.

This Test Report is intended for the investigations of laboratory equipment for in vitro diagnostic (IVD) use and shall not be used without the CB Test Report covering the evaluation of the product according to IEC 61010-1, Part 1, General Requirements.

This Test Report includes the assessment of group differences to complete the assessment according to the last valid edition the relevant EN standards. Those requirements / differences are included at the end of the test case section (main body).

General product information:

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001 and IEC/EN 61010-2-101, IEC/EN 61010-2-081
- i-CHROMA is basic model which was tested.
- For test, AC/DC adaptor model MPU50-105, manufacturerd by Sinpro electronics Co., Ltd. was used.

Product Service

Clause	Requirement + Test	Result - Remark	Verdict
5.	**MARKING AND DOCUMENTATION**		**P**
5.1.1	General		P
	Additional symbols cannot be confused with the international ones		N/A
5.1.2	Identification		P
	Equipment is identified by:		—
5.1.2a)	Manufacturer's name or trademark and address	Boditech	P
5.1.2b)	Model number, name or other means	i-CHROMA	P
5.1.2c)	The name and address of the authorized representative of the manufacturer	On the label	P
	The equipment or packaging or the instructions for use include:		—
	1) The serial-number or the batch code preceded by "LOT" symbol 102 of table 1		P
	2 i) Indication that the equipment is IVD medical equipment		P
	2 ii) Indication that the equipment is self-test IVD medical equipment	No self-test IVD medical equipment	N/A
	2 iii) Identification of detachable components		N/A
	2 iv) Expiry date of consumable parts		N/A
5.1.101	Transport and storage		P
	Packaging labelled to indicate special conditions for transport or storage	In manual	P
5.2	Warning markings		P
	Potentially infectious equipment marked with symbol 101 of table 1		N/A
	Equipment that can be hazardous due to the use of chemical substances marked with the appropriate symbol; or		N/A
	with Symbol 14 of Table 1 (if none is available)		N/A
	Containers or bags for biohazardous waste material which can be removed from the equipment during NORMAL USE marked with symbol 101 of table 1		N/A
5.3	Durability of markings		P
	The required markings resist the effects of temperature and rubbing, and of solvent and reagents likely to be encountered in NORMAL USE		P
	Resistant also against agents specified by manufacturer for cleaning and decontamination procedure		P

Product Service

Clause	Requirement + Test	Result - Remark	Verdict
5.4	Documentation		P
5.4.1	General		P
	Information about any RISKS not reduced to a TOLERABLE RISK level		N/A
	Information included in documentation on:		—
	Training; or		N/A
	Protective devices; or		N/A
	Personal protective equipment to reduce RISKS to a TOLERABLE RISK level specified:		—
5.4.3	Equipment transportation, installation and assembly instructions		P
	Documentation for the RESPONSIBLE BODY includes:		—
5.4.3.a)	Instructions for transportation after delivery to the RESPONSIBLE BODY		N/A
5.4.3.b)	Floor loading requirements		N/A
5.4.3.c)	Individual weights of principal heavy subassemblies		N/A
5.4.3.d)	Location and mounting instructions		N/A
5.4.3.e)	Assembly instructions		N/A
5.4.3.f)	Instructions for protective earthing		N/A
5.4.3.g)	The sound data required by 12.5.1		N/A
5.4.3.h)	Instructions relating to the handling, containment and exhaust of hazardous substances		N/A
5.4.3.i)	Any drainage systems required		N/A
5.4.3.j)	Protective measures relating to hazardous radiation		N/A
5.4.3.k)	Connections to the supply		N/A
5.4.3.l)	PERMANENTLY CONNECTED EQUIPMENT only:		—
	1) Mains supply requirements and details of connections		N/A
	2) If external switch or circuit-breaker, requirements and location recommendation		N/A
5.4.3.m)	Special services including pressure limits		N/A
5.4.4	Equipment operation		P
	Instructions for use include:		P
5.4.4a)	Details of operating controls		P
5.4.4b)	Positioning for disconnection		N/A
5.4.4c)	Interconnection		N/A

Product Service

Clause	Requirement + Test	Result - Remark	Verdict
5.4.4d)	Specification of intermittent operation limits		N/A
5.4.4e)	Explanation of symbols used		N/A
5.4.4.f)	Any actions to be taken by an OPERATOR in case of a malfunction		N/A
5.4.4.g)	Cleaning and decontamination (see 11.2) incl. materials		P
5.4.4.h)	Disposal of waste		P
5.4.4.i)	Hazardous substances, use, need for training, or personal protection measures		N/A
5.4.4.j)	Infectiouse substances, need to use protective gloves or other protective means		N/A
5.4.4.k)	Hazardous vapours, instructions for protection of the mouth, nose or eyes		N/A
5.4.4.l)	Hazardous radiation, instructions and requirements for protective devices		N/A
5.4.4.m)	A statement about protection impairment if used in a manner not specified by the manufacturer		N/A
5.4.4.101	Self-test IVD medical equipment		N/A
	Instructions for use for self-test equipment comply with annex BB		N/A
5.4.101	Removal of equipment from use for repair or disposal		P
	Instructions for the RESPONSIBLE BODY for eliminating or reducing HAZARDS includes:		—
	Removal from use		N/A
	Transportation or disposal		P
	Requirements for minimizing biohazards		N/A
5.4.102	Transport and storage		P
	Permissible environmental conditions for transport and storage specified:		—
	In documentation; and		P
	On outside of packaging		P
8	**MECHANICAL RESISTANCE TO SHOCK AND IMPACT**		
8.1.101	Transport and storage		N/A
	Records of tests performed by the manufacturer show conformity (Guidance ASTM D4169 of ISTA)	(See test records attached)	N/A
11	**PROTECTION AGAINST HAZARDS FROM FLUIDS**		
11.3	Spillage		N/A

Product Service

Clause	Requirement + Test	Result - Remark	Verdict
	Potentially aggressive substances (such as corrosive, toxic or flammable liquids) taken into account		N/A
	Potentially aggressive substances compatible with contacted parts of the equipment		N/A
13	**PROTECTION AGAINST LIBERATED GASES AND SUBSTANCES, EXPLOSION AND IMPLOSION**		
13.1	Poisonous and injurious gases and substances		N/A
	Attached data/test reports demonstrate conformity (in NC and SFC)	(see Form A.1)	N/A
	Dangerous amounts of poisonous or injurious gases or substances not liberated in NORMAL CONDITION or in SINGLE FAULT CONDITION		N/A
	If potentially hazardous substances are liberated:		—
	OPERATOR not be wetted nor able to inhale quantities likely to be hazardous		N/A
	Protective covers or similar means of protection		N/A
14	**COMPONENTS**		
14.3	Overtemperature protection devices		N/A
14.3 c)	Does not operate in NORMAL USE		N/A
	Not self-resetting in self-test IVD equipment		N/A
Annex AA	**RISK MANAGEMENT**		
	EN ISO 14971 applied		N/A
	Conformity demonstrated	(see documents attached)	N/A
			N/A
	GROUP DEVIATIONS OF EN 61010-2-101: 2002		
5.4.4	Equipment operation		N/A
	Instructions for IVD medical equipment for commercial use comply with EN 591	(see documents attached)	N/A
	Instructions for self-test IVD medical equipment use comply with EN 592	(see documents attached)	N/A
5.4.4.101	~~Self-test IVD medical equipment~~	Clause deleted	N/A

Product Service

4.4.2	**TABLE: Summary of SINGLE FAULT CONDITIONS**			**Form A.1**	**P**
Subclause	Title	Does not apply	Carried out	Comments	
4.4.2.1	PROTECTIVE IMPEDANCE	X			
4.4.2.2	Protective conductor	X		see Form A.8	
4.4.2.3	Equipment or parts for short-term or intermittent operation	X			
4.4.2.4	Motors		X		
4.4.2.5	Capacitors	X			
4.4.2.6	Mains transformers Attach drawing of MAINS Txs showing all protective devices (see Forms A.29 and A.30)	X			
4.4.2.7	Outputs	X			
4.4.2.8	Equipment for more than one supply	X			
4.4.2.9	Cooling – air holes closed – fans stopped – coolant stopped	X X X X			
4.4.2.10	Heating devices – timer overridden – temperature controller overridden – loss of cooling liquid – overfilled or empty or both	X X X X X			
4.4.2.11	Insulation between circuits and parts	X			
4.4.2.12	Interlocks	X			
4.4.2.101	Incorrect voltage selection	X			
List below all SINGLE FAULT CONDITIONS not covered by 4.4.2.1 to 4.4.2.101:					
13.1	Poisonous and injurious gases and substances	X			
NOTE – Record surface temperatures of flammable liquids and parts in contact with them in Form A.20A					
Supplementary information: (see Form A.2 for details of tests)					

Product Service

TEST REPORT

IEC 61010-2-081

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

Report Reference No.....:	CPSZ0928781
Tested by (name and signature).....:	Albert. Lee
Approved by (name and signature) ..:	Harry. Kwon
Date of issue.....:	2011-08-22
Contents .....:	3 pages
Modification Test Report Reference Number .....:	CPSA0142849
Modification to appliance .....:	Applicant address

Testing Laboratory.....:	TÜV SÜD Korea Laboratory (TKL)
Address .....:	#315 and 316, MARIO Tower, 222-12, Guro-Dong, Guro-Gu, 152-050, Seoul, Korea
Testing location/procedure .....:	as above CBTL [x] SMT [ ] TMP [ ]
Address .....:	as above

Applicant's name.....:	Boditech Med Inc.
Address .....:	1144-2 Geoduri, Dongnaemyeon, Chuncheon, Gangwon-do, 200-883, Republic of KOREA

Test specification:

Standard .....:	IEC/EN 61010-2-081
Test procedure .....:	CE-LVD
Non-standard test method.....:	—

Test Report Form No.....:	IEC61010_2_081A
TRF Originator.....:	IMQ S.p.A.
Master TRF.....:	Dated March 2002

Test item description.....:	Blood and urine analyzer
Trademark .....:	Boditech
Model/Type reference.....:	i-CHROMA
Rating(s) .....:	12 V d.c., 3.0 A

Product Service

IEC 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

Test item particulars ..... :	
Type of item tested ..... :	Blood and urine analyzer
Description of equipment function..... :	Analyzing of blood and urine
Installation/overvoltage category..... :	II
Pollution degree..... :	2
Environmental rating..... :	Standard
Equipment mobility ..... :	Movable
Connection to mains supply ..... :	Detachable cord set
Operating conditions..... :	Continuous
Overall size of the equipment (L x W x H)..... :	250 mm X 185 mm X 80 mm
Mass of the equipment (kg)..... :	1.2 kg
Marked degree of protection to IEC 60529 ..... :	N/A
Accessories and detachable parts included in the evaluation ..... :	N.A
Options ..... :	N/A
Test case verdicts:	
Test case does not apply to the test object..... :	N/A
Test object does meet the requirement ..... :	P(Pass)
Test object does not meet the requirement ..... :	F(Fail)
Testing ..... :	
Date of receipt of test item ..... :	N/A
Date (s) of performance of tests ..... :	N/A

General remarks:

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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

The test results presented in this report relate only to the item(s) tested.

"(see remark #)" refers to a remark appended to the report.
"(see Annex #)" refers to an annex appended to the report.
"(see Form A.#)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

IEC 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

Copy of marking plate:

Summary of test results (information/comments):

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001, IEC/EN 61010-2-101 and IEC/EN 61010-2-081.

Product Service

TEST REPORT

IEC 61010-2-081

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

Report Reference No.....:	**CPSA0142849**
Tested by (name and signature).....:	Edward.Yang
Approved by (name and signature) ..:	Thomas. Kim
Date of issue.....:	2009-11-27
Contents .....:	20 Pages

Testing Laboratory.....:	TÜV SÜD Korea Laboratory (TKL)
Address .....:	#315 and 316, MARIO Tower, 222-12, Guro-Dong, Guro-Gu, 152-050, Seoul, Korea
Testing location/procedure .....:	as above CBTL [x] SMT [ ] TMP [ ]
Address .....:	as above

Applicant's name.....:	Boditech Med Inc.
Address .....:	#3-2,Bioventure Plaza 198-60, HupyeongDong, Chuncheon, Kangwon, 200-160, Republic of Korea

Test specification:

Standard .....:	IEC/EN 61010-2-081
Test procedure .....:	CE-LVD
Non-standard test method.....:	—

Test Report Form No.....:	IEC61010_2_081A
TRF Originator.....:	IMQ S.p.A.
Master TRF.....:	Dated March 2002

Test item description..... :	Blood and urine analyzer
Trademark.....:	Boditech
Model/Type reference.....:	i-CHROMA
Rating(s) .....:	12 V d.c., 3.0 A

Product Service

Test item particulars ..... :	
Type of item tested ..... :	Blood and urine analyzer
Description of equipment function..... :	Analyzing of blood and urine
Installation/overvoltage category..... :	II
Pollution degree..... :	2
Environmental rating..... :	Standard
Equipment mobility ..... :	Movable
Connection to mains supply ..... :	Detachable cord set
Operating conditions..... :	Continuous
Overall size of the equipment (L x W x H)..... :	250 mm X 185 mm X 80 mm
Mass of the equipment (kg)..... :	1.2 kg
Marked degree of protection to IEC 60529 ..... :	N/A
Accessories and detachable parts included in the evaluation ..... :	N.A
Options ..... :	N/A
Test case verdicts:	
Test case does not apply to the test object..... :	N/A
Test object does meet the requirement ..... :	P(Pass)
Test object does not meet the requirement ..... :	F(Fail)
Testing ..... :	
Date of receipt of test item ..... :	2009-10-26
Date (s) of performance of tests ..... :	2009-10-26 until 2009-11-20

General remarks:

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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

The test results presented in this report relate only to the item(s) tested.

"(see remark #)" refers to a remark appended to the report.
"(see Annex #)" refers to an annex appended to the report.
"(see Form A.#)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

Product Service

Copy of marking plate:

Summary of test results (information/comments):

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001 and IEC/EN 61010-2-101, IEC/EN 61010-2-081
- i-CHROMA is basic model which was tested.
- For test, AC/DC adaptor model MPU50-105, manufacturerd by Sinpro electronics Co., Ltd. was used.

	TABLE: 1 - Documents attached to this report	
Document No.	Document description	Page Numbers
Attachment 1	Photos	2

Product Service

	TABLE: 2 - Test equipment list				P
Item	Type	Equipment No.	Calibration date		Comments
			Last[1]	Due	
1-A	Temperature & Humidity Chamber	ER-35MHHP	2009-02-02	2010-02-02	
2-A	Temperature Chamber	EPRH-432-2T	2009-02-02	2010-02-02	
7-A	DC Power Supply	DRP305DN	2009-02-02	2010-02-02	
8-B	Temperature Recorder	DR230	2009-02-03	2010-02-03	
15-A	Dielectric Strength Tester	TOS9201	2009-02-02	2010-02-02	
23-A	DC mA Meter	2011	2009-02-02	2010-02-02	
25-A	True RMS Multi-Meter	187	2009-02-02	2010-02-02	
51-A	IEC61032 Test Probe B	P1032-B	2009-04-28	2010-04-28	
55-A	Drop Test Check Jig & Scale	IT0410	2009-04-24	2012-04-24	
59-A	Hard Wood Surface	-	2009-10-07	2010-04-07	
65-A	Stop Watch	HS-3	2009-06-10	2010-06-10	
68-B	Isopropyl alcohol	16.788.07	-	-	
35-B	Push-pull gauge	DPS-5K	2009-02-23	2010-02-23	
51-I	IEC60950-1 Fig.2C Test probe	P0330	2009-04-28	2012-04-28	

1) or interval between calibrations.

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict

	TABLE: 3 - List of components and circuits relied on for safety				P
Unique component reference or location (including drawing reference if required)	Application/Function	Manufacturer (NOTE 1)	Part number	RATING (NOTE 2)	Evidence of acceptance (NOTE 3)
AC/DC Adaptor	-	Sinpro electronics Co., Ltd.	MPU50-105	Input : 100-240 V~, 47-63 Hz, 1.35 A Output : 12 V d.c., 3.75 A	UL, TUV Rheinland
Power switch	-	Zhongxun	KCD11	250 V~, 3 A	TUV Rheinland
Motor	-	Saehan Electronics	4S42Q-T12034SD	12 V d.c.	Tested with appliance
Lithium battery(BT1)	-	Panasonic	CR2032	3 V d.c. Max. abnormal charging current : 10 mA	UL
LCD panel	-	Shenzhen Topway Technology co.,LTD	LMB164ACD	6 V d.c., 1.3 mA	Tested with appliance
Laser diode in measuring module	-	QSI Co., Ltd.	QL63D	-	SEMKO
Enclosure	-	BASF Corp.	GP-35	Min.thickness 2.5 mm, HB	UL
PCB	-	EUNSUNG ELECCOM.CO.LTD	1, 2	94V-0, 105 ℃, Min. thickness 1.6 mm	UL

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict

	TABLE: 3 - List of components and circuits relied on for safety				P
Unique component reference or location (including drawing reference if required)	Application/Function	Manufacturer (NOTE 1)	Part number	RATING (NOTE 2)	Evidence of acceptance (NOTE 3)
NOTE 1 - List all manufacturers concerned. NOTE 2 - Electrical, mechanical, flammability, etc. NOTE 3 - Licence number, file number or other documentary evidence of acceptance					

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict
5	MARKING AND DOCUMENTATION		—
5.1.1	General		—
	Letter symbols (IEC 60027) used		P
	Graphic symbols (IEC 61010-1: Table 1) used	No biohazard	N/A
	If other additional symbols are required, it shall not be possible to confuse them with the international symbols		P
	There are no colour requirements for symbols except for symbol 101 (see Table 1).		P
	Graphic symbols shall be explained in the documentation.		P
5.1.5	Terminals, connections and operating devices		—
5.1.5.101	Gas and liquid connections		—
	The equipment shall be clearly marked near to the connector on the equipment with:	None of gas and liquid connections	N/A
5.1.5.101 a)	a means of identifying the gas or liquid to be used.		N/A
	Where no internationally recognized symbol (including chemical formulae) exists, the equipment shall be marked with symbol 14 of Table 1;		N/A
5.1.5.101 b)	the maximum permitted pressure; or		N/A
	symbol 14 of Table 1 (see 5.4.3).		N/A
5.2	Warning markings		—
	Equipment that can be potentially infectious due to the samples or reagents used shall be prominently marked with symbol 101 of Table 1	No biohazard	N/A
	Equipment that can be hazardous due to the use of chemical substances shall be marked with the appropriate symbol, or (if none is available) symbol 14 of Table 1.		N/A
	Protective covers shall be marked to warn the operator not to open or remove them except as permitted by 7.2.101 or 7.2.102.		N/A
	Any part of the equipment that contains biohazardous waste material which can be removed from the equipment during normal use shall be marked with symbol 101 of Table 1.	No bio hazardous material	N/A
	Other warning markings are specified in 5.1.5.1 c), 6.1.2 b), 6.5.1.2 Q), 6.6.2, 7.2 c), 7.2.101f), 7.2.102 c), 7.3, 10.1, 13.2.2.		P

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict
5.3	Durability of markings		—
	Markings required by 5.1.2 to 5.2 shall be permanently affixed and shall remain clear and legible under conditions of normal use, and resist the effects of temperature and rubbing, and of solvent and reagents likely to be encountered in normal use, including cleaning and decontaminating agents specified by the manufacturer.	(see Form A.4)	P
5.4	Documentation		—
5.4.1	General		—
	Information shall be given about any risks not reduced to a tolerable risk level by the protective measures specified in this standard.		P
	If there is a need for training or for the use of additional protective devices or personal protective equipment to reduce risks to a tolerable risk level, these shall be specified.		P
5.4.3	Equipment transportation, installation and assembly instruction		—
	Documentation for the responsible body shall include the following as applicable:		—
5.4.3a)	instructions for transportation after delivery to the responsible body;		P
5.4.3b)	floor loading requirements;		P
5.4.3c)	individual weights of principal heavy sub-assemblies;	None of heavy sub-assemblies	N/A
5.4.3d)	location and mounting instructions, including the space required for ventilation, and for safe and efficient operator maintenance;		P
5.4.3e)	assembly instructions;		P
5.4.3f)	instructions for protective earthing;		P
5.4.3g)	the sound data required by 12.5.1 ;	No sound level	N/A
5.4.3h)	instructions relating to the handling, containment and exhaust of hazardous substances, including any requirements for preventing back-syphonage;	No hazardous substances	N/A
5.4.3i)	any drainage systems required where a hazard could occur from the discharge of biological and chemical substances and hot fluids;	No drainage systems	N/A
5.4.3j)	details of protective measures relating to hazardous radiation (see clause.12);	No hazardous radiation	N/A
5.4.3k)	instructions for connections to the supply		P
5.4.3l)	for permanently connected equipment only:		N/A

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict
	1) mains supply requirements and details of connections, including the rated temperature of the cable required at maximum rated ambient temperature;		N/A
	2) requirements for any external switches, circuit-breakers (see 6.11.2.1) or overcurrent protection devices (see 9.5). A recommendation that a switch or circuit breaker be near the equipment shall also be included if this is necessary for safety;		N/A
5.4.3m)	requirements far special services (far example air, cooling liquid) including pressure limits.		N/A
5.4.4	Equipment operation		—
	Instructions for use include:		—
5.4.4a)	details of operating controls and their use in all operating modes with any sequence of operation		P
5.4.4b)	an instruction not to position the equipment so that it is difficult to operate the disconnecting device (see 6.11);		P
5.4.4c)	instructions for interconnections to accessories and other equipment, including details of suitable accessories, detachable parts and any special materials;		N/A
5.4.4d)	limits for intermittent operation;	Continuous operation	N/A
5.4.4e)	an explanation of symbols used on the equipment and, where hazards are involved, the reason for using a symbol in each particular case;		P
5.4.4f)	Instructions for any actions to be taken by an operator in case of a malfunction;		P
5.4.4g)	instructions and recommendations for cleaning and decontamination, with materials recommended (see 11.2);		P
5.4.4h)	instructions for the disposal of waste;		P
5.4.4i)	if normal use involves the handling of hazardous substances, instructions on correct use and any need for training or personal protection measures;	No hazardous substances	N/A
5.4.4j)	if there could be contact with the skin when handling potentially infectious substances (such as human samples or reagents), the need to use protective gloves;	No potentially infectious substances	N/A
5.4.4k)	if the equipment could emit hazardous aerosol vapours in normal use, instructions for protection of the mouth, nose or eyes;	No hazardous aerosol	N/A

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict
5.4.4l)	if potentially hazardous visible or invisible radiation could be emitted, instructions and requirements for protective devices, such as protective glasses;		N/A
5.4.4m)	Instructions relating to access to moving parts (see 7.2.1 01 and 7.2.102).		N/A
5.4.101	Instructions shall be provided for the responsible body for eliminating or reducing hazards involved in removal from use, transportation or disposal.		N/A
	These instructions shall include requirements for minimizing biohazards.		N/A
7	PROTECTION AGAINST MECHANICAL HAZARDS		—
7.2.101	Accessibility during normal use	No accessibility during normal use	—
	If moving parts are unavoidably exposed in normal use, risk management (see annex AA) shall be carried out to establish whether the moving parts could cause injury to the operator.		P
	Any risks shall be minimized as far as practicable by protective measures, in the following order of priority:		P
	a) protective devices (interlock systems or other means, removable only with a tool);		N/A
	b) protective covers;		P
	c) mechanical barriers;		N/A
	d) sufficient distance between safe areas and moving parts		N/A
	e) warning signals (audible or visible);		N/A
	f) warning markings (see 5.2).		N/A
	If moving parts are unavoidably exposed during normal use, the instructions shall specify that procedures which could result in injury are carried out only by operators who have been warned of the potential hazards and have received adequate training in carrying out the procedures in the safest possible manner.		N/A
7.2.102	Accessibility outside normal use		—
	If an operator carrying out routine maintenance outside normal use has to perform a procedure, which requires access to hazardous moving parts, access is permitted provided that all of the following precautions have been taken:		N/A

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict
	a) access to moving parts protected by devices specified in 7.2.101 a) is not possible without the use of a tool		N/A
	b) the instructions for the responsible body include a statement that operators must be trained before being allowed to perform the hazardous procedure;		N/A
	c) there are warning markings (see 5.2) on any covers or parts which have to be removed to obtain access and the warning prohibits access by untrained operators		N/A
	As an alternative, symbol 14 of Table 1 shall be placed on the covers or parts and the warnings included in the documentation.		N/A
8	MECHANICAL RESISTANCE TO SHOCK AND IMPACT		—
	After the tests of 8.1.2 and 8.2.1:		—
	Voltage tests	(see Form A.14)	P
	Inspections:		—
8 a)	HAZARDOUS LIVE parts not accessible	No hazardous live parts	N/A
8 b)	ENCLOSURE shows no cracks (hazard)		P
8 c)	CLEARANCES not less than their permitted values	(see Form A.13)	N/A
8 d)	BARRIERS not damaged or loosened		N/A
8 e)	No moving parts exposed, except permitted by 7.2		P
8 f)	No damage which could cause spread of fire		P
11	PROTECTION AGAINST HAZARDS FROM FLUIDS		—
11.3	Spillage	(See Form A.23)	N/A
	If in normal use, liquid is likely to be spilled into the equipment, the equipment shall be designed so that no hazard will occur, as a result of the wetting of insulation or of internal uninsulated parts which are hazardous live, or as a result of the contact of potentially aggressive substances (such as corrosive, toxic or flammable liquids) with parts of the equipment.		N/A
13	PROTECTION AGAINST LIBERATED GASES AND SUBSTANCES, EXPLOSION AND IMPLOSION		—
13.1	Poisonous and injurious gases and substances	No such gases and substances	N/A

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict
	Equipment shall not liberate dangerous amounts of poisonous or injurious gases or substances in normal condition or in single fault condition.		N/A
	If potentially hazardous substances are liberated, the operator shall not be wetted nor be able to inhale quantities likely to be hazardous. The areas of the equipment containing such substances shall be equipped with protective covers or similar means of protection.		N/A

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict

5.3	**TABLE: Durability of markings**	**Form A.4**	P

Marking method (see NOTE)	Agent
1) Printed on label, fixed by adhesive on enclosure	A Water
2) Silk-screened on parts	B Isopropyl alcohol
3)	C (specify agent)
4)	D (specify agent)
5)	E (specify agent)

NOTE – Where applicable include print method, label material, ink or paint type, fixing method, adhesive and surface to which marking is fixed.

Marking location	Marking method (see above)
Identification (5.1.2)	1)
Mains supply (5.1.3)	1)
Fuses (5.1.4)	1)
TERMINALS and operating devices (5.1.5.1)	N/A
Measuring circuit TERMINALS (5.1.5.2)	N/A
Switches and cricuit breakers (5.1.6)	2)
DOUBLE/REINFORCED equipment (5.1.7)	N/A
Field wiring TERMINAL boxes (5.1.8)	N/A
Warning marking (5.2)	1)
Battery charging (13.2.2)	N/A

Method	Test agent	Remains legible Verdict	Label loose Verdict	Curled edges Verdict	Comments
Rubbed by cloth	Isopropyl alcohol	Yes	No	No	Pass

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict

6.7	**TABLE: CLEARANCES and CREEPAGE DISTANCES** **Form A.13**	**P**
8	Mechanical resistance to shock and impact	P
10.5.1	Integrity of CLEARANCES and CREEPAGE DISTANCES	P

Location (see Form A.5)	Measured (initial – 6.7)		Verdict	Mechanical tests (note)					Test at max. RATED ambient (10.5.1)	Measured after test (if required)		Verdict	Comments
	CREEPAGE DISTANCE mm	CLEARANCE mm		Applied force (6.7) N	Rigidity (8.1) Static	Rigidity (8.1) Dynamic	Drop (8.2) Normal	Drop (8.2) Hand-held/ Plug-in		CREEPAGE DISTANCE mm	CLEARANCE mm		
A (Reinforced insulation)	-	-	P	10	30 N	5 J	Corner drop	N/A	40	-	-	P	With EN 60601-1 certified AC/DC adaptor.

NOTE – Refer to Form A.12 for dielectric strength tests following the above tests.

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict

6.8	**TABLE: Dielectric strength tests**	**Form A.14**	**P**
4.4.4.1 b)	Conformity after application of fault conditions[1]		P
6.4	Protection in NORMAL CONDITION		P
6.5.2	DOUBLE INSULATION and REINFORCED INSULATION		P
6.6.1	Connections to external circuits		N/A
6.7.3.1 c)	CLEARANCE values – General: reduced CLEARANCES for homogeneous construction		N/A
6.10.2.5	Fitting of non-detachable MAINS SUPPLY cords[1]		N/A
8	Mechanical resistance to shock and impact		P
9.1 a) 2)	Eliminating or reducing the sources of ignition within the equipment		N/A
9.3 c)	Limited-energy circuit		N/A
11.2	Cleaning[1]		P
11.3	Spillage[1]		N/A
11.4	Overflow[1]		N/A
11.6	Specially protected equipment[1]		N/A
[1] Record the fault, test or treatment applied before the dielectric strength test			
	Test site altitude .....:	< 250 m	—
	Test voltage correction factor (see Table 10)....:	N/A	—

Location or references from Forms A.2 and A.5	Clause or sub-clause	Humidity Yes/No	Working voltage V	Test voltage r.m.s./peak/d.c V	Comments	Verdict
A, Sample #1-1/3	4.4.4.1 b)	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	4.4.4.1 b)	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	4.4.4.1 b)	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-1/3	6.5.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	6.5.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	6.5.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-1/3	6.4	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	6.4	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	6.4	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-1/3	11.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	11.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	11.2	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-1/3	8	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-2/3	8	No	240 Vrms	2224 Vrms	No breakdown	P
A, Sample #1-3/3	8	No	240 Vrms	2224 Vrms	No breakdown	P

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict

Supplementary information:

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict

8	**TABLE: Mechanical resistance to shock and impact**	**Form A.23**	**P**
11	**Protection against hazards from fluids**		**P**

Voltage tests can be carried out once after performing the tests of clause **8** and clause **11**. However, if voltage tests are carried out separately after each set of tests, two forms can be used.

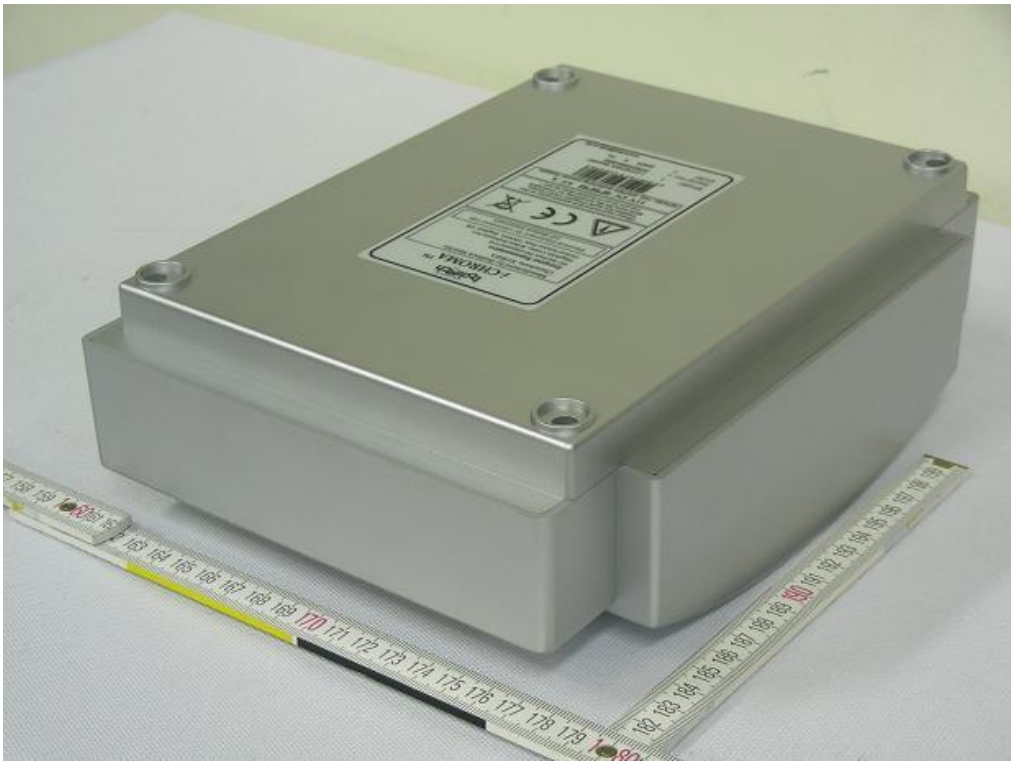
	Clause 8 tests				Clause 11 tests							
Location (see form A.5)	Static	Dynamic	Normal	Handheld Plug-in	Cleaning (11.2)	Spillage (11.3)	Overflow (11.4)	IEC 60529 (11.6)	Working voltage V	Test voltage V	Verdict	Comments
A	30 N	5J	Corner drop	N/A	Isopropyl alcohol	N/A	N/A	N/A	240	2224	P	With certified AC/DC adaptor

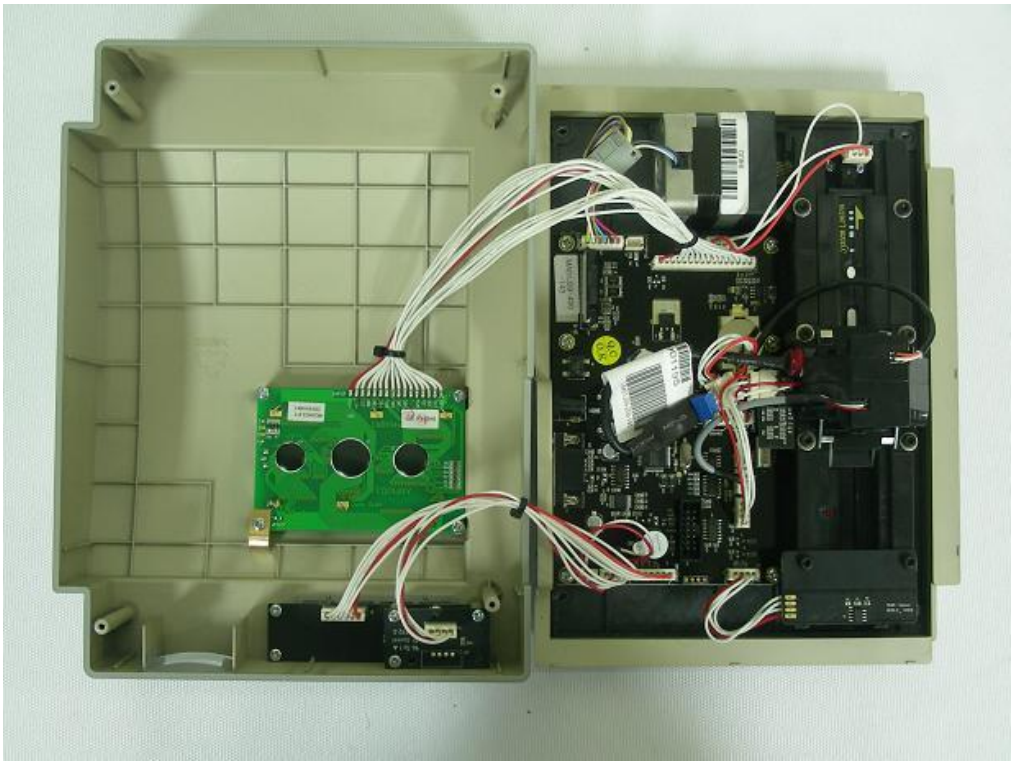
NOTE – Use r.m.s., d.c. or peak to indicate the used test voltage.

IEC 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

Remarks

Product Service





Product Service

TEST REPORT

IEC 61010-1/ EN 61010-1

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 1: General requirements

Report Reference No.....:	**CPSA0142849M1**
Tested by (name and signature).....:	Edward.Yang
Approved by (name and signature) ..:	Thomas.Kim
Date of issue.....:	2010-03-18
Contents .....:	5 Pages
Modification Test Report Reference Number .....:	CPSA0142849
Modification to appliance.....:	Correction for list of components and circuits relied on for safety
Modification on clause.....:	Clause 12.1, 12.6, Table 3
Pages concerned.....:	7, 24, 25
Testing Laboratory.....:	TÜV SÜD Korea Laboratory (TKL)
Address .....:	#315 and 316, MARIO Tower, 222-12, Guro-Dong, Guro-Gu, 152-050, Seoul, Korea
Testing location/procedure .....:	CE-LVD
Address .....:	Same as above
Applicant's name.....:	Boditech Med Inc.
Address .....:	#3-2,Bioventure Plaza 198-60, HupyeongDong, Chuncheon, Kangwon, 200-160, Republic of Korea
Test specification:	
Standard.....:	EN 61010 – 1 : 2001 (2nd Edition)
Test procedure .....:	CE-LVD
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC61010_C
TRF Originator.....:	VDE
Master TRF.....:	Dated 01-07-27

Test item description .....:	Blood and urine analyzer
Trademark.....:	Boditech
Model/Type reference.....:	i-CHROMA
Rating(s).....:	12 V d.c., 3.0 A

Product Service

Test item particulars ..... :	Blood and urine analyzer
Type of item tested ..... :	Laboratory (IVD equipment)
Description of equipment function..... :	Analyzing of blood and urine
Installation/overvoltage category..... :	N/A
Pollution degree..... :	2
Environmental rating..... :	Normal
Equipment mobility ..... :	Movable
Connection to mains supply ..... :	N/A
Operating conditions..... :	Continuous
Overall size of the equipment (L x W x H)..... :	250 mm X 185 mm X 80 mm
Mass of the equipment (kg)..... :	1.2 kg
Marked degree of protection to IEC 60529 ..... :	N/A
Accessories and detachable parts included in the evaluation ..... :	N/A
Options ..... :	N/A
Test case verdicts:	
Test case does not apply to the test object..... :	N/A
Test object does meet the requirement ..... :	P(Pass)
Test object does not meet the requirement ..... :	F(Fail)
Testing ..... :	
Date of receipt of test item ..... :	N/A
Date (s) of performance of tests ..... :	N/A

General remarks:

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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

The test results presented in this report relate only to the item(s) tested.

"(see remark #)" refers to a remark appended to the report.
"(see Annex #)" refers to an annex appended to the report.
"(see Form A.#)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

Product Service

Copy of marking plate:

Summary of test results (information/comments): Pass

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001 and IEC/EN 61010-2-101, IEC/EN 61010-2-081
- i-CHROMA is basic model which was tested.
- For test, AC/DC adaptor model MPU50-105, manufactured by Sinpro electronics Co., Ltd. was used.
- **This test report is amended from report No CPSA0142849 because of correction for list of components and circuits relied on for safety.**

Product Service

	TABLE: 3 - List of components and circuits relied on for safety				P
Unique component reference or location (including drawing reference if required)	Application/Function	Manufacturer (NOTE 1)	Part number	RATING (NOTE 2)	Evidence of acceptance (NOTE 3)
AC/DC Adaptor	-	Sinpro electronics Co., Ltd.	MPU50-105	Input : 100-240 V~, 47-63 Hz, 1.35 A Output : 12 V d.c., 3.75 A	UL, TUV Rheinland
Power switch	-	Zhongxun	KCD11	250 V~, 3 A	TUV Rheinland
Motor	-	Saehan Electronics	4S42Q-T12034SD	12 V d.c.	Tested with appliance
Lithium battery(BT1)	-	Panasonic	CR2032	3 V d.c. Max. abnormal charging current : 10 mA	UL
LCD panel	-	Shenzhen Topway Technology co.,LTD	LMB164ACD	6 V d.c., 1.3 mA	Tested with appliance
Laser module for measuring	**-**	**IEMBIO**	**Laser_M**	**33 mA, Wavelength : 625 nm**	**KTL (IEC 60825-1)**
Enclosure	-	BASF Corp.	GP-35	Min.thickness 2.5 mm, HB	UL
PCB	-	EUNSUNG ELECCOM.CO.LTD	1, 2	94V-0, 105 ℃, Min. thickness 1.6 mm	UL

NOTE 1 - List all manufacturers concerned.
NOTE 2 - Electrical, mechanical, flammability, etc.
NOTE 3 - Licence number, file number or other documentary evidence of acceptance
NOTE 4 – **Bold is for correction.**

Product Service

IEC 61010-1/EN 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict
12	PROTECTION AGAINST RADIATION, INCLUDING LASER SOURCES, AND AGAINST SONIC AND ULTRASONIC PRESSURE		—
12.1	General		—
	Equipment provides protection		P
12.6	Laser sources (IEC 60825-1)		P

Product Service

TEST REPORT

IEC 61010-2-081

Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

Report Reference No.....:	**CPSA0142849M1**
Tested by (name and signature).....:	Edward.Yang
Approved by (name and signature) ..:	Thomas. Kim
Date of issue.....:	2010-03-18
Contents .....:	6 Pages
Modification Test Report Reference Number .....:	CPSA0142849
Modification to appliance.....:	Correction for list of components and circuits relied on for safety
Modification on clause.....:	Table 3
Pages concerned.....:	7, 8

Testing Laboratory.....:	TÜV SÜD Korea Laboratory (TKL)
Address .....:	#315 and 316, MARIO Tower, 222-12, Guro-Dong, Guro-Gu, 152-050, Seoul, Korea
Testing location/procedure .....:	as above CBTL [x] SMT [ ] TMP [ ]
Address .....:	as above

Applicant's name.....:	Boditech Med Inc.
Address .....:	#3-2,Bioventure Plaza 198-60, HupyeongDong, Chuncheon, Kangwon, 200-160, Republic of Korea

Test specification:

Standard .....:	IEC/EN 61010-2-081
Test procedure .....:	CE-LVD
Non-standard test method.....:	—

Test Report Form No.....:	IEC61010_2_081A
TRF Originator.....:	IMQ S.p.A.
Master TRF.....:	Dated March 2002

Test item description..... :	Blood and urine analyzer
Trademark .....:	Boditech

Product Service

Model/Type reference..... :	i-CHROMA
Rating(s) ..... :	12 V d.c., 3.0 A

Test item particulars ..... :	
Type of item tested ..... :	Blood and urine analyzer
Description of equipment function..... :	Analyzing of blood and urine
Installation/overvoltage category..... :	II
Pollution degree..... :	2
Environmental rating..... :	Standard
Equipment mobility ..... :	Movable
Connection to mains supply ..... :	Detachable cord set
Operating conditions..... :	Continuous
Overall size of the equipment (L x W x H)..... :	250 mm X 185 mm X 80 mm
Mass of the equipment (kg)..... :	1.2 kg
Marked degree of protection to IEC 60529 ..... :	N/A
Accessories and detachable parts included in the evaluation ..... :	N.A
Options ..... :	N/A
Test case verdicts:	
Test case does not apply to the test object..... :	N/A
Test object does meet the requirement ..... :	P(Pass)
Test object does not meet the requirement ..... :	F(Fail)
Testing ..... :	
Date of receipt of test item ..... :	N/A
Date (s) of performance of tests ..... :	N/A

General remarks:

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"(see Form A.#)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

Product Service

Copy of marking plate:

Summary of test results (information/comments):

- The presented unit was found to be in compliance with the standard of IEC/EN 61010-1:2001 and IEC/EN 61010-2-101, IEC/EN 61010-2-081
- i-CHROMA is basic model which was tested.
- For test, AC/DC adaptor model MPU50-105, manufactured by Sinpro electronics Co., Ltd. was used.
- **This test report is amended from report No CPSA0142849 because of correction for list of components and circuits relied on for safety.**

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict

	TABLE: 3 - List of components and circuits relied on for safety				P
Unique component reference or location (including drawing reference if required)	Application/Function	Manufacturer (NOTE 1)	Part number	RATING (NOTE 2)	Evidence of acceptance (NOTE 3)
AC/DC Adaptor	-	Sinpro electronics Co., Ltd.	MPU50-105	Input : 100-240 V~, 47-63 Hz, 1.35 A Output : 12 V d.c., 3.75 A	UL, TUV Rheinland
Power switch	-	Zhongxun	KCD11	250 V~, 3 A	TUV Rheinland
Motor	-	Saehan Electronics	4S42Q-T12034SD	12 V d.c.	Tested with appliance
Lithium battery(BT1)	-	Panasonic	CR2032	3 V d.c. Max. abnormal charging current : 10 mA	UL
LCD panel	-	Shenzhen Topway Technology co.,LTD	LMB164ACD	6 V d.c., 1.3 mA	Tested with appliance
Laser module for measuring	**-**	**IEMBIO**	**Laser_M**	**33 mA, Wavelength : 625 nm**	**KTL (IEC 60825-1)**
Enclosure	-	BASF Corp.	GP-35	Min.thickness 2.5 mm, HB	UL
PCB	-	EUNSUNG ELECCOM.CO.LTD	1, 2	94V-0, 105 ℃, Min. thickness 1.6 mm	UL

IEC 61010-2-081			
Clause	Requirement + Test	Result – Remark	Verdict

	TABLE: 3 - List of components and circuits relied on for safety				P
Unique component reference or location (including drawing reference if required)	Application/Function	Manufacturer (NOTE 1)	Part number	RATING (NOTE 2)	Evidence of acceptance (NOTE 3)
NOTE 1 - List all manufacturers concerned. NOTE 2 - Electrical, mechanical, flammability, etc. NOTE 3 - Licence number, file number or other documentary evidence of acceptance NOTE 4 – **Bold is for correction.**					

Product Service

IEC 61010-1			
Clause	Requirement + Test	Result – Remark	Verdict

Remarks