Technical Documentation for IVD

According to the IVD Medical Devices Directive 98/79/EC Related to

Magnetic Immunoassay Analyzer

Products:

Device designation	Catalogue number
Magnetic Immunoassay Analyzer	XacPro-E

Writer	Reviewer	Approver

Document number:

Outline

- 1. Introduction
- 2. Essential Requirement Checklist
- 3. Risk Management
- 4. Design Master File
- 5. Test Reports
- 6. Clinical Evaluation Report
- 7. Package
- 8. Labels
- 9. Manufacturing
- 10. Vigilance System
- 11. Conclusion
- 12. Declaration of Conformity
- 13. Applied Standards

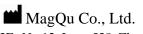
Chapter 1 Introduction

1. Introduction

Hereby this Technical File to be a statement of Magnetic Immunoassay Analyzer and manufacturing process are functional and with well quality. This Technical File include thirteen chapters which illustrate manufacture, technical document, relevant test reports, certificates, package, labels and some advertising materials.

1.1 Introduction of Company

MagQu Co., Ltd. was founded in early 2008 in Taiwan with a group of professional physicists and medical doctors. MagQu owns IP's and the ability to prepare versatile anti-bodies/antigens/single-strain-DNA coated magnetic beads for magnetically labeled bio-detection. These magnetic beads are referred as to immunomagnetic beads/particles. Besides, MagQu offers two-types of analyzers (electronic XacPro-E and superconductive XacPro-S) for assays. Through our proprietary methodology, so-called ImmunoMagnetic Reduction (IMR), MagQu provides a high-sensitivity, wash-free, easy-operation, color-independence, and on-site-test platform for quantitatively assaying proteins, bacteria, viruses, DNA, and other bio-molecules in human, agricultural, aquatic and animal products. Quality managements for both immunomagnetic beads and immunoassay analyzers are certificated with ISO 13485:2003 and ISO 9001:2008. In 2014, MagQu owns 18 employees, 900 m² in-area office/factory, and NT 150,400,000 in capitals. The contact information is shown in Fig. 1.1.



3F., No.12, Lane 538, Zhongzheng Rd., Xindian Dist., New Taipei City 231, Taiwan

Tel: +886-2-8667-1897 Fax: +886-2-8667-1809 E-mail: <u>info@magqu.com</u> Website : <u>www.magqu.com</u>

Fig. 1.1. Contact information of MagQu Co., Ltd.

1.1.1 Company Profile

• MagQu Co., Ltd. (MagQu)

Address:	3F., No.12, Lane 538, Zhongzheng Rd., Xindian			
	Dist., New Taipei City 231, Taiwan			
TEL:	+886-2-8667-1897			
FAX:	+886-2-8667-1809			
E-mail address:	info@magqu.com			
Website:	www.magqu.com			
President:	Charles S.Y. Yang			
Management representative:	Elvis Yang			

• European Representative:

Company Name: MedNet GmbH

Address: Borkstrasse 1048163 Muebster, Germany Contact person: amy.qian@medneteurope.com

Tel: +49 251 32266-0

1.1.2 Business Items

The business items of MagQu mainly include the design, manufacture, and sale of immunomagnetic-bead reagents, immunoassay analyzers, and antibodies.

Product Name	Certificate/DoC
Magnetic Immunoassay Analyzer XacPro-E	CE, DoC
MagQu Carcinoembryonic Antigen (CEA) IMR Reagent	CE, DoC

1.1.3 Company Milestone

MagQu was found in 2008. There are many milestones since 2008, as listed in the following table.

Year	Month	Milestone
	May	Certificated wit ISO13485:2003 and ISO9001:2008
	October	Certificated with Medical-device Good Manufacture
2009	October	Practicing (GMP)
2009		Award with the 16 th Taiwan Small & Medium Enterprises
	November	Innovation Award issued by Ministry of Economic Affairs,
		Taiwan
2010	March	Award with the 8 th Taiwan Gold Root Award
	February	Sign up distribution agreements in Japan and China
	September	Award with Taiwan Healthcare and Agriculture Biotech
2011		Industries Innovation and Excellent Awards
	December	Issue the first IMR assay kit for aquatic disease: Grouper
		viruses
	March	Sign up distribution agreements for bio-functionalized
	March	magnetic nanoparticles in Taiwan and Japan
		Initiate the development and clinic trial for assaying blood
2012	September	CEA with the financial support by Ministry of Economics,
		Taiwan
	December	Move to self-owned office/factory in New Taipei City
	December	Award with Excellence in Agriculture Technology Award by

		Council of Agriculture, Taiwan
	Ionnomy	Issue magnetic micro-beads "Qbeads" for purifications of
	January	antibodies, proteins, pathogens, and nuclei acids
2013		Award with Excellence of Industrial Nanotechnology Award
2013	September	by Taiwan Nanotechnology Industry Development
		Association
	December	Invested by venture capital companies in Taiwan (~ US 5M)
	February	Certificated with ISO13485:2003 and ISO9001:2008
	April	Certificated with Medical-device GMP, Taiwan
	May	Approval for Class-I Medical Device by Ministry of Health
		and Welfare, Taiwan: Magnetic Immunoassay Analyzer
	June	Sign up distribution agreements for bio-functionalized
2014		magnetic nanoparticles and micro-beads in US and Malaysia
	Inly	Establish Animal Room (mice) for manufacturing
	July	monoclonal antibodies
	September	Initiate internal control/audit system
	November	Award with Excellent Incubated Industry issued by Ministry
	november	of Economics, Taiwan

1.2 Introduction of product

The Magnetic Immunoassay Analyzer XacPro-E designed by MagQu Co., Ltd. is used to measure the change in the ac magnetic susceptibility of a sample over time. If the sample is a mixture of a magnetic reagent and an object to be detected, XacPro-E can be used to detect the concentration of bio-molecules in the object according to the change in the ac magnetic susceptibility, which is so-called immunomagentic reduction. The details of XacPro-E are described in this report.

1.2.1 Outward Appearance of XacPro-E

The picture of XacPro-E is shown in Fig. 1. XacPro-E is 700 mm in width, 610 mm in depth, and 610 mm in height. The input electricity is 100-240 VAC, 50/60Hz.



Fig. 1. Photo of magnetic immunoassay analyzer XacPro-E.

1.2.2 Mechanism of Immunomagnetic Reduction

The Magnetic Immunoassay Analyzer XacPro-E utilizes the so-called immunomagnetic reduction (IMR) as its assay principle. The theoretical derivation of IMR is given in Refs. 2.1-2.4. The conceptual description of immunomagnetic reduction is illustrated as follows.

Under external ac magnetic fields of which frequencies range from tens to millions of hertz, individual magnetic beads in a magnetic reagent will be driven by the external ac magnetic fields and swirl. The magnetic reagent produces ac magnetic signals (χ_{ac}) accordingly. Hereafter, the χ_{ac} of pure magnetic reagent is referred as to $\chi_{ac,o},$ as shown in Fig. 2. When the magnetic reagent is mixed with the sample containing to-be-detected bio-molecules, bio-molecules will bind with magnetic beads via bioprobes (e.g. antibodies) on surface of the magnetic beads. In this way, part of magnetic beads in the reagent will get enlarged, even many magnetic beads will gather together. In such case, compared with the number of swirling magnetic beads before the magnetic reagent is mixed with the sample, number of swirling magnetic beads in the reagent driven by external field is much fewer. So the ac magnetic signal (χ_{ac}) of magnetic reagent will reduce due to the binding between bio-molecules in the sample with magnetic beads; that's why we call the detection method as magnetic reduction immunoassay detection. Hereafter, the χ_{ac} of magnetic reagent mixed with a sample is denoted with $\chi_{ac,\phi}$. According to the description above, more bi-molecules the sample contains, more bindings between magnetic beads and bi-molecules will occur, and more magnetic reduction will appear. Thus we can detect amounts of bi-molecule in the sample in reference to measurement on magnetic reduction of magnetic reagent.

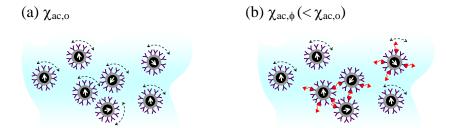


Fig. 2. Illustration of mechanism of immunomagnetic reduction to detect biotargets. (a) Each magnetic nanoparticle oscillates individually with the applied alternative-current magnetic field before binding with biotargets. (b) Portions of magnetic nanoparticles become larger due to the binding with biotargets. The bound magnetic nanoparticles in (b) contribute to the reduction in the alternative-current magnetic susceptibility χ_{ac} of the reagent.

To quantify the reduction in the χ_{ac} of magnetic reagent due to the binding between magnetic nanoparticles and biomolecules hereafter is defined as:

IMR (%) =
$$(\chi_{ac,o} - \chi_{ac,\phi})/\chi_{ac,o} \times 100\%$$
, (2.1)

where IMR(%) is referred as to IMR signal.

Furthermore, IMR signal was found as function of the biomolecular concentration ϕ via logistic function

$$IMR(\%) = \frac{A - B}{1 + (\frac{\phi}{\phi_o})^{\gamma}} + B,$$
(2.2)

where A, B, ϕ_0 , and γ are fitting parameters.

1.2.3 Principle of Magnetic Immunoassay Analyzer XacPro-E

According the mechanism of IMR, ac magnetic fields are applied to magnetic reagent. The time-evolution ac magnetic signal of magnetic reagent is detected. Thus, the magnetic immunoassay analyzer XacPro-E is equipped with sets of excitation coils, which generate ac magnetic fields to magnetize magnetic reagents. A signal generator is used to applied ac current through the excitation coils. Once magnetic reagent is placed inside excitation coils, the reagent is magnetized. An ac magnetic signal of reagent is induced. To sense the induced ac magnetic signal of reagent, a pick-up coil is used. Then, the sensed ac magnetic signal of reagent is transferred to an electronical signal. The signal which is first leaded to a band pass filter and amplifies is acquired by DAQ system and transport to computers via USB cable. Thus, the ac magnetic signal of reagent can be detected. With the time-evolution ac magnetic signal of

reagent, the IMR signal can be measured. The temperature control module with TE cooler can help the bio-reaction of the reagent more stable. All the details of working principle of XacPro-E as shown in Fig. 3 are available in Refs. 2.5 and 2.6.

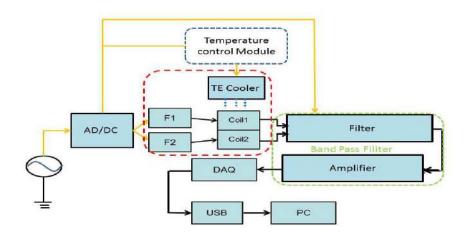


Fig. 3. Schematic configuration of XacPro-E for detecting ac magnetic signal of magnetic reagent.

1.2.4 Hardware

A picture to reveal the hardware of XacPro-E is as shown in Fig. 4.



Fig. 4. Magnetic immunoassay analyzer XacPro-E is consisted of three modules: sensing part, coils, and electronics

Briefly speaking, XacPro-E is consisted of two modules:

1. Coils

Coils include excitation coils, pick-up coils. Sample is located inside excitation coils.

2. Electronics

Electronics are consisted of a signal generator, BP filter, amplifier, temperature control modules, and DAQ card.

The detailed specifications and dimensions of all the components are described in Chapter III of the Operation & Maintenance Manual.

1.2.5 Functional Feature

The functional features of XacPro-E are listed below.

• Specifications of the power converter:

Input: 100 -230 VAC

Output: Max. 24VDC/200W

• Specifications of AC Wave Generator:

Output power: AC +/-3V to AC +/-24V, 50mA/50mA

Output Frequency: 100 to 50 kHzSpecifications of amplifier circuit:

Wave band: 1 k to 30 kHz

Voltage magnification: 1 to 2000

• Specifications of solenoid assembly:

Excitation coil: resistance = $100 \sim 200 \Omega$

coil density = $400 \sim 550$ turns/cm Pick-upcoil: resistance = $40 \sim 70 \Omega$ coil density = $400 \sim 550$ turns/cm

• Software platform: Windows XP, Windows 7

XacPro-E is capable of quantitatively detecting the low concentration of bio-targets with aids of reagents with adequate bio-functionalized magnetic particles. The low-detection limits using XacPro-E are listed for examples.

Bio-target	Reagent	Low-detection limit
	MagQu Carcinoembryonic	
CEA	Antigen (CEA) IMR reagent	0.13 ng/ml
	(MF-CEA-0061)	

1.2.6 Warning And Precautions

(1). Prevent fire or personal injury

Use proper power line. Please use only the power line designated for the product and approved in the country where the product is used.

(2). Correct connection & disconnection

Before lunching computer, please confirm whether the power is switching on. Switch off the power after shutting down the computer.

(3). Ground the product.

The product is grounded through a ground conductor of the power cord. In order to avoid electric shock, the grounding conductor must be connected to the ground. Please confirm whether the product is grounded correctly before connecting the input and output terminal of the product.

(4). Observe power of all terminals. Please notice power and relevant mark of the

- product in order to prevent any risk of fire or electric shock. Before connecting the product, please read the product manual so as to further understand relevant power information.
- (5). Disconnect power. Please refer to concerned instructions to confirm the position to disconnect the product from power. Please do not hinder the power switch and it is accessible at any time when the product is in use.
- (6). Please do not operate before the cover is fitted on. Please do not operate the product when the cover is taken off. Be careful for refill liquid nitrogen and putting samples.
- (7). Please do not operate when doubting there is a fault. If you doubt the product is damaged, please allow qualified maintenance personnel to check it.
- (8). Prevent circuit exposed. Please do not touch any exposed connector and component when the current is conveyed.
- (9). Please do not operate under a moist condition.
- (10). Please do not operate in the flammable and combustible air.
- (11). Please keep the product surface clean and dry.
- (12). Keep good ventilation. Please refer to installation instructions of the manual for detailed information on how to install the product and provide it with good ventilation.
- (13). Disposal of product discarded

 Please refer to following instructions when recycling any instrument or component.
- (14). Equipment recycling: nature resources of the equipment need to be recycled and reused. In the event that the equipment is not disposed correctly during discard, it may produce substances hazardous to the environment or human health. In order to avoid emission of such substances in the environment and reduce use of natural resources, recycling the product with a proper system is recommended for the purpose of ensuring most materials can be recycled and reused appropriately.

1.2.7 Intended use of Device

The Magnetic Immunoassay Analyzer XacPro-E designed by MagQu Co., Ltd. is used to measure the change in the ac magnetic susceptibility of a sample over time. If the sample is a mixture of a magnetic reagent and an object to be detected, XacPro-E can be used to detect the concentration of bio-molecules in the object according to the change in the ac magnetic susceptibility, which is so-called immunomagentic reduction.

1.2.8 Classification

This device is General IVD (Article 9-non-List A or B; not for performance evaluation; not for self-testing) according to Annex II of 98/79/EC on In Vitro Diagnosis Medical Device Directive.

1.2.9 Conformity Assessment Route

This declaration is based on conformity assessment procedure of Directive 98/79/EC Annex III (excluding section 6).

1.3 Licences and Certificate

1.3.1 Certificates of Quality system

- Certificated with ISO13485:2003 (TW14/10079)
- Certificated with ISO 9001:2008 (TW14/10080)
- Certification of Good Manufacturing Practice (GMP) (053711)

1.3.2 Certificates of CE

- Certificate of Compliance with European Low Voltage Directive, 2006/95/EC (T1303269-762)
- Applicable to EUROPEAN COUNCIL DIRECTIVE 2004/108/EC (The Information Technology Equipment) (1303269)

1.3.3 Certificates of Taiwan

• Approval of Class-I Medical Device in Taiwan (005218)

Reference

- 2.1. C.Y. Hong, C.C. Wu, Y.C. Chiu, S.Y. Yang, H.E. Horng, and H.C. Yang, "Magnetic Susceptibility Reduction Method for Magnetically Labeled Immunoassay", Appl. Phys. Lett., **88**, 212512 (2006).
- 2.2. C.C. Yang, S.Y. Yang, J.J. Chieh, H.E. Horng, C.Y. Hong, and H.C. Yang, "Universal behavior of bio-molecule-concentration dependent reduction in ac magnetic susceptibility of bio-reagents", IEEE Magn. Lett. 3, 1500104 (2012).
- 2.3. C.C. Yang, S.Y. Yang, H.H. Chen, W.L. Weng, H.E. Horng, J.J. Chieh, C.Y. Hong, and H.C. Yang, "Effect of molecule-particle binding on the reduction in the mixed-frequency ac magnetic susceptibility of magnetic bio-reagents", J. Appl. Phys. 112, 24704 (2012).
- 2.4. S.Y. Yang, J.J. Chieh, K.W. Huang, C.C. Yang, T.C. Chen, C.S. Ho, S.F. Chang, H.H. Chen, H.E. Horng, C.Y. Hong, and H. C. Yang, "Molecule-assisted nanoparticle clustering effect in immunomagnetic reduction assay", J. Appl. Phys. 113, 144903 (2013).
- 2.5. J.J. Cheih, S.Y. Yang, H.E. Horng, C.Y. Yu, C.L. Lee, H.L. Wu, C.Y. Hong, and H.C. Yang, "Immunomagnetic reduction assay using high-T_c superconducting-quantum-interference-device-based magnetosusceptometry", J. Appl. Phys. **107**, 074903-1-074903-5 (2010).
- 2.6. M. J. Chiu, H. E. Horng, J. J. Chieh, S. H. Liao, C. H. Chen, B. Y. Shih, C. C. Yang, C. L. Lee, T. F. Chen, S. Y. Yang, C. Y. Hong, and H. C. Yang, "Multi-channel SQUID-based ultra-high-sensitivity in-vitro detections for bio-markers of Alzheimer's disease via Immunomagnetic Reduction", IEEE Trans. Appl. Supercond., 21, 477 (2011).

Certification of ISO 13485:2003



Certification of ISO 9001:2008

Certificate TW14/10080

SGS

The management system of

MagQu Co., Ltd.

3F, No. 12, Ln. 538, Zhongzheng Rd., Xindian Dist., New Taipei City 231, Taiwan, R.O.C.

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Design and Manufacture of non-sterile magnetic beads for bio-assay, separation and diagnosis. Design and Manufacture of Magnetic Immunoassay Analyzer.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 27 January 2014 until 27 January 2017 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 21 October 2016 Issue 1. Certified since 27 January 2014

Authorised by



SGS United Kingdom Ltd. Systems & Services Certification Rossmore Business Park. Ellesmere Port. Cheshire. CH65 3EN: UK t +44 (0)151 350-8686. f +44 (0)151 350-8600. www.sgs.com

SGS 9001-8 01 0311

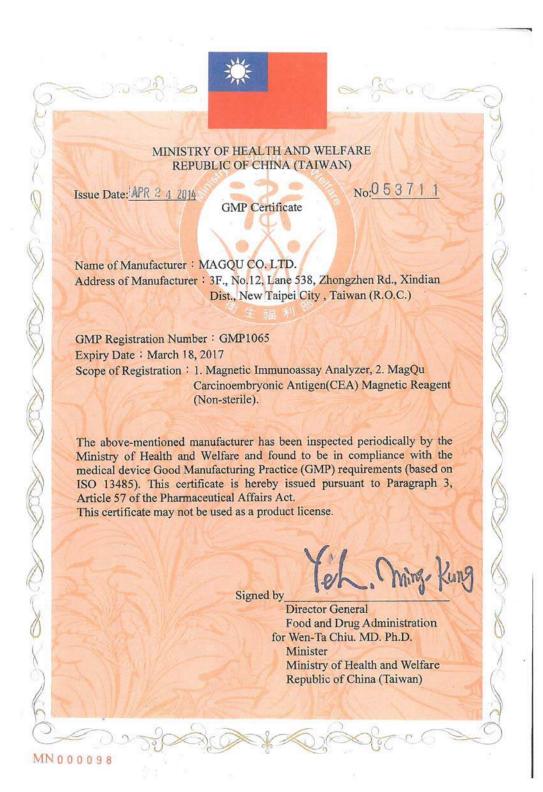
Page 1 of





This document is issued by the Company sidelect to its General Conditions of Certification Services accessible in leve regionarities, and conditions like. Altereding it was to the limitations of liability indemnification and justiciscon scause catalished therein. This authorities of this document may be verified and http://www.sgs.com/en/Cur-Company/Certified-Client-Directories/Certified-Client-Directories aspo. Any consolirorised alteration, largery or fulfilledization of the content or agreearmen of this document is unleasted and offendation step.

Certification of Good Manufacturing Practice (GMP)



Certificate of Compliance With

European Low Voltage Directive

No. T1303269-762

Type of equipment: Magnetic Immunoassay Analyzer

Certificate holder: MagQu Co., Ltd.

Type designation: XacPro-E301

Technical data: 100-240Vac, 50/60Hz; 1.5-0.8A, Class I

A sample of the equipment has been tested in according to the EC Low Voltage Directive, 2006/95/EC.

Standard used for showing compliance with the essential requirements of the directive:

Standard(s): Test report(s): Issued by: Date(s):

IEC/EN 61010-1:2010 and T1303269-62 Cerpass October 16, 2013

IEC/EN 61010-2-101:200

The referred test report(s) show that the product fulfills the essential requirements in the Low Voltage Directive for CE marking. On this basis, together with the manufacturer's own documented production control, the manufacturer (or his European authorized representative) can in his EC Declaration of Conformity verify compliance with the Low Voltage Directive.



14.

Vincent Tan
Engineering Department

ATTESTATION OF CONFORMITY



Date of Issue: 2013/10/09

Attestation Number: 1303269

Product: Magnetic Immunoassay Analyzer

Model No.: XacPro-E301

Applicant: MagQu Co., Ltd.

Address: 3F., No.12, Ln. 538, Zhongzheng Rd., Xindian Dist., New Taipei City 231,

Taiwan

And, in accordance to the following Applicable Directives

Applicable to EUROPEAN COUNCIL DIRECTIVE 2004/108/EC

(The Information Technology Equipment)

That this product has been assessed against the following Applicable Standards

EN 55011:2009/A1:2010 Group 1 (Class A)

EN 61000-3-2:2006+A1:2009+A2:2009

EN 61000-3-3:2008

EN 61326-1:2013

EN 61326-2-1:2013

IEC 61000-4-2:2008

IEC 61000-4-3:2006+A1:2007+A2:2010

IEC 61000-4-4:2012 IEC 61000-4-5:2005

IEC 61000-4-6:2008

IEC 61000-4-8:2009

IEC 61000-4-11:2004

CERPASS hereby acknowledges that:

The measurements shown in this test report may issue a DECLARATION of CONFORMITY and apply the CE mark in accordance to European Union Rules.

Attestation by:

Hill Chen

1 Il Chen

2013/10/09

Date

EMC/RF B.U. Assistant Manager

Approval of Class-I Medical Device in Taiwan



Chapter 2 Essential Requirements Checklist

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
Ι	General requirements				
1.	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: — reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and — consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN 61010-1:2010 EN 61010-2-101:2002 EN 61326-1:2006 EN 55011:2009	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 _Risk Management Report No. RM02-02 Product research file (XacPro-E)	
2.	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: — eliminate or reduce risks as far as possible (inherently safe design and construction), — where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, — inform users of the residual risks due to any shortcomings of the protection measures adopted.	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD02 _Risk Management Report No. RM02-02 Product research file (XacPro-E)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
3.	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer	YES	Directive 98/79/EC ENISO13485:2012	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD02	
4.	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	No			The device never directly touches patients in any material or energy pathway which can be imagined.
5.	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 _Risk Management Report No. RM02-02 Product user Manual (XacPro-E, ver.201309)	
6.	Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012	System Cert. No TW14/10079 _Risk Management Report No. RM02-02	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
6.a.	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	No			
II	Requirements regarding design and construction				
7. 7.1.	Chemical, physical and biological properties The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General requirements'. Particular attention must be paid to: — the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, — the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device. — where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 _Risk Management Report No. RM02-02 Product user Manual (XacPro-E, ver.201309)	
7.2.	The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 Product user Manual (XacPro-E, ver.201309)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
7.3.	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN61010-1:2010 EN61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 Product user Manual (XacPro-E, ver.201309)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
7.4.	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (I) on the quality and safety of the substance including the clinical benefitrisk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of the substance into the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefitrisk profile of the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefitrisk profile of the intended purpose of the device, seek as scientific opinion from the EMEA, acting particularly through the clinical benefitrisk profile of the device. When its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the sub	No 6			

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
7.5.	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (1).	No			
	If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.				
	If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures				
7.6.	Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN61010-1:2010 EN61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 _Risk Management Report No. RM02-02	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
8 . 8.1.	Infection and microbial contamination The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	No			The device never directly touches patients or operators in any biological pathway which can be imagined.
8.2.	Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies shall retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	No			The device never directly touches patients or operators in any biological pathway which can be imagined.
8.3.	Devices delivered in a sterile state must be designed, manufactured, and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	No			The device never directly touches patients or operators in any biological pathway which can be imagined.

Clause	Description	Appli- cable or not?	Standard/Sub-clause(s)	Report/Document	Comments
8.4.	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	No			The device never directly touches patients or operators in any biological pathway which can be imagined.
8.5.	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	No			The device never directly touches patients or operators in any biological pathway which can be imagined.
8.6.	Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	No			The device never directly touches patients or operators in any biological pathway which can be imagined.
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	No			The device never directly touches patients or operators in any biological pathway which can be imagined.

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
9 . 9.1.	Construction and environmental properties If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN61010-1:2010 EN61010-2-101:2002 EN15223-1:2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 _Risk Management Report No. RM02-02 Product user Manual (XacPro-E, ver.201309)	
9.2.	 Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: the risk of injury, in connection with their physical features, including the volume/pressure ration, dimensional and where appropriate ergonomic features, risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration, the risks of reciprocal interference with other devices normally used in the investigations of for the treatment given, risks arising when maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism. 	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN61010-1:2010 EN61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079 _Risk Management Report No. RM02-02 Product user Manual (XacPro-E, ver.201309)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
9.3.	Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	YES	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN61010-1:2010 EN61010-2-101:2002 EN15223-1:2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 _Risk Management Report No. RM02-02	
10.	Devices with a measuring function Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.	YES	Directive 98/79/EC ENISO13485:2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 _Risk Management Report No. RM02-02 Product user Manual (XacPro-E, ver.201309)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
10.2.	The measurement, monitoring, and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	YES	Directive 98/79/EC ENISO13485:2012	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD02 _Product Master file No. MF02 Product user Manual (XacPro-E, ver.201309)	
10.3.	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.	No			
11. 11.1. 11.1.1	Protection against radiation General Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	No			The device is a low voltage device and never generates high energy radiation.

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
11.2. 11.2.1 11.2.2	Intended radiation Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters. Where devices are intended to emit potentially hazardous, visible, and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	No			The device is a low voltage device and never generates high energy radiation.
11.3. 11.3.1	Unintended radiation Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	No			The device is a low voltage device and never generates high energy radiation.
11.4. 11.4.1	Instructions The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse of eliminating the risks inherent in installation.	No			The device is a low voltage device and never generates high energy radiation.
11.5. 11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	No			The device is a low voltage device and never generates high energy radiation.

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	No			The device is a low voltage device and never generates high energy radiation.
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, and energy and where appropriate the quality of radiation.	No			The device is a low voltage device and never generates high energy radiation.
12 . 12.1.	Requirements for medical devices connected to or equipped with an energy source Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability, and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	Yes	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN55011:2009 EN61326-1:2006 EN61010-1:2010 EN61010-2-10:2002	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD02 _Risk Management Report No. RM02-02 Product user Manual (XacPro-E, ver.201309)	
12.1.a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification	No			

Clause	Description	Appli- cable or not?	Standard/Sub-clause(s)	Report/Document	Comments
12.2.	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	No			The device never directly touches patients in any material or energy pathway which can be imagined.
12.3.	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	No			The device never directly touches patients in any material or energy pathway which can be imagined.
12.4.	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	No			The device is not intend to monitor patients.

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
12.5.	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields, which could impair the operation of other devices or equipment in the usual environment.	Yes	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN55011:2009 EN61326-1:2006 EN61010-1:2010 EN61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD02 _Product Master file No. MF02 _Risk Management Report No. RM02-02 Product research files (XacPro-E)	
12.6.	Protection against electrical risks Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	Yes	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN 61010-1:2010 EN 61010-2-101:2002 EN5011:2009 EN61326-1:2006	ISO 13485 Quality System Cert. No TW14/10079 _Risk Management Report No. RM02-02 Product research files (XacPro-E)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
12.7. 12.7.1	Protection against mechanical and thermal risks Devices must be designed and manufactured in such a way as to protect the patient and user against mechanical risk connected with, for example, resistance, stability, and moving parts.	Yes	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN 61010-1:2010 EN 61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079 _Risk Management Report No. RM02-02 Product user Manual (XacPro-E, ver.201309)	
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	Yes	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN 61010-1:2010 EN 61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD02 _Risk Management Report No. RM02-02 Product user Manual (XacPro-E, ver.201309)	
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	No			The device can not work in the surroundings full of the noise.

Clause	Description	Appli- cable or not?	Standard/Sub-clause(s)	Report/Document	Comments
12.7.4	Terminals and connectors to the electricity, gas, or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	Yes	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN 61010-1:2010 EN 61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD02 _Risk Management Report No. RM02-02 Product research files (XacPro-E)	
12.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	Yes	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN 61010-1:2010 EN 61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD02 _Risk Management Report No. RM02-02 Product user Manual (XacPro-E, ver.201309)	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
12.8. 12.8.1	Protection against the risks posed to the patient by energy supplies or substances Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	No			The device never directly touches patients in any material or energy pathway which can be imagined.
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate, which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	No			The device never directly touches patients in any material or energy pathway which can be imagined.
12.9.	The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	Yes	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN 61010-1:2010 EN 61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 _Risk Management Report No. RM02-02 Product research files (XacPro-E) Product user Manual (XacPro-E, ver.201309)	
13. 13.1.	Information supplied by the manufacturer Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of	Yes	Directive 98/79/EC ENISO13485:2012 EN61010-1:2010 EN61010-2-101:2002	ISO 13485 Quality System Cert. No TW14/10079	

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
13.2	the potential users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions	Vac	EN15223-1:2012 Directive 98/79/EC	Product Master file No. MF02 Product user Manual (XacPro-E, ver.201309)	
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.	Yes	ENISO13485:2012 EN61010-1:2010 EN61010-2-101:2002 EN15223-1:2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 Product user Manual (XacPro-E, ver.201309)	
13.3.	 The label must bear the following particulars: (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer 	Yes	Directive 98/79/EC ISO 13485 : 2012 EN 15223-1 : 2012 EN 61010-1 : 2010 EN 61010-2-101 : 2002	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 Product user Manual	c, f, g, h, i, j, and m are excluded

Clause	Description	Appli- cable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	does not have a registered place of business in the Community;			(XacPro-E, ver.201309)	
	(b) the details strictly necessary for the user to identify the device and the contents of the packaging;				
	(c) where appropriate, the word 'STERILE'				
	(d) where appropriate, the batch code, preceded by the work 'LOT', or the serial number				
	(e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and the month				
	(f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community				
	(g) if the device is custom-made, the words 'custom-made device'				
	(h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'				
	(i) any special storage and/or handling conditions				
	(j) any special operating instructions				
	(k) any warnings and/or precautions to take				
	(l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number				
	(m) where applicable, method of sterilization				

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
13.4.	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	Yes	Directive 98/79/EC ISO 13485 : 2012 EN 61010-1 : 2010 EN 61010-2-101 : 2002 EN 15223-1 : 2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 Product user Manual (XacPro-E, ver.201309)	
13.5.	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Yes	Directive 98/79/EC ISO 13485 : 2012 ISO 14971 : 2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF07 Product user Manual (XacPro-E, ver.201309)	
13.6.	 Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for it intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination; (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the 	Yes	Directive 98/79/EC ISO 13485 : 2012 EN 61010-1 : 2010 EN 61010-2-101 : 2002 EN 15223-1 : 2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF02 Product user Manual (XacPro-E, ver.201309)	g, i, k, l, m, n, o, p, and q are excluded

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;				
	(e) where appropriate, information to avoid certain risks in connection with implantation of the device;				
	(f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment				
	(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilization;				
	(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses.				
	Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I;				
	If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request;				
	(i) details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.);				
	(j) in the case of devices emitting radiation for medical purposes,				

Clause	Description	Applicable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	details of the nature, type intensity and distribution of this radiation.				
	The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:				
	(k) precautions to be taken in the event of changes in the performance of the device;				
	(l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;				
	(m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered;				
	(n) precautions to be taken against any special, unusual risks related to the disposal of the device;				
	(o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4;				
	(p) degree of accuracy claimed for devices with a measuring function.				
	(q) date of issue or the latest revision of the instructions for use.				

Chapter 3 Risk Management

1. Risk Management

The risk management reports are for the product "Magnetic Immunoassay Analyzer, XacPro-E".

Product name: Magnetic Immunoassay Analyzer

Product code: XacPro-E

Version: 2015-01

In general this risk assessment report for XacPro-E made by MagQu Co., Ltd. was carried out in accordance with the requirements of ISO 14971:2007, in which an explicit risk assessment procedure has been described. The detailed assessment was made according to the requirement and the relevant annexes set out on the standards:

1.1 Risk Management Flow Chart

The flow chart is shown in Fig. 1.1.

Flow Verification (ISO14971:2007) Intendeduse Risk analysis Estimate risk(s) for each hazardous situation(s)(4.4) Is risk Identify appropriate risk control easure(s), record risk control requirements (6.2) Implement, record and venty appropriate measures (6.3) Do medical benefits outweigh the residual risk? Are all identified szards consider erall resid medical benef Prepare risk management report (clause 8) Unacceptable

Fig. 1.1. Flow chart of risk management for XacPro-E.

1.2 Question That Can Be Used to Identify Medical Device Characteristics That Could Impact on Safety

C.2.1: What is the intended use/purpose and how is the medical device to be used?

Ans.: To measure the immunomagnetic reduction signal. The reagent used in the test are also made by MagQu Co., Ltd.

C.2.2 Is the medical device intended to be implanted?

Ans.: No

C.2.3: Is the medical device intended to be in contact with the patient or other person? Ans.: Only contact with user.

C.2.4: What materials and/or components utilized in the medical device or are used with, or are in contact with, the medical device?

Ans.: Magnetic fluid reagent, and test samples.

C.2.5: Is energy delivered to and/or , extracted from the patient?

Ans.: No

C.2.6: Are substances delivered to and/or extracted from the patient?

Ans.: No

C.2.7: Are biological materials processed by medical device for subsequent re-use, transfusion or transplantation?

Ans.: No

C.2.8: Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?

Ans.: No

C.2.9: Is the medical device intended to be routinely cleaned and disinfected by the user?

Ans.: No

C.2.10: Is the medical device intended to modify the patient environment?

Ans.: No

C.2.11: Are measurements taken?

Ans.: Yes, to measure the IMR signal form reagents.

C2.12: Is the medical device interpretative?

Ans.: Yes

C.2.13: Is the medical device intended for use in conjunction with other medical device, medicines or other medical technologies?

Ans.: Yes, the samples should be measured with reagents.

C.2.14: Are the unwanted outputs of energy or substances?

Ans.: No

C2.15: Is the medical device susceptible to environmental influences?

Ans.: Yes, the performance of the reagent would be affected by unstable temperatures and strong magnetic environment.

C.2.16: Does the medical device influence the environment?

Ans.: Yes, it provides magnetic field and heat.

C.2.17: Are there essential consumables or accessories associated with the medical device?

Ans.: No.

C.2.18: Is the maintenance and/or calibration necessary?

Ans.: Yes, the maintaining methods should be describing in operation manual.

C.2.19: Does the medical device contain software?

Ans.: No.

C2.20: Does the medical device have a restricted shelf-life?

Ans.: Yes

C.2.21: Are there any delayed and/or long-term use effects?

Ans.: It may occur.

C.2.22: To what mechanical forces will the medical device be subjected?

Ans.: No, the XacPro-E is not working by mechanical force.

C.2.23: What determines the lifetime of the medical device?

Ans.: Using frequency.

C.2.24: Is the medical device intended for signal use?

Ans.: Yes

C.2.25: Is safe decommissioning or disposal of the medical device necessary?

Ans.: Yes

C.2.26: Does installation or use the medical devices require the special training or special skill?

Ans.: Yes

C.2.27 How will information for safe use be provided?

Ans.: Presented in the manual or package insert

C.2.28: Will new manufacturing processes need to be established or introduced?

Ans.: No

C2.29: Is successful application of the medical device critically dependent on human factors such as the user interface?

Ans.: No

C.2.29.1 Can you user interface design features contribute to use error?

Ans.: No

C.2.29.2 Is the medical device used in an environment where distractions can cause use error?

Ans.: Yes

C.2.29.3 Dose the medical device has connecting parts or accessories?

Ans.: Yes

C.2.29.4: Dose the medical device have a control interface?

Ans.: Yes

C.2.29.5: Dose the medical device display information?

Ans.: Yes

C.2.29.6: Is the medical device controlled by a menu?

Ans.: No

C.2.29.7 Will the medical device be use by persons with special needs?

Ans.: Yes

C.2.29.8 Can the user interface be used to initiate user action?

Ans.: No

C.2.30 Dose the medical device use an alarm system?

Ans.: No

C.2.31 In what way(s) might the medical device be deliberately misused?

Ans.: No

C.2.32 Does the medical device hold data critical to patient care?

Ans.: No

C.2.33 Is the medical device intended to be mobile or portable?

Ans.: No

C.2.34 Dose the use of the medical device depends on essential performance?

Ans.: No

1.3 Risk Assessment Methodology

Fills in the scoring (from 1~10) in the blank space according to the anticipated harmful risk probability, the grading standard is as follows: The definition of happening probability is divided into following two kinds of considerations:

1.3.1 Probability of Failures

Definition	Probability	Rating
Continues to occur	< 1/2	10
High occurs	< 1/20	8
Occasionally occur	< 1/200	6
Low occurs	< 1/2000	4
Hardly occurs	< 1/20000	2
Does not occur	0	1

1.3.2 Severity

Definition	Influence	Rating
High	Cause to death	10
Medium High	Cause to damage forever	8
Mrdium Low	Cause to damage seriously	6
Low	Cause to damage minor	4
Slightly	Almost no damage	2
No risk	No damage	1

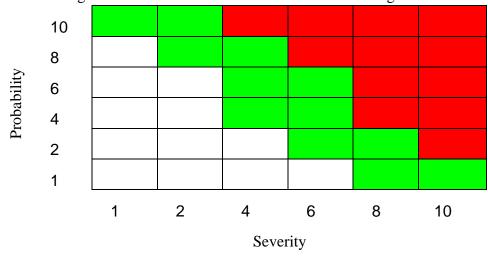
1.3.3 Risk Priority Number (RPN)

1.3.3.1 RPN = Probability* Severity, Risk Priority Number methodology is a technique for analyzing the risk associated with potential problems identified during a Failure Mode and Effects Analysis (FMEA):

Red : Non acceptable

Green: ALARP White: Acceptable

1.3.3.2 Rating scales means the risk level defined as following listed



1.4 Assessment Result

General principle: Identification of possible hazards and contributing factors associated with medical device refer to ISO 14971.

Dz Energy nazards				
Item	Description	Available	N/A	
2.1	Electricity	✓		
2.2	Heat	✓		
2.3	Mechanical force		✓	
2.4	Magnetic fields	✓		
2.5	Ionizing radiation		√	
2.6	Non-ionizing radiation		✓	
2.7	Moving parts		✓	
2.8	Non-anticipates movement		\checkmark	
2.9	Suspended masses		\checkmark	
2.10	Patient support device failure		√	
2.11	Pressure		✓	
2.12	Acoustic pressure		\checkmark	
2.13	Vibration		√	

Item	Description	Available	N/A
3.1	Bio-contamination		\checkmark
3.2	Bio-incompatibility		✓
3.3	Incorrect formulation		✓

3.4	Toxicity	✓
3.5	Allergenicity	✓
3.6	Mutagenicity	✓
3.7	Carcinogenicity	✓
3.8	Teratogenicity	\checkmark
3.9	Pyrogenicity	\checkmark
3.10	(cross-) infection	✓
3.11	Bio-burden	\checkmark
3.12	Inability to maintain hygienic safety	✓
3.13	Degradation	\checkmark

D4 Environmental hazards ☑ Available □ Not available

Item	Description	Available	N/A
4.1	Electromagnetic interference	✓	
4.2	Electromagnetic restrain	✓	
4.3	Electromagnetic shoot		✓
4.4	Inadequate supply of power	✓	
4.5	Inadequate supply of coolant		✓
4.6	Likelihood of operation outside prescribed		1
	environmental conditions		v
4.7	Incompatibility with other devices	✓	
4.8	Accidental mechanical damage		✓
4.9	Contamination due to waste products		/
	and/or device disposal		•

D5 Hazards related to the use of the device ✓ Available □ Not available

Item	Description	Available	N/A
5.1	Inadequate labeling	✓	
5.2	Inadequate operating instructions	✓	
5.3	Use by unskilled/ untrained personnel		✓
5.4	Reasonably foreseeable misuse		✓
5.5	Insufficient warning of side effects		✓
5.6	Inadequate warning of hazards likely with		√
	re-use of single use devices		,
5.7	Incorrect measurements and other	✓	
	metrological aspects	,	
5.8	Incompatibility with consumables/		✓
	accessories/ other devices		•
5.9	sharp-pointed		√

D6 Hazards related to the user interface ✓ Available Not available

Item	Description	Available	N/A
6.1	confusing or missing instructions for use	✓	
6.2	complex or confusing control system		✓
6.3	slips, laps and mistakes		✓
6.4	poor mapping of controls to actions, or of displayed information to actual state		✓
6.5	controversial modes or mapping as compared to existing equipment		✓

6.6	ambiguous or unclear presentation of		
	settings, measurements or other information	ŕ	
6.7	misrepresentation of results		✓
6.8	insufficient visibility, audibility or tactility		✓
6.9	incompatibility with		
	consumables/accessories/other medical		\checkmark
	devices		
6.10	incorrect measurement and other		1
0.10	metrological aspects		v

D7 Hazard arising from functional failure, maintenance and aging ☑ Available ☐ Not available

Item	Description	Available	N/A
7.1	Inadequacy of performance characteristics		√
	for the intended use		•
7.2	Lack of, or inadequate specification for		
	maintenance including inadequate		
	specification of post maintenance	· ·	
	functional checks		
7.3	Inadequate maintenance	✓	
7.4	Lack of adequate determination of device		1
	life time		•
7.5	Loss of mechanical integrity		✓
7.6	Inadequate packaging		✓
7.7	re-use or improper re-use		√
7.8	Functional Failure	√	

1.5 Measures to Eliminate The Risk & Its Improvement

1.5.1 Failure Mode and Effect Analysis (FMEA)

11.	Potential Effe	ects of Haz	ard			Curre	nt Design (Controls
hazards	Possible description	Probability	Severity	RPN	Recommended actions	Probability	Severity	RPN
hazards related to the use of the device								
2.1 Electricity	Leakage current may cause operator getting shock	4	8	32 Not Acceptable	Every single part of product which transports power should be accessed by safety guild.	2	4	8 Acceptable
2.2 Heat	Surrounding temperature may influence measuring result	8	2	16 ALARP	Build a temperature controlling system to restrict temperature changes.	4	2	8 Acceptable
2.4 Magnetic fields	The product will generate magnetic field and the magnetic fields surround may influence measuring result	8	1	8 Acceptable	Build a shielding.			
4.1 Electromagnetic interference	Electromagnetic will influence measuring result	8	1	8 Acceptable	Build a shielding.			
4.2 Electromagnetic restrain	Electromagnetic wave may be restrain by shielding	4	1	4 Acceptable	Set equipment out of other equipments which work by electromagnetic force			
4.4 Inadequate supply of power	Inadequate power may shut down the equipment	4	4	16 ALARP	Every single part of product which transports power should be accessed by safety guild.	2	4	8 Acceptable
4.7 Incompatibility with other devices	Other devices which work by electromagnetic force may influence measuring result and may be influenced by electromagnetic restraining	2	2	4 Acceptable	Set equipment out of other equipments which work by electromagnetic force			
5.1 Inadequate labeling	Inadequate warnings.	2	2	4 Acceptable	Write sufficient warning in the operation and maintain manual			

5.2 Inadequate operating instructions	Inadequate setting may damage the device	6	6	36 ALARP	Setting devices by users themselves is forbidden	1	6	6 Acceptable
5.7 Incorrect measurements and other metrological aspects	Inadequate reagent may cause incorrect measurement	4	1	4 Acceptable	The operators should be well-trained			
6.1 confusing or missing instructions for use	Inadequate reagent may cause incorrect measurement	4	1	4 Acceptable	The operators should be well-trained			
6.6 ambiguous or unclear presentation of settings, measurements or other information	Inadequate reagent or inadequate measuring steps may cause incorrect measurement	4	1	4 Acceptable	The operators should be well-trained. Also, the measuring steps should be clearly described in the operation and maintaining manual			
7.2 Lack of, or inadequate specification for maintenance including inadequate specification of post maintenance functional checks	The manual may lose some situations which seldom occur.	4	1	4 Acceptable	The sales or agent should do setting training to operators while the device first setting			
7.3 Inadequate maintenance	The manual may lose some situations which seldom occur.	4	1	4 Acceptable	The sales or agent should do setting training to operators while the device first setting			
7.8 Functional Failure	Hardware may shut down for some unknown reasons and it will cause incorrect measurement or give electrical shot to operators	2	6	12 ALARP	Every single part of product which transports power should be accessed by safety guild to prevent any harm to operators while functional failure	2	2	4 Acceptable

1.6 Risk/Benefit Comparison

The risk management report demonstrated the benefit of XacPro-E made by MagQu Co. Ltd. is better than risk to use it.

1.7 Residual Risk Evaluation

According to risk analysis process and management, the residual risk is low and can be acceptable.

1.8 Post-production Information

The MagQu Co. Ltd. will collect the relating information of post-production such as customers' complain expert's suggestions and the accident case of the similar product in marketing feedback in the risk management activities as ISO 14971 describing.

1.9 Conclusion

According to above risk management report, the magnetic immunoassay analyzer (XacPro-E) made by MagQu Co. Ltd. is safe enough, and its potential risks are eliminated and its advantages are much more than its disadvantages and residual risks.

Prepared by:	
Approved by:	
Dated:	

Risk management report Summary

(job title)

N	MagQu Co. Ltd Risk Manago (Comply with ISO 1497)	-	rt		
Product Name: Magnetic	ro-E R	eport No.:			
Report Date: 2015.02.16		V	ersion: 1 st		
Ci -Product Name: Magno -Risk Management Re -Risk Management Tea	F., No.12, Lane 538, Zhongzh ty 231, Taiwan etic Immunoassay Analyzer, X presentative: Elvis Yang	CacPro-E			
 (B) Risk Management: -Flow Verification - Q&A that can be used to identify medical device characteristics that could impact on safety - Possible hazards and contributing factors associated with Medical devices - Risk Evaluations/Analysis/Control/Ranking list (FMEA) - Confirm the Benefits Overweight the Residual Risk 					
(C) Post Market Surveilla	During the life time				
Input *Engineering change *Customer complaint *CAPA/NCAR *Returned product *Advisory notice *Recall	2015 2016 20	017 201	8 (Year)		
Δ: to be happened, but no @: to be happened, impact X: to be non-happened	impact the risk analysis result t the risk analysis result.	·.			
Initial Prepared By	Initial Reviewed By	Init	tial Approval By		
(name)	(name)	(na	me)		

(job title)

(job title)

Chapter 4 Design Master File

4. Design Master File

The design master file for Magnetic Immunoassay Analyzer, XacPro-E is given.

4.1 Design Master File for Magnetic Immunoassay Analyzer, XacPro-E

4.1.1 Product Code and Illustration

Product code: XacPro-E

Product illustration: The Magnetic Immunoassay Analyzer XacPro-E designed by

MagQu Co., Ltd. is used to measure the change in the ac magnetic susceptibility of a sample over time. If the sample is a mixture of a magnetic reagent and an object to be detected, XacPro-E can be used to detect the concentration of bio-molecules in the object according to the change in the ac magnetic susceptibility, which is so-called immunomagentic

reduction.

4.1.2 Bill OF Material

No.	Project	Quantity
1	Coil	1
2	Electronics	1
3	Shell	1

4.1.3. Specification of Materials Used

Name	Test Project	Standard	Method
	Exterior	No collision damage, distortion or other adverse circumstances	Visual
Coil	Specification	Excitation coil 1: \$\phi\$ 61\pm 61\pm 0.5 mm, 17\pm 0.5 mm in length Excitation coil 2: \$\phi\$ 61\pm 0.5 mm, 11\pm 0.5 mm in length Pick-up coil: \$\phi\$ 30\pm 0.5 mm, 6\pm 0.5 mm in length	Actual test
	Exterior	No collision damage, distortion or other adverse circumstances	Visual
Electronics	Specification	Input voltage: 100-240V 60Hz DC Output voltage: 0~5V AC Output frequency: 100Hz-50KHz Fan works normally	Actual test
	Exterior	No collision damage, distortion or other adverse circumstances	Visual
Shell	Specification	Temperature Box: L: 450 W: 350 H: 150 Detection Box: L: 600 W: 700 H: 250 (Unit: mm)	Actual test

The details for inspecting the standards of materials used are clearly illustrated in MQ-WIQ-03, Quality Management System following ISO 13485 and ISO9001.

4.1.4 Software Information

The software can be designed by users. However, the basic software is still available from MagQu Co., Ltd. Furthermore, the version of the software should be also memorized in the software list before packaging. Further, the serial number of product should also involve the version of software.

For ensuring the software of product is working, every single product should do the sample test between QC and labeling. The sample is MagQu Carcinoembryonic Antigen (CEA) IMR reagent (MF-CEA-0061) made by MagQu Co. Ltd. With CEA antigen provide by MagQu Co., Ltd. The signal from the software should be 30 to 60.

After sample test, the serial number on the labeling will be attached two more numbers for software version before "MQ", which are the last two numbers of serial number, for better traceability.

4.1.5 Packing List

Packing materials	Quantity
XacPro-E	1 set
Operating and maintaining manual	1 set
Labeling	1 set

4.2 Product Validation & Verification

4.2.1 Compliance with Standards

4.2.1.1 Issued Standards

The XacPro-E is issued for Low-Voltage Directive (2006/95/EC) with standards EN 61010-1:2010 (Third Edition) and EN 61010-2-101:2002 which are also including In Vitro Diagnosis (IVD) Directive (98/79/EC) on Oct. 16th, 2013, and Electromagnetic Compatibility Directive (2004/108/EC) with standards EN 61326-1:2013 and EN 55011:2009/A1:2010 Group 1 (Class A) on Oct. 9th, 2013 by Cerpass. The Magnetic Immunoassay Analyzer on MagQu is also assessed and certified the meeting the requirements of ISO 13485:2012 and ISO 9001:2008 by SGS. The other standards are listed on Chapter 1.

4.2.2 Performance Evaluation-Clinical Data

4.2.2.1 Subjects

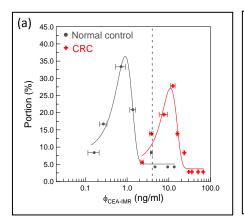
24 serum samples from healthy subjects (Normal control) and 30 serum samples from patients with colorectal cancer (CRC) were used for the IMR CEA assay. The CEA concentrations in human serum samples will be determined using the IMR signals. CRC patients were identified using either pathological evidence or an immunoassay. All of the enrolled patients provided informed consent before undergoing the procedure and this study was approved by National Taiwan University Hospital Research Ethics Committee (No.201105996RC).

4.2.2.2 Specimen Collection and Preparation

- Collect all blood samples by wearing protective equipment and following universal precautions for venipuncture. 5 ml of whole blood is collected in an anticoagulant-free serum separation tube (BD Vacutainer® SSTTM II Advance).
- Each sample (5 ml) is equally divided into two groups for both study and reference assay.
- Ensure that complete clot formation has taken place prior to centrifugation.
- Centrifuge the serum separation tube for 10 minutes at 1,500-2,000x g to separate the serum from the red blood cells.
- After centrifugation, serum is taken by pippetman and equally divided into four 1.5 ml microcentrifuge tubes (1 ml each). Serum samples are labeled and deep frozen (-20°C or colder) until needed. Avoid repeated freezing or thawing.

4.2.2.3 IMR Assays of serum CEA protein for diagnose of colorectal cancer

The CEA concentrations in human serum samples were determined by using the IMR CEA reagent. 24 serum samples from healthy subjects (Normal control) and 30 serum samples from patients with colorectal cancer (CRC) were used for the CEA assay, using the IMR method. CRC patients were identified using either pathological evidence or an immunoassay. The detected CEA concentrations ϕ CEA-IMR of these serum samples are plotted in Figure X(a). The ϕ CEA-IMR values for the normal control group are distributed over a relatively lower range than those for CRC patients. Most of ϕ CEA-IMR values for the normal control group are within the range, 0.6 ng/ml to 1.5 ng/ml, but the ϕ CEA-IMR values for CRC patients range from 6.0 ng/ml to 20 ng/ml. An analysis of the receiver operating characteristic (ROC) curve shown in Figure X(b) shows that the threshold for the diagnosis of CRC by an assay of CEA in serum, using the IMR method, is 4.05 ng/ml, which results in the clinic sensitivity of 0.90 and a specificity of 0.87.



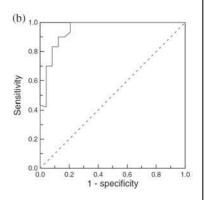


Fig. X. (a) Measured CEA concentration, $\phi_{CEA-IMR}$, using IMR CEA reagent and analyzer for normal subjects (normal control) and patients with colorectal cancer (CRC), (b) The ROC curve for the analysis of the clinical sensitivity and the specificity for the diagnosis of colorectal cancer, using the detected CEA concentration ϕ CEA-IMR in serum.

Reference

Che-Chuan Yang, Shieh-Yueh Yang, Chia-Shin Ho, Jui-Feng Chang, Bing-Hsien Liu and Kai-Wen Huang. "Development of antibody functionalized magnetic nanoparticles for the immunoassay of carcinoembryonic antigen: a feasibility study for clinical use." Journal of Nanobiotechnology 2014, 12:44.

Chapter 5 Test Reports

5.1 Particular requirements for in vitro diagnostic (IVD)	
medical equipment	



TEST REPORT IEC/EN 61010-1 & IEC/EN 61010-2-101

Safety requirements for electrical equipment for measurement, control, and laboratory use

Part 1: General requirements

Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

T1303269-762
Wison Huang Wigon
Jasson Shiu
October 21, 2013
CERPASS TECHNOLOGY CORP.
9f, No. 200, Gangcian Rd., Neihu District, Taipei City 114, Taiwan
as above
MagQu Co., Ltd.
4F., No. 14, Ln. 130, Minquan Rd., Xindian Dist., New Taipei City 231, Taiwan (R.O.C.)
IEC/EN 61010-1:2010 and IEC/EN 61010-2-101:2002
IVD / LVD Verification Report
NA
NA
IEC61010_1F
Cerpass
Magnetic Immunoassay Analyzer
Magou
XacPro-E301
100-240Vac, 50/60Hz; 1.5-0.8A, Class I
Same as Applicant



Test item particulars:

Type of item: Measurement / Control / Laboratory

Connection to MAINS supply: Permanent / Detachable cord set /

Non detachable cord set / None / Direct plug-in

Installation category: II

POLLUTION DEGREE 2

Protection class: Class I

Environmental rating: Standard / Extended (Specify):

Operating conditions: Continuous /-Short-time / Intermittent

Marked degree of protection to IEC 60529 Ordinary

Possible test case verdicts:

- Test case does not apply to the test object...... N/A (Not Applicable)

- Test object does meet the requirement P (Pass)

- Test object does not meet the requirement F (Fail)

Testing:

General remarks:

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 Form A.xx)" refers to a table appended to the report.

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

Copy of marking plate::

Magou

Magnetic Immunoassay Analyzer

Model NO:XacPro-E301

Serial NO: XacPro-E-201308001-MQ Rating: 100-240VAC,50/60Hz,1.5-0.8A

M.D.:08-2013 MagQu Co.,Ltd

http://www.magqu.com







Made in Taiwan



Clause	Requirement + Test	Result - Remark	Verdict
4.4	Testing in SINGLE FAULT CONDITIONS		Р
4.4.1	Fault tests	(see Form A.1 and A.2)	Р
4.4.2	Application of SINGLE FAULT CONDITIONS		Р
4.4.2.1	SINGLE FAULT CONDITIONS not covered by 4.4.2.1 to 4.4.2.14	(see Form A.1 and A.2)	_
4.4.2.2	PROTECTIVE IMPEDANCE	No protective impedance	N/A
4.4.2.3	PROTECTIVE CONDUCTOR		Р
4.4.2.4	Equipment or parts for short-term or intermittent operation	Continuous operate	N/A
4.4.2.5	Motors	(see Form A.1 and A.2)	Р
4.4.2.6	Capacitors	No motor capacitor	N/A
4.4.2.7	MAINS transformers	In the approved power unit	N/A
4.4.2.7.2	Short circuit	Same as above	N/A
4.4.2.7.3	Overload	Same as above	N/A
4.4.2.8	Outputs	No outputs	N/A
4.4.2.9	Equipment for more than one supply	Single supply	N/A
4.4.2.10	Cooling	(see Form A.1 and A.2)	Р
4.4.2.11	Heating devices	No heating device	N/A
4.4.2.12	Insulation between circuits and parts		N/A
4.4.2.13	Interlocks	No interlock	N/A
4.4.2.14	Voltage selectors	No such parts	N/A
4.4.3	Duration of tests	(see Form A.1 and A.2)	Р
4.4.4	Conformity after application of fault conditions	(see Form A.1; A.2; A.8, A.14)	Р
4.4.2.101	Incorrect voltage selection	No voltage selection	N/A
	(IEC 61010-2-101)		
5	MARKING AND DOCUMENTATION		Р
5.1.1	General		Р

5	MARKING AND DOCUMENTATION		Р
5.1.1	General		Р
	Required equipment markings are:		_
	visible:		Р
	From the exterior; or	On the enclosure	Р
	After removing a cover; or		N/A
	Opening a door		N/A
	After removal from a rack or panel		N/A



	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
	Required markings are not put on parts which can be removed by an OPERATOR (IEC 61010-2-101)		Р
	Letter symbols (IEC 60027) used (IEC 61010-2-101)		Р
	Graphic symbols (table 1) used (IEC 61010-2-101)	Comply with Table 1	Р
5.1.2	Identification		_
	(IEC 61010-2-101)		
	Equipment shall, as a minimum, be marked with the following information: (IEC 61010-2-101)		Р
	a) manufacturer's name or trade mark, and the address. The address shall include at least the city and country;	MagQu	Р
	b) model number, name, or other means of identifying the equipment;	See page 1	Р
	c) where this is required by regulation, the name and address of the authorized representative of the manufacturer; (IEC 61010-2-101)		Р
	The following additional information shall be marked on the equipment or packaging or in the instructions for use: (IEC 61010-2-101)		Р
	1) the serial-number, for example SN XXXX or alternatively the batch code, preceded by 'LOT', using symbol 102 of Table 1; (IEC 61010-2-101)	LOT No. is marked	Р
	2) the following information: (IEC 61010-2-101)		-
	i) a clear indication that the equipment is IVD medical equipment; (IEC 61010-2-101)	Marked on the label	Р
	ii) if applicable, a clear indication that the equipment is self-test IVD medical equipment; (IEC 61010-2-101)	Not a self-test IVD	N/A
	iii) if a potential RISK is posed, the identification of detachable components by manufacturer and part identification, and where appropriate the batch code, etc. (IEC 61010-2-101)	Stated in the manual	Р
	iv) any expiry date of consumable parts, expressed as the year, the month and (where relevant) the day, in that order. (IEC 61010-2-101)		N/A
5.1.3	Mains supply		Р
	Equipment is marked as follows:		Р
	a) Nature of supply:	~	_
	a.c. RATED MAINS frequency or range of frequencies:	Frequency is marked for the adpater	Р
	2) d.c. with symbol 1	For the equipment	Р
	b) RATED supply voltage(s) or range:	100-240V~	Р
	c) Max. RATED power (W or VA) or input current:	See page 1	Р



IEC/EN 61010-1 + IEC/EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	The marked value not less than 90 % of the maximum value	(see Form A.3)	Р
	If more than one voltage range:	Single range	N/A
	Separate values marked; or		N/A
	Values differ by less than 20 %	(see Form A.3)	N/A
	d) OPERATOR-set for different RATED supply voltages:	No voltage selector	N/A
	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
	e) Accessory MAINS socket-outlets accepting standard MAINS plugs are marked:	No mains socket outlet	N/A
	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:		N/A
	The maximum rated current or power; or		N/A
	Symbol 14 with full details in the documentation		N/A
5.1.4	Fuses	Fuse is marked	Р
	Operator replaceable fuse marking (see also 5.4.5):		Р
5.1.5	TERMINALS, connections and operating devices		Р
5.1.5.1	General		Р
	Where necessary for safety, indication of purpose of TERMINALS, connectors, controls and indicators marked	Purpose is marked	Р
	If insufficient space, symbol 14 used	Adequately marked	Р
	Push-buttons and actuators of emergency stop devices and indicators:	No emergency stop	_
	used only to indicate a warning of danger or		N/A
	the need for urgent action		N/A
	coloured red		N/A
	coded as specified in IEC 60073		N/A
	Supplementary means of coding provided, if meaning of colour relates (see IEC 60073):		N/A
	to safety of persons; or		N/A
	safety of the environment		N/A



	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
5.1.5.2	TERMINALS		Р
	MAINS supply TERMINAL identified		Р
	Other TERMINAL marking:		Р
	a) FUNCTIONAL EARTH TERMINALS (symbol 5 used) =	No functional earth	N/A
	b) PROTECTIVE CONDUCTOR TERMINALS:	Appliance inlet is used	Р
	Symbol 6 is placed close to or on the TERMINAL; or		N/A
	Part of appliance inlet		Р
	c) TERMINALS of control circuits (symbol 7 used)	No symbol 7 is needed	N/A
	d) HAZARDOUS LIVE TERMINALS supplied from the interior	No live terminal supplied from interior	N/A
	Standard MAINS socket outlet; or		N/A
	RATINGS marked; or		N/A
	Symbol 14 used		N/A
5.1.6	Switches and circuit breakers		Р
	If disconnecting device, off position clearly marked	Not used as disconnecting device	N/A
	If push-button used as power supply switch:	Not of push-button type	N/A
	Symbol 9 and 15 used for on-position		N/A
	Symbol 10 and 16 used for off-position		N/A
	Pair of symbols 9, 15 and 10, 16 close together		N/A
5.1.7	Equipment protected by DOUBLE INSULATION OF REINFORCED INSULATION		
	Protected throughout (symbol 11 used)		N/A
	Only partially protected (symbol 11 not used)	Class I product	Р
5.1.8	Field-wiring TERMINAL boxes	No field wiring box	N/A
	If TERMINAL or ENCLOSURE exceeds 60 °C:	(see Form A.21A)	N/A
	Cable temperature RATING marked:		N/A
	Marking visible before and during connection or beside TERMINAL		N/A
5.1.101	Transport and storage		_
	(IEC 61010-2-101)		
	Packaging shall be labelled to indicate any special conditions for transport or storage. (IEC 61010-2-101)		Р
5.2	Warning markings		Р
	Visible when ready for NORMAL USE		Р



IEC/EN 61010-1 + IEC/EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	T	Γ	-
	Are near or on applicable parts		Р
	Symbols and text correct dimensions and colour:		_
	a) symbols min 2,75 mm and text 1,5 mm high and contrasting in colour with background		P
	b) symbols and text moulded, stamped or engraved in material min. 2,0 mm high and	All by printing	N/A
	0.5 mm depth or raised if not contrasting in colour		N/A
	If necessary marked with symbol 14	Symbol 14 is marked	Р
	Statement to isolate or disconnect the power if access by using a tool to HAZARDOUS LIVE parts is permitted by user		N/A
	Advise how to avoid contact with HAZARDOUS live parts (IEC 61010-2-101)		Р
	Equipment that can be potentially infectious due to the samples or reagents used shall be prominently marked with symbol 101 of Table 1 (IEC 61010-2-101)	Symbol 101 is marked	Р
	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. (IEC 61010-2-101)	Symbol 14 is marked	Р
	Containers or bags for biohazardous waste material which can be removed from the equipment during NORMAL USE shall be marked with symbol 101 of Table 1. (IEC 61010-2-101)	Symbol 101 is marked	Р
	- Other warning markings are specified in 5.1.5.1 c), 6.1.2 b), 6.5.1.2 g), 6.6.2, 7.2 c), 7.3, 10.1, 13.2.2. (IEC 61010-2-101)	Provided	Р
5.3	Durability of markings		Р
	(IEC 61010-2-101)		
	Durability of markings; the required markings remain clear and legible (NORMAL USE) (IEC 61010-2-101)	(see Form A.4)	Р
5.4	Documentation		Р
5.4.1	General	Accompanied by documentation for safety purposes	Р
	Equipment is accompanied by documentation for safety purposes for OPERATOR or RESPONSIBLE BODY (IEC 61010-2-101)		Р
	Safety documentation for service personnel authorized by the manufacturer		Р
	Documentation necessary for safe operation is provided in printed media or	In printed media	Р
	in electronic media if available at any time		N/A



N/A

	IEC/EN 64040 1 + IEC/EN 64	010 2 101	
Clause	IEC/EN 61010-1 + IEC/EN 610		\/ordigt
Clause	Requirement + Test	Result - Remark	Verdict
	Documentation includes:	<u> </u>	Γ_
	a) intended use	The user's manual provided with the relevant safety statements	Р
	b) technical specification		Р
	c) name and address of manufacturer or supplier		Р
	d) Information specified in 5.4.2 to 5.4.6		Р
	e) information to mitigate residual RISK		Р
	f) accessories for safe operation of the equipment specified		Р
	g) guidance provided to check correct function of the equipment, if incorrect reading may cause a HAZARD from harmful or corrosive substances of HAZARDOUS live parts		Р
	h) instructions for lifting and carrying		Р
	Warning statements and a clear explanation of warning symbols:		
	Provided in the documentation; or	Stated in manual	Р
	Information is marked on the equipment		Р
	Information shall be given about any RISKS not reduced to a TOLERABLE RISK level by the protective measures specified in this standard. 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. (IEC 61010-2-101)	Stated in the manual	Р
5.4.2	Equipment ratings		Р
	Documentation includes:		
	a) Supply voltage or voltage range:	100-240V~	Р
	Frequency or frequency range:	See page 1	Р
	Power or current rating:	See page 1	Р
	b) Description of all input and output connections in accordance to 6.6.1 a)	Stated in the manual	Р
	c) RATING of insulation of external circuits in accordance to 6.6.1 b)		Р
	d) Statement of the range of environmental conditions (see 1.4)		Р
	e) Degree of protection (IEC 60529)	IP20	Р
	f) if impact rating less than 5 J:	5J is tested	N/A
	IK code in accordance to IEC 62262 marked or	No IK code is marked	N/A
•			

symbol 14 of table 1 marked, with



IEC/EN 61010-1 + IEC/EN 61010-2-101				
Clause	Requirement + Test		Result - Remark	Verdict

	RATED energy level and test method stated		N/A
5.4.3	Equipment transportation, installation and assembly instructions (IEC 61010-2-101)		Р
	Documentation for the RESPONSIBLE BODY shall include the following as applicable: (IEC 61010-2-101)		Р
	a) instructions for transportation after delivery to the RESPONSIBLE BODY; (IEC 61010-2-101)		Р
	b) floor loading requirements; (IEC 61010-2-101)	Table top	N/A
	c) individual weights of principal heavy subassemblies; (IEC 61010-2-101)	Light equipment	N/A
	d) location and mounting instructions, including the space required for ventilation, and for safe and efficient OPERATOR maintenance; (IEC 61010-2-101)		Р
	e) assembly instructions; (IEC 61010-2-101)	Stated in the manual	Р
	f) instructions for protective earthing; (IEC 61010-2-101)		Р
	g) the sound data required by 12.5.1; (IEC 61010-2-101)		N/A
	h) instructions relating to the handling, containment and exhaust of hazardous substances, including any requirements for preventing back-syphonage; (IEC 61010-2-101)		Р
	i) any drainage systems required where a HAZARD could occur from the discharge of biological and chemical substances and hot fluids; (IEC 61010-2-101)	No drainage required	N/A
	j) details of protective measures relating to hazardous radiation (see clause 12); (IEC 61010-2-101)	No radiation hazards	N/A
	k) connections to the supply; (IEC 61010-2-101)		Р
	I) for PERMANENTLY CONNECTED EQUIPMENT only: (IEC 61010-2-101)	Not a permanently connected equipment	N/A
	1) MAINS supply requirements and details of connections, including the RATED temperature of the cable required at maximum RATED ambient temperature; (IEC 61010-2-101)		N/A
	2) requirements for any external switch or circuit- breaker (see 6.11.2.1) and external overcurrent protection devices (see 9.5.1) and a recommendation that the switch or circuit-breaker be near the equipment if this is necessary for safety; (IEC 61010-2-101)		N/A
	m) requirements for special services (for example air, cooling liquid) including pressure limits. (IEC 61010-2-101)		N/A



	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
5.4.4	Equipment operation	The user's manual provided with the relevant statements	Р
	Instructions for use include:		Р
	a) details of operating controls and their use in all operating modes; with any sequence of operation; (IEC 61010-2-101)		Р
	b) an instruction not to position the equipment so that it is difficult to operate the disconnecting device (see 6.12); (IEC 61010-2-101)		Р
	c) instructions for interconnections to accessories and other equipment, including details of suitable accessories, detachable parts and any special materials; (IEC 61010-2-101)		Р
	d) limits for intermittent operation; (IEC 61010-2-101)	Continuous operation	N/A
	e) an explanation of symbols used on the equipment and, where HAZARDS are involved, the reason for using a symbol in each particular case; (IEC 61010-2- 101)		Р
	f) instructions for any actions to be taken by an OPERATOR in case of a malfunction; (IEC 61010-2-101)	Trouble shooting is provided in the manual	Ρ
	g) instructions and recommendations for cleaning and decontamination, with materials recommended (see 11.2); (IEC 61010-2-101)	Stated in the manual	Р
	h) instructions for the disposal of waste; (IEC 61010-2-101)		Р
	i) if NORMAL USE involves the handling of hazardous substances, instructions on correct use and any need for training or personal protection measures; (IEC 61010-2-101)	Stated in the manual	Р
	j) 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 or other protective means; (IEC 61010-2-101)		Р
	k) if the equipment could emit hazardous aerosol vapours in NORMAL USE, instructions for protection of the mouth, nose or eyes; (IEC 61010-2-101)	No vapour	N/A
	I) if potentially hazardous visible or invisible radiation could be emitted, instructions and requirements for protective devices, such as protective glasses; (IEC 61010-2-101)	No radiation	N/A
	m) a statement in the instructions that, if the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. (IEC 61010-2-101)		Р



IEC/EN 61010-1 + IEC/EN 61010-2-101				
Clause	Requirement + Test		Result - Remark	Verdict

	Further requirements on instructions for use, see EN 591 for IVD medical equipment for professional use, EN 592 for self-test IVD medical equipment. (IEC 61010-2-101)	Not a self-test IVD	N/A
5.4.4.101	Self-test IVD medical equipment (IEC 61010-2-101)	Void	_
5.4.5	Equipment maintenance		Р
	Instructions for RESPONSIBLE BODY include:		_
	Instructions sufficient in detail permitting safe maintenance and inspection and continued safety:	The user's manual provided with the relevant statements	Р
	Instruction against the use of detachable MAINS supply cord with inadequate rating		Р
	Specific battery type of user replaceable batteries	No battery for user	N/A
	Any manufacturer specified parts		Р
	Rating and characteristics of fuses		Р
	Instructions include following subjects permitting safe servicing and continued safety:		Р
	a) product specific RISKS may affect service personnel		Р
	b) protective measures for these RISKS		Р
	c) verification of the safe state after repair		Р
5.4.6	Integration into systems or effects resulting from special conditions		Р
	Aspects described in documentation		Р
5.4.101	Removal of equipment from use for repair or disposal		Р
5.4.101	(IEC 61010-2-101)		
	Instructions shall be provided for the RESPONSIBLE BODY for eliminating or reducing HAZARDS involved in removal from use, transportation or disposal. These instructions shall include requirements for minimizing biohazards. (IEC 61010-2-101)		Р
5.4.102	Transport and storage (IEC 61010-2-101)		Р
	The manufacturer shall specify the conditions for transport and storage. The documentation shall contain a specification of the permissible environmental conditions for transport and storage which shall be repeated on the outside of the packaging of the equipment (see 5.1). (IEC 61010-2-101)		Р

6	PROTECTION AGAINST ELECTRIC SHOCK		Р
6.1	General	(see Form A.5)	Р

6.3.1

Levels in NORMAL CONDITION



	IEC/EN 61010-1 + IEC/EN 61	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
6.1.1	Requirements	<u>T</u>	
0.1.1	•	In normal and single fault	— Р
	Protection against electric shock maintained in NORMAL CONDITION and SINGLE FAULT CONDITION	In normal and single fault condition not hazardous live	F
	ACCESSIBLE parts not HAZARDOUS LIVE	Conform with the request	Р
	Voltage, current, charge or energy below the limits in NORMAL CONDITION and in SINGLE FAULT CONDITION between:		_
	ACCESSIBLE parts and earth		Р
	two ACCESSIBLE parts on same piece of the equipment within a distance of 1,8 m		Р
	Conformity is checked by the determination of 6.2 and 6.3 followed by the tests of 6.4 to 6.11		Р
6.1.2	Exceptions		Р
	Following HAZARDOUS LIVE parts may be accessible to an OPERATOR:	No hazardous live part is accessible	N/A
	a) parts of lamps and lamp sockets after lamp removal	No HV lamp	N/A
	b) parts to be replaced by operator only by the use of tool and warning marking	No tool is needed	N/A
	Those parts not HAZARDOUS LIVE 10 s after interruption of supply	(see Forms A.6)	N/A
	Capacitance test if charge is received from internal capacitor	(see Forms A.6 and A.7)	N/A
6.2	Determination of accessible parts	(see Form A.6)	Р
6.2.1	General		Р
	Unless obviously determination of accessible parts as specified in 6.2.2 to 6.2.4		Р
6.2.2	Examination		Р
	- with jointed test finger (as specified B.2)	Complied with the finger test	Р
	- with rigid test finger (as specified B.1) and a force of 10 N	Same as above	Р
6.2.3	Openings above parts that are HAZARDOUS LIVE		Р
	- test pin with length of 100 mm and 4 mm in diameter applied		Р
6.2.4	Openings for pre-set controls	No pre-set control opening	N/A
	- test pin with length of 100 mm and 3 mm in diameter applied		N/A
6.3	Limit values for ACCESSIBLE parts		Р
		(=)	

(see Form A.7)

Ρ



IEC/EN 61010-1 + IEC/EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Voltage limits less than 33 V r.m.s. and 46,7 V peak or 70 V d.c.	The accessible voltage levels not exceed 33V r.m.s. and 46.7V peak or 70V d.c.	Р
	for wet locations voltage limits less than 16 V r.m.s. and 22,6 V peak or 35 V d.c.	Dry location only	N/A
	Voltages are not HAZARDOUS LIVE the levels of:		_
	b) Current less than 0,5 mA r.m.s. for sinusoidal, 0,7 mA peak non sinusoidal or mixed frequencies or 2 mA d.c. when measured with measuring circuit A.1 or A.2 if less than 100 Hz	The accessible voltage levels not exceed 33V r.m.s. and 46.7V peak or 70V d.c.	N/A
	for wet locations measuring circuit A.4 used, or		N/A
	c) Levels of capacitive charge or energy less:		N/A
	1) 45 µC for voltages up to 15 kV peak or d.c. or line A of Figure 3		N/A
	2) 350 mJ stored energy for voltages above 15 kV peak or d.c.		N/A
6.3.2	Levels in SINGLE FAULT CONDITION	(see Form A.7)	Р
	a) Voltage limits less than 33 V r.m.s. and 46,7 V peak or 70 V d.c.	The accessible voltage levels not exceed 33V r.m.s. and 46.7V peak or 70V d.c.	Р
	for wet locations voltage limits less than 16 V r.m.s. and 22,6 V peak or 35 V d.c.	Dry location only	N/A
	Voltages are not HAZARDOUS LIVE the levels of:		_
	b) Current less than 0,5 mA r.m.s. for sinusoidal, 0,7 mA peak non sinusoidal or mixed frequencies or 2 mA d.c. when measured with measuring circuit A.1 or A.2 if less than 100 Hz	The accessible voltage levels not exceed 33V r.m.s. and 46.7V peak or 70V d.c	N/A
	for wet locations measuring circuit A.4 used, or		N/A
	c) Levels of capacitive charge or energy less:		N/A
	1) 45 µC for voltages up to 15 kV peak or d.c. or line A of Figure 3		N/A
	2) 350 mJ stored energy for voltages above 15 kV peak or d.c.		N/A
6.4	Primary means of protection		Р
6.4.1	ACCESSIBLE parts prevented from being HAZARDOUS LIVE by one or more of following means:	Enclosures and barriers surrounding the hazardous live meet the rigidity requirements	Р
	a) ENCLOSURES OF PROTECTIVE BARRIERS (see 6.4.2)		Р
	b) BASIC INSULATION (see 6.4.3)		Р



N/A

Ρ

IEC/EN 61010-1 + IEC/EN 61010-2-101				
Clause	Requirement + Test	Result - Remark	Verdict	
	c) Impedance (see 6.4.4)	Not protect by impedance	N/A	
6.4.2	, , , ,	(see Form A.13)	P	
0.4.2	- meet rigidity requirements of 8.1	(See Form A.13)	Р	
	- meet requirements for BASIC INSULATION, if protection is provided by insulation		P	
	- meet requirements of 6.7 for CREEPAGE and CLEARANCES between ACCESSIBLE parts and HAZARDOUS live parts, if protection is provided by limited access		Р	
6.4.3	BASIC INSULATION	(see Form A.13)	Р	
	- meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7		Р	
6.4.4	Impedance	(see Form A.12)	N/A	
	Impedance used as primary means of protection meets all of following requirements:	Not protect by impedance	_	
	a) limits current or voltage to level of 6.3.2	(see Form A.7)	N/A	
	b) RATED for maximum WORKING VOLTAGE and the amount of power it will dissipate		N/A	
	c) CLEARANCE, CREEPAGE DISTANCE between terminations of the impedance meet requirements of BASIC INSULATION of 6.7	(see Form A.13)	N/A	
6.5	Additional means of protection in case of SINGLE FAULT C	ONDITION	Р	
6.5.1	ACCESSIBLE parts are prevented from becoming HAZARDOUS live by the primary means of protection and supplemented by one of:		Р	
	a) PROTECTIVE BONDING (see 6.5.2)	Class I	Р	
	b) SUPPLEMENTARY INSULATION (see 6.5.3)		Р	
	c) automatic disconnection of the supply (see 6.5.5)		N/A	
	d) current- or voltage-limiting device (see 6.5.6)		Р	
	Alternatively one of the single means of protection is used:		Р	
	e) REINFORCED INSULATION (see 6.5.3)	For the insulating parts	Р	
	f) PROTECTIVE IMPEDANCE (see 6.5.4)		N/A	
6.5.2	PROTECTIVE BONDING	(see Form A.9, A.10 and A.11)	Р	
6.5.2.1	ACCESSIBLE conductive parts, may become HARZARDOUS LIVE in SINGLE FAULT CONDITION:	Plastic encased	N/A	
	Bonded to the PROTECTIVE CONDUCTOR TERMINAL; or		N/A	

Separated by conductive screen or barrier bonded to

PROTECTIVE CONDUCTOR TERMINAL

Integrity of PROTECTIVE BONDING

6.5.2.2



Clause	Deguirement L Toot	Decult Demails	\/o.u.cl! - 1
Clause	Requirement + Test	Result - Remark	Verdict
	a) PROTECTIVE BONDING consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses	Protective bonding are direct connected to structural parts	Р
	b) Soldered connections:	Secured then soldered to earthing terminal of Appliance Inlet	Р
	Independently secured against loosening		Р
	Not used for other purposes	Solely for earthing	Р
	c) Screw connections are secured	Connections are secured against loosening	Р
	d) PROTECTIVE BONDING not interrupted; or	No part of the equipment is removable by the operator	Р
	exempted as removable part carries MAINS SUPPLY INPUT connection	For the appliance inlet	Р
	e) Any moveable PROTECTIVE BONDING connection specifically designed, and meets 6.5.2.4	No moveable PE	N/A
	f) No external metal braid of cables used (not regarded as PROTECTIVE BONDING)	No such cables is used	N/A
	g) IF MAINS SUPPLY PASSES THROUGH:	No mains passes through	N/A
	Means provided for passing protective conductor;		N/A
	Impedance meets 6.5.2.4		N/A
	h) Protective conductors bare or insulated, if insulated, green/yellow	Green/ Yellow wires are used	Р
	Exceptions:		N/A
	1) earthing braids;		N/A
	2) internal protective conductors etc.;		N/A
	Green/yellow not used for other purposes		Р
	TERMINAL suitable for connection of a PROTECTIVE CONDUCTOR, and meets 6.5.2.3		Р
6.5.2.3	PROTECTIVE CONDUCTOR TERMINAL	The ground of the appliance inlet is considered as the PE TERMINAL	Р
	a) Contact surfaces are metal	Closed-loop metal ring terminal	Р
	b) Appliance inlet used	See appended table 14.1 – approved of components	Р
	c) For rewirable cords and PERMANENTLY CONNECTED EQUIPMENT, PROTECTIVE CONDUCTOR TERMINAL is close to MAINS supply TERMINALS	Appliance inlet is used	N/A
	d) If no MAINS supply is required, any PROTECTIVE CONDUCTOR TERMINAL:	Connected to mains supply	N/A



	IEC/EN 61010-1 + IEC/EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict	
	Is near terminals of circuit for which protective earthing is necessary		N/A	
	External if other terminals external		N/A	
	e) Equivalent current-carrying capacity to MAINS supply TERMINALS	Appliance inlet has enough current-carrying capacity to mains	Р	
	f) If plug-in, makes first and breaks last	Not of plug-in type	N/A	
	g) If also used for other bonding purposes, protective conductor:		N/A	
	Applied first;		N/A	
	Secured independently;		N/A	
	Unlikely to be removed by servicing		N/A	
	h) PROTECTIVE CONDUCTOR of measuring circuit:		N/A	
	Current RATING equivalent to measuring circuit TERMINAL;		N/A	
	 PROTECTIVE BONDING shall not be interrupted; (Devices used for indirect bonding in test and measurement circuits are permitted to be part of the PROTECTIVE BONDING): 		N/A	
	i) FUNCTIONAL EARTH TERMINALS allow independent connection		N/A	
	j) If a binding screw used for PROTECTIVE CONDUCTOR TERMINAL:		N/A	
	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	
	Passes tightening torque test		N/A	
	k) Contact pressure not capable being reduced by deformation of materials		N/A	
6.5.2.4	Impedance of PROTECTIVE BONDING of plug-connected equipment	0.010hm measured passing 25Aac current from earthing terminal of inlet to inside metal part (see Form A.10)	Р	
	Impedance between PROTECTIVE CONDUCTOR TERMINAL and each ACCESSIBLE part where PROTECTIVE BONDING is specified, is:		_	
	less than 0,1 Ohm; or		Р	
	less than 0,2 Ohm if equipment is provided with non detachable cord	Inlet is used	N/A	
6.5.2.5	Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT	(see Form A.10) Not permanently connected	N/A	
	1	<u> </u>	l	



Ρ

			•
	IEC/EN 61010-1 + IEC/EN 61	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
6.5.2.6	Transformer PROTECTIVE BONDING screen	(see Form A.11)	N/A
	Transformer provided with screen for protective bonding:	No such screen is used	N/A
	screen bonding consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses (see 6.5.2.2 a)		N/A
	screen bonding with soldered connection (see 6.5.2.2 b) is:		N/A
	- Independently secured against loosening		N/A
	- Not used for other purposes		N/A
6.5.3	SUPPLEMENTARY and REINFORCED INSULATION		Р
	- meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7		Р
6.5.4	PROTECTIVE IMPEDANCE	(see Form A.12)	N/A
	Limits current or voltage to level of 6.3.1 in NORMAL and to level of 6.3.2 in SINGLE FAULT CONDITION	No protective impedance is used	N/A
	CLEARANCE, CREEPAGE DISTANCE between terminations of the impedance meet requirements of DOUBLE or REINFORCED INSULATION of 6.7	(see Form A.13)	N/A
	The protective impedance consists of one or more of the following:	(see Table 3 and Form A.12)	_
	appropriate single component suitable for safety and reliability for protection, it is:		N/A
	1) RATED twice the maximum WORKING VOLTAGE		N/A
	resistor RATED for twice the power dissipation for maximum WORKING VOLTAGE		N/A
	b) combination of components		N/A
	Single electronic device not used as PROTECTIVE IMPEDANCE		N/A
6.5.5	Automatic disconnection of the supply	No such device is used	N/A
	a) RATED to disconnect the load within time specified in Figure 2		N/A
	b) RATED for the maximum load conditions of the equipment		N/A
6.5.6	Current- or voltage limiting devices		Р
	Device complies with all of:	For the fuse	Р
	a) RATED to limit the current or voltage to the level of 6.3.2	(see Form A.8)	Р
-			

b) RATED for the maximum working voltage; and

6.7.1

The nature of insulation



	IEC/EN 61010-1 + IEC/EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict	
	RATED for the maximum operational current if applicable		Р	
	c) CLEARANCE, CREEPAGE DISTANCE between	(see Form A.13)	Р	
	terminations of the impedance meet requirements of SUPPLEMENTARY INSULATION of 6.7	Complied with insulation		
6.6	Connections to external circuits		Р	
6.6.1	Connections do not cause ACCESSIBLE parts of the following to become HAZARDOUS LIVE IN NORMAL CONDITION OF SINGLE FAULT CONDITION:		Р	
	- the external circuits		Р	
	- the equipment		Р	
	Protection achieved by separation of circuits; or		Р	
	short circuit of separation does not cause a HAZARD		N/A	
	Instructions or markings for each terminal include:		Р	
	a) RATED conditions for TERMINAL		Р	
	b) Required RATING of external circuit INSULATION		N/A	
6.6.2	TERMINALS for external circuits	No terminals which are hazardous live	N/A	
	TERMINALS which receive a charge from an internal capacitor are not HAZARDOUS LIVE after 10 s of interrupting supply connection	(see Form A.7)	N/A	
6.6.3	Circuits with terminals which are HAZARDOUS LIVE	No terminals which are hazardous live	N/A	
	These circuits are:		N/A	
	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	No such terminal	N/A	
	No RISK of accidental contact because:		N/A	
	Located or shielded		N/A	
	Self-evident or marked whether or not connected to ACCESSIBLE conductive parts		N/A	
	ACCESSIBLE TERMINALS will not work loose		N/A	
6.7	Insulation requirements	(see Form A.5)	Р	
		-		



IEC/EN 61010-1 + IEC/EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
6.7.1.1	Insulation between ACCESSIBLE parts or between separate circuits consist of CLEARANCES, CREEPAGE DISTANCES and solid insulation if provided as protection against a HAZARD	Complied with insulation requirement	Р
6.7.1.2	CLEARANCES		Р
	Required CLEARANCES reflecting factors of 6.7.1.1	(see Form A.5)	Р
	Equipment rated for operating altitude greater than 2000 m correction factor of Table 3 of 61010-1 applied	Not over 2000m	N/A
6.7.1.3	CREEPAGE DISTANCES		Р
	Required CLEARANCES reflecting factors of 6.7.1.1	(see Form A.5)	Р
	CTI material group reflected by requirements		Р
	CTI test performed		Р
6.7.1.4	Solid insulation		Р
	Required CLEARANCES reflecting factors of 6.7.1.1	(see Form A.5)	Р
6.7.1.5	Requirements for insulation according to type of circuit	(see Form A.5)	Р
	a) 6.7.2 MAINS circuits of OVERVOLTAGE CATEGORY II up to nominal supply voltage of 300 V	CAT II and not over 300V	Р
	b) 6.7.3 Secondary circuits separated from circuits defined in a) by transformer	Same as above	Р
	c) K.1 mains circuits of Overvoltage category III and IV or Overvoltage category II over 300 V	CAT II and not over 300V	N/A
	d) K.2 Secondary circuits separated from circuits defined in c) by transformer		N/A
	e) K.3 Circuits having one or more of(Insulation in circuits not addressed in 6.7, K.1 or K.2, and in measuring circuits where MEASUREMENT CATEGORIES do not apply):		N/A
	maximum TRANSIENT OVERVOLTAGE is limited to known level below the level of MAINS CIRCUIT		N/A
	maximum TRANSIENT OVERVOLTAGE above the level of MAINS CIRCUIT		N/A
	WORKING VOLTAGE is the sum of more than one circuit or a mixed voltage		N/A
	4) Working voltage includes recurring peak voltage, may include non-sinusoidal or non-periodic waveform		N/A
	5) WORKING VOLTAGE with a frequency above 30 kHz		N/A
6.7.2	Insulation for MAINS CIRCUITS of OVERVOLTAGE CATEGORY II with a nominal supply voltage up to 300 V	CAT II and not over 300V	Р
6.7.2.1	CLEARANCES and CREEPAGE DISTANCES	(see Form A.13)	Р



IEC/EN 61010-1 + IEC/EN 61010-2-101				
Clause	Requirement + Test		Result - Remark	Verdict

	Values for MAINS CIRCUITS of table 4 are met	CAT II and not over 300V	Р
	Coatings to achieve reduction to POLLUTION DEGREE I comply with requirements of Annex H	Pollution 2 is considered	N/A
6.7.2.2	Solid insulation		Р
6.7.2.2.1	Withstands electrical and mechanical stresses in normal use and all RATED environmental conditions of 1.4		Р
	Equipment passed voltage tests of 6.8.3 with values of Table 5	(see Form A.14)	Р
	Complies as applicable:		Р
	a) ENCLOSURE OF PROTECTIVE BARRIER Clause 8		Р
	b) moulded and potted parts requirements of 6.7.2.2.2	No potted part	Р
	c) inner layers of printed wiring boards requirements of 6.7.2.2.3		N/A
	d) thin-film insulation requirements of 6.7.2.2.4		Р
6.7.2.2.2	Moulded and potted parts		N/A
	Conductors between same two layers are separated by at least 0,4 mm after moulding is completed		N/A
6.7.2.2.3	Inner insulation layers of printed wiring boards		N/A
	Separated by at least 0,4 mm between same two layers		N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		N/A
	a) thickness at least 0,4 mm		N/A
	b) insulation is assembled of minimum two separate layers, each RATED for test voltage of Table 5 for BASIC INSULATION		N/A
	c) insulation is assembled of minimum two separate layers, where the combination is rated for test voltage of Table 5 for REINFORCED INSULATION		N/A
6.7.2.2.4	Thin-film insulation	No such parts	N/A
	Conductors between same two layers are separated by applicable CLEARANCES and CREEPAGE DISTANCES	Same as above	N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		N/A
	a) thickness at least 0,4 mm		N/A
	b) insulation is assembled of min two separate layers, each RATED for test voltage of Table 5 for BASIC INSULATION		N/A



	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
	c) insulation is assembled of min three separate layers, where the combination of two layers passed voltage tests of 6.8.3 with values of Table 5 for REINFORCED INSULATION	(see Form A.14)	N/A
6.7.3	Insulation for secondary circuits derived from MAINS of OVERVOLTAGE CATEGORY II up to 300 V		Р
6.7.3.1	Secondary circuits where separation from MAINS CIRCUITS is achieved by a transformer providing:		_
	- REINFORCED INSULATION		Р
	- DOUBLE INSULATION		Р
	- screen connected to the PROTECTIVE CONDUCTOR TERMINAL	No such parts	N/A
6.7.3.2	CLEARANCES		Р
	 a) meet the values of Table 6 for BASIC INSULATION and SUPPLEMENTARY INSULATION; 		Р
	twice the values of Table 6 for REINFORCED INSULATION, or		Р
	b) pass the voltage tests of 6.8 with values of Table 6; with following adjustments:	(see Form A.14)	N/A
	values for REINFORCED INSULATION are 1,6 times the values for BASIC INSULATION	Complied with the R/I test	N/A
	if operating altitude is greater than 2000 m values of CLEARANCES multiplied with factor of Table 3	Not over 2000 m	N/A
	3) minimum CLEARANCE is 0,2 mm for POLLUTION DEGREE 2 and 0,8 mm for POLLUTION DEGREE 3		N/A
6.7.3.3	CREEPAGE DISTANCES		Р
	Based on WORKING VOLTAGE meets the values of Table 7 for BASIC and SUPPLEMENTARY INSULATION		Р
	Values for REINFORCED INSULATION are twice the values of BASIC INSULATION		Р
	Coatings to achieve reduction to POLLUTION DEGREE I comply with requirements of Annex H	No coating	N/A
6.7.3.4	Solid insulation		N/A
6.7.3.4.1	Withstands electrical and mechanical stresses in normal use and all RATED environmental conditions of 1.4		N/A
	Equipment passed voltage test of 6.8.3.1 for 5 s with VALUES of Table 6 for BASIC and SUPPLEMENTARY INSULATION	(see Form A.14)	N/A
	values for REINFORCED INSULATION are 1,6 times the	Complied with R/I test	Р

values of BASIC INSULATION



	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
	b) if WORKING VOLTAGE exceeds 300 V, equipment passed voltage test of 6.8.3.1 for 1 min with a test	(see Form A.14)	N/A
	voltage of 1,5 times working voltage for BASIC or SUPPLEMENTARY INSULATION	Not over 300V	
	value for REINFORCED INSULATION are twice the WORKING VOLTAGE	Same as above	N/A
	Complies as applicable:		N/A
	1) ENCLOSURE or protective barrier Clause 8		N/A
	2) moulded and potted parts requirements of 6.7.3.4.2		N/A
	3) inner layers of printed wiring boards requirements of 6.7.3.4.3		N/A
	4) thin-film insulation requirements of 6.7.3.4.4		N/A
6.7.3.4.2	Moulded and potted parts		N/A
	Conductors between same two layers are separated by applicable distances of Table 8		N/A
6.7.3.4.3	Inner insulation layers of printed wiring boards		N/A
	Separated by at least by applicable distances of Table 8 between same two layers		N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		N/A
	a) thickness at least applicable distance of Table 8		N/A
	b) insulation is assembled of minimum two separate layers, each RATED for test voltage of Table 6 for BASIC INSULATION		N/A
	c) insulation is assembled of min two separate layers, where the combination is rated for 1,6 times the test voltage of Table 6		N/A
6.7.3.4.4	Thin-film insulation		N/A
	Conductors between same two layers are separated by applicable CLEARANCES and CREEPAGE DISTANCES		N/A
	REINFORCED INSULATION have adequate electric strength; one of following methods used:		N/A
	a) thickness at least applicable distance of Table 8		N/A
	b) insulation is assembled of min two separate layers, each RATED for test voltage of Table 6 for BASIC INSULATION		N/A
	c) insulation is assembled of min three separate layers, where the combination of two layers passed voltage tests with 1,6 time values of Table 6:	(see Form A.14)	N/A
	a.c. test of 6.8.3.1; or		N/A



N/A

N/A

	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
		<u>T</u>	1
	d.c. test of 6.8.3.2 for circuits stressed only by d.c. voltages		N/A
6.8	Procedure for dielectric strength tests	(see Form A.5 and A.14)	Р
6.9	Constructional requirements for protection against electric shock		Р
6.9.1	If a failure could cause a HAZARD:		Р
	a) Security of wiring connections		Р
	b) Screws securing removable covers		Р
	c) Accidental loosening		Р
	d) CREEPAGE and CLEARANCES not reduced below the values of basic insulation by loosening		Р
6.9.2	Material not to be used for safety relevant insulation:		Р
-	Easily damaged materials not used	No such material is used	Р
	Non-impregnated hydroscopic materials not used	Same as above	Р
6.9.3	Colour coding		Р
	Green-and-yellow insulation shall not be used except:	G/Y wires are only used for earthing or bonding	Р
	a) protective earth conductors;		Р
	b) protective bonding conductors;		Р
	c) potential equalization conductors;	No such terminal	N/A
	d) functional earth conductors		Р
6.10	Connection to MAINS supply source and connections between parts of equipment		Р
6.10.1	Mains supply cords	By means of appliance inlet	N/A
	RATED for maximum equipment current (see 5.1.3c)		N/A
-	Cable complies with IEC 60227 or IEC 60245		N/A
	Heat-resistant if likely to contact hot parts		N/A
	Temperature RATING (cord and inlet):		N/A
	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	By means of appliance inlet	N/A
6.10.2.1	Cord entry		N/A
	<u> </u>		h : / A

Inlet or bushing smoothly rounded; or

Insulated cord guard protruding >5D



N/A

	IEC/EN 61010-1 + IEC/EN 61	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
6.10.2.2	Cord anchorage	By means of appliance inlet	N/A
0.10.2.2	Protective earth conductor is the last to take the strain	by means of appliance inlet	N/A
	a) Cord is not clamped by direct pressure from a screw		N/A
	b) Knots are not used		N/A
	c) Cannot push the cord into the equipment to cause a HAZARD		N/A
	d) No failure of cord insulation in anchorage with metal parts		N/A
	e) Not to be loosened without a tool		N/A
	 f) Cord replacement does not cause a HAZARD and method of strain relief is clear 		N/A
	Push-pull and or torque test	(see Form A.15)	N/A
6.10.3	Plugs and connectors		Р
	MAINS supply plugs, connectors etc., conform with relevant specifications	By means of appliance inlet	Р
	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	60320 inlet is used	Р
	MAINS type plugs used only for connection to MAINS supply		Р
	Plug pins which receive a charge from an internal	(see Form A.7)	Р
	capacitor	The pin not is hazardous live 5s after disconnection of the supply.	
	Accessory MAINS socket outlets:		_
	a) Marking if accepts a standard MAINS plug (see 5.1.3e)	No mains socket outlet	N/A
	b) Input has a protective earth conductor if outlet has EARTH TERMINAL CONTACT		N/A
6.11	Disconnection from supply source	By means of appliance inlet	Р
6.11.1	Disconnects all current carrying conductors		Р
6.11.2	Exceptions	The disconnecting means will disconnect all current-carrying conductors	Р
6.11.3	Requirements according to type of equipment		Р
6.11.3.1	PERMANENTLY CONNECTED EQUIPMENT and multi-phase equipment:	Non permanently connected	N/A

Employs switch or circuit-breaker



	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
			•
	If switch or circuit-breaker is not part of the equipment, documentation requires:		_
	a) Switch or circuit-breaker to be included in building installation		N/A
	b) Suitable location easily reached		N/A
	c) Marking as disconnecting for the equipment		N/A
6.11.3.2	Single-phase cord-connected equipment		Р
	Equipment is provided with one of the following:		_
	a) Switch or circuit-breaker		N/A
	b) Appliance coupler (disconnectable without tool)	By means of appliance inlet	Р
	c) Separable plug (without locking device)		N/A
6.11.4	Disconnecting devices		Р
	Electrically close to the SUPPLY		Р
6.11.4.1	Switches and circuit-breakers	No switch is used as the disconnection device	N/A
	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
6.11.4.2	Appliance couplers and plugs		Р
	Where an appliance coupler or separable plug is used as the disconnecting device (see 6.11.3.2):		Р
	Readily identifiable and easily reached by the operator		Р
	Single-phase portable equipment cord length not more than 3 m		Р
	PROTECTIVE EARTH CONDUCTOR connected first and disconnected last	60320 inlet is used	Р

7	PROTECTION AGAINST MECHANICAL HAZARDS		Р
7.1	Equipment does not cause a mechanical HAZARD in NORMAL nor in SINGLE FAULT CONDITION	Operation not leads to a mechanical hazard in normal or single fault condition	Р
	Conformity is checked by 7.2 to 7.7		Р
7.2	Sharp edges	No sharp edges	Р
	Easily touched parts are smooth and rounded		Р
	Do not cause injury during NORMAL USE and		Р

7.3.5.2

Access normally prevented



	IEC/EN 61010-1 + IEC/EN 61	010-2-101		
Clause	Requirement + Test	Result - Remark	Verdict	
		T		
	Do not cause injury during SINGLE FAULT CONDITION		Р	
7.3	Moving parts	Moving part are enclosed	Р	
7.3.1	HAZARDS from moving parts limited to a tolerable level with the conditions specified in 7.3.2 and 7.3.5		Р	
	RISK assessment in accordance with 7.3.3 carried out		Р	
7.3.2	Exceptions	Moving part are enclosed	N/A	
	Access to HAZARDOUS moving parts permitted under following circumstances:		N/A	
	a) obviously intended to operate on parts or materials outside of the equipment	Not operate outside the equipment	N/A	
	inadvertent touching of moving parts minimized by equipment design (e .g. guards or handles)		N/A	
	b) If operator access is unavoidable outside normal use following precautions have been taken:		N/A	
	1) Access requires TOOL	Access is not possible without the use of a tool	N/A	
	2) Statement about training in the instructions		N/A	
	Warning markings on covers prohibiting access by untrained operators		N/A	
	or symbol 14 with full details in documentation		N/A	
7.3.3	RISK assessment for mechanical HAZARDS to body parts	Moving part are enclosed	N/A	
	RISK is reduced to a tolerable level by protective measures as specified in Table 12		N/A	
	Minimum protective measures:		_	
	A. Low level measures		N/A	
	B. Moderate measures		N/A	
	C. Stringent measures		N/A	
7.3.4	Limitation of force and pressure	(see Form A.16)	N/A	
	Following levels are met in normal and single fault condition:	Moving part are enclosed	N/A	
	Continuous contact pressure below 50 N / cm² with force below 150 N		N/A	
	Temporary force below 250 N for an area at least of 3 cm² for a maximum duration of 0,75 s		N/A	
7.3.5	Gap limitations between moving parts	(see Form A.16)	N/A	
7.3.5.1	Access normally allowed	Moving part are enclosed	N/A	
	If levels of 7.3.4 exceeded and body part may be inserted minimum gap as specified in Table 13 assured in NORMAL and in SINGLE FAULT CONDITION		N/A	
			1	



IEC/EN 61010-1 + IEC/EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
		·	
	Maximum gap as specified in Table 14 assured in NORMAL and in SINGLE FAULT CONDITION	Gap is less than 4mm	Р
7.4	Stability		Р
	Equipment not secured to building structure is physical stable	Equipment and assemblies of equipment is physically stable in normal use	Р
	Stability maintained after opening of drawers etc. by automatic means, or	No drawer or the likes	N/A
	warning marking requires the application of means	No means provided for ensuring of the stability	N/A
	Compliance checked by following tests as applicable:		
	a) 10° tilt test for other than handheld equipment		Р
	b) multi-directional force test for equipment exceeds height of 1 m and mass of 25 kg	No the specified equipment	N/A
	c) downward force test for floor-standing equipment	Same as above	N/A
	d) overload test with 4 times maximum load for castor or support that supports greatest load	Same as above	N/A
	e) castor or support that supports greatest load removed from equipment	Same as above	N/A
7.5	Provisions for lifting and carrying	No such parts	N/A
7.5.1	Equipment more than 18 kg :	<18kg	_
	Has means for lifting or carrying; or		N/A
	Directions in documentation		N/A
7.5.2	Handles or grips	No handle or grips	N/A
	Handles or grips withstand four times weight		N/A
7.5.3	Lifting devices and supporting parts	No lifting device	N/A
	Rated for maximum load; or		N/A
	tested with four times maximum static load		N/A
7.6	Wall mounting	The equipment is not for wall mount	N/A
	Mounting brackets withstand four times weight		N/A
7.7	Expelled parts		Р
	Equipment contains or limits the energy	Complied with the test of 4.4	Р
	Protection not removable without the aid of a tool	Tool is needed	Р
		,	
8	RESISTANCE TO MECHANICAL STRESSES		Р
8.1	Equipment does not cause a HAZARD when subjected to mechanical stresses in NORMAL USE		Р
	Normal protection level is 5 J	Tested with 5J	Р



<u> </u>			
	IEC/EN 61010-1 + IEC/EN 610)10-2-101	T
Clause	Requirement + Test	Result - Remark	Verdict
	Levels below 5 J but not less than 1 J are acceptable if all of following criteria are met:	Same as above	N/A
	a) lower level justified by RISK assessment of manufacturer		N/A
	b) equipment installed in its intended application is not easily touched		N/A
	c) only occasional access during NORMAL USE		N/A
	d) IK code in accordance to IEC 62262 marked or symbol 14 used with full information in the documentation	Tested with 5J	N/A
	For non-metallic ENCLOSURES rated below 2 °C ambient temperature value chosen for minimum rated temperature		N/A
	Impact energies between IK values, the IK code marked for nearest lower value		N/A
	Conformity is checked by performing following tests:		_
	1) static test of 8.2.1		Р
	2) impact test of 8.2.2 with 5 J except for HAND-HELD EQUIPMENT		Р
	if impact energy not selected to 5 J alternate method of IEC 62262 used		N/A
	3) drop test of 8.3.1 or 8.3.2 except for FIXED and EQUIPMENT with mass over 100 kg		Р
	Equipment rated with an impact rating of IK 08 that obviously meets the criteria	Not so rated	N/A
	After the tests inspection with following results:		
	- HAZARDOUS LIVE parts above the limits of 6.3.2 not ACCESSIBLE		Р
	- insulation pass the voltage tests of 6.8	(see Form A.24)	Р
	i) no leaks of corrosive and harmful substances		Р
	ii) ENCLOSURE shows no cracks resulting in a HAZARD	No cracks which could cause a hazard	Р
	iii) CLEARANCES not less than their permitted values	No less than their permitted values and the insulation of internal wiring remain undamaged	Р
	iv) insulation of internal wiring remains undamaged	No damage	Р
	v) PROTECTIVE BARRIERS not damaged or loosened	No damaged or loosened	Р
	vi) No moving parts exposed, except permitted by 7.3	No moving parts exposed	Р
	vii) no damage which could cause spread of fire	No damage	Р
8.2	ENCLOSURE rigidity test		Р



01	IEC/EN 61010-1 + IEC/EN 61	1	1,
Clause	Requirement + Test	Result - Remark	Verdict
0.04	Touris to a		T 5
8.2.1	Static test		P
	- 30 N with 12 mm rod to each part of ENCLOSURE		Р
	- in case of doubt test conducted at maximum RATED ambient temperature		Р
8.2.2	Impact test		Р
	Impact applied to any part of ENCLOSURE causing a HAZARD if damaged		Р
	Impact energy level and corresponding IK code:	No IK coded	N/A
	Non-metallic ENCLOSURES cooled to minimum RATED ambient temperature if below 2 °C		Р
8.3	Drop test		Р
8.3.1	Other than HAND-HELD and DIRECT-PLUG-IN EQUIPMENT	Portable equipment	Р
	Tests conducted with a drop height or angle of:	Drop from 30°	Р
8.3.2	HAND-HELD and DIRECT-PLUG-IN EQUIPMENT	Portable equipment	N/A
	Non-metallic ENCLOSURES cooled to minimum RATED ambient temperature if below 2 °C		N/A
	Drop test conducted with an height of 1 m		N/A
8.101	Transport and storage (IEC 61010-2-101)		Р
	When packed in the manufacturer's packaging, equipment shall not cause a HAZARD during NORMAL USE after transport or storage in the conditions specified by the manufacturer (see 5.1.101 and 5.4.101). (IEC 61010-2-101)		Р
		T	_
9	PROTECTION AGAINST THE SPREAD OF FIRE		Р
9.1	No spread of fire in NORMAL and SINGLE FAULT CONDITION	There is no spread of fire outside the equipment in normal or single fault condition	P
	MAINS supplied equipment meets requirements of 9.6 additionally	OCP is provided in the adapter	Р
	Conformity is checked by minimum one or a combination of the following (see Figure 11):		Р
	a) Fault test of 4.4; or	(see Form A.1 and Form A.2)	Р
	b) Application of 9.2 (eliminating or reducing the sources of ignition); or		Р
	c) Application of 9.2 (containment of fire within the equipment)		Р



	IEC/EN 61010-1 + IEC/EN 61010-2-101		
Clause	Requirement + Test	Result - Remark	Verdict
9.2	Eliminating or reducing the sources of ignition within the equipment	Considered to be reduced to a tolerable level.	Р
	a) 1) Limited-energy circuit (see 9.4); or	Not determine to Limited- energy circuit	N/A
	BASIC INSULATION provided for parts of different potential; or	(see Form A.5 and A.14) Insulation between parts at different potentials meets the requirements for basic insulation	Р
	Bridging the insulation does not cause ignition	(see Form A.2)	Р
		It can be demonstrated that bridging the insulation will not cause ignition	
	b) Surface temperature of liquids and parts (see 9.5)	No flammable liquid or parts	N/A
	c) No ignition in circuits designed to produce heat	(see Form A.2)	N/A
		No circuit designed to produce heat	
9.3	Containment of the fire within the equipment, should it occur	The equipment meets one of the following construction requirement	Р
	a) Energizing of the equipment is controlled by an operator held switch	No held switch is provided	N/A
	b) ENCLOSURE is conform with constructional requirements of 9.3.1; and	See 9.3.1	Р
	Requirements of 9.5 are met	No flammable liquid is provided	N/A
9.3.1	Constructional requirements		Р
	a) Connectors and insulating material have flammability classification V-2 or better		Р
	b) Insulated wires and cables are flame retardant (VW-1 or equivalent)		Р
	c) ENCLOSURE meets following requirements:		Р
	Bottom and sides in arc of 5 ° (see Figure 13) to non-limited circuits (9.4) meets:	No hazardous live parts in area D of Figure 13 for the side opening	Р
	i) no openings; or	No bottom opening	N/A
	ii) perforated as specified in Table 16; or		N/A
	iii) metal screen with a mesh; or		N/A
	iv) baffles as specified in Figure 12		N/A
	Material of ENCLOSURE and any baffle or flame barrier is made of:		Р
	Metal (except magnesium); or	Plastic encased	N/A
			_



	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
	Non-metallic materials have flammability classification V-1 or better	Complied with V-1 for the adapters	Р
	ENCLOSURE and any baffle or flame barrier have adequate rigidity	The enclosure have adequate rigidity	Р
9.4	Limited-energy circuit	(see Form A.19)	N/A
		Not evaluated to limited energy	
	a) Potential not more than 30 r.m.s. and 42.4 V peak, or 60 V dc		N/A
	b) Current limited by one of following means:		N/A
	1) Inherently or by impedance (see Table 17); or		N/A
	Over current protective device (see Table 18); or		N/A
	A regulating network limits also in SINGLE FAULT CONDITION (see Table 17)		N/A
	c) Is separated by at least BASIC INSULATION		N/A
	Fuse or a nonadjustable electromechanical device is used		N/A
9.5	Requirements for equipment containing or using flammable liquids	No flammable liquid is provided	N/A
	Flammable liquids contained in or specified for use with equipment do not cause spread of fire	(see Form A.20)	N/A
	RISK is reduced to a tolerable level :		N/A
	a) The temperature of surface or parts in contact with flammable liquids is 25 °C below fire point		N/A
	b) The quantity of liquid is limited		N/A
	c) Flames are contained within the equipment		N/A
	Detailed instructions for RISK-reduction provided		N/A
9.6	Overcurrent protection		Р
9.6.1	MAINS supplied equipment protected	In the power supply	Р
	BASIC INSULATION between MAINS parts of opposite polarity provided	(see Form A.14)	Р
	Devices not in the protective conductor	Not be fitted in the protective conductor	Р
	Fuses or single-pole circuit-breakers not fitted in neutral (multi-phase)	Not fitted in Neutral	Р
9.6.2	PERMANENTLY CONNECTED EQUIPMENT	Not a permanently connected equipment	N/A
	Overcurrent device:		N/A
	Fitted within the equipment; or		N/A



Clause	Requirement + Test	Result - Remark	Verdict
Ciaaco	Troquitoment : Took	Trebuit Tremain	vordiot
	Specified in manufacturer's instructions		N/A
9.6.3	Other equipment		Р
	Protection within the equipment	Provided in the adapter	Р
10	EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT		Р
10.1	Surface temperature limits for protection against burns		Р
	Easily touched surfaces within the limits in NORMAL and in SINGLE FAULT CONDITION:	(see Form A.21A)	Р
	- at an specified ambient temperature of 40°C	Not exceed the values of table 19 in normal condition, or 105°C in single fault condition (ambient 40°C)	Р
	- for equipment rated above 40 °C ambient temperature limits not exceeded raised by the difference to 40 °C	Rated 40°C	N/A
	Heated surfaces necessary for functional reasons exceeding specified values:	No functional heated surface is provided	N/A
	Are recognizable as such by appearance or function; or		N/A
	Are marked with symbol 13		N/A
	Guards are not removable without tool		N/A
10.2	Temperatures of windings		Р
	Limits not exceeded in:	(see Form A.21)	Р
	NORMAL CONDITION	Not exceed the vales of table 20	Р
	SINGLE FAULT CONDITION	Not exceed the vales of table 20	Р
10.3	Other temperature measurements		Р
	Following measurements conducted if applicable:	(see Form A.21A)	Р
	a) Value of 60 °C of field-wiring terminal box not exceeded	No field-wiring terminal box	N/A
	b) Surface of flammable liquids and parts in contact with this liquids	No flammable liquid	N/A
	c) Surface of non-metallic ENCLOSURES		Р
	d) Parts made of insulating material supporting parts connected to MAINS supply		Р
	e) Terminals carrying a current more than 0,5 A		Р
10.4	Conduct of temperature test		Р
10.4.1	Tests conducted under reference test conditions and manufacturer's instructions	(see Form A.21A)	Р
		1	



	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
10.4.2	Temperature measurement of heating equipment	No heating element is provided	N/A
	Tests conducted in test corner	(see Form A.21A)	N/A
10.4.3	Equipment intended for installation in a cabinet or wall	Table top	N/A
	Equipment built in as specified in installation	(see Form A.21A)	N/A
	instructions	Same as above	
10.5	Resistance to heat		Р
10.5.1	Integrity of CLEARANCE and CREEPAGE DISTANCES	(see Form A.13)	Р
10.5.2	Non-metallic ENCLOSURES	(see Form A.22)	Р
	Within 10 min after treatment:		_
	Equipment subjected to suitable stresses of 8.2 and 8.3 complying with criteria of 8.1	No dielectric breakdown	Р
10.5.3	Insulating material		Р
	a) Parts supporting parts connected to MAINS supply	The insulation which supports the terminals did not soften to an extent that could cause a hazard of further short circuits	Р
	b) TERMINALS carrying a current more than 0.5 A		Р
	Examination of material data; or		Р
	in case of doubt:		Р
	Ball pressure test; or		Р
	2) Vicat softening test of ISO 306		N/A
44	PROTECTION ACAINOT HAZARRO FROM FILLIDO		
11.1	PROTECTION AGAINST HAZARDS FROM FLUIDS Protection to OPERATORS and surrounding area provided by EQUIPMENT		P P
	All fluids specified by manufacturer considered		Р
11.2	Cleaning	(see Form A.24)	Р
11.3	Spillage	(see Form A.24)	Р
	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. (IEC 61010-2-101)		N/A
11.4	Overflow	(see Form A.24)	N/A
11.5	Battery electrolyte	No battery	N/A



	IEC/EN 61010-1 + IEC/EN 61	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
	Dettem electroliste legicore procesto no 11271 DD	1	NI/A
14.0	Battery electrolyte leakage presents no HAZARD	(5 101)	N/A
11.6	Specially protected equipment	(see Form A.24) No IP rating	N/A
11.7	Fluid pressure and leakage	Two ii rating	N/A
11.7.1	Maximum pressure:	(see Form A.25)	N/A
	Maximum pressure of any part does not exceed P _{RATED}	(666 / 6111 / 1126)	N/A
11.7.2	Leakage and rupture at high pressure		N/A
	Fluid containing parts subjected to hydraulic test if:	(see Form A.25)	N/A
	a) product of pressure and volume > 200 kPal; and	(666 1 61111 7 (1.26)	N/A
	b) pressure > 50 kPa		N/A
	Parts of refrigerating systems meets pressure-related requirements of IEC 60335-24 or IEC 60335-24	No refrigeration	N/A
11.7.3	Leakage from low-pressure parts	(see Form A.25)	N/A
11.7.4	Overpressure safety device		N/A
	Does not operate in NORMAL USE		N/A
	a) Connected as close as possible to parts intended to be protected		N/A
	b) Easy access for inspection, maintenance and repair		N/A
	c) Adjustment only with TOOL		N/A
	d) No discharge towards person		N/A
	e) No HAZARD from deposit of discharged material		N/A
	f) Adequate discharge capacity		N/A
	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		N/A
12.1	Equipment provides protection		N/A
12.2	Equipment producing ionizing radiation		N/A
12.2.1	Ionizing radiation	(see Form A.26)	N/A
12.2.1.1	Equipment meets the following requirements:	Not producing ionizing radiation	N/A
	a) if intended to emit radiation meets requirements of 12.2.1.2; or		N/A
	tested, classified and marked in accordance to IEC 60405		N/A



	IEC/EN 61010-1 + IEC/EN 610	T	
Clause	Requirement + Test	Result - Remark	Verdict
		T	
	b) if only emits stray radiation meets requirements of 12.2.1.3		N/A
12.2.1.2	Equipment intended to emit radiation	No ionizing radiation	N/A
	Effective dose rate of radiation measured:		N/A
	If dose rate exceeds 5 µSv/h marked with the following:		N/A
	a) Symbol 17 (ISO 361)		N/A
	b) Abbreviations of the radionuclides:		N/A
	c) With maximum dose at 1 m; or:		N/A
	with dose rate value between 1 μSv/h and 5 μSv/h in m		N/A
12.2.1.3	Equipment not intended to emit radiation		N/A
	Limit for unintended stray radiation of 1 µSv/h at any easily reached point kept:		N/A
12.2.2	Accelerated electrons	No accelerated electrons	N/A
	Compartments opened only by the use of a TOOL		N/A
12.3	Ultraviolet (UV) radiation	No ultra-violet radiation	N/A
	No unintentional HAZARDOUS escape of UV radiation:		_
	- checked by inspection; and		N/A
	- evaluation of RISK assessment documentation		N/A
12.4	Micro-wave radiation	No micro-wave generator	N/A
	Power density does not exceed 10 W/m ² :		N/A
12.5	Sonic and ultrasonic pressure	No such pressure	N/A
12.5.1	Sound level	(see Form A.27)	N/A
	No HAZARDOUS sound emission		N/A
	Maximum sound pressure level measured and calculated for maximum sound power level as specified in ISO 3746 or ISO 9614-1		N/A
	Instruction describes measures for protection		N/A
12.5.2	Ultrasonic pressure	(see Form A.27)	N/A
	Equipment not intended to emit ultrasound does not exceed limit of 110 dB between 20 kHz and 100 kHz	No ultrasonic pressure	N/A
	Equipment intended to emit ultrasound:		N/A
	Outside useful beam does not exceed limit of 110 dB between 20 kHz and 100 kHz		N/A
	If inside useful beam above values exceeded:		N/A
	Marked with Symbol 14 of Table 1		N/A
	and following information in the documentation:		_



	IEC/EN 61010-1 + IEC/EN 61010-2-101				
Clause	Requirement + Test	Result - Remark	Verdict		
		1	N1/A		
	a) dimensions of useful beam		N/A		
	b) area where ultrasonic pressure exceed 110 dB		N/A		
	c) maximum sound pressure inside beam area		N/A		
12.6	Laser sources	No laser source	N/A		
	Equipment meets requirements of IEC 60825-1		N/A		
		T			
13	PROTECTION AGAINST LIBERATED GASES, EXPLOSION AND IMPLOSION		N/A		
13.1	Poisonous and injurious gases	No such gases	N/A		
	No poisonous or injurious gases or substances liberated in NORMAL CONDITION		N/A		
	Attached data/test reports demonstrate conformity		N/A		
	Equipment shall not liberate dangerous amounts of poisonous or injurious gases or substances in NORMAL CONDITION or in SINGLE FAULT CONDITION. (IEC 61010-2-101)		N/A		
	If potentially hazardous substances are used in the equipment, 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. (IEC 61010-2-101)		N/A		
13.2	Explosion and implosion	Components not likely to explode in overheated	N/A		
13.2.1	Components		N/A		
	Components liable to explode:		_		
	Pressure release device provided; or		N/A		
	Apparatus incorporates operator protection (see also 7.7)		N/A		
	Pressure release device:		_		
	Discharge without danger		N/A		
	Cannot be obstructed		N/A		
13.2.2	Batteries and battery charging	(see Form A.28)	N/A		
	If explosion or fire HAZARD could occur:	No battery	_		
	Protection incorporated in the equipment; or		N/A		
	Instructions specify batteries with built-in protection		N/A		
	In case of wrong type of battery used:		_		
	No hazard; or		N/A		
	Warning by marking and within instructions		N/A		



	IEO/EN 04040 4 - IEO/EN 04	040.0.404	
	IEC/EN 61010-1 + IEC/EN 610	1	T
Clause	Requirement + Test	Result - Remark	Verdict
	Equipment with means to charge rechargeable batteries:		_
	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		N/A
	Single component failure		N/A
	Polarity reversal test		N/A
13.2.3	Implosion of cathode ray tubes	No cathode ray tubes is used	N/A
	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
14	COMPONENTS AND SUBASSEMBLIES		Р
14.1	Where safety is involved, components and subassemblies meet relevant requirements	Components used in accordance with their specified ratings	Р
14.2	Motors		Р
14.2.1	Motor temperatures		Р
	Does not present a HAZARD when stopped or prevented from starting; or	(see Form A.21)	Р
	Protected by over-temperature or thermal protection device conform with 14.3	No such parts	N/A
14.2.2	Series excitation motors		N/A
	Connected direct to device, if over-speeding causes a HAZARD		N/A
14.3	Overtemperature protection devices	Protected by approved unit	N/A
	Devices operating in a SINGLE FAULT CONDITION	(see Form A.29)	N/A
	a) Reliable function is ensured		N/A
	b) RATED to interrupt maximum current and voltage		N/A
	c) Does not operate in NORMAL USE		N/A
	If self-resetting device used to prevent a HAZARD, protected part requires intervention before restarting		N/A



	IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
14.4	Fuse holders		Р
	No access to HAZARDOUS LIVE parts		Р
14.5	MAINS voltage selecting devices	No such parts	N/A
	Accidental change not possible		N/A
14.6	MAINS transformers tested outside equipment		N/A
14.7	Printed circuit boards		Р
	Data shows conformity with V-1 of IEC 60695-11-10 or better; or	Printed circuit boards of material with a flammability classification of FV-0 min. of IEC60707 or UL94	Р
	Test shows conformity with V-1 of IEC 60695-11-10 or better	(see Form A.18)	N/A
	Not applicable for printed wiring boards with limited- energy circuits (9.4)		N/A
14.8	Circuits or components used as transient overvoltage limiting devices	No such parts	N/A
	Test conducted between each pair of MAINS SUPPLY TERMINALS	(see Form A.30)	N/A
	No HAZARD resulting from rupture or overheating of the component:		N/A
	- no bridging of safety relevant insulation		N/A
	- no heat to other parts above the self-ignition points		N/A
			Г
15	PROTECTION BY INTERLOCKS		N/A
15.1	Interlocks are designed to remove a HAZARD before OPERATOR exposed	No interlock	N/A
15.2	Prevention of reactivation		N/A
15.3	Reliability		N/A
	Single fault unlikely to occur; or		N/A
	Cannot cause a HAZARD		N/A
16	HAZARDS RESULTING FROM APPLICATION		Р
16.1	REASONABLY FORESEEABLE MISUSE		Р
	No HAZARDS arising from settings not intended and not described in the instructions		Р
	Other cases of REASONABLY FORESEEABLE MISUSE addressed by RISK assessment		Р
16.2	Ergonomic aspects		Р



	IEC/EN 61010-1 + IEC/EN 61	010-2-101	
Clause	Requirement + Test	Result - Remark	Verdict
	Factors giving rise to a HAZARD the RISK assessment is reflecting those aspects:		Р
	a) limitation of body dimensions	Not a big equipment	Р
	b) displays and indicators	Readily to read	Р
	c) accessibility and conventions of controls	Readily to access	Р
	d) arrangement of TERMINALS		Р
		1	
17	RISK assessment		N/A
	RISK assessment conducted, if HAZARD might arise and not covered by Clauses 6 to 16	No hazards other than addressed in Cl. 6 to 16	N/A
	TOLERABLE RISK achieved by iterative documented process covering the following:		N/A
	a) RISK analysis		N/A
	Identifies HAZARDS and estimates RISK		N/A
	b) RISK evaluation		N/A
	Plan to judge acceptability of resulting RISK level based on the estimated severity and likelihood of a RISK		N/A
	c) RISK reduction		N/A
	Initial RISK reduced by counter measures;		N/A
	Repeated RISK evaluation without new RISKS introduced		N/A
	RISKS remaining after RISK assessment addressed in instructions to RESPONSIBLE BODY:		N/A
	Information contained how to mitigate these RISKS		N/A
	Following principles in methods of RISK reduction applied by manufacturer in given order:		N/A
	1) RISKS eliminated or reduced as far as possible		N/A
	Protective measures taken for RISKS that cannot be eliminated		N/A
	User information about residual RISK due to any defect of the protective measures		N/A
	Indication of particular training is required		N/A
	Specification of the need for personal protective equipment		N/A
	Conformity checked by evaluation of the RISK assessment documentation		N/A

Page 40 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict

IEC 61010-1 + EN61010-2-101				
Clause	Requirement — Test		Result — Remark	Verdict

4.4.2	TABLE: Summary of SINGLE FAULT COND		Form A.1 P			
Subclause	Title	Does not Carried Comme apply out		Comments		
4.4.2.1	SINGLE FAULT CONDITIONS not covered by 4.4.2.2 to 4.4.2.14		√	see Form A.2		
4.4.2.2	PROTECTIVE IMPEDANCE	✓		No protective impedance	е	
4.4.2.3	PROTECTIVE CONDUCTOR		✓	see Form A.2		
4.4.2.4	Equipment or parts for short-term or intermittent operation	✓		Continuous operate		
4.4.2.5	Motors	✓		No motor		
	- stopped while fully energized	✓				
	- prevented from starting	✓				
	- one phase interrupted (multi-phase)	✓		Not multi-phase		
4.4.2.6	Capacitors	✓		No motor capacitor		
4.4.2.7	MAINS transformers Attach drawing of MAINS transformers showing all protective devices	✓		Approved power unit		
4.4.2.8	Outputs	✓		No output		
4.4.2.9	Equipment for more than one supply	✓		Single supply		
4.4.2.10	Cooling		✓	see Form A.2		
	- air holes closed	✓		No filters		
	– fans stopped		✓	see Form A.2		
	- coolant stopped	✓		No coolant		
	- loss of cooling liquid	✓		No cooling liquid		
4.4.2.11	Heating devices	✓		No heating device		
	– timer overridden	✓				
	- temperature controller overridden	✓				
4.4.2.12	Insulation between circuits and parts	✓		Approved power unit		
4.4.2.13	Interlocks	✓		No interlock		
4.4.2.14	Voltage selectors	✓		No voltage selectors		
List below a	all SINGLE FAULT CONDITIONS not covered by	4.4.2.2 to	4.4.2.14:			
					-	
0	tary information:					

Supplementary information: (see Form A.2 for details of tests)





IEC/EN 61010-1 + IEC/EN 61010-2-101				
Clause	Requirement — Test	Result — Remark	Verdict	

Page 41 of 66

4.4	TABLE: Te	esting in SINGLE FAULT CONDITION - Results	Form A.2				
Test subclause	Fault No.	Fault description	Td 4.4.3 (NOTE)	How was test terminated Comments	Meets 4.4.4		
4.4.2.1	1	Wrong setting on functional knob	30min	No hazards occurred and no accessible conductive parts have become hazardous live	Р		
4.4.2.3	2	Open Protective conductor	1Hr	No hazards and no accessible voltage over the limit	Р		
4.4.2.7	3	Short output of transformer (N2)	2Hr	Until thermal steady and no accessible conductive parts have become hazardous live and no over temperature limits of Table 20.	Р		
4.4.2.10	4	Locked fan (top)	60min	No accessible conductive parts have become hazardous live and no over temperature limits of Table 20.	Р		
4.4.2.10	5	Locked fan (rear, right)	60min	No accessible conductive parts have become hazardous live and no over temperature limits of Table 20.	Р		
4.4.2.10	6	Locked fan (rear, left)	60min	No accessible conductive parts have become hazardous live and no over temperature limits of Table 20.	Р		
4.4.2.12	7	Short Capacitor (C61)	2Hr	Until thermal steady and no accessible conductive parts have become hazardous live and no over temperature limits of Table 20.	Р		

NOTE Td = Test duration in hh:mm:ss
Record dielectric strength test on Form A.14 and temperature tests on Form A.21.
Record in the comments column for each test whether carried out during or after SINGLE FAULT CONDITION.

Supplementary information:

Page 42 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101						
Clause	Requirement + Test		Result - Remark	Verdict		

5.1.3c)	TABLE: MAINS supply			Form A.3	Р
	Marked rating:	100-240	V		_
	Phase:	1	~		_
	Frequency:	50/60	Hz		_
	Current:	1.5-0.8	Α		_
	Power:		W		_
	Power:		VA		_

Test	Voltage	Power in	Current	Power in	Comments
No.	V	W	mA	VA	
1	90	65.3	1.17	105.3	Sample is operated with all parameters set at maximum setting
2	100	64.8	1.09	109	Sample is operated with all parameters set at maximum setting
3	120	64.7	0.95	114	Sample is operated with all parameters set at maximum setting
4	230	67.3	0.64	147.2	Sample is operated with all parameters set at maximum setting
5	240	67.7	0.63	151.2	Sample is operated with all parameters set at maximum setting
6	264	68.8	0.60	158.4	Sample is operated with all parameters set at maximum setting

Note – Measurements are only required for marked ratings.

Supplementary information:

Page 43 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101					
Clause	Requirement + Test		Result - Remark	Verdict	

5.3	TABLE: Dur	ability of markings		Form A.4	Ρ		
	Markin	g method (see NO	ΓE)		Agent		
1) Adhesive	e label			A Water			
2) Ink printe	ed			B Isopropyl alcoh	nol 70%		
3) Laser ma	arked			C (specify agent))		
4) Film coa	ted (plastic foi	control panel)		D (specify agent))		
5) Imprinted	d on plastic (m	oulded in)		E (specify agent))		
		de print method, label m face to which marking is		, ,			
	Marking loc	ation	Marking method (see above)				
Identificatio	n (5.1.2)		1				
Mains supp	ly (5.1.3)		1				
Fuses (5.1.	4)		1				
terminals a	and operating of	devices (5.1.5.2)	2				
Switches a	nd circuit brea	kers (5.1.6)	2				
Double/rein	forced equipm	nent (5.1.7)	N/A				
Field wiring	Terminal box	es (5.1.8)	N/A				
Warning ma	arking (5.2)		2				
Battery cha	rging (13.2.2)		N/A				
Method	Test agent	Remains legible	Label loose	Curled edges	Comments	3	
		Verdict	Verdict	Verdict			
1	A & B	Yes	No	No	Р		
2	A & B	Yes	N/A N/A P				



IEC/EN 61010-1 + IEC/EN 61010-2-101					
Clause	Requirement + Test		Result - Remark	Verdict	

TABLE: Protection against electric shock - Block diagram of systemForm A.5	Р
43 6 4	
Ø + 3	
↑ B	
- Comment	
(±) L*	

Dallutian	doaroo	2
Pollution	degree	_

Overvoltage category..... II

Location or	Insulation type	Maximum working			CLEARANCE (NOTE 3)	Test voltage	Comments			
description	(NOTE 1)	voltage (NOTE 2)	PWB mm	CTI	Other mm	СТІ	mm	(NOTE 2) V		
Primary to accessible parts	ВІ	240Vac	1.5	-	3.0	-	1.5	1500Vac	Pass	
Primary to SELV	RI	240Vac	3.0	-	6.0	-	3.0	3000Vac	Pass	

NOTE 1 – Type of insulation:

NOTE 2 - Types of voltage

NOTE 3 - INSTALLATION CATEGORIES

BI = BASIC INSULATION

Peak impulse test voltage (pulse)

(OVERVOLTAGE CATEGORIES)

DI = DOUBLE INSULATION

r.m.s.

or POLLUTION DEGREES which differ from

PI = PROTECTIVE IMPEDANCE

d.c.

these should be shown under "Comments".

RI = Reinforced INSULATION

peak

SI = Supplementary Insulation

Supplementary Information:

Page 45 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101						
Clause	Requirement + Test		Result - Remark	Verdict		

6.2	TABLE: List of ACCESSIBLE parts			Form A.6	Р			
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	V, R, J and P3						
2	Connector	V, R, J and P3						
NOTE 1 - Test fingers and pins are to be applied without force unless a force is specified (see 6.2.2)								
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 6.4).
- NOTE 4 Capacitor test may be required (see Form A.7).

NOTE 5 - The determination methods are: V = visual; R = rigid test finger; J = jointed test finger; P3 = pin 3 mm diameter; P4 = pin 4 mm diameter.

Supplementary information:



Page 46 of 66



	IEC/EN 61010-1 + IEC/EN 61010-2-101						
Clause	Requirement — Test	Result — Remark	Verdict				

6	TABLE: \	Values in N	NORMAL CO	NDITION									Form A.7	Р
6.1.2	Exception	ns						11.2 Cleaning and decontamination						_
6.3.1	Values in	NORMAL CO	ONDITION (see NOTE 1)			11.3 Spillage						_
6.6.2	Terminals	for extern	al circuit					11.4 Overflow					_	
6.10.3	Plugs and	Plugs and connections											_	
Item		Voltage			Current			Capacitance 10 s / 5 s test (NOTE)			Comments			
(see Form A.6)	V r.m.s.	V peak	V d.c.	Test circuit A1/A2/A3	mA r.m.s.	mA peak	mA d.c.	μС	mJ	V	μC	mJ		
1	<2	<2	<0.1										Mains switch: ON	
2	<2	<2	<0.1										Mains switch: ON	

NOTE – A 10 s test is specified in 6.1.2 a) b). A 5 s test is specified in 6.10.3. The capacitance level versus voltage below the limits given from figure 3 of IEC 61010-1.





	IEC/EN 61010-1 + IEC/EN 61010-2-101							
Clause	Requirement — Test	Result — Remark	Verdict					

6.3.2	TABLE: Values in SIN	IGLE FAUL	T CONDITION	ON								Form A.8	Р
Item	Subclause and	Voltage		Transient (see NOTE)		Current				Capacitance			
(see Form A.6)	fault No. (see Form A.2)	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.	μF (see NOTE)	Comments	
1	1 to 5	<2	<2	<0.1									
2	1 to 5	<2	<2	<0.1									

NOTE – Transient voltages must be below the limits given from Figure 2 and the capacitance below the limits from figure 3 of IEC 61010-1.

Page 48 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101								
Clause	Requirement + Test		Result - Remark	Verdict				

6.5.2.2	TABLE: Cross-sectiona	ABLE: Cross-sectional area of bonding conductors Form A.9						
Con	DUCTOR LOCATION	CROSS-SECTIONAL AREA mm²		VERDICT				
GND pin of i	nlet to enclosure	0.8mm ²		Р				

6.5.2.4	TABLE: Bonding impedar	ABLE: Bonding impedance of plug connected equipment Form A.10								
ACCES	SSIBLE part under test	Test current A	Voltage attained after 1 min V (NOTE 2)	Calculated resistance (Maximum 0,1 or 0,2 Ω) Ω (NOTE 1)	Verdict					
Enclosure		25A	0.25	0.01Ω	Р					

NOTE 1 – For none-detachable power cord the impedance between protective conductor plug pin of MAINS cord and each ACCESSIBLE part shall not exceed 0,2 Ohm.

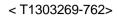
Supplementary information:

6.5.2.5 TABLE: Bonding impedance of permanently connected equipment								
ACCESSIBLE part	under test	Test current A	Voltage attained after 1 min (maximum 10 V) V	Verdict				

Supplementary information:

6.5.2.6	TABLE: Transformer P	ROTECIVE BON	NDING screen	Form A.11	N/A
ACCES	SIBLE part under test	Test current (see NOTE) A	Voltage attained after 1 min (maximum 10 V) V	Calculated resistance (maximum 0,1 Ω)	Verdict

NOTE – Test current must be twice the value of the overcurrent protection means of the winding. Test is specified in 6.5.2.6 a) or b).

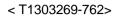


Page 49 of 66



	IEC/EN 61010-1 + IEC/EN 61010-2-101							
Clause	Requirement — Test		Result — Remark		Verdict			

5.4	TABLE: protective in	npedance								Form A.12	N/A
				A sinç	gle compo	nent					
	Component	Location		Measured		Calculated	Ra	Rated		Comments	
			Wo vo		Current	Power dissipation W	Working voltage V	Power dissipation W			
				A combina	tion of cor	nponents					
	Component			Location				Comments			
IOTE – A	PROTECTIVE IMPEDANCE shall not	be a single electronic d	levice that em	nploys electron o	conduction in	a vacuum, gas	or semicondu	ctor.			
Supplem	entary information: No P	rotective impedan	се								



Page 50 of 66



	IEC/EN 61010-1 + IEC/EN 61010-2-101							
Clause	Requirement — Test	Result — Remark	Verdict					

6.7	TABLE: C	LEARANCES	and CRE	EPAGE di	stances								Form A.13	Р
6.4.2	Enclosuri	ES and prote	ective ba	rriers				8	Mechanic	al resistand	ce to shock	and imp	pact	_
6.4.4	Impedance	9						9.6.1	Overcurrent protection basic insulation between MAINS parts				between MAINS parts	_
6.5.4	Protective	impedance						10.5.1	Integrity of CLEARANCES and CREEPAGE distances				distances	_
6.5.6	Current- or	r voltage-lim	niting dev	rice)									_
Location		sured - 6.7)	Verdict		Mechanical tests (note) Test at max. Measured after test Verdict Comm				Comments					
(see Form A.5)	CREEPAGE DISTANCE	CLEARANCE		Applied force		gidity 3.2)		Prop 8.3)		CREEPAGE DISTANCE	CLEARANCE			
	mm	mm		J	Static (8.2.1)	Impact (8.2.2)	Normal (8.3.1)	Hand-held, Plug-in	(10.5.1)	mm	mm			
Primary to accessible parts	>3	>1.5	Р	5	√	✓	√		40	>3	>1.5	Р		
Primary to Secondary	>6	>3	Р	5	✓	√	√		40	>6	>3	Р		

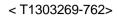
NOTE – Refer to Form A.14 for dielectric strength tests following the above tests.



IEC/EN 61010-1 + IEC/EN 61010-2-101							
Clause	Requirement + Test		Result - Remark	Verdict			

6.8	TABLE: Dielec	tric strength tests		Form A.14	Р					
4.4.4.1 b)	Conformity after	r application of SINGLE F	AULT CONDITIONS ¹							
6.4	Primary means	of protection ²								
6.6	Connections to	external circuits								
6.7.	Insulation requi	rements² (see Annex K)								
6.10.2	Fitting of non-de	Fitting of non-detachable MAINS supply cords								
9.2 a) 2)	Eliminating or re	Eliminating or reducing the sources of ignition within the equipment								
9.4 c)	Limited-energy	Limited-energy circuit								
9.6.1	Overcurrent protection basic insulation between MAINS - parts									
1 Record the fau	ult, test or treatment a	applied before the dielectric st	trength test. ² Humidity pre	conditioning required.						
	Test site altitude	ə	:	1-500 m	_					
	Test voltage con	rrection factor (see Tab	le 10):	1.16						
references f	ation or from Forms A.2 nd A.5	Working voltage V	Test voltage r.m.s./peak/d.cV	Comments	Verdict					
L/N to Earth		240	1680Vac	No break down	Р					
L/N to acces	sible parts	240	3480Vac	No break down	Р					
L/N to secon	ndary	240	3480Vac	No break down	Р					

6.10.2	TABLE: Core	d anchora	age				Form A.15 N/A
Location		Mass Pull kg N		Verdict	Torque Nm	Verdict	Comment
Dielectric stre	ength test for 1	min. (6.8.	3.1)	:		V r.m	.s.
Supplementa	ry information:						·
	-						



Page 52 of 66



	IEC/EN 61010-1 + IEC/EN 61010-2-101						
Clause	Requirement — Test	Result — Remark	Verdict				

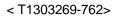
7.	TABLE	: Protection agair	nst mechanica	HAZAF	RDS										F	orm A.16	Р
7.3.4	Limitation	on of force and pre	ssure												_		
7.3.5	Gap lim	itations between m	noving parts			4mm								_			
	Clause 7.3.4			Clause 7.3.5.1				Clause 7.3.5.2		3.5.2							
	Continuous Temporary				Minimum gaps (mm)				Maximum gaps (mm)								
Part / Loc	•		Head 300	Leg 180	Foot 120	Toes 50	Arm 120	Hand 100	Finger 25	Head 120	Foot 35	Finger 4	Verdict	Comr	nents		
Enclosure		-	-	-	-	-	-	-	-	-	-	-	-	2mm	Р		

Page 53 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101									
Clause	Requirement + Test		Result - Remark	Verdict					

9.3.2	TABLE: Constructional red	quirements		For	m A.18	N/A
14.7	Printed circuit boards					
	•					
Material t	ested	:				_
Generic r	name	:				_
Material r	manufacturer	:				_
		·				
Туре		:				_
						_
Condition	ning details	:				_
					•	
			Sample 1	Sample 2	San	nple 3
Thicknes	s of specimen	mm				
Duration	of flaming after first Application	s				
	of flaming plus glowing ond application	s				
Specimer	n burns to holding clamp	Yes/No				
Cotton igi	nited	Yes/No				
Sample re	esult	Pass/Fail				
	entary information: Printed circ of IEC60707 or UL94 is used	uit boards of	material with a f	lammability clas	sification	on of



Page 54 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101						
Clause	Requirement — Test	Result — Remark	Verdict			

9.4	TABLE: Lim	nited-energy circuit						Form A.19	N/A
	Item	9.4 a)	9.4 b) Current and power limitation			9.4 c)	Decision		
or Location		Maximum potential in circuit voltage r.m.s./d.c.	Maximum available available protection after 120 s A VA A		Circuit separation	Yes/No	Comments		

Supplementary information: Not evaluated

9.5	TABLE: Requirements for equipment containing or using flammable liquids Form A.20						
	Type of liquid	9.5 Flammable liquids					
		b) Quantity	c) Containment				

Supplementary information: No flammable liquid

Page 55 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101								
Clause	Requirement + Test		Result - Remark	Verdict				

10.	TABLE : Temperature Measurements Form A.21A							Р
10.1	Surface temperature limits - NORMAL CONDITION and / or SINGLE FAULT CONDITION							
10.2	Temperature of windings- NORMAL CONDITION and / or SINGLE FAULT CONDITION							
10.3	Other ten	nperature measur	em	ents				
Operating c	onditions:	Max setting						
Frequency.	:	50/50 Hz	Т	est room ambi	ent temperat	ture (ta):	23.7/23.6 °C	;
Voltage	:	90/264 V	Т	est duration		:	5 h 10 m	in
Part / Location			<i>t</i> ₀ °(<i>t</i> _{max} °C	Verdict	Comment s	
				90V	264V			
Appliance Ir	nlet (with E	mi filter)		47.5	48.6	85	Р	
Transforme	r coil (pow	er board 1)		78.1	83.0	105	Р	
Transforme	r coil (pow	er board 2)		53.2	58.1	105	Р	
Transforme	r coil (pow	er board 3)		50.3	55.0	105	Р	
Transforme	r coil (pow	er board 4)		44.4	45.8	105	Р	
PCB (under	Q3)			48.7	50.4	105	Р	
PCB (under	C6)			49.4	51.0	105	Р	
Case (Temp	perature co	ontonrller)		53.6	56.5	85	Р	
Enclosure (Тор)			44.1	44.5	65	Р	
Enclosure (Side)			43.2	43.6	65	Р	
PCB (Heate	er)			46.6	46.6	105	Р	
Appliance				42.1	42.3	85	Р	
T1 coil				41.8	42.1	105	Р	
C6 body				41.9	42.3	105	Р	
Enclosure (Top)			41.7	42.0	65	Р		
Enclosure (Side)			46.4	46.5	65	Р		
Ambient	Ambient			40.0	40.0		Р	
Supplement	tary inform	ation:						

Page 56 of 66



		IEC/EN 61010-1 + IEC/EN 610)10-2-101	
Clause	Requirement + Test		Result - Remark	Verdict

	Т			
10.5.2	TABLE: Resistance to heat of non-me	tallic ENCLO	SURES Form A.22	Р
	Non operative treatment	:	[✓]	-
	Empty ENCLOSURE	[]	-	
	Operative treatment	:	[]	-
	Temperature during tests	70°C	_	
	ENCLOSURE samples tested were	All set		
	Description		Comments	Verdict
	Whole set	N	o deform or discolour	Р
NOTE – Within	n 10 minutes of the end of treatment suitable tests in	acc. to 8.2 and	8.3 must be conducted and pass criter	ia of 8.1.
Supplemen	tary information:			

10.5.3	TABLE: Ins	ulating Mate	erials		Form A.23	N/A
10.5.3 1)	Ball pressur	e test				
	Max. allowe	d impression	diameter:	2 mm		_
Part T		rest temperature Imp		ression Diameter (mm)	Verdict	
Supplemen	tary information	on:				
10.5.3 2)	Vicat soften	ing test (ISO	306)			N/A
	Part		Vicat softening temperature °C		Thickness of sample (mm)	Verdict
Supplemen	tary information	on:				

Page 57 of 66



	IEC/EN 61010-1 + IEC/EN 61010-2-101				
Clause	Requirement — Test	Result — Remark	Verdict		

8	TABLE: Mechanical resistance to shock and impact	Form A.24	Р
11	Protection against HAZARDS from fluids		

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 (8.2.1) 30 N	Impact (8.2.2)	Normal (8.3.1)	Handheld Plug-in	Cleaning (11.2)	Spillage (11.3)	Overflow (11.4)	IEC 60529 (11.6)	Working voltage V	Test voltage V	Verdict	Comments
TOP Enclosure	Pass	Pass	Pass		Pass				240V	3480V	Р	Plastic parts
Side Enclosure	Pass	Pass	Pass	_	Pass	_	-	_	240V	3480V	Р	Plastic parts
Rear Enclosure	Pass	Pass	Pass	_	Pass	_		_	240V	3480V	Р	Plastic parts
Front Enclosure	Pass	Pass	Pass	_	Pass	_	_	_	240V	3480V	Р	Plastic parts

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



		IEC/EN 61010-1 + IEC/EN 610	010-2-101	
Clause	Requirement + Test		Result - Remark	Verdict

11.7.2	TABLE:	TABLE: Leakage and rupture at high pressure						Form A.25	N/A
Part		Maximum permissible working pressure	Test pressure	Leakag	je	Deformation	Burst	Comme	nts
		Мра	MPa	Yes / N	О	Yes / No	Yes / No		
NOTE – see a	also Annex G	with requirement	s for USA an	d Canada.					
Supplement	tary inforn	nation:							
11.7.3	Leakage	from low-pre	essure pa	rts					N/A
Part Test Leakage				Leakage Yes / No			Comme	ents	
Supplement	Supplementary information:								

12.2.1	TABLE: Ionizing	radiation		Form A 26	N/A	
12.2.1.2	Equipment intende	ed to emit radiation				
Loca	ations tested	Measured values Verdict µSv/h		Comments		
Supplemen	ntary information:		1	1		
12.2.1.3	Equipment not inte	ended to emit radiation			N/A	
	Max. allowed effect	tive dose rate at 100 m	m:	1 μSv/h	_	
Loca	ations tested	Measured values μSv/h	Verdict	Comments		
Supplemen	Supplementary information:					

Page 59 of 66



		IEC/EN 61010-1 + IEC/EN 610)10-2-101	
Clause	Requirement + Test		Result - Remark	Verdict

12.5.1	TABLE: Sound level			Form A.27	N/A
l	ocations tested		ed values BA	Calculated maximum sound pressure level	
	rator's normal position bystanders' positions				
a)					
b)					
c)					
d)					
e)					
f)					
Suppleme	ntary information:				
12.5.2	Ultrasonic pressure				N/A
L	ocations tested	Measure	ed values	Comments	
		dB	kHz		
At operato	r's normal position				
At 1 m fro	m the ENCLOSURE				
a)					
b)					
c)					
d)					
e)					
NOTE – No applicable from	limit is specified at present, but a equencies between 20 kHz and	a limit of 110 of 100 kHz.	dB above the	reference pressure value of 20 μPa is under consider	ation for
Suppleme	ntary information:				

Page 60 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101					
Clause	Requirement + Test		Result - Remark	Verdict	

Battery load and charging circuit diagram: Battery type	13.2.2	TABLE: Batteries			Form A.28	N/A		
Battery manufacturer/model/catalogue No		Battery load and charging circuit diag	ıram:					
Battery ratings		Battery type						
Reverse polarity instalment test Single component failures Component Open circuit Short circuit		Battery manufacturer/model/catalogu	e No:			_		
Single component failures Component Open circuit Short circuit		Battery ratings:						
Component Open circuit Short circuit		Reverse polarity instalment test						
		Single component failures		Ve	erdict			
		Component	Open o	circuit	Short circ	uit		
	•							
Supplementary information: No battery is used								

14.1	TABLE: co	mponents			Р
object/part	No.	manufac- turer/trademark	type/model	technical data	mark(s) of conformity ¹)
РСВ		Interchangeable	Interchangeable	105°C min, V-1 min	UL
Inlet (with	fuse holder)	LCR	083.01001.00	250V,10A	VDE
Fuse (2 pr	ovided)	Interchangeable	Interchangeable	250V, F6.3A	VDE or Semko
Enclosure		Chi Mei	PA-764A	V-0, 85°C	UL
Process controller		Delta	DTB4848	-	UL, DoC
Power Sw	itch	Everel	82.XX.8	250V, 16A, 4P	ENEC
(3 provided)					
Power sup	ply unit	Mean Well	NES-75-12	I/P:100-240V, 50-60Hz, 1.5A	TUV
(3 provided)				O/P: 12V/6.2A	
Fan		Evercool	EC7015L12CA	12Vdc, 0.14A, 1.68W	UL
- alterna	ate	Evercool	EC7010L12X	12Vdc, 0.18A, 2.16W	UL
- alterna	ate	Evercool	EC8015M12X	12Vdc, 0.16A, 1.92W	UL

Page 61 of 66



IEC/EN 61010-1 + IEC/EN 61010-2-101					
Clause	Requirement + Test		Result - Remark	Verdict	

14.3	TABLE: Overtem	Form A.29	N/A				
Reliability test							
Component		Type (NOTE)	Verdict		Comments		
NOTE:		•	•				
NSR = non-se	lf-resetting (10 times	s)					
NR = non-rese	NR = non-resetting (1 time)						
SR = self-resetting (200 times)							
Supplemen	Supplementary information:						

< T1303269-762>

Page 62 of 66



	IEC/EN 6	61010-1 + IEC/EN 61010-2-101	
Clause	Requirement — Test	Result — Remark	Verdict

14.8	TABLE: Trans	ient overvolt	age limiting de	vices							Form A.30	N/A
Componer	nt / Designation	Overvoltage Category	MAINS voltage V rms	Test voltage V	t _m °C	t _c °C	t _{max} °C	Rupture Yes / No	Circuit breaker tripped	Verdict	Comments	S
Test room a	ambient tempera	ture:	°C									
NOTE - t _m = measured temperature t _c = t _m corrected (t _m -t _s + 40 °C or max. RATED ambient) t _{max} = maximum permitted temperature Conformity is checked by applying 5 positive and 5 negative impulses with the applicable impulse withstand voltage, spaced up to 1 min apart, from a hybrid impulse generator (see IEC 61180-1). Supplementary information:												



PHOTOS:

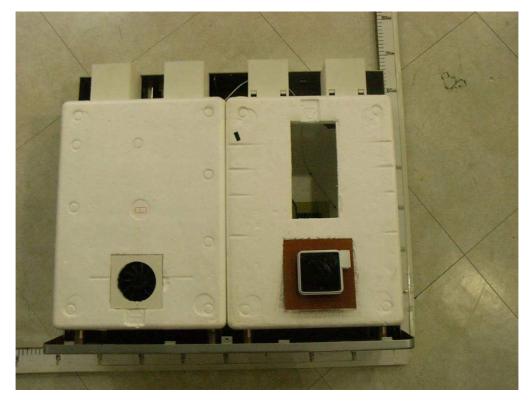






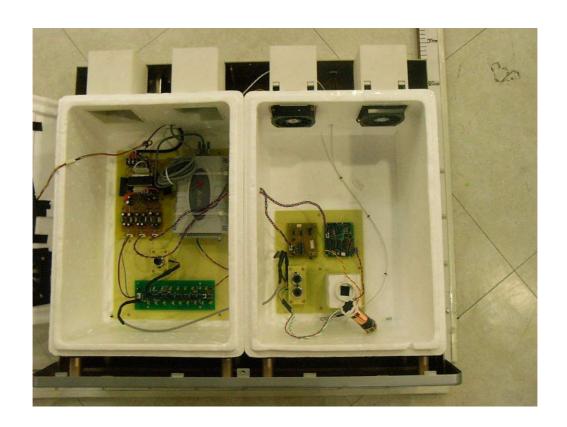
PHOTOS:







PHOTOS:



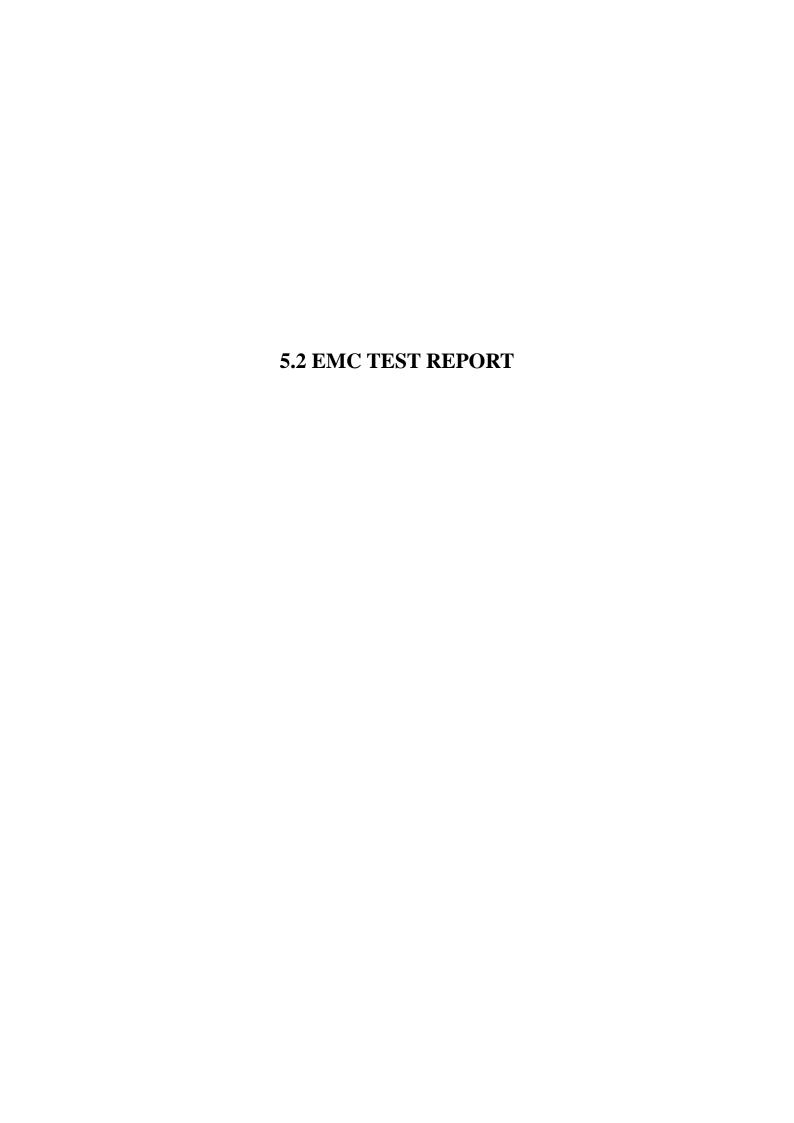


Page 66 of 66



REMARKS:

- 1. The CE marking may only be used if all relevant and effective CE procedures are complied with.
- 2. This report is submitted for the exclusive use of the client to whom it is addressed. Its significance is subject to the adequacy and representative character of the sample(s) and to the comprehensiveness of the tests, examinations or surveys made.
- **3.** This report justified only the submitted samples exclusively and not necessarily implies that all other samples are also to be found in same result.
- 4. The instruction specified by the standard has to be in official language of each country, however, only English is checked for this report. It is the applicant's responsibility to provide instruction in official language of the national.





EMC TEST REPORT

According to

EN 55011:2009/A1:2010 Group 1 (Class A) EN 61000-3-2:2006+A1:2009+A2:2009

EN 61000-3-3:2008

EN 61326-1:2013 EN 61326-2-1:2013

IEC 61000-4-2:2008

IEC 61000-4-3:2006+A1:2007+A2:2010

Page No.

: 1 of 50

IEC 61000-4-4:2012 IEC 61000-4-5:2005 IEC 61000-4-6:2008 IEC 61000-4-8:2009

IEC 61000-4-11:2004

Applicant : MagQu Co., Ltd.

Address 3F., No.12, Ln. 538, Zhongzheng Rd., Xindian Dist.,

New Taipei City 231, Taiwan

Equipment : Magnetic Immunoassay Analyzer

Model No. : XacPro-E301

Trade Name: MagQu

• The test result refers exclusively to the test presented test model / sample.

• Without written approval of *Cerpass Technology Corp.* the test report shall not be reproduced except in full.

This test report is only applicable to European Community.

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

: 2 of 50

Page No.

Contents

1.	Summ	nary of Test Procedure and Test Results	6
2.	Immu	nity Testing Performance Criteria Definition	6
3.	Test C	Configuration of Equipment under Test	7
	3.1.	Feature of Equipment under Test	
	3.2.	Test Manner	7
	3.3.	Description of Test System	
	3.4.	General Information of Test	9
	3.5.	Measurement Uncertainty	
4.	Test o	f Conducted Emission	
	4.1.	Test Limit	_
	4.2.	Test Procedures	
	4.3.	Typical test Setup	
	4.4.	Measurement Equipment	
	4.5.	Test Result and Data	
	4.6.	Test Photographs	
5.	Test o	f Radiated Emission	
	5.1.	Test Limit	
	5.2.	Test Procedures	_
	5.3.	Typical Test Setup	
	5.4.	Measurement Equipment	
	5.5.	Test Result and Data	
	5.6.	Test Photographs	
6.		onics Test	
	6.1.	Limits of Harmonics Current Measurement	
	6.2.	Test Result and Data	
7.	_	ge Fluctuations Test	
	7.1.	Test Procedure	
	7.2.	Measurement Equipment	
	7.3.	Test Result and Data	
	7.4.	Test Photographs	
8.		ostatic Discharge Immunity Test	
	8.1.	Test Procedure	
	8.2.	Test Setup for Tests Performed in Laboratory	
	8.3.	Test Severity Levels	
	8.4.	Measurement Equipment	
	8.5.	Test Result and Data	
	8.6.	Test Photographs	
9.		Frequency Electromagnetic Field Immunity Test	
	9.1.	Test Procedure	
	9.2.	Test Severity Levels	
	9.3.	Measurement Equipment	
	9.4.	Test Result and Data	
	9.5.	Test Photographs	35



CERPASS TECHNOLOGY CORP.





10. Electri	cal Fast Transient/ Burst Immunity Test	36
10.1.	Test Procedure	36
10.2.	Test Severity Levels	36
10.3.	Measurement Equipment	36
10.4.	Test Result and Data	37
10.5.	Test Photographs	38
11. Surge	Immunity Test	39
11.1.	Test Procedure	39
11.2.	Test Severity Level	39
11.3.	Measurement Equipment	40
11.4.	Test Result and Data	40
11.5.	Test Photographs	41
12. Condu	ction Disturbances induced by Radio-Frequency Fields	42
12.1.	Test Procedure	42
12.2.	Test Severity Levels	42
12.3.	Measurement Equipment	42
12.4.	Test Result and Data	43
12.5.	Test Photographs	44
13. Power	Frequency Magnetic Field Immunity Test	45
13.1.	Test Setup	45
13.2.	Test Severity Levels	45
13.3.	Measurement Equipment	45
13.4.	Test Result and Data	46
13.5.	Test Photographs	47
14. Voltage	e Dips and Voltage Interruptions Immunity Test Setup	48
14.1.	Test Conditions	48
14.2.	Measurement Equipment	48
14.3.	Test Result and Data	49
14.4.	Test Photographs	50
Appendix	A. Photographs of EUT	A1~A6

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : 3 of 50



History of this test report

)R	IGI	IN	Α	L.

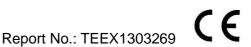
 \square Additional attachment as following record:

Attachment No.	Issue Date	Description

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : 4 of 50



CERTIFICATE OF COMPLIANCE

According to

EN 55011:2009/A1:2010 Group 1 (Class A) EN 61000-3-2:2006+A1:2009+A2:2009

EN 61000-3-3:2008

EN 61326-1:2013 EN 61326-2-1:2013

IEC 61000-4-2:2008

IEC 61000-4-3:2006+A1:2007+A2:2010

IEC 61000-4-4:2012 IEC 61000-4-5:2005 IEC 61000-4-6:2008

IEC 61000-4-8:2009 IEC 61000-4-11:2004

Applicant : MagQu Co., Ltd.

Address 3F., No.12, Ln. 538, Zhongzheng Rd., Xindian

Dist., New Taipei City 231, Taiwan

Equipment : Magnetic Immunoassay Analyzer

Model No. : XacPro-E301

I HEREBY CERTIFY THAT:

The measurements shown in this test report were made in accordance with the procedures given in **EUROPEAN COUNCIL DIRECTIVE 2004/108/EC**.

The test was carried out on Oct. 04, 2013 at Cerpass Technology Corp.

Signature

Hill Chen

EMC/RF B.U. Assistant Manager

Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

: 5 of 50

Page No.



1. Summary of Test Procedure and Test Results

Test Item	Normative References	Test Result
Conducted Emission	EN 55011:2009/A1:2010 Group 1	PASS
Radiated Emission	EN 55011:2009/A1:2010 Group 1	PASS
Harmonics	EN 61000-3-2:2006+A1:2009+A2:2009	N/A
Voltage Fluctuations	EN 61000-3-3:2008	PASS
EN 61326	6-1:2013, EN 61326-2-1:2013	
Electrostatic Discharge Immunity Test (ESD)	IEC 61000-4-2:2008	PASS
Radio Frequency electromagnetic field immunity test (RS)	IEC 61000-4-3:2006+A1:2007+A2:2010	PASS
Electrical Fast Transient/ Burst Immunity Test (EFT)	IEC 61000-4-4:2012	PASS
Surge Immunity Test	IEC 61000-4-5:2005	PASS
Conduction Disturbances induced by Radio-Frequency Fields	IEC 61000-4-6:2008	PASS
Power Frequency Magnetic Field Immunity Test	IEC 61000-4-8:2009	PASS
Voltage Dips and Voltage Interruptions Immunity Test	IEC 61000-4-11:2004	PASS

2. Immunity Testing Performance Criteria Definition

Criteria A: normal performance within levels specified by the manufacturer, requestor or purchaser

Criteria B: temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the EUT recovers its normal performance, without operator intervention

Criteria C: temporary loss of function or degradation of performance, the correction of which requires operator intervention

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 6 of 50



CE

Report No.: TEEX1303269

3. Test Configuration of Equipment under Test

3.1. Feature of Equipment under Test

Please refer to the user manual

3.2. Test Manner

- a. During testing, the interface cables and equipment positions were varied according to Europe Standard EN 55011, EN 61326-1 and EN 61326-2-1.
- b. The complete test system included Notebook, Mouse, Printer and EUT for EMI test.
- c. The complete test system included Notebook and EUT for EMS test.
- d. The following test modes were performed for conduction and flicker test:
 Test Mode 1. Dectection Box + Temperature Box Working, Main: Dectection Box.
 Test Mode 2. Dectection Box + Temperature Box Working, Main: Temperature Box.
- e. The following test mode was performed for radiation and EMS test: Test Mode 1. Dectection Box + Temperature Box, Working.
- f. An executive program, "EMI.exe" under WIN 7, which generates a complete line of continuously repeating "H" pattern was used as the test software.

The program was executed as follows:

- 1. Turn on the power of all equipment.
- 2. The PC reads the test program from the hard disk drive and runs it.
- 3. The PC sends "H" messages to the monitor, and the monitor displays "H" patterns on the screen.
- 4. The PC sends "H" messages to the internal Hard Disk, and the Hard Disk reads and writes the message.
- 5. Repeat the steps from 2 to 4.
- g. An executive program, "Xac Pro-E" under WIN 7 was executed to read and write from EUT.

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Page No. : 7 of 50





3.3. Description of Test System

EMI:

Device	Manufacturer	Model No.	Description
Notebook	Toshiba	Satellite L730	Power Cable, Non-Shielded, 1.8m
Mouse	DELL	MOC5UO	Data Cable, USB Shielding, 1.85m
Printer	НР	D2660	Power Cable, Non-Shielded, 1m Data Cable, USB Shielding, 1.6m

EMS:

Device	Manufacturer	Model No.	Description
Notebook	Toshiba	Satellite L730	Power Cable, Non-Shielded, 1.8m

Use Cable:

Cable	Quantity	Description		
USB	1	Shielding, 1.8m		
RS232	1	Shielding, 0.8m		
15 Pin Com Port	1	Shielding, 0.8m		

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Page No. : 8 of 50



3.4. General Information of Test

Test Site :	Cerpass Technology Corp. 2F-11, No. 3, Yuan Qu St., (Nankang Software Park), Taipei, Taiwan 115, R.O.C.
Test Site Location (OATS2-SD) :	No.68-1, Shihbachongsi, Shihding Township, Taipei City 223, Taiwan, R.O.C.
FCC Registration Number :	TW1049, TW1056, TW1061, 390316, 488071, 982971
IC Registration Number :	4934B-1, 4934D-1
VCCI Registration Number :	T-1173 for Telecommunication Test C-4139 for Conducted emission test R-3428 for Radiated emission test G-97 for Radiated emission test above 1GHz
Frequency Range Investigated :	Radiated emission test: from 30 MHz to 1,000 MHz Radio frequency electromagnetic field immunity test: 80-2700 MHz
Test Distance :	The test distance of radiated emission below 1GHz from antenna to EUT is 10 M. The test distance of radiated emission above 1GHz from antenna to EUT is 3 M.

3.5. Measurement Uncertainty

Measurement Item	Measurement Frequency	Polarization	Uncertainty
Conducted Emission 9 kHz ~ 30 MHz		LINE / NEUTRAL	3.25 dB
Dedicted Emission	30 MHz ~ 1,000 MHz	Vertical / Horizontal	3.93 dB
Radiated Emission	1,000 MHz ~ 18,000 MHz	Vertical / Horizontal	5.18 dB

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Page No. : 9 of 50



4. Test of Conducted Emission

4.1. Test Limit

Conducted Emissions were measured from 150 kHz to 30 MHz with a bandwidth of 9 KHz on the 120 VAC power and return leads of the EUT according to the methods defined in ANSI C63.4-2009 Section 3.1. The EUT was placed on a nonmetallic stand in a shielded room 0.8 meters above the ground plane as shown in section 2.2. The interface cables and equipment positioning were varied within limits of reasonable applications to determine the position produced maximum conducted emissions.

Conducted Emission Limits:

Frequency (MHz)	Quasi Peak (dB μ V)	Average (dB μ V)		
0.15 – 0.5	66-56*	56-46*		
0.5 - 5.0	56	46		
5.0 - 30.0	60	50		

4.2. Test Procedures

- a. The EUT was placed 0.4 meter from the conducting wall of the shielding room was kept at least 80 centimeters from any other grounded conducting surface.
- b. Connect EUT to the power mains through a line impedance stabilization network (LISN).
- c. All the support units are connecting to the other LISN.
- d. The LISN provides 50 ohm coupling impedance for the measuring instrument.
- e. The FCC states that a 50 ohm, 50 micro-Henry LISN should be used.
- f. Both sides of AC line were checked for maximum conducted interference.
- g. The frequency range from 150 kHz to 30 MHz was searched.
- h. Set the test-receiver system to Peak Detect Function and Specified Bandwidth with Maximum Hold Mode.

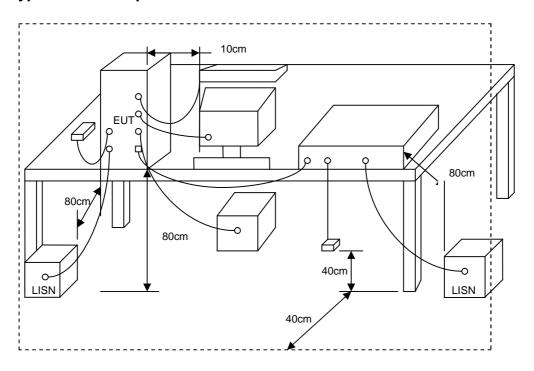
Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Page No.

: 10 of 50

Tel:886-2-2655-8100 Fax:886-2-2655-8200

4.3. Typical test Setup



4.4. Measurement Equipment

Instrument	strument Manufacturer		nufacturer Model No. Serial No. C		Valid Date	
EMI Receiver	MI Receiver R&S		eiver R&S ESCI 101200		2013/09/07	2014/09/06
LISN Schwarzbeck		NSLK 8127	8127-516	2013/03/08	2014/03/07	
LISN	LISN Schwarzbeck		8127-568	2013/08/30	2014/08/29	
Attenuator	Attenuator HAMEG			2013/03/07	2014/03/06	

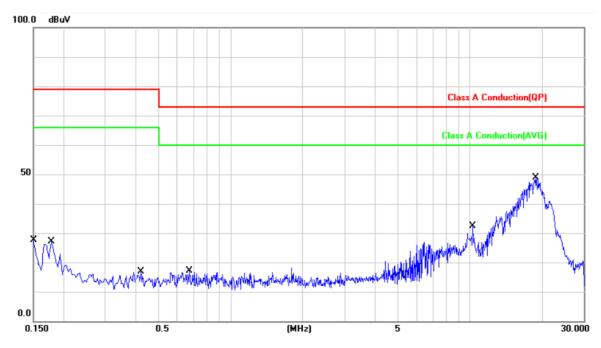
Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Page No. : 11 of 50



Power	:	AC 230V / 50Hz	Pol/Phase :	LINE
Test Mode 1	:	Dectection Box+Temperature Box Working, Main: Dectection Box.	Temperature :	23 °C
Test Date	:	Sep. 30, 2013	Humidity :	52 %
			Atmospheric :	998 hPa



No.	Frequency (MHz)	Factor (dB)	Reading (dBuV)	Level (dBuV)	Limit (dBuV)	Margin (dB)	Detector	P/F
1	0.1500	10.44	8.36	18.80	79.00	-60.20	QP	Р
2	0.1500	10.44	3.69	14.13	66.00	-51.87	AVG	Р
3	0.1780	10.40	15.07	25.47	79.00	-53.53	QP	Р
4	0.1780	10.40	10.24	20.64	66.00	-45.36	AVG	Р
5	0.4220	10.29	-1.02	9.27	79.00	-69.73	QP	Р
6	0.4220	10.29	-4.14	6.15	66.00	-59.85	AVG	Р
7	0.6740	10.28	1.73	12.01	73.00	-60.99	QP	Р
8	0.6740	10.28	-2.20	8.08	60.00	-51.92	AVG	Р
9	10.2940	10.73	19.01	29.74	73.00	-43.26	QP	Р
10	10.2940	10.73	17.08	27.81	60.00	-32.19	AVG	Р
11	19.0180	11.06	35.28	46.34	73.00	-26.66	QP	Р
12	19.0180	11.06	31.63	42.69	60.00	-17.31	AVG	Р

Note: Level = Reading + Factor Margin = Level - Limit

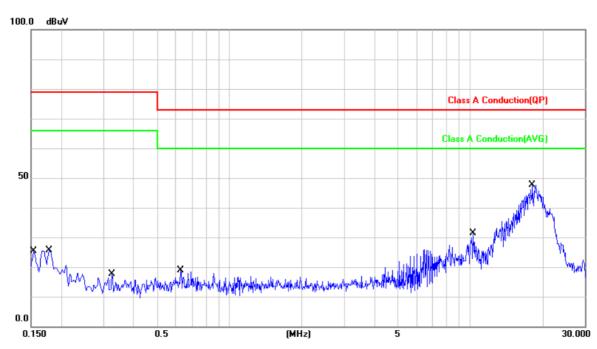
Cerpass Technology Corp. Issued Date : Oct. 09, 2013 Page No. : 12 of 50

Tel:886-2-2655-8100 Fax:886-2-2655-8200



Report No.: TEEX1303269

Power	:	AC 230V / 50Hz	Pol/Phase :	NEUTRAL
Test Mode 1	:	Dectection Box+Temperature Box Working ,Main: Dectection Box.	Temperature :	23 °C
Test Date	:	Sep. 30, 2013	Humidity :	52 %
			Atmospheric :	998 hPa



No.	Frequency (MHz)	Factor (dB)	Reading (dBuV)	Level (dBuV)	Limit (dBuV)	Margin (dB)	Detector	P/F
1	0.1539	10.43	12.47	22.90	79.00	-56.10	QP	Р
2	0.1539	10.43	7.84	18.27	66.00	-47.73	AVG	Р
3	0.1780	10.39	14.95	25.34	79.00	-53.66	QP	Р
4	0.1780	10.39	10.05	20.44	66.00	-45.56	AVG	Р
5	0.3260	10.31	-1.00	9.31	79.00	-69.69	QP	Р
6	0.3260	10.31	-4.00	6.31	66.00	-59.69	AVG	Р
7	0.6300	10.27	1.67	11.94	73.00	-61.06	QP	Р
8	0.6300	10.27	-2.22	8.05	60.00	-51.95	AVG	Р
9	10.2980	10.72	17.71	28.43	73.00	-44.57	QP	Р
10	10.2980	10.72	13.19	23.91	60.00	-36.09	AVG	Р
11	18.1900	11.03	34.73	45.76	73.00	-27.24	QP	Р
12	18.1900	11.03	30.73	41.76	60.00	-18.24	AVG	Р

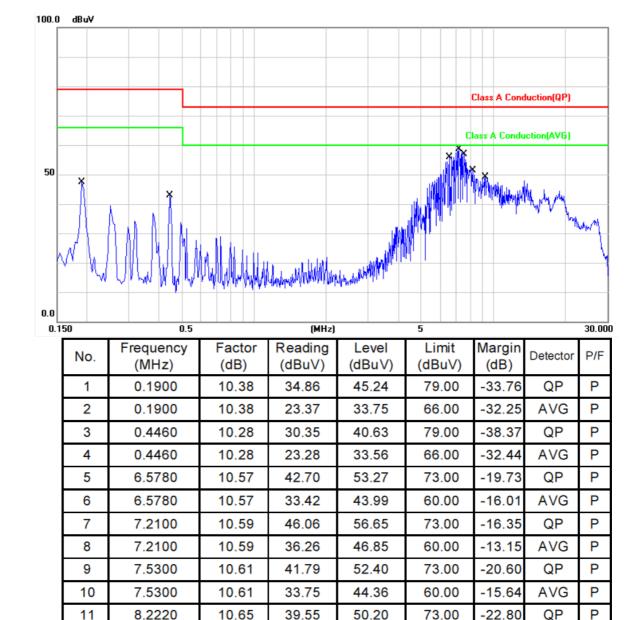
Note: Level = Reading + Factor Margin = Level - Limit

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 13 of 50



Power	:	AC 230V / 50Hz	Pol/Phase :	LINE
Test Mode 2		Dectection Box+Temperature Box Working, Main: Temperature Box.	Temperature :	23 °C
Test Date		Sep. 30, 2013	Humidity :	52 %
			Atmospheric .	998 hPa



Note: Level = Reading + Factor Margin = Level - Limit

8.2220

9.2940

9.2940

10.65

10.70

10.70

32.24

36.41

30.37

42.89

47.11

41.07

Tel:886-2-2655-8100 Fax:886-2-2655-8200

12 13

14

Issued Date : Oct. 09, 2013
Page No. : 14 of 50

AVG

QP

AVG

P

Р

P

-17.11

-25.89

-18.93

60.00

73.00

60.00

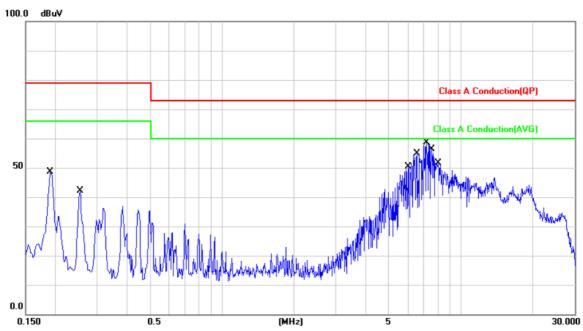


CERPASS TECHNOLOGY CORP.



Report No.: TEEX1303269

Power	:	AC 230V / 50Hz	Pol/Phase :	NEUTRAL
Test Mode 2		Dectection Box+Temperature Box Working, Main: Temperature Box.	Temperature :	23 °C
Test Date		Sep. 30, 2013	Humidity :	52 %
			Atmospheric .	998 hPa



No.	Frequency (MHz)	Factor (dB)	Reading (dBuV)	Level (dBuV)	Limit (dBuV)	Margin (dB)	Detector	P/F
1	0.1900	10.37	37.07	47.44	79.00	-31.56	QP	Р
2	0.1900	10.37	26.43	36.80	66.00	-29.20	AVG	Р
3	0.2540	10.34	31.50	41.84	79.00	-37.16	QP	Р
4	0.2540	10.34	23.36	33.70	66.00	-32.30	AVG	Р
5	6.0020	10.53	35.53	46.06	73.00	-26.94	QP	Р
6	6.0020	10.53	27.89	38.42	60.00	-21.58	AVG	Р
7	6.5780	10.55	42.50	53.05	73.00	-19.95	QP	Р
8	6.5780	10.55	33.24	43.79	60.00	-16.21	AVG	Р
9	7.2100	10.57	45.72	56.29	73.00	-16.71	QP	Р
10	7.2100	10.57	35.97	46.54	60.00	-13.46	AVG	Р
11	7.5300	10.60	41.40	52.00	73.00	-21.00	QP	Р
12	7.5300	10.60	33.27	43.87	60.00	-16.13	AVG	Ը
13	8.0300	10.62	39.85	50.47	73.00	-22.53	QP	Р
14	8.0300	10.62	32.86	43.48	60.00	-16.52	AVG	Գ

Note: Level = Reading + Factor Margin = Level - Limit

Test engineer:

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : 15 of 50

4.6. Test Photographs



Front View



Rear View

Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 16 of 50

Issued Date : Oct. 09, 2013



ERPASS TECHNOLOGY CORP. Report No.: TEEX1303269

5. Test of Radiated Emission

5.1. Test Limit

The EUT and its simulators are placed on a turn table which is 0.8 meter above ground.

The turn table can rotate 360 degrees to determine the position of the maximum emission level.

The EUT was positioned such that the distance from antenna to the EUT was 10 meters.

The antenna can move up and down between 1 meter and 4 meters to find out the maximum emission level.

Both horizontal and vertical polarization of the antenna are set on measurement. In order to find the maximum emission, all of the interface cables must be manipulated on radiated measurement.

Radiated emissions were invested over the frequency range from 30MHz to1GHz using a receiver bandwidth of 120kHz. Radiated was performed at an antenna to EUT distance of 10 meters.

Limits for radiated disturbances at a measuring distance of 10m

Frequency range	Class A Equipment	Class B Equipment				
(MHz)	Quasi-Peak dB (μV/m)	Quasi-Peak dB (μV/m)				
30 – 230	40	30				
230 – 1000	47	37				

Remark:

- 1. The tighter limit shall apply at the edge between two frequency bands.
- Distance refers to the distance in meters between the measuring instrument antenna and the closed point of any part of the device or system.

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Page No.

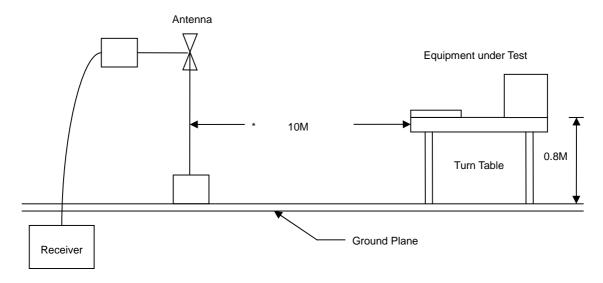
: 17 of 50



5.2. Test Procedures

- a. The EUT was placed on a rotatable table top 0.8 meter above ground.
- b. The EUT was set 10 meters from the interference receiving antenna which was mounted on the top of a variable height antenna tower.
- c. The table was rotated 360 degrees to determine the position of the highest radiation.
- d. The antenna is a half wave dipole and its height is varied between one meter and four meters above ground to find the maximum value of the field strength both horizontal polarization and vertical polarization of the antenna are set to make the measurement.
- e. For each suspected emission the EUT was arranged to its worst case and then tune the antenna tower (from 1 M to 4 M) and turn table (from 0 degree to 360 degrees) to find the maximum reading.
- f. Set the test-receiver system to Peak Detect Function and specified bandwidth with Maximum Hold Mode.
- g. If the emission level of the EUT in peak mode was 3 dB lower than the limit specified, then testing will be stopped and peak values of EUT will be reported, otherwise, the emissions which do not have 3 dB margin will be repeated one by one using the quasi-peak method and reported.

5.3. Typical Test Setup



5.4. Measurement Equipment

Instrument	Manufacturer	Model No.	Serial No.	Calibration Date	Valid Date
Amplifier	Agilent	8447D	2944A10531	2012/10/17	2013/10/16
Bilog Antenna	Schaffner	CBL6112B	2840	2013/03/27	2014/03/26
EMI Receiver	R&S	ESCI	100821	2013/01/15	2014/01/14

Page No.

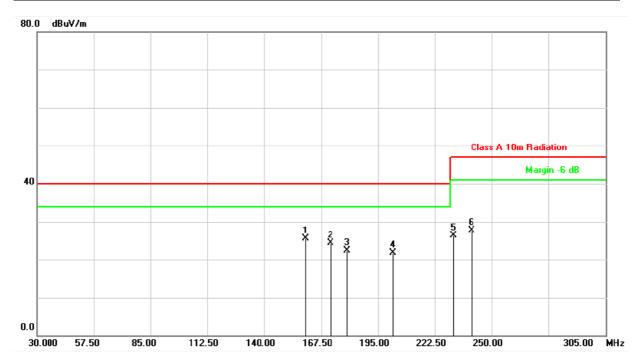
: 18 of 50

Cerpass Technology Corp. Issued Date : Oct. 09, 2013



5.5. Test Result and Data

Power	:	AC 230V / 50Hz	Pol/Phase :	VERTICAL
Test Mode		Dectection Box+Temperature Box, Working	Temperature :	26 °C
Test Date		Oct. 01, 2013	Humidity :	72 %
			Atmospheric :	1000 hPa



No.	Frequency (MHz)	Factor (dB/m)	Reading (dBuV)	Level (dBuV/m)	Limit (dBuV/m)	Margin (dB)	Detector	Height (cm)	Azimuth	P/F
1	160.0000	-14.97	40.56	25.59	40.00	-14.41	QP	100	209	Р
2	172.1750	-15.39	39.68	24.29	40.00	-15.71	QP	400	0	Р
3	180.1500	-15.57	37.86	22.29	40.00	-17.71	QP	400	0	Р
4	202.1500	-15.27	37.06	21.79	40.00	-18.21	QP	400	0	Р
5	231.5750	-13.71	40.06	26.35	47.00	-20.65	QP	400	0	Р
6	240.1000	-12.67	40.28	27.61	47.00	-19.39	QP	400	0	Р

Note: Level = Reading + Factor Margin = Level - Limit

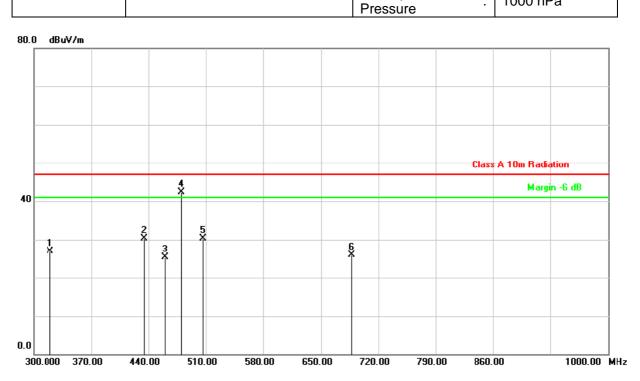
Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Page No.

: 19 of 50



Power	:	AC 230V / 50Hz	Pol/Phase :	VERTICAL
Test Mode	:	Dectection Box+Temperature Box, Working	Temperature :	26 °C
Test Date	:	Oct. 01, 2013	Humidity :	72 %
			Atmospheric :	1000 hPa



No.	Frequency (MHz)	Factor (dB/m)	Reading (dBuV)	Level (dBuV/m)	Limit (dBuV/m)	Margin (dB)	Detector	Height (cm)	Azimuth (")	P/F
1	319.6000	-9.47	36.43	26.96	47.00	-20.04	QP	100	0	Р
2	435.1000	-6.31	36.57	30.26	47.00	-16.74	QP	100	0	Р
3	459.6000	-5.75	31.11	25.36	47.00	-21.64	QP	100	0	Р
4	479.8999	-5.35	47.68	42.33	47.00	-4.67	QP	100	59	Р
5	506.5000	-4.75	35.15	30.40	47.00	-16.60	QP	100	0	Р
6	687.8000	-2.46	28.37	25.91	47.00	-21.09	QP	100	0	Р

Note: Level = Reading + Factor Margin = Level - Limit

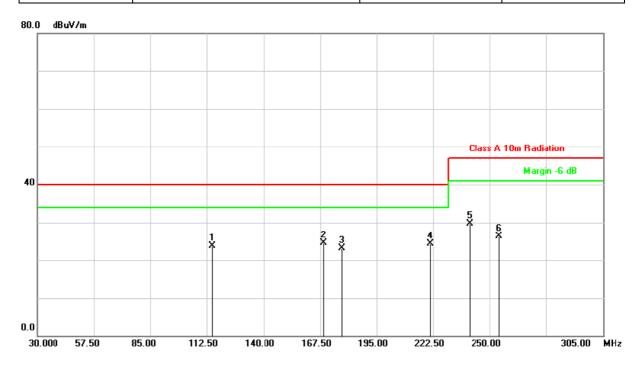
Cerpass Technology Corp.Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : 20 of 50



Power	:	AC 230V / 50Hz	Pol/Phase :	HORIZONTAL
Test Mode	:	Dectection Box+Temperature Box, Working	Temperature :	26 °C
Test Date	:	Oct. 01, 2013	Humidity :	72 %
			Atmospheric .	1000 hPa



No.	Frequency (MHz)	Factor (dB/m)	Reading (dBuV)	Level (dBuV/m)	Limit (dBuV/m)	Margin (dB)	Detector	Height (cm)	Azimuth	P/F
1	115.2500	-13.75	37.53	23.78	40.00	-16.22	QP	400	0	Р
2	169.1500	-15.30	39.77	24.47	40.00	-15.53	QP	400	0	Р
3	178.2250	-15.53	38.66	23.13	40.00	-16.87	QP	400	0	Р
4	221.1250	-15.00	39.28	24.28	40.00	-15.72	QP	400	0	Р
5	240.1000	-12.67	42.30	29.63	47.00	-17.37	QP	400	0	Р
6	254.6750	-10.79	37.19	26.40	47.00	-20.60	QP	400	0	Р

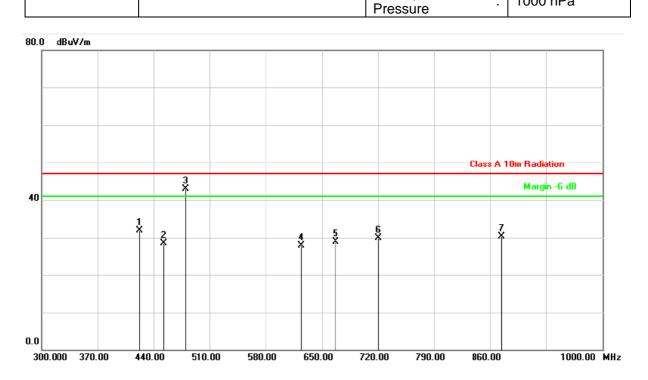
Note: Level = Reading + Factor Margin = Level - Limit

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 21 of 50



Power	:	AC 230V / 50Hz	Pol/Phase :	HORIZONTAL
Test Mode	:	Dectection Box+Temperature Box, Working	Temperature :	26 °C
Test Date	:	Oct. 01, 2013	Humidity :	72 %
			Atmospheric	1000 hPa



No.	Frequency (MHz)	Factor (dB/m)	Reading (dBuV)	Level (dBuV/m)	Limit (dBuV/m)	Margin (dB)	Detector	Height (cm)	Azimuth	P/F
1	422.5000	-6.61	38.51	31.90	47.00	-15.10	QP	100	0	Р
2	452.6000	-5.88	34.36	28.48	47.00	-18.52	QP	100	0	Р
3	479.9000	-5.35	48.21	42.86	47.00	-4.14	QP	400	200	Р
4	624.1000	-2.99	30.92	27.93	47.00	-19.07	QP	100	0	Р
5	666.8000	-2.55	31.48	28.93	47.00	-18.07	QP	100	0	Р
6	720.0000	-1.95	31.89	29.94	47.00	-17.06	QP	100	0	Р
7	874.7000	1.02	29.26	30.28	47.00	-16.72	QP	100	0	Р

Note: Level = Reading + Factor Margin = Level - Limit

Test engineer:

Cerpass Technology Corp.Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : 22 of 50

5.6. Test Photographs



Front View



Issued Date : Oct. 09, 2013

Rear View

Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 23 of 50



6. Harmonics Test

6.1. Limits of Harmonics Current Measurement

Limits for CI	ass A equipment
Harmonics	Max. Permissible
Order	harmonics
n	current
	Α
Odd	harmonics
3	2.30
5	1.14
7	0.77
9	0.40
11	0.33
13	0.21
15<=n<=39	0.15×15/n
Even	harmonics
2	1.08
4	0.43
6	0.30
8<=n<=40	0.23×8/n

Limits for Class D equip	ment
Max. Permissible	Max. Permissible
harmonics current per	harmonics current
watt mA/W	Α
Odd Harmonics onl	у
3.4	2.30
1.9	1.14
1.0	0.77
0.5	0.40
0.35	0.33
0.30	0.21
3.85/n	0.15 x15/n
	Max. Permissible harmonics current per watt mA/W Odd Harmonics onl 3.4 1.9 1.0 0.5 0.35 0.30

Report No.: TEEX1303269

NOTE:

- Class A and Class D are classified according to item section 5 of EN 61000-3-2: 2006 +A1:2009+A2:2009.
- According go section 7 of EN 61000-3-2: 2006+A1:2009+A2:2009, the above limits for all
 equipment except for lighting equipment are for all applications having a rated power > 75
 W and no limits apply for equipment with an active input power up to and including 75 W.

6.2. Test Result and Data

The limits are not specified for equipment with a rated power of 75W or less.

The EUT meets the above condition, so it conforms to EN 61000-3-2.

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Page No.

: 24 of 50



7. Voltage Fluctuations Test

7.1. Test Procedure

The equipment shall be tested under the conditions of Clause 5.

The total impedance of the test circuit, excluding the appliance under test, but including the internal impedance of the supply source, shall be equal to the reference impedance.

The stability and tolerance of the reference impedance shall be adequate to ensure that the overall accuracy of $\pm 8\%$ is achieved during the whole assessment procedure.

7.2. Measurement Equipment

Instrument	Manufacturer	Model No.	Serial No.	Calibration Date	Valid Date
Power & Harmonics Analyzer	TTI	HA1600	198226	2013/09/13	2014/9/12

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Page No.

: 25 of 50



Page No. : 26 of 50

7.3. Test Result and Data

: PASS Final Test Result

Basic Standard : EN 61000-3-3 Temperature : 25 °C **Test Data** : Oct. 03, 2013 Relative Humidity : 58 %

Dectection Box

Frequency: 50.03 Hz Supply Voltage: 233.9 to 234.1 Vrms 330.3 Vpk

THD: 0.7% Crest Factor: 1.411 peak at: 94.0 deg

0.007 kVA Power Factor: 0.701 0.004 kW Load Power:

0.07 Apk Crest Factor: 2.389 0.03 to 0.03 Arms Load Current:

Voltage Variations

Pst classifier:

Highest Half-cycle level: +1.87% Lowest Half-cycle level: +1.63%

Pass d(max): 0.24%

Number of Change Intervals:

Highest d(t) for 500 ms: Longest d(t) over 3.30%: 0.00% Pass

0.00 seconds

`Steady State' definition: >1000 ms below 0.32%

1.72% Highest Steady State level: 1.72%

Lowest Steady State level: max d(c) between adjacent: 0.00% Pass

0.00% max d(c) between any:

Flicker

Long-term Flicker indicator Plt : 0.00

Short-term Flicker indicator Pst :

Plt Interval 0.02 1:

2: 0.02 0.02 3:

0.02 4: 5: 0.02

6: 0.02 7: 0.02 8: 0.02

9: 0.02 0.02 10: 0.02 11:

12: 0.02

> Duration Flicker 0.01 0.1% 0.7% 0.00

1.0% 0.00 1.5% 0.00

0.00 2.2% 3% 0.00 48 0.00

6왕 0.00 88 0.00 0.00 10% 0.00 13% 17% 0.00

0.00 30% 50% 0.00 808 0.00

Issued Date : Oct. 09, 2013 Cerpass Technology Corp.

Final Test Result : PASS

Basic Standard : EN 61000-3-3 Temperature : 25 °C Test Data : Oct. 03, 2013 Relative Humidity : 58 %

Temperature Box

Frequency: 50.00 Hz Supply Voltage: 233.9 to 234.1 Vrms 330.3 Vpk peak at: 93.7 deg

Crest Factor: 1.411 0,7% THD:

0.142 kVA Power Factor: 0.547 0.016 to 0.078 kW Load Power:

Crest Factor: 2.744 0.23 to 0.61 Arms 1.91 Apk Load Current:

Voltage Variations

Highest Half-cycle level: +1.86% Lowest Half-cycle level: +1.64%

Pass d(max): 0.22%

Number of Change Intervals: Pass 0.00%

Highest d(t) for 500 ms: Longest d(t) over 3.30%: 0.00 seconds

>1000 ms below 0.32%

`Steady State' definition: Highest Steady State level: 1.80% 1.80% Lowest Steady State level:

Pass 0.00% max d(c) between adjacent:

max d(c) between any:

Flicker

Long-term Flicker indicator Plt : 0.00 Short-term Flicker indicator Pst :

Pst Plt Interval 0.00 1: 2: 0.02 0.02 3: 0.00 4: 0.02 5: 0.02 6: 0.02 7: 0.00 8:

0.00 9: 0.02 10: 0.02 11: 0.00 12:

Flicker Duration Pst classifier: 0.00 0.1%

0.00 0.7% 0.00 1.0% 0.00 1,5% 0.00 2.2% 0.00 3% 4% 0.00 0.00 68 0.00 88 10% 0.00 0.00 138 0.00 17% 30% 0.00 0.00 50%

0.00

Test engineer:

Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 27 of 50

80%

Issued Date : Oct. 09, 2013

Issued Date : Oct. 09, 2013

7.4. Test Photographs



Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 28 of 50



8. Electrostatic Discharge Immunity Test

8.1. Test Procedure

- a. In the case of air discharge testing the climatic conditions shall be within the following ranges:
 - ambient temperature: 15°C to 35°C;
 - relative humidity: 30% to 60%;
 - atmospheric pressure: 86 KPa (860 mbar) to 106 KPa (1060 mbar).
- b. Test programs and software shall be chosen so as to exercise all normal modes of operation of the EUT. The use of special exercising software is encouraged, but permitted only where it can be shown that the EUT is being comprehensively exercised.
- c. The test voltage shall be increased from the minimum to the selected test severity level, in order to determine any threshold of failure. The final severity level should not exceed the product specification value in order to avoid damage to the equipment.
- d. The test shall be performed with both air discharge and contact discharge. On reselected points at least 20 single discharges (in the most sensitive polarity) shall be applied on air discharge. On reselected points at least 20 single discharges (in the most sensitive polarity) shall be applied on contact discharge.
- e. For the time interval between successive single discharges an initial value of one second is recommended. Longer intervals may be necessary to determine whether a system failure has occurred.
- f. In the case of contact discharges, the tip of the discharge electrode shall touch the EUT before the discharge switch is operated.
- g. In the case of painted surface covering a conducting substrate, the following procedure shall be adopted :
 - If the coating is not declared to be an insulating coating by the equipment manufacturer, then the pointed tip of the generator shall penetrate the coating so as to make contact with the conducting substrate.
 - Coating declared as insulating by the manufacturer shall only be submitted to the air discharge.
 - The contact discharge test shall not be applied to such surfaces.
- h. In the case of air discharges, the round discharge tip of the discharge electrode shall be approached as fast as possible (without causing mechanical damage) to touch the EUT. After each discharge, the ESD generator (discharge electrode) shall be removed from the EUT. The generator is then retriggered for a new single discharge. This procedure shall be repeated until the discharges are completed. In the case of an air discharge test, the discharge switch, which is used for contact discharge, shall be closed.

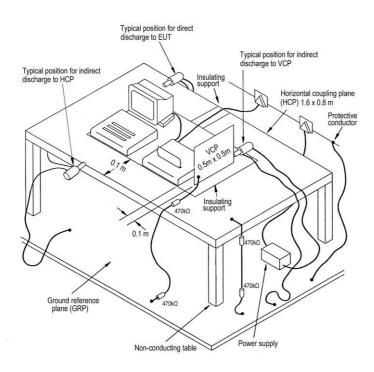
Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Page No.

: 29 of 50



8.2. Test Setup for Tests Performed in Laboratory



The test setup consists of the test generator, EUT and auxiliary instrumentation necessary to perform DIRECT and INDIRECT application of discharges to the EUT as applicable, in the follow manner:

- a. CONTACT DISCHARGE to the conductive surfaces and to coupling plane;
- b. AIR DISCHARGE at insulating surfaces.

The preferred test method is that of type tests performed in laboratories and the only accepted method of demonstrating conformance with this standard. The EUT was arranged as closely as possible to arrangement in final installed conditions.

8.3. Test Severity Levels

	Contact Discharge		Air Discharge			
Level	Test Voltage (KV) of Contact discharge	Level	Test Voltage (KV) of Air Discharge			
1	±2	1	±2			
2	±4	2	±4			
3	±6	3	±8			
4	±8	4	±15			
Х	Specified	Х	Specified			
	Remark: "X" is an open level.					

8.4. Measurement Equipment

Instrument	Manufacturer	Model No.	Serial No.	Calibration Date	Valid Date
ESD SIMULATOR	Schaffner	NSG438	878	2013/03/29	2014/03/28

Page No.

: 30 of 50

Cerpass Technology Corp. Issued Date : Oct. 09, 2013



8.5. Test Result and Data

Final Test Result : PASS

Pass performance criteria : A

Required performance criteria: B

Basic Standard : IEC 61000-4-2

Product Standard : EN 61326-1

Test Voltage $\pm 2 / \pm 4 / \pm 8$ KV for air discharge,

±2 / ±4 KV for contact discharge

Temperature : 27°C

Relative Humidity : 50 %

Atmospheric Pressure : 1011 hPa

Test Date : Oct. 4, 2013

	Co	Contact Discharge			Air Discharge					
		<u>25 </u>	imes /	each						
Voltage	2	<v< td=""><td>4 I</td><td>ΚV</td><td>2 l</td><td><v< td=""><td>4 l</td><td><v< td=""><td colspan="2">8 KV</td></v<></td></v<></td></v<>	4 I	ΚV	2 l	<v< td=""><td>4 l</td><td><v< td=""><td colspan="2">8 KV</td></v<></td></v<>	4 l	<v< td=""><td colspan="2">8 KV</td></v<>	8 KV	
Point\Polarity	+	_	+	_	+	_	+	_	+	_
HCP	Α	Α	Α	Α						
VCP	Α	Α	Α	Α						
Case					Α	Α	Α	Α	Α	Α
Screw	Α	Α	Α	Α						
Power Port					Α	Α	Α	Α	Α	Α
USB Port					Α	Α	Α	Α	Α	Α
Console Port	Α	Α	Α	Α						
Button Port					Α	Α	Α	Α	Α	Α
Panel Port					В	В	В	В	В	В

Note:" A" normal performance within levels specified by the manufacturer, requestor or purchaser.

Note:" B" temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the EUT recovers its normal performance, without operator intervention.

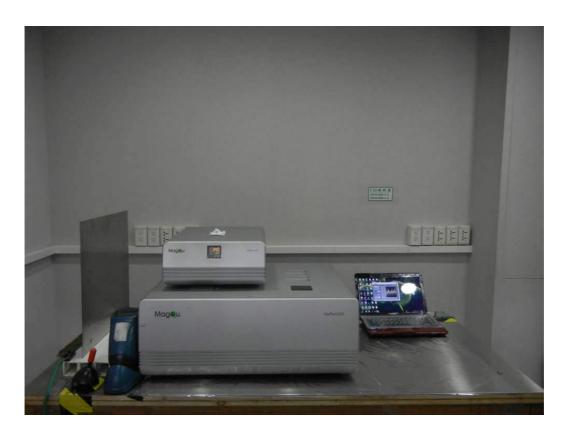
Test engineer:

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 31 of 50



8.6. Test Photographs



Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : 32 of 50



9. Radio Frequency Electromagnetic Field Immunity Test

9.1. Test Procedure

- a. The equipment to be tested is placed in the center of the enclosure on a wooden table. The equipment is then connected to power and signal leads according to pertinent installation instructions.
- b. The bilog antenna which is enabling the complete frequency range of 80-1000MHz, 1400-2700MHz is placed 3m away from the equipment. The required field strength is determined by placing the field strength meter(s) on top of or directly alongside the equipment under test and monitoring the field strength meter via a remote field strength indicator outside the enclosure while adjusting the continuous-wave to the applicable antennae.
- c. The test is normally performed with the generating antenna facing each of four sides of the EUT. The polarization of the field generated by the broadband (bilog) antenna necessitates testing each position twice, once with the antenna positioned vertically and again with the antenna positioned horizontally.
- d. The dwell time at each frequency shall not be less than the time necessary for the EUT to be exercised, and able to respond. Sensitive frequencies e.g. clock frequency(ies) and harmonics or frequencies of dominant interest shall be analyzed separately.
- e. At each of the above conditions, the frequency range is swept 80-1000MHz, 1400-2700MHz, pausing to adjust the R.F. signal level or to switch oscillators and antenna. The rate of sweep is in the order of 1.5*10-3 decades/s. The sensitive frequencies or frequencies of dominant interest may be discretely analyzed.

9.2. Test Severity Levels

Frequency Band: 80-1000 MHz, 1400-2700MHz				
Level	Test field strength (V/m)			
1	1			
2	3			
3	10			
X	Specified			
Remark: "X" is an open class.				

9.3. Measurement Equipment

Instrument	Manufacturer	Model No.	Serial No.	Calibration Date	Valid Date
Amplifiers 80-1000MHz/100W	SCHAFFNER CBA9413B 43510		43510	N/A	N/A
Amplifiers 80-3000MHz/20W	SCHAFFNER	CBA9428	43515	N/A	N/A
Antenna	SCHAFFNER	CBL6141A	4257	N/A	N/A
Power Meter	Boonton	4231A-01	115902	2013/09/14	2014/09/13
Field Probe	HOLADAY	HI-6105	00144727	2013/09/20	2014/09/19
Signal Generator	HP	8648C	3629U00612	2013/09/11	2014/09/10
Power Sensor	Boonton	51011-EMC	33312	2013/09/14	2014/09/13

Issued Date : Oct. 09, 2013 Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200

: 33 of 50

Page No.



: 34 of 50

9.4. Test Result and Data

Final Test Result : PASS

Pass performance criteria : A Required performance criteria: A

Basic Standard IEC 61000-4-3 **Product Standard** : EN 61326-1

Frequency Range : 80-1000 MHz, 1400-2000 MHz, 2000-2700 MHz

10 V/m (unmodulated, r.m.s) 80% AM (1 kHz) – for 80-1000 MHz

Report No.: TEEX1303269

Field Strength : 3 V/m (unmodulated, r.m.s) 80% AM (1 kHz) – for 1400-2000 MHz

1 V/m (unmodulated, r.m.s) 80% AM (1 kHz) - for 2000-2700 MHz

Temperature 25°C : 58 % Relative Humidity

Atmospheric Pressure : 1011 hPa

Test Date : Oct. 03, 2013

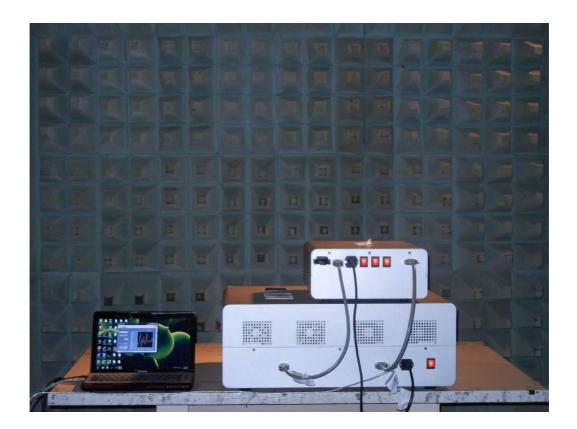
Modulation : AM 80% , 1KHz sine wave, Dwell time: 3 S Frequency Step Size : 1 % of preceding frequency value							
Frequency (MHz)	Antenna Polarization	Face	Field strength (V/m)	Result			
80~1000	Vertical	Front, Rear, Left, Right	10 V/m	А			
80~1000	Horizontal	Front, Rear, Left, Right	10 V/m	А			
1400~2000	Vertical	Front, Rear, Left, Right	3 V/m	А			
1400~2000	Horizontal	Front, Rear, Left, Right	3 V/m	А			
2000~2700	Vertical	Front, Rear, Left, Right	1 V/m	Α			
2000~2700	Horizontal	Front, Rear, Left, Right	1 V/m	Α			

Note:" A" normal performance within levels specified by the manufacturer, requestor or purchaser.

Issued Date: Oct. 09, 2013 Cerpass Technology Corp. Page No.



9.5. Test Photographs



Cerpass Technology Corp.Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

: 35 of 50

Page No.

10. Electrical Fast Transient/ Burst Immunity Test

10.1. Test Procedure

- a. In order to minimize the effect of environmental parameters on test results, the climatic conditions when test is carrying out shall comply with the following requirements:
 - ambient temperature: 15°C to 35°C;
 - relative humidity: 45% to 75%;
 - Atmospheric pressure: 86 Kpa (860 mbar) to 106 Kpa (1060 mbar).
- b. In order to minimize the effect of environmental parameters on test results, the electromagnetic environment of the laboratory shall not influence the test results.
- c. The variety and diversity of equipment and systems to be tested make it difficult to establish general criteria for the evaluation of the effects of fast transients/bursts on equipment and systems.
- d. Test on Power Line:
 - The EFT/B-generator was located on the GRP. For floor standing equipment 1,0 m

For table top equipment 0,5 m

- The EFT/B-generator provides the ability to apply the test voltage in a non-symmetrical condition to the power supply input terminals of the EUT.
- e. Test on Communication Lines
 - The coupling clamp is composed of a clamp unit for housing the cable (length more than 3 m), and was placed on the GRP.
 - The coupling clamp provides the ability of coupling the fast transient/bursts to the cable under test.
- f. The test results may be classified on the basic of the operating conditions and the functional specification of the equipment under test, according to the following performance criteria:
 - · Normal performance within the specification limits.
 - Temporary degradation or loss of function or performance which is self-recoverable.
 - Temporary degradation or loss of function or performance which requires operator intervention or system reset.
 - Degradation or loss of function which is not recoverable due to damage of equipment (components).

10.2. Test Severity Levels

The following test severity levels are recommended for the fast transient/burst test:

Open circuit output test voltage ± 10%						
Level	Level On Power Supply On I/O signal, data and control li					
1	0.5 KV	0.25 KV				
2	1.0 KV	0.50 KV				
3	2.0 KV	1.00 KV				
4	4.0 KV	2.00 KV				
X	Specified	Specified				

Remark: "X" is an open level. The level is subject to negotiation between the user and manufacturer or is specified by the manufacturer.

10.3. Measurement Equipment

Instrument	Manufacturer	Model No.	Serial No.	Calibration Date	Valid Date
TESQ NSG3060	TESQ	NSG3060	1385	2013/4/11	2014/4/10

Issued Date : Oct. 09, 2013 Cerpass Technology Corp.

Page No.

: 36 of 50



10.4. Test Result and Data

Final Test Result : PASS

Pass performance criteria : A Required performance criteria: В

Basic Standard IEC 61000-4-4 **Product Standard** EN 61326-1

Test Voltage On Power Line -- ± 0.5 KV, ± 1.0 KV, ± 2.0 KV

: 25°C Temperature Relative Humidity : 58 % Atmospheric Pressure : 1011 hPa **Test Date** : Oct. 03, 2013

Pulse : 5/50 n	S	Repetition Rate: <u>5 kHz</u>					
Burst : 15m/30	00ms	Test time	: 1 min/ead	ch condition	n		
Voltage/ Mode	e/ Polarity/	0.5	<u>5</u> kV	1.0	<u>)</u> kV	2.0	<u>)</u> kV
Result/ Phase			+		_	+	
	L	Α	Α	Α	Α	Α	Α
	N	Α	Α	Α	Α	Α	Α
	L-N	А	А	А	Α	Α	Α
Power Line	PE	А	А	А	Α	Α	Α
	L-PE	А	А	А	Α	Α	Α
	N-PE	Α	А	А	А	Α	Α
	L-N-PE	Α	Α	Α	А	Α	Α

Note:" A" normal performance within levels specified by the manufacturer, requestor or purchaser.

Test engineer:

Cerpass Technology Corp. Issued Date : Oct. 09, 2013 Page No. : 37 of 50



Issued Date : Oct. 09, 2013

10.5. Test Photographs



Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 38 of 50

11. Surge Immunity Test

11.1.Test Procedure

a. Climatic conditions

The climatic conditions shall comply with the following requirements :

- ambient temperature : 15 °C to 35 °C
- relative humidity: 10 % to 75 %
- atmospheric pressure : 86 kPa to 106 kPa (860 mbar to 1060 mbar)
- b. Electromagnetic conditions

the electromagnetic environment of the laboratory shall not influence the test results.

- c. The test shall be performed according the test plan that shall specify the test set-up with
 - generator and other equipment utilized;
 - test level (voltage/current);
 - generator source impedance;
 - internal or external generator trigger;
 - number of tests: at least five positive and five negative at the selected points;
 - repetition rate: maximum 1/min.
 - inputs and outputs to be tested;
 - representative operating conditions of the EUT;
 - · sequence of application of the surge to the circuit;
 - phase angle in the case of AC. power supply;
 - · actual installation conditions, for example :

AC: neutral earthed,

DC: (+) or (-) earthed to simulated the actual earthing conditions.

- d. If not otherwise specified the surges have to be applied synchronized to the voltage phase at the zero-crossing and the peak value of the AC. voltage wave (positive and negative).
- e. The surges have to be applied line to line and line(s) and earth. When testing line to earth, the test voltage has to be applied successively between each of the lines and earth, if there is no other specification.
- f. The test procedure shall also consider the non-linear current-voltage characteristics of the equipment under test. Therefore the test voltage has to be increased by steps up to the test level specified in the product standard or test plan.
- g. All lower levels including the selected test level shall be satisfied. For testing the secondary protection, the output voltage of the generator shall be increased up to the worst-case voltage breakdown level (let-through level) of the primary protection.
- h. If the actual operating signal sources are not available, that may be simulated. Under no circumstances may the test level exceed the product specification. The test shall be carried out according to a test plan.
- i. To find all critical points of the duty cycle of the equipment, a sufficient number of positive and negative test pulses shall be applied. For acceptance test previously unstressed equipment shall be used to the protection devices shall be replaced.

11.2. Test Severity Level

Level	Open-circuit test voltage, ± 10%, KV					
1	0.5					
2 1.0						
3 2.0						
4 4.0						
X Specified						
NOTE: "X" is a	NOTE: "X" is an open class. This level can be specified in the product specification.					

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Page No.

: 39 of 50





: 40 of 50

11.3. Measurement Equipment

Instrument	Manufacturer	Model No.	Serial No.	Calibration Date	Valid Date
TESQ NSG3060	TESQ	NSG3060	1385	2013/4/11	2014/4/10

11.4. Test Result and Data

Final Test Result : PASS

Pass performance criteria : A Required performance criteria : B

Basic Standard : IEC 61000-4-5 **Product Standard** : EN 61326-1

Test Voltage : Input AC Power Port -- \pm 0.5 kV, \pm 1.0 kV, \pm 2.0 kV

: 25°C Temperature Relative Humidity : 58 % Atmospheric Pressure : 1011 hPa **Test Date** : Oct. 03, 2013

Power Port

Waveform : 1.2/50µs(8/20µs)		Repetition	n rate : 60 s	ec Time :	Time: 5 time/each condition		
Phase Voltage / I	/ Result	0°	90°	180°	270°		
0.5 k)/ 1.0k)/	0.5 137 4.0137		Α	Α	Α	Α	
0.5 kV, 1.0kV	L-N	_	Α	Α	Α	Α	
	L-PE	+	Α	Α	Α	Α	
2.0kV	L-PC	_	Α	Α	Α	Α	
2.UKV		+	Α	A	A	A	
	N-PE	_	A	A	Α	A	

Note:" A" normal performance within levels specified by the manufacturer, requestor or purchaser.

Test engineer:

Issued Date: Oct. 09, 2013 Cerpass Technology Corp. Page No.

11.5. Test Photographs



Page No. : 41 of 50

Issued Date : Oct. 09, 2013



12. Conduction Disturbances induced by Radio-Frequency Fields

12.1. Test Procedure

- a. The EUT shall be operated within its intended climatic conditions. The temperature and relative humidity should be recorded.
- b. This test method test can be performed without using a sell shielded enclosure. This is because the disturbance levels applied and the geometry of the setups are not likely to radiated a high amount of energy, especially at the lower frequencies. If under certain circumstances the radiated energy is too high, a shielded enclosure has to be used.
- c. The test shall be performed with the test generator connected to each of the coupling and decoupling devices in turn while the other non-excited RF-input ports of the coupling devices are terminated by a 50 ohm load resistor.
- d. The frequency range is swept from 150 KHz to 80 MHz, using the signal levels established during the setting process, and with the disturbance signal 80% amplitude modulated with a 1KHz sign wave, pausing to adjust the RF-signal level or to switch coupling devices as necessary. The rate of sweep shall no exceed 1.5 x 10⁻³ decades/s. Where the frequency is swept incrementally, the step size shall no exceed 1% of the start and thereafter 1% of the preceding frequency value.
- e. The dwell time at each frequency shall not be less than the time necessary for the EUT to be exercised, and able to respond. Sensitive frequencies e.g. clock frequency (ies) and harmonics or frequencies of dominant interest shall be analyzed separately.
- f. An alternative test procedure may be adopted, wherein the frequency range is swept incrementally, with a step size not exceeding 4% of the start ad thereafter 4% of the preceding frequency value. The test level should be at least twice the value of the specified test level.
- g. In cases of dispute, the test procedure using a step size not exceeding 1% of the start and thereafter 1% of preceding frequency value shall take precedence.
- h. Attempts should be made to fully exercise the EUT during testing, and to fully interrogate all exercise modes selected for susceptibility.
- i. The use of special exercising programs is recommended.
- j. Testing shall be performed according to a Test Plan, which shall be included in the test report.
- k. It may be necessary to carry out some investigatory testing in order to establish some aspects of the test plan.

12.2. Test Severity Levels

Level	Voltage Level (e.m.f.)				
1	1 V				
2	3 V				
3	10 V				
Х	Specified				
NOTE - x is an open cla	ass. This level can be specified in the product specification.				

12.3. Measurement Equipment

Instrument	Manufacturer	Model No.	Serial No.	Calibration Date	Valid Date
CS GENERATOR	Schaffner	NSG 2070	1059	2013/09/11	2014/09/10
CDN (M2+M3)	Schaffner	M016	20056	2013/09/14	2014/09/13

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Page No.

: 42 of 50



12.4. Test Result and Data

Final Test Result : PASS

Pass performance criteria : A Required performance criteria : A

Basic Standard : IEC 61000-4-6 Product Standard : EN 61326-1

Coupling mode : CDN-(M3) for AC power ports

Temperature : 25°C
Relative Humidity : 58 %
Atmospheric Pressure : 1011 hPa
Test Date : Oct. 13, 2013

Frequency: 0.15~80MHz, Modulation: AM 80%,1KHz sine wave, Dwell time: 3s Frequency Step Size: 1 % of preceding frequency value					
Frequency Test Mode Voltage(V) Result					
0.15 ~ 80MHz					

Note:" A" normal performance within levels specified by the manufacturer, requestor or purchaser.

Test engineer:

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 43 of 50



Issued Date : Oct. 09, 2013

12.5. Test Photographs

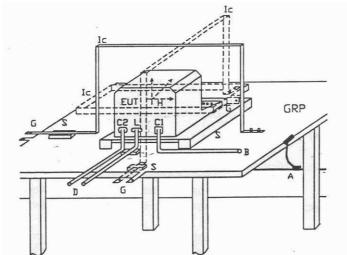


Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 44 of 50



13. Power Frequency Magnetic Field Immunity Test

13.1. Test Setup



GPR Ground plane C1 Power supply circuit

Safety earth C2 Signal circuit

Insulating support Communication line L **EUT** Equipment under test В To power supply source Induction coil D To signal source, simulator Lc

Ε Earth terminal G To the test generator

13.2. Test Severity Levels

Level	Magnetic field strength (A/m)				
1	1				
2	3				
3	10				
4	30				
5	100				
X ¹⁾ special					
NOTE 1 "X" is an open level. This level can be given in the product specification.					

13.3. Measurement Equipment

Instrument	Manufacturer	Model No.	Serial No.	Calibration Date	Valid Date
MAGNETIC FIELD GENERATOR	KeyTek	F-1000-4-8-G -125A	N/A	2013/09/12	2014/09/11

Cerpass Technology Corp. Issued Date: Oct. 09, 2013 Page No. : 45 of 50



13.4. Test Result and Data

Final Test Result : PASS

Pass performance criteria : A Required performance criteria : A

Basic Standard : IEC 61000-4-8 Product Standard : EN 61326-1

Temperature : 25°C Relative Humidity : 58

Atmospheric Pressure : 1011 hPa
Test Date : Oct. 13, 2013

Power Frequency Magnetic Field : 50 Hz, 30 A/m						
Coil Orientation Testing duration Results						
X-axis	1.0 Min	Α				
Y-axis	1.0 Min	Α				
Z-axis	1.0 Min	А				

Note:" A" normal performance within levels specified by the manufacturer, requestor or purchaser.

Test engineer:

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 46 of 50



13.5. Test Photographs



Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : 47 of 50



14. Voltage Dips and Voltage Interruptions Immunity Test Setup

14.1. Test Conditions

- 1. Source voltage and frequency: 100/230/240 / 50Hz, Single phase.
- 2. Test of interval: 10 sec.
- 3. Level and duration: Sequence of 3 dips/interrupts.
- 4. Voltage rise (and fall) time: 1 \sim 5 μ s.
- 5. Test severity:

Voltage dips and Interrupt	Test Duration
reduction (%)	(period)
>95%	250
30%	25
>95%	0.5

14.2. Measurement Equipment

Instrument	Manufacturer	Model No.	Serial No.	Calibration Date	Valid Date
TESQ NSG3060	TESQ	NSG3060	1385	2013/4/11	2014/4/10

Cerpass Technology Corp. Issued Date : Oct. 09, 2013

Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 48 of 50





14.3. Test Result and Data

Final Test Result : PASS

Pass performance Criteria : B for voltage interruption, A for voltage dips Required performance Criteria: C for voltage interruption, B/C for voltage dips

Basic Standard : IEC 61000-4-11

Product Standard : EN 61326-1

Temperature : 25°C : 58 % Relative Humidity Atmospheric Pressure : 1011 hPa Test Date : Oct. 13, 2013

Voltage(UT): AC 230	V <u>50</u> Hz	Interval(s):	<u>10s</u> Times : <u>3</u>
Test mode	Test level reduction %	Durations (period)	Result
	0%	0.5	А
Voltage dips	0%	1	А
	30%	25	А
Voltage interruptions	0%	250	С

Note: "A" normal performance within levels specified by the manufacturer, requestor or purchaser.

"C" temporary loss of function or degradation of performance, the correction of which requires operator intervention.

	NOKO
Test engineer:	you

Issued Date : Oct. 09, 2013 Tel:886-2-2655-8100 Fax:886-2-2655-8200 Page No. : 49 of 50



14.4. Test Photographs



Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : 50 of 50



Report No.: TEEX1303269

ϵ

Appendix A. Photographs of EUT

Dectection Box



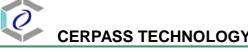


Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : A1 of A6

Report No.: TEEX1303269





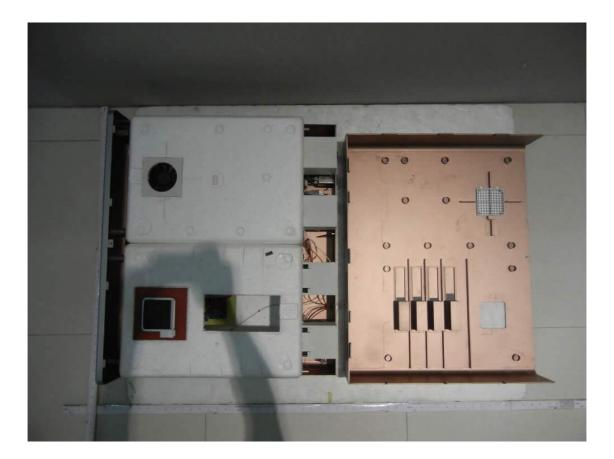


Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : A2 of A6





Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : A3 of A6

Temperature Box



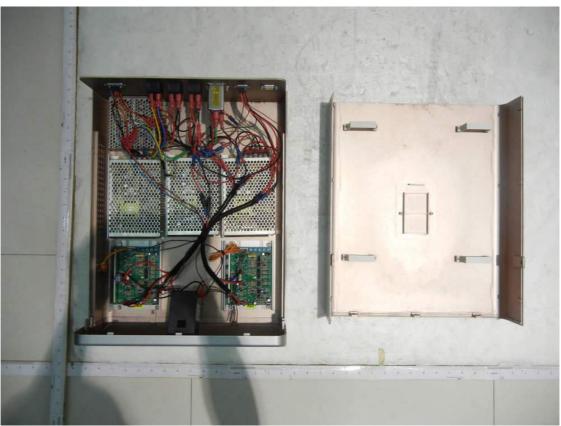


Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : A4 of A6





Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : A5 of A6



Cerpass Technology Corp.

Tel:886-2-2655-8100 Fax:886-2-2655-8200

Issued Date : Oct. 09, 2013

Page No. : A6 of A6

Chapter 6 Clinical Evaluation Report

Performance Evaluation-Clinical Data

1. Subjects

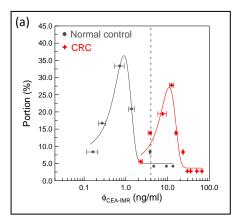
24 serum samples from healthy subjects (Normal control) and 30 serum samples from patients with colorectal cancer (CRC) were used for the IMR CEA assay. The CEA concentrations in human serum samples will be determined using the IMR signals. CRC patients were identified using either pathological evidence or an immunoassay. All of the enrolled patients provided informed consent before undergoing the procedure and this study was approved by National Taiwan University Hospital Research Ethics Committee (No.201105996RC).

2. Specimen Collection and Preparation

- Collect all blood samples by wearing protective equipment and following universal precautions for venipuncture. 5 ml of whole blood is collected in an anticoagulant-free serum separation tube (BD Vacutainer® SSTTM II Advance).
- Each sample (5 ml) is equally divided into two groups for both study and reference assay.
- Ensure that complete clot formation has taken place prior to centrifugation.
- Centrifuge the serum separation tube for 10 minutes at 1,500-2,000x g to separate the serum from the red blood cells.
- After centrifugation, serum is taken by pippetman and equally divided into four 1.5 ml microcentrifuge tubes (1 ml each). Serum samples are labeled and deep frozen (-20°C or colder) until needed. Avoid repeated freezing or thawing.

3. IMR Assays of serum CEA protein for diagnose of colorectal cancer

The CEA concentrations in human serum samples were determined by using the IMR CEA reagent. 24 serum samples from healthy subjects (Normal control) and 30 serum samples from patients with colorectal cancer (CRC) were used for the CEA assay, using the IMR method. CRC patients were identified using either pathological evidence or an immunoassay. The detected CEA concentrations ϕ CEA-IMR of these serum samples are plotted in Figure X(a). The ϕ CEA-IMR values for the normal control group are distributed over a relatively lower range than those for CRC patients. Most of ϕ CEA-IMR values for the normal control group are within the range, 0.6 ng/ml to 1.5 ng/ml, but the ϕ CEA-IMR values for CRC patients range from 6.0 ng/ml to 20 ng/ml. An analysis of the receiver operating characteristic (ROC) curve shown in Figure X(b) shows that the threshold for the diagnosis of CRC by an assay of CEA in serum, using the IMR method, is 4.05 ng/ml, which results in the clinic sensitivity of 0.90 and a specificity of 0.87.



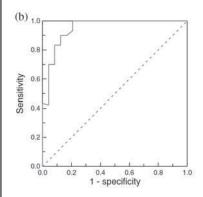


Fig. X. (a) Measured CEA concentration, $\phi_{CEA\text{-}IMR}$, using IMR CEA reagent and analyzer for normal subjects (normal control) and patients with colorectal cancer (CRC), (b) The ROC curve for the analysis of the clinical sensitivity and the specificity for the diagnosis of colorectal cancer, using the detected CEA concentration ϕ CEA-IMR in serum.

Reference

Che-Chuan Yang, Shieh-Yueh Yang, Chia-Shin Ho, Jui-Feng Chang, Bing-Hsien Liu and Kai-Wen Huang. "Development of antibody functionalized magnetic nanoparticles for the immunoassay of carcinoembryonic antigen: a feasibility study for clinical use." Journal of Nanobiotechnology 2014, 12:44.

Chapter 7 Package

7. Package

The package information for Magnetic Immunoassay Analyzer XacPro-E is given.

7.1 Packaging Materials of Product

The packaging materials of Magnetic Immunoassay Analyzer XacPro-E include Analyzer, Operating and maintaining manual and Labeling, as listed in Table 7.1.

Table 7.1. Packing materials of Carcinoembryonic Antigen (CEA) IMR Reagent.

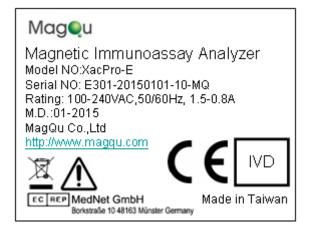
Packaging materials	Quantity
XacPro-S	1 Set
Operating and maintaining manual	1 Set
Labeling	1 Set

Chapter 8 Labels

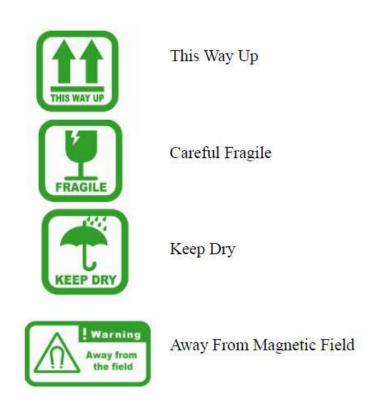
8. Labels

The labels for Magnetic Immunoassay Analyzer, XacPro-E are given.

8.1 Labeling



8.2 Symbols



8.3 Operation & Maintenance Manual



Magnetic Immunoassay Analyzer XacPro-E301

Operation & Maintenance Manual

(Version: 201309)



Table of Contents

Safety Instructions	
Environmental Considerations	4
Chapter I Brief Introduction to Applications of Magnetic Immunoassay Analyze	r 5
Chapter II Principle of Magnetic Reduction Immunoassay	6
Chapter III Introduction of Magnetic Immunoassay Analyzer XacPro-E301	7
Section I Power Converter (AC/DC)	8
Section II Dynamic Signal Processor (DSP)	9
Section III Coils	9
Section IV Signal Amplification Circuit (Amplifier)	10
Section V Signal Output Module (Micro-control)	10
Section VI Thermoelectric Cooler (TE Cooler)	11
Chapter IV Operation Procedure	12
Section I Operating Procedure for Installation	12
Section II Setting & Start-up Procedure of XacPro-E301	18
Section III χ_{ac} Measurement Procedure	20
Section IV Reagent Preparation Method	23
Section V Magnetic Reduction Signal Analysis	23
Chapter V Debugging and Maintenance	25
Chapter VI Attentions	26
Section I Cleaning & Maintenance	26
Section II After-sale Service & Guarantees	26
Appendix A Structural Block of XacPro-E301	28
B Dimensional Drawing of Power Converter	29
C Specifications of XacPro-E301	30
D List of Packing Inserts	31
E Warning Icon Description	32

Email Box: info@magqu.com Tel: +886-2-86671897 Fax: +886-2-86671809

Safety Instructions

Please review following safety warnings to avoid personal injuries and damages to the

product and any related product.

In order to avoid potential risk, please use the product in compliance with relevant

instructions.

Only qualified maintenance personnel can conduct maintenance procedure.

Prevent Fire or Personal Injury

Use Proper Power Line. Please use only the power line designated for the product and

approved in the country where the product is used.

Correct Connection & Disconnection. Before connecting a computer, please confirm

whether the computer is started. Switch on power of the product after starting the

computer. Before shutting down the product and disconnecting the computer, please

interrupt and remove relevant software at first.

Ground the product. The product is grounded through a ground conductor of the

power cord. In order to avoid electric shock, the grounding conductor must be

connected to the ground. Please confirm whether the product is grounded correctly

before connecting the input and output terminal of the product.

Observe power of all terminals. Please notice power and relevant mark of the product

in order to prevent any risk of fire or electric shock. Before connecting the product,

please read the product manual so as to further understand relevant power information.

Disconnect power. Please refer to concerned instructions to confirm the position to

disconnect the product from power. Please do not hinder the power switch and it is

accessible at any time when the product is in use.

Please do not operate before the cover is fitted on. Please do not operate the product

when the cover is taken off.

Please do not operate when doubting there is a fault. If you doubt the product is

damaged, please allow qualified maintenance personnel to check it.

MagQu Co., Ltd.

3F, No. 12, Lane 538, ZhongZheng Road, Xindian District, New Taipei City 231, Taiwan

Prevent circuit exposed. Please do not touch any exposed connector and component when the current is conveyed.

Please do not operate under a moist condition.

Please do not operate in the flammable and combustible air.

Please keep the product surface clean and dry.

Keep good ventilation. Please refer to installation instructions of the manual for detailed information on how to install the product and provide it with good ventilation.



Warnings indicate the operation conditions that may cause injury or death.



Cautions suggest conditions or operations that may cause damage to the product or other objects.

Environmental Considerations

The section provides information relevant to the impact of the product on the environment.

Disposal of Product Discarded

Please refer to following instructions when recycling any instrument or component.

Equipment Recycling: nature resources of the equipment need to be recycled and reused. In the event that the equipment is not disposed correctly during discard, it may produce substances hazardous to the environment or human health. In order to avoid emission of such substances in the environment and reduce use of natural resources, recycling the product with a proper system is recommended for the purpose of ensuring most materials can be recycled and reused appropriately.



Chapter I Brief Introduction to Applications of Magnetic

Immunoassay Analyzer

The Magnetic Immunoassay Analyzer XacPro-E301 launched by MagQu Co., Ltd. is used to measure the change in the ac magnetic susceptibility of a sample over time. If the sample is a mixture of a magnetic reagent and an object to be detected, it can be used to detect the concentration of bio-molecules in the object according to the change in the ac magnetic susceptibility. XacPro-E301 is advantageous for bio-molecular assays in many ways, such as its operation is very simple, there is no need for users to calibrate concentration of the to-be-detected bio-molecules, it adopts CAA (Computer Automatic Analysis) with high accuracy and sensitivity and can detect low-concentration bio-molecules. Therefore XacPro-E301 can be applied in not only research, but clinical diagnosis and field trials.

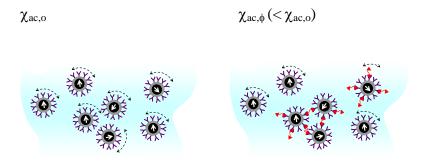
To-be-detected bio-molecules mentioned above include protein, cytohormone, virus, nuclei acids, bacteria, even small molecular compounds. XacPro-E301 can help you to establish standard detection curves for new kinds of bio-molecules to be detected, further to measure content of the bio-molecules in the samples. So it is expected that XacPro-E301 can be applied in the fields of in-vitro quantitative detection including agriculture, forest, fishing, stockbreeding, food and human body.



Chapter II Principle of Magnetic Reduction Immunoassay

The Magnetic Immunoassay Analyzer XacPro-E301 utilizes the so-called immunomagnetic reduction (IMR) as its assay principle. The principle of immunomagnetic reduction is described as follows.

Under external ac magnetic fields of which frequencies range from tens to millions of hertz, individual magnetic beads in a magnetic reagent will be driven by the external ac magnetic fields and swirl. The magnetic reagent produces ac magnetic signals (χ_{ac}) accordingly. When the magnetic reagent is mixed with the sample containing to-be-detected bio-molecules, bio-molecules will bind with magnetic beads via bioprobes (e.g. antibodies) on surface of the magnetic beads. In this way, part of magnetic beads in the reagent will get enlarged, even many magnetic beads will gather together. In such case, compared with the number of swirling magnetic beads before the magnetic reagent is mixed with the sample, number of swirling magnetic beads in the reagent driven by external field is much fewer. So the ac magnetic signal (χ_{ac}) of magnetic reagent will reduce due to the binding between bio-molecules in the sample with magnetic beads; that's why we call the detection method as magnetic reduction immunoassay detection. According to the description above, more bi-molecules the sample contains, more bindings between magnetic beads and bi-molecules will occur, and more magnetic reduction will appear. Thus we can detect amounts of bi-molecule in the sample in reference to measurement on magnetic reduction of magnetic reagent. In Chapter III, every component of XacPro-E301 will be described in detail:



Chapter III Introduction of Magnetic Immunoassay Analyzer

XacPro-E301

Picture and scheme of XacPro-E301 is as shown in Fig. 1. XacPro-E301 is consisted of two modules:

- 1. Detection Box (AC/DC, DSP, Coils, Amplifiers, Micro-Control unit and TE cooler indicated by Fig. 1)
- 2. Temperature Control Box (Electronics shown in Fig. 1)

Specifications and functions of these two modules are described in the following sections.

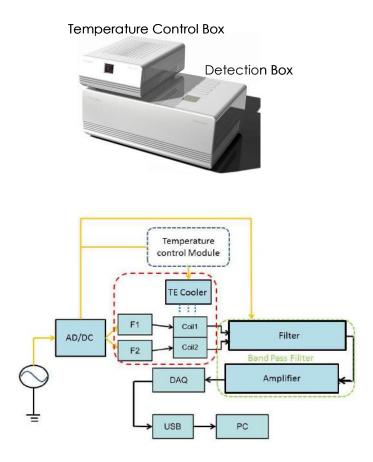


Fig. 1. Picture and scheme of XacPro-E301.

Section I Power Converter (AC/DC)

The section will introduce icon and function of the power converter (AC/DC).

1. Diagram

The power converter is as shown in Fig. 2. Input voltage of the power converter ranges from 100 V to 240 V. The output is direct-current voltage ± 11 V which used as the power necessary for operation amplifier in other circuits.

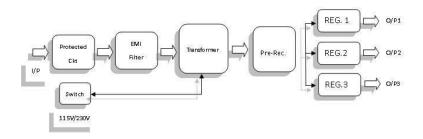


Fig 2. XacPro-E301Power supply diagram.

2. Function

Since electric circuits of other components of XacPro-E301 are driven by DC voltage, the power converter is used to convert AC power of city mains into the DC power required by the electric circuits when XacPro-E301 works. The DC power after conversion provides ± 11 V DC voltage.

Section II Function generating circuit (F1 & F2)

1. Circuit Diagram

The digital AC waves to drive coils are generated by Function generating circuit (F1 and F2). The AC waves typically involve two frequencies: one is at hundreds of hertz and the other is at dozens of kilohertz. The AC waves of two frequencies are connected with coils through digital/analog converter (D/A) shown in Fig. 3.

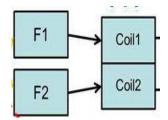


Fig. 3. Circuit diagram of digital/analog converter for AC waves

2. Function

The AC wave generator is used to supply AC voltages at multiple frequencies to generate AC currents flowing through the coils. The coils then generate AC magnetic fields.

Section III Coils

1. Structure Diagram

Structure of coils is shown as Fig. 4, including three different coaxial solenoids shown on the right of Fig. 4 and made of plastic steel and wound with copper wires.

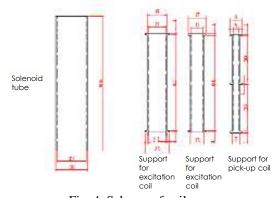


Fig. 4. Scheme of coils.

2. Function

After the AC signals generated by DSP mentioned above pass through copper wires of two excitation coils, respectively. Each coil generates an AC magnetic field to magnetize magnetic reagent located inside the pick-up coil. The two excitation coils and the pick-up coil are assembled co-axially. The AC magnetic signals generated by the magnetic reagent are sensed by the pick-up coil, and are guided to the amplifier and feedback control circuit.

Section IV Signal Amplification Circuit (Amplifier)

Actually AC magnetic signals generated by the magnetic reagent and sensed by the pick-up coil are consisted of weak signals at multiple frequencies. For the purpose of amplifying the weak signals at specific frequency which is to be measured, the amplifier is adopted to filter and amplify the signals sensed by the pick-up coil.

Section V Signal Output Module (Micro-control)

1. Circuit Diagram

Circuit diagram of the micro-control is shown as Fig. 5. The amplified signals are input by DSP and output to the computer (USB to PC in Fig. 5) after passing through the micro processor (MCU in Figure 5) and USB signal output converter.

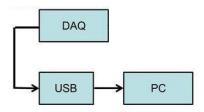


Fig. 5. Diagram of Micro-control

2. Function

When the amplified signals are input at terminal P8 of DSP shown in Fig. 5, the instantaneous signals will be converted

into spectrum signals in DSP and MCU. Then the signal at specific frequency will be selected out by MCU and input to the external computer. XacPro-E301 is connected to the external PC by USB, so a USB signal output converter (USB 2.0) is fitted between MCU and the external PC.

Section VI Thermoelectric Cooler (TE Cooler)

XacPro-E301 uses a cooling chip to control temperature in the test box; the thermoelectric cooler (TE Cooler) will conduct cooling process automatically when the temperature is higher than the set value and TE Cooler will conduct heating process automatically when the temperature is lower than the set value. The control circuit of TE Cooler is fitted in the temperature control box.

Chapter IV Operation Procedure

- Driver used with the operating software is provided by Adlink Technology and National Instruments without amendments by our company and can be requested from the former two companies directly.
- 2. It is required to calibrate XacPro-E301 with the standard solution produced by our company every three months to ensure accuracy of the instrument.
- The following operational programs are the series product of Windows launched by Microsoft, which are used as OS and not applicable for Mac series and Linux System.

Section I Installation of Software

1. Put the software disk in to cd-rom of the computer. Then, double click "Labview driver." Click "Next."



2. Labview driver is provided by National Instruments named Labview run time Engine. Users must follow the terms of use from NI, and click "next."



MagQu Co., Ltd. 3F, No. 12, Lane 538, ZhongZ

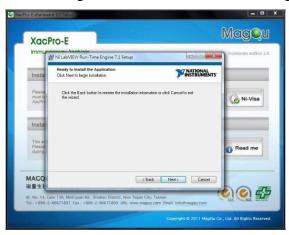
Website: www.magqu.com

Email Box: info@magqu.com Tel: +886-2-86671897 Fax: +886-2-86671809

1. Set the installing pathway and click "next."



2. Follow the guild and click "next" for starting installation.



- 3. Please wait for installation.
- 4. Click "Finish" and end the installation.



5. Enter the Adlink file folder and double click Setup file.



6. Double click "USB DAQ Module."



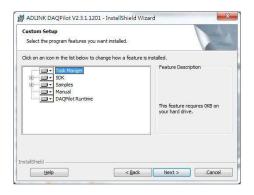
7. Both DAQ Pilot & Driver installation should be installed.

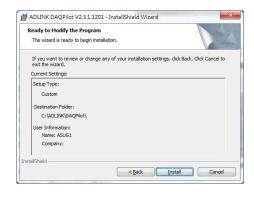


8. DAQ Pilot is provided by ADLink Technology. Users must follow the terms of use of ADLink Technology. Then click "Next."



9. Follow the installing guild and click "Next" and "Install."

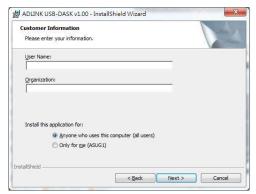




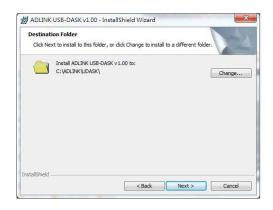


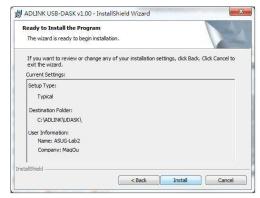
10.After finish installation of DAQ Pilot, click Driver installation in step 7. Follow the guild to undergo next installation.

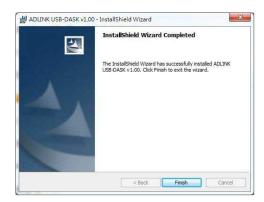




11. Choose the folder path and click "next." The installation will start after users click "Install," and finish when users click "Finish."







12.Click exit and X to finish the installation.





Section II Setting & Start-up Procedure of XacPro-E301

1. XacPro-E301 is consisted of a temperature control box and detection box. Please put the detection box on a flat table gently at first; then place the temperature box on it or a flat table gently.



2. There are three switches on the back of temperature box, which are designed for the temperature box and the detection box, and need to be switch on and off simultaneously. A power line should be connected on the left of the switches and the 15-pin connector on the left of the power line should be jointed to the 15-pin connector on the detection box. There are two 9-pin connectors on the right of the switches, between which the left one should be jointed to the 9-pin connector on the left of the 15-pin connector on the detection box and the right one should be jointed to the 9-pin connector on the right of the 15-pin connector mentioned above.

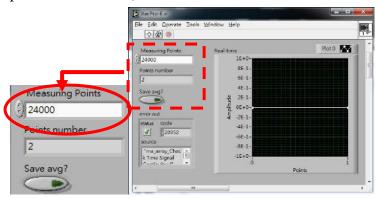


3. There is a control panel in the front of the temperature box. After opening the acryl cover, push down the green button "<"; and then adjust the temperature with \(\simeq \) (green numbers below). Commonly the most appropriate working temperature is about 5 to 10 degrees above room temperature.

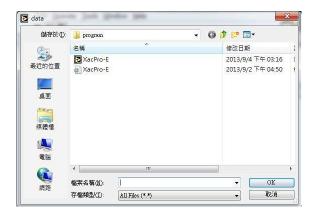


Section III Xac Measurement Procedule

1. Launch XacPro-E and setting the measuring points (1 point for 5 seconds).



2. Setting the path of data file.



3. Prepared the samples before measurement and put them in the thermostatic box side to the sensor coil. After few minutes, put the sample in the sensor coil and click OK to start the measurement.



Section IV Reagent Preparation Method

- 1. Take the magnetic reagent and the sample to be detected out of frig and shake them with Vortex for about 15 seconds separately.
- 2. Add 40 μ l magnetic reagent and 60 μ l sample to be detected into a detector tube commonly.
- 3. Shake the glass tube with Vortex for about 15 seconds to mix the magnetic reagent with the sample to be detected.
- 4. Place the detector tube into the thermostatic bath of XacPro-E301 to measure the AC magnetic permeability χ_{ac} .

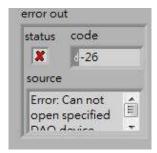
Section V Magnetic Reduction Signal Analysis

- 1. Open the notepad file saved with data process software and plot.
- 2. Calculate the mean values for relevant points before and after the reaction and adopt them in the following formula: IMR (%) = $(\chi_{ac,o} \chi_{ac,\phi})/\chi_{ac,o} \times 100\%$, in which $\chi_{ac,o}$ is the ac magnetic susceptibility signal before the reaction and $\chi_{ac, \phi}$ is the ac magnetic susceptibility signal after the reaction.

Chapter V Debugging and Maintenance

Common error information and simple troubleshooting are shown as following:

1. The "X" signal shows in the status of error out diagram (shown as below) refers to the program fails to seize signal from the instrument. Please restart PC and the program after confirming the connection is in good condition.



- Frequent "Cease and Save" and "Stop warming" will lead to a fault of the instrument. It is recommended sending the instrument back to our company for repair every season if you use the two commands above frequently.
- 3. If it is impossible to achieve balanced for the temperature control system with specified usage pattern, please send the instrument back to our company for repair.
- 4. If the lights at the back of temperature box are not bright after start, please send the instrument back to our company for repair.
- 5. If the program is damaged or unable to start, please reinstall it. If there is any other fault, please reinstall or repair the Window system in PC. If there is still any problem unsolved, please contact our company as soon as possible.

As for any situation not listed in the error information mentioned above, please contact our company as soon as possible. Tel: +886-2-86671897.

Chapter VI Attentions

- Please confirm whether the transformer suitable for the voltage in the situation where the analyzer is used before using it.
- Please connect the analyzer with power supply to warm up for an hour before using it.
- Please store the analyzer in a location without direct sunlight at room temperature.
- Do not place the analyzer in a location with much dust please.
- Please store the analyzer in a location unlikely to shake and please do not keep it under heavy pressure during transportation.
- Please operate the analyzer with genuine consumables from our company (please contact our company if you need to order the consumables at telephone number 02-8667-1897)



Do not place the analyzer XacPro-E301 close to a strong magnetic field or high-power electrical products.

Section I Cleaning & Maintenance

- 1. You only need to use a piece of soft cloth soaked with water or mild solvent to wipe and clean the analyzer.
- 2. Please do not use any organic solvent to clean the housing or accessories.
- 3. Please do not detach the analyzer discretionally; contact the distributor if you need to repair it.
- 4. Please use the original packing container when transporting the analyzer.

Section II After-sale Services & Guarantee

1. The product is provided with 1 year of free warranty term after sale.

- 2. As for the following cases, the services will be charged properly even in the warranty term:
 - (a) Any damage or fault due to improper use or act of God such as lightning etc.
 - (b) Any damage or fault due to discretional repair, modification or repair by any other third party.
 - (c) Any damage or fault due to change of installation location, transportation or falling down etc.
- 3. Please deliver the analyzer XacPro-E301 to distributors when requiring repair. As the analyzer is a precision instrument, it must be transported carefully in compliance with the following instructions.
 - (a) Please use the original packing container for transportation.
 - (b) Convey shall not be conducted until the power is shut off.
 - (c) Prevent the product from pressing or falling.

Appendix A Structural Block of XacPro-E301

Dimensional drawing of Magnetic Immunoassay Analyzer XacPro-E301 is shown as the following:

Detection Box:



Temperature Box:



X Net weight 15.8 kg ⋅

Appendix B Specifications of XacPro-E301

- Refer to Addendum A for detailed dimensions of the analyzer
- Specifications of the power converter:

Input: 100 – 230 VAC

Output: Max. 24VDC/200 W

• Specifications of AC Wave Generator:

Output power: AC +/- 3V to AC +/- 24V, 50mA/50mA

Output Frequency: 100 to 50 kHz

• Specifications of amplifier circuit:

Wave band: 1 k to 30 kHz

Voltage magnification: 1 to 2000

• Specifications of solenoid assembly:

Excitation coil: resistance = $100 \sim 200 \Omega$

coil density = $400 \sim 550 \text{ turns/cm}$

Pick-up coil: resistance = $40 \sim 70 \Omega$

coil density = $400 \sim 550 \text{ turns/cm}$

Software platform: Windows XP, Windows 7

Appendix C List of Packing Inserts

Accessory Name	Quantity
XacPro-E301 Detection Box	1
XacPro-E301Temperature Control Box	1
USB Transmission Line	1
Power Line	2
9-pin Signal Transmission Line	1
15-pin Signal Transmission Line	1
Original Software Disk	1
Operation Manual	1

Appendix D Warning Icon Description



This Way Up



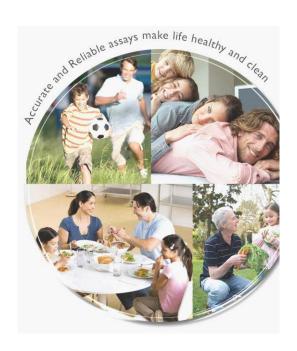
Careful Fragile



Keep Dry



Away From Magnetic Field



Chapter 9 Manufacturing

9. Manufacturing

The manufacturing details of Magnetic Immunoassay Analyzer, XacPro-E are illustrated in MagQu's Quaility Management System, i.e. ISO13485:2003.

9.1 Manufacturing Process

Following are steps to manufacture XacPro-E:

- Manufacturing coils
 - Round copper wire to the coils, then put the coils into the shell.
- Manufacturing Electronics
 - Build function generating system, temperature control system, filter and amplifier system and data acquiring system and put them into the shell.
- QC and packaging

The background value should be less than 15, and the signal of the sample should be 30 to 60. After QC pass and labeling, surround the device by cushion material and corrugated carton if necessary. The manual should be also put into the carton.

All the details about manufacture, QC, and packing are regulated in MQ-WIM-03, MQ-WIM-03-01/-02/-03/-04, Quality Management System following ISO 13485 and ISO9001.

Chapter 10 Vigilance System

Vigilance System

1. General

- 1.1. This procedure applies to written or oral complaints initiated by a customer, sales representative, MagQu Co., Ltd. employee or any other source such as a government agency, etc.
- 1.2. Customers complaints are handled according to controlled and defined processes, from receiving of the complaint until the end of its processing i.e., identification of the malfunction/problem, solution, implementation in the field, (if applicable), through reply to the client after investigation is completed.
- 1.3. This procedure describe the system for the notification and evaluation of incidents and field safety corrective actions (FSCA) in the European Community.
- 1.4. Corrective action includes, but may not be limited to: a device recall; the issue of a field safety notice; additional surveillance/modification of devices in use; modification to future device design, components or manufacturing process; modification to labeling or instructions for use.

2. Purpose

- 2.1. The purpose of this procedure is to define a clear and effective policy for collecting, documenting and handling of customer complaints and vigilance reporting.
- 2.2. This procedure defines the responsibilities and authorities.

3. References

- 3.1. Corrective and Preventive Action procedure # MQ-QP23
- 3.2. Post Marketing Surveillance procedure # MQ-QP25
- 3.3. Recall procedure # MQ-QP25
- 3.4. Customer Complaint form # MQ-QP24-01
- 3.5. Incident Report form # MQ-QP23-01
- 3.6. Field Safety Corrective Action Report form # MQ-QP24-01
- 3.7. ISO 13485-2003 Paragraphs 8.5.2 and 8.5.3.
- 3.8. Medical Device Vigilance System MEDDEV 2.12/1 rev.5:2007.

4. Definitions

4.1. Intended purpose

The use for which the device is intended according to the data supplied by the manufacturer on the labeling, in the instructions and/or in promotional materials.

4.2. Complaint

Any written or oral expression of dissatisfaction with a product related to its identity, durability, reliability, safety, effectiveness, or performance.

4.3. Malfunction

The failure of the device to meet any of its performance specifications or otherwise to perform as intended. Performed specifications include all claims made in the instructions for use of the device.

4.4. <u>Investigation</u>

A comprehensive survey of the design and related documentations, executed when there is a doubt about the performance of the device.

4.5. Harm

Physical injury or damage to the health of people, or damage to property or the environment.

4.6. Incident

Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health or any incident that requires intervention by a medical care professional to preclude permanent impairment of a body function or permanent damage to body function, or unanticipated damage to body structure.

4.7. Near Incident – a near incident, is an incident that was prevented due to early detection of the potential discrepancy.

Note: in Europe, near incident is considered as an "Incident".

4.8. Safety Related Complaint – A complaint related to an "incident" or to a "near incident".

4.9. Serious public health threat

Any event type which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action. This would include events that are of significant and unexpected nature such that they become alarming as a potential public health hazard.

4.10. Unanticipated

A deterioration in state of health is considered unanticipated if the condition leading to the event was not considered in the risk analysis.

4.11. Use error

Act that has a different result to that intended by the manufacturer or expected by the operator of the medical device.

4.12. Vigilance Reporting

Mandatory reporting to the authorities of any deterioration in the characteristics of the device or its functionality, which cause or may cause any incident.

4.13. Regulatory authorities

Any authority that provide certificate / license to market the device (such as FDA, Notified body, Health Canada etc.).

4.14. Corrective action

An action to eliminate the cause of a potential nonconformity or other undesirable situation.

4.15. Field Safety Corrective Action (FSCA)

A field safety corrective action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions should be notified via a field safety notice. The FSCA may include:

- 4.15.1. The return of a medical device to the supplier (recall).
- 4.15.2. Device modification.
- 4.15.3. <u>Device exchange.</u>
- 4.15.4. Device destruction.
- 4.15.5. Retrofit by purchaser of manufacturer's modification or design change.
- 4.15.6. Advice given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use).

- 4.15.7. <u>Permanent or temporary changes to the labeling or instructions</u> for use.
- 4.15.8. Software upgrades including those carried out by remote access.
- 4.15.9. <u>Modification to the clinical management of patients to address a risk of death or serious deterioration in state of health related specifically to the characteristics of the device.</u>

4.16. Field safety notice (FSN)

An official communication to customers and/or users sent out by a manufacturer or its representative in relation to a field safety corrective action.

5. Procedure

- 5.1. A customer complaint can be reported at any stage in the product life cycle:

 from the moment the product left the company, by the agent/distributor and/or by the customer (doctor, medical center, etc.).
- 5.2. The receiver of the complaint shall ask the complainant or his representative to give the most thorough details about the complaint, additional documents that attest it, examinations of the patient etc.
- 5.3. At the time of receiving the complaint, no assumptions or solutions will be given regarding the complaint, the reason for the problem or the conclusions. The purpose of the communications at this stage is only to obtain the maximum amount of information.
- 5.4. In case a physician's complaint is received indirectly, for example through a distributor or a salesman, the complaint receiver shall inquire about the physician's contact details and about other persons who were present when the problem was discovered.
- 5.5. The receiver of the complaint shall document the complaint details and forward it to the QA manager.

5.6. Review of the complaint

- 5.6.1. Once the complaint is received at the company, the following actions shall be taken:
 - 5.6.1.1. <u>The complaint will be given an identification</u> number for follow-up.
 - 5.6.1.2. <u>A "Customer complaint" form will be filled out including: product information, complaining customer information, and complaint information.</u>
- 5.6.2. The QA manager will verify the complaint details and will perform a comprehensive investigation to determine the direct and/or indirect causes for the failure. In addition, all variables that might affect process capability to comply with the requirements should be identified.

- As applicable, the Operations department and/or other individuals shall participate in the investigation.
- 5.6.3. The QA manager shall inform the Senior VP Operations and the QA/RA Director in case that an investigation is required.
- 5.6.4. As applicable, based on the information received, the QA manager will locate all the information related to the device involved in the complaint, from the incoming inspection of raw materials until it's marketing, including: test results, manufacturing records etc. A copy of all relevant documents will be attached to the complaint file.
- 5.6.5. All complaint files shall be reviewed to gather additional relevant information. Complaint reports shall be reviewed in order to verify that there is no significant problem recurring periodically.

5.7. Interaction with the customer

- 5.7.1. A confirmation shall be delivered to the client within one week from receiving the complaint, as applicable it will be clarified that final response shall be delivered following completion of the investigation and conclusions.
- 5.7.2. The QA manager will keep in continuous contact with the reporting customer. A copy of all correspondence with the reporting customer will be filed together with the complaint form.
- 5.7.3. The QA manager shall summarize the results of the investigation and shall prepare a written response to the customer, including a detailed description of the corrective action performed. The CEO and/or the QA/RA Director will approve the written response. A copy of the written response will be kept together with the complaint form.
- 5.7.4. In order to close a complaint, the QA manager shall:
 - 5.7.4.1. Review the Customer complaint form to verify its completeness and accuracy.
 - 5.7.4.2. Sign the Customer complaint form.
 - 5.7.4.3. Close the complaint in the complaints log file.

5.8. Corrective action

5.8.1. The QA manager and Senior VP Operations shall determine whether additional corrective actions are required and will perform a follow-up on each corrective action until it is completed. If no corrective actions were deemed to be necessary, the rationale for this decision shall be documented in the complaint form. Corrective actions shall be performed according to "Corrective and Preventive Action" procedure.

5.9. Handling of safety related complaints

- 5.9.1. If the nature of the complaint is categorized as a safety related it should be immediately reported to the CEO and QA/RA Director.
- 5.9.2. In any case of safety related complaint, it is mandatory to perform investigation and risk assessment review in order to evaluate the affect of the complaint on product risks.

5.9.3. As required, the QA manager is responsible to verify notification of the appropriate regulatory authorities.

5.10. Vigilance, general principles

- 5.10.1. Based on the complaint details, the CEO, QA/RA Director and QA manager shall decide if the complaint is a reportable complaint and should be reported to the relevant authorities according to the European vigilance reporting system.
- 5.10.2. The QA manager shall notify the relevant authorities about incidents and field safety corrective actions when the reporting criteria are met.
- 5.10.3. As a general principle there is predisposition to report rather than not to report in case of doubt on the reportability of an incident.

5.11. Non reportable events – Europe only

Reporting under the European medical device vigilance system is not required in the following conditions:

- 5.11.1. <u>Deficiencies of a device found by the user prior to its use that are always detected.</u>
- 5.11.2. Event caused by patient conditions.
- 5.11.3. The only cause for the event was that the device exceeded its service life or shelf-life and the failure mode is not unusual.
- 5.11.4. <u>Use error which did not result in death or serious deterioration in state of health or serious public health threat.</u>
- 5.11.5. <u>Protection against a fault functioned correctly (as a precondition, there must be no danger for the patient to justify not reporting).</u>
- 5.11.6. Expected and foreseeable side effects which meet all the following criteria:
 - Clearly identified in the device labeling.
 - Clinically well known as being foreseeable and having a certain qualitative and quantitative predictability when the device is used and performs as intended.
 - Took in account in the risk assessment.
- 5.11.7. <u>Negligible likelihood of occurrence of death or serious deterioration in state of health.</u>

Note: A decision to not report must be justified and documented.

5.12. Vigilance reporting authorities

- 5.12.1. Complaint originating from a member state in the EU
 - 5.12.1.1. <u>The Competent Authority in the relevant state</u>, where the incident occurred
 - 5.12.1.2. The Notified Body that certify the device
 - 5.12.1.3. The EU Authorized Representative
- 5.12.2. If the complaint was reported from a non EU member or Switzerland, then the report will be based on the actual law of each country in addition (if applicable) the following authorities should be notified:
 - 5.12.2.1. The Competent Authority responsible for the EU Authorized Representative

- 5.12.2.2. The EU Authorized Representative
- 5.12.2.3. The Notified Body that certify the device

Note: Incidents which occurred outside the EU and do not lead to a FSCA relevant to these geographic areas do not need to be reported.

5.12.3. The list of vigilance contact points within the EU national competent authorities can be found at:

http://europa.eu.int/comm/enterprise/medical_devices/ca/ca_vig.htm

5.13. Reporting authorities - Field Safety Corrective Actions (FSCA)

As applicable, the following authorities shall be reported on FSCA taken on a basis of incidents:

- 5.13.1. Competent Authorities of all countries affected.
- 5.13.2. The Competent Authority responsible for the EU Authorized Representative.
- 5.13.3. The EU Authorized Representative.
- 5.13.4. The Notified Body that certify the device.

5.14. Vigilance Reporting

- 5.14.1. <u>In Europe, the reporting shall be done initially by the "Incident Report" form, followed by follow-up report and after the complaint is closed by final report (unless the initial and the final report are combined into one report).</u>
- 5.14.2. The final report shall include a written statement of the outcome of the investigation and of any action. Examples of actions may include:
 - **5.14.2.1.** No action
 - **5.14.2.2.** Additional surveillance of devices in use
 - **5.14.2.3.** Preventive action on future production
 - 5.14.2.4. FSCA

5.15. The timetable for the initial reporting of an incident – Europe:

- 5.15.1. <u>Serious public health threat: immediately but not later than 2 calendar days.</u>
- 5.15.2. Death or unanticipated serious deterioration in state of health:

 Immediately (without any delay that could not be justified) after establishing a link between the device and the event but not later than 10 calendar days following the date of awareness of the event.
- 5.15.3. Others: immediately after establishing a link between the device and the event but not later than 30 calendar days following the date of awareness of the event.
- 5.15.4. If after becoming aware of a potentially reportable incident there is still uncertainty about whether the event is reportable, a report must submitted within the timeframe required for that type of incident.
- 5.16. If it appears that a complaint might be related to other marketed devices and safety hazard exist, the CEO QA/RA Director and QA manager shall consider initiating an FSCA and/or sending field safety notice to the

customers.

5.17. Field Safety Corrective Action (FSCA).

- 5.17.1. The national competent authority must be reported on any technical or medical reason leading to a systematic recall of devices of the same type by the manufacturer.
 - Those reasons includes:
 - 5.17.1.1. <u>Any malfunction or deterioration in the characteristics and/or performance of a device</u>
 - 5.17.1.2. Any inadequacy in the instructions for use which might lead to the death of a patient or user or to a serious deterioration in his state of health.
- 5.17.2. <u>Removals from the market for purely commercial non-safety</u> related reasons are not included.
- 5.17.3. The company shall issue a notification to the competent authorities of all countries affected at the same time and if applicable, also to the national competent authority responsible for the Authorized Representative.
- 5.17.4. The "Field Safety Corrective Action Report" form shall include all relevant documents necessary to monitor the FSCA:
 - 5.17.4.1. Relevant parts from the risk analysis.
 - 5.17.4.2. <u>Background information and reason for the FSCA</u> (including description of the potential hazard).
 - 5.17.4.3. <u>Description and justification of the action</u> (corrective/preventive).
 - 5.17.4.4. <u>Advice on actions to be taken by the distributor and the user in order to reduce the risks.</u>
 - 5.17.4.5. <u>Affected devices and serial / lot numbers range</u> (explanation why other devices are not affected).
 - **5.17.4.6.** Copy of the Field Safety Notice.
- 5.17.5. The QA manager shall inform the coordinating competent authority once the FSCA has been completed. The report shall include information on the effectiveness of the action per country involved.

5.18. Field Safety Notice (FSN):

The field safety notice should be on a company letterhead and include the following:

- 5.18.1. A clear title: "urgent field safety notice" followed by the commercial name of the affected product.
- **5.18.2.** The information defined in sections **5.17.4.1 5.17.4.5**.
- 5.18.3. Specific details to easily identify the affected products.
- 5.18.4. <u>A request to pass the FSN to all those who need to be aware of it</u> within the organization.
- 5.18.5. <u>Confirmation that the relevant national competent authorities</u> have been advised of the FSCA.
- 5.18.6. <u>Contact point for customers how and when to reach the</u> designated person.

- 5.19. Following the handling of a critical and/or safety related complaint and as required, appropriate notification shall be sent to all company distributors.
- 5.20. All the data regarding the complaint, including the information provided by the customer, the forms and the investigation report and conclusions, the corrective action taken and the written response to the customer will be kept in the company archive for at least five years from the date of distribution of the last unit of the same device family.
- 5.21. <u>Customer Complaints and the following corrective actions including its effectiveness shall be reported in management reviews.</u>

6. Responsibility

6.1. The QA manager is responsible to verify the implementation of this specification.

Chapter 11 Conclusion

11. Conclusions

The Magnetic Immunoassay Analyzer XacPro-E designed by MagQu Co., Ltd. is used to measure the change in the ac magnetic susceptibility of a sample over time. If the sample is a mixture of a magnetic reagent and an object to be detected, XacPro-E can be used to detect the concentration of bio-molecules in the object according to the change in the ac magnetic susceptibility, which is so-called immunomagentic reduction.

With this technical file to illustrate the Magnetic Immunoassay Analyzer XacPro-E developed by MagQu Co. Ltd. has been designed in a careful and considerate way. All its materials and manufacturing process are certificated and qualified in international regulations.

Moreover, the tests including safety and Performance of Magnetic Immunoassay Analyzer XacPro-E has been tested and compliance with guidance and international standards.

The Magnetic Immunoassay Analyzer XacPro-E packed with well package and label in a international and easy to understanding way.

In addition, MagQu Co. Ltd. provides a rationale vigilance system for post-market product to follow up.

In summary, the material properties, processing, physical design and product package of Magnetic Immunoassay Analyzer XacPro-E are well planned to assure the best safety concerns and intend use.

Chapter 12 Declaration of Conformity

12.1 EC declaration of conformity

Declaration of Conformity

The following

Type of product: Magnetic Immunoassay Analyzer

Type Designation: XacPro-E301

is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the Laws of the Member States relating to the Low Voltage Directive (2006/95/EC) and Electromagnetic Compatibility (2004/108/EC).

For the evaluation of above mentioned Directives, the following harmonized European Standards or Technical Specifications were applied:

Standard Report No.

IEC/EN 61010-1:2010 and T1303269-762

IEC/EN 61010-2-101:2002

EN 61326-1:2013, EN 61326-2-1:2013, TEEX1309269

EN 55011:2009/A1:2010,

EN 61000-3-2:2006+A1:2009+A2:2009, EN 61000-3-3:2008, IEC 61000-4-2:2008, IEC 61000-4-3:2006+A1:2007+A2:2010, IEC 61000-4-4:2012, IEC61000-4-5:2005,

IEC 61000-4-6:2008, IEC 61000-4-8:2009 and

IEC 61000-4-11:2004

The following manufacturer is responsible for sole responsibility for this declaration:

Company Name: MagQu Co., Ltd.

Address: 3F., No.12, Ln. 538, Zhongzheng Rd., Xindian Dist., New

CE

Taipei City 231, Taiwan

Signature:

Print Name:

Title:

Date/Place: October 16, 2013 / Taiwan

12.2 EU representative contract

Chapter 13 Applied Standards

13. Applied standards

13.1 QMS Related

EN ISO 13485:2012 Quality Systems - Medical devices-System requirements for

regulatory purposes.

13.2 Medical Device

EN ISO 14971:2012 Medical devices- Application of risk management to medical

devices.

13.3 IVD medical equipment

EN61010-1:2010 Safety requirements for electrical equipment for measurement,

control, and laboratory use. General requirements.

EN61010-2-101:2002 Medical electrical equipment - Part 1-2: General requirements

for safety - Collateral standard: Electromagnetic compatibility.

EN61326-1:2006 Electrical equipment for measurement, control and laboratory

use. EMC requirements. General requirements.

EN55011:2009 Industrial, scientific and medical equipment– Radio-frequency

disturbance characteristics Limits and methods of measurement.

13.4 IFU & Label

EN 15223-1:2012 Medical devices -- Symbols to be used with medical device

labels, labelling and information to be supplied -- Part 1:

General requirements