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-S

Document number:
RDR-14-0004

Outline

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1. Declaration of Conformity

1.1 Declared Product

Type of product: Magnetic Immunoassay analyzer

Type Designation: XacPro-S

1.2 Applied Standard

EN 61010-1:2010 (Third Edition)

EN 61010-2-101:2002

EN 61326-1:2013

EN 55011:2009/A1:2010

1.3 Declared Company

Company Name: MagQu Co., Ltd.

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

1.4 Declaration Date and Place

April 8, 2014/Taiwan

1.5 Reference

Further information is described in Appendix A to C.

2. Product Description

2.1 Introduction

The Magnetic Immunoassay Analyzer XacPro-S 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-S 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-S are described in this report.

2.2 General Description

2.2.1 Outward Appearance of XacPro-S

The picture of XacPro-S is shown in Fig. 2.1. XacPro-S is 2.35 m in width, 0.95 m in depth, and 1.2 m in height. The input electricity is 100/230 VAC, 50/60Hz.

Fig. 2.1. Photo of magnetic immunoassay analyzer XacPro-S.

2.2.2 Mechanism of Immunomagnetic Reduction

The Magnetic Immunoassay Analyzer XacPro-S 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. 2.2. 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.

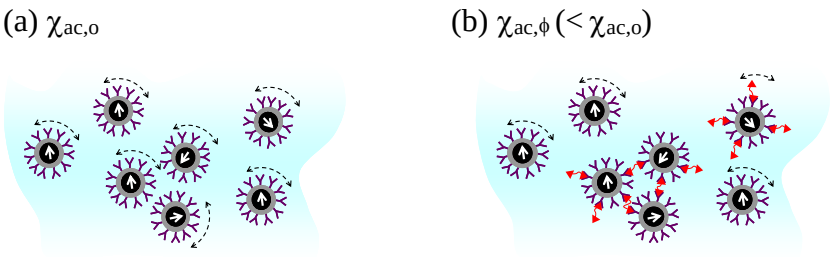


Fig. 2.2. Illustration of mechanism of immunomagnetic reduction to detect biotargets. (a) Each magnetic nanoparticle oscillates individually with the applied alternative-current magnetic field before binding with biotargets. (b) Portions of magnetic nanoparticles become larger due to the binding with 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:

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

where IMR(%) is referred as to IMR signal.
Furthermore, IMR signal was found as function of the biomolecular concentration ϕ via logistic function

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

where A, B, ϕ_o, and γ are finting parameters.

2.2.3 Principle of Magnetic Immunoassay Analyzer XacPro-S

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-S 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, as schematically shown in Fig. 2.3. Then, the sensed ac magnetic signal of

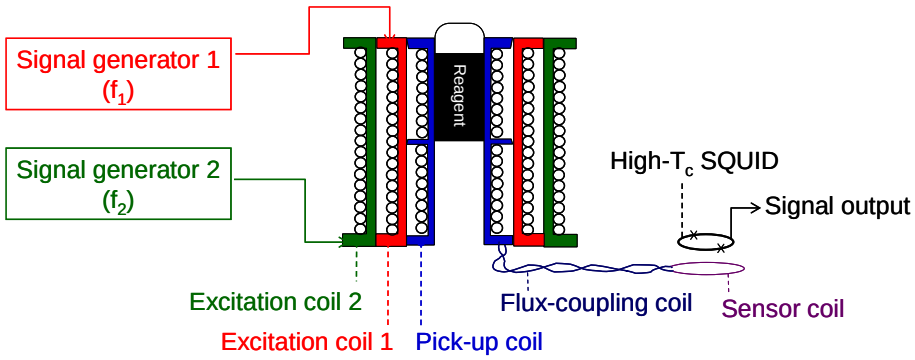


Fig. 2.3. Schematic configuration of XacPro-S for detecting ac magnetic signal of magnetic reagent.

reagent is transferred to a magnetic sensor via a flux-coupling coil. One end of the flux-coupling coil is connected in serious with the pick-up coil, the other end of the flux-coupling coil is connected in serious with the sensor coil. A high-T_c superconducting quantum interference device (SQUID) magnetometer is used to detect the transferred magnetic signal at the sensor coil. 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. All the details of working principle of XacPro-S are available in Refs. 2.5 and 2.6.

2.2.4 Hardware

A picture to reveal the hardware of XacPro-S is as shown in Fig. 2.3.

Fig. 2.3. Magnetic immunoassay analyzer XacPro-S is consisted of three modules: sensing part, coils, and electronics.

Briefly speaking, XacPro-S is consisted of three modules:

1. Sensing part

   This part mainly contains a high-T_c SQUID magnetometer and its controller, a 5-L/10-L dewar, and electromagnetically shielded can.
2. Coils

   Coils include excitation coils, pick-up coils, flux-coupling coil, and sensor coil. Sample is located inside excitation coils.
3. Electronics

   Electronics are consisted of a signal generator, switches, DAQ card, and a computer.

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

2.3 Functional Feature

The functional features of XacPro-S are listed below.

- Noise level < 65 μV/$Hz^{1/2}$ at operating frequency
- Signal to noise ratio > 10 for the mixture of 80-μl 0.3 emu/g magnetic fluid and 40-μl PBS solution
- Signal stability: CV < 10 %
- Amplitude of applied ac magnetic field < 20 Gauss
- Input voltage: 110/230 V_{ac}, 50/60 Hz, 500 W
- Magnetic-signal sensor: HTS SQUID Magnetometer
- Operation temperature: 25 ± 2 ^oC
- Operation humidity < 50 %
- Sample volume = 120 μl

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

Bio-target	Reagent	Low-detection limit
β-amyloid-40	Amyloid β1-40 IMR reagent (MF-AB0-0060)	4.91 pg/ml
β-amyloid-42	Amyloid β1-42 IMR reagent (MF-AB2-0060)	7.53 pg/ml
Tau protein	Tau protein IMR reagent (MF-TAU-0060)	0.002 pg/ml

2.4 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

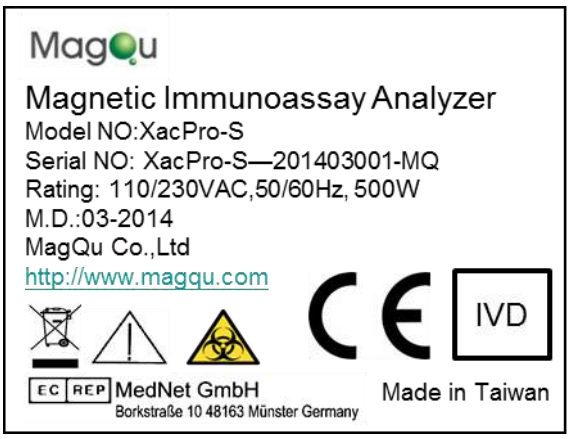
   Before lunching computer, please confirm whether the power is switching on. Switch off the power after shutting down the computer.
3. Ground the product.

   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. Other guild line: Indoor use
    - Altitude: 2000 m
    - Temperature: 5 ^{o}C to 40 ^{o}C
    - Humidity: Maximum 80% RH at 31 ^{o}C decreasing to 50% RH at 40 ^{o}C
    - Transient overvoltage at mains supply: 2500V
    - Pollution degree: 2
14. Disposal of product discarded

    Please refer to following instructions when recycling any instrument or component.
15. 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.

2.5. Duet Labeling



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).

3. Production

3.1 Bill OF Material

No.	Project	Quantity
1	Coil	1
2	SQUID System	1
3	Electronics	1
4	Shielding and shell	1

3.2 Specification of Materials Used

Name	Test Project	Standard	Method
Coil	Exterior	No collision damage, distortion or other adverse circumstances	Visual
	Specification	Excitation coil 1: ϕ 198±5 mm, 32±2 mm in length Excitation coil 2: ϕ 198±5 mm, 26±2 mm in length Pick-up coil: ϕ 8.5±1 mm, 6±1 mm in length	Actual test
SQUID	Specification	No collision damage, distortion or other adverse circumstances	Visual
	Specification	Input voltage : 110-230V Power : -72 ~ -118dBm Frequency : 405-710MHz	Actual test
Electronics	Exterior	No collision damage, distortion or other adverse circumstances	Visual
	Specification	Input voltage : 100/230V 60Hz AC Output voltage : 0-20V AC Output frequency : 0-1MHz DC Output: 5±0.5V	Actual test
Shielding and shell	Exterior	No collision damage, distortion or other adverse circumstances	Actual test
	Specification	Shielding Factor > -60 dB Aluminum or other magnetic restraining materials	Visual Visual

The details for inspecting the standards of materials used are clearly illustrated in MQ-WIQ-08, Quality Management System following ISO 13485 and ISO9001.

3.3 Manufacturing Processes

Follow the five steps to manufacture XacPro-S:

- Manufacturing shielding barrel:
  Use μ Metal, copper mesh, carbon fiber, or aluminum as the basic materials to produce shielding barrels with shielding factor better than -60 dB.
- Cooling down the SQUID
  Lower down the temperature of the SQUID magnetometer to 78K by liquid nitrogen and place them into shielding barrels.
- Manufacturing coils
  Round copper wire to the coils.
- Manufacturing Electronics
  Build function generating system and data acquiring system.
- QC and packaging
  The SNR should be better than 10, and the CV value should be better than 10%. After QC pass and labeling, surround the device by cushion material and wood box if necessary. The manual should be also put into the cushion material or wood box.

All the details about manufacture, QC, and packing are regulated in MQ-WIM-08, MQ-WIM-08-01/-02/-03/-05, Quality Management System following ISO 13485 and ISO9001.

3.4 Software Information

The software may be upgrade with time. Therefore, the version of the software should be 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 Tau protein IMR reagents (MF-TAU-0060) made by MagQu Co. Ltd. With Tau antigen provide by MagQu Co., Ltd. The IMR signal from the software should be higher than 5 %.

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.

3.5 Packing List

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

4. Essential Requirement of the Medical Device Directive

Check List for Medical Directive 93/42/EEC

Annex I

Essential Requirement

The following **harmonized standard** is applied to the essential requirement.
The all content shall be updated, according to the 93/42/EEC-M5; 2007/47/EC

- **ENISO13485:2012 –**Medical Devices, Quality Management Systems
- **ENISO14971:2012 –** Medical devise- Application of risk management to medical devices
- **EN15223-1:2012–**Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
- **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
- **EN62304:2006 –**Medical device software- Software life cycle processes
- **EN55011:2009 –**Industrial, scientific and medical equipment– Radio-frequency disturbance characteristics Limits and methods of measurement

Medical Devices Directive 93/42 EEC

As amended by 2007/47/EC

Product Description

Product ☐ Medicinal Magnetic Immunoassay Analyzer ☐ HSA ☐ Animal tissue	
Product class according to Medical Devices Directive Minor (Class I)	GMDN Code:
Model/type XacPro-S	
Product Description including intended use The Magnetic Immunoassay Analyzer XacPro-S 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, it can be used to detect the concentration of bio-molecules in the object according to the change in the ac magnetic susceptibility.	

Manufacturer (pls. stamp)

Company	MagQu Co., Ltd.
Address	3F, No. 12, Lane 538, Zhongzheng Rd., Xindian Dist., New Taipei City, Taiwan
Postal address	231

Conformity Assessment Procedure according to the following Annex of the Directive 93/42/EEC (pls. tick):

☐ Annex II ☐ incl ☐ excl. section 4 ☐ Annex V

Signature

The manufacturer confirms that all information given in the checklist is correct.		
Place and date	For the Manufacturer	Signature
The Lead Auditor confirms that the documents referred to in this checklist are implemented in the QS, which has been assessed to determine conformity with the directive 93/42/EEC.		
Place and date	Name of Lead Auditor	Signature
The MD Expert confirms that the product documentation is according to the requirements in directive 93/42/EEC		
Place and date	Name of MD Expert	Signature

Clause	Description	Appli-cable or not?	Standard/Sub-clause(s)	Report/Document	Comments
I	***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 EN 62304:2006	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF07 _Risk Management Report No. RM07-02 Product research file (XacPro-S)	
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 EN 62304:2006	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD07 _Risk Management Report No. RM07-02 Product research file (XacPro-S)	

Clause	Description	Appli-cable 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.RD07	
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. MF07 _Risk Management Report No. RM07-02 Product user Manual (XacPro-S, ver.201411)	
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 ENISO623074:206	System Cert. No TW14/10079 _Risk Management Report No. RM07-02	

Clause	Description	Appli-cable 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 EN 62304:2006	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF07 _Risk Management Report No. RM07-02 Product user Manual (XacPro-S, ver.201411)	
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 EN 62304:2006	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF07 Product user Manual (XacPro-S, ver.201411)	

Clause	Description	Appli-cable 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. MF07 Product user Manual (XacPro-S, ver.201411)	

Clause	Description	Appli-cable 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 (1) on the quality and safety of the substance including the clinical benefit/risk 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 incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account 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 benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notify body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure	No			

Clause	Description	Appli-cable 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). 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	No			
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. MF07 _Risk Management Report No. RM07-02	

Clause	Description	Appli-cable 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	Appli-cable 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. MF07 _Risk Management Report No. RM07-02 Product user Manual (XacPro-S, ver.201411)	
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. RM07-02 Product user Manual (XacPro-S, ver.201411)	

Clause	Description	Appli-cable 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 sub-stances 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. MF07 _Risk Management Report No. RM07-02	
10. 10.1.	**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 EN62304:2006	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF07 _Risk Management Report No. RM07-02 Product user Manual (XacPro-S, ver.201411)	

Clause	Description	Appli-cable 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 EN62304:2006	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD07 _Product Master file No. MF07 Product user Manual (XacPro-S, ver.201411)	
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.	YES	EN62304:2006	_Product Master file No. MF07	
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	Appli-cable 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	*Ionizing radiation* 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	Appli-cable 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.RD07 _Risk Management Report No. RM07-02 Product user Manual (XacPro-S, ver.201411)	

Clause	Description	Appli-cable or not?	Standard/Sub-clause(s)	Report/Document	Comments
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	Yes	Directive 98/79/EC ENISO13485:2012 ENISO14971:2012 EN62304:2006	ISO 13485 Quality System Cert. No TW14/10079 _Design Verification and Validation report No.RD07 _Risk Management Report No. RM07-02 Product Research files (XacPro-S)	
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	Appli-cable 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.RD07 _Product Master file No. MF07 _Risk Management Report No. RM07-02 Product research files (XacPro-S)	
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. RM07-02 Product research files (XacPro-S)	

Clause	Description	Appli-cable 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. RM07-02 Product user Manual (XacPro-S, ver.201411)	
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.RD07 _Risk Management Report No. RM07-02 Product user Manual (XacPro-S, ver.201411)	
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.RD07 _Risk Management Report No. RM07-02 Product research files (XacPro-S)	
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.RD07 _Risk Management Report No. RM07-02 Product user Manual (XacPro-S, ver.201411)	

Clause	Description	Appli-cable 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 EN 62304-2006	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF07 _Risk Management Report No. RM07-02 Product research files (XacPro-S) Product user Manual (XacPro-S, ver.201411)	
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	Appli-cable or not?	Standard/Sub-clause(s)	Report/Document	Comments
	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		EN15223-1:2012	_Product Master file No. MF07 Product user Manual (XacPro-S, ver.201411)	
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	Directive 98/79/EC ENISO13485:2012 EN61010-1:2010 EN61010-2-101:2002 EN15223-1:2012	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF07 Product user Manual (XacPro-S, ver.201411)	
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	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. MF07 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
	manufacturer does not have a registered place of business in the Community; (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			(XacPro-S, ver.201411)	

Clause	Description	Appli-cable 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. MF07 Product user Manual (XacPro-S, ver.201411)	
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-S, ver.201411)	
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 EN 62304 : 2006	ISO 13485 Quality System Cert. No TW14/10079 _Product Master file No. MF07 Product user Manual (XacPro-S, ver.201411)	g, i, k, l, m, n, o, p, and q are excluded

Clause	Description	Appli-cable 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	Appli-cable 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.				

Note. (Please see Appendix B and C to get further information)

5. Risk Management

Product name: Magnetic Immunoassay Analyzer
Product code: XacPro-S
Version: 2014-04

In general this risk assessment report for XacPro-S made by MagQu Co., Ltd. was carried out in accordance with the requirements of ISO 14971:2007 and ISO 62304:2006, 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:

5.1 Risk Management Flow Chart

The flow chart is shown in Fig. 5.1.

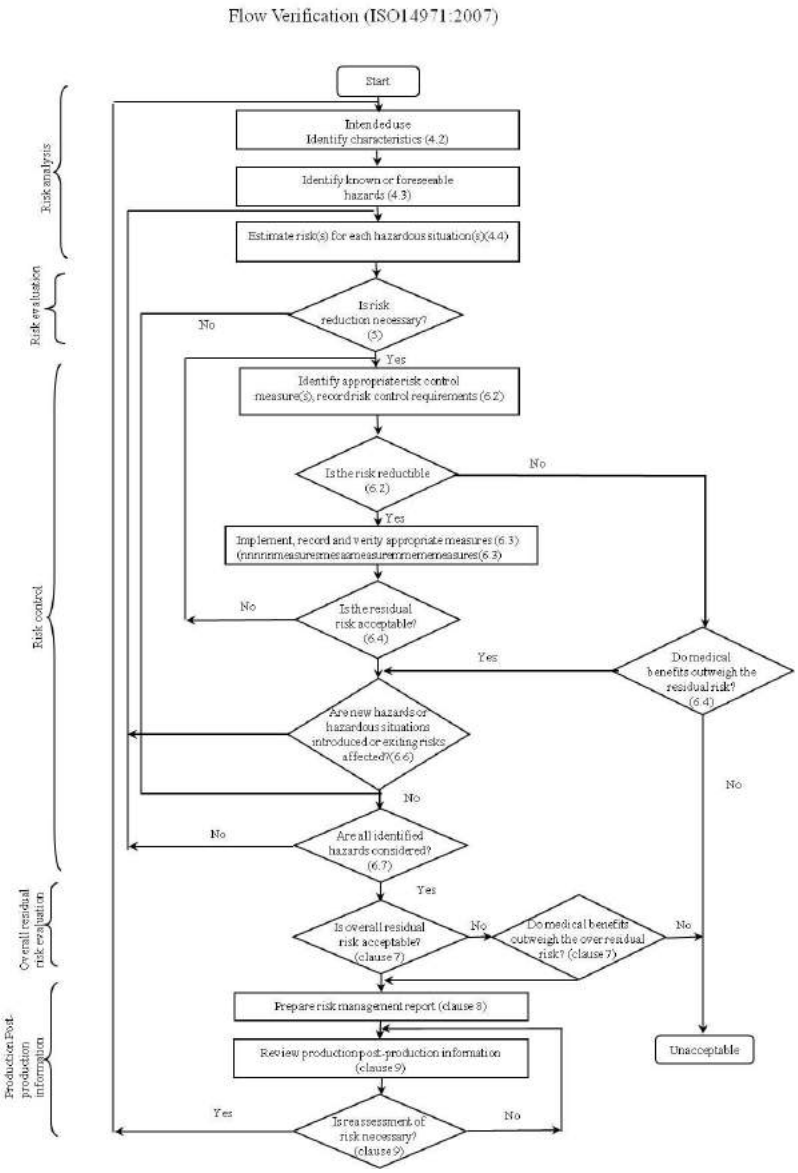


Fig. 5.1. Flow chart of risk management for XacPro-S.

5.2 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.: Yes, the software is a part of the XacPro-S

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-S 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.: No

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.: Yes

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.: Yes

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

5.3 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:

5.3.1 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

5.3.2 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

5.3.3 Risk Priority Number (RPN)

5.3.3.1 RPN = Probability* Severity, Risk Priority Number methodology is a

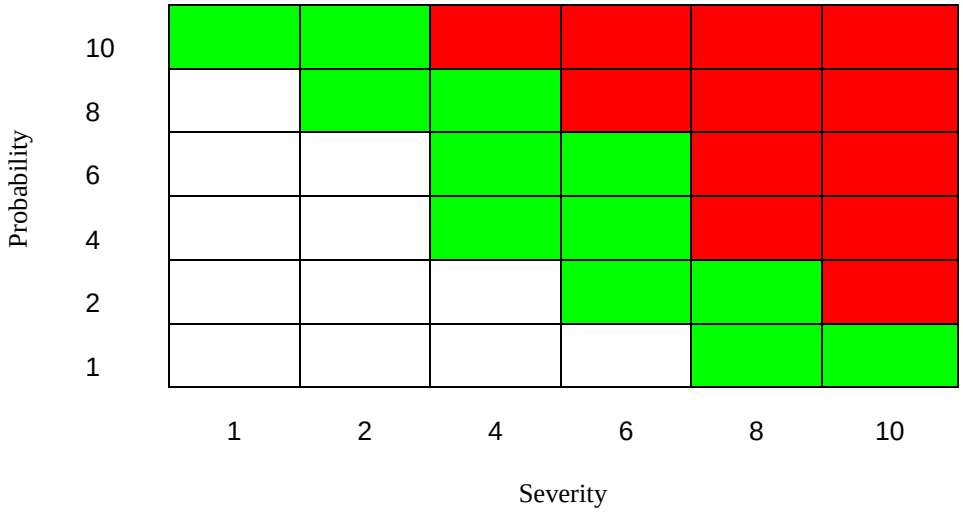
technique for analyzing the risk associated with potential problems identified during a Failure Mode and Effects Analysis (FMEA)：

Red ：Non acceptable

Green：ALARP

White：Acceptable

5.3.3.2 Rating scales means the risk level defined as following listed



5.4 Assessment Result

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

D2 Energy hazards ☑ Available □ Not available

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		✓
2.9	Suspended masses		✓
2.10	Patient support device failure		✓
2.11	Pressure		✓
2.12	Acoustic pressure		✓
2.13	Vibration		✓

D3 Biological hazards ☑ Available □ Not available

Item	Description	Available	N/A
3.1	Bio-contamination		✓
3.2	Bio-incompatibility		✓

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

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 environmental conditions		✓
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	✓	
6.7	misrepresentation of results		✓
6.8	insufficient visibility, audibility or tactility		✓
6.9	incompatibility with consumables/accessories/other medical devices		✓
6.10	incorrect measurement and other metrological aspects		✓

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 life time	✓	
7.5	Loss of mechanical integrity		✓
7.6	Inadequate packaging		✓
7.7	re-use or improper re-use		✓
7.8	Functional Failure	✓	

4.5 Measures to Eliminate The Risk & Its Improvement

4.5.1 Failure Mode and Effect Analysis (FMEA)

hazards	Potential Effects of Hazard					Current Design Controls		
	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	1	8 Acceptable	Set equipment into temperature-controlled room.			
2.4 Magnetic fields	The product will generate magnetic field and the magnetic fields surround may influence measuring result	8	1	8 Acceptable	Use Aluminum as a shielding.			
3.11 Bio-burden	Inadequacy measuring or recycling reagent may cause bio-burden	1	4	4 Acceptable	Bio-hazard warning should be present.			
4.1 Electromagnetic interference	Electromagnetic will influence measuring result	8	1	8 Acceptable	Use Aluminum as a shielding.			
4.2 Electromagnetic restrain	Electromagnetic wave may be restrain by Aluminum 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	2	2	4 Acceptable	Set equipment out of other equipments which work by electromagnetic force			

	electromagnetic restraining							
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	Software or 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

4.6 Risk/Benefit Comparison
The risk management report demonstrated the benefit of XacPro-S made by MagQu Co. Ltd. is better than risk to use it.

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

4.8 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.

4.9 Conclusion
According to above risk management report, the magnetic immunoassay analyzer (XacPro-S) 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:	Yen Fu Lee
Approved by:	Shieh-Yueh Yang
Dated:	2014/12/10

6. Applicable Standards

6.1 Applied Standards for Low Voltage Directive and In Vitro Diagnostic Directive

EN 61010-1: 2010 (Third Edition)

EN 61010-2-101: 2002

6.2 Applied Standards for Electromagnetic Compatibility Directive

EN 61326-1: 2013

EN 55011: 2009/ A1: 2010

6.3 Applied Standards for Software Life Cycle Processes

EN 62304: 2006

6.4 Applied Standards for Risk Management

ISO 13485: 2012

ISO 14971: 2007

ISO 9001:2008

7. Product Validation & Verification

7.1 Compliance with Standards

7.1.1 Issued Standards

The XacPro-S is issued for Low-Voltage Directive (2006/95/EC) and In Vitro Diagnosis (IVD) Directive (98/79/EC) and Electromagnetic Compatibility Directive (2004/108/EC) by Cerpass with standards EN 61010-1:2010 (Third Edition) and EN 61010-2-101:2002 on April 8th, 2014, and EMC by PMC with standards EN 61326-1:2013 and EN 55011:2009/A1:2010 on March 14th, 2014. 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.

7.1.2 References

Please see Appendix B-G for further information.

7.2 Performance Evaluation-Clinical Data

7.2.1 Subjects

In total, we recruited 109 control subjects (age: 15-81 years old; 62 women, 47 men), 24 subjects with mild cognition impairment (MCI) due to Alzheimer's disease (AD) (age: 55-95 years old; 12 women, 12 men), and 62 subjects with AD (age: 53-89 years old; 28 women, 34 men). In AD group, 32 subjects are with early-stage AD, and 30 subjects are with mild/severe AD. Subjects are grouped into control, MCI due to AD, early-stage AD, and mild/severe AD based on their clinical dementia rating (CDR) scores. Subjects with MCI due to AD or AD were recruited from the memory clinic at the National Taiwan University Hospital. Following routine tests at the memory clinic, they received a comprehensive clinical checkup including a review of their history, physical and neurological examinations, laboratory tests, and neuroimaging studies. Subjects with AD fulfilled the NINCDSADRDA criteria for probable AD. The AD subjects were further evaluated using the Hachinski ischemic scale, and those with a score greater than 4 were excluded. Following the Mayo clinic criteria, any subject with deficits in any recall subtest of the Taiwan version of the Wechsler Memory Scale-Third Edition, a CDR score of 0.5, and consistently normal activities of daily living/ instrumental activities of daily living (ADL/IADL) was diagnosed with MCI due to AD. The control subjects were selected from healthy volunteers. The volunteers were given a medical checklist of major systemic diseases, operations, and hospitalizations. Volunteers reporting uncontrolled medical conditions including heart failure, recent myocardial infarction (in the past 6 months), malignancy (in the past 2 years), or poorly controlled diabetes (HbA1C > 8.5) were excluded. Volunteers also received physical and neurological examinations and were scored on a short-form Geriatric Depression Scale (GDS-S). Those who had a GDS-S

score greater than 9 were excluded. Control subjects had normal cognitive function, confirmed by a battery of neuropsychological tests. All subjects or their primary caregivers gave informed consent. This study was approved by the ethics committee of the university hospital.

7.2.2 Specimen Collection and Preparation

Participants were asked to provide a 10-ml non-fasting venous blood sample (K3 EDTA, lavender-top tube). Each sample was assigned a registry number following the sampling sequence; hence, colleagues in the laboratory were blind to the clinical status and the demographic data of the subjects. In consideration of the possible circadian changes and food effects on plasma Aβ, all blood samples were collected between 10 AM and 2 PM and were postprandial. The blood samples were centrifuged (2500 x *g* for 15 minutes) within one hour of collection, and plasma was aliquoted into cryotubes and stored at -80 ℃ for less than three months until thawed for measurement.

7.2.3 IMR Assays with Plasma Aβ1-40, Aβ1-42, and Tau-protein

7.2.3.1 Ratio of plasma Aβ1-40 to Aβ1-42 for the Risk Evalution of Patients

Plasma samples of all subjects are used for Aβ1-40 and Aβ1-42 assays using MF-AB0-0060 and MF-AB2-0060, respectively. It was found that the concentration ratio of plasma Aβ1-42 to Aβ1-40, i.e. $\phi_{A\beta 1\text{-}42}/\phi_{A\beta 1\text{-}40}$, can be a good diagnostic parameter for MCI or AD. The plasma $\phi_{A\beta 1\text{-}42}/\phi_{A\beta 1\text{-}40}$ distribution for normal controls, MCI due to AD, early-stage AD, and mild/serve AD are shown in Fig. 7.1. According to the results, the $\phi_{A\beta 1\text{-}42}/\phi_{A\beta 1\text{-}40}$ of normal controls is relatively lower than that of patients with either MCI due to AD or AD. Through the receiver operating characteristic (ROC) curve analysis shown in Fig. 7.2, the threshold of plasma

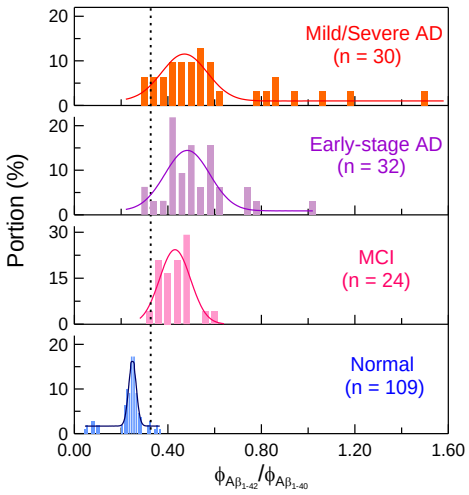


Fig. 7.1. Plasma $\phi_{A\beta 1\text{-}42}/\phi_{A\beta 1\text{-}40}$ distribution for normal controls, MCI due to AD, early-stage AD, and mild/serve AD assayed by using Amyloid β1-40, Amyloid β1-42 IMR reagents.

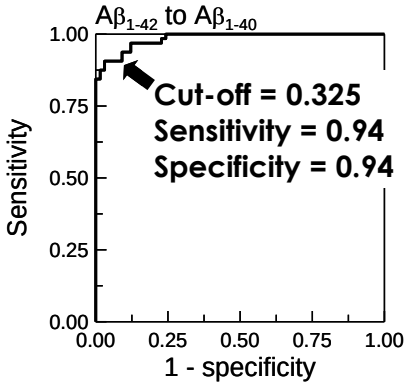


Fig. 7.2. ROC curve for finding the threshold of plasma $\phi_{A\beta1\text{-}42}/\phi_{A\beta1\text{-}40}$ for distinguishing MCI due to AD or AD from normal controls.

$\phi_{A\beta1\text{-}42}/\phi_{A\beta1\text{-}40}$ for distinguishing MCI due to AD or AD from normal controls is 0.325, which corresponds to 94 % sensitivity and 94 % specificity.

7.2.3.2 Product with Plasma Aβ1-42 and Tau Protein for the Risk Evaluation of MCI

In clinics, it is very important to distinguish MCI-due-to-AD patients from early-stage AD patients. The results in Fig. 7.1 show that $\phi_{A\beta1\text{-}42}/\phi_{A\beta1\text{-}40}$ is not a suitable diagnostic parameter for distinguishing MCI-due-to-AD patients from early-stage AD patients. Instead, the product of concentrations of plasma Aβ1-42 and tau protein, i.e. $\phi_{A\beta1\text{-}42}x\phi_{tau}$, can be a nice disgnostic parameter. The distributions of the plasma $\phi_{A\beta1\text{-}42}x\phi_{tau}$ for MCI-due-to-AD patients and early-stage AD patients are shown in Fig. 7.3. The plasma $\phi_{A\beta1\text{-}42}x\phi_{tau}$ of MCI-due-to-AD patients is smaller than that of early-stage AD patients. Through the receiver operating characteristic (ROC) curve analysis shown in Fig. 7.4, the threshold of plasma $\phi_{A\beta1\text{-}42}x\phi_{tau}$ for distinguishing MCI-due-to-AD patients from AD patients is 643.96 $(pg/ml)^2$, which corresponds to 85 % sensitivity and 84 % specificity.

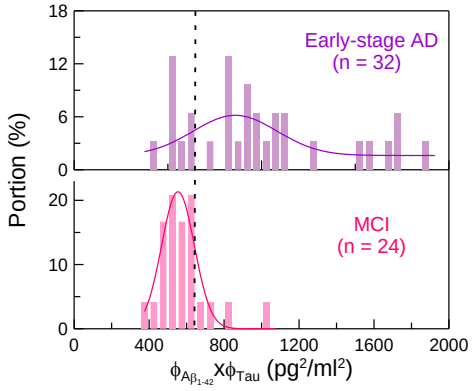


Fig. 7.3. Plasma $\phi_{A\beta1\text{-}42}x\phi_{tau}$ distribution for MCI-due-to-AD patients and early-stage AD patients assayed by using Amyloid β1-42 and Tau protein IMR reagents.

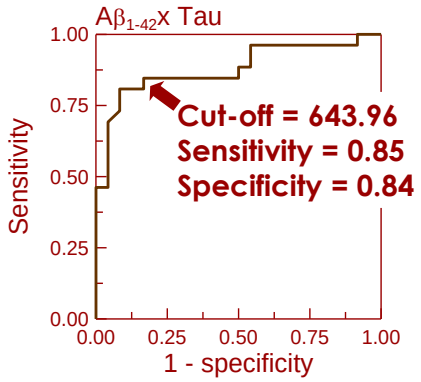


Fig. 7.4. ROC curve for finding the threshold of plasma $\phi_{A\beta 1\text{-}42}x\phi_{tau}$ for distinguishing MCI due to AD from early-stage AD.

7.2.4 IMR Assay Results vs. Medical Imaging

7.2.4.1 Plasma Aβ Ratio vs. PiB-PET

The amyloid plaques in brain cortex are imaged by using GE Healthcare Discovery ST4 PET/CT scanner (2D mode, 47 image planes, 15.0 cm axial field of view) for forty-three subjects of normal controls, MCI-due-to-AD patients and early-stage AD patients after injecting 370–555 MBq of 11C PiB. This is so-called PiB-PET. The detailed procedures of PiB-PET are given in Ref. 7.1. Meanwhile, the ratio of plasma $\phi_{A\beta 1\text{-}42}$ to $\phi_{A\beta 1\text{-}40}$ of each subject is detected by using Amyloid β1-42 and Amyloid β1-40 IMR reagents. The typical PiB-PET images and the corresponding plasma $\phi_{A\beta 1\text{-}42}/\phi_{A\beta 1\text{-}40}$'s are shown in Fig. 7.5. It was found that the plasma Aβ ratio increases

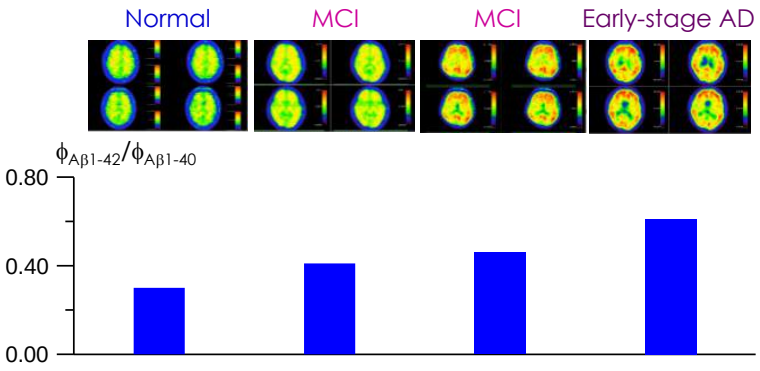


Fig. 7.5. PiB-PET images for amyloid plaques on brain cortex and corresponding plasma $\phi_{A\beta 1\text{-}42}/\phi_{A\beta 1\text{-}40}$.

as more the amyloid plaques were imaged. The plasma $\phi_{A\beta 1\text{-}42}/\phi_{A\beta 1\text{-}40}$ versus normalized amyloid plaques on brain cortex is shown in Fig. 7.5. The normalized amyloid plaques on brain cortex is represented in terms of adjust predict value. The results in Fig. 7.6 show that a positive correlation (correlation coefficient ~ 0.67) exists for the relationship the plasma Aβ ratio and amyloid plaques on brain cortex. All the details are reported in Ref. 7.1.

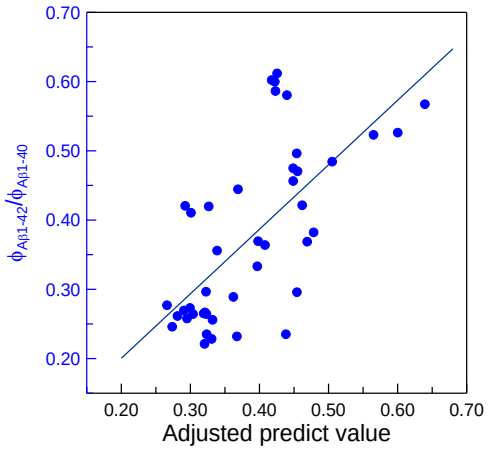


Fig. 7.6. Plasma $\phi_{A\beta1\text{-}42}/\phi_{A\beta1\text{-}40}$ versus normalized amyloid plaques on brain cortex. The plasma $\phi_{A\beta1\text{-}42}$ and $\phi_{A\beta1\text{-}40}$ are assayed with Amyloid β1-42 and Amyloid β1-40 IMR reagents. The normalized amyloid plaques on brain cortex is represented in terms of adjusted predict value.

7.2.4.2 Plasma Tau-protein Concentration vs. MRI

The AD patients are usually accompanied with the atrophy of hippocampus, which causes the express of tau protein in cerebrospinal fluid. The tau protein concentration in plasma would be varied due to the atrophy of hippocampus. Thus, the relationship between the plasma tau protein concentration and hippocampal volume is investigated. The hippocampal volumes of normal persons (n = 30), MCI-due-to-AD patients (n = 20), and early-stage AD patients (n = 10) are measured by using 1.5 T magnetic resonance imaging (MRI) scanner (EXCITE, General Electric, Milwaukee, USA). The detailed procedures of MRI are described in Ref. 7.2. For each case, the hippocampal volume is scaled to the whole brain volume. The plasma tau protein concentrations of these subjects are detected by using Tau Protein IMR Reagent. The typical MR images and the corresponding tau-protein concentrations are shown in Fig. 7.7. It was found that atrophy of the hippocampus

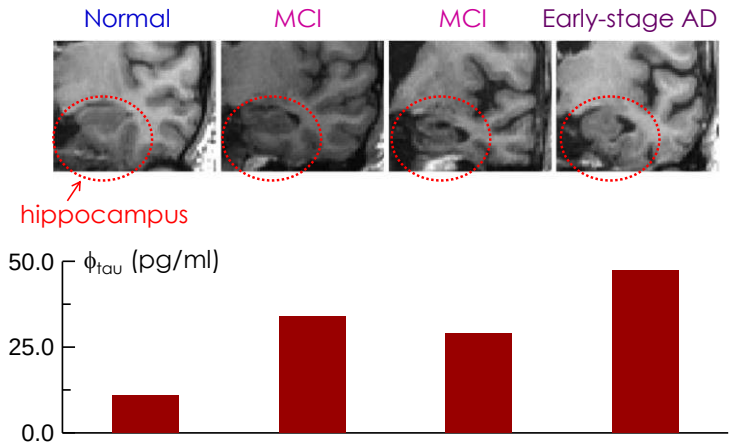


Fig. 7.7. MR images for hippocampal volumes and corresponding plasma tau protein concentration.

occurs for MCI due to AD and early-stage AD patients. Meanwhile, the plasma tau-protein concentration increases. The relationship between the scaled hippocampal volume and plasma tau-protein concentration is plotted in Fig. 7.8. A negative correlation with the coefficient of -0.61 is found for the relationship between the scaled hippocampal volume and plasma tau-protein concentration.

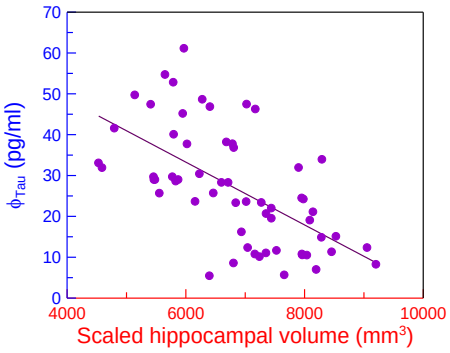


Fig. 7.8. Plasma tau protein concentration versus scaled hippocampal volume. The plasma tau protein is assayed with Tau Protein IMR reagent.

Reference

7.1. K.Y. Tzen, S.Y. Yang, T.F. Chen, T.W. Cheng, H.E. Horng, H.P. Wen, Y.Y. Huang, C.Y. Shiu, and M.J. Chiu, "Plasma Aβ but not tau related to brain PiB retention in early Alzheimer's disease", ACS Neuro. Chem. **5**, 830 (2014).

7.2 M.J. Chiu, Y.F. Chen, T.F. Chen, S.Y. Yang, F.P. Gloria Yang, T.W. Tseng, J.J. Chieh, J.C. Rare Chen, K.Y. Tzen, M.S. Hua, and H.E. Horng, "Plasma tau as a window to the brain-negative associations with brain volume and memory function in mild cognitive impairment and early Alzheimer's disease", Human Brain Mapping, 15 Oct. (2013).

Appendix A: Declaration of Conformity

Declaration of Conformity

The following

Type of product : **Magnetic Immunoassay Analyzer**

Type Designation : **XacPro-S**

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.
EN 61010-1:2010 (Third Edition) and EN 61010-2-101:2002	T1402142-253
EN 61326-1:2013 and EN 55011:2009/A1:2010	N3E11-103R0454-018

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

Company Name: *MagQu Co., Ltd.*

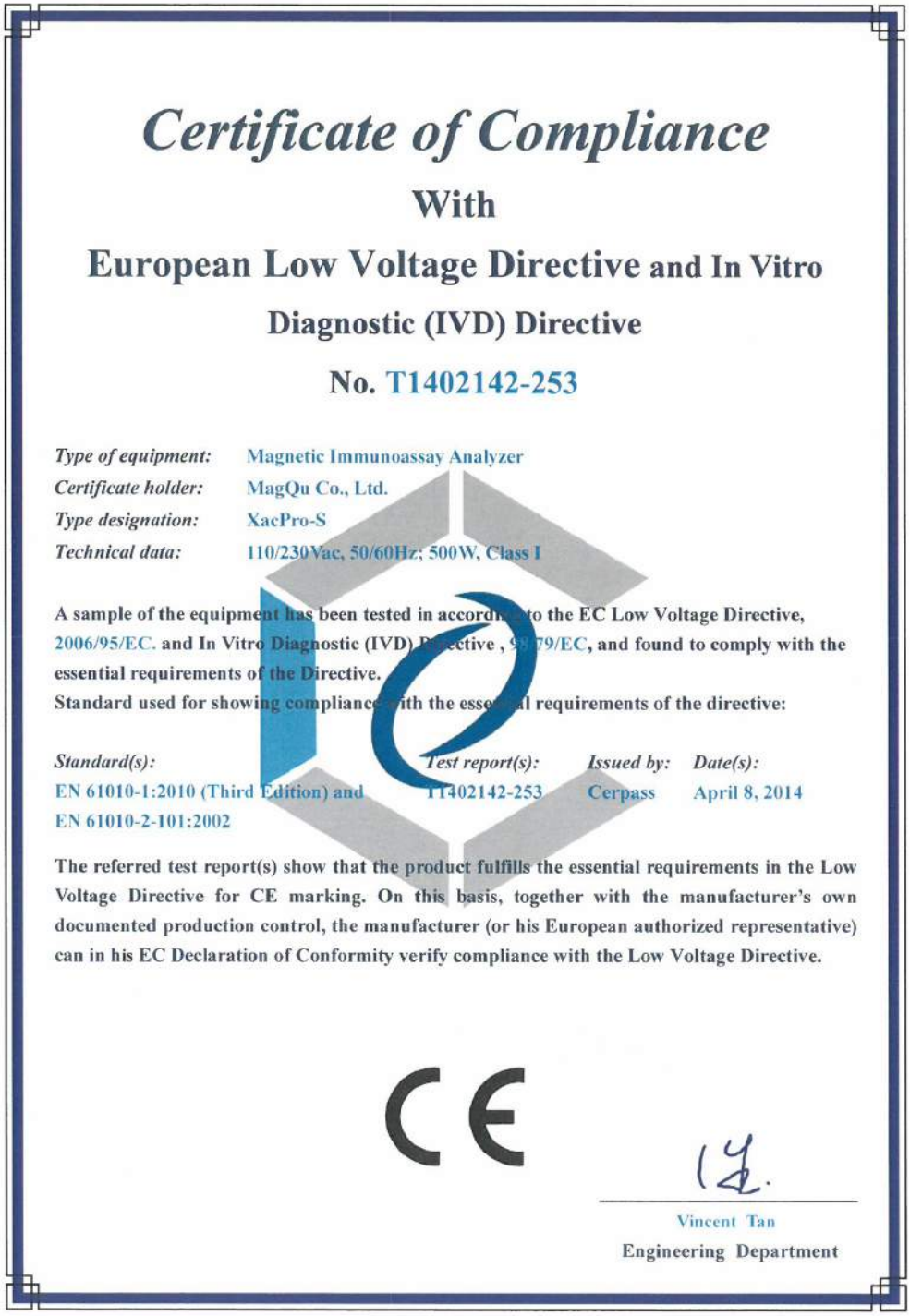
Address: *3F., No.12, Ln. 538, Zhongzheng Rd., Xindian Dist., New Taipei City 231, Taiwan*

Signature: Shieh-Yueh Yang
Print Name: Shieh-Yueh Yang
Title: President

Date/ Place: *April 8, 2014 / Taiwan*

CE

Appendix B: Certificate of Compliance with European Low Voltage Directive and In Vitro Diagnostic (IVD) Directive



Certificate of Compliance

With

European Low Voltage Directive and In Vitro Diagnostic (IVD) Directive

No. T1402142-253

Type of equipment: Magnetic Immunoassay Analyzer
Certificate holder: MagQu Co., Ltd.
Type designation: XacPro-S
Technical data: 110/230Vac, 50/60Hz; 500W, Class I

A sample of the equipment has been tested in accordance to the EC Low Voltage Directive, 2006/95/EC. and In Vitro Diagnostic (IVD) Directive , 98/79/EC, and found to comply with the essential requirements of the Directive.
Standard used for showing compliance with the essential requirements of the directive:

Standard(s):	*Test report(s):*	*Issued by:*	*Date(s):*
EN 61010-1:2010 (Third Edition) and EN 61010-2-101:2002	T1402142-253	Cerpass	April 8, 2014

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.

CE

Vincent Tan
Engineering Department

TEST REPORT

EN 61010-1 & 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

Report reference No.....:	T1402142-253
Tested by (printed name and signature).....:	Marty Chen
Approved by (printed name and signature).....:	Jasson Shiu
Date of issue.....:	April 8, 2014
Testing Laboratory name.....:	CERPASS TECHNOLOGY CORP.
Address.....:	9f, No. 200, Gangcian Rd., Neihu District, Taipei City 114, Taiwan
Testing location.....:	as above
Applicant's Name .....:	MagQu Co., Ltd.
Address.....:	3F., No.12, Ln. 538, Zhongzheng Rd., Xindian Dist., New Taipei City 231, Taiwan
Test specification.....:	
Standard.....:	EN 61010-1:2010 and EN 61010-2-101:2002
Test procedure .....:	IVD / LVD Verification Report
Procedure deviation .....:	NA
Non-standard test method .....:	NA
Test Report Form No. .....:	EN61010_1F
Test Report Form(s) Originator.....:	Cerpass
Test item description.....:	Magnetic Immunoassay Analyzer
Trademark .....:	MagQu
Model and/or type reference .....:	XacPro-S
Rating(s) .....:	110/230Vac, 50/60Hz; 500W, Class I
Manufacturer .....:	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):~~
Equipment mobility	:	~~Portable / Hand-held~~ / Floor standing ~~/ Fixed / Built in~~
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)

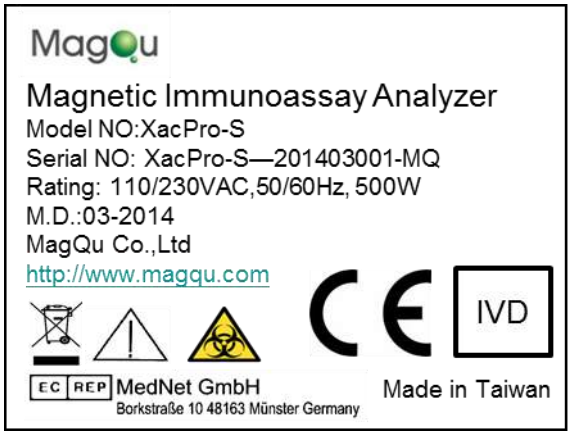
Testing ..... :

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::



EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
4.4	Testing in SINGLE FAULT CONDITIONS		P
4.4.1	Fault tests	(see Form A.1 and A.2)	P
4.4.2	Application of SINGLE FAULT CONDITIONS		P
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		P
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)	P
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	No fan	N/A
4.4.2.11	Heating devices	No heating device	N/A
4.4.2.12	Insulation between circuits and parts	In the approved power unit	N/A
4.4.2.13	Interlocks	No interlock	N/A
4.4.2.14	Voltage selectors	Setting voltage range before the factory	N/A
4.4.3	Duration of tests	(see Form A.1 and A.2)	P
4.4.4	Conformity after application of fault conditions	(see Form A.1; A.2; A.8, A.14)	P
4.4.2.101	Incorrect voltage selection (EN 61010-2-101)	Setting voltage range before the factory	N/A
5	MARKING AND DOCUMENTATION		P
5.1.1	General		P
	Required equipment markings are:		—
	visible:		P
	From the exterior; or	On the enclosure	P
	After removing a cover; or		N/A
	Opening a door		N/A
	After removal from a rack or panel		N/A

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	Required markings are not put on parts which can be removed by an OPERATOR (EN 61010-2-101)		P
	Letter symbols (IEC 60027) used (EN 61010-2-101)		P
	Graphic symbols (table 1) used (EN 61010-2-101)	Comply with Table 1	P
5.1.2	Identification (EN 61010-2-101)		—
	Equipment shall, as a minimum, be marked with the following information: (EN61010-2-101)		P
	a) manufacturer's name or trade mark, and the address. The address shall include at least the city and country;	Magqu	P
	b) model number, name, or other means of identifying the equipment;	See page 1	P
	c) where this is required by regulation, the name and address of the authorized representative of the manufacturer; (EN 61010-2-101)		P
	The following additional information shall be marked on the equipment or packaging or in the instructions for use: (EN 61010-2-101)		P
	1) the serial-number, for example SN XXXX or alternatively the batch code, preceded by 'LOT', using symbol 102 of Table 1; (EN 61010-2-101)	SN No. is marked	P
	2) the following information: (EN 61010-2-101)		-
	i) a clear indication that the equipment is IVD medical equipment; (EN 61010-2-101)	Marked on the label	P
	ii) if applicable, a clear indication that the equipment is self-test IVD medical equipment; (EN 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. (EN 61010-2-101)	Stated in the manual	P
	iv) any expiry date of consumable parts, expressed as the year, the month and (where relevant) the day, in that order. (EN 61010-2-101)		N/A
5.1.3	MAINS supply		P
	Equipment is marked as follows:		P
	a) Nature of supply:	~	—
	1) a.c. RATED MAINS frequency or range of frequencies .....:	Frequency is marked for the adpater	P
	2) d.c. with symbol 1	For the equipment	P
	b) RATED supply voltage(s) or range .....:	110/230V~	P
	c) Max. RATED power (W or VA) or input current....:	See page 1	P

EN 61010-1 + 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)	P
	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:		P
	Indicates the equipment set voltage		P
	Portable equipment indication is visible from the exterior		P
	Changing the setting changes the indication		P
	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	No operator replaceable fuse	N/A
	Operator replaceable fuse marking (see also 5.4.5)..... :		N/A
5.1.5	TERMINALS, connections and operating devices		P
5.1.5.1	General		P
	Where necessary for safety, indication of purpose of TERMINALS, connectors, controls and indicators marked	Purpose is marked	P
	If insufficient space, symbol 14 used 	Adequately marked	P
	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

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	safety of the environment		N/A
5.1.5.2	TERMINALS		P
	MAINS supply TERMINAL identified		P
	Other TERMINAL marking:		P
	a) FUNCTIONAL EARTH TERMINALS (symbol 5 used)	No functional earth	N/A
	b) PROTECTIVE CONDUCTOR TERMINALS:	Power cord is used	P
	Symbol 6 is placed close to or on the TERMINAL; or		P
	Part of appliance inlet		N/A
	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	Breaker is used	P
	If disconnecting device, off position clearly marked		P
	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 or REINFORCED INSULATION		—
	Protected throughout (symbol 11 used)		N/A
	Only partially protected (symbol 11 not used)	Class I product	P
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 (EN 61010-2-101)		—
	Packaging shall be labelled to indicate any special conditions for transport or storage. (EN 61010-2-101)		P
5.2	Warning markings		P
	Visible when ready for NORMAL USE		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	Are near or on applicable parts		P
	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	P
	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 (EN 61010-2-101)		P
	Equipment that can be potentially infectious due to the samples or reagents used shall be prominently marked with symbol 101 of Table 1 (EN 61010-2-101)	Symbol 101 is marked	P
	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. (EN 61010-2-101)	Symbol 14 is marked	P
	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. (EN 61010-2-101)	Symbol 101 is marked	P
	- 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. (EN 61010-2-101)	Provided	P
5.3	Durability of markings (EN 61010-2-101)		P
	Durability of markings; the required markings remain clear and legible (NORMAL USE) (EN61010-2-101)	(see Form A.4)	P
5.4	Documentation		P
5.4.1	General	Accompanied by documentation for safety purposes	P
	Equipment is accompanied by documentation for safety purposes for OPERATOR or RESPONSIBLE BODY (EN 61010-2-101)		P
	Safety documentation for service personnel authorized by the manufacturer		P
	Documentation necessary for safe operation is provided in printed media or	In printed media	P
	in electronic media if available at any time		N/A

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	Documentation includes:		—
	a) intended use	The user's manual provided with the relevant safety statements	P
	b) technical specification		P
	c) name and address of manufacturer or supplier		P
	d) Information specified in 5.4.2 to 5.4.6		P
	e) information to mitigate residual RISK		P
	f) accessories for safe operation of the equipment specified		P
	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		P
	h) instructions for lifting and carrying		P
	Warning statements and a clear explanation of warning symbols:		—
	Provided in the documentation; or	Stated in manual	P
	Information is marked on the equipment		P
	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. (EN 61010-2-101)	Stated in the manual	P
5.4.2	Equipment ratings		P
	Documentation includes:		—
	a) Supply voltage or voltage range..... :	110/230V~	P
	Frequency or frequency range .....:	See page 1	P
	Power or current rating.....:	See page 1	P
	b) Description of all input and output connections in accordance to 6.6.1 a)	Stated in the manual	P
	c) RATING of insulation of external circuits in accordance to 6.6.1 b)		P
	d) Statement of the range of environmental conditions (see 1.4)		P
	e) Degree of protection (IEC 60529)	IP20	P
	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		N/A

EN 61010-1 + 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 (EN 61010-2-101)		P
	Documentation for the RESPONSIBLE BODY shall include the following as applicable: (EN 61010-2-101)		P
	a) instructions for transportation after delivery to the RESPONSIBLE BODY; (EN 61010-2-101)		P
	b) floor loading requirements; (EN 61010-2-101)		P
	c) individual weights of principal heavy subassemblies; (EN 61010-2-101)		P
	d) location and mounting instructions, including the space required for ventilation, and for safe and efficient OPERATOR maintenance; (EN 61010-2-101)		P
	e) assembly instructions; (EN 61010-2-101)	Stated in the manual	P
	f) instructions for protective earthing; (EN 61010-2-101)		P
	g) the sound data required by 12.5.1; (EN 61010-2-101)		N/A
	h) instructions relating to the handling, containment and exhaust of hazardous substances, including any requirements for preventing back-syphonage; (EN 61010-2-101)		P
	i) any drainage systems required where a HAZARD could occur from the discharge of biological and chemical substances and hot fluids; (EN 61010-2-101)	No drainage required	N/A
	j) details of protective measures relating to hazardous radiation (see clause 12); (EN 61010-2-101)	No radiation hazards	N/A
	k) connections to the supply; (EN 61010-2-101)		P
	l) for PERMANENTLY CONNECTED EQUIPMENT only: (EN 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; (EN 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; (EN 61010-2-101)		N/A
	m) requirements for special services (for example air, cooling liquid) including pressure limits. (EN 61010-2-101)		N/A

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

EN 61010-1 + 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. (EN 61010-2-101)	Not a self-test IVD	N/A
5.4.4.101	Self-test IVD medical equipment (EN 61010-2-101)	Void	—
5.4.5	Equipment maintenance		P
	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	P
	Instruction against the use of detachable MAINS supply cord with inadequate rating		P
	Specific battery type of user replaceable batteries	No battery for user	N/A
	Any manufacturer specified parts		P
	Rating and characteristics of fuses		P
	Instructions include following subjects permitting safe servicing and continued safety:		P
	a) product specific RISKS may affect service personnel		P
	b) protective measures for these RISKS		P
	c) verification of the safe state after repair		P
5.4.6	Integration into systems or effects resulting from special conditions		P
	Aspects described in documentation		P
5.4.101	Removal of equipment from use for repair or disposal (EN 61010-2-101)		P
	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. (EN 61010-2-101)		P
5.4.102	Transport and storage (EN 61010-2-101)		P
	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). (EN 61010-2-101)		P

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

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
6.1.1	Requirements		—
	Protection against electric shock maintained in NORMAL CONDITION and SINGLE FAULT CONDITION	In normal and single fault condition not hazardous live	P
	ACCESSIBLE parts not HAZARDOUS LIVE	Conform with the request	P
	Voltage, current, charge or energy below the limits in NORMAL CONDITION and in SINGLE FAULT CONDITION between:		—
	ACCESSIBLE parts and earth		P
	two ACCESSIBLE parts on same piece of the equipment within a distance of 1,8 m		P
	Conformity is checked by the determination of 6.2 and 6.3 followed by the tests of 6.4 to 6.11		P
6.1.2	Exceptions		P
	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)	P
6.2.1	General		P
	Unless obviously determination of accessible parts as specified in 6.2.2 to 6.2.4		P
6.2.2	Examination		P
	- with jointed test finger (as specified B.2)	Complied with the finger test	P
	- with rigid test finger (as specified B.1) and a force of 10 N	Same as above	P
6.2.3	Openings above parts that are HAZARDOUS LIVE	No top openings	N/A
	- test pin with length of 100 mm and 4 mm in diameter applied		N/A
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		P
6.3.1	Levels in NORMAL CONDITION	(see Form A.7)	P

EN 61010-1 + 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.	P
	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)	P
	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 55V r.m.s. and 78V peak or 140V d.c.	P
	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 55V r.m.s. and 78V peak or 140V 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		P
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	P
	a) ENCLOSURES or PROTECTIVE BARRIERS (see 6.4.2)		P
	b) BASIC INSULATION (see 6.4.3)		P

EN 61010-1 + 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	ENCLOSURES or PROTECTIVE BARRIERS	(see Form A.13)	P
	- meet rigidity requirements of 8.1		P
	- 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		P
6.4.3	BASIC INSULATION	(see Form A.13)	P
	- meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7		P
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 CONDITION		P
6.5.1	ACCESSIBLE parts are prevented from becoming HAZARDOUS live by the primary means of protection and supplemented by one of:		P
	a) PROTECTIVE BONDING (see 6.5.2)	Class I	P
	b) SUPPLEMENTARY INSULATION (see 6.5.3)		P
	c) automatic disconnection of the supply (see 6.5.5)		N/A
	d) current- or voltage-limiting device (see 6.5.6)		P
	Alternatively one of the single means of protection is used:		P
	e) REINFORCED INSULATION (see 6.5.3)	For the insulating parts	P
	f) PROTECTIVE IMPEDANCE (see 6.5.4)		N/A
6.5.2	PROTECTIVE BONDING	(see Form A.9, A.10 and A.11)	P
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		N/A
6.5.2.2	Integrity of PROTECTIVE BONDING		P

EN 61010-1 + EN 61010-2-101			
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	P
	b) Soldered connections:	Power cord is used	N/A
	Independently secured against loosening		P
	Not used for other purposes		P
	c) Screw connections are secured	Connections are secured against loosening	P
	d) PROTECTIVE BONDING not interrupted; or	No part of the equipment is removable by the operator	P
	exempted as removable part carries MAINS SUPPLY INPUT connection		N/A
	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	P
	Exceptions:		N/A
	1) earthing braids;		N/A
	2) internal protective conductors etc.;		N/A
	Green/yellow not used for other purposes		P
	TERMINAL suitable for connection of a PROTECTIVE CONDUCTOR, and meets 6.5.2.3		P
6.5.2.3	PROTECTIVE CONDUCTOR TERMINAL	Approved power cord is used	P
	a) Contact surfaces are metal	Closed-loop metal ring terminal	P
	b) Appliance inlet used		P
	c) For rewirable cords and PERMANENTLY CONNECTED EQUIPMENT, PROTECTIVE CONDUCTOR TERMINAL is close to MAINS supply TERMINALS	Appliance inlet is used Approved power cord is used	N/A
	d) If no MAINS supply is required, any PROTECTIVE CONDUCTOR TERMINAL:	Connected to mains supply	N/A
	Is near terminals of circuit for which protective earthing is necessary		N/A
	External if other terminals external		N/A

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	e) Equivalent current-carrying capacity to MAINS supply TERMINALS	Approved power cord is used	P
	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
	1) Current RATING equivalent to measuring circuit TERMINAL;		N/A
	2) 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	0.02ohm measured passing 25Aac current from earthing terminal of inlet to inside metal part (see Form A.10)	P
	Impedance between PROTECTIVE CONDUCTOR TERMINAL and each ACCESSIBLE part where PROTECTIVE BONDING is specified, is:		—
	less than 0,1 Ohm; or		N/A
	less than 0,2 Ohm if equipment is provided with non detachable cord	0.02ohm	P
6.5.2.5	Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT	(see Form A.10) Not permanently connected	N/A
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

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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		P
	- meet CLEARANCE, CREEPAGE DISTANCE and solid insulation requirements of 6.7		P
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 Form A.12)	—
	a) appropriate single component suitable for safety and reliability for protection, it is:		N/A
	1) RATED twice the maximum WORKING VOLTAGE		N/A
	2) 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		P
	Device complies with all of:	For the fuse	P
	a) RATED to limit the current or voltage to the level of 6.3.2	(see Form A.8)	P
	b) RATED for the maximum working voltage; and		P
	RATED for the maximum operational current if applicable		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	c) CLEARANCE, CREEPAGE DISTANCE between terminations of the impedance meet requirements of SUPPLEMENTARY INSULATION of 6.7	(see Form A.13) Complied with insulation	P
6.6	Connections to external circuits		P
6.6.1	Connections do not cause ACCESSIBLE parts of the following to become HAZARDOUS LIVE in NORMAL CONDITION or SINGLE FAULT CONDITION:		P
	- the external circuits		P
	- the equipment		P
	Protection achieved by separation of circuits; or		P
	short circuit of separation does not cause a HAZARD		N/A
	Instructions or markings for each terminal include:		P
	a) RATED conditions for TERMINAL		P
	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)	P
6.7.1	The nature of insulation		—
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	P
6.7.1.2	CLEARANCES		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	Required CLEARANCES reflecting factors of 6.7.1.1	(see Form A.5)	P
	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		P
	Required CLEARANCES reflecting factors of 6.7.1.1	(see Form A.5)	P
	CTI material group reflected by requirements		P
	CTI test performed		P
6.7.1.4	Solid insulation		P
	Required CLEARANCES reflecting factors of 6.7.1.1	(see Form A.5)	P
6.7.1.5	Requirements for insulation according to type of circuit	(see Form A.5)	P
	a) 6.7.2 MAINS circuits of OVERVOLTAGE CATEGORY II up to nominal supply voltage of 300 V	CAT II and not over 300V	P
	b) 6.7.3 Secondary circuits separated from circuits defined in a) by transformer	Same as above	P
	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
	1) maximum TRANSIENT OVERVOLTAGE is limited to known level below the level of MAINS CIRCUIT		N/A
	2) maximum TRANSIENT OVERVOLTAGE above the level of MAINS CIRCUIT		N/A
	3) 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	P
6.7.2.1	CLEARANCES and CREEPAGE DISTANCES	(see Form A.13)	P
	Values for MAINS CIRCUITS of table 4 are met	CAT II and not over 300V	P
	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		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
6.7.2.2.1	Withstands electrical and mechanical stresses in normal use and all RATED environmental conditions of 1.4		P
	Equipment passed voltage tests of 6.8.3 with values of Table 5	(see Form A.14)	P
	Complies as applicable:		P
	a) ENCLOSURE or PROTECTIVE BARRIER Clause 8		P
	b) moulded and potted parts requirements of 6.7.2.2.2	No potted part	P
	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		P
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
	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		P
6.7.3.1	Secondary circuits where separation from MAINS CIRCUITS is achieved by a transformer providing:		—

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	- REINFORCED INSULATION		P
	- DOUBLE INSULATION		P
	- screen connected to the PROTECTIVE CONDUCTOR TERMINAL	No such parts	N/A
6.7.3.2	CLEARANCES		P
	a) meet the values of Table 6 for BASIC INSULATION and SUPPLEMENTARY INSULATION;		P
	twice the values of Table 6 for REINFORCED INSULATION, or		P
	b) pass the voltage tests of 6.8 with values of Table 6; with following adjustments:	(see Form A.14)	N/A
	1) values for REINFORCED INSULATION are 1,6 times the values for BASIC INSULATION	Complied with the R/I test	N/A
	2) 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		P
	Based on WORKING VOLTAGE meets the values of Table 7 for BASIC and SUPPLEMENTARY INSULATION		P
	Values for REINFORCED INSULATION are twice the values of BASIC INSULATION		P
	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
	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 values of BASIC INSULATION	Complied with R/I test	P
	b) if WORKING VOLTAGE exceeds 300 V, equipment passed voltage test of 6.8.3.1 for 1 min with a test voltage of 1,5 times working voltage for BASIC or SUPPLEMENTARY INSULATION	(see Form A.14) Not over 300V	N/A
	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

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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
	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)	P
6.9	Constructional requirements for protection against electric shock		P
6.9.1	If a failure could cause a HAZARD:		P
	a) Security of wiring connections		P
	b) Screws securing removable covers		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Accidental loosening		P
	d) CREEPAGE and CLEARANCES not reduced below the values of basic insulation by loosening		P
6.9.2	Material not to be used for safety relevant insulation:		P
	Easily damaged materials not used	No such material is used	P
	Non-impregnated hydroscopic materials not used	Same as above	P
6.9.3	Colour coding		P
	Green-and-yellow insulation shall not be used except:	G/Y wires are only used for earthing or bonding	P
	a) protective earth conductors;		P
	b) protective bonding conductors;		P
	c) potential equalization conductors;	No such terminal	N/A
	d) functional earth conductors		P
6.10	Connection to MAINS supply source and connections between parts of equipment		P
6.10.1	MAINS supply cords	Approved power cord is used	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		P
6.10.2.1	Cord entry		P
	Inlet or bushing smoothly rounded; or		P
	Insulated cord guard protruding >5D		P
6.10.2.2	Cord anchorage		P
	Protective earth conductor is the last to take the strain		P
	a) Cord is not clamped by direct pressure from a screw		P
	b) Knots are not used		P
	c) Cannot push the cord into the equipment to cause a HAZARD		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	d) No failure of cord insulation in anchorage with metal parts		P
	e) Not to be loosened without a tool		P
	f) Cord replacement does not cause a HAZARD and method of strain relief is clear		P
	Push-pull and or torque test	(see Form A.15)	P
6.10.3	Plugs and connectors	Approved power cord is used	P
	MAINS supply plugs, connectors etc., conform with relevant specifications		P
	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		P
	MAINS type plugs used only for connection to MAINS supply		P
	Plug pins which receive a charge from an internal capacitor	(see Form A.7) The pin not is hazardous live 5s after disconnection of the supply.	P
	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		P
6.11.1	Disconnects all current carrying conductors		P
6.11.2	Exceptions	The disconnecting means will disconnect all current-carrying conductors	P
6.11.3	Requirements according to type of equipment		P
6.11.3.1	PERMANENTLY CONNECTED EQUIPMENT and multi-phase equipment:	Non permanently connected	N/A
	Employs switch or circuit-breaker		N/A
	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		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	Equipment is provided with one of the following:		—
	a) Switch or circuit-breaker		N/A
	b) Appliance coupler (disconnectable without tool)		N/A
	c) Separable plug (without locking device)		P
6.11.4	Disconnecting devices		P
	Electrically close to the SUPPLY		P
6.11.4.1	Switches and circuit-breakers	Breaker is used	P
	When used as disconnection device:		—
	Meets IEC 60947-1 and IEC 60947-3		P
	Marked to indicate function ..... :		P
	Not incorporated in MAINS cord		P
	Does not interrupt PROTECTIVE EARTH CONDUCTOR		P
6.11.4.2	Appliance couplers and plugs		P
	Where an appliance coupler or separable plug is used as the disconnecting device (see 6.11.3.2):		P
	Readily identifiable and easily reached by the operator		P
	Single-phase portable equipment cord length not more than 3 m		P
	PROTECTIVE EARTH CONDUCTOR connected first and disconnected last		P
7	**PROTECTION AGAINST MECHANICAL HAZARDS**		P
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	P
	Conformity is checked by 7.2 to 7.7		P
7.2	Sharp edges	No sharp edges	P
	Easily touched parts are smooth and rounded		P
	Do not cause injury during NORMAL USE and		P
	Do not cause injury during SINGLE FAULT CONDITION		P
7.3	Moving parts	Moving part are enclosed	P
7.3.1	HAZARDS from moving parts limited to a tolerable level with the conditions specified in 7.3.2 and 7.3.5		P
	RISK assessment in accordance with 7.3.3 carried out		P
7.3.2	Exceptions	Moving part are enclosed	N/A
	Access to HAZARDOUS moving parts permitted under following circumstances:		N/A

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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
	3) 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
7.3.5.2	Access normally prevented		P
	Maximum gap as specified in Table 14 assured in NORMAL and in SINGLE FAULT CONDITION	Gap is less than 4mm	P
7.4	Stability		P
	Equipment not secured to building structure is physical stable	Equipment and assemblies of equipment is physically stable in normal use	P
	Stability maintained after opening of drawers etc. by automatic means, or	No drawer or the likes	N/A

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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		P
	b) multi-directional force test for equipment exceeds height of 1 m and mass of 25 kg		P
	c) downward force test for floor-standing equipment		P
	d) overload test with 4 times maximum load for castor or support that supports greatest load	No the specified equipment	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 :		—
	Has means for lifting or carrying; or		N/A
	Directions in documentation		P
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		P
	Equipment contains or limits the energy	Complied with the test of 4.4	P
	Protection not removable without the aid of a tool	Tool is needed	P
8	RESISTANCE TO MECHANICAL STRESSES		P
8.1	Equipment does not cause a HAZARD when subjected to mechanical stresses in NORMAL USE		P
	Normal protection level is 5 J	Tested with 5J	P
	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

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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		P
	2) impact test of 8.2.2 with 5 J except for HAND-HELD EQUIPMENT		P
	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	Fixed equipment	N/A
	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		P
	- insulation pass the voltage tests of 6.8	(see Form A.24)	P
	i) no leaks of corrosive and harmful substances		P
	ii) ENCLOSURE shows no cracks resulting in a HAZARD	No cracks which could cause a hazard	P
	iii) CLEARANCES not less than their permitted values	No less than their permitted values and the insulation of internal wiring remain undamaged	P
	iv) insulation of internal wiring remains undamaged	No damage	P
	v) PROTECTIVE BARRIERS not damaged or loosened	No damaged or loosened	P
	vi) No moving parts exposed, except permitted by 7.3	No moving parts exposed	P
	vii) no damage which could cause spread of fire	No damage	P
8.2	ENCLOSURE rigidity test		P
8.2.1	Static test		P
	- 30 N with 12 mm rod to each part of ENCLOSURE		P
	- in case of doubt test conducted at maximum RATED ambient temperature		P
8.2.2	Impact test		P
	Impact applied to any part of ENCLOSURE causing a HAZARD if damaged		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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		P
8.3	Drop test		P
8.3.1	Other than HAND-HELD and DIRECT-PLUG-IN EQUIPMENT	Floor-standing equipment	P
	Tests conducted with a drop height or angle of ..... :	Drop from 30°	P
8.3.2	HAND-HELD and DIRECT-PLUG-IN EQUIPMENT	Floor-standing 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 (EN 61010-2-101)		P
	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). (EN 61010-2-101)		P
9	PROTECTION AGAINST THE SPREAD OF FIRE		P
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	P
	Conformity is checked by minimum one or a combination of the following (see Figure 11):		P
	a) Fault test of 4.4; or	(see Form A.1 and Form A.2)	P
	b) Application of 9.2 (eliminating or reducing the sources of ignition); or		P
	c) Application of 9.2 (containment of fire within the equipment)		P
9.2	Eliminating or reducing the sources of ignition within the equipment	Considered to be reduced to a tolerable level	P
	a) 1) Limited-energy circuit (see 9.4); or	Not determine to Limited-energy circuit	N/A
	2) 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	P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	Bridging the insulation does not cause ignition	(see Form A.2) It can be demonstrated that bridging the insulation will not cause ignition	P
	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) No circuit designed to produce heat	N/A
9.3	Containment of the fire within the equipment, should it occur	The equipment meets one of the following construction requirement	P
	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	P
	Requirements of 9.5 are met	No flammable liquid is provided	N/A
9.3.1	Constructional requirements		P
	a) Connectors and insulating material have flammability classification V-2 or better		P
	b) Insulated wires and cables are flame retardant (VW-1 or equivalent)		P
	c) ENCLOSURE meets following requirements:		P
	1) 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	P
	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
	2) Material of ENCLOSURE and any baffle or flame barrier is made of:		P
	Metal (except magnesium); or	Plastic encased	N/A
	Non-metallic materials have flammability classification V-1 or better	Complied with V-1 for the adapters	P
	3) ENCLOSURE and any baffle or flame barrier have adequate rigidity	The enclosure have adequate rigidity	P
9.4	Limited-energy circuit	(see Form A.19) Not evaluated to limited energy	N/A

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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
	2) Over current protective device (see Table 18); or		N/A
	3) 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		P
9.6.1	MAINS supplied equipment protected	In the power supply	P
	BASIC INSULATION between MAINS parts of opposite polarity provided	(see Form A.14)	P
	Devices not in the protective conductor	Not be fitted in the protective conductor	P
	Fuses or single-pole circuit-breakers not fitted in neutral (multi-phase)	Not fitted in Neutral	P
9.6.2	PERMANENTLY CONNECTED EQUIPMENT	Not a permanently connected equipment	N/A
	Overcurrent device:		N/A
	Fitted within the equipment; or		N/A
	Specified in manufacturer's instructions		N/A
9.6.3	Other equipment		P
	Protection within the equipment	Provided in the adapter	P
10	EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
10.1	Surface temperature limits for protection against burns		P
	Easily touched surfaces within the limits in NORMAL and in SINGLE FAULT CONDITION:	(see Form A.21A)	P
	- 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)	P
	- 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		P
	Limits not exceeded in:	(see Form A.21)	P
	NORMAL CONDITION	Not exceed the vales of table 20	P
	SINGLE FAULT CONDITION	Not exceed the vales of table 20	P
10.3	Other temperature measurements		P
	Following measurements conducted if applicable:	(see Form A.21A)	P
	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		P
	d) Parts made of insulating material supporting parts connected to MAINS supply		P
	e) Terminals carrying a current more than 0,5 A	No such aprts	N/A
10.4	Conduct of temperature test		P
10.4.1	Tests conducted under reference test conditions and manufacturer's instructions	(see Form A.21A)	P
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	Floor-standing equipment	N/A
	Equipment built in as specified in installation instructions	(see Form A.21A) Same as above	N/A

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
10.5	Resistance to heat		P
10.5.1	Integrity of CLEARANCE and CREEPAGE DISTANCES	(see Form A.13)	P
10.5.2	Non-metallic ENCLOSURES	(see Form A.22)	P
	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	P
10.5.3	Insulating material		P
	a) Parts supporting parts connected to MAINS supply		P
	b) TERMINALS carrying a current more than 0.5 A	< 0.5A	N/A
	Examination of material data; or		N/A
	in case of doubt:		—
	1) Ball pressure test; or		N/A
	2) Vicat softening test of ISO 306		N/A
11	PROTECTION AGAINST HAZARDS FROM FLUIDS		P
11.1	Protection to OPERATORS and surrounding area provided by EQUIPMENT		P
	All fluids specified by manufacturer considered		P
11.2	Cleaning	(see Form A.24)	P
11.3	Spillage	(see Form A.24)	P
	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. (EN 61010-2-101)		P
11.4	Overflow	(see Form A.24)	P
11.5	Battery electrolyte	No battery	N/A
	Battery electrolyte leakage presents no HAZARD		N/A
11.6	Specially protected equipment	(see Form A.24) No IP rating	N/A
11.7	Fluid pressure and leakage		N/A
11.7.1	Maximum pressure .....:	(see Form A.25)	N/A
	Maximum pressure of any part does not exceed P_{RATED}		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

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	a) product of pressure and volume > 200 kPal; and		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	No 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
	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

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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:		—
	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
13	PROTECTION AGAINST LIBERATED GASES, EXPLOSION AND IMPLOSION		N/A

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
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. (EN 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. (EN 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
	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

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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		P
14.1	Where safety is involved, components and subassemblies meet relevant requirements	Components used in accordance with their specified ratings	P
14.2	Motors	No motor is used	N/A
14.2.1	Motor temperatures		N/A
	Does not present a HAZARD when stopped or prevented from starting; or	(see Form A.21)	N/A
	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
14.4	Fuse holders	No operator replaceable fuse	N/A
	No access to HAZARDOUS LIVE parts		N/A
14.5	MAINS voltage selecting devices	Setting voltage range before the factory	N/A
	Accidental change not possible		N/A
14.6	MAINS transformers tested outside equipment		N/A
14.7	Printed circuit boards		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
	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	P
	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
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		P
16.1	REASONABLY FORESEEABLE MISUSE		P
	No HAZARDS arising from settings not intended and not described in the instructions		P
	Other cases of REASONABLY FORESEEABLE MISUSE addressed by RISK assessment		P
16.2	Ergonomic aspects		P
	Factors giving rise to a HAZARD the RISK assessment is reflecting those aspects:		P
	a) limitation of body dimensions	Not a big equipment	P
	b) displays and indicators	Readily to read	P
	c) accessibility and conventions of controls	Readily to access	P
	d) arrangement of TERMINALS		P

EN 61010-1 + EN 61010-2-101			
Clause	Requirement + Test	Result - Remark	Verdict
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
	2) Protective measures taken for RISKS that cannot be eliminated		N/A
	3) 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

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

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

4.4.2	**TABLE: Summary of SINGLE FAULT CONDITIONS**			**Form A.1**	P
Subclause	Title	Does not apply	Carried out	Comments	
4.4.2.1	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	
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 – air holes closed – fans stopped – coolant stopped – loss of cooling liquid	✓ ✓ ✓ ✓ ✓		No such parts No filters No fan No coolant No cooling liquid	
4.4.2.11	Heating devices – timer overridden – temperature controller overridden	✓ ✓ ✓		No heating device	
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 all SINGLE FAULT CONDITIONS not covered by 4.4.2.2 to 4.4.2.14:					
Supplementary information: (see Form A.2 for details of tests)					

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

4.4	**TABLE: Testing in SINGLE FAULT CONDITION – Results**			**Form A.2**	P
Test subclause	Fault No.	Fault description	Td 4.4.3 (NOTE)	How was test terminated Comments	Meets 4.4.4
4.4.2.1	1	Wrong setting on functional knob	30min	No hazards occurred and no accessible conductive parts have become hazardous live	P
4.4.2.3	2	Open Protective conductor	1Hr	No hazards and no accessible voltage over the limit	P
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:					

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

5.1.3c)	**TABLE: MAINS supply**		**Form A.3**	P
	Marked rating ..... :	110/230	V	—
	Phase ..... :	1	~	—
	Frequency ..... :	50/60	Hz	—
	Current ..... :	--	A	—
	Power ..... :	500	W	—
	Power ..... :	--	VA	—

Test	Voltage	Power in	Current	Power in	Comments
No.	V	W	A	VA	
1	99	138	2.1	207.9	Sample is operated with all parameters set at maximum setting
2	110	142	1.98	217.8	Sample is operated with all parameters set at maximum setting
3	120	150	1.78	213.6	Sample is operated with all parameters set at maximum setting
4	230	143	1.04	239.2	Sample is operated with all parameters set at maximum setting
5	240	145	1.01	242.4	Sample is operated with all parameters set at maximum setting
6	253	150	0.99	250.5	Sample is operated with all parameters set at maximum setting

Note – Measurements are only required for marked ratings.

Supplementary information:

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

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

Marking method (see NOTE)	Agent
1) Adhesive label	A Water
2) Ink printed	B Isopropyl alcohol 70%
3) Laser marked	C (specify agent)
4) Film coated (plastic foil control panel)	D (specify agent)
5) Imprinted on plastic (moulded in)	E (specify agent)

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

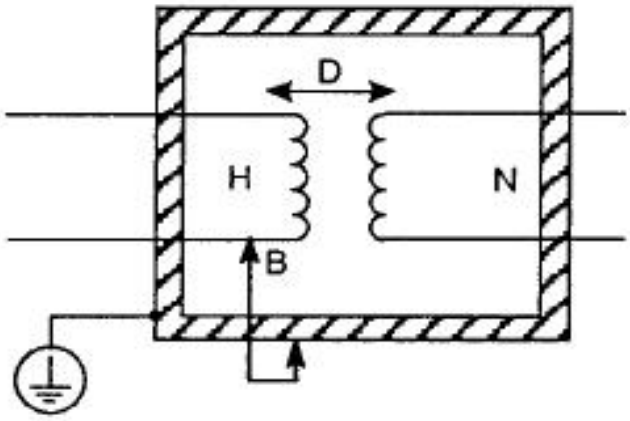
Marking location	Marking method (see above)
Identification (5.1.2)	1
MAINS supply (5.1.3)	1
Fuses (5.1.4)	N/A
terminals and operating devices (5.1.5.2)	N/A
Switches and circuit breakers (5.1.6)	2
Double/reinforced equipment (5.1.7)	N/A
Field wiring Terminal boxes (5.1.8)	N/A
Warning marking (5.2)	2
Battery charging (13.2.2)	N/A

Method	Test agent	Remains legible	Label loose	Curled edges	Comments
		Verdict	Verdict	Verdict	
1	A & B	Yes	No	No	P
2	A & B	Yes	N/A	N/A	P

Supplementary information:

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

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



Pollution degree.....: 2	Overvoltage category.....: II

Location or description	Insulation type (NOTE 1)	Maximum working voltage (NOTE 2)	CREEPAGE Distance (NOTE 3)				CLEARANCE (NOTE 3)	Test voltage	Comments
			PWB mm	CTI	Other mm	CTI	mm	(NOTE 2) V	
Mains to accessible parts (GND)	BI	230Vac	1.5	-	3.0	-	1.5	1500Vac	Pass
Mains to SELV	RI	230Vac	3.0	-	6.0	-	3.0	3000Vac	Pass

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

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

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

Supplementary Information:

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

6.2	**TABLE: List of ACCESSIBLE parts**		**Form A.6**	P
6.1.2	Exceptions			—
6.2	Determination of ACCESSIBLE parts			—
Item	Description	Determination method (NOTE 5)	Exception under 6.1.2 (NOTE 4)	
1	Enclosure	V, R and J	--	
2	Connector	V, R and J	--	

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:

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

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

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

6.3.2	**TABLE: Values in SINGLE FAULT CONDITION**										**Form A.8**	P
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 2	<2	<2	<0.1	--	--	--	--	--	--	--	
2	1 to 2	<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.												
Supplementary information:												

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

6.5.2.2	TABLE: Cross-sectional area of bonding conductors	Form A.9	P
CONDUCTOR LOCATION	CROSS-SECTIONAL AREA mm²		VERDICT
GND pin of inlet to enclosure	0.8mm^2		P

6.5.2.4	TABLE: Bonding impedance of plug connected equipment			Form A.10	P
ACCESSIBLE 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	0.5	0.02Ω		P
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			N/A
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 PROTECIVE BONDING screen			Form A.11	N/A
ACCESSIBLE part under test	Test current (see NOTE) A	Voltage attained after 1 min (maximum 10 V) V	Calculated resistance (maximum 0,1 Ω) 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).					
Supplementary information:					

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

6.5.4	**TABLE: protective impedance**	**Form A.12**	N/A

A single component

Component	Location	Measured		Calculated	Rated		Verdict	Comments
		Working voltage V	Current A	Power dissipation W	Working voltage V	Power dissipation W		

A combination of components

Component	Location	Comments

NOTE – A PROTECTIVE IMPEDANCE shall not be a single electronic device that employs electron conduction in a vacuum, gas or semiconductor.

Supplementary information: **No Protective impedance**

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

6.7	**TABLE: CLEARANCES and CREEPAGE distances**		**Form A.13**	P
6.4.2	ENCLOSURES and protective barriers	8	Mechanical resistance to shock and impact	—
6.4.4	Impedance	9.6.1	Overcurrent protection basic insulation between MAINS parts	—
6.5.4	Protective impedance	10.5.1	Integrity of CLEARANCES and CREEPAGE distances	—
6.5.6	Current- or voltage-limiting device			—

Location	Measured (initial – 6.7)		Verdict	Mechanical tests (note)					Test at max.	Measured after test (if required)		Verdict	Comments
(see Form A.5)	CREEPAGE DISTANCE	CLEARANCE		Applied force	Rigidity (8.2)		Drop (8.3)		RATED ambient	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		
Mains to accessible parts (GND)	>3	>1.5	P	5	✓	✓	✓	--	40	>3	>1.5	P	
Mains to Secondary	>6	>3	P	5	✓	✓	✓	--	40	>6	>3	P	

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

Supplementary information:

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

6.8	**TABLE: Dielectric strength tests**	**Form A.14**	P
4.4.4.1 b)	Conformity after application of SINGLE FAULT CONDITIONS[1]		
6.4	Primary means of protection[2]		
6.6	Connections to external circuits		
6.7.	Insulation requirements[2] (see Annex K)		
6.10.2	Fitting of non-detachable MAINS supply cords		
9.2 a) 2)	Eliminating or reducing the sources of ignition within the equipment		
9.4 c)	Limited-energy circuit		
9.6.1	Overcurrent protection basic insulation between MAINS - parts		

[1] Record the fault, test or treatment applied before the dielectric strength test. [2] Humidity preconditioning required.

	Test site altitude..... :	1-500 m	—
	Test voltage correction factor (see Table 10)..... :	1.16	—

Location or references from Forms A.2 and A.5	Working voltage V	Test voltage r.m.s./peak/d.cV	Comments	Verdict
Mains to Earth	230	1680Vac	No break down	P
Mains to accessible parts	230	3480Vac	No break down	P
Mains to secondary	230	3480Vac	No break down	P

Supplementary information:

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

Dielectric strength test for 1 min. (6.8.3.1)..... :		V r.m.s.	

Supplementary information:

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

7.	**TABLE: Protection against mechanical HAZARDS**	**Form A.16**	P
7.3.4	Limitation of force and pressure		—
7.3.5	Gap limitations between moving parts	4mm	—

	Clause 7.3.4		Clause 7.3.5.1								Clause 7.3.5.2				
	Continuous	Temporary	Minimum gaps (mm)								Maximum gaps (mm)				
Part / Location	Contact présure max. 50 N /cm² @ max. 150 N	max. 250 N / 3 cm² @ max. 0,75 s	Torso 500	Head 300	Leg 180	Foot 120	Toes 50	Arm 120	Hand 100	Finger 25	Head 120	Foot 35	Finger 4	Verdict	Comments
Enclosure	-	-	-	-	-	-	-	-	-	-	-	-	2mm	P	

Supplementary information:

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

9.3.2	**TABLE: Constructional requirements**			**Form A.18**	N/A
14.7	Printed circuit boards				
Material tested.....:					—
Generic name.....:					—
Material manufacturer .....:					—
Type .....:					—
Colour.....:					—
Conditioning details.....:					—
		Sample 1	Sample 2	Sample 3	
Thickness of specimen	mm				
Duration of flaming after first Application	s				
Duration of flaming plus glowing After second application	s				
Specimen burns to holding clamp	Yes/No				
Cotton ignited	Yes/No				
Sample result	Pass/Fail				

Supplementary information: **Printed circuit boards of material with a flammability classification of FV-0 min. of IEC60707 or UL94 is used**

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

9.4	TABLE: Limited-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. V	Maximum available current A	Maximum available power VA	Overload protection after 120 s A	Circuit separation	Yes/No	Comments
Supplementary information: **Not evaluated**							

9.5	TABLE: Requirements for equipment containing or using flammable liquids		Form A.20	N/A
Type of liquid	9.5 Flammable liquids			Verdict
	b) Quantity	c) Containment		
Supplementary information: **No flammable liquid**				

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

10.	**TABLE : Temperature Measurements**	**Form A.21A**	P
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 temperature measurements		

Operating conditions:	Max setting		
Frequency .....:	60/60 Hz	Test room ambient temperature (ta)…:	21.8/20.7 °C
Voltage .....:	99/253 V	Test duration ..... ……..:	3 h 00 min

Part / Location	t_c °C		t_{max} °C	Verdict	Comments
	99V	*253V*			
Top enclosure of Multifunction synthesizer (WF1944B)	52.4	54.3	--	P	--
Inner of Multifunction synthesizer (WF1944B)	59.0	56.1	105	P	--
Power supply (rear)	47.0	54.0	85	P	--
Controller	47.6	48.0	--	P	--
Relay (5Vdc)	45.4	46.2	105	P	--
Enclosure (outer)	40.6	41.0	65	P	--

Supplementary information:

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

10.5.2	**TABLE: Resistance to heat of non-metallic ENCLOSURES**	**Form A.22**	P
	Non operative treatment ..... :	[✓]	-
	Empty ENCLOSURE ..... :	[ ]	-
	Operative treatment ..... :	[ ]	-
	Temperature during tests ..... :	70°C	—
	ENCLOSURE samples tested were ..... :	All set	—

Description	Comments	Verdict
Whole set	No deform or discolour	P

NOTE – Within 10 minutes of the end of treatment suitable tests in acc. to 8.2 and 8.3 must be conducted and pass criteria of 8.1.

Supplementary information:

10.5.3	**TABLE: Insulating Materials**	**Form A.23**	N/A
10.5.3 1)	Ball pressure test		
	Max. allowed impression diameter ..... :	2 mm	—

Part	Test temperature °C	Impression Diameter (mm)	Verdict

Supplementary information:

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

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

Supplementary information:

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

8	**TABLE: Mechanical resistance to shock and impact**	**Form A.24**	P
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	—	—	—	230V	3480V	P	Plastic parts
Side Enclosure	Pass	Pass	Pass	—	Pass	—	—	—	230V	3480V	P	Plastic parts
Rear Enclosure	Pass	Pass	Pass	—	Pass	—	—	—	230V	3480V	P	Plastic parts
Front Enclosure	Pass	Pass	Pass	—	Pass	—	—	—	230V	3480V	P	Plastic parts

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

Supplementary information:

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

11.7.2	**TABLE: Leakage and rupture at high pressure**				**Form A.25**	N/A
Part	Maximum permissible working pressure Mpa	Test pressure MPa	Leakage Yes / No	Deformation Yes / No	Burst Yes / No	Comments
NOTE – see also Annex G with requirements for USA and Canada.						
Supplementary information:						

11.7.3	**Leakage from low-pressure parts**	N/A
Part	Test pressure Mpa	Leakage Yes / No	Comments
Supplementary information:			

12.2.1	**TABLE: Ionizing radiation**	**Form A 26**	N/A
12.2.1.2	Equipment intended to emit radiation		

Locations tested	Measured values µSv/h	Verdict	Comments
Supplementary information:			

12.2.1.3	Equipment not intended to emit radiation	N/A
	Max. allowed effective dose rate at 100 mm……: 1 µSv/h	—

Locations tested	Measured values µSv/h	Verdict	Comments
Supplementary information:			

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

12.5.1	**TABLE: Sound level**	**Form A.27**	N/A

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

12.5.2	Ultrasonic pressure	N/A

Locations tested	Measured values		Comments
	dB	kHz	
At operator's normal position			
At 1 m from the ENCLOSURE			
a)			
b)			
c)			
d)			
e)			
NOTE – No limit is specified at present, but a limit of 110 dB above the reference pressure value of 20 μPa is under consideration for applicable frequencies between 20 kHz and 100 kHz.			
Supplementary information:			

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

13.2.2	**TABLE: Batteries**	**Form A.28**	N/A
	Battery load and charging circuit diagram:		
	Battery type .....:		—
	Battery manufacturer/model/catalogue No. .....:		—
	Battery ratings .....:		—
	Reverse polarity instalment test		N/A

Single component failures	Verdict	
Component	Open circuit	Short circuit
-		

Supplementary information: No battery is used

14.1	**TABLE: components**			P
object/part No.	manufac-turer/trademark	type/model	technical data	mark(s) of conformity[1])
PCB	Interchangeable	Interchangeable	105°C, V-0	UL
Power inlet	Interchangeable	Interchangeable	250V,10A	VDE
Breaker	Schneider	EZC100F3015A	15A / 3KA	TUV, UL
Power supply	DEUTRONIC	DTPN25N	I/P: 100-240V, 60-50Hz, 0.6-0.3A O/P: +15Vdc, 0.9A	TUV_GS
Power supply (by PC)	Interchangeable	Interchangeable	100-240V, 50/60Hz, 350W	TUV, UL
Relay	Interchangeable	Interchangeable	5Vdc, 1A	UL
N2 (Nitrogen , Liquid)	Interchangeable	Interchangeable	5 liter	-

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

14.3	**TABLE: Overtemperature protection devices**	**Form A.29**	N/A

Reliability test			
Component	Type (NOTE)	Verdict	Comments

NOTE:

NSR = non-self-resetting (10 times)

NR = non-resetting (1 time)

SR = self-resetting (200 times)

Supplementary information:

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

14.8	**TABLE: Transient overvoltage limiting devices**									**Form A.30**	N/A
Component / 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	
Test room ambient temperature ….:		°C									

NOTE - t_m = measured temperature

t_c = t_m corrected (t_m–t_a+ **40 °C** or max. RATED ambient)

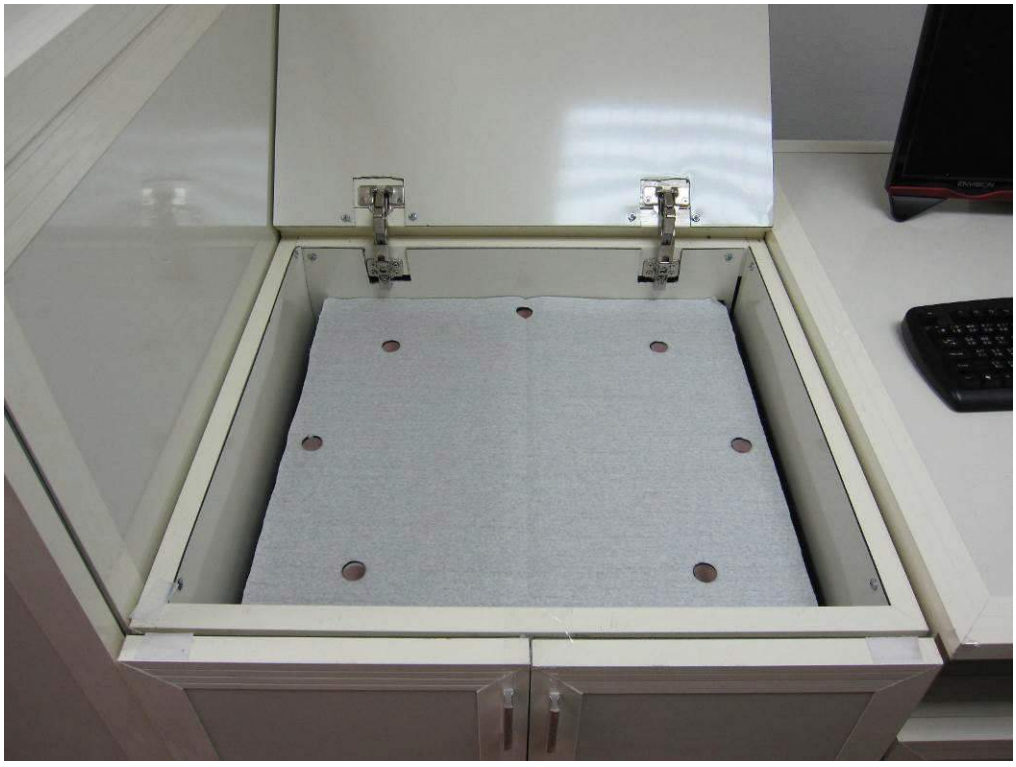
t_{max} = maximum permitted temperature

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).

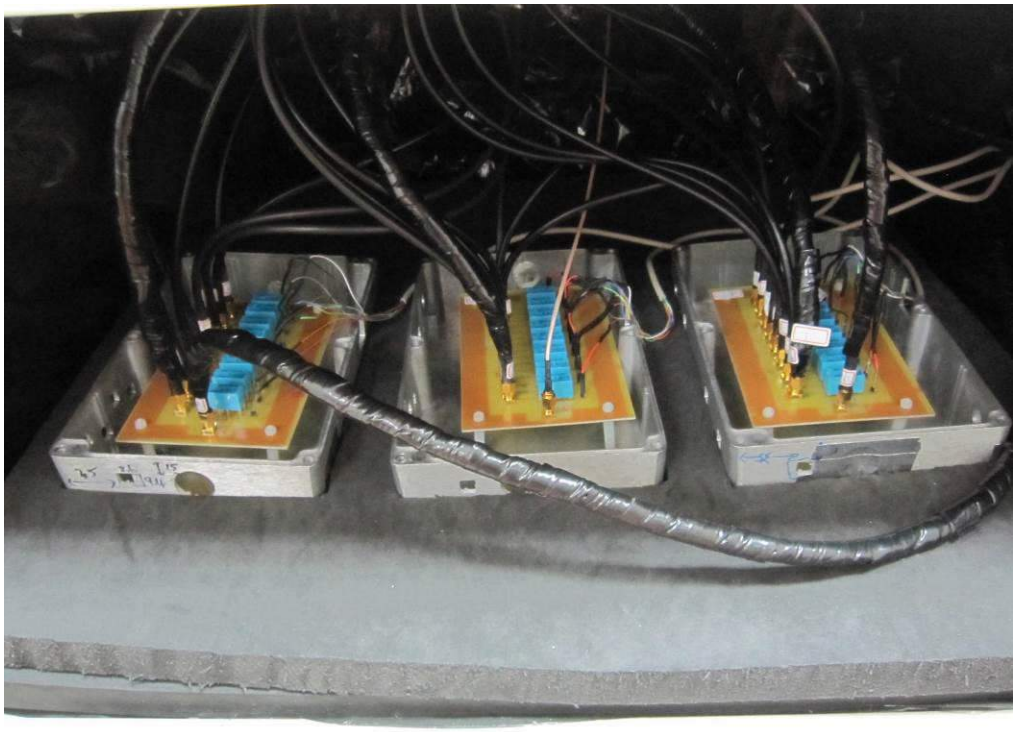
Supplementary information:

PHOTOS:

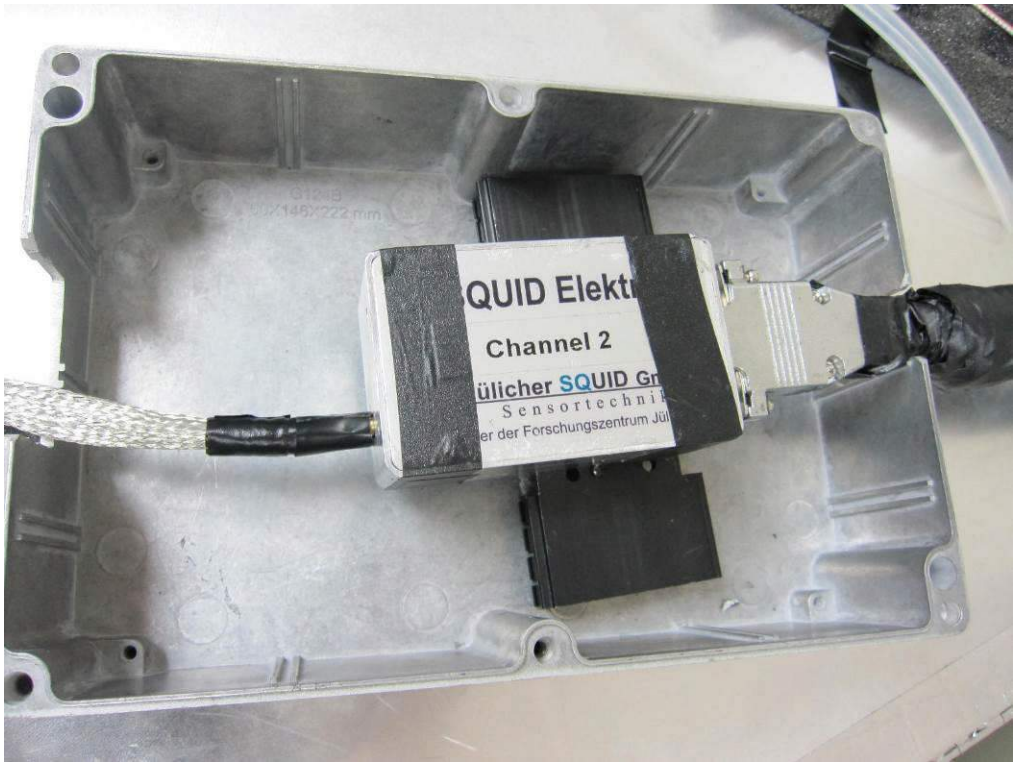
PHOTOS:



PHOTOS:



PHOTOS:



PHOTOS:

PHOTOS:


DEUTRONIC
DTP 25N
DSP 25N


15MHz MULTIFUNCTION SYNTHESIZER WF1944B
WAVE FACTORY

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.

Appendix C: Verification of EMC

PMC

Precision Machinery Research & Development Center

CE **Verification of Certificate**

Issued to :

MagQu Co., Ltd.

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

In respect of machinery manufactured by :

MagQu Co., Ltd.

Product Name : Magnetic Immunoassay Analyzer
Main Model : XacPro-S
Serial No. : S001-140401-MQ

The verification of compliance refers to the above mentioned product that is chosen to address the electromagnetic compatibility of EN 61326-1:2013 and EN 55011: 2009/A1:2010, which also fulfils the requirements of the electromagnetic compatibility Directive 2004/108/EC, this is to certify that the specimen is in conformity with the assessment requirement mentioned above, this verification does not imply assessment of production of the product.

Verification No.: 103R0454-018
Test Report No.: N3E11-103R0454-018
Issued Date: March 14, 2014
Expires: March 14., 2017

Approved by PMC

Address : No.27, 37th Road, Taichung Industrial Park, Taichung, Taiwan, R.O.C.
Tel : 886-4-23599009 Fax : 886-4-23598847

財團法人精密機械研究發展中心
Precision Machinery Research & Development Center
TEL: 886-4-2359-9009
FAX: 886-4-2359-8847
www.pmc.org.tw

TEST REPORT NO.: N3E11-103R0454-018
ISSUE NO.: 1

CE EMC TEST REPORT

TESTING

OF

MODEL：XacPro-S

Magnetic Immunoassay Analyzer

FOR

MagQu Co., Ltd.

Issued by

Precision Machinery Research & Development Center
No.27, 37th Road Taichung Industrial Park, Taichung, Taiwan
Tel : 886-4-23599009 Fax : 886-4-23598847

PMC 財團法人精密機械研究發展中心
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FAX: 886-4-2359-8847
www.pmc.org.tw

CE EMC TEST REPORT

Applicant	:	MagQu Co., Ltd. 3F No. 12, Ln. 538, Zhongzheng Rd., Xindian Dist., New Taipei City 231 Taiwan
Manufacturer	:	MagQu Co., Ltd. 3F No. 12, Ln. 538, Zhongzheng Rd., Xindian Dist., New Taipei City 231 Taiwan
Product Name	:	Magnetic Immunoassay Analyzer
Model Name.	:	XacPro-S
Serial No.	:	S001-140401-MQ
Controller	:	JSQ rf SQUID Magnetometer and rf SQUID Electronics with Touch Panel Controller
Test Date	:	2014/03/11 and 2014/03/12
Standards	:	EN 61326-1:2013 EN 55011:2009 /A1:2010
Test Result	:	**PASS**
Test Laboratory	:	PMC Electromagnetic Compatibility Testing Laboratory No.27, 37th Road, Taichung Industrial Park, Taichung, Taiwan. TEL: +886-4-2359-9009 FAX:+886-4-2359-8847

Tested by **Lee Hsin Chang** Signature March 14, 2014 Date

Approved by **Tim Hise** Signature March 17, 2014 Date

Note：
1. The test results only responds to the tested sample, and is invalid as separately used.
2. The test results are invalid without examination stamp and signature of this laboratory.
3. The test results are not reproduced except in full without the written approved of PMC Lab.

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10. IMMUNITY TEST OF RADIATED RADIO—FREQUENCY ELECTROMAGNETIC FILED—PULSE MODULATED 42

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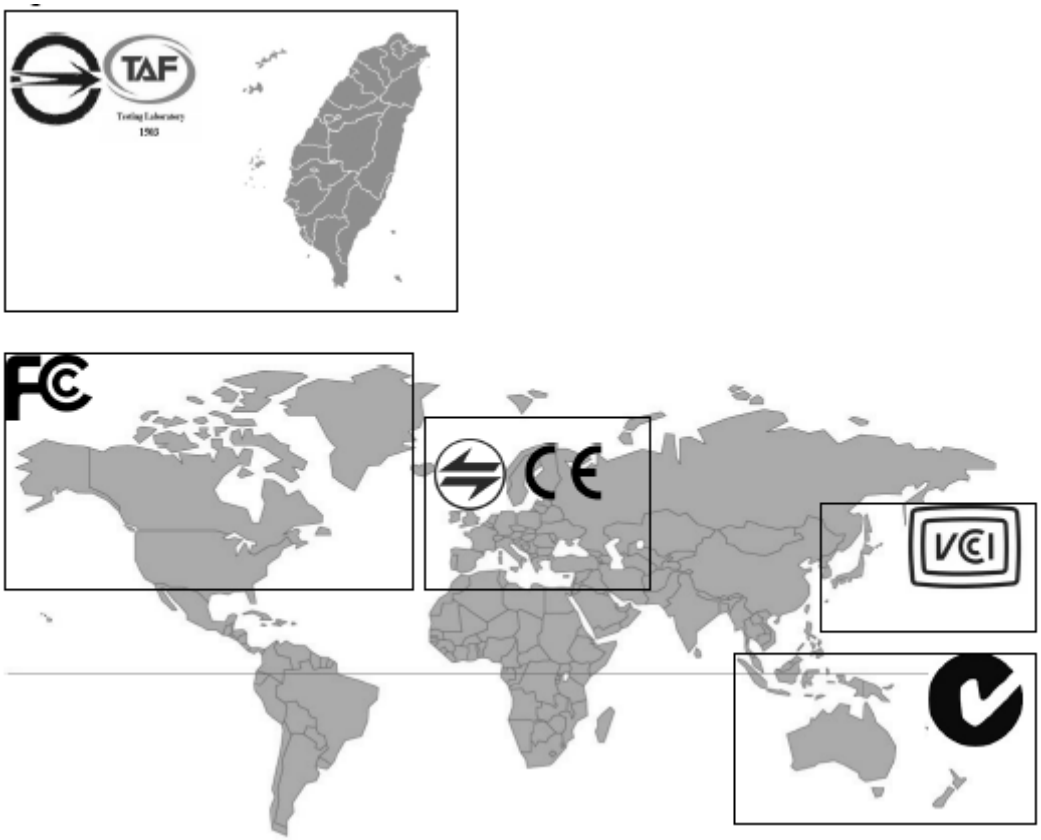
Attachment：Photograph of EUT
Attachment：Parts List

Laboratory Information

Precision Machinery Research & Development Center (PMC) was founded by government and Taiwan Association of Machinery Industry, established on June 1st, 1993. We are a non-profit organization to help manufacturers to value up the products and comply with the EMC and Safety requirement. And, our facilities and ability of measurement are approved by the following organizations and countries.



If you have any comments, please don't hesitate to contact us. Our contact information is as below:

PMC Testing Laboratory :

No.27, 37th Road Taichung Industrial Park, Taichung, Taiwan.
TEL:+886-4-2359-9009 #312 / FAX:+886-4-2359-8847

1. General Description of EUT

1.1 Description of EUT

Test Location	:	MagQu Co., Ltd. 3F No.12, Ln. 538, Zhongzheng Rd., Xindian Dist., New Taipei City 231 Taiwan
Production Name	:	Magnetic Immunoassay Analyzer
Model Name.	:	XacPro-S
Series No.	:	S001-140401-MQ
Power Source	:	1~,220Vac, 60Hz
Power Cord	:	2.0mm^2 ×3C Unshielded Power Cable

1.2 Operation procedures of the EUT

1. Turn on Main Switch.
2. Turn on computer.
3. Launch SQUID software.
4. Click start button after samples are ready in sample region.
5 Continuous auto running.

1.3 Description of worst case evaluation

After estimating, PMC have evaluated cycle running was taken would be the worst case for testing.

2. General Information of Test

2.1 Summary of test result

Standard	Edition	Comment
EN 61326-1	2013	PASS
EN 55011	2009/A1:2010	PASS
Electro-Magnetic Susceptibility		
Standard	Edition	Comment
EN 61000-4-2	2009	PASS
EN 61000-4-3	2006/A2:2010	PASS
EN 61000-4-4	2004/A1:2010	PASS
EN 61000-4-5	2006	PASS
EN 61000-4-6	2009	PASS

2.2 Performance criteria of immunity test

Performance Criterion A：
The equipment shall continue to operate as intended without operator intervention. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance.

Performance Criterion B：
After the test, the equipment shall continue to operate as intended without operator intervention. No degradation of performance or loss of function is allowed after the application of the phenomena below a performance level specified by the manufacturer, when the equipment is used as intended. During the test, degradation of performance is allowed. However, no change of actual operating state or stored data is allowed to persist after the test.

Performance Criterion C：
Loss of function is allowed, provided the function is self recoverable or can be restored by the operation of the controls by the user in accordance with the manufacturer instructions.

2.3 Test equipment

Item	Brand / Model	Series No.	Calibration Due	Used
EMI Test Receiver	ROHDE & SCHWARZ ESCS 30	847793/004	18, Jul., 2014	☑ Used
Bilog Antenna	CHASE CBL 6111B	2085	30, Jun., 2014	☑ Used
L.I.S.N.	SCHWARZBECK MESS-ELEKTRONIK NNLK8129	8129129	02, Jan., 2015	☑ Used
Power Clamp	MDS-21	848818/012	19, Jan., 2015	☐ Used
Harmonic and Flicker Analyzer	EM TEST/DPA 500	V0503100065	10, Nov., 2014	☐ Used
ESD Test Unit	EM TEST/ESD 30C	V0822103834	03, Jul., 2014	☑ Used
Signal Generator	ROHDE & SCHWARZ/SMY01	844934/058	31, Oct., 2014	☑ Used
Signal Generator	Angilent 8648C	4037U03276	02, Jan., 2015	☑ Used
Power Amplifier	KALMUS/747LC	8680-1	20, Dec., 2014	☑ Used
EFT Test Unit	EM TEST/EFT 500	0596-32	04, Ju1., 2014	☑ Used
Surge Generator	EM TEST/VCS 500	0397-09	04, Ju1., 2014	☑ Used
6 dB Attenuator	BNOS ELECTRONICS	522055	20, Dec., 2014	☑ Used
CDN	FCC/801-M3-25A	05033	06, Nov., 2014	☑ Used
Power Fail Simulator	EM TEST/PFS 503	0897-03	10, Nov., 2014	☐ Used

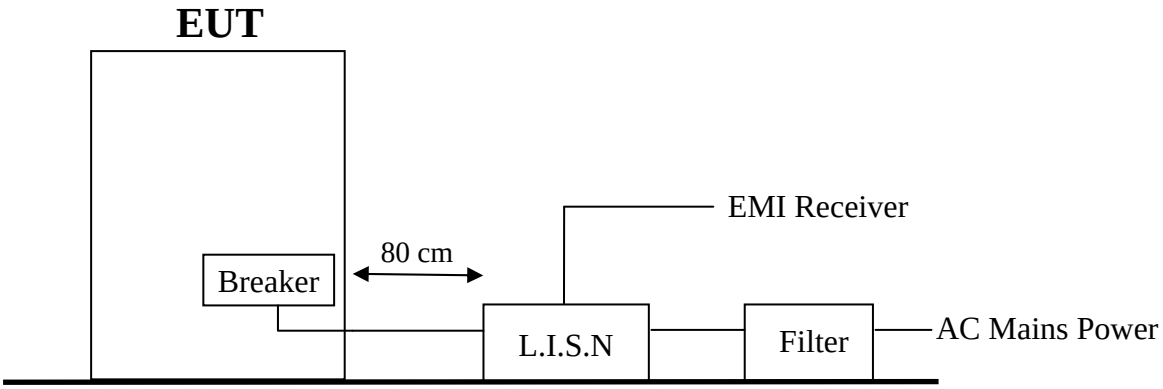
Item	Brand / Model	Series No.	Calibration Due	Used
PFMF Generator	EM TEST/MC26100	N/A	10, Jun., 2014	☐ Used
B.C.I.	FCC/F-140A	155	08, May, 2014	☑ Used
PFMF Antenna	EM TEST/MS100	N/A	10, Jun., 2014	☐ Used
FM Transmitter	ICOM/IC-W32E	86AR0069	N/A	☑ Used
Mobile Phone	MOTOROLA W220	M2AG7009D6	N/A	☑ Used
Wireless Router	D-Link/DIR-300	P1DY18C003321	N/A	☑ Used

3. Conducted Emission Test

3.1 Limits of terminal disturbance voltage

Port	Frequency Range	Limits < 16 A Per Phase	Basic Standard
AC Mains	0.15 MHz-0.50 MHz	79 dB (uV) quasi-peak 66 dB (uV) average	EN 55011
	0.50 MHz-5 MHz	73 dB (pV) quasi-peak 60 dB (uV) average	
	5 MHz-30 MHz	73 dB (pV) quasi-peak 60 dB (uV) average	

3.2 Test setup



3.3 Environmental conditions

Test Date	Ambient Temperature	Relative Humidity	Atmospheric Pressure
Mar. 11, 2014	24.8℃	55.5 %	1018 mbar

3.4 Description of the test

1. Positive-peak was done first to find the frequency ranges required then to do the quasi-peak value and average value measurement. Each phase of power lines was to be tested.
2. The power cores should be equipped with main breaker. Each of phases has tested as the following pages.

3.5 Test result

The following pages show the results of conducted emission test. Judging from these data, it is reasonable to assume that the EUT would pass the test to the limits.

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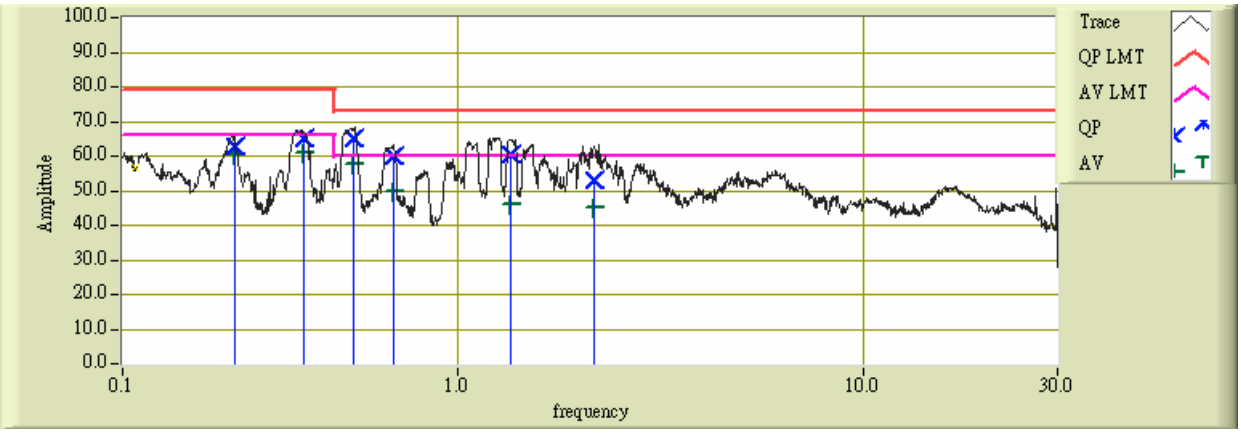
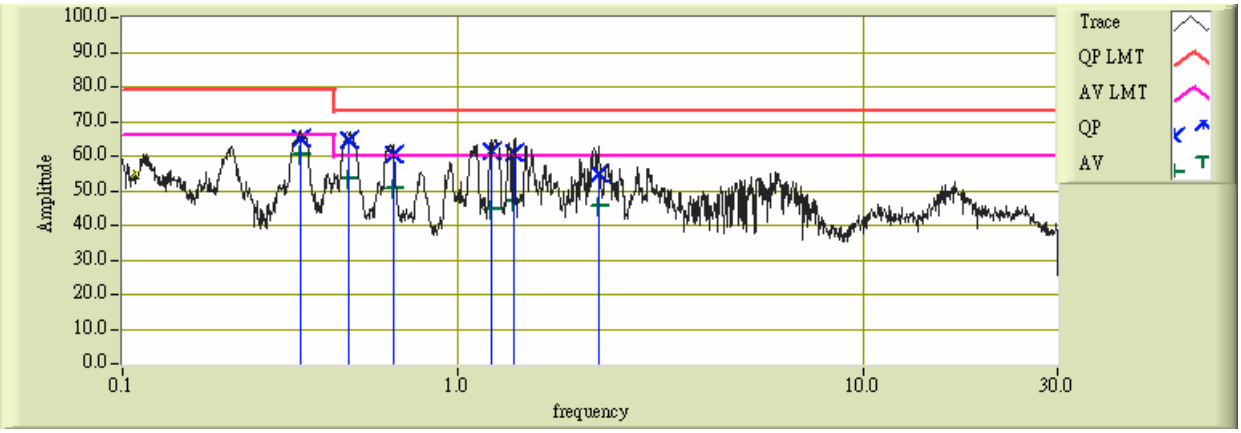
EMC LOG SHEET OF CE TEST-L PHASE



No.	Freq. (MHz)	Read AV (dBuV)	Read QP (dBuV)	Corr. (dB)	Result AV (dBuV)	Result QP (dBuV)	Limit AV (dBuV)	Limit QP (dBuV)	Margin AV (dB)	Margin QP (dB)
1	0.282	50.630	52.589	10.050	60.679	62.638	66.000	79.000	-5.321	-16.362
2	0.417	50.675	55.055	10.059	60.734	65.114	66.000	79.000	-5.266	-13.886
3	0.558	46.788	55.168	10.066	56.854	65.234	60.000	73.000	-3.146	-7.766
4	0.697	39.921	50.103	10.073	49.994	60.176	60.000	73.000	-10.006	-12.824
5	1.353	35.913	50.546	10.122	46.035	60.668	60.000	73.000	-13.965	-12.332
6	2.167	34.717	42.763	10.188	44.905	52.951	60.000	73.000	-15.095	-20.049

EMC LOG SHEET OF CE TEST-N PHASE



No.	Freq. (MHz)	Read AV (dBuV)	Read QP (dBuV)	Corr. (dB)	Result AV (dBuV)	Result QP (dBuV)	Limit AV (dBuV)	Limit QP (dBuV)	Margin AV (dB)	Margin QP (dB)
1	0.410	50.496	55.242	10.059	60.554	65.300	66.000	79.000	-5.446	-13.700
2	0.540	43.578	54.513	10.065	53.643	64.578	60.000	73.000	-6.357	-8.422
3	0.698	40.470	50.535	10.073	50.543	60.608	60.000	73.000	-9.457	-12.392
4	1.212	34.709	51.404	10.109	44.818	61.513	60.000	73.000	-15.182	-11.487
5	1.383	36.684	51.005	10.125	46.809	61.130	60.000	73.000	-13.191	-11.870
6	2.225	35.468	44.731	10.190	45.658	54.921	60.000	73.000	-14.342	-18.079

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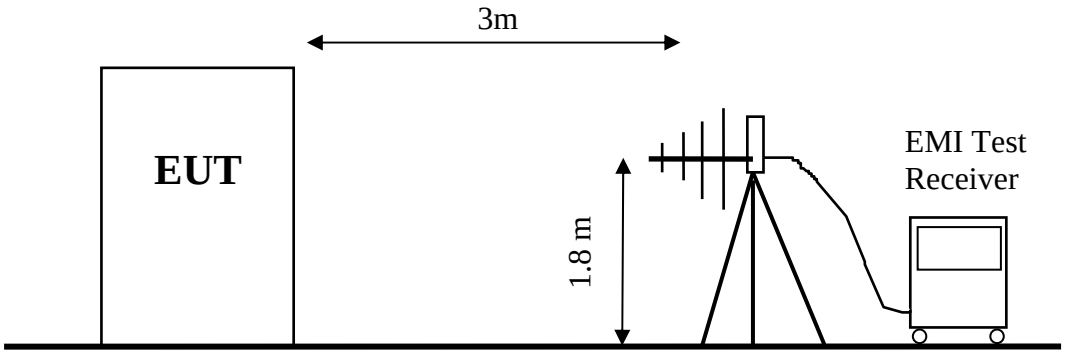
3.6 Photo during the test

4. Radiated Emission Test

4.1 Limits of terminal disturbance voltage

Port	Frequency range	10m Limits	3m Limits	Basic standard
Enclosure	30 MHz - 230 MHz	40 dB (uV/m)quasi-peak, measured at 10m distance	50 dB (uV/m) quasi-peak, measured at 3m distance	EN 55011
	230 MHz - 1000 MHz	47 dB (uV/m) quasi-peak, measured at 10m distance	57 dB (uV/m) quasi-peak, measured at 3m distance	

4.2 Test setup



4.3 Environmental conditions

Test Date	Ambient Temperature	Relative Humidity	Atmospheric Pressure
Mar. 11, 2014	24.8℃	55.5 %	1018 mbar

4.4 Description of the test

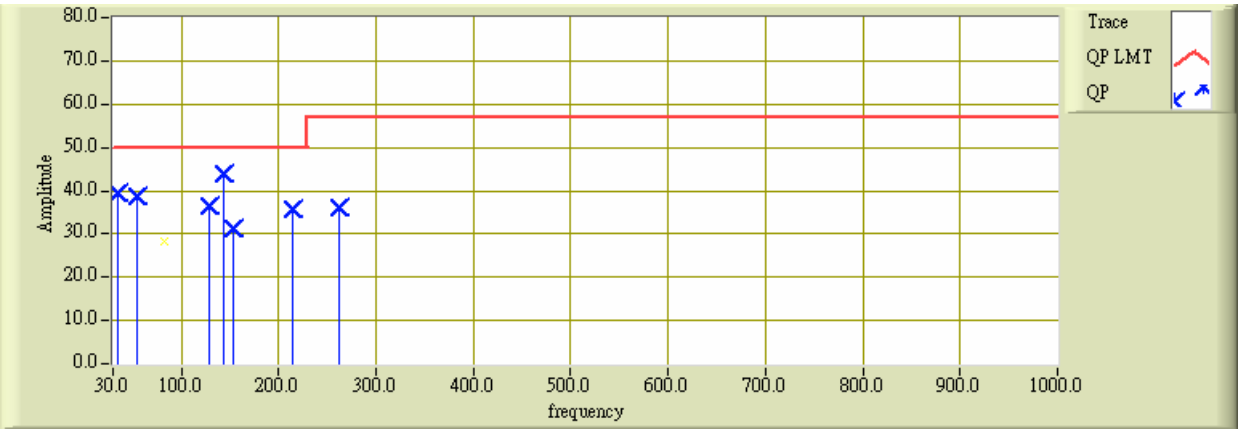
1. The receiving antenna was set 3 meters in front and right-front of EUT was mounted on the tripod. The height of the antenna was 1.8m above the ground. Measurement was made with the antenna having both horizontal and vertical polarities.
2. We found the worse case on the front side of electronic box and recorded the measurement results.

4.5 Test result

The following pages show the results with antenna having both horizontal and vertical polarities. And the following table shows quasi-peak values in some certain frequency ranges which are local maximums in the curves.

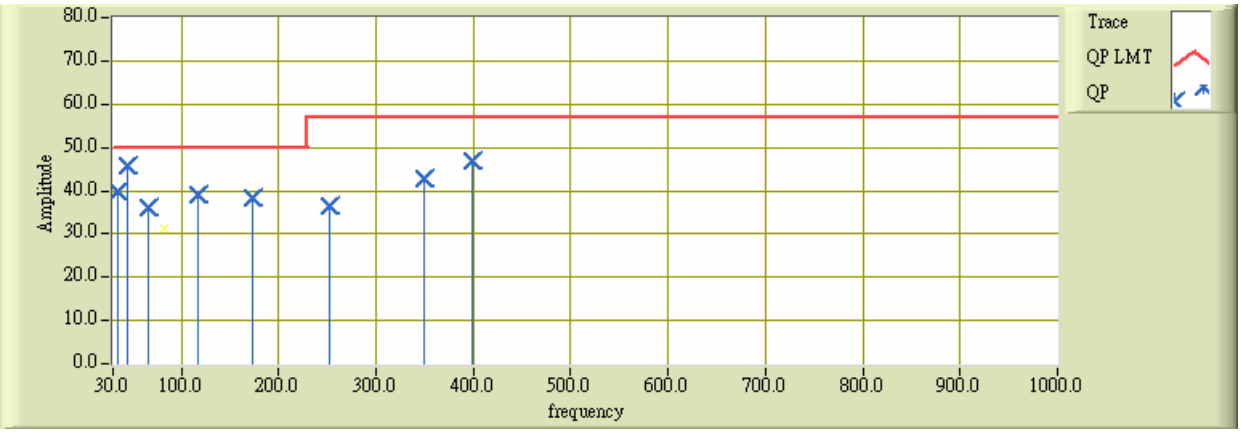
Judging from these data is reasonable to assume that the EUT would pass the test to the limits.

EMC LOG SHEET OF RE TEST IN FRONT OF EUT-HOR.(3m)



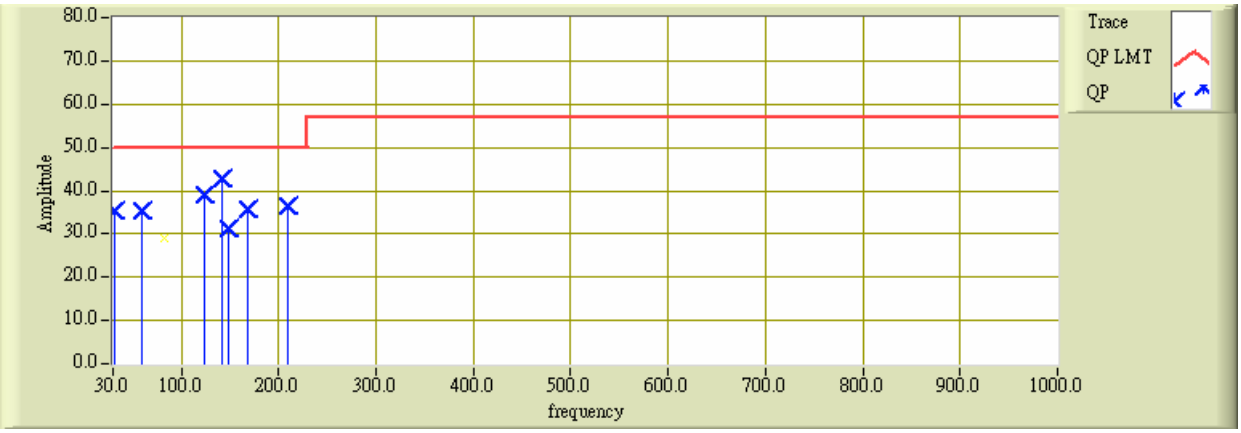
No.	Freq. (MHz)	Reading (dBuV)	Corr. (dB)	Result (dBuV/m)	Limit (dBuV/m)	Margin (dB)
1	34.850	23.059	16.429	39.487	50.000	-10.513
2	54.250	31.307	7.564	38.870	50.000	-11.130
3	129.425	24.011	12.430	36.441	50.000	-13.559
4	143.975	32.187	11.795	43.981	50.000	-6.019
5	153.137	20.108	11.254	31.362	50.000	-18.638
6	214.300	25.870	9.755	35.625	50.000	-14.375
7	262.800	21.828	14.332	36.160	57.000	-20.840

EMC LOG SHEET OF RE TEST IN FRONT OF EUT-VER.(3m)



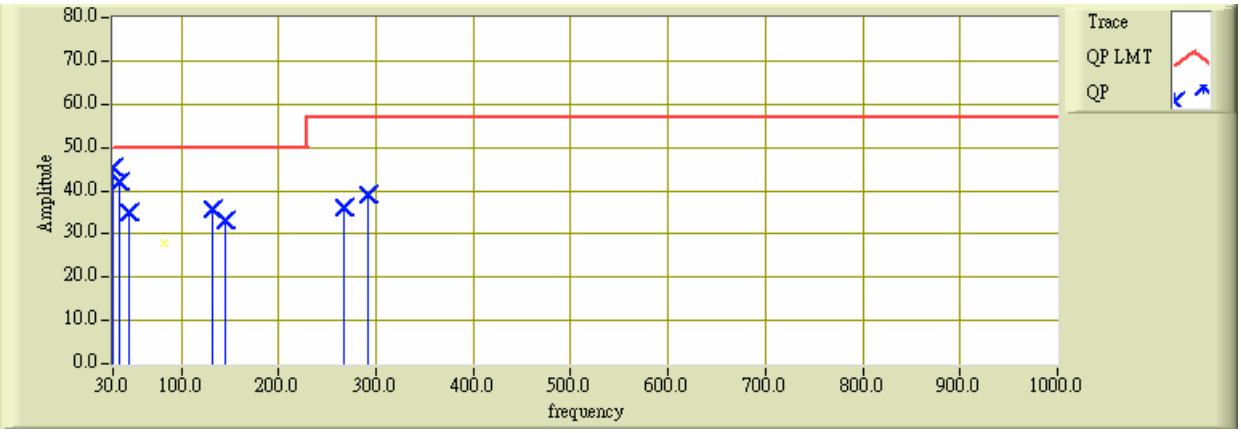
No.	Freq. (MHz)	Reading (dBuV)	Corr. (dB)	Result (dBuV/m)	Limit (dBuV/m)	Margin (dB)
1	35.575	23.910	16.027	39.937	50.000	-10.063
2	44.550	34.714	11.108	45.822	50.000	-4.178
3	66.375	29.655	6.461	36.116	50.000	-13.884
4	117.300	26.899	12.066	38.965	50.000	-11.035
5	173.075	28.323	9.987	38.309	50.000	-11.691
6	253.100	22.796	13.680	36.475	57.000	-20.525
7	350.100	27.766	15.066	42.832	57.000	-14.168
8	398.600	30.237	16.724	46.961	57.000	-10.039

EMC LOG SHEET OF RE TEST IN RIGHT-FRONT OF EUT-HOR.(3m)



No.	Freq. (MHz)	Reading (dBuV)	Corr. (dB)	Result (dBuV/m)	Limit (dBuV/m)	Margin (dB)
1	32.425	17.923	17.536	35.459	50.000	-14.541
2	59.100	28.914	6.519	35.433	50.000	-14.567
3	124.575	26.918	12.330	39.247	50.000	-10.753
4	141.550	30.725	11.963	42.687	50.000	-7.313
5	149.187	19.641	11.433	31.074	50.000	-18.926
6	168.225	25.431	10.348	35.778	50.000	-14.222
7	209.450	26.885	9.646	36.531	50.000	-13.469

EMC LOG SHEET OF RE TEST IN RIGHT-FRONT OF EUT-VER.(3m)



No.	Freq. (MHz)	Reading (dBuV)	Corr. (dB)	Result (dBuV/m)	Limit (dBuV/m)	Margin (dB)
1	30.000	26.818	18.644	45.462	50.000	-4.538
2	37.275	26.925	15.043	41.968	50.000	-8.032
3	46.975	24.882	9.929	34.810	50.000	-15.190
4	131.850	23.294	12.373	35.667	50.000	-14.333
5	144.725	21.358	11.743	33.100	50.000	-16.900
6	267.650	22.447	13.752	36.199	57.000	-20.801
7	291.900	25.295	13.892	39.187	57.000	-17.813

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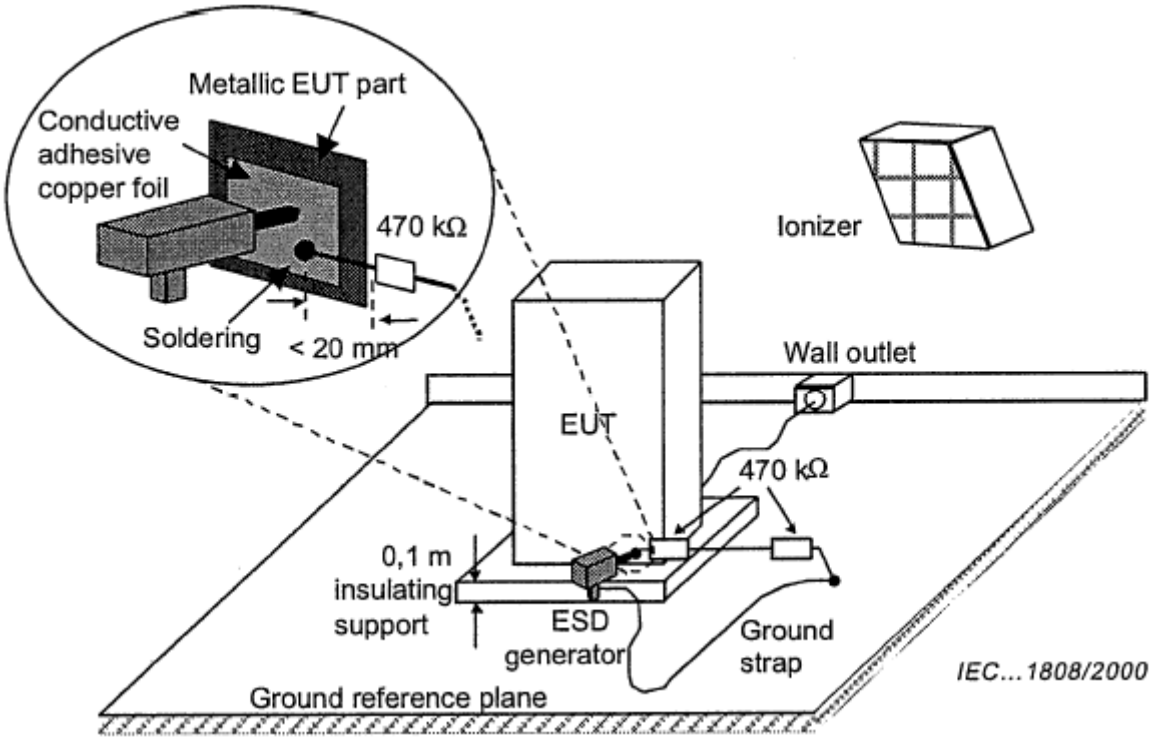
4.6 Photos during the test

5. Electrostatic Discharge Immunity Test

5.1 Test specification and performance criteria

Test Port	Test Specification	Units	Basic Standard	Remarks	Performance Criteria
Enclosure	±4 Contact ±8Air Discharge	kV (Charge Voltage)	EN 61000-4-2	Note 1	B
Note 1: The ±4kV contact discharge shall be applied to conductive accessible parts. Metallic contacts, suck as in battery compartments or in socket outlets are excluded from this requirement.					

5.2 Test setup



5.3 Environmental conditions

Test Date	Ambient Temperature	Relative Humidity	Atmospheric Pressure
Mar. 12, 2014	24.6℃	53.8 ％	1012 mbar

5.4 Description of the test

1. Discharges were carried out both by conduct and through the air at vulnerable points likely to easily touched or approached point on the operator's panel and loading /unloading area of EUT. For each test, increasing severity until the required level was reached according to the standard did the discharge.
2. For each test point, ten discharges were done.
3. The performance was observed according to the intentional movement defined by the manufacturer and any discrepancies were noted.
4. The test was repeated when the EUT was in idle (standby) state.

5.5 Test result

The following pages show the process of testing in both auto mode and idle state. It can be seen that there were no unintentional movement on the EUT. And, according to the standard, the test was passed successfully.

EMC LOG SHEET OF ESD TEST

	Test Method		
	Air	Contact	H/VCP
Test Point	1. Controller 2. Signal generator 3. Handle of door	Screw	Panel

Severity Level	Requirement			Performance (Criteria)			Test Result
	Air	Contact	H/VCP	Air	Contact	H/VCP	
±2kV	B	B	A	A	A	A	**PASS**
±4kV	B	B	A	**B**	**B**	**B**	**PASS**
±8kV	B	N/R	N/R	**B**	N/R	N/R	**PASS**

Note : 1. N/R means no requirement.
2. Test points :
2.1. air discharge for non- conducted parts.
2.2. contact discharge for conducted parts.
2.3. "B" mean the controller was reset.

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5.6 Photos during the test

6. Immunity Test of Radiated Radio—Frequency Electromagnetic Field—Amplitude Modulated

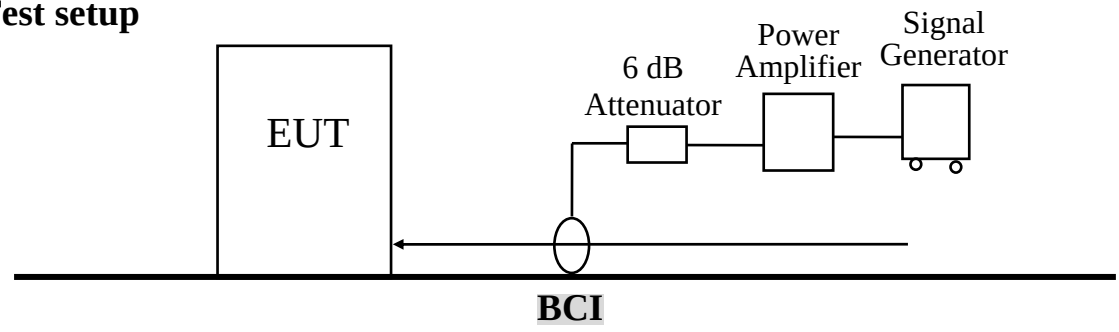
6.1 Test specification and performance criteria

Phenomena	Test Specification	Units	Basic Standard	Test Setup	Performance Criteria
Radio-Frequency Electromagnetic Field. Amplitude Modulated .	80-1000/10 1400-2000/3 2000-2700/1 80	MHz/ V/m MHz/ V/m MHz/ V/m (Unmodulated,rms) % AM (1KHZ)	EN 61000-4-3	See Note1&2	A

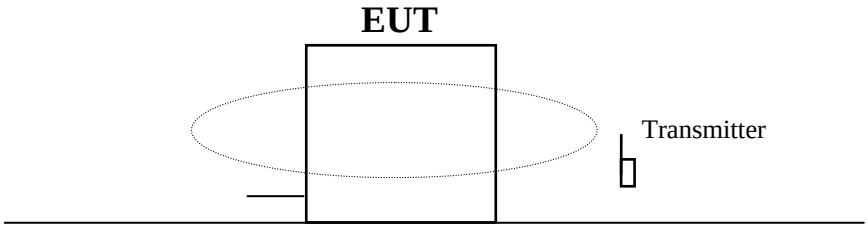
Note 1 : As testing did not carry out inside a shielded enclosure, bulk current injection (BCI) was used in accordance with EN 61000-4-6 and ISO 11451-4.

Note 2 : Additionally the dual band (144 & 440MHz) transmitter is to be used for RS testing at the fixed frequency.

6.2 Test setup



BCI



6.3 Environmental conditions

Test Date	Ambient Temperature	Relative Humidity	Atmospheric Pressure
Mar. 12, 2014	24.6℃	53.8 %	1012 mbar

6.4 Description of the test

1. During the test, the frequency range was swept from 80 to 400MHz incrementally with 1% step size of each frequency. The test signal was 80 % amplitude modulated with 1 kHz sine wave.
2. The dual band (144MHz & 440MHz) transmitter shall be placed in horizontal and vertical to EUT for testing.
3. The performance was observed according to the intentional movement defined by the manufacturer and any discrepancies were noted.
4. The test was repeated when the EUT was in idle (standby) state.

6.5 Test result

The following pages show the process of testing in both auto mode and idle state. It can be seen that there were no unintentional movement on the EUT. And, according to the standard, the test was passed successfully.

EMS LOG SHEET OF RS TEST (AMPLITUDE MODULATION)

Description	Requirement	Performance (Criteria)	Test Result	
			BCI	Transmitter
AC Input Power Cable (L, N, PE)	A	A	**PASS**	N/R
Enclosure	A	A	N/R	**PASS**
Control Panel	A	A	N/R	**PASS**

Note : N/R means no requirement.

6.6 Photos during the test

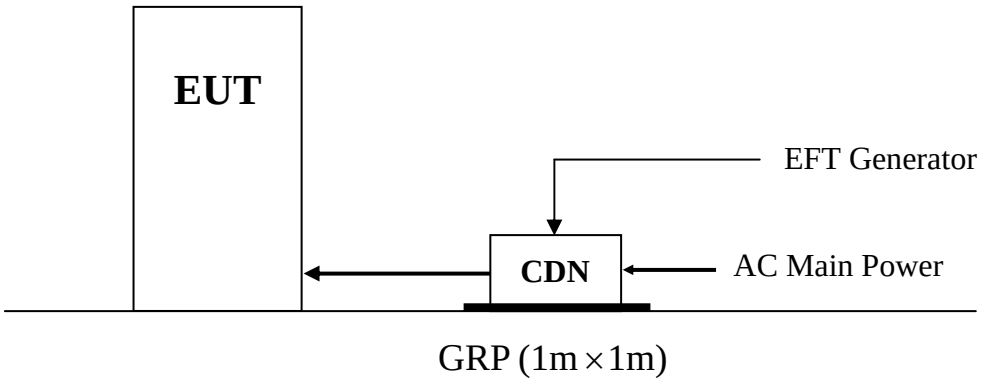
7. Electrical Fast Transient/Burst Immunity Test

7.1 Test specification and performance criteria

AC input and AC output power ports

Phenomena	Test Specification	Units	Basic Standard	Test Setup	Performance Criteria
Fast Transients	±2 5/50 5	kV (Peak) Tr / Td ns Rep. Frequency kHz	EN 61000-4-4	See 7.2	B

7.2 Test setup



7.3 Environmental conditions

Test Date	Ambient Temperature	Relative Humidity	Atmospheric Pressure
Mar. 12, 2014	24.6℃	53.8 ％	1012 mbar

7.4 Description of the test

1. The test was setup by coupling/decoupling network and a series of positive and negative polarity transients was direct injection on AC Input power cable, or Amps of the main power of the EUT more than 32A use capacitive clamp to represent by coupling/ decoupling network.
2. The performance was observed according to the intentional movement defined by the manufacturer and any discrepancies were noted.
3. The test was repeated when the EUT was in idle (standby) state.

7.5 Test result

The following pages show the process of testing in both auto mode and idle state. It can be seen that there were no unintentional movement on the EUT. And, according to the standard, the test was passed successfully.

EMS LOG SHEET OF EFT TEST

Coupling Mode / Severity Level	Requirement		Performance (Criteria)		Test Result
	AC Line	Earth Port	AC Line	Earth Port	
±0.25kV	N/R	B	N/R	A	**PASS**
±0.5kV	B	B	A	A	**PASS**
±1.0kV	B	B	A	A	**PASS**
±2.0kV	B	B	**B**	**B**	**PASS**

Note : N/R means no requirement.
"B" means monitor flash.

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7.6 Photo during the test

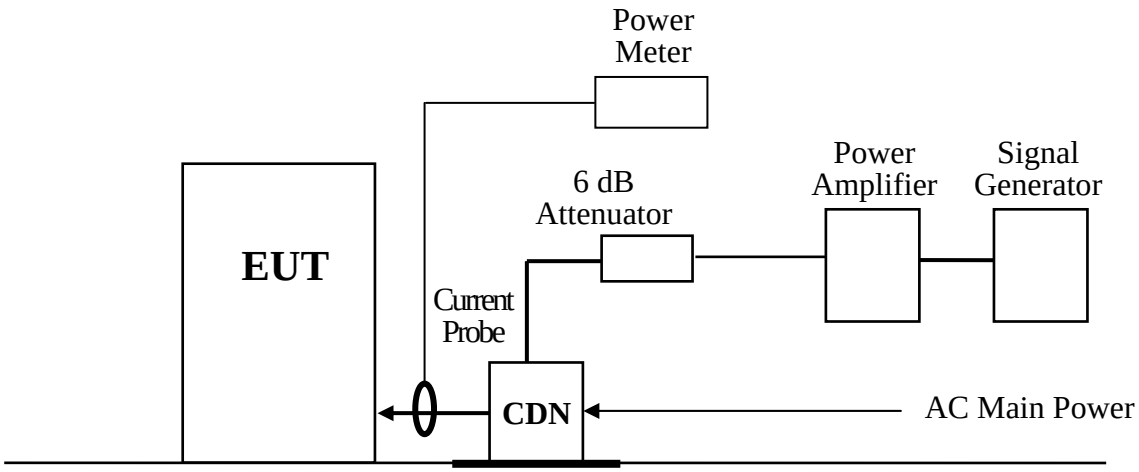
8. Immunity Test of Conducted Disturbances Induced by Radio—Frequency Fields

8.1 Test specification and performance criteria

AC input and AC output power ports

Phenomena	Test Specification	Units	Basic Standard	Test Setup	Performance Criteria
Radio-Frequency Common Mode Amplitude Modulated.	0.15-80 3 80 150	MHz V(rms) (Unmodulated,rms) % AM (1kHz) Source Impedance Ω	EN 61000-4-6	See 8.2	A

8.2 Test setup



8.3 Environmental conditions

Test Date	Ambient Temperature	Relative Humidity	Atmospheric Pressure
Mar. 12, 2014	24.6℃	53.8 %	1012 mbar

8.4 Description of the test

1. During the test, the frequency range was swept from 0.15 to 80 MHz incrementally with 1% step size of each frequency. The test signal was 80 % amplitude modulated with 1 kHz sine wave.
2. The performance was observed according to the intentional movement defined by the manufacturer and any discrepancies were noted.
3. The test was repeated when the EUT was in idle (standby) state.

8.5 Test result

The following pages show the process of testing in both auto mode and idle state. It can be seen that there were no unintentional movement on the EUT. And, according to the standard, the test was passed successfully.

RESULTS OF CS TEST

Description	Requirement	Performance (Criteria)	Test Result
AC Input Power Cable (L, N)	A	A	**PASS**
Earth Port	A	A	**PASS**

Note : N/R means no requirement.

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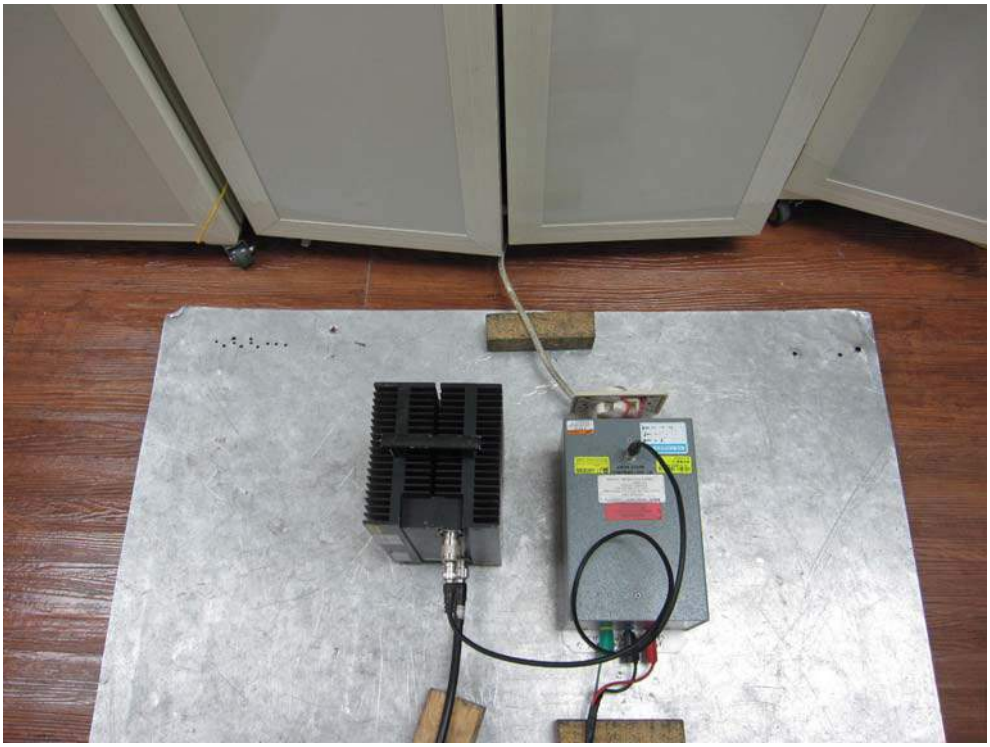
8.6 Photo during the test

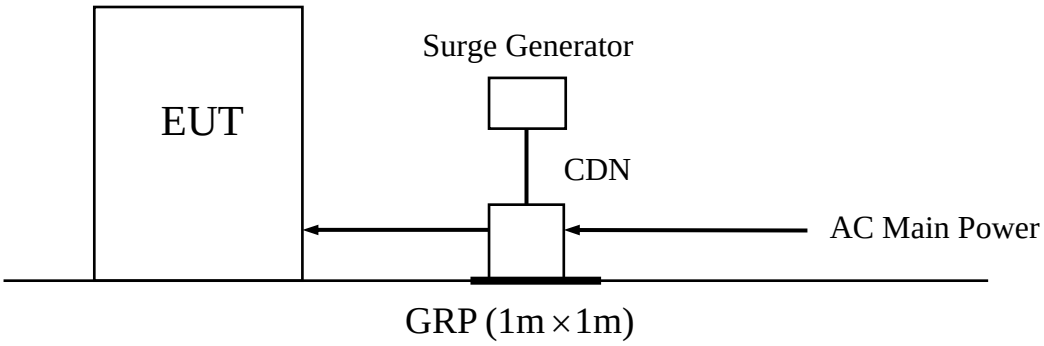


9. Surge Immunity Test

9.1 Test specification and performance criteria

Test Port	Test Specification	Units	Basic Standard	Performance Criteria
A.C. Power Port	1.2/50(8/20)	Tr/Td μs		
Line to PE	±2	kV	EN 61000-4-5	B
Line to Line	±1	kV		

9.2 Test setup



9.3 Environmental conditions

Test Date	Ambient Temperature	Relative Humidity	Atmospheric Pressure
Mar. 12, 2014	24.6℃	53.8 %	1012 mbar

9.4 Description of the test

1. Overview 5 negative and 5 positive Impulses and Source impedance generator: line to line=2Ω,line /neutral to earth=12Ω. Phase shifting in between 0°~360° versus the A.C. line phase angle and steps is 90° .
2. The performance was observed according to the intentional movement defined by the manufacturer and any discrepancies were noted.
3. The test was repeated when the EUT was in idle (standby) state.

9.5 Test result

The following pages show the process of testing in both auto mode and idle state. It can be seen that there were no unintentional movement on the EUT. And, according to the standard, the test was passed successfully.

RESULTS OF SURGE TEST

Severity Level	Requirement		Performance (Criteria)		Test Result
Coupling Mode	AC Line - Line	AC Line - PE	AC Line - Line	AC Line - PE	
± 0.5kV	B	B	A	A	**PASS**
± 1.0kV	B	B	A	A	**PASS**
± 2.0kV	N/R	B	N/R	**B**	**PASS**

Note : N/R means no requirement.
"B" means monitor flash

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9.6 Photo during the test

10. Immunity Test of Radiated Radio—Frequency Electromagnetic Filed—Pulse Modulated

10.1 Test specification and performance criteria

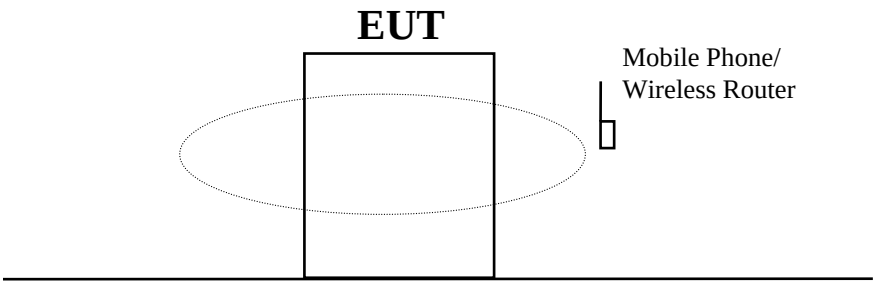
Phenomena	Test Specification	Units	Basic Standard	Performance Criteria
Radio-Frequency Electromagnetic Field. Pulse Modulated.	900 Note 1 2.4 10	MHz GHz V/M (Unmodulated,rms)	ENV 50204	A

Note 1 ：The frequency : Trasmitted frequency: 890~915MHz,
Receiving frequency: 935~960 MHz.

Note 2 ：This test was replaced with actual licensed transmitter MOTOROLA W220.
The specification was described in section 7.4.

Note3 ：The Wireless Router is to be used for RS testing at the fixed frequency 2.4GHz.

10.2 Test setup



10.3 Environmental conditions

Test Date	Ambient Temperature	Relative Humidity	Atmospheric Pressure
Mar. 12, 2014	24.6℃	53.8 %	1012 mbar

10.4 Description of the test

1. The field strength of the mobile phone and wireless router were measured by the EMI test receiver. We found the distance to the antenna where the field strength was 10 V/M and kept this distance to the EUT during the test.
2. The performance was observed according to the intentional movement defined by the manufacturer and any discrepancies were noted.
3. The test was repeated when the EUT was in idle (standby) state.

10.5 Test result

The following pages show the process of testing in both auto mode and idle state. It can be seen that there were no unintentional movement on the EUT. And, according to the standard, the test was passed successfully.

EMC LOG SHEET OF RS TEST (PULSE MODULATION)

Description	Requirement	Performance (Criteria)	Test Result
Enclosure	A	A	**PASS**
Control Panel	A	A	**PASS**
Observation on EUT			
No unexpected movement was occurred.			

10.6 Photos during the test

ATTACHMENT

Photograph of EUT

1. Overview of EUT

2. Overview of EUT

3. Overview of EUT

4. Overview of EUT

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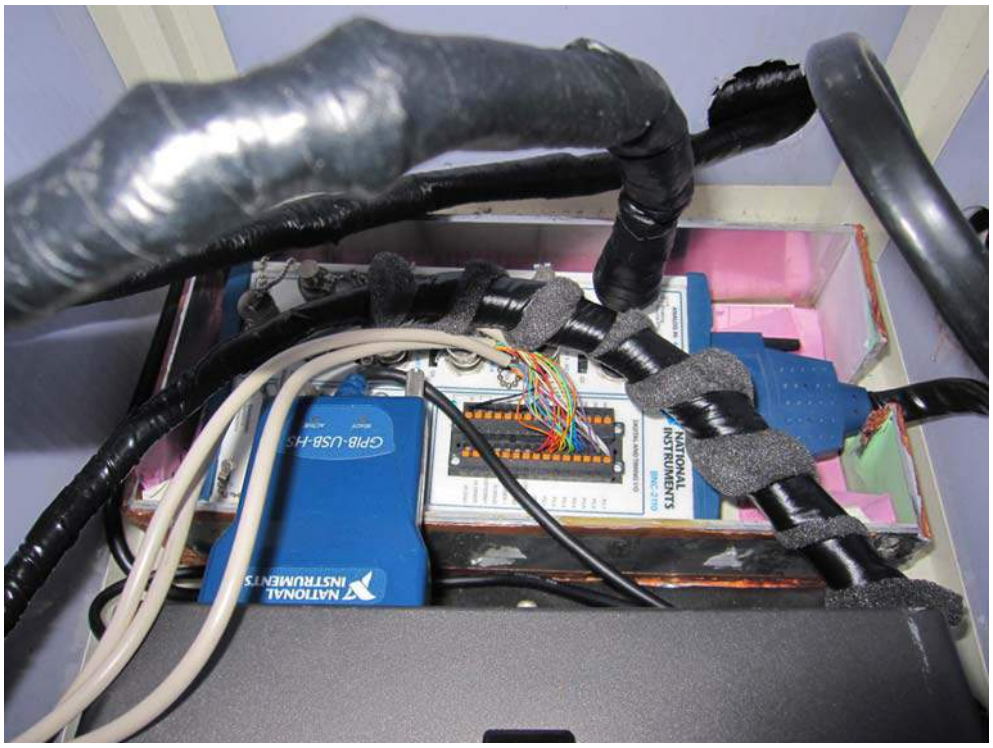
5. Inside of EUT

6. Inside of EUT(1-1)

7. Inside of EUT(1-2)

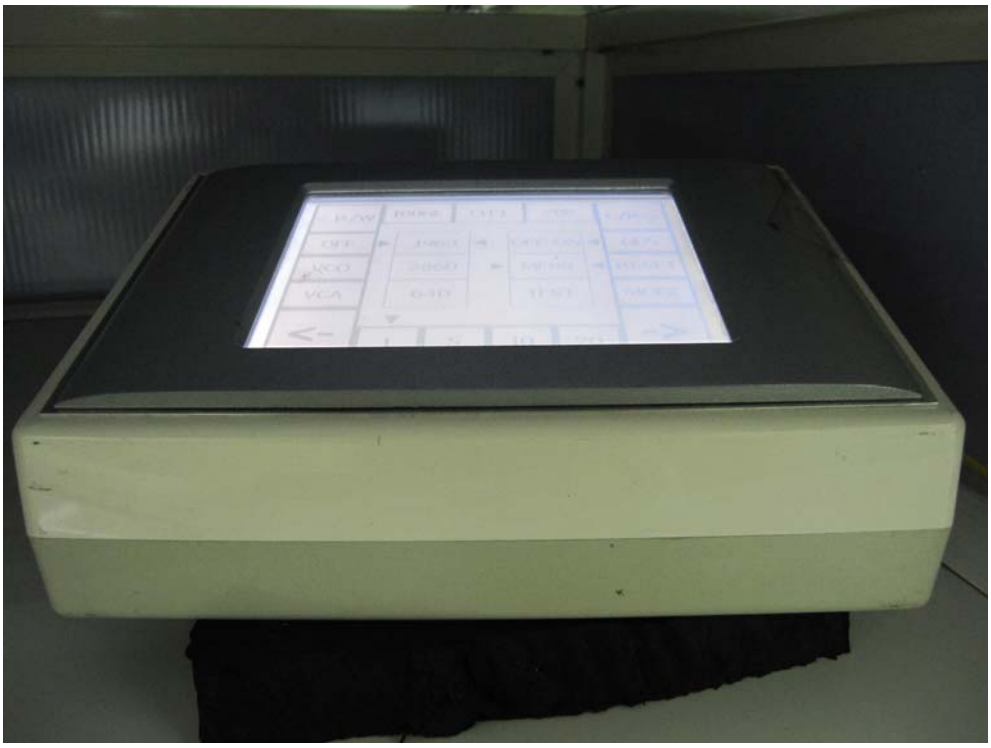
8. Inside of EUT(1-3)

9. Inside of EUT(1-4)



10. Inside of EUT(1-5)

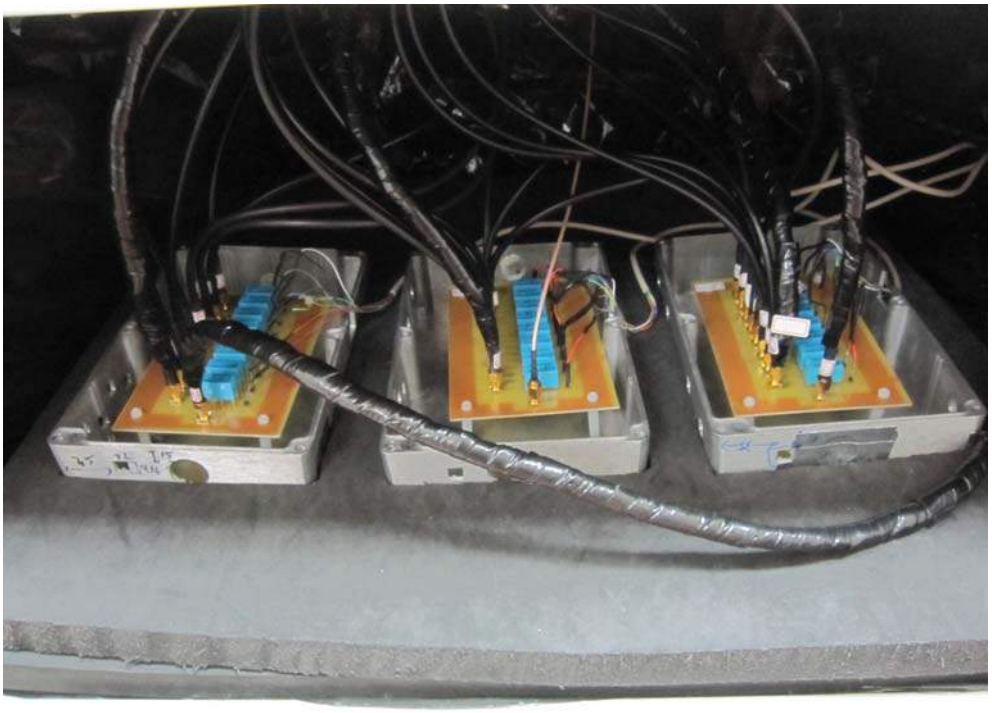
11. Inside of EUT(1-6)



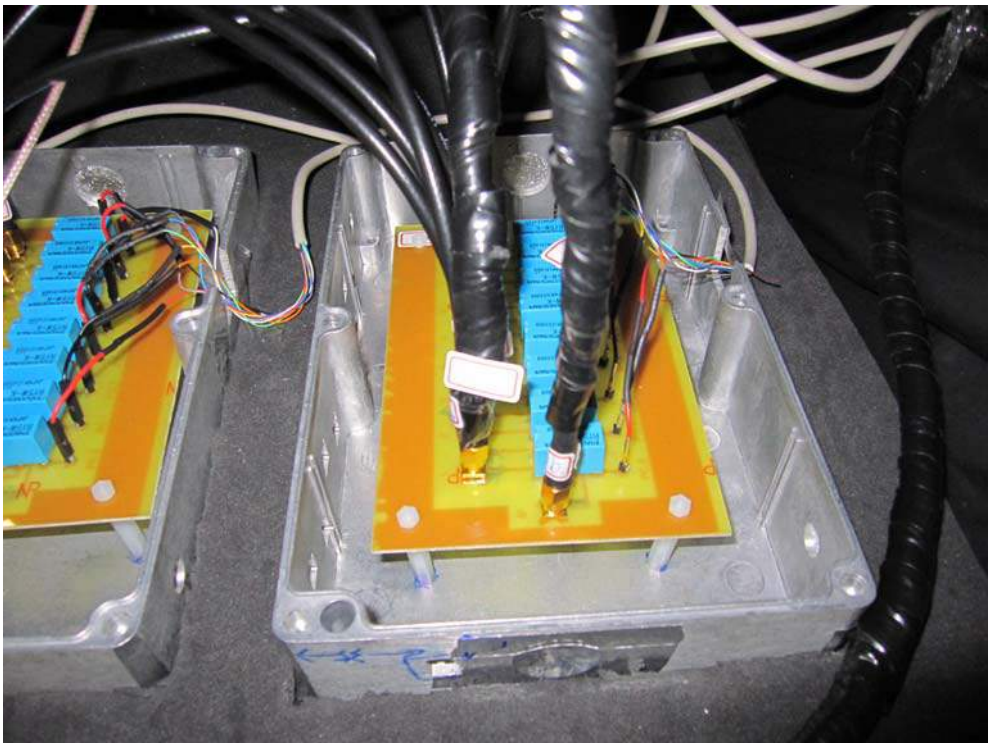
12. Inside of EUT(2-1)

13. Inside of EUT(2-2)

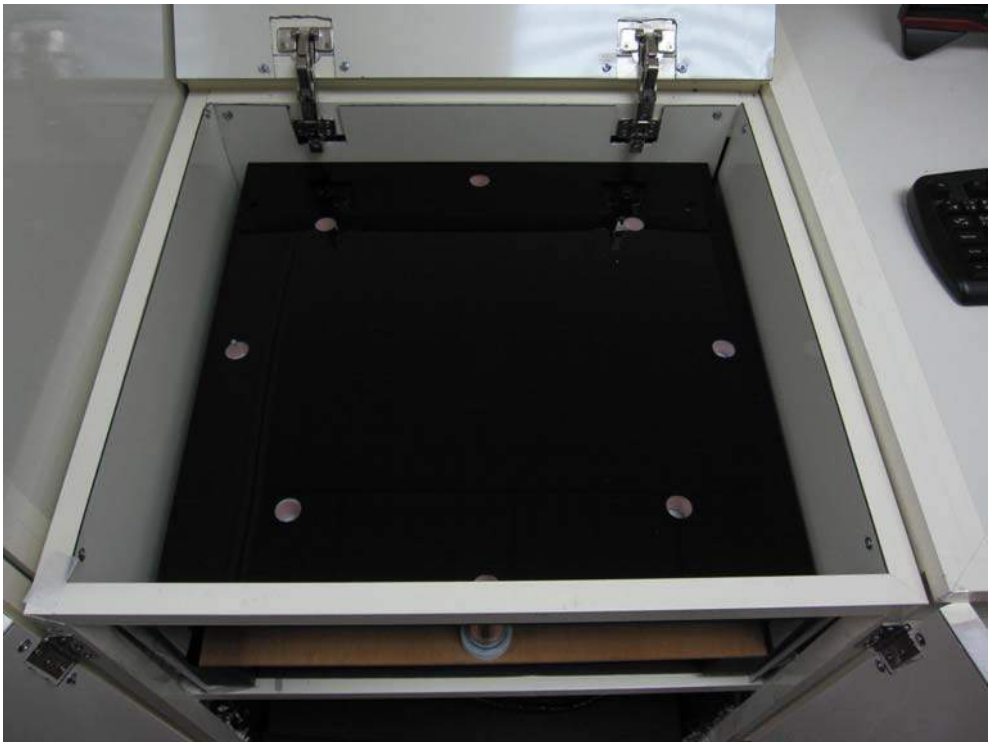
14. Inside of EUT(2-3)



15. Inside of EUT(2-4)



16. Inside of EUT(2-5)



17. Inside of EUT(3-1)

18. Inside of EUT(3-2)

19. Inside of EUT(3-3)

20. Inside of EUT(3-4)

ATTACHMENT

Parts List

財團法人精密機械研究發展中心
Precision Machinery Research & Development Center
No.27, 37th Road, Taichung Industrial Park, Taichung, Taiwan, R.O.C.
TEL: 886-4-2359-9009
FAX: 886-4-2359-8847
www.pmc.org.tw

XacPro-S Parts List :

Part No.	Manufacturer/ Trademark	Type/Model	Technical Data
Function generator	NF	WF1944B	Input AC100-240V MAX 500VA
SQUID sensor	JSQ	rf SQUID Magnetometer	77K
SQUID controller	JSQ	rf SQUID Electronics	Output -72dBm to -118dBm
SQUID control panel	JSQ	Touch Panel Controller	Input DC 15V Output MAX Vpp 20V
PC	---	OS: Windows XP	Input AC100-240V / 350W
DAQ system	NI	PCI-6221 BNC2110	Input ±10V
Coils	MagQu	8channel	Input Max AC 10V
Switch circuit	MagQu	8channel 3line switch	Input DC 5V
Dewar	MVE	Lab5	5L 77K

Appendix D: Certification of ISO 13485:2003

Certificate TW14/10079

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 13485:2003
EN ISO 13485:2012

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.

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)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0612

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Appendix E: Certification of ISO 9001:2008

Certificate TW14/10080

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
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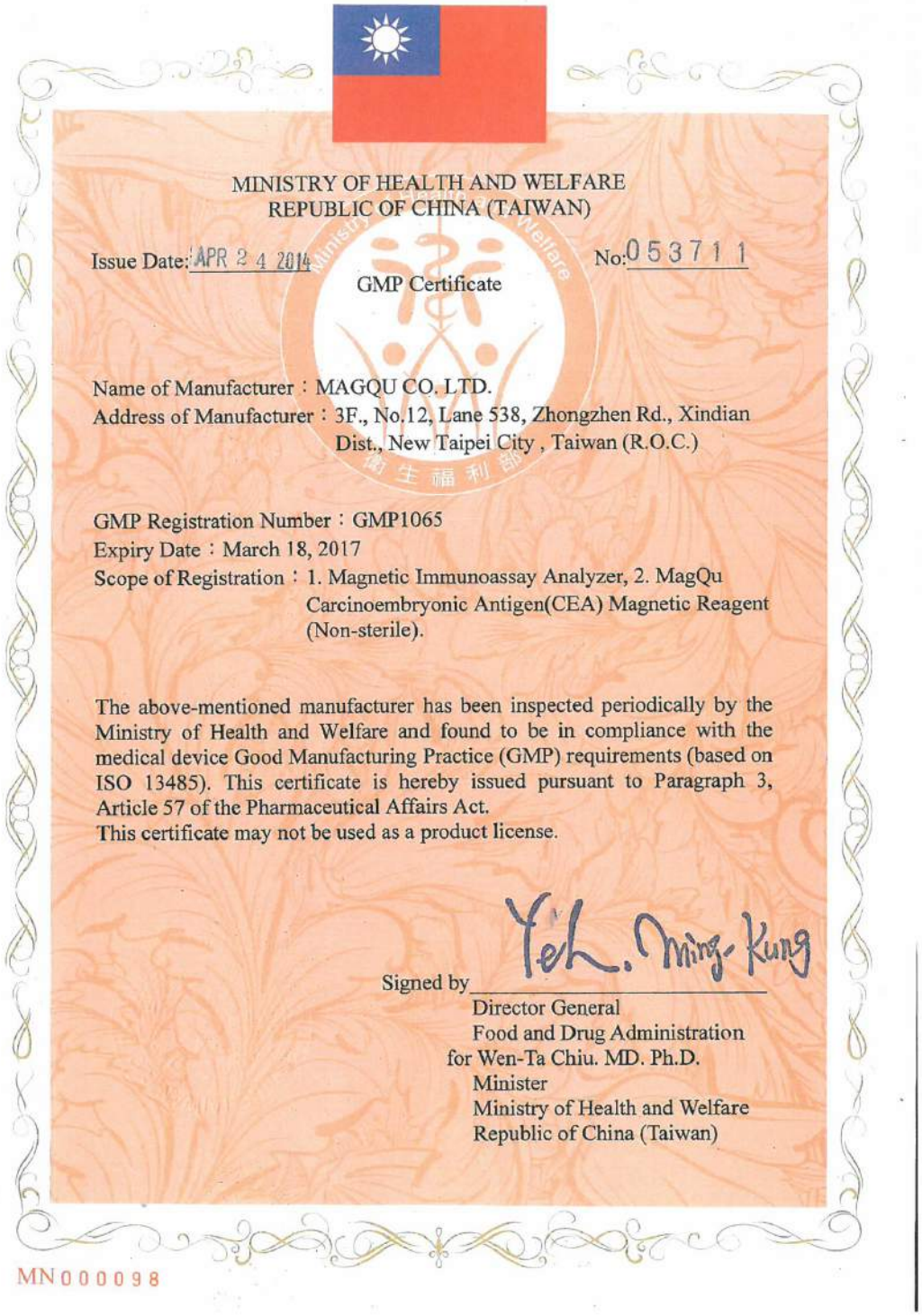
Appendix F: Certification of Good Manufacturing Practice (GMP)



MINISTRY OF HEALTH AND WELFARE
REPUBLIC OF CHINA (TAIWAN)

Issue Date: APR 2 4 2014 No: 053711

GMP Certificate

Name of Manufacturer：MAGQU CO. LTD.
Address of Manufacturer：3F., No.12, Lane 538, Zhongzhen Rd., Xindian Dist., New Taipei City , Taiwan (R.O.C.)

GMP Registration Number：GMP1065
Expiry Date：March 18, 2017
Scope of Registration：1. Magnetic Immunoassay Analyzer, 2. MagQu Carcinoembryonic Antigen(CEA) Magnetic Reagent (Non-sterile).

The above-mentioned manufacturer has been inspected periodically by the Ministry of Health and Welfare and found to be in compliance with the medical device Good Manufacturing Practice (GMP) requirements (based on ISO 13485). This certificate is hereby issued pursuant to Paragraph 3, Article 57 of the Pharmaceutical Affairs Act.
This certificate may not be used as a product license.

Signed by Yeh. Ming-Kung
Director General
Food and Drug Administration
for Wen-Ta Chiu. MD. Ph.D.
Minister
Ministry of Health and Welfare
Republic of China (Taiwan)

MN000098