Risk Management Report

Organization's Name .....:	
Address.....:	
Kind of Device.....	Medical LCD Monitor
Model and/or Type Reference ..:	MEDDP-515xxx-xx-xxxx, MEDDP-517xxx-xx-xxxx, MEDDP-519xxx-xx-xxxx (where x can be 0-9, A-Z for marketing purpose only, no technical difference)
Scope of the risk analysis.....:	1. Intended use and identification of characteristics related to the safety of the medical equipment 2. Identification of hazards 3. Estimation of the risk for each hazardous situation 4. "Design, Development and Manufacture" of the product in question.

Prepared:		Quality Assurance:	
Safety:		Sales:	
R&D:		President:	

Version	Description	Date
1.0	Initial	

Table of Content

1. Introduction

This report specifies a process to identify the hazards associated with medical devices to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

Bibliography:

Item	Standard no.
safety	IEC60601-1: 2005+ A1: 2012 ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) CAN/CSA-C22.2 No. 60601-1:14 EN60601-1:2006+A11:2011+A1:2013+A12:2014
EMC	IEC 60601-1-2
Risk Management	ISO14971: 2007

2. Risk Management Policy

Criteria for risk acceptability has defined based upon applicable national or regional regulations and relevant International Standards, and taken into account available information such as the generally accepted state of the art and known stakeholder concerns.

Based on the guidelines being set up by the company management the identified risks will be evaluated in the risk management worksheet and reported in annual risk management reports as follows (according to ISO 14971):

In determining acceptable risk, we will research pertinent regulations, standards and associated literature to identify state of the art for power supply with medical and dental equipment. The criteria of risk acceptability were according to requirement of IEC 60601-1.

3. Risk management process

3.1 Risk management process

The risk management process will be conducted follow Standard ISO 14971 clause 3.1, in figure 1 as below.

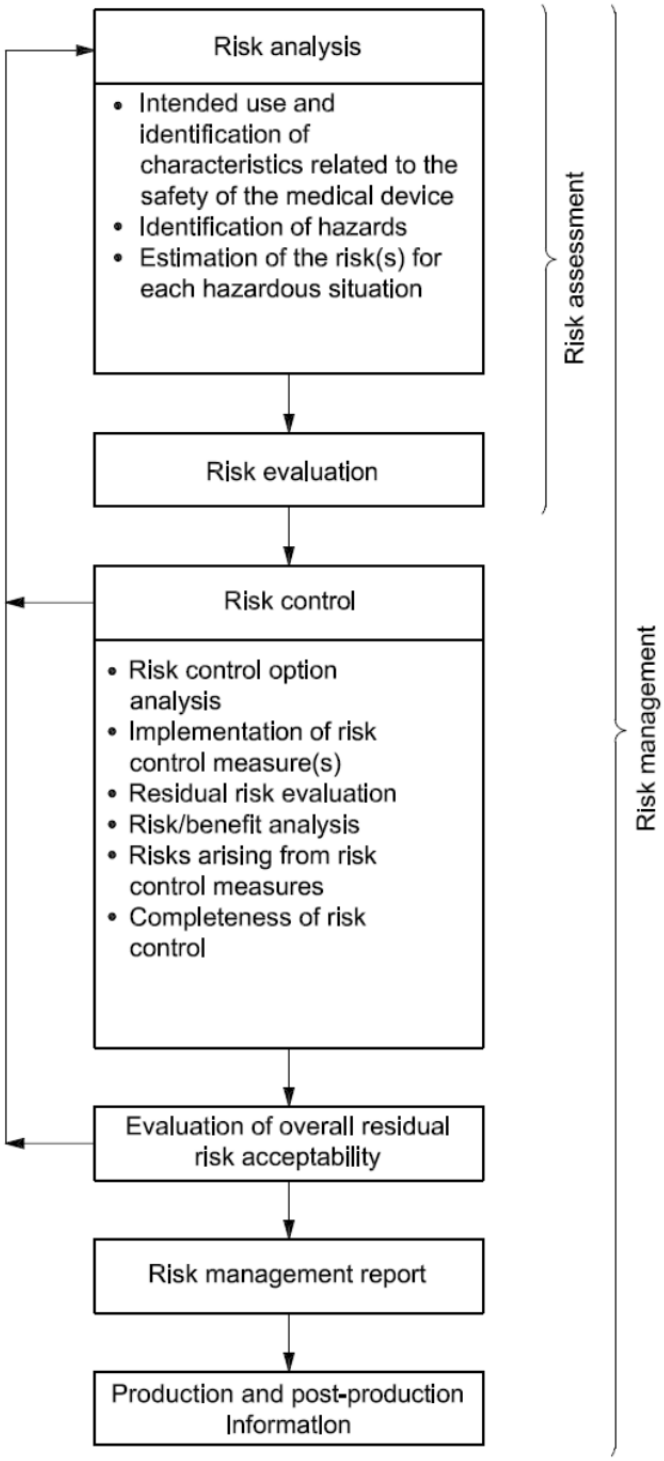

Figure 1 – A schematic representation of the risk management process

3.2 Management responsibilities

Top management / President opened the meeting for risk management process for following item
- Assignment of qualified personnel
- Adequate Resources
- Policy for determining criteria for risk acceptability

See “meeting record of risk management” for details.

3.3 Qualification of personnel

Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them

Assigned Responsibility	Name	Responsibilities in the whole Process	Qualification Record Ref. No.
Engineering Representative (R&D)	Kevin	- Responsible for carrying out the RM report (The person shall be trained ISO14971 or with relevant working experience.)	ISO14971 Training Record
Safety section	Leo	- Responsible for reviewing the RM report. (The person shall be trained ISO14971 or with relevant working experience.)	ISO14971 Training Record
Sales department	Kay	- Responsible for collects data and from customer and market	ISO14971 Training Record
Quality Assurance (QA) Representative	Ken	- Responsible for document any decisions and actions taken.	ISO14971 Training Record
President	TK	- Responsibilities as below - Ensuring the provision of adequate resources - Ensuring the assignment of qualified personnel for risk management.	ISO14971 Training Record

3.4 Risk management plan

Risk management activities was refer to Risk management plan (Document No “RP1511051”), include the following:

a) The scope of the risk management plan is specified by the product LCD Monitor. And describing the medical device and the life-cycle phases for which each element of the plan is applicable.

b) Assignment of responsibilities and authorities; See clause 3.3 for details.

c) The review requirements of risk management activities was specified in Risk management plan (Document No “RP1511051”).

d) The criteria for accepting risks shall considering the applicable national or regional requlations and relevant international standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns. The risk index matrix is disclosed in clause 3.4.1

e) The final verification of the risk control shall be performed on the prototype samples. The compliance reports according to IEC60601-1, IEC 60601-1-2 and qualification test report.

f) Activities related to collection and review of relevant production and post-production information.

See Attachment for Risk management plan for details.

3.4.1 Evaluation System

Based on the guidelines being set up by the company management the identified risks will be evaluated

A: Probability of Occurrence (Improbable/Remote/Occasional/Probable/Frequent)

Probability (Likelihood of event occurrence)		**Definition**
Common term	Rank (1=lowest)	
Frequent	5	With a probability of occurrence more than 10^{-3}, or occurs more than once a month
Probable	4	With a probability of occurrence less than 10^{-3} but greater than 10^{-4}, or occurs more than once a season
Occasional	3	With a probability of occurrence less than 10^{-4} but greater than 10^{-5}, or occurs more than once a year
Remote	2	With a probability of occurrence less than 10^{-5} but greater than 10^{-6}, or occurs more than once a product life-cycle
Improbable	1	With a probability of occurrence less than 10^{-6}, unlikely to occur, but possible.

B: Severity of Harm (Negligible, Minor, Serious, Critical, Catastrophic)

Severity (Impact of event occurrence)		**Definition**
Common term	Rank (1=lowest)	
Catastrophic	5	Could result in death, or life-threatening injury
Critical	4	Could result in permanent partial disability, injuries
Serious	3	Could result in injury requiring professional medical intervention
Minor	2	Could result in temporary injury not requiring professional medical intervention
Negligible	1	Inconvenience or temporary discomfort, these do not require any medical treatment.

The acceptance criteria are as following:
Risk Index Matrix

Severity rank / Probability rank	1	2	3	4	5
4	Acceptable, Insignificant risk	Unacceptable, moderate risk	Unacceptable, high risk	Unacceptable, high risk	Unacceptable, extreme risk
3	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Unacceptable, moderate risk	Unacceptable, high risk	Unacceptable, high risk
2	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Unacceptable, moderate risk	Unacceptable, moderate risk
1	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Acceptable, Insignificant risk	Unacceptable, moderate risk
Risk (index) acceptability level : Risk= Severity x Probability Result: Risk=1 to 4 is acceptable; Risk = 5 to 25 is unacceptable					

The criteria was refer form risk Management Plan (Doc: RP1507063)

3.5 Risk management file

Records of risk management activities, including any significant changes, are maintained

	Description and reference to (ref number of) existing documents
Product tests according to	設計及開發程式 PN:QP0702
Process input (goods, resources, design etc.)	製程管制程序 P/N:QP0707 成品檢驗規定 P/N:QP0805
Post–production information and product surveillance on the markets	客訴流程管理辦法 P/N: QP0709 設計變更作業規定 P/N: QP0703 Product Problem record P/N: QP0710

4. Risk analysis

4.1 Risk analysis process

Risk analysis performed as described according to ISO 14971, clause 4.2 to 4.4. The implementation of the planned risk analysis activities and the results of the risk analysis were recorded in the risk management file.

4.2 Intended use and identification of characteristics related to the safety of the medical device

(a) Questions: The following questions can aid the person in identifying all the characteristics of the medical device that could affect safety. (Which according to ISO 14971)

Item	Questions	Answer / Comments
C.2.1	What is the intended use and how is the medical device to be used?	The LCD Monitor is intended to serve as a display-integrated computing platform for integration with hospital system. This device is designed for general purpose for hospital environment. For data collection and display for reference. It shall not be used for life-supporting system.
C.2.2	Is the medical device intended to be implanted?	No, they are not intended to be implanted.
C.2.3	Is the medical device intended to be in contact with the patient or other person?	No applied part
C.2.4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	The materials & components used are listed in BOM (bill of material).
C.2.5	Is energy delivered to or extracted from the patient?	No energy delivered to or extracted from the patient.
C.2.6	Are substances delivered to or extracted from the patient?	No delivered to or extracted from the patient.
C.2.7	Are biological materials processed by the medical device for sub-sequent re-use, transfusion or transplantation?	No biological materials process used.
C.2.8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	Not supplied sterile function or intended to be sterilized by the user.
C.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?	Not intended to be routinely cleaned and disinfected by the user.
C.2.10	Is the medical device intended to modify the patient environment?	No modify the patient environment function.
C.2.11	Are measurements taken?	No measurement function.
C.2.12	Is the medical device interpretative?	No data interpretative.
C.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No, they are not.
C.2.14	Are there unwanted outputs of energy or substances?	Yes, they will bring about high temperature, leakage current and EMC.
C.2.15	Is the medical device susceptible to	Yes, they may influence by temperature,

	environmental influences?	humidity, vibrations
C.2.16	Does the medical device influence the environment?	Yes, they may influence temperature and EMC
C.2.17	Are there essential consumables or accessories associated with the medical device?	No
C.2.18	Is maintenance or calibration necessary?	No
C.2.19	Does the medical device contain software?	No
C.2.20	Does the medical device have a restricted shelf life?	No
C.2.21	Are there any delayed or long-term use effects?	No
C.2.22	What mechanical forces will the medical device be subjected to?	This LCD Monitor is subjected to such mechanical hazards as gravity (or instability), impact and drop.
C.2.23	What determines the lifetime of the medical device?	The service life is based on previous records and feedback of marketing in previous models.
C.2.24	Is the medical device intended for single use?	This device not intended for single use.
C.2.25	Is safe decommissioning or disposal of the medical device necessary?	Yes, This device needs safe decommissioning or disposal.
C.2.26	Does installation or use of the medical device require special training or special skills?	It has to read the instruction manual before installation.
C.2.27	How will information for safe use be provided?	Product specification or product data sheet Safety instructions will be provided according to IEC 60601-1:2005.
C.2.28	Will new manufacturing processes need to be established or introduced?	No
C.2.29	Is successful application of the medical device critically dependent on human factors such as the user interface?	No, it shall be evaluated in the final system.
C.2.29.1	Can the user interface design features contribute to use errors?	No
C.2.29.2	Is the medical device used in an environment where distractions can cause errors?	No
C.2.29.3	Does the medical device have connecting parts or accessories?	No
C.2.29.4	Does the medical device have a control interface?	No
C.2.29.5	Does the medical device display information?	No
C.2.29.6	Is the medical device controlled by a menu?	No
C.2.29.7	Will the medical device be used by persons with special needs?	No, it shall be evaluated in the final system.
C.2.29.8	Can the user interface be used to initiate user actions?	No
C.2.30	Does the medical device use an alarm system?	No
C.2.31	In what way(s) might the medical device be	No

	deliberately misused?	
C.2.32	Does the medical device hold data critical to patient care?	No
C.2.33	Is the medical device intended to be mobile or portable?	No, the device is a fixed installed equipment.
C.2.34	Does the use of the medical device depend on essential performance?	No, it shall be evaluated in the final system.

(b) Intended use and & most unfavorable maximum working load condition

These Medical LCD Monitors are designed to use in displaying medical imaging data applications. These products cannot be used in patient vicinity. The LCD displays and the power supply must not be used outdoors or in areas where an explosion hazard may occur. They are intended to connect to specified power adaptor and equipped with VGA/HDMI/DP ports. The user has to make sure that requirements from IEC 60601-1 are fulfilled, especially in combination from monitor with other electrical equipment. It shall not be used for life supporting system.

The unit can only use with switching power adapter as following

Power Adapter	ADAPTER TECHNOLOGY CO LTD.	ATM065-P120	I/P: 100-240 Vac, 50/60 Hz, 1.6-0.7A O/P: 12 Vdc, 5A; 60W Two MOPP insulation is provided between primary and secondary circuit in evaluated power adapter.

Maximum operation temperature 40 degree C

The metal enclosure of LCD Monitor can be touched within 1 sec to 10 sec and plastic enclosure can be touched within 10 sec to 1 mins. Power adapter can be touched within 10 sec to 1 mins. Touch screen can be touched within 10 sec to 1 mins.

Pollution degree of equipment: Pollution Degree 2

Operation altitude of equipment: 0-3000m

Model	MEDDP-515xxx-xx-xxxx (DC)
LCD Panel Size: Pixel Pitch: Brightness: Contrast Ratio: Response Time:	 15” 0.297mm 450 cd/㎡ 800:1(typ.) 8mS(typ.)
Maximum viewable size	15 inch (38.1cm)
Video Input	Analog:15-pin, D-sub connector Digital: DVI,DP,HDMI connector
Display area	304.128mmx 228.096mm (H×V)
Input voltage: Consumption	12V DC / 2A 12 watts maximum
External controls	Power-switch, VGA, DVI,DP,HDMI Brightness, Contrast, Volume, Color temperature (User,6500°K,9300°K), Clock, Phase, H-position, V-position, OSD-control, Recall, Sharpness, Exit
Horizontal frequency	30-60KHz
Vertical frequency	50-75Hz
Dimensions(with carton)	410mm×140mm×420mm (W×D×H)
Max. Resolution	1920×1080 (Non-Interlaced)
Power Saving	With EPA standard
Plug & Play	DDC 1/2B
Weight	N.W.:3.2 Kgs G.W.:4.0 Kgs
Ambient temperature Operation: Non-operating	 5°C – 40°C -10°C – 60°C
Humidity Operating: Storage:	 20%-80% 10%-90%

*Specifications are subject to change without notice.

Model	MEDDP-517xxx-xxxxxxx (DC)
LCD Panel Size: Pixel Pitch: Brightness: Contrast Ratio: Response Time:	 17” 0.264mm 350 cd/㎡ 1000:1(typ.) 5mS(typ.)
Maximum viewable size	17 inch (43.2cm)
Video Input	Analog:15-pin, D-sub connector Digital: DVI,DP,HDMI connector
Display area	337.920mmx 270.336mm (H×V)
Input voltage: Consumption	12V DC / 3A 15 watts maximum
External controls	Power-switch, VGA, DVI,DP,HDMI Brightness, Contrast, Volume, Color temperature (User,6500°K,9300°K), Clock, Phase, H-position, V-position, OSD-control, Recall, Sharpness, Exit
Horizontal frequency	30-60KHz
Vertical frequency	50-75Hz
Dimensions(with carton)	435mm×150mm×450mm (W×D×H)
Max. Resolution	1920×1080 (Non-Interlaced)
Power Saving	With EPA standard
Plug & Play	DDC 1/2B
Weight	N.W.:4.0 Kgs G.W.:4.9 Kgs
Ambient temperature Operation: Non-operating	 5°C – 40°C -10°C – 60°C
Humidity Operating: Storage:	 20%-80% 10%-90%

*Specifications are subject to change without notice.

Model	MEDDP-519xxx-xxxxxxx (DC)
LCD Panel Size: Pixel Pitch: Brightness: Contrast Ratio: Response Time:	 19” 0.294mm 350 cd/㎡ 1000:1(typ.) 5mS(typ.)
Maximum viewable size	19 inch (48.26cm)
Video Input	Analog:15-pin, D-sub connector Digital: DVI,DP,HDMI connector
Display area	376.32mmx 301.06mm (H×V)
Input voltage: Consumption	12V DC / 3A 19.7 watts maximum
External controls	Power-switch, VGA, DVI,DP,HDMI Brightness, Contrast, Volume, Color temperature (User,6500°K,9300°K), Clock, Phase, H-position, V-position, OSD-control, Recall, Sharpness, Exit
Horizontal frequency	30-60KHz
Vertical frequency	50-75Hz
Dimensions(with carton)	490mm×155mm×500mm (W×D×H)
Max. Resolution	1920×1080 (Non-Interlaced)
Power Saving	With EPA standard
Plug & Play	DDC 1/2B
Weight	N.W.:4.9 Kgs G.W.:5.8 Kgs
Ambient temperature Operation: Non-operating	 5°C – 40°C -10°C – 60°C
Humidity Operating: Storage:	 20%-80% 10%-90%

*Specifications are subject to change without notice.

The reasonably foreseeable misuse listed as below table.

Following list are on known and foreseeable hazards associated with the medical device in both normal and fault conditions.

Item	Foreseeable misuse and hazards identification
A1	Output overload of power adapter
A2	Output short of power adapter
A3	Supply voltage mismatch
A4	Unit drop.
A5	Unit subjected to force.
A7	Premature unpacking, transport or storage
A8	Premature or excessive cleaning

4.3 Identification of hazards

Following list are identification of hazard for medical device,
(Note: the evaluation of possible hazards by R/D engineer base on engineering judgment and ISO 14971)

Item	hazards identification	Hazards Type
B1	Line voltage from mains to cause hazard.	Electromagnetic energy - Electric Shock
B2	Touch current (Enclosure leakage current) of accessible parts to cause hazard.	Electromagnetic energy - Leakage current
B3	Touch current (Output leakage current) of accessible parts to cause hazard.	Electromagnetic energy - Leakage current
B4	Stored energy to cause hazard.	Electromagnetic energy - Electric Shock
B5	High temperature to cause hazard.	Thermal energy – High temperature
B6	Input current of Label less than measured value of equipment may cause fire hazard.	Labelling - Inadequate description of performance characteristics
B7	X capacitor connected between Line and Neutral may cause electric shock.	Electromagnetic energy - Electric Shock
B8	Fuse may not operate to cause fire hazard.	Electromagnetic energy - Electric Shock
B9	Unsuitable rating of critical component to cause fire hazard.	Electromagnetic energy - Electric Shock Thermal energy – High temperature
B10	Critical component fault to cause fire hazard	Electromagnetic energy - Electric Shock Thermal energy – High temperature
B11	High electrical voltage to cause insulating materials dielectric breakdown	Electromagnetic energy - Electric Shock
B12	Critical component or wires displaced to cause hazard	Mechanical energy - Vibration
B13	Physically equipment unstable in normal use to cause hazard	Mechanical energy - falling

Item	hazards identification	Hazards Type
B14	Overheat to cause thermoplastic materials shrinkage or distortion	Thermal energy – High temperature
B15	Openings of enclosure to cause fire hazard	Thermal energy – High temperature
B16	Equipment expose at high humidity preconditioning treatment to cause electric shock.	Electromagnetic energy - Electric Shock
B17	Markings of Label were not clearly readable to cause hazard.	Labelling - Inadequate description of performance characteristics
B18	Instructions or technical description document not provided to cause hazard.	Labelling - Inadequate description of performance characteristics
B19.	Information of instructions not enough to cause hazard.	Labelling - Inadequate description of performance characteristics
B20	The Instruction not included the disposal of waste products, residues, etc to cause hazard.	Labelling - Inadequate description of performance characteristics
B21	User modified the ME equipment to cause hazard.	Labelling - Inadequate disclosure of limitations
B22	The resistance to heat of insulation material (plastic enclosure or bobbin etc) are not retained to cause hazard	Thermal energy – High temperature
B23	Components of equipment, the unwanted movement or vibration to cause hazard.	Mechanical energy - Vibration
B24	The accidental detachment of wirings to cause hazard.	Mechanical energy - Vibration
B25	Wiring contact with a moving part or from friction at sharp corners and edges to cause hazard	Mechanical energy – sharp, edges
B26	No fuses provided on each supply lead to cause hazard.	Electromagnetic energy - Electric Shock
B27	Rough surfaces, sharp corners and edges of ME equipment to cause hazard.	Mechanical energy - Torsion, shear and tensile
B28	The equipment placed in a corner in normal used to cause fire hazard.	Thermal energy – High temperature
B29	Constructional of Fire Enclosure not meet IEC 60601-1, 3rd to cause hazard.	Thermal energy – High temperature
B30	Rating misused for Component	Electromagnetic energy - Electric Shock Thermal energy – High temperature
B31	Setting change of controls device	Operational hazards - Function
B32	Indicator of power status	Operational hazards – User error
B33	Arrangement of controls and indicators	Operational hazards – User error
B34	SIO / SOP incorrect connected	Operational hazards – User error

4.4 Estimation of the risks for each hazardous situation

The decision of each hazardous risk were referred to recommendation of ISO14971, requirement of IEC 60601-1 and IEC 60601-1-2.

Item	Initial Risk Estimation				
	Risk	Probability	Severity of the harm	Risk level (refer to chapter 3.3 Risk Index Matrix for details)	Date of Assessment
A1	Output overload of power adapter	4	4	16	
A2	Output short of power adapter	4	3	12	
A3	Voltage mismatch.	4	4	16	
A4	Unit drop.	4	4	16	
A5	Unit subjected to force.	4	4	16	
A7	Premature unpacking, transport or storage	3	3	9	
A8	Premature or excessive cleaning	4	4	16	
B1	Line voltage from mains	3	5	15	
B2	Touch current (Enclosure leakage current) of accessible parts to cause hazard.	3	5	15	
B3	Touch current (Output leakage current) of accessible parts to cause hazard.	5	4	20	
B4	Stored energy	5	3	15	
B5	High temperature	5	2	10	
B6	Input current of Label less than measured value of equipment may cause fire hazard.	4	4	16	
B7	X capacitor connected between Line and Neutral may cause electric shock.	4	4	16	
B8	Fuse may not operate to cause fire hazard.	3	3	9	
B9	Unsuitable rating of critical component (transformer, main transistor, Bridge Rectifier, wiring….) to cause fire hazard.	5	4	20	
B10	Critical component fault (transformer, main transistor, Photo coupler, Bridge Rectifier…..) to cause fire hazard	5	4	20	
B11	High electrical voltage to cause insulating materials dielectric breakdown	5	4	20	
B12	Critical component or wires displaced to cause hazard	4	4	16	

Item	Initial Risk Estimation				
	Risk	Probability	Severity of the harm	Risk level (refer to chapter 3.3 Risk Index Matrix for details)	Date of Assessment
B13	Physically equipment unstable in normal use to cause hazard	3	3	9	
B14	Overheat to cause thermoplastic materials shrinkage or distortion	5	4	20	
B15	Openings of enclosure to cause fire hazard	5	3	15	
B16	Equipment expose at high humidity preconditioning treatment to cause electric shock.	4	4	16	
B17	Markings of Label were not clearly readable to cause hazard.	4	3	12	
B18	Instructions or technical description document not provided to cause hazard.	4	3	12	
B19	Information of instructions not enough to cause hazard.	3	3	9	
B20	The Instruction not included the disposal of waste products, residues, etc to cause hazard.	3	4	12	
B21	User modified the ME equipment to cause hazard.	3	3	9	
B22	The resistance to heat of insulation material (plastic enclosure or bobbin etc) are not retained to cause hazard	4	4	16	
B23	Components of equipment, the unwanted movement or vibration to cause hazard.	4	4	16	
B24	The accidental detachment of wirings to cause hazard.	3	3	9	
B25	wiring contact with a moving part or from friction at sharp corners and edges to cause hazard	4	3	12	
B26	No fuses provided on each supply lead to cause hazard.	4	3	12	
B27	Rough surfaces, sharp corners and edges of ME equipment to cause hazard.	4	3	12	
B28	The equipment placed in a corner in normal used to cause fire hazard.	4	3	12	

Item	Initial Risk Estimation				
	Risk	Probability	Severity of the harm	Risk level (refer to chapter 3.3 Risk Index Matrix for details)	Date of Assessment
B29	Constructional of Fire Enclosure not meet IEC 60601-1 to cause hazard.	4	3	15	
B30	Rating misused for Component	4	4	16	
B31	Setting change of controls device	5	1	5	
B32	Indicator of power status	3	4	12	
B33	Arrangement of controls and indicators	3	4	12	
B34	SIO / SOP incorrect connected	3	4	12	
Note:					

5. Risk evaluation

For each identified hazardous situation, the manufacturer shall decide, using the criteria defined in the risk management plan (Doc. No: P1006017), if risk reduction is required.

If risk reduction is not required, the requirements given in 6.2 to 6.6 do not apply for this hazardous situation.

The results of this risk evaluation were recorded as below.

Item	Risk	Risk level Risk=Severity x probability Result: Risk=1~4, acceptable; 5~25, unacceptable	Date of Assessment
A1	Output overload.	16 (unacceptable, to be reduced)	
A2	Output short.	12 (unacceptable, to be reduced)	
A3	Voltage mismatch.	16 (unacceptable, to be reduced)	
A4	Unit drop.	16 (unacceptable, to be reduced)	
A5	Unit subjected to force.	16 (unacceptable, to be reduced)	
A6	Unit subjected to impact.	16 (unacceptable, to be reduced)	
A7	Premature unpacking, transport or storage	9 (unacceptable, to be reduced)	
A8	Premature or excessive cleaning	16 (unacceptable, to be reduced)	
B1	Line voltage from mains	15 (unacceptable, to be reduced)	
B2	Touch current (Enclosure leakage current) of accessible parts to cause hazard.	15 (unacceptable, to be reduced)	
B3	Touch current (Output leakage current) of accessible parts to cause hazard.	20 (unacceptable, to be reduced)	
B4	Stored energy	15 (unacceptable, to be reduced)	
B5	High temperature	10 (unacceptable, to be reduced)	
B6	Input current of Label less than measured value of equipment may cause fire hazard.	16 (unacceptable, to be reduced)	
B7	X capacitor connected between Line and Neutral may cause electric shock.	16 (unacceptable, to be reduced)	
B8	Fuse may not operate to cause fire hazard.	9 (unacceptable, to be reduced)	
B9	Unsuitable rating of critical component (transformer, main transistor, Bridge Rectifier, wiring….) to cause fire hazard.	20 (unacceptable, to be reduced)	
B10	Critical component fault (transformer, main transistor,	20 (unacceptable, to be reduced)	

Item	Risk	Risk level Risk=Severity x probability Result: Risk=1~4, acceptable; 5~25, unacceptable	Date of Assessment
	Photo coupler, Bridge Rectifier…..) to cause fire hazard		
B11	High electrical voltage to cause insulating materials dielectric breakdown	20 (unacceptable, to be reduced)	
B12	Critical component or wires displaced to cause hazard	16 (unacceptable, to be reduced)	
B13	Physically equipment unstable in normal use to cause hazard	9 (unacceptable, to be reduced)	
B14	Overheat to cause thermoplastic materials shrinkage or distortion	20 (unacceptable, to be reduced)	
B15	Openings of enclosure to cause fire hazard	15 (unacceptable, to be reduced)	
B16	Equipment expose at high humidity preconditioning treatment to cause electric shock.	16 (unacceptable, to be reduced)	
B17	Markings of Label were not clearly readable to cause hazard.	12 (unacceptable, to be reduced)	
B18	Instructions or technical description document not provided to cause hazard.	12 (unacceptable, to be reduced)	
B19	Information of instructions not enough to cause hazard.	9 (unacceptable, to be reduced)	
B20	The Instruction not included the disposal of waste products, residues, etc to cause hazard.	12 (unacceptable, to be reduced)	
B21	User modified the ME equipment to cause hazard.	9 (unacceptable, to be reduced)	
B22	The resistance to heat of insulation material (plastic enclosure or bobbin etc) are not retained to cause hazard	16 (unacceptable, to be reduced)	
B23	Components of equipment, the unwanted movement or vibration to cause hazard.	16 (unacceptable, to be reduced)	
B24	The accidental detachment of wirings to cause hazard.	9 (unacceptable, to be reduced)	
B25	wiring contact with a moving part or from friction at sharp corners and edges to cause hazard	12 (unacceptable, to be reduced)	

Item	Risk	Risk level Risk=Severity x probability Result: Risk=1~4, acceptable; 5~25, unacceptable	Date of Assessment
B26	No fuses provided on each supply lead to cause hazard.	12 (unacceptable, to be reduced)	
B27	Rough surfaces, sharp corners and edges of ME equipment to cause hazard.	12 (unacceptable, to be reduced)	
B28	The equipment placed in a corner in normal used to cause fire hazard.	12 (unacceptable, to be reduced)	
B29	Constructional of Fire Enclosure not meet IEC 60601-1 to cause hazard.	15 (unacceptable, to be reduced)	
B30	Rating misused for Component	16 (unacceptable, to be reduced)	
B31	Setting change of controls device	16 (unacceptable, to be reduced)	
B32	Indicator of power status	16 (unacceptable, to be reduced)	
B33	Arrangement of controls and indicators	16 (unacceptable, to be reduced)	
B34	SIO / SOP incorrect connected	16 (unacceptable, to be reduced)	

6. Risk control

6.1 Risk reduction

Risk control activities was according to ISO 14971, clause 6.2 to 6.7

6.2 Risk control option analysis

One of following risk control options apply:
a) inherent safety by design;
b) protective measures in the medical device itself or in the manufacturing process;
c) information for safety

Item	Risk	Risk control option analysis	Note
A1	Output overload of power adapter	a) inherent safety by design	Used with IEC 60601-1 certificated power adapter. The specified power adaptor were designed regulating network of OVP, OCP into circuit to Comply with IEC 60601-1, clause 13, single fault conditions test requirement.
A2	Output short of power adapter	a) inherent safety by design	Used with IEC 60601-1 certificated power adapter. The specified power adaptor were designed regulating network of OVP, OCP into circuit to Comply with IEC 60601-1, clause 13, single fault conditions test requirement.
A3	Voltage mismatch.	a) inherent safety by design	Used with IEC 60601-1 certificated power adapter. The specified power adaptor were designed auto range (100-240Vac) for input circuit to Comply with IEC 60601-1, clause 13, single fault conditions test requirement. And provided with polarized DC jack.
A4	Unit drop.	a) inherent safety by design	Provided a solid and hard enclosure to covered unit to Comply with IEC 60601-1, clause 15.3, drop impact test requirement.
A5	Unit subjected to force.	a) inherent safety by design	Provided a solid and hard enclosure to covered unit to Comply with IEC 60601-1, clause 15.3, enclosure mechanical strength test requirement.
A6	Unit subjected to impact.	a) inherent safety by design	Provided a solid and hard enclosure to covered unit to Comply with IEC 60601-1, clause 15.3, drop impact test requirement.
A7	Premature unpacking, transport or storage	a) inherent safety by design	The outside of packaging marked environmental conditions for transport and storage according to IEC 60601-1, ISO 780 and ISO15223..
A8	Premature or excessive cleaning	a) inherent safety by design	Provided method of cleaning into user manual according to IEC 60601-1
B1	Line voltage from mains	a) inherent safety by design	Used with IEC 60601-1 certificated power adapter. The specified power adaptor were provided a solid enclosure to covered unit. And provided Double/Reinforced insulation and two MOPP between primary and secondary according to IEC 60601-1.

B2	Touch current (Enclosure leakage current) of accessible parts to cause hazard.	a) inherent safety by design	Used with IEC 60601-1 certificated power adapter. The touch current for the output of adapter were met require of IEC 60601-1.
B3	Touch current (Output leakage current) of accessible parts to cause hazard	a) inherent safety by design	Used with IEC 60601-1 certificated power adapter. The touch current for the outer enclosure of adapter were met require of IEC 60601-1.
B4	Stored energy	a) inherent safety by design	Used with IEC 60601-1 certificated power adapter. The discharge of AC inlet pins were met require of IEC 60601-1
B5	High temperature	a) inherent safety by design	Used with IEC 60601-1 certificated power adapter. And designed used with Low Power CPU.
B6	Input current of Label less than measured value of equipment may cause fire hazard.	a) inherent safety by design	Provided rating information on label drawing of unit to Comply with IEC 60601-1, clause 4.11, power input test requirement.
B7	X capacitor connected between Line and Neutral may cause electric shock.	a) inherent safety by design	Provided rating information on label drawing of unit to Comply with IEC 60601-1, clause 8.4.3, voltage limitation test requirement.
B8	Fuse may not operate to cause fire hazard.	a) inherent safety by design	Used with IEC 60601-1 certificated power adapter. The specified power adaptor provided with main fuse, the fuse with IEC60127 standard approved to Comply with IEC 60601-1, clause 13, single fault conditions test requirement.
B9	Unsuitable rating of critical component to cause fire hazard.	a) inherent safety by design	According to our QMS procedure, all component are used within their specified ratings.
B10	Critical component fault to cause fire hazard	a) inherent safety by design	According to our QMS procedure, all components and wiring are used within their specified ratings. and AC power Adapter Comply with IEC 60601-1, clause 13, single fault conditions test requirement.
B11	High electrical voltage to cause insulating materials dielectric breakdown	a) inherent safety by design	Insulation materials were used withstand voltage complies with standard requirement. And application was complying with IEC 60601-1 requirements.
B12	Critical component or wires displaced to cause hazard	a) inherent safety by design	The equipment designed provided two fixings (Mechanically securing, glue, soldering, physical fit…..) to prevent such movement. According to IEC 60601-1 requirement.
B13	Physically of equipment unstable in normal use to cause hazard	a) inherent safety by design	Designed steady and solid enclosure to covered unit. According to IEC 60601-1 requirement.
B14	Overheat to cause thermoplastic materials shrinkage or distortion	a) inherent safety by design	Used high thermal rating of thermoplastic enclosure with UL94 approved to meet with to IEC 60601-12 requirement.
B15	Openings of enclosure to cause fire hazard	a) inherent safety by design	Provided a solid and hard enclosure without openings to covered unit to Comply with IEC 60601-1 requirement.
B16	Equipment expose at high humidity preconditioning	a) inherent safety by design	Provided a solid, hard and tight enclosure to covered unit to Comply with IEC 60601-1, clause 5.7 requirement.