EC Certificate Production Quality Assurance System FI20/07014

The management system of

KASO Medical Technology Co., Ltd.

4th Floor, Building 2, Donghua Industrial Area, Shakeng, Luocun,
Shishan, Nanhai District,
Foshan City, Guangdong Province,
P.R.China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex V

For the following products

Dental Units

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 29 April 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 29 April 2020
This certification is based on decision: FI20/07022P0

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

Seppo Vahasalo
Notified Body Manager

SGS Fimko Ltd., Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

Digitally signed by Jighili Tatiana
Date: 2021.05.20 10:17:01 EEST
Reason: MoldSign Signature
Location: Moldova

Attachment 1 to SGS Fimko Ltd. EC certificate FI20/07014 Issue 1

Manufacturer	KASO Medical Technology Co., Ltd.
Address	4th Floor, Building 2, Donghua Industrial Area, Shakeng, Luocun, Shishan, Nanhai District, Foshan City, Guangdong Province, P.R.China
Activity and Medical Device Product Category	93/42/EEC Annex V Dental Units

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Trademark(s) and Model(s)/type(s)
Dental Unit	IIa	KS-DLX301
Dental Unit	IIa	KS-D106

DECISION

29 April 2020

FI20/07022P0

KASO Medical Technology Co., Ltd.
4th Floor, Building 2, Donghua Industrial Area, Shakeng, Luocun,
Shishan, Nanhai District,
Foshan City, Guangdong Province,
P.R.China

EC-certification application 18/105-1, dated 03 April 2020 (update from 18/105-0, dated 15 Nov 2018)

Subject	Certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex V Section 3.
Manufacturer	KASO Medical Technology Co., Ltd. 4th Floor, Building 2, Donghua Industrial Area, Shakeng, Luocun, Shishan, Nanhai District, Foshan City, Guangdong Province, P.R.China
Decision	A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	Model	Class
Dental Unit	KS-DLX301	IIa
Dental Unit	KS-D106	IIa

Justification	SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex V of Medical Device Directive 93/42/EEC. The decision is based on audit and technical file review report(s) 29875, dated 18 and 19 November 2019. The manufacturer has signed the undertaking to follow the obligations of Annex V of the Directive 93/42/EEC.
Certificate related to decision	FI20/07014, Issue 1
Attachment to certificate	Attachment 1
Valid until	This decision is valid until 24 May 2024 providing the requirements of the certification are fulfilled.
Date	Helsinki, 29 April 2020

Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd, Notified Body 0598

Certificate of Registration

This is to certify that the Quality Management System of

KASO Medical Technology Co., Ltd.

Unified Social Credit Code: 91440605MA4WE7RW2A

Operation Address: Floor 4, Building 2, Donghua Industrial Area, Shakeng, Luocun, Shishan Town, Nanhai District, Foshan City, Guangdong Province, China

Registered Address: Floor 4, Building 2, Donghua Industrial Area, Shakeng, Luocun, Shishan Town, Nanhai District, Foshan City, Guangdong Province, China(Domicile Declaration)

applicable to

The design, production and sales of dental unit(within the scope of qualification)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number **44487**

Date: 28 February 2018

Reissue Date: 18 January 2021

Valid Until: 28 February 2024

UKAS MANAGEMENT SYSTEMS 015

DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993

CONCERNING MEDICAL DEVICES

MANUFACTURER: KASO MEDICAL TECHNOLOGY CO., LTD
4TH FLOOR, BUILDING 2, DONGHUA INDUSTRY AREA,SHAKENG, LUOCUN, SHISHAN, NANHAI DISTRICT, FOSHAN CITY, GUANGDONG PROVINCE,CHINA

MEDICAL DEVICE: DENTAL UNIT
MODEL : KS-DLX301，KS-D106
CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 9
CONFORMITY ASSESSMENT ROUTE: ANNEX VII + V

WE, KASO MEDICAL TECHNOLOGY CO., LTD, HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTERNATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC.

STANDARDS APPLIED: EN ISO 15223-1:2016, EN ISO 9687:2015, EN 1041:2008, EN ISO 14971:2012, EN 1639:2009, EN 1640:2009, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 80601-2-60:2015, EN 62366-1:2015, EN ISO7494-1:2011, EN ISO7494-2:2015, EN ISO 6875:2011, EN ISO 9680:2014, EN ISO 10993-1:2009/AC:2010, EN 62304:2006 +A1-2015, EN ISO 11144:1996, EN ISO 7405:2018, ENISO 10993-1:2009/AC:2010, EN 62471:2008

NOTIFIED BODY: SGS FIMKO OY
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EMAIL: SGS.FIMKO@SGS.COM
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IDENTIFICATION NUMBER CE 0598

EC REP

EUROPEAN REPRESENTATIVE: LOTUS NL B.V.
KONINGIN JULIANAPLEIN 10, 1E VERD, 2595AA, THE HAGUE, NETHERLANDS.

(EC) CERTIFICATE(S):

FI20/07014

START OF CE-MARKING:

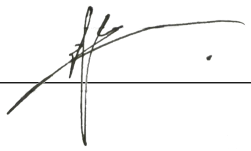
2020.4.29

CERTIFICATE VALIDITY:

2024.5.24

PLACE,DATE OF ISSUE: FOSHAN CITY,GUANGDONG, P.R.CHINA 2020.4.29

SIGNATURE: NAME MR. YUXING LIU (GENERAL MANAGER)



Dental chair (armchair)

	Specification requested by customer		Specifications proposed by the manufacturer
	Parameters Specification		**KS-DLX301**
	Dental chair "Tilt angle from	100 ° to 180 °	yes
	Adjustable headrest	Ascent / descent ≥ 40 cm	yes
	Maximum allowed capacity	≥ 200 kg	yes
	Pedal control	control buttons on the back of the patient's chair	yes
	Surface	resistance to chemical processing	yes
	Positioning programs	min. 5	yes ,9 memories
	Accessory	armrests, rotating right armrest	yes
	Automatic return to starting position	Yes	yes
	Urgent stop command	Yes	yes
	Multifunctional mobile foot control	Voltage 220-240V Frequency 50-60 Hz	yes
	Manufacturer's certificate attesting to the quality of the ISO 13485 product	Yes	yes
	EC certificate or EC declaration of conformity based on assessment of conformity with the corresponding annexes for the products offered	Yes	yes
	Service manuals in one of the international languages (Russian / English) and user manual with presentation of the translation at the time of delivery in the state language	Yes	yes
	Manufacturer's catalog / prospectuses / technical documents, on paper or in electronic format, with the indication / marking of the reference number / model of the article assigned to the lot number provided.	Yes	yes

Test Report issued under the responsibility of:

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No. ..... :	**GZME180300025001**
Date of issue ..... :	**2019-01-08**
Total number of pages..... :	**131**
Testing Laboratory ..... :	**SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch**
Address ..... :	**198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China**
Applicant's name ..... :	**KASO Medical Technology Co., Ltd.**
Address ..... :	**Floor 4, Building 2, Donghua Industry Area, Shakeng, Luocun, Shishan, Nanhan District, Foshan City, Guangdong Province, China.**
Test specification:	
Standard..... :	**IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)**
Test procedure..... :	**SGS-CSTC**
Non-standard test method..... :	**N/A**
Test Report Form No. ..... :	IEC60601_1K
Test Report Form Originator ..... :	UL(US)
Master TRF ..... :	2015-11

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

General disclaimer:

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 CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description ..... :	Integral Dental Unit (Dental unit)		
Trade Mark ..... :	KASO		
Manufacturer ..... :	Same as applicant		
Model/Type reference ..... :	KS-DLX301, KS-D106		
Ratings ..... :	AC 220-230 V; 50 Hz; 400 VA		
Testing procedure and testing location:			
☒ **Testing Laboratory:**	SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch		
Testing location/ address ..... :	198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China		
☐ **Associated CB Testing Laboratory:**			
Testing location/ address ..... :			
Tested by (name + signature) ..... :	Seema Chen /project engineer	Seema Chen	
Approved by (name + signature) ..... :	Lyn Shang /reviewer	Lyn	
☐ **Testing procedure: TMP/CTF Stage 1:**			
Testing location/ address ..... :			
Tested by (name + signature) ..... :			
Approved by (name + signature) ..... :			
☐ **Testing procedure: WMT/CTF Stage 2:**			
Testing location/ address ..... :			
Tested by (name + signature) ..... :			
Witnessed by (name + signature) ..... :			
Approved by (name + signature) ..... :			
☐ **Testing procedure: SMT/CTF Stage 3 or 4:**			
Testing location/ address ..... :			
Tested by (name + signature) ..... :			
Witnessed by (name + signature) ..... :			
Approved by (name + signature) ..... :			
Supervised by (name + signature) ..... :			

List of Attachments:

Attachment 1: Photo documentation (From page 121 to page 130)
Attachment 2: Electrical wiring diagram (Page 131)

Summary of testing	
Tests performed (name of test and test clause): **Tests according to the following standards were carried out:** **IEC 60601-1: 2005 + A1:2012** **EN 60601-1: 2006 + A1:2013** The submitted samples KS-DLX301 fulfilled the requirements of specified standards except the following clauses were not evaluated in this test report: Clause 11.6.7 Sterilization assessment according to ISO 17665-1 Clause 11.7 Biocompatibility Clause 12.2 and 15.1 Usability Clause 14 PEMS KS-DLX301 was subjected to full test and KS-D106 was only subjected to construction check.	**Testing location:** **198 Kezhu Road, Science City, Economic & Technology Development Area, Guangzhou, Guangdong, China**

Summary of compliance with National Differences

List of countries addressed:

None

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NBs or NCBs that own these marks.

Dental unit			
Model:	KS-DLX301	Safety Class:	Class I Type B
Input Voltage:	AC 220-230V, 50/60Hz	Power:	400VA
Registration No:		Production Date:	2017.08.01
Serial Number:	17080101	Service Life:	5 Year
Manufacturer:	KASO MEDICAL TECHNOLOGY CO., LTD	Operation Mode:	Intermittent operation
Address:	Floor4, Bulding2, DonghuaIndustry Area, Shakeng, Luocun, Shishan, Nanhai District, Foshan City, Guangdong Province, China.		
Telephone:	+86-757-22183501		

Label for KS-DLX301

Dental unit			
Model:	KS-D106	Safety Class:	Class I Type B
Input Voltage:	AC 220-230V, 50/60Hz	Power:	400VA
Registration No:		Production Date:	2017.08.01
Serial Number:	17080102	Service Life:	5 Year
Manufacturer:	KASO MEDICAL TECHNOLOGY CO., LTD	Operation Mode:	Intermittent operation
Address:	Floor4, Bulding2, DonghuaIndustry Area, Shakeng, Luocun, Shishan, Nanhai District, Foshan City, Guangdong Province, China.		
Telephone:	+86-757-22183501		

Label for KS-D106

Height of WEEE logo shall not be less than 7 mm
Height of CE logo shall not be less than 5 mm

Instrument plate tolerance≤1.5KG

Symbol for “Follow Instruction For Use” was additional marked on instrument tray

F 5AL250V

The label is corrected

Fuse specification marked adjacent to accessible fuse-holder and on the inner fuse holder

Input water pressure
0.2-0.4MPa
Flow rate≥10L/min

Input air pressure
0.5-0.6 MPa
Flow rate≥50L/min

Incoming water and air supply was marked near the connection

IPX4

IPX4 marked on foot switch

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	Integral Dental Unit (Dental unit)
Classification of installation and use..... :	Fixed equipment
Device type (component/sub-assembly/ equipment/ system) :	Equipment
Intended use (Including type of patient, application location) :	See “General product information”
Mode of operation..... :	Non-continuous operation for dental chair max. 2 min. ON / 18 min. OFF
Supply connection	Non-detachable power supply cord
Accessories and detachable parts included..... :	None
Other options include..... :	None
Testing	
Date of receipt of test item(s) ..... :	2018-04-09
Dates tests performed..... :	2018-04-09 to 2019-01-08
Possible test case verdicts:	
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	Pass (P)
- test object was not evaluated for the requirement ..... :	N/E (collateral standards only)
- test object does not meet the requirement..... :	Fail (F)
Abbreviations used in the report:	
- normal condition ..... : N.C.	- single fault condition ..... : S.F.C.
- means of Operator protection ..... : MOOP	- means of Patient protection .... : MOPP

General remarks:

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
The tests 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 testing laboratory.

List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
This test report is for use in conjunction with test reports of IEC 80601-2-60 and EN 80601-2-60 with number GZME180300025002 & ISO 6875 and EN ISO 6875 with number GZME180300025003& & ISO 7494-1 and EN ISO 7494-1 with number GZME180300025004& ISO 7494-2 and EN ISO 7494-2 with number GZME180300025005.
Throughout this report a ☒ comma / ☐ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided.....:	☐ **Yes** ☒ **Not applicable**

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies).....:	Same as applicant

General product information:

Integral dental unit (Dental l unit) is used to supply power and serves as a base for dental handpieces and other accessories. It is Use for dental diagnosis, treatment, surgery.

Dental handpieces include strong and weak suction handpiece, three-way syringe.

The standard configuration of the dental unit consists of a power unit for electricity, air and water connection, a dental patient chair, dental instrument tray with control panel, X-film viewer, dental operating light(LEC-FSA), mounted pillar for operating light, cuspidor with pipe for bowl flush and cup filter, water heater and foot switch.

No dental electrical motor or electrical powered dental handpiece was submitted for evaluation.
The dental unit is driven by two low-voltage silent DC motor for functional operation for dentist and was configured with intelligent computerized control system. Dental patient chair is used to support and position the patient during treatment and provide with a range of movements. A foot operates control, a foot switch and two control panels, control full functions.
Non-continuous operation mode with duty cycle of 20%. ON: 2 min. OFF: 18 min.

Protection against electric shock: Class I

IPX4 for foot switch. IPX0 for main unit.

According to the declaration of applicant, both models are identical except the colour and appearance are different.

So, KS-DLX301 was subjected to full test and KS-D106 was only subjected to construction check.

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

INSULATION DIAGRAM

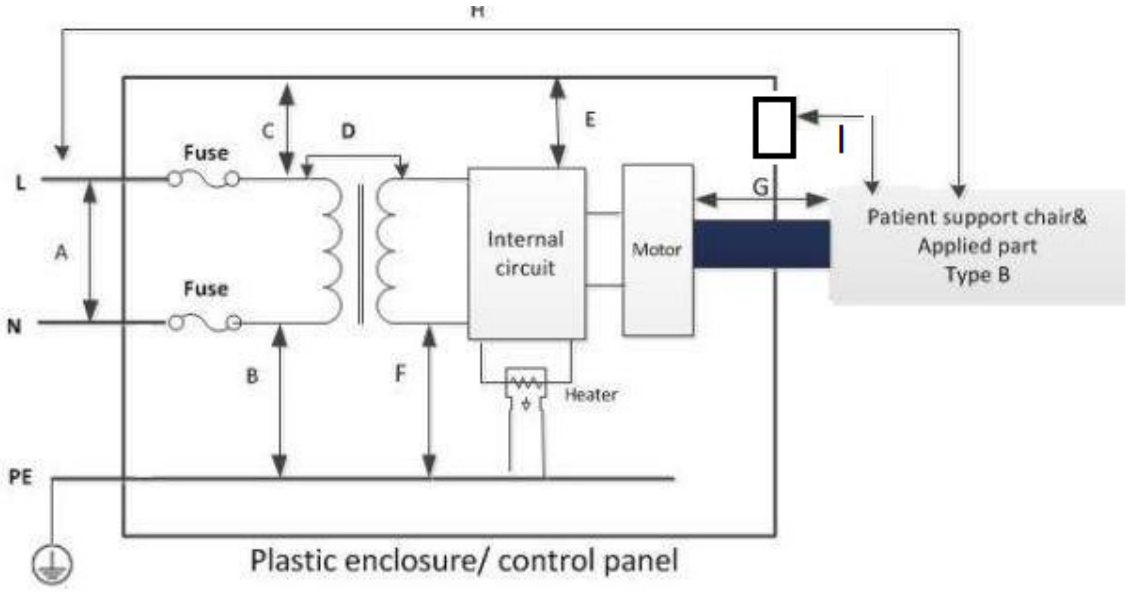


TABLE: INSULATION DIAGRAM		P
Pollution degree ..... :	2	—
Overvoltage category ..... :	II	—
Altitude ..... :	a≤2000 m	—
Additional details on parts considered as applied parts..... :	☒ None ☐ Areas _____	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage[1)]		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V_{rms}	V_{pk}					
A	1 MOOP	IIIb	230V_{rms}	325 V_{pk}	2,5	2,0	>3,25[2)]	>2,6[2)]	L to N before fuse
B	1 MOPP	IIIb	230V_{rms}	325 V_{pk}	4,0	2,5	>5,2[2)]	>3,25[2)]	Between mains part and protectively earthed metal part
C	2 MOOP	IIIb	230V_{rms}	325 V_{pk}	5,0	4,0	>6,5[2)]	>5,2[2)]	Between mains part and plastic enclosure
D	2 MOPP	IIIb	255V_{rms}	360 V_{pk}	8,2[1)]	7,0	>10,66[2)]	>9,1[2)]	Between primary to secondary of transformer

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

E	**2 MOPP**	**IIIb**	**24 V_{rms}**	**34 V_{pk}**	**4,0**	**2,0**	**>5,2[2)]**	**>2,6[2)]**	**Between secondary circuit and enclosure**
F	**1 MOPP**	**IIIb**	**24 V_{rms}**	**34 V_{pk}**	**2,0**	**1,0**	**>2,6[2)]**	**>1,3[2)]**	**Between secondary circuit and protective earth part**
G	**2 MOPP**	**IIIb**	**24 V_{rms}**	**34 V_{pk}**	**4,0**	**2,0**	**>5,2[2)]**	**>2,6[2)]**	**Between secondary circuit and applied part**
H	**2 MOPP**	**IIIb**	**230V_{rms}**	**325 V_{pk}**	**8,0**	**5,0**	**>10,4[2)]**	**>6,5[2)]**	**Between mains part to applied part; Depend on D and G**
I	**1 MOPP**	**IIIb**	**250V_{rms}**	**354 V_{pk}**	**4,0**	**2,5**	**>5,2[2)]**	**>3,25[2)]**	**Between applied part and accessible part that is not protectively earthed**

Supplementary Information:

[1)] linear interpolation is used for determining the required value of creepage and air clearance.

[2)] Refer to CTL decision DSH 0791: in case that the measured minimum or maximum value is exceeding or is below the limit value for more than 30%, the value given in the TRF should be >[minimum required value + 30%] or should be < [maximum required value - 30%].

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer
  windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4	**GENERAL REQUIREMENTS**		**P**
4.1	**Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse**		**P**
4.2	**RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS**		**P**
4.2.2	**General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007) .....:**	See Appended RM Results Table 4.2.2.	**P**
4.2.3	**Evaluating RISK**		**P**
4.2.3.1	**a) Compliance with the standard reduces residual risk to an acceptable level**		**P**
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN.....:	Risk Management Procedure, Document No. KASO-CE-01-09.2	**P**
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		**P**
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		**P**
4.2.3.2	**MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.**	Refer to risk management report KASO-CE-01-09.2	**P**
4.3	**Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.**	No essential performance specified by manufacturer	**N/A**
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		**N/A**
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		**N/A**
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE.....:		**N/A**
	- RISK CONTROL measures implemented		**N/A**
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		**N/A**
4.4	**EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....:**	Five years	**P**
4.5	**Alternative RISK CONTROL methods utilized:**	No alternative risk control methods	**N/A**
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Alternative means based scientific data or clinical opinion or comparative studies .....:		**N/A**
4.6	**RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10.....:**	No such parts	**N/A**
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient ....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
	Assessment identified the APPLIED PART TYPE requirements.....:		**N/A**
4.7	**ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2 .....:**	Remained single fault safe	**P**
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....: **(ISO 14971 Cl. 4.2-4.4)**	RMF reference from specific RISK: RM report KASO-CE-01-09.2, Cl. 4.2 (ISO 14971 Cl. 4.2-4.4)	**P**
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically .....:	See appended Table 13.2 for simulated physical test	**P**
4.8	**All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified....:**	Used according to their applicable ratings	**P**
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		**N/A**
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION...:	See appended Table 8.10	**P**
	Components determined to be acceptable where used as a MEANS OF PROTECTION.....:	See appended Table 8.10	**P**
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following		**P**
	a) Applicable safety requirements of a relevant IEC or ISO standard		**P**
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		**P**

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4.9	**A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately.....:**	No component with high-integrity characteristics	**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:		**N/A**
4.10	**Power supply**		**P**
4.10.1	**ME EQUIPMENT is suitable for connection to indicated power source** (select applicable).....**:**	Connection to supply mains	**P**
4.10.2	**Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:**		**P**
	- 250 V for HAND-HELD ME EQUIPMENT (V) ..... :		**N/A**
	– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V) ..... :	220-230 V AC	**P**
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		**N/A**
4.11	**Power input**		**P**
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10% ..... :	See appended Table 4.11	**P**

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**P**
5.1	**Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods.....:**		**N/A**
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. **(ISO 14971 Cl. 4.2-4.4)**		**N/A**
5.3	**Tests conducted within the environmental conditions specified in technical description**		**P**
	Temperature (ºC), Relative Humidity (%) .....:	Temperature: 5℃ - 40℃; Relative Humidity: ≤80 %	**—**
	Atmospheric Pressure (kPa).....:	86 kPa - 106 kPa	**—**
5.5	**a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V) .....:**	90% and 110% of rated voltage considered	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :	50 Hz	**P**
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current ..... :		**N/A**
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered..... :		**N/A**
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions..... :		**N/A**
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use		**N/A**
5.7	**ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3 ..... :**	Partly	**P**
	ME EQUIPMENT heated to a temperature between T and T + 4℃ for at least 4 h and placed in a humidity chamber and ambient within 2 ℃ of T in range of +20℃ to +32℃ for indicated time	Temp.: 25℃ Relative Humidity: 93% Duration : 168 h for foot switch (IPX4) 48 h for other parts	**—**
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		**P**
5.9.1	**APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS..... :**	Dental patient chair and dental handpieces are considered as one applied part. Type B.	**P**
5.9.2	**ACCESSIBLE PARTS**		**P**
5.9.2.1	**Accessibility determined using standard test finger of Fig. 6**	See appended Table 5.9.2	**P**
5.9.2.2	**Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s**		**P**
5.9.2.3	**Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS.....:**		**N/A**
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL .....:		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	**CLASS I ME EQUIPMENT, externally powered**		**P**
	CLASS II ME EQUIPMENT, externally powered		**N/A**
	INTERNALLY POWERED ME EQUIPMENT		**N/A**
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		**N/A**
	TYPE B APPLIED PART		**P**
	TYPE BF APPLIED PART		**N/A**
	TYPE CF APPLIED PART		**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS		**N/A**
6.3	**ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529..... :**	IPX4 for foot switch IPX0 for main unit	**P**
6.4	**ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use..... :**	By moist heat. Sterilization of handle and nozzle of three-way syringe	**P**
6.5	**ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2**	No intended for use in an OXYGEN RICH ENVIRONMENT	**N/A**
6.6	**CONTINUOUS or Non-CONTINUOUS OPERATION ..... :**	Non-CONTINUOUS OPERATION for dental chair. Duty cycle: On :2 min. / OFF :18 min.	**P**

7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		**P**
7.1.2	**Legibility of Markings Test for Markings specified in Clause 7.2-7.6..... :**	See appended Table 7.1.2	**P**
7.1.3	**Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE**	See appended Table 7.1.3	**P**
7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
7.2.1	**At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ..... :**	See copy of marking plate	**P**
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS ..... :	See Operation Manual	**P**
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Single use item marked .....:	No single use part	**N/A**
7.2.2	**ME EQUIPMENT marked with:**		**P**
	– the name or trademark and contact information of the MANUFACTURER	See copy of marking plate	**P**
	– a MODEL OR TYPE REFERENCE	KS-DLX301, KS-D106	**P**
	– a serial number or lot or batch identifier; and	Series number	**P**
	– the date of manufacture or use by date	Manufacture date	**P**
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or		**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.4)**		**N/A**
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and		**N/A**
	– a MODEL OR TYPE REFERENCE		**N/A**
	Software forming part of a PEMS identified with a unique identifier.....:	Version 01	**P**
7.2.3	**Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS**		**N/A**
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	Symbol  marked	**P**
7.2.4	**ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and.....:**		**N/A**
	- with a MODEL or TYPE REFERENCE		**N/A**
	– a serial number or lot or batch identifier		**N/A**
	– the date of manufacture or use by date		**N/A**
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		**N/A**
7.2.5	**ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following**	Not received power from other equipment	**N/A**
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or		**N/A**
	– Table D.2, safety sign No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.		**N/A**
7.2.6	**Connection to the Supply Mains**		**P**
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point		**P**
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	Not permanently installed ME equipment	**N/A**
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V) .....:	AC 220-230 V	**P**
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..:		**N/A**
	– Nature of supply and type of current.....:	AC	**P**
	Symbols 1-5, Table D.1 (used for same parameters.....:	Single phase	**N/A**
	– RATED supply frequency or RATED frequency range in hertz.....:	50 Hz	**P**
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT.....:		**N/A**
7.2.7	**RATED input in amps or volt-amps, (A, VA) ..... :**	400 VA	**P**
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) ..... :		**N/A**
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W) .....:		**N/A**
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) .....:		**N/A**
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA) .....:		**N/A**
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W) .....:		**N/A**
7.2.8	**Output connectors**		**N/A**
7.2.8.2	**Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment**	No electrical output connector	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Rated Voltage (V), Rated Current (A) .....:		—
	Rated Power (W), Output Frequency (Hz).....:		—
7.2.9	**ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0. ..:**	IPX4 for foot switch	**P**
7.2.10	**Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols .....:**	See copy of marking plate	**P**
	TYPE B APPLIED PARTS with symbol 19 of Table D.1	Symbol  marked	**P**
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1.....:		**N/A**
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1.....:		**N/A**
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 .....:		**N/A**
	Proper symbol marked adjacent to or on connector for APPLIED PART .....:	Symbol marked on label outside the equipment, considered the requirement of IEC 80601-2-60	**P**
	Safety sign 2 of Table D.2 placed near relevant outlet.....:		**N/A**
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use.....:		**N/A**
7.2.11	**ME EQUIPMENT suitable for CONTINUOUS OPERATION**		**N/A**
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time.....:	Non-continuous operation for dental chair See copy of marking plate	**P**
7.2.12	**Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder**		**P**
	Fuse type.....:	See appended Table 8.10	—
	Voltage (V) and Current (A) rating.....:	250 V; 5 A	—
	Operating speed (s) and Breaking capacity ....:	F; L	—
7.2.13	**Physiological effects – safety sign and warning statements .....:**	No physiological effects	**N/A**
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.2.14	**HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1**	No high voltage terminal device	**N/A**
7.2.15	**Requirements for cooling provisions marked ..:**		**N/A**
7.2.17	**Packaging marked with special handling instructions for transport and/or storage.....:**	Marked on outside of packaging	**P**
	Permissible environmental conditions marked on outside of packaging..... :	-20℃ to 55℃; ≤80% R.H.; 86 kPa-106kPa	**P**
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK.....:		**N/A**
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK. .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)**		**N/A**
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization		**N/A**
7.2.18	**RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and ..... :**	Input air pressure: 0,5-0,6 MPa, flow rated:≥50 L/min Input water pressure: 0,2 -0,4 MPa, flow rate≥10 L/min	**P**
	- the RATED flow rate also marked	Marked adjacent to the connector	**P**
7.2.19	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL.....:**	No functional earth terminal	**N/A**
7.2.20	**Removable protective means marked to indicate the necessity for replacement when the function is no longer needed.....:**		**N/A**
7.2.21	**MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms ....:**	Not mobile equipment	**N/A**
7.3	**Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**		**P**
7.3.1	**Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W).....:**	The maximum power loading was marking on the enclosure of water heater	**P**
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		**N/A**
7.3.2	**Symbol 24 of Table D.1, or safety sign No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts.....:**	No high voltage part	**N/A**
7.3.3	**Type of battery and mode of insertion marked:**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL .....:		**N/A**
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK ..... :		**N/A**
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**		**N/A**
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD.....:		**N/A**
7.3.4	**Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified .....:**	Specification of fuses on PCB marked on the PCB	**P**
	Voltage (V) and Current (A) rating.....:	See appended Table 8.10	**—**
	Operating speed(s), size & breaking capacity.:	See appended Table 8.10	**—**
7.3.5	**PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1**		**P**
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		**P**
7.3.6	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS**	No functional earth terminals	**N/A**
7.3.7	**Terminals for supply conductors marked adjacent to terminals.....:**	Marked on terminal block	**P**
	Terminals for supply connections are not marked, the RISK MANAGEMENT FILE includes an assessment of the RISKS resulting from misconnections .....: **(ISO 14971 Cl. 4.3)**		**N/A**
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings		**N/A**
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3		**N/A**
	Marking for connection to a 3-phase supply, complies with IEC 60445		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		**N/A**
7.3.8	**"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections**		**N/A**
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		**N/A**
7.4	**Marking of controls and instruments**		**P**
7.4.1	**The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 or**	Symbol | and ◯ marked	**P**
	– indicated by an adjacent indicator light, or	Illuminated switch	**P**
	– indicated by other unambiguous means		**N/A**
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and		**N/A**
	– status indicated by adjacent indicator light		**N/A**
	– status indicated by other unambiguous means		**N/A**
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or		**N/A**
	– status indicated by adjacent indicator light		**N/A**
	– status indicated by other unambiguous means		**N/A**
7.4.2	**Different positions of control devices/switches indicated by figures, letters, or other visual means**		**P**
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2, 6.3)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, annex 2 _7.4.2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)	**P**
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE.....:	No unacceptable risk	**N/A**
	– or an indication of direction in which magnitude of the function changes		**N/A**
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.4.3	**Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units**		**N/A**
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units		**N/A**
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3 .....:		**N/A**
7.5	**Safety signs**		**P**
	Safety sign with established meaning used	Safety Sign Used: 	**P**
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**		**N/A**
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		**N/A**
	Specified colours in ISO 3864-1 used for safety signs.....:	The colour of the safety signs comply with ISO 3864-1	**P**
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		**N/A**
	Safety signs including any supplementary text or symbols described in instructions for use		**P**
	- and in a language acceptable to the intended OPERATOR		**N/A**
7.6	**Symbols**		**P**
7.6.1	**Meanings of symbols used for marking described in instructions for use.....:**	Refer to Operation Manual	**P**
7.6.3	**Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable**		**P**
7.7	**Colours of the insulation of conductors**		**P**
7.7.1	**PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation**		**P**
7.7.2	**Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations**		**P**
7.7.3	**Green and yellow insulation identify only following conductors:**		**P**
	– PROTECTIVE EARTH CONDUCTORS		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– conductors specified in 7.7.2		**P**
	– POTENTIAL EQUALIZATION CONDUCTORS		**N/A**
	– FUNCTIONAL EARTH CONDUCTORS		**N/A**
7.7.4	**Neutral conductors of POWER SUPPLY CORDS are "light blue"**	Approved power supply cord, see appended Table 8.10	**P**
7.7.5	**Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1**	Approved power supply cord, see appended Table 8.10	**P**
7.8	**Indicator lights and controls**		**P**
7.8.1	**Red indicator lights used only for Warning**		**N/A**
	Yellow indicator lights used only for Caution		**N/A**
	Green indicator lights used only for Ready for use		**P**
	Other colours: Meaning other than red, yellow, or green (colour, meaning).....:		**N/A**
7.8.2	**Red used only for emergency control**	Emergency stop switch	**P**
7.9	**ACCOMPANYING DOCUMENTS**		**P**
7.9.1	**ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description**		**P**
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		**P**
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to ..... :	Manufacturer's name, address and website	**P**
	– MODEL or TYPE REFERENCE ..... :	Refer to Operation Manual	**P**
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT		**N/A**
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use		**P**
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		**P**
7.9.2	**Instructions for use include the required information**		**P**
7.9.2.1	**– use of ME EQUIPMENT as intended by the MANUFACTURER:**		**P**
	– frequently used functions,		**P**
	– known contraindication(s) to use of ME EQUIPMENT		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient		**P**
	– name or trademark and address of the MANUFACTURER		**P**
	– MODEL OR TYPE REFERENCE		**P**
	Operation Manual included the following when the PATIENT is an intended OPERATOR:	The patient is not an intended operator	**N/A**
	– the PATIENT is an intended OPERATOR		**N/A**
	– warning against servicing and maintenance while the ME EQUIPMENT is in use		**N/A**
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		**N/A**
	–maintenance the PATIENT can perform		**N/A**
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT		**P**
	Instructions for use are in a language acceptable to the intended operator	In a language acceptable to the intended operator	**P**
7.9.2.2	**Instructions for use include all warning and safety notices**		**P**
	Warning statement for CLASS I ME EQUIPMENT included		**P**
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments		**P**
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference		**P**
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided		**N/A**
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS		**N/A**
7.9.2.3	**Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions**		**N/A**
7.9.2.4	**Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source**	No any additional power source	**N/A**
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.3)**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time..... :		**N/A**
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided ..... :		**N/A**
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK ..... :		**N/A**
7.9.2.5	**Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE**		**P**
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to		**P**
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected		**P**
	APPLIED PARTS specified		**P**
7.9.2.6	**Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation**		**P**
7.9.2.7	**Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device**		**P**
7.9.2.8	**Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation**		**P**
7.9.2.9	**Information provided to operate ME EQUIPMENT**		**P**
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use		**P**
7.9.2.10	**A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message**	Refer to Operation Manual	**P**
7.9.2.11	**Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT**		**P**
7.9.2.12	**Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified**		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use		**N/A**
7.9.2.13	**Instructions provided on preventive inspection, calibration, maintenance and its frequency**		**P**
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT		**P**
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application		**P**
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL		**N/A**
7.9.2.14	**A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided**		**N/A**
	Other equipment providing power to ME SYSTEM sufficiently described		**N/A**
7.9.2.15	**Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the Operation Manual.....:**	Refer to Operation Manual	**P**
7.9.2.16	**Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)**		**P**
7.9.2.17	**Operation Manual for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation**		**N/A**
7.9.2.18	**The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization**		**N/A**
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		**N/A**
7.9.2.19	**The instructions for use contain a unique version identifier.....:**	DENTAL UNIT MANUAL INSTRUCTION FOR INSTALLATION, Version: 01	**P**
7.9.3	**Technical description**		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.9.3.1	**All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use**		**P**
	Technical description separable from instructions for use contains required information, as follows		**N/A**
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT	Provided as one	**N/A**
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		**N/A**
	a unique version identifier.....:		**N/A**
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		**N/A**
7.9.3.2	**The technical description contains the following required information**		**P**
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT .....:	Not permanently installed ME equipment	**N/A**
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and		**P**
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and		**P**
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component		**P**
7.9.3.3	**Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair**		**P**
7.9.3.4	**Means used to comply with requirements of 8.11.1 clearly identified in technical description**		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		**P**
8.1	**Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS**		**P**
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION ..... : **(ISO 14971 Cl. 4.3)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5 (ISO 14971 Cl. 4.3)	**P**
8.2	**Requirements related to power sources**		**N/A**
8.2.1	**Connection to a separate power source**		**N/A**
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM		**N/A**
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		**N/A**
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		**N/A**
8.2.2	**Connection to an external d.c. power source**		**N/A**
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source		**N/A**
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		**N/A**
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset		**N/A**
8.3	**Classification of APPLIED PARTS**		**P**
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF		**N/A**
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		**N/A**
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	Type B	**P**
8.4	**Limitation of voltage, current or energy**		**P**
8.4.2	**ACCESSIBLE PARTS and APPLIED PARTS**		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT :	See appended Table 8.7	**P**
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT..... :	See appended Table 8.7	**P**
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed		**P**
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.)..... :		**P**
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J)..... :		**P**
	d) Voltage and energy limits specified in c) above also applied to the following:		**N/A**
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and		**N/A**
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL		**N/A**
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		**N/A**
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		**N/A**
	Test repeated with a TOOL specified in instructions for use		**N/A**
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		**N/A**
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION		**N/A**
	A TOOL is required when it is possible to prevent the devices from operating		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.4.3	**Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V) ..... :**	See appended Table 8.4.3	**P**
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC.. :	Not exceeded 60V	**N/A**
8.4.4	**Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC .. :**		**N/A**
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		**N/A**
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description .....:		**N/A**
8.5	**Separation of parts**		**P**
8.5.1	**MEANS OF PROTECTION (MOP)**		**P**
8.5.1.1	**Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4**		**P**
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		**P**
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		**P**
8.5.1.2	**MEANS OF PATIENT PROTECTION (MOPP)**		**P**
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test..... :	See appended Table 8.8.3	**P**
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12	See Insulation Diagram and Insulation Table	**P**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		**P**
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ..... :	No Y1 or Y2 capacitor used	**N/A**
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c..... :		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		**N/A**
	Voltage $_{Total\ Working}$ (V) and C $_{Nominal}$ (µF)..... :		**—**
8.5.1.3	**MEANS OF OPERATOR PROTECTION (MOOP)**		**P**
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		**P**
	– dielectric strength test ..... :	See appended Table 8.8.3	**P**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		**N/A**
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		**P**
	– limits of Tables 13 to 16 (inclusive); or		**P**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		**N/A**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		**N/A**
	– or with requirements and tests of IEC 60950-1 for protective earthing ..... :		**N/A**
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION..... :		**N/A**
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION..... :		**N/A**
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		**N/A**
	Voltage $_{Total\ Working}$ (V) and C $_{Nominal}$ (µF)..... :		**—**
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		**P**
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION..... :		**N/A**
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION .... :	See Insulation Diagram	**P**
8.5.2	**Separation of PATIENT CONNECTIONS**		**P**
8.5.2.1	**PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE ..... :**	Type B	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		**N/A**
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		**N/A**
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :		**N/A**
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		**N/A**
	LEAKAGE CURRENT tests conducted per 8.7.4 .... :		**N/A**
	Dielectric strength test conducted per 8.8.3.... :		**N/A**
	CREEPAGE and CLEARANCES measured ..... :		**N/A**
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		**N/A**
8.5.2.2	**PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED .... :**		**N/A**
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and	Dental handpiece considered	**P**
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		**P**
	LEAKAGE CURRENT tests conducted per 8.7.4 .... :		**N/A**
	Dielectric strength test conducted per 8.8.3.... :		**N/A**
	Relevant CREEPAGE and CLEARANCES measured		**N/A**
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits.....: **(ISO 14971 Cl. 4.2-4.4, 5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5)	**P**
8.5.2.3	**A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE**		**N/A**
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT..... :	No patient lead or patient cable	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		**N/A**
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		**N/A**
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1		**N/A**
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,		**N/A**
	Test finger test (10 N) ..... :		**N/A**
	Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces ..... : **(ISO 14971 Cl. 4.2-4.4, 5)**		**N/A**
8.5.4	**WORKING VOLTAGE**		**P**
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V) ..... :	See Insulation Table	**P**
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V) ..... :		**N/A**
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) ..... :	See Insulation Diagram and Insulation Table	**P**
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth		**P**
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V) ..... :		**N/A**
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) ..... :		**N/A**
8.5.5	**DEFIBRILLATION-PROOF APPLIED PARTS**	No defibrillation-proof applied part	**N/A**
8.5.5.1	**Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety**		**N/A**
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		**N/A**
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :		**N/A**
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS..... :		**N/A**
8.5.5.2	**Means provided to limit energy delivered to a 100 Ω load ..... :**		**N/A**
8.6	**Protective and functional earthing and potential equalization of ME EQUIPMENT**		**P**
8.6.1	**Requirements of 8.6.2 to 8.6.8 applied**		**P**
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		**P**
8.6.2	**PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR ..... :**	By a protective earth conductor in a power supply cord and a suitable plug	**P**
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		**P**
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside .... :	Screw securely	**P**
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		**N/A**
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.6.3	**PROTECTIVE EARTH CONNECTION not used for a moving part,**		**P**
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
8.6.4	**a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop ..... :**	See appended Table 8.6.4	**P**
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits ..... :		**N/A**
8.6.5	**Surface coatings**		**P**
	Poorly conducting surface coatings on conductive elements removed at the point of contact		**P**
	Coating not removed when requirements for impedance and current-carrying capacity met		**N/A**
8.6.6	**Plugs and sockets**		**P**
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		**P**
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		**N/A**
8.6.7	**Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR**		**N/A**
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	No potential equalization terminal	**N/A**
	–accidental disconnection avoided in NORMAL USE		**N/A**
	– Terminal allows conductor to be detached without a TOOL		**N/A**
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		**N/A**
	– Terminal marked with symbol 8 of Table D.1		**N/A**
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		**N/A**
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.6.8	**FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION**	No functional earth terminal	**N/A**
8.6.9	**Class II ME EQUIPMENT**		**N/A**
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow		**N/A**
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		**N/A**
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		**N/A**
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		**P**
8.7.1	**a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3 ..... :**	See appended Tables 8.7	**P**
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7..... :	See appended Tables 8.7	**P**
8.7.2	**Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except**		**P**
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		**N/A**
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		**P**
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		**P**
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		**P**
8.7.3	**Allowable Values**		**P**
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b. :	Measured based on Fig 12 a)	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz..... :	See appended Table 8.7	**P**
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC}) ..... :	See appended Table 8.7	**P**
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC})..... :	See appended Table 8.7	**P**
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 ..... :		**N/A**
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device..... :	See appended Table 8.7	**P**
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION ..... :		**N/A**
8.7.4	**LEAKAGE and PATIENT AUXILIARY CURRENTS measurements ..... :**	See appended Table 8.7	**P**
8.8	**Insulation**		**P**
8.8.1	**Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing**		**P**
	Insulation exempted from test (complies with clause 4.8)		**P**
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		**N/A**
8.8.2	**Distance through solid insulation or use of thin sheet material**		**P**
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		**P**
	a) 0.4 mm, min, distance through insulation, or	The thickness of insulation layer between primary and secondary winding can be more than 0,4 mm	**P**
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:	Approved transformer used See appended Table 8.8.3	**N/A**
	– at least two layers of material, each passed the appropriate dielectric strength test ..... :		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test .....:		**N/A**
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		**N/A**
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		**N/A**
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		**N/A**
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		**N/A**
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		**N/A**
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		**N/A**
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		**N/A**
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		**N/A**
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		**N/A**
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		**N/A**
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension..... :		**N/A**
	Finished component complied with routine dielectric strength tests of 8.8.3.....:		**N/A**
	Tests of Annex L not repeated since material data sheets confirm compliance.....:		**N/A**
8.8.3	**Dielectric Strength**		**P**
	Solid insulating materials with a safety function withstood dielectric strength test voltages ....:	See appended Table 8.8.3	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.8.4	**Insulation other than wire insulation**		**P**
8.8.4.1	**Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT**		**P**
	ME EQUIPMENT and design documentation examined..... :	Checked relevant documents	**P**
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :		**N/A**
	Tests conducted in absence of satisfactory evidence for resistance to heat..... :	See ball pressure test	**P**
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus... :	See appended Table 8.8.4.1	**P**
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C)..... :	See appended Table 8.8.4.1	**P**
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		**P**
8.8.4.2	**Resistance to environmental stress**		**P**
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		**P**
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		**N/A**
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		**N/A**
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 ℃ ± 2 ℃ for 96h, and afterwards, left at room temperature for at least 16h		**N/A**
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		**P**
8.9.1.1	**CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)..... :**	See Insulation Diagram and Insulation Table	**P**
8.9.1.15	**CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1**		**N/A**
8.9.2	**a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied..... :**	See Insulation Diagram and Insulation Table	**P**
8.9.3	**Spaces filled by insulating compound**		**N/A**
8.9.3.1	**Only solid insulation requirements applied where distances between conductive parts filled with insulating compound**	No such insulating compound	**N/A**
	Thermal cycling, humidity preconditioning, and dielectric strength tests		**N/A**
8.9.3.2	**For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage)..... :**		**N/A**
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		**N/A**
8.9.3.3	**Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint**		**N/A**
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		**N/A**
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage ..... :		**N/A**
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.9.4	**Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree .....**	Pollution degree:2	**P**
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES	Refer to Insulation Diagram supplemental information for location and force used	**P**
8.10	**Components and wiring**		**P**
8.10.1	**Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely ..... :**	Mounted securely	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components ..... : **(ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
8.10.2	**Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment ..... :**	Adequately secured	**P**
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS		**N/A**
8.10.3	**Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken .....:**		**N/A**
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		**P**
8.10.4.1	**Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION**	No electrically powered dental handpiece submitted for evaluation Foot operate considered	**P**
8.10.4.2	**Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3**	Not result in hazardous situation in 13.1	**N/A**
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3		**N/A**
8.10.5	**Mechanical protection of wiring**		**P**
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges..... :	The cables were free of stress and friction with such parts	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS		**P**
8.10.6	**Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead**		**P**
8.10.7	**a) Insulating sleeve adequately secured ..... :**		**P**
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		**N/A**
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C..... :		**N/A**
8.11	**MAINS PARTS, components and layout**		**P**
8.11.1	**a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles..... :**	Non-detachable power supply cord and mains plug used	**P**
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	.	**N/A**
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position		**N/A**
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		**P**
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ..... :	Mains plug is incorporated in ME equipment	**P**
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV ..... :		**N/A**
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		**P**
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		**N/A**
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH ..... :		**N/A**
	g) A fuse or a semiconductor device not used as an isolating means		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		**N/A**
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering		**N/A**
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage		**N/A**
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		**N/A**
	Standard test finger applied		**N/A**
8.11.2	**MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2**	No multiple socket-outlets	**N/A**
8.11.3	**POWER SUPPLY CORDS**		**P**
8.11.3.1	**MAINS PLUG not fitted with more than one POWER SUPPLY CORD**		**P**
8.11.3.2	**POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53)... :**	See appended Table 8.10	**P**
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ..... :		**N/A**
8.11.3.3	**NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17..... :**	See appended Table 8.10	**P**
8.11.3.4	**APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6 ..... :**		**N/A**
8.11.3.5	**Cord anchorage**		**P**
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		**P**
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N/A
	– metal provided with an insulating lining affixed to cord anchorage		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		P
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components		P
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals		P
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		P
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 ..... :		P
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests		P
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		P
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		P
8.11.3.6	POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment	Not applied for fixed equipment	N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g) ..... :		N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D..... :		**N/A**
8.11.4	**MAINS TERMINAL DEVICES**		**N/A**
8.11.4.1	**PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection**	Non-detachable power supply cord	**P**
	Terminals alone are not used to keep conductors in position		**N/A**
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors		**N/A**
	Screws and nuts clamping external conductors do not serve to secure any other component		**N/A**
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		**N/A**
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection		**N/A**
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		**N/A**
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		**N/A**
8.11.4.3	**Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times**		**N/A**
8.11.4.4	**Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened**		**N/A**
8.11.4.5	**Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors**		**N/A**
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test		**N/A**
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		**P**
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection . :	Two fuses equipped with class I equipment	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT ..... :		**N/A**
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT		**N/A**
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART		**N/A**
	Protective devices have adequate breaking capacity to interrupt the max. fault current ..... :	See appended Table 8.10	**P**
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		**P**
	Justification for omission of fuses or OVER-CURRENT RELEASES documented ..... :		**N/A**
8.11.6	**Internal wiring of the MAINS PART**		**P**
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable ..... :	See appended Table 8.10	**P**
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient ..... :	Complied	**P**

9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		**P**
9.2	**HAZARDS associated with moving parts**		**P**
9.2.1	**When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level . :**	Product performance, handling precautions and emergency stop switch configured	**P**
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		**P**
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and		**P**
	RISK CONTROLS implemented ..... :	Labeling and handling precautions included in Operation Manual	**P**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**

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Clause	Requirement + Test	Result - Remark	Verdict
	All RISKS associated with moving parts have been reduced to an acceptable level		P
9.2.2	TRAPPING ZONE		P
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:		P
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		P
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		P
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20..... :		N/A
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 ..... :		N/A
9.2.2.4	GUARDS and other RISK CONTROL measures		N/A
9.2.2.4.1	A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK .... :		N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with any applicable tests		N/A
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and		N/A
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or		N/A
	ME EQUIPMENT is SINGLE FAULT SAFE		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.2.2.5	**Continuous activation**		**P**
	Continuous activation used as a RISK CONTROL, complies with the following		**P**
	a) movement was in OPERATOR'S field of view		**P**
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR		**P**
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or	Emergency stop device equipped	**P**
	- the continuous activation system is SINGLE FAULT SAFE		**N/A**
9.2.2.6	**Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement**		**P**
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		**P**
9.2.3	**Other MECHANICAL HAZARDS associated with moving parts**		**P**
9.2.3.1	**Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated**		**N/A**
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or		**N/A**
	- activation does not result in an unacceptable RISK		**N/A**
9.2.3.2	**Over travel past range limits of the ME EQUIPMENT prevented..... :**	Micro switch within actuator and limit-stop switch on travel range equipped	**P**
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse... :	See appended Table 9.2.3.2	**P**
9.2.4	**Emergency stopping devices**		**P**
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power..... :	Interrupt all powers	**P**
	a) Emergency stopping device reduced RISK to an acceptable level		**P**
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		**P**
	c) Emergency stopping device actuator was readily accessible to OPERATOR		**P**
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		**P**
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		**P**
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		**P**
	g) Means for stopping of movements operate as a result of one single action		**P**
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		**P**
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"	Symbol  used	**P**
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		**N/A**
	k) Emergency stopping device is suitable for its application		**N/A**
9.2.5	**Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping..... :**		**N/A**
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		**N/A**
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		**N/A**
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.3	**Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered..... :**	Avoid such risk	**P**
9.4	**Instability HAZARDS**		**N/A**
9.4.1	**ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE**	Fixed equipment	**N/A**
9.4.2	**Instability – overbalance**		**N/A**
9.4.2.1	**ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested ..... :**	Fixed equipment	**N/A**
9.4.2.2	**Instability excluding transport**		**N/A**
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE, ...:		**N/A**
	A warning provided when overbalance occurred during 10° inclined plane test		**N/A**
9.4.2.3	**Instability from horizontal and vertical forces**		**N/A**
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it		**N/A**
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK		**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)		**N/A**
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping		**N/A**
	ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning.....:		**N/A**
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b) ..... :		**N/A**
9.4.2.4	**Castors and wheels**		**N/A**
9.4.2.4.1	**Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE**	No castors and wheels	**N/A**
9.4.2.4.2	**Force required to move MOBILE ME EQUIPMENT did not exceed 200 N..... :**		**N/A**
9.4.2.4.3	**MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold ..... :**		**N/A**
9.4.3	**Instability from unwanted lateral movement (including sliding)**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.4.3.1	**a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control**	Fixed equipment	**N/A**
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements		**N/A**
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1		**N/A**
9.4.3.2	**Instability excluding transport**		**N/A**
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test .....:		**N/A**
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test		**N/A**
9.4.4	**Grips and other handling devices**		**N/A**
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method	No grips or handling devices	**N/A**
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		**N/A**
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		**N/A**
	c) Carrying handles and grips and their means of attachment withstood loading test.....:		**N/A**
9.5	**Expelled parts HAZARD**		**N/A**
9.5.1	**Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE..... :** **(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)**	No expelled parts	**N/A**
	All identified RISKS associated with expelled parts mitigated to an acceptable level		**N/A**
9.5.2	**Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965..... :**		**N/A**
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**		**P**
9.6.1	**Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and**	Not exceed the limit	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity..... :		**N/A**
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and (ISO 14971 Cl. 4.2-44, 5, 6.2-6.5)		**N/A**
	All identified RISKS mitigated to an acceptable level		**N/A**
9.6.2	**Acoustic energy**		**P**
9.6.2.1	**PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE**		**P**
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:	42,0 dBA	**—**
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:	/	**—**
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB).....:	/	**—**
9.6.2.2	**RISK MANAGEMENT FILE examined.....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No infrasound and ultrasound energy	**N/A**
9.6.3	**Hand-transmitted vibration**		**N/A**
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values		**N/A**
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) .....:		**N/A**
	– Accelerations for different times, inversely proportional to square root of time (m/s^2).....:		**N/A**
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		**P**
9.7.2	**Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE..... :** **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		**P**
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		**P**
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		**P**
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		**N/A**
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		**N/A**
9.7.3	**Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:**		**P**
	a) RATED maximum supply pressure from an external source	Air pressure: 0,5 - 0,6 MPa Water pressure: 0,2 -0,4 MPa	**P**
	b) Pressure setting of a pressure-relief device provided as part of assembly		**N/A**
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		**N/A**
9.7.4	**Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests ..... :**	0,2 Mpa	**P**
9.7.5	**A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was more than 50 kPa, and product of pressure and volume was more than 200 kPal ..... :**	Refer to EN ISO 6875 report with number GZME180300025003	**N/A**
9.7.6	**Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE . :**		**N/A**
9.7.7	**Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests..... :**		**N/A**
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Installed to be readily accessible for inspection, maintenance, and repair		**N/A**
	c) Could be adjusted or rendered inoperative without a TOOL		**N/A**
	d) With discharge opening located and directed as to not to release material towards any person		**N/A**
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		**N/A**
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		**N/A**
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		**N/A**
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		**N/A**
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device .....: **(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)**		**N/A**
9.8	**HAZARDS associated with support systems**		**P**
9.8.1	**ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK .. :**	Patient support dental chair considered	**P**
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		**P**
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		**N/A**
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		**P**
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		**N/A**
9.8.2	**Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest**	Support system of patient chair: 5 Instrument tray: 2,5 Dental operating light mounted pillar: 2,5	**P**
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing...:	Complied with the requirements	**P**
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system.....: **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	All identified RISKS are mitigated to an acceptable level		**P**
	When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK .....:	Test force of 135 kg x 5 at the least favourite position of patient chair Test force of 2,5 kg x 2,5 at the instrument tray Test force of 1,5 kg x 2,5 at the operating light mounted pillar, in period of 1 min, equipment at equilibrium	**P**
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results.....: **(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**		**N/A**
9.8.3	**Strength of PATIENT or OPERATOR support or suspension systems**		**P**
9.8.3.1	**ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints..... :**	Dental patient chair and instrument tray complied with the requirement	**P**
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		**P**
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER	Safe working load of patient chair: 135 kg instrument tray: 2,5 kg operating light mounted pillar: 1,5 kg	**P**
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		**N/A**
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		**N/A**
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS		**N/A**
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance ..... :	See instruction for use Label	**P**
9.8.3.2	**a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR..... :**		**N/A**
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests..... :		**N/A**
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK		**P**
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test..... :	See appended Table 9.8.3.2	**P**
9.8.3.3	**Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test**	See appended Table 9.8.3.3	**P**
9.8.4	**Systems with MECHANICAL PROTECTIVE DEVICES**		**N/A**
9.8.4.1	**a) A MECHANICAL PROTECTIVE DEVICE provided for the support system**	No such mechanical protective device	**N/A**
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		**N/A**
	– Designed based on TOTAL LOAD		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests ..... :		N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE		N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE :		N/A
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal		N/A
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE		N/A
	– Compliance confirmed by examination and following test ..... :		N/A
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		P
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES..... :	See test of 9.8.2	P

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system .....: **(ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		**N/A**
10.1	**X-Radiation**		**N/A**
10.1.1	**The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT .....:**	No X-Radiation	**N/A**
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE		**N/A**
10.1.2	**RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or.....:**		**N/A**
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
10.2	**RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE.....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No particle radiation	**N/A**
10.3	**The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2**		**N/A**
	Microwave radiation is propagated intentionally		**N/A**
10.4	**Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.**	Replaced by IEC 80601-2-60	**N/A**
10.5	**RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No electromagnetic radiation	**N/A**
10.6	**RISK associated with infrared radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No infrared radiation	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
10.7	**RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No ultraviolet radiation	**N/A**
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		**P**
11.1	**Excessive temperatures in ME EQUIPMENT**		**P**
11.1.1	**Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and ..... :**	See appended Table 11.1.1	**P**
	Surfaces of test corner did not exceed 90 °C		**P**
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		**P**
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.3)	**P**
11.1.2	**Temperature of APPLIED PARTS**		**P**
11.1.2.1	**APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply..... :**	Applied part not intended to supply heat	**N/A**
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		**N/A**
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		**N/A**
11.1.2.2	**APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION. :**		**P**
	APPLIED PARTS surface temperature exceeds 41 °C disclosed in the instruction manual:		**N/A**
	Maximum Temperature..... :		**—**
	Conditions for safe contact, e.g. duration or condition of the PATIENT ..... :	Refer to remarks of table 11,1,1	**—**
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.3)	**P**
	APPLIED PARTS surface temperature of equal to or less than 41 °C		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted..... :		**N/A**
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
11.1.3	**Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Measurement made	**N/A**
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.3)	**P**
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE..... :		**P**
11.1.4	**GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL**	No such guard	**N/A**
11.2	**Fire prevention**		**P**
11.2.1	**ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3**		**P**
11.2.2	**Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS**		**N/A**
11.2.2.1	**RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of ..... :**	Not used in conjunction with oxygen rich environment	**N/A**
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions		**N/A**
	1) when temperature of material raised to its ignition temperature		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300℃ or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300℃, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :		N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three ..... :		N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3..... :		N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%) ..... :		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		**N/A**
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE ..... :		**N/A**
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases ..... :		**N/A**
11.2.2.2	**RISK of ignition did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT**		**N/A**
11.2.2.3	**Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks**		**N/A**
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		**N/A**
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		**N/A**
11.2.3	**SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered**		**N/A**
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) ..... :	Not used in oxygen rich environments	**N/A**
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :		**N/A**
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :		**N/A**
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a) ..... :		**N/A**
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas ..... :		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		**N/A**
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2..... :		**N/A**
	Constructional requirements were met, or		**N/A**
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
	Justification, when requirement not met ..... :		**N/A**
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials..... :		**N/A**
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data..... :		**N/A**
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		**N/A**
	b) Fire ENCLOSURE met following:		**N/A**
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		**N/A**
	2) No openings on the sides within the area included within the inclined line C in Fig 39		**N/A**
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials..... :		**N/A**
11.4	**ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics**		**N/A**
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	Not use with flammable anaesthetics	**N/A**
11.5	**ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents**		**N/A**
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	Not use in conjunction with flammable agents	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT**		**P**
11.6.1	**Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT .....:**	See appended Table 11.6.1	**P**
11.6.2	**Overflow in ME EQUIPMENT**		**P**
	ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE ..... :	See appended Table 11.6.1	**P**
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.		**N/A**
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		**P**
11.6.3	**Spillage on ME EQUIPMENT and ME SYSTEM**		**P**
	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test ..... : **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill ..... :	See appended Table 11.6.1	**P**
11.6.5	**Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		**P**
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :	IPX4 for foot switch	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION.. :	Maintained basic safety	**P**
11.6.6	**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS**		**P**
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use..... :	See appended Tables 11.6.1	**P**
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER ..... :	See risk management reports	**P**
11.6.7	**Sterilization of ME EQUIPMENT and ME SYSTEMS**		**P**
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests..... :	By moist heat sterilization of handle and nozzle of three-way syringe Test according to sterilization process, comply with basic safety and essential performance Assessment and document reference from ISO 17665-1: 2006 was not evaluated in this report	**N/E**
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific risks: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
11.6.8	**RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS.....** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
11.7	**ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented**	Biocompatibility was not evaluated in this report	**N/E**
11.8	**Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		**P**
12.1	**RISKS associated with accuracy of controls and instruments stated..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
12.2	**RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING ..... :**	Usability was not evaluated in this report	**N/E**
12.3	**MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. ..... :**	No alarm system	**N/A**
12.4	**Protection against hazardous output**		**N/A**
12.4.1	**RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No hazardous output	**N/A**
12.4.2	**- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
12.4.3	**RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS ..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
12.4.4	**RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
12.4.5	**Diagnostic or therapeutic radiation**		**N/A**
12.4.5.1	**Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation**		**N/A**
	Radiation safety ensured by compliance with requirements of appropriate standards		**N/A**
12.4.5.2	**ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3..... :**		**N/A**
12.4.5.3	**RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as ..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
12.4.5.4	**RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as ..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
12.4.6	**RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**N/A**
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		**P**
13.1	**Specific HAZARDOUS SITUATIONS**		**P**
13.1.2	**Emissions, deformation of ENCLOSURE or exceeding maximum temperature**		**P**
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		**P**
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		**P**
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24..... :	See appended Table 13.2.4 and 13.2	**P**
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 ..... :	See appended Table 13.2.4 and 13.2	**P**
	–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded		**P**
	Limits for windings in Tables 26, 27, and 31 not exceeded		**P**
	Table 22 not exceeded in all other cases		**P**
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		**P**
13.1.3	**– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed ..... :**	See appended Table 8.7	**P**
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed..... :	Not exceed the limit	**P**
13.2	**SINGLE FAULT CONDITIONS**		**P**
13.2.1	**During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination**		**P**
	ME EQUIPMENT complied with 13.2.2 -13.2.12..... :	See appended Table 13.2	**P**
	RISK MANAGEMENT FILE includes and assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		**P**
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
13.2.13	**ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of the temperature in the test environment**		**P**
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		**P**
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		**P**
13.2.13.2	**ME EQUIPMENT with heating elements**		**P**
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	Built-in heating element in water heater	**P**
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests		**N/A**
	a 3) other ME EQUIPMENT with heating elements met test		**N/A**
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		**P**
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		**N/A**
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		**N/A**
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		**N/A**
	b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V) ..... :	110 % of rated supply voltage	**P**
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		**P**
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		**N/A**
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		**P**
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS	Thermostat short circuit under test See appended Table 13.2	**P**
	2) When more than one control provided, they were disabled in turn		**N/A**
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		**N/A**
13.2.13.3	**ME EQUIPMENT with motors**		**P**
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	Checked by tests of 13.2.8, 13.2.10	**P**
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		**N/A**
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		**P**
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		**P**
	b) Motor met running overload protection test of this clause when:		**N/A**
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or	Not intended to be remotely or automatically controlled	**N/A**
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	Not continuous operation while unattended	**N/A**
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) ..... :		**N/A**
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		**N/A**
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		**N/A**
	Test not conducted based on other justifications (justification)..... :		**N/A**
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		**N/A**
13.2.13.4	**ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION**		**N/A**
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	The dental unit has to be kept switched on manually	**N/A**
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		**N/A**
	Motor winding temperatures did not exceed values in 13.2.10 ..... :		**N/A**
	Insulation Class ..... :		**—**
	Maximum temperature measured (°C) ..... :		**—**

14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		**N/E**
14.1	**Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or**	PEMS was not evaluated in this report	**N/E**
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK ..... :		**N/E**
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)		**N/E**
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		**N/E**
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304 ..... :		**N/E**
	Software development process applied according to Clause 5 of IEC 62304 ..... :		**N/E**

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Clause	Requirement + Test	Result - Remark	Verdict
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 ..... :		N/E
	Software development process Configuration Management applied according to Clause 8 of IEC 62304 ..... :		N/E
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304..... :		N/E
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process..... :		N/E
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan		N/E
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		N/E
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/E
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N/E
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		N/E
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/E
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained		N/E
14.6	RISK MANAGEMENT PROCESS		N/E
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS ..... :		N/E
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems.....: (ISO 14971 Cl. 4.3)		N/E

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2 :		N/E
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure.....: (ISO 14971 Cl. 6.1)		N/E
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem ..... : (ISO 14971 Cl. 6.3)		N/E
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems .... : (ISO 14971 Cl. 6.3)		N/E
14.9	Design is broken up into sub systems and descriptive data on design environment documented ..... :		N/E
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures..... : (ISO 14971 Cl. 6.3)		N/E
	– milestone(s) when VERIFICATION is to be performed for each function		N/E
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N/E
	– selection and utilization of VERIFICATION tools		N/E
	– coverage criteria for VERIFICATION		N/E
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE ..... :		N/E
	Methods used for PEMS VALIDATION documented		N/E
	The person with overall responsibility for PEMS VALIDATION is independent		N/E
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)		N/E
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		N/E

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Clause	Requirement + Test	Result - Remark	Verdict
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304 ..... :		N/E
	Software Process for Software changes applied according to Clause 5 of IEC 62304 ..... :		N/E
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304 ..... :		N/E
	Configuration management of software changes applied per Clause 8 of IEC 62304 .... :		N/E
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 .... :		N/E
14.13	For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following..... :		N/E
	a) Purpose of the PEMS connection to an IT-NETWORK		N/E
	b) required characteristics of the IT-NETWORK		N/E
	c) required configuration of the IT-NETWORK		N/E
	d) technical specifications of the network connection, including security specifications		N/E
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK		N/E
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the characteristics required (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)		N/E
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		N/E
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties		N/E
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS		N/E
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis		N/E

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- Changes to the IT-NETWORK include: **- changes in network configuration** **- connection of additional items** **- disconnection of items** **- update of equipment** **- upgrade of equipment**		**N/E**
15	**CONSTRUCTION OF ME EQUIPMENT**		**P**
15.1	**RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS ..... :**	Usability was not evaluated in this report	**N/E**
15.2	**Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance**		**P**
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		**P**
15.3	**Mechanical strength**		**P**
15.3.1	**Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**		**P**
15.3.2	**Push test conducted..... :**	See appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained		**P**
15.3.3	**Impact test conducted ..... :**	See appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK sustained		**P**
15.3.4	**Drop test**		**P**
15.3.4.1	**Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested..... :**	See appended Table 15.3	**P**
	No unacceptable RISK resulted		**P**
15.3.4.2	**Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test .....:**		**N/A**
	No damage resulting in an unacceptable RISK sustained		**N/A**
15.3.5	**MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests..... :**		**N/A**
	No damage resulting in an unacceptable RISK sustained		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
15.3.6	**Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK**		**P**
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10℃ over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 ℃ ..... :	See appended Table 15.3	**P**
	No damage resulting in an unacceptable RISK		**P**
15.3.7	**INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT**		**P**
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		**P**
15.4	**ME EQUIPMENT components and general assembly**		**P**
15.4.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists,..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		**P**
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions, ... :	No patient leads or patient cables	**N/A**
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection ..... :	No medical gas	**N/A**
15.4.2	**Temperature and overload control devices**		**P**
15.4.2.1	**a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION ..... :** **(ISO 14971 Cl. 4.2-4.4, 5)**	See risk management report	**P**
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	No such thermal cut-out used	**N/A**
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided..... : **(ISO 14971 Cl. 4.2-4.4)**	Self-resetting thermal cut-out used	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE .... : **(ISO 14971 Cl. 4.2-4.4)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		**N/A**
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests:		**P**
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17		**N/A**
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13..... :	See appended Table 13.2	**P**
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards	Approved self-resetting thermal cut-out in water heater See appended Table 8.10	**P**
	- In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times		**N/A**
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		**N/A**
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		**N/A**
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		**N/A**
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating	See appended Table 13.2	**P**
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating. : **(ISO 14971 Cl. 4.2-4.4)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
15.4.2.2	**Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS**		**N/A**
15.4.3	**Batteries**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
15.4.3.1	**Battery housings provided with ventilation.... :** **(ISO 14971 Cl. 4.2-4.4)**	No battery equipped	**N/A**
	Battery compartments designed to prevent accidental short circuiting		**N/A**
15.4.3.2	**Means provided to prevent incorrect connection of polarity..... :**		**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries ..... : **(ISO 14971 Cl. 4.2-4.4)**		**N/A**
15.4.3.3	**Overcharging of battery prevented by virtue of design..... :**		**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries ..... : **(ISO 14971 Cl. 4.2-4.4)**		**N/A**
15.4.3.4	**Primary lithium batteries comply with IEC 80086-4**		**N/A**
	Secondary lithium batteries comply with IEC 62133		**N/A**
15.4.3.5	**A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire..... :**		**N/A**
	Protective device has adequate breaking capacity		**N/A**
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		**N/A**
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPs provided, or		**N/A**
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION		**N/A**
15.4.4	**Indicator lights provided to indicate ME EQUIPMENT is ready for..... :**	Indicator on control panel provided	**P**
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	No stand-by state or warm-up state	**N/A**
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational		**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters ..... : **(ISO 14971 Cl. 4.2-4.4)**		**N/A**
	Requirement not applied to heated stylus-pens for recording purposes		**N/A**
	Indicator lights provided on ME EQUIPMENT to indicate an output exists		**N/A**
	Colours of indicator lights complied with 7.8.1		**P**
	Charging mode visibly indicated		**N/A**
15.4.5	**RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		**P**
15.4.6.1	**a) Actuating parts cannot be pulled off or loosened during NORMAL USE**		**P**
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		**P**
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	Not separated without use of a tool	**N/A**
	When torque values per Table 30 applied knobs did not rotate ..... :	1,0 Nm under test	**P**
	Tests conducted with no unacceptable RISK . :	No unacceptable risk	**P**
15.4.6.2	**Stops on rotating/ movable parts of controls are of adequate mechanical strength ..... :**	See appended Table 15.4.6	**P**
	Torque values in Table 30 applied ..... :	1,0 Nm under test	**P**
	No unexpected change of the controlled parameter when tested ..... :	No hazardous situation identified	**P**
15.4.7	**Cord-connected HAND-HELD and foot-operated control devices**		**P**
15.4.7.1	**a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1**	See appended Table 15.3	**P**
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage ..... :	No damage	**P**
15.4.7.2	**Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :**	No unacceptable risk	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		**P**
15.4.7.3	**a) Foot-operated control device is at least rated IPX1** ..... :	IPX4 See appended Table 11.6.1	**P**
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.... :		**N/A**
15.4.8	**Aluminium wires less than 16 mm^2 in cross-sectional area are not used**		**P**
15.4.9	**a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed**	No oil container	**N/A**
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		**N/A**
	A pressure-release device operating during NORMAL USE is provided		**N/A**
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		**N/A**
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		**N/A**
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		**N/A**
15.5.1	**Overheating**		**N/A**
15.5.1.1	**Transformers of ME EQUIPMENT are protected against overheating ..... :**	Transformer had been approved by EN 60601-1:2006+A1:2013 Details refer to Table 8.10	**N/A**
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		**N/A**
	Dielectric strength test conducted after short circuit and overload tests ..... :		**N/A**
15.5.1.2	**Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ..... :**		**N/A**
	Short circuit applied directly across output windings		**N/A**
15.5.1.3	**Multiple overload tests conducted on windings ..... :**		**N/A**
15.5.2	**Transformers operating at a frequency above 1kHz tested according to clause 8.8.3 ..... :**		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Transformer windings provided with adequate insulation		**N/A**
	Dielectric strength tests were conducted ..... :		**N/A**
15.5.3	**Transformers forming MEANS OF PROTECTION as required by 8.5 comply with ..... :**		**N/A**
	- Means provided to prevent displacement of end turns		**N/A**
	- protective earth screens with a single turn have insulated overlap		**N/A**
	- Exit of wires form internal windings of toroid transformers protected with double sleeving		**N/A**
	- insulation between primary and secondary windings complies with 8.8.2		**N/A**
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		**N/A**
16	**ME SYSTEMS**		**N/A**
16.1	**After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK**	Not ME System	**N/A**
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM.....: **(ISO 14971 Cl. 4.2-4.4, 5)**		**N/A**
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		**N/A**
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		**N/A**
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		**N/A**
	– tests performed in NORMAL CONDITION, except as specified		**N/A**
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		**N/A**
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		**N/A**
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR		**N/A**
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N/A
	c) the required information is provided:		N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		N/A
	– additional safety measures to be applied during installation of ME SYSTEM		N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		N/A
	– additional measures to be applied during preventive maintenance		N/A
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor		N/A
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM		N/A
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		N/A
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM		N/A
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer		N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		N/A
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		N/A
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		N/A
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		N/A
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements		N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS..... :		N/A
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified		N/A
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)		N/A
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed		N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :		N/A
16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100 µA.....:		N/A
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR.....:		N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA....:		N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values.....:		N/A
16.7	ME SYSTEM complied with applicable requirements of Clause 9 .....:		N/A
16.8	Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A
16.9	ME SYSTEM connections and wiring		N/A
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result..... :		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results		N/A
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable		N/A
16.9.2	MAINS PARTS, components and layout		N/A
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:		N/A
	– ENCLOSURE complied with 8.4.2 d)		N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	– RATINGS of components are not in conflict with conditions of use ..... :		N/A
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	– POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	– Separating transformer complied with this standard or IEC 61558-2-1, ...:		N/A
	– Separating transformer is CLASS I		N/A
	– Degree of protection against ingress of water specified as in IEC 60529		N/A
	– Separating transformer assembly marked according to 7.2 and 7.3		N/A
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
16.9.2.2	**The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 mΩ**		**N/A**
	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part		**N/A**
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL		**N/A**
16.9.2.3	**Conductors connecting different items within an ME SYSTEM protected against mechanical damage**		**N/A**
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**P**
	RISKS associated confirmed by review ..... :	Risk management report examined	**P**
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :	Stated in Operation Manual	**P**
	RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: KASO-CE-01-09.2, 6,5&7,2 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)	**P**
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems		**P**
ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		**N/A**
G.2	**Locations and basic requirements**		**N/A**
G.2.1	**Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5**		**N/A**
G.2.2	**FLAMMABLE AESTHETIC MIXTURE WITH**		**N/A**
G.2.3	**A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE**		**N/A**
G.2.4	**ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5**		**N/A**

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Clause	Requirement + Test	Result - Remark	Verdict
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6		N/A
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	Marking, ACCOMPANYING DOCUMENTS		N/A
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1) ..... :		N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A
	When above marking not possible, relevant information included in instructions for use ... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1) ..... :		N/A
	Marking is as large as possible for the particular case		N/A
	When above marking not possible, the relevant information included in instructions for use ... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.3	The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts		N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts		N/A
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG		N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION		N/A
	b) Connections protected against accidental disconnection		N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,		N/A
G.4.2	Construction details		N/A
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) ENCLOSURE complies with..... :		N/A
	– no openings on top covers of ENCLOSURE,		N/A
	– openings in side-covers prevented penetration of a solid cylindrical test rod		N/A
	– openings in base plates prevented penetration of a solid cylindrical test		N/A
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION		N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures		N/A
	– Use of antistatic materials with a limited electrical resistance..... :		N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882..... :		N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N/A
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components		N/A
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5		N/A
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5..... :		N/A
G.5.2	Temperature limits..... :		N/A
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1 ..... :		N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :		N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N/A
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2		N/A
	No extrapolation made for voltages above 242V		N/A
	U_{max} determined using actual resistance R		N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		N/A
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open		N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed		N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit... :		N/A
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max} , and C_{max} determined with application of Figs G.1-G.3 .. :		N/A
	Alternatively, compliance was verified by examination of design data .....:		N/A
G.5.4	External ventilation with internal overpressure		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa) ..... :		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Overpressure maintained at the site of potential ignition		**N/A**
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE		**N/A**
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		**N/A**
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa) ..... :		**N/A**
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C..... :		**N/A**
G.5.5	**ENCLOSURES with restricted breathing**		**N/A**
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		**N/A**
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing		**N/A**
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h. :		**N/A**
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained		**N/A**
	Cords are fitted with adequate anchorages to limit stresses as determined by test		**N/A**
	Overpressure not reduced below 200 Pa		**N/A**
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		**N/A**
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C)..... :		**N/A**
	Steady state operating temperature of ENCLOSURE also measured (°C) ..... :		**N/A**
G.6	**CATEGORY APG ME EQUIPMENT, parts and components thereof**		**N/A**
G.6.1	**ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION**		**N/A**
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test		**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :		N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or		N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 .... :		N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :		N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N/A
	– C_{max} and L_{max} are values occurring in relevant circuit		N/A
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- requirement not applied to transformers complying with this standard		N/A
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N/A
	Temperature measurements made in accordance with 11.1 ..... :		N/A
	- or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 ..... :		N/A
	Alternatively, compliance verified by comparison with design data .....:		N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 ..... :		N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	Test apparatus for flammable mixtures according to this Clause and Fig G.7		N/A

ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		N/A
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex		N/A
L.2	Wire construction		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component		N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A
L.3	Type Test		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified		N/A
	Temperature (°C)..... :		—
	Humidity (%)..... :		—
L.3.1	Dielectric strength		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:		N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 6000 V for REINFORCED INSULATION (V)..... :		N/A
L.3.2	Flexibility and adherence		N/A
	Sample subjected to flexibility and adherence		N/A
	Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown		N/A
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V)..... :		N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :		N/A
L.3.3	Heat Shock		N/A
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V)..... :		N/A
	Oven temperature based on Table L.2 (°C)..... :		—
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2)..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
L.3.4	Retention of electric strength after bending		N/A
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests		N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V)..... :		N/A
	Test voltage applied between the shot and conductor		N/A

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2)..... :		**N/A**
L.4	**Tests during manufacture**		**N/A**
L.4.1	**Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3.....:**		**N/A**
L.4.2	**Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:**		**N/A**
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V).....:		**N/A**
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) .....:		**N/A**
L.4.3	**Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1).....:**		**N/A**
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		**N/A**
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION ..... :		**N/A**
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION..... :		**N/A**

EN 60601-1:2006 + A1:2013
The text of the International Standard IEC 60601-1:2005 + A1:2012 was approved by CENELEC as a European Standard without any modification.

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
3.1	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Chapter 3	—	Risk Management Process (excluding production and post-production)	**P**
3.2	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Chapter 2	—	Adequate Resources	**P**
3.2	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.3.4.2	—	Assignment of qualified personnel	**P**
3.2	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.3.2	—	Policy for determining criteria for risk acceptability	**P**
3.3	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.3.3	Qualification of personnel	**P**
3.4a	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.3.4	Scope of the planned risk management activities, identifying and describing the medical device and the life-cycle phases	**P**
3.4b	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.34.2	Assignment of responsibilities and authorities	**P**
3.4c	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.3.4.3	Requirements for review of risk management activities	**P**
3.4d	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.3.4.4	Criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk, including criteria for accepting risks when the probability of occurrence of harm cannot be estimated	**P**
3.4e	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.3.4.5	Verification activities	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
3.5	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.3.4	Risk management file	**P**
4.1	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.3.1	Risk analysis procedure/Flow Chart	**P**
4.2	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.6.2&6.5	Product Specifications (intended use and characteristics related to the safety)	**P**
4.3	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.6.2&6.5	Identification of known or foreseeable hazards	**P**
4.4	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.6.2&6.5	Assessment of the risk severity & probability level for each hazard	**P**
5	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Chapter 7	Risk evaluation	**P**
6.2	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Chapter 7	Option analysis	**P**
6.3	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Chapter 7	Implementation of risk control measure(s)	**P**
6.4	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Chapter 7	Residual risk evaluation	**P**
6.5	—	--	Risk/benefit analysis	**N/A**
6.6a	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.8	The introduction of new hazards or hazardous situations	**P**
6.6b	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.8	Affection of introduction of the risk control measures	**P**
6.7	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.8	Completeness of risk evaluation	**P**
7	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.8	Overall residual risk evaluation	**P**
8	—	Risk Management Report No. KASO-CE-01-09.2, Version C/01, Cl.8	Risk management report	**P**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

4.2.2	**RM RESULTS TABLE: General requirements for RISK MANAGEMENT**			**P**
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
Supplementary Information: **Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.**				

4.3	**TABLE: ESSENTIAL PERFORMANCE**	**N/A**
List of ESSENTIAL PERFORMANCE functions	**MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)**	**Remarks**
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.		

4.11	**TABLE: Power Input**				**P**
Operating Conditions / Ratings	**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (VA)**	**Power factor (cos φ)**
Normal operation (Full loading)	220	50	0,98	225,40	--
Normal operation (Full loading)	230	50	1,00	220,00	--
Supplementary Information: Rating : AC 220-230 V; 50 Hz; 400 VA					

5.9.2	**TABLE: Determination of ACCESSIBLE parts**	**P**
Location	**Determination method (NOTE1)**	**Comments**
Enclosure	Visual; rigid test finger; test finger; test hook	Accessible part
Power unit	Visual; rigid test finger; test finger;	Accessible part
Control panel	Visual; rigid test finger; test finger;	Accessible part
Hoses	Visual; rigid test finger; test finger;	Accessible part
Supplementary information: NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.		

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

7.1.2	TABLE: Legibility of Marking		P
Markings tested		**Ambient Illuminance (lx)**	**Remarks**
Outside Markings (Clause 7.2) ..... :		100 & 1500	Legible
Inside Markings (Clause 7.3) ..... :		100 & 1500	Legible
Controls & Instruments (Clause 7.4) ..... :		100 & 1500	Legible
Safety Signs (Clause 7.5)..... :		100 & 1500	Legible
Symbols (Clause 7.6) ..... :		100 & 1500	Legible

Supplementary information:

Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

7.1.3	TABLE: Durability of marking test		P
Characteristics of the Marking Label tested:			**Remarks**
Material of Marking Label ..... :		Metal label	Clear
Ink/other printing material or process..... :		--	Clear
Material (composition) of Warning Label ..... :		Adhesive label	Clear
Ink/other printing material or process..... :		Ink	Clear
Other..... :		Controls	Clear
Marking Label Tested:			**Remarks**
Warning Label			P

Supplementary information:

Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					N/A
Test supply voltage/frequency (V/Hz)[1] ..... :						
Location From/To	**Measured values**					**Remarks**
	Vrms	**Vpk or Vdc**	**Peak-to-peak ripple[2]**	**Power W/VA**	**Energy (J)**	

Supplementary Information:

1. The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.
2. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.3	TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply	P

Maximum allowable voltage (V) ..... :	60

Voltage measured (V)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	0	0	0	0	0	0	0	0	0	0
Plug pin 1 and plug earth pin	0	0	0	0	0	0	0	0	0	0
Plug pin 2 and plug earth pin	0	0	0	0	0	0	0	0	0	0
Plug pin 1 and enclosure	0	0	0	0	0	0	0	0	0	0
Plug pin 2 and enclosure	0	0	0	0	0	0	0	0	0	0

Maximum allowable stored charge when measured voltage exceeded 60 v (µc) ..... :	45

Calculated stored charge (µc)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and plug earth pin	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT		N/A
Maximum allowable residual voltage (V):			60 V
Maximum allowable stored charge when residual voltage exceeded 60 V :			45 µC

Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	Measured residual voltage (V)	Calculated stored charge (µC)	Remarks

Supplementary information:

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies					N/A
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks	

Supplementary information:

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time				N/A
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks	

Supplementary information:

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

8.5.5.2	**TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load**			**N/A**
Test Voltage applied to		**Measured Energy E1 (mJ)**	**Measured Energy E2 (mJ)**	**Energy E1 as % of E2 (%)**
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth				
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth				
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth				
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth				
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 Ω with ME Equipment connected; E2= Measured energy delivered to 100 Ω without ME equipment connected.				

8.6.4	**TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS**				**P**
Type of ME EQUIPMENT & impedance measured between parts		**Test current (A) /Duration (s)**	**Voltage drop measured between parts (V)**	**Maximum calculated impedance (mΩ)**	**Maximum allowable impedance (mΩ)**
Equipment with a detachable power supply cord, impedance between the protective earth pin in the mains plug and a protectively earthed part		25 A / 10 s	2,6	104	200
Supplementary information: **PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ** **ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 mΩ** **ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 mΩ**					

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

8.7	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)		**Supply voltage (V)**	**Supply frequency (Hz)**	**Measured max. value (µA)**	**Remarks**
Fig. 13 - Earth Leakage (ER)		(V)	(Hz)	B(µA)/A(µA)	Maximum allowed values: 5 mA NC; 10 mA SFC
ER, NC, S1=1, S5=N, S12=0		253	50	~~<0,1/<0,1~~35/35	
ER, NC, S1=1, S5=R, S12=0		253	50	~~<0,1/<0,1~~35/35	
ER, NC, S1=1, S5=N, S12=1		253	50	~~<0,1/<0,1~~35/35	
ER, NC, S1=1, S5=R, S12=1		253	50	~~<0,1/<0,1~~35/35	
ER,SFC(Neutral open), S1=0, S5=N, S12=0		253	50	~~<0,1/<0,1~~64/64	
ER,SFC(Neutral open), S1=0, S5=R, S12=0		253	50	~~<0,1/<0,1~~64/64	
ER,SFC(Neutral open), S1=0, S5=N, S12=1		253	50	~~<0,1/<0,1~~64/64	
ER,SFC(Neutral open), S1=0, S5=R, S12=1		253	50	~~<0,1/<0,1~~64/64	
Fig. 14 - Touch Current (TC)		(V)	(Hz)	B(µA)/A(µA)	Maximum allowed values: 100 µA NC; 500 µA SFC
TC, NC, S1=1, S5=N, S12=0		253	50	<0,1/<0,1	The MD1 was connected between enclosure and reference to earth
TC, NC, S1=1, S5=R, S12=0		253	50	<0,1/<0,1	
TC, NC, S1=1, S5=N, S12=1		253	50	<0,1/<0,1	
TC, NC, S1=1, S5=R, S12=1		253	50	<0,1/<0,1	
TC, SFC(Neutral open), S1=0, S5=N, S7=1, S12=0		253	50	<0,1/<0,1	
TC, SFC(Neutral open), S1=0, S5=R, S7=1, S12=0		253	50	<0,1/<0,1	
TC, SFC(Neutral open), S1=0, S5=N, S7=1, S12=1		253	50	<0,1/<0,1	
TC, SFC(Neutral open), S1=0, S5=R, S7=1, S12=1		253	50	<0,1/<0,1	
TC, SFC(Ground open), S1=1, S5=N, S7=0, S12=0		253	50	<0,1/<0,1	
TC, SFC(Ground open), S1=1, S5=R, S7=0, S12=0		253	50	<0,1/<0,1	
TC, SFC(Ground open), S1=1, S5=N, S7=0, S12=1		253	50	<0,1/<0,1	
TC, SFC(Ground open), S1=1, S5=R, S7=0, S12=1		253	50	<0,1/<0,1	
TC, NC, S1=1, S5=N, S12=0		253	50	<0,1/<0,1	The MD2 was connected between parts of enclosure

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Clause	**Requirement + Test**		**Result - Remark**	**Verdict**

TC, NC, S1=1, S5=R, S12=0	253	50	<0,1/<0,1	
TC, NC, S1=1, S5=N, S12=1	253	50	<0,1/<0,1	
TC, NC, S1=1, S5=R, S12=1	253	50	<0,1/<0,1	
TC, SFC(Neutral open), S1=0, S5=N, S7=1, S12=0	253	50	<0,1/<0,1	
TC, SFC(Neutral open), S1=0, S5=R, S7=1, S12=0	253	50	<0,1/<0,1	
TC, SFC(Neutral open), S1=0, S5=N, S7=1, S12=1	253	50	<0,1/<0,1	
TC, SFC(Neutral open), S1=0, S5=R, S7=1, S12=1	253	50	<0,1/<0,1	
TC, SFC(Ground open), S1=1, S5=N, S7=0, S12=0	253	50	<0,1/<0,1	
TC, SFC(Ground open), S1=1, S5=R, S7=0, S12=0	253	50	<0,1/<0,1	
TC, SFC(Ground open), S1=1, S5=N, S7=0, S12=1	253	50	<0,1/<0,1	
TC, SFC(Ground open), S1=1, S5=R, S7=0, S12=1	253	50	<0,1/<0,1	
Fig. 15 - Patient Leakage Current (P)	(V)	(Hz)	B(µA)/A(µA)	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
P, NC, S1=1, S5=N, S7=1,S13=1	253	50	d.c.:<0,1/<0,1	
			a.c.:<0,1/<0,1	
P, NC, S1=1, S5=R, S7=1,S13=1	253	50	d.c.:<0,1/<0,1	
			a.c.:<0,1/<0,1	
P, NC, S1=1, S5=N, S7=1,S13=0	253	50	d.c.:<0,1/<0,1	
			a.c.:<0,1/<0,1	
P, NC, S1=1, S5=R, S7=1,S13=0	253	50	d.c.:<0,1/<0,1	
			a.c.:<0,1/<0,1	
P, SFC(Neutral open), S1=0, S5=N, S7=1,S13=1	253	50	d.c.:<0,1/<0,1	
			a.c.:<0,1/<0,1	
P, SFC(Neutral open), S1=0, S5=R, S7=1,S13=1	253	50	d.c.:<0,1/<0,1	
			a.c.:<0,1/<0,1	
P, SFC(Neutral open), S1=0, S5=N, S7=1,S13=0	253	50	d.c.:<0,1/<0,1	
			a.c.:<0,1/<0,1	
P, SFC(Neutral open), S1=0, S5=R, S7=1,S13=0	253	50	d.c.:<0,1/<0,1	
			a.c.:<0,1/<0,1	

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Clause	**Requirement + Test**			**Result - Remark**	**Verdict**
P, SFC(Ground open), S1=1, S5=N, S7=0, S13=1	253	50	d.c.:<0,1/<0,1 a.c.:<0,1/<0,1		
P, SFC(Ground open), S1=1, S5=R, S7=0, S13=1	253	50	d.c.:<0,1/<0,1 a.c.:<0,1/<0,1		
P, SFC(Ground open), S1=1, S5=N, S7=0, S13=0	253	50	d.c.:<0,1/<0,1 a.c.:<0,1/<0,1		
P, SFC(Ground open), S1=1, S5=R, S7=0, S13=0	253	50	d.c.:<0,1/<0,1 a.c.:<0,1/<0,1		
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	(V)	(Hz)	B(µA)/A(µA)	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA	
N/A					
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	(V)	(Hz)	B(µA)/A(µA)	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)	
N/A					
Fig. 18 - Patient leakage current with external voltage on accessible Part that is not Protectively Earthed	(V)	(Hz)	B(µA)/A(µA)	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A	
PM, S1=1, S5=N, S7=1, S9=N	253	50	<0,1/<0,1		
PM, S1=1, S5=R, S7=1, S9=N	253	50	<0,1/<0,1		
PM, S1=1, S5=N, S7=1, S9=R	253	50	<0,1/<0,1		
PM, S1=1, S5=R, S7=1, S9=R	253	50	<0,1/<0,1		
Fig. 19 – Patient Auxiliary Current Between patient chair and hand piece	(V)	(Hz)	B(µA)/A(µA)	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)	
PA, NC, S1=1, S5=N, S7=1	253	50	<0,1/<0,1		
PA, NC, S1=1, S5=R, S7=1	253	50	<0,1/<0,1		
PA, SFC(Neutral open), S1=0, S5=N, S7=1	253	50	<0,1/<0,1		
PA, SFC(Neutral open), S1=0, S5=R, S7=1	253	50	<0,1/<0,1		
PA, SFC(Ground open), S1=1, S5=N, S7=0	253	50	<0,1/<0,1		
PA, SFC(Ground open), S1=1, S5=R, S7=0	253	50	<0,1/<0,1		

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	(V)	(Hz)	B(μA)/A(μA)	Maximum allowed values: Type B or BF AP: 50 μA NC; 100μA SFC (d.c. current); 500 μA NC; 1000 μA SFC (a.c.); Type CF AP: 50 μA NC; 100 μA SFC (d.c. or a.c. current)
N/A				
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	(V)	(Hz)	B(μA)/A(μA)	Maximum allowed values: Type B or BF AP: 50 μA NC; 100μA SFC (d.c. current); 500 μA NC;1000 μA SFC (a.c.); Type CF AP: 50 μA NC; 100 μA SFC (d.c. or a.c. current)
N/A				
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	(V)	(Hz)	B(μA)/A(μA)	Maximum allowed values: Type B: NA Type BF: 5000 μA Type CF: 100 μA
N/A				
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	(V)	(Hz)	B(μA)/A(μA)	Maximum allowed values: Type B & BF: 1000 μA Type CF: N/A
N/A				
Function Earth Conductor Leakage Current (FECLC)	(V)	(Hz)	B(μA)/A(μA)	Maximum allowed values: 5 mA NC; 10 mA SFC

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;
Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.
Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

Note 6: After sterilization, there is no effect on the leakage current test result.

ER - Earth leakage current
TC – Touch current
P - Patient leakage current
PA – Patient auxiliary current
TP – Total Patient current
PM - Patient leakage current with mains on the applied parts
MD - Measuring device

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity
NC - Normal condition
SFC - Single fault condition

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

8.8.3	**TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)**	**P**

Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1]	Dielectric breakdown after 1 minute Yes/No[2]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
A	1 MOOP	325 V_{pk}	--	1500 V	No
B	1 MOPP	325 V_{pk}	--	1500 V	No
C	2 MOOP	325 V_{pk}	--	3000 V	No
D	2 MOPP	360 V_{pk}	--	4018 V	No
E	2 MOPP	--	24 V	1000 V	No
F	1 MOPP	--	24 V	500 V	No
G	2 MOPP	--	24 V	1000 V	No
H	2 MOPP	325 V_{pk}	--	4000 V	No
I	1 MOPP	354 V_{pk}	--	1500 V	No

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.
[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

8.8.4.1	**TABLE: Resistance to heat - Ball pressure test of thermoplastic parts**		**P**
	Allowed impression diameter (mm) ..... :	**≤ 2 mm**	**—**
	Force (N)..... :	**20**	**—**

Part/material	Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts		
Plastic enclosure	75	0,95
Fuse holder	125	0,71
Terminal block	125	1,24
Supplementary information:		

8.9.2	**TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4**	**N/A**

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1]	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks

Supplementary information:
Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts			N/A
Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**
	68 h at T1 ± 2 °C = ___°C [1]			
	1 h at 25 °C ± 2 °C			
	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			

Supplementary information:
[1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

8.9.3.3	**Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3)**			**N/A**
Part tested	**Sample**	**Each test duration and temperature**	**Dielectric test voltage**	**Dielectric strength test, Breakdown: Yes/No**
	1	**10 Cycles conducted of the following:**		
		1 - 68 h at T1 ± 2 °C = ___°C[1]		
		2 - 1 h at 25 °C ± 2 °C		
		3 - 2 h at 0 °C ± 2 °C		
		4 - 1 or more h at 25 °C ± 2 °C		
	2	**Humidity Conditioning per 5.7**		
	3	**Humidity Conditioning per 5.7**		

Supplementary information:

[1] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

8.10	TABLE: List of critical components				P
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity [1]**
Plug	Ningbo Qiaopu Electric Co.,Ltd	D03	16A; AC250V	DIN VDE 0620-2-1 (VDE 0620-2-1):2016-01	VDE 40002872
Power supply cord	Ningbo QiaoPu electric co.,LTD	H05VV-F	AC250V; 3x0,75mm2	DIN EN 50525-2-11 (VDE 0285-525-2-11):2012-01; EN 50525-2-11:2011	VDE 40035976
Internal wire	Foshan Yuejiaxin Wire & Cable Co.,ltd	53(RVV)	0.75mm2	EN 50525-1 IEC 60227-5 IEC 60227-7 IEC 60228	ECM certificate No. 0B160818.FYWTT00
Fuse link	Dongguan Better Electronics Technology Co.,Ltd.	521	F5AL250V	DIN EN 60127-1 (VDE 0820-1):2015-12; EN 60127-1:2006+A1:2011 +A2:2015 DIN EN 60127-2 (VDE 0820-2):2015-07; EN 60127-2:2014 IEC 60127-1(ed.2);am1;am2 IEC 60127-2(ed.3)	VDE 40022236
Fuse holder	Lesheng Electric Appliances Co., Ltd	PTF35	AC 250 V; 10 A	IEC 60127-6	VDE 40018957
Mains Switch	Ningbo Soken Electrical Co., Ltd	RK1-01	250V AC; 16(6)A; T100/55	IEC 61058-1	VDE 40012988
Mains filter	Shenzhen Will honor technology co.,LTD	YB12D2-8A-Q(R)	AC250V 8A 50/60Hz	EN 60939-1:2010 EN 60939-2:2005	TUV B141289931001
PCB	KINGBOARD LAMINATES HOLDINGS LTD	KB-2150	V-0，105	ANSI/UL 94 ANSI/UL 746B	UL QMTS8.E123995
Transformer	Foshan Huapin Electrical Hardware Co.,Ltd.	HB-100/P-808-180VA	I/P:220V-230V 50/60Hz O/P:0V～24V;0V～10.5V～12V	IEC/EN 60601-1	SGS MED GZME 1704000305ME

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

			Class：A		
Thermal cut-out in transformer	Foshan City Haobao Electrical Co.,Ltd	BW-9700 *	AC250V， 0℃ to140℃, Protect temperature：42℃	DIN EN 60730-1 (VDE 0631-1):2012-10; EN 60730-1:2011; DIN EN 60730-2-2 (VDE 0631-2-2):2006-09; EN 60730-2-2:2002+A1:2006 +A11:2005	VDE 40033909
Solenoid valve	ZHONGSHAN JIADA SOLENOID VALVES CO.,LTD	W-2H	Pressure range: 0~0.8Mpa	EN 60730-1 EN 60730-2	TUS: CE 099044-1002/CN
Lift motor	Zhejiang Xinyi Control System CO.,LTD	XYA3-8000N-325-130-0.8E	8000N Input：24VDC Outptu：70Max	IEC 60601-1:2005	TUV: 17030519001
Motor	Zhejiang Xinyi Control System CO.,LTD	XYA2-4000N-325-150-1.9E	4000N Input：24VDC Outptu：40Max	IEC 60601-1:2005	TUV: 17030519001
Limit switch	Zhejiang Zhongxun Electronics Co., Ltd.	KW11-7	16A; AC250V	EN 61058-1:2002	TUV: R50046626
Thermostat	Tongbao-Hualong Controls Co.,Ltd	KSD301-R	AC250V，10A/16A，	EN 60730-2-9:2002+A1+A2+A11+A12 EN 60730-1:2000+A1+A2+A12+A13+A14+A16	TUV: R50161094
Thermal cut-out in water heater	Tongbao-Hualong Controls Co.,Ltd	KSD301A	AC250V，5A，150℃ ,100000	ANSI/UL 60730-1，	UL: E137238
Water heater	Zhaoqing duzhou district xinhao hardware processing department	Hp2460	24 V AC; 80W	IEC/EN 60601-1	Tested with equipment
Foot switch	Foshan Scsway technology co. LTD	SH-J01	IPX4 5VDC	IEC 60601-1	Tested with equipment
Emergency stop switch	Zhejiang Yijia Industrial Electrical Co.,	YJ	24 V	EN 60947-1:2007+A1:2011 +A2:2014 EN 60947-5-	ATT certificate No. ATT1606140106

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Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

	Ltd			1:2004+A1：2009	5
Plastic enclosure	FOSHAN SHUNDE LI CHANG HARDWARE ELECTRONIC COMPOSITE MATERIAL CO LTD	LC900A	V-0; 130 ℃	UL 746A UL 94	UL: E347031
Supplementary information: 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

8.10 b	TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS				N/A
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity [1]**
Supplementary information: 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

8.11.3.5	TABLE: Cord anchorages			P
Cord under test	**Mass of equipment (kg)**	**Pull (N)**	**Torque Nm)**	**Remarks**
Cord/anchorage of floor box	<4 Kg	50	0,25	
Supplementary information:				

8.11.3.6	TABLE: Cord guard			N/A
Cord under test	**Test mass**	**Measured curvature**	**Remarks**	
Supplementary information:				

9.2.2.2	TABLE: Measurement of gap “a” according to Table 20 (ISO 13852: 1996)			N/A
Part of body	**Allowable adult gap[1], mm**	**Measured adult gap, mm**	**Allowable children gap[1], mm**	**Measured children gap, mm**
Body	**> 500**		**> 500**	
Head	**> 300 or < 120**		**> 300 or < 60**	

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

Leg	**> 180**		**> 180**	
Foot	**> 120 or < 35**		**> 120 or < 25**	
Toes	**> 50**		**> 50**	
Arm	**> 120**		**> 120**	
Hand, wrist, fist	**> 100**		**> 100**	
Finger	**> 25 or < 8**		**> 25 or < 4**	
Supplementary information: [1] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.				

9.2.3.2	**TABLE: Over-travel End Stop Test**	**P**
ME EQUIPMENT end stop	**Test Condition (cycles, load, speed)**	**Remarks**
Motor driven	1 cycle, defeat all switches simultaneously, and run at maximum speed	
Supplementary information: Micro switch within actuator and external limit-stop switch equipped		

9.4.2.1	**TABLE: Instability—overbalance in transport position**	**N/A**
ME EQUIPMENT preparation	**Test Condition (transport position)**	**Remarks**
Supplementary information:		

9.4.2.2	**TABLE: Instability—overbalance excluding transport position**	**N/A**
ME EQUIPMENT preparation	**Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)**	**Remarks**
Supplementary information:		

9.4.2.3	**TABLE: Instability—overbalance from horizontal and vertical forces**	**N/A**
ME EQUIPMENT preparation	**Test Condition (force used, direction of force, weight of equipment, location of force)**	**Remarks**
Supplementary information:		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion		N/A
ME EQUIPMENT preparation		Test Condition (force location and height)	Remarks
Supplementary information:			

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold		N/A
ME EQUIPMENT preparation		Test Condition (speed of movement)	Remarks
Supplementary information:			

9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position		N/A
ME EQUIPMENT Preparation		Test Condition (transport position, working load, locking device(s), caster position)	Remarks
Supplementary information:			

9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position		N/A
ME EQUIPMENT Preparation		Test Condition (working load, locking device(s), caster position, force, force location, force direction)	Remarks
Supplementary information:			

9.4.4	TABLE: Grips and other handling devices		N/A
Clause and Name of Test		Test Condition	Remarks
Supplementary information:			

9.7.5	TABLE: Pressure vessels	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

9.7.5	TABLE: Pressure vessels					N/A
Hydraulic, Pneumatic or Suitable Media and Test Pressure	**Vessel Burst**	**Permanent Deformation**	**Leaks**	**Vessel fluid substance**	**Remarks**	
Supplementary Information:						

9.8.3.2	TABLE: PATIENT support/suspension system - Static forces			P
ME EQUIPMENT part or area	**Position**	**Load**	**Area**	**Remarks**
Dental chair	Surface of sitting	810 N	Sitting area	--
Supplementary Information:				

9.8.3.3	TABLE: Support/Suspension System – Dynamic forces due to loading from persons			P
ME EQUIPMENT part or area	**Position**	**Safe Working Load**	**Area**	**Remarks**
Dental chair	Surface of sitting	1350 N	Sitting area	--
Supplementary Information:				

10.1.1	TABLE: Measurement of X - radiation		N/A
Maximum allowable radiation pA/kg (µSv/h) (mR/h)	**36 (5 µSv/h) (0.5 mR/h)**		
Surface area under test Surface no./ Description[1]	**Measured Radiation, pA/kg (µSv/h) (mR/h)**	**Remarks**	
1/ /			
2/ /			
3/ /			
4/ /			
5/ /			
6/ /			
7/ /			
8/ /			
9/ /			
10/ /			
Supplementary information: [1] Measurements made at a distance of 5 cm from any surface to which			

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access

11,1,1	TABLE: Excessive temperatures in ME EQUIPMENT				P
Model No,..... :	KS-DLX301				
Test ambient (°C) ..... :	40°C				
Test supply voltage/frequency (V/Hz)[4] .. :	198/253 V; 50 Hz				
Model No,	**Thermo-couple No,**	**Thermocouple location[3]**	**Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)**	**Max measured temperature[2], (°C)**	**Remarks**
KS-DLS301	102	Switch	71	55,4	
	103	Fuse holder	70	43,8	
	104	Mains connector in floor box	For ball pressure	43,1	
	105	Internal wire	180	45,2	
	202	Transformer winding	95	52,5	Class A
	212	PCB of process control circuit	130	48,4	
	214	Relay for motor	Ref.	51,3	
	203	Lift motor	95	50,7	Class A
	204	Backrest motor	95	48,1	Class A
	205	Limit stop switch	Ref.	43,2	
	113	Solenoid valve	95	44,2	
	201	PCB of main control circuit	130	42,7	
	111	Water heater	Ref.	57,9	
	116	Main control panel	48	45,6	
	211	Control panel	48	45,3	
	106	Enclosure of floor box	48	42,7	
	109	Foot switch	48	40,9	
	207	Surface of X ray film viewer	60	44,6	
	208	Lamp cover	71	64,4	
	209	Lamp holder	60	42,7	
	210	Patient chair surface	43	40,5	
	114	Operator side of dental hand-piece	56	39,3	

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

	115	**Multifunctional air and water hand-piece**	**48**	**42,5**	**t < 1 min**

Supplementary information:

1) Maximum allowable temperature on surfaces of test corner is 90 °C

2) Max temperature determined in accordance with 11.1.3e)

3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

4) Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.

- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

5) **APPLIED PARTS** intended to supply heat to a **PATIENT - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

6) Tested in both 207 V and 253 V, only recorded the highest temperature value.

Information from Risk Management, as applicable:
Refer to risk management report No. KASO-CE-01-09.2, Version C/01, Cl.11.1

11.1.3d	**TABLE: Temperature of windings by change-of-resistance method**	**N/A**

Temperature T of winding:	**t_1 (°C)**	**R_1 (Ω)**	**t_2 (°C)**	**R_2 (Ω)**	**T (°C)**	**Allowed T_{max} (°C)**	**Insulation class**

Supplementary information:
Transformer had been approved by EN 60601-1:2006+A1:2013
Details refer to Table 8.10

11.2.2.1	**TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source**	**N/A**

Areas where sparking might cause ignition:	**Remarks**
1.	
2.	
3.	
4.	
5.	
6.	
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):	**Remarks**
1.	
2.	
3.	
4.	
5.	
6.	

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**
Oxygen concentration (%)..... :		
Fuel..... :		
Current (A)..... :		
Voltage (V)..... :		
Capacitance (μF)..... :		
Inductance or resistance (h or Ω).... :		
No. of trials (300 Min)..... :		
Sparks resulted in ignition (Yes/No) :		
Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur. **Information from Risk Management, as applicable:**		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

11.6.1	**TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances**		**P**
Clause / Test Name	**Test Condition**	**Part under test**	**Remarks**
11.6.2/ Overflow	The liquid reservoir is filled completely and subsequently a further quantity equal to 15 % of the capacity of the reservoir is added poured in steadily over a period of 1 min.	Liquid reservoir	No break down
11.6.3/ Spillage	A quantity of 200 ml of normal tap water is poured steadily on an arbitrary point on the top surface of the equipment, for approximately 15 s, from a height not exceeding 5 cm	Top surface of equipment	No break down
13.6.2/ Leakage	Applied small amount of water near coupling and tubing connection	Water bottle and incoming water connection point	No break down
11.6.5/ Ingress of water	IPX4	Foot switch	No break down
11.6.6/ Cleaning, disinfection	According to Operation Manual	Whole equipment	No break down
11.6.7/ Sterilization	According to Operation Manual	Handle and nozzle of three-way syringe	No break down

Supplementary information:

Information from Risk Management, as applicable:

Refer to risk management report KASO-CE-01-09.2, annex 2 _11.6 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4)

After required sterilization procedure, the equipment was tested by leakage current test and dielectric strength test. No obvious effect on the result.

13.1.2	**TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances**			**P**
Power dissipated less than (W)..... :		**15**		
Energy dissipated less than (J)..... :		**900**		
Part or component tested	**Measured power dissipated (W)**	**Calculated energy dissipated (J)**	**SINGLE FAULT CONDITIONS waived (Yes/No)**	**Remarks**
Output capacitance	20 VA	/	No	--

Supplementary information:

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive		P
Clause No.	**Description of SINGLE FAULT CONDITION**	**Results observed**	**HAZARDOUS SITUATION (Yes/No)**
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Clause 8.1:**	—	—
	Output capacitance	No control work, device did not work as normally. No other hazardous situation	No
13.2.3	**Overheating of transformers per Clause 15.5:**	—	—
	Transformer had been approved by EN 60601-1:2006+A1:2013 Details refer to Table 8.10		
13.2.4	**Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:**	—	—
	Short circuit thermostat	Thermal cut-out operated and self-resetting	No
	Heating with water container empty	Thermal cut-out operated and self-resetting	No
13.2.5	**Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:**	—	—
	N/A		
13.2.6	**Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)**	—	—
	Refer to RM report KASO-CE-01-09.2	Electric part was not wet	No
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	—	—
	Single ventilation fans locked consecutively	N/A	
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	N/A	
	Simulated blocking of filters	N/A	
	Flow of a cooling agent interrupted	N/A	
13.2.8	**Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:**	—	—
	Lock lifting motor for 30s	No obvious temperature rise; The temperature of other parts below the limited value	No

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Lock backrest motor for 30s	No obvious temperature rise; The temperature of other parts below the limited value	No
13.2.9	**Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10**	**—**	**—**
	N/A		
13.2.10	**Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:**	**—**	**—**
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time:	Lock motors for 30s, see 13.2.8	NO
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices	--	--
	Temperatures measured as specified in 11.1.3 d)	--	--
	Temperatures did not exceed limits of Table 26	--	--
13.2.11	**Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:**	**—**	**—**
	N/A		
13.2.12	**Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):**	**—**	**—**
	Failure of the movement limit device	No over-travel or unintended movement	No

Supplementary information:

[1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

Information from Risk Management, as applicable:

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

15.3	**TABLE: Mechanical Strength tests** [1)]		**P**
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	**Push Test**	**Force = 250 N ± 10 N for 5 s**	**Pass**
15.3.3	**Impact Test**	**Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m**	**Pass**
15.3.4.1	**Drop Test (hand-held), hand piece**	**Free fall height (m) = 1m**	**Pass (dental handpiece)**
15.3.4.2	**Drop Test (portable)**	**Drop height (cm) =**	**N/A**
15.3.5	**Rough handling test**	**Travel speed (m/s) =**	**N/A**
15.3.6	**Mould Stress Relief**	**7 h in oven at temperature (°C) = 70**	**Pass**
Supplementary information:			

15.4.6	**TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests**				**P**
Rotating control under test	**Gripping diameter "d" of control knob (mm)[1]**	**Torque from Table 30 (Nm)**	**Axial force applied (N)**	**Unacceptable RISK occurred Yes/No**	**Remarks**
Water pressure adjustment valve of hand piece	8,7	1,0 Nm	100 N	No	--
Supplementary information: [1] Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)					

15.5.1.2	**TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION**						**N/A**
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)[1] ....:							**—**
RATED input frequency (Hz) .....:							**—**
Winding tested	**Class of insulation (A, B, E, F, or H)**	**Type of protective device (fuse, circuit breaker) /Ratings**	**Protective device operated Yes/No**	**Time to THERMAL STABILITY (when protective device did not operate)(Min)**	**Maximum allowed temp from Table 31 (ºC)**	**Maximum winding temp measured (ºC)**	**Ambient (ºC)**
Supplementary information: [1] Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION. Transformer had been approved by EN 60601-1:2006+A1:2013, Details refer to Table 8.10							

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**

15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated		N/A
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1].. :			
RATED input frequency (Hz) ..... :			
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A) ..... :			
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A)..... :			

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)

Supplementary information:
[1] Loads on other windings between no load and their NORMAL USE load.
Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32.
Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.

Transformer had been approved by EN 60601-1:2006+A1:2013, Details refer to Table 8.10

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				N/A
Transformer Model/Type/ Part No	**Test voltage applied between**	**Test voltage, (V)**	**Test frequency (Hz)**	**Breakdown Yes/No**	**Deterioration Yes/No**

Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

Transformer had been approved by EN 60601-1:2006+A1:2013, Details refer to Table 8.10

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS				N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	**Allowable TOUCH CURRENT in NORMAL CONDITION (µA)**	**Measured TOUCH CURRENT in NORMAL CONDITION (µA)**	**Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)**	**Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)**	
Supplementary information:					

Attachment 1: Photo documentation

Details of: KS-DLX301

View:

[☒] general

[ ] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Attachment 1: Photo documentation

Details of: KS-DLX301

View:

[☒] general

[☒] front

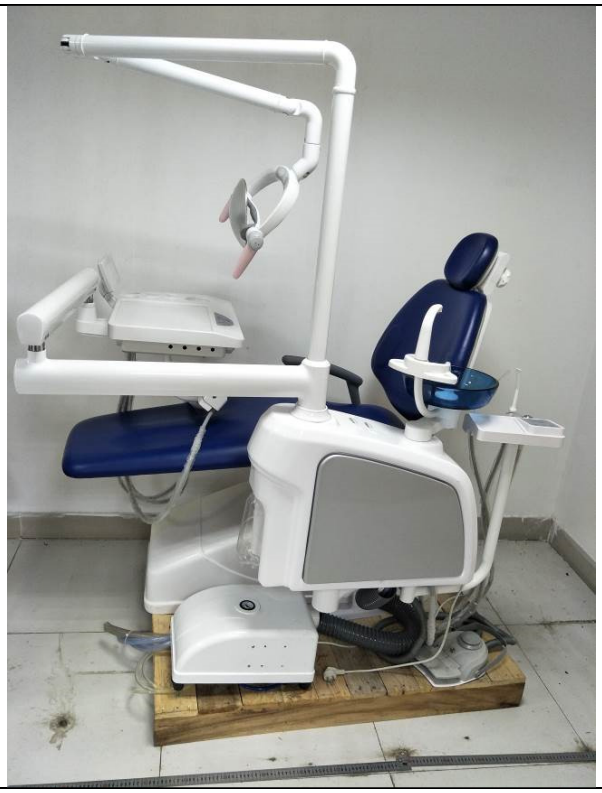
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo documentation

Details of: KS-DLX301
Support system

View:

[☒] general

[☒] front

[ ] rear

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[ ] top

[ ] bottom

Attachment 1: Photo documentation

Details of: KS-DLX301
Support system

View:

[☒] general

[☒] front

[ ] rear

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[ ] bottom

Attachment 1: Photo documentation

Details of: KS-DLX301
Motor

View:

[☒] general

[☒] front

[ ] rear

[ ] right

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[ ] top

[ ] bottom

Details of: KS-DLX301
Internal view of motor

View:

[☒] general

[☒] front

[ ] rear

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Attachment 1: Photo documentation

Details of: KS-DLX301
Heter

View:

[☒] general

[☒] front

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Details of: KS-DLX301
Thermal state of heater

View:

[☒] general

[☒] front

[ ] rear

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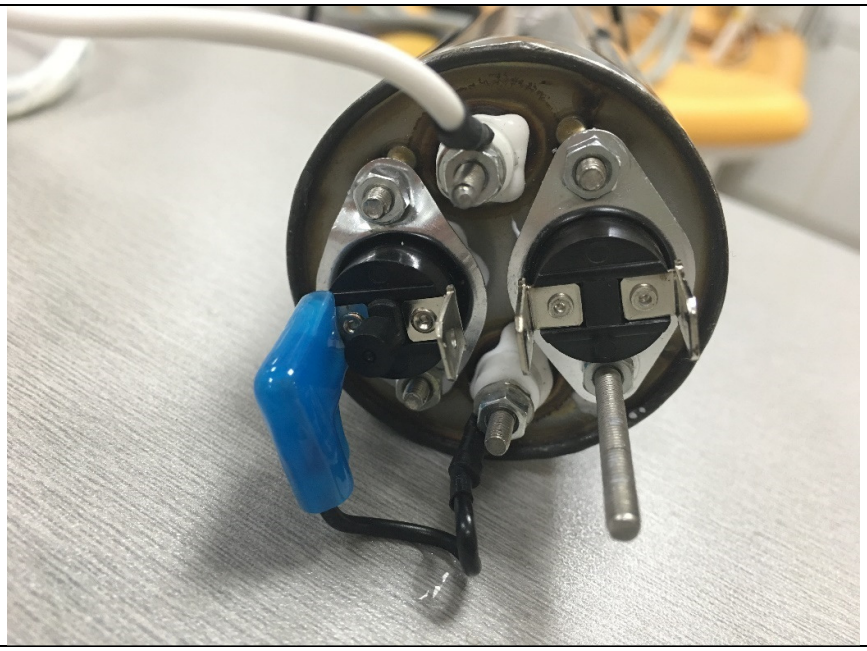

Attachment 1: Photo documentation

Details of: KS-DLX301
Control panel

View:

[☒] general

[☒] front

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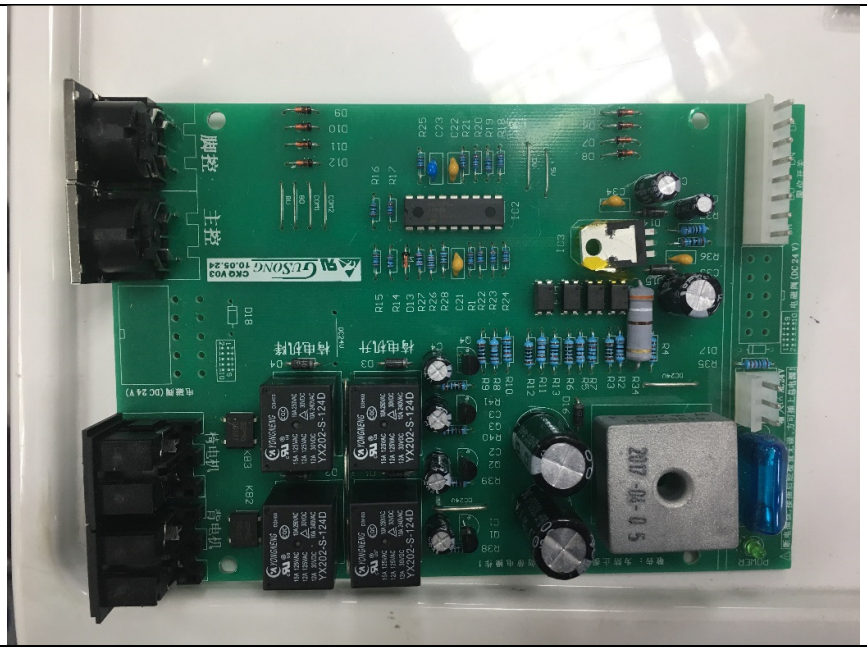

Details of: KS-DLX301
Control panel

View:

[☒] general

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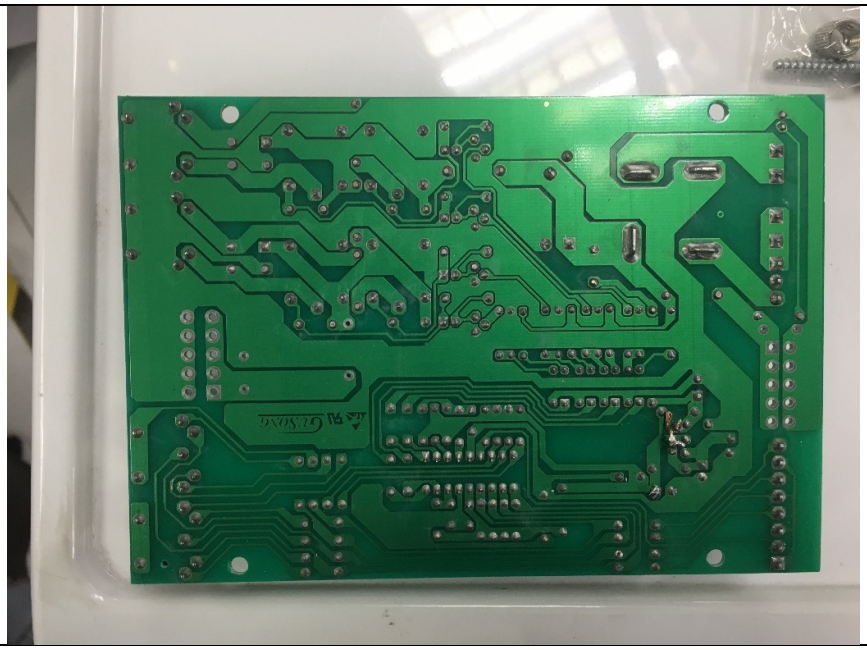

Attachment 1: Photo documentation

Details of: KS-DLX301
Transformer

View:

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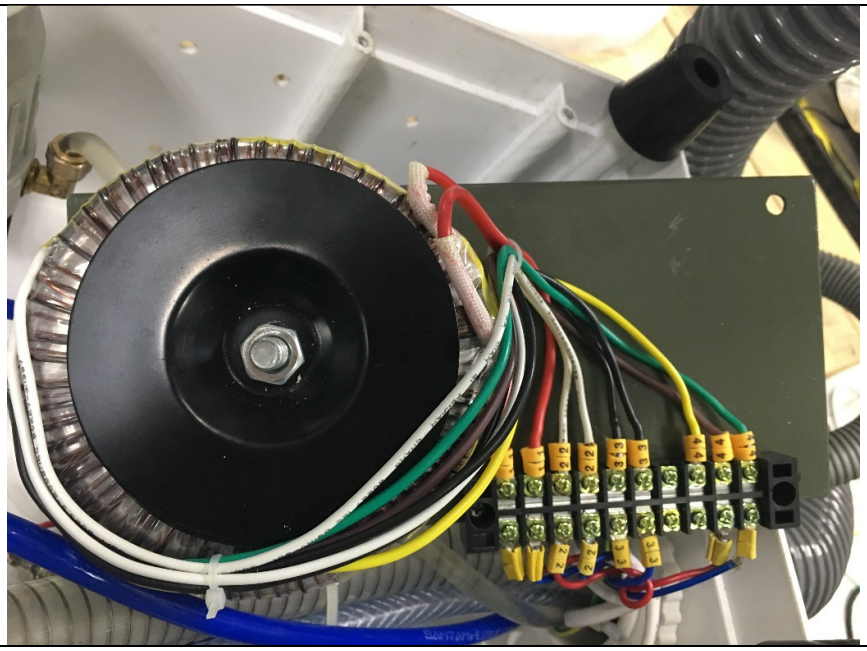


Details of: KS-DLX301
Foot switch

View:

[☒] general

[☒] front

[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom

Attachment 1: Photo documentation

KS-DLX301
Details of: Foot switch internal view
Customers have added waterproof adhesive and waterproof film between gaps

View:

[☒] general

[☒] front

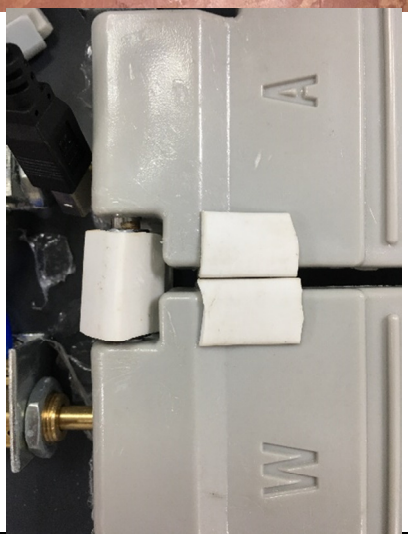
[ ] rear

[ ] right

[ ] left

[ ] top

[ ] bottom



Attachment 1: Photo documentation

Details of: KS-D106

View:

[☒] general

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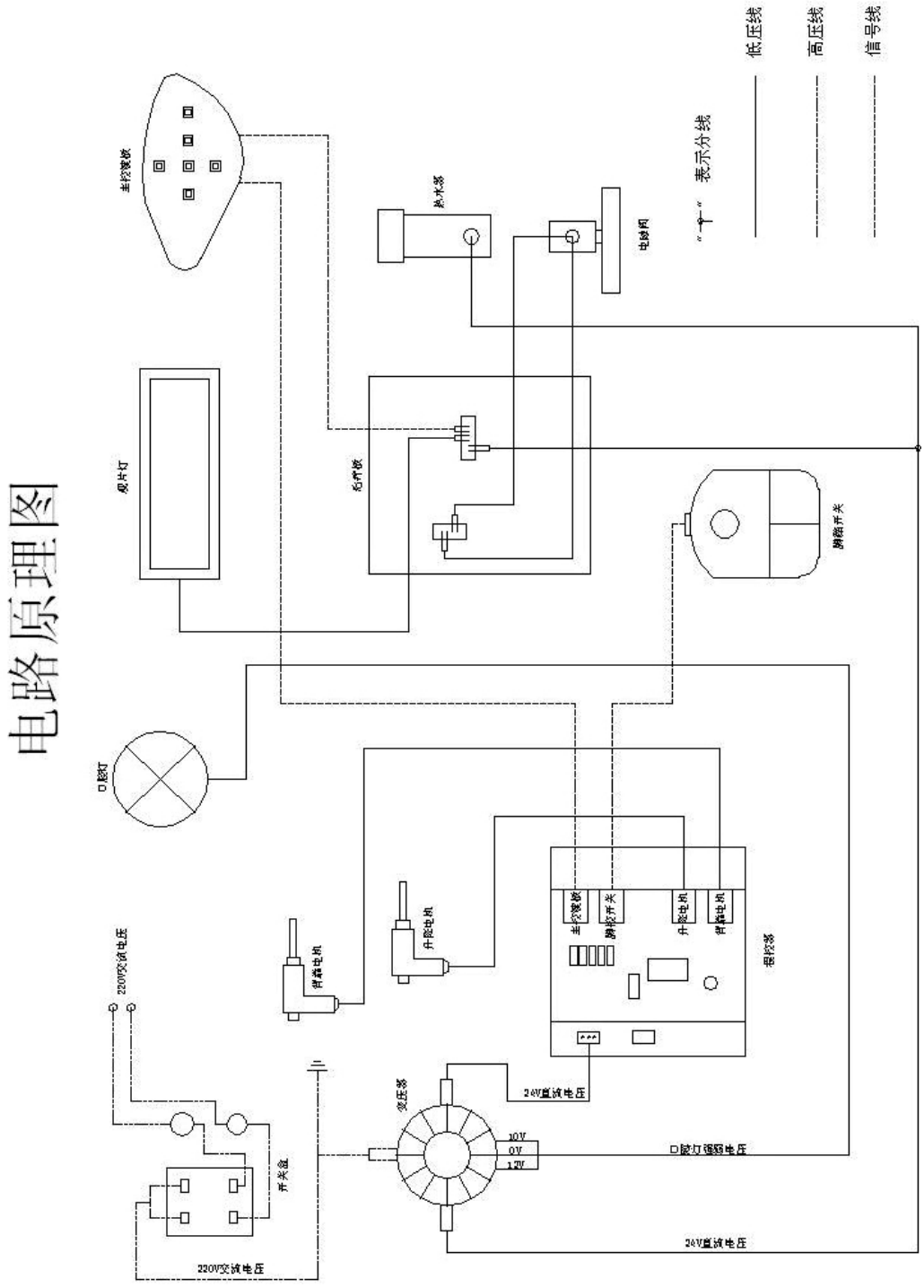
Attachment 2: Electrical wiring diagram

Electrical diagram document



-- End of the report --

ISO 13485：2016

Foshan City Kaso Medical Equipment Co., Ltd.

Manual of Dental Comprehensive Treatment Machine

KS-DLX301

Catalog

一. Main Safety features

1. Classification by the types of electric shock prevention: Class I.
2. Classification by the type of electric shock protection: B type application.
3. Classification by the degree of protection against fluid intake: Pedal switch IPX1.
4. Classification by the degree of safety when using flammable anesthesia gas mixed with air or with oxygen or nitrous oxide: non-AP/APG type.
5. Classification by operation mode: intermittent operation.

二. Main technical parameters

Rated voltage and frequency: AC 220V, 50Hz
Input power: 800VA
protective tube: 5*20mm, F5AL250V
Emission capacity: ≥50L/min
High-speed hand piece: No-load speed 300000-500000 r/min (four holes) Working pressure: 0.22MPa
Low-speed hand piece: No-load Speed < 20000r/min (four Holes) Working Pressure: 0.30MPa
Oral lamp illumination: no less than 8000lx-20000lx
Radiation heat: <350 W/m2 (maximum illumination)
Dental chair load capacity: 140 kg
Strong dental pump: When the pressure is 400 kPa, the pumping rate is more than 1000 ml/min.
Weak dental pump: When the water pressure is 200 kPa, the pumping rate is more than 400 ml/min.
Input air pressure: 0.50-0.6 MPa Flow Rate ≥50L/min (Oil-free compressed air)
Input water pressure: 0.2-0.4 MPa Flow rate ≥10L/min (water quality indicators such as hardness ≤ 2.14 mmol/l should meet the drinking water standards, and take heed of the laws and regulations of water quality
Temperature of mouthwash water: 40 +5 ℃
Spittoon drainage rate: no less than 4L/min.
Noise: < 70 dB(A)
Pedal switch: IPX1
View-box: LED bulb
Brightness: ≥800cd/m^2 Operating voltage: AC24V Frequency: 50Hz Rated power consumption: ≤25w
The color temperature of the light source through the observation screen: no less than 6500K.
The stability of the brightness of the observation screen: less than 2%.
Conditions of use: Environmental illumination ≤100lx. The screen should be checked for dark spots once a month.
Sizes and types of suitable photographs: oral medical X-ray film (140 x 70 mm)
Overall size: Complete shrinkage: length (1500mm)x width (950mm)x height (1600mm)
Complete extension: length (3200mm)*width (2100mm)*height (1850mm)
The total mass: 200 kg.
Working environment requirements:
Ambient temperature: 5-40 ℃ Relative humidity ≤ 80%
Specification of filter element: water < 90um, gas < 25um
Water pipeline: polyurethane material, colorless and transparent; Gas pipeline: polyurethane material, blue
The load capacity of the locking device of instrument tray: ≤5 Kg; Range of up-down movement: ＞300 mm; Rotation angle: ＞160 °
When the instrument tray is extended, it should be noted that the maximum distance between the center of the instrument tray and the center of the pillar should be: ≤1200mm, and the load capacity on the instrument tray should be: ≤5kg, otherwise it is easy to cause the rollover of dental chair.
The maximum height of the cushion: ≥880 mm.
The minimum height of the cushion: ≤480 mm.
The range of backward tilt angel of the headrest: 105 °-170 ° Expansion rate of hear rack: 150mm

Maximum backward tilt angle of cushion: ≥12°

二. **Ranage of application:** For the diagnosis and treatment of stomatology department in medical sector.

三. Structure composition

The dental treatment machine is composed of a dental chair and a treatment control machine.

1. The dental chair mainly consists of motor, programmable controller, cushion, backrest and headrest.

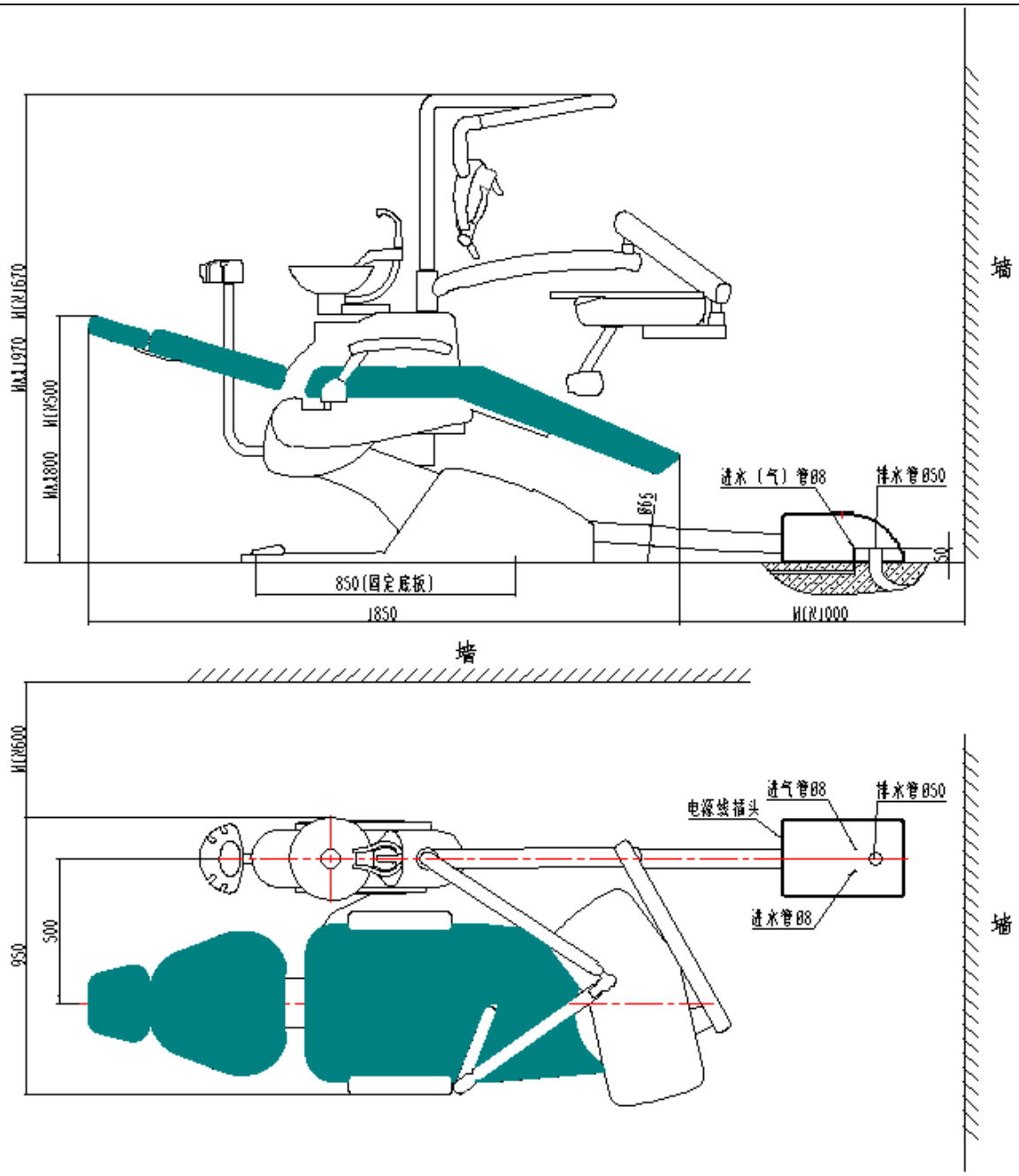
2. The control part of the treatment machine mainly includes: vertical box, ground box, spittoon, instrument tray, balance arm of instrument tray, auxiliary control box, oral lamp, balance arm of oral lamp, viewing lamp, three-purpose spray gun, pedal switch and strong or weak dental pump.

4 5 6 7

1. Main body of dental chair 2, Backrest 3, Headrest 4, Auxiliary control box 5, Spittoon 6, Oral lamp 7, Balance arm of oral lamp 8. Balance arm of apparatus disk 9, Viewing lamp 10, Apparatus disk 11, Hand piece hanger 12, Ground box 13, Pedal switch

一.Installation & Adjustment

＊ Installation



1. According to the general layout of your clinic, illumination, convenience for use and other specific circumstances, determine the installation location of the equipment (see figure above). The working environment requires to be clean, dry, and in good ventilation with shade. The floor contacted by the dental chair should be smooth and firm, and no obstacles will be encountered during the whole lifting process.
2. Take out the floor plate of dental chair, screw six M12 hexagonal adjusting screws in the accessories into the threaded holes around the corner of the floor, adjust the dental chair into a horizontal and stable position, and then cover the floor plate.

3.The standard of this machine is built-in ground box

(optional external ground box, and the connection method is the same

as the built-in ground box), and the water and gas intake joints are in the

built-in ground box. Take out the two φ8×5mm pipes in the accessories and connect the water intake and gas intake joints (colorless pipes are water pipes, blue pipes are gas pipes) in the floor box with external water and gas sources, so as to ensure that the connection is firm without leakage. (See the right diagram)

Note: Install a one-way valve on the intake pipe to prevent the back suction of treated water.

1.Insert the headrest rod into the long square hole on the back, and adjust it to a suitable position and loosen it.

2. Insert the three drainage pines into the φ50mm PVC drainage pipe as shown in the diagram, and reset the front cover of the dental chair.

3. Connect the wires in the lamp arm with those in the case rack through decorative rings and lamp post; cover the lamp post with decorative rings on the case rack; connect the lamp arm with the oral lamp and fasten it with screws, as shown in the pictures below.

* Adjustment

After all the installations are completed, it enters the adjusting stage of the machine. Connect the power supply, water source and gas source, so that the equipment is in standby state (the power indicator lights on the control panel of the instrument panel).

1. Open the front shell to observe whether the barometer reading on the air filter pressure-relief valve is 0.6Mpa. If the pressure is too high or too low, it is necessary to adjust the air filter pressure-relief valve to maintain 0.6Mpa. (Specific method is: first pull up the knob on the top of the air filter pressure-relief valve, then rotate the knob. Clockwise rotating increases pressure, while anti-clockwise rotating decreases

pressure).

Air filter pressure-relief valve

2. Pull the pedal-controlled electric switch on the pedal switch to observe whether the lifting movement of the dental chair is normal. The same operation is done to the lifting button of the dental chair on the control panel of the instrument tray and the assistant rack to observe whether the movement of the chair is normal.

3. Turn on the oral lamp to see if the light switch is normal; turn on the viewing lamp to see if it is normally lit. (See pictures below)

4. Install high-speed and low-speed hand pieces separately to check whether the water and gas functions are normal. The working pressure of high-speed hand piece is about 0.22 Mpa, while that of low-speed hand piece is about 0.32 Mpa. (See picture below)

Note: This dental treatment machine must connect and use a hand piece with anti-suction function.

图

5. Install the heads of three-purpose spray guns, strong and weak dental pumps to check whether their functions are normal. Carefully inspect the dental pumps: adjust the intake pressure as follows: 0.2Mpa-0.4Mpa take a glass of water, pick up the pumping head from the auxiliary hanger, put the pumping head into the water, and observe whether the water suction is smooth (about 300ml after 30 seconds is normal).

Note: 84 disinfection water inhalation method can be applied to disinfect the contact areas with patients and pipelines.

六. **Operation Instruction**

Turn on the power, water, and air sources of the equipment, adjust the dental comprehensive treatment machine to a suitable position, and put the machine on standby.

1. Three-purpose gun: After removing the three-purpose gun, press the corresponding water (air) button to spray water (air), and press at the same time to spray.
2. Strong and weak saliva suction device: Pull the strong and weak saliva suction device from the shelf to use, and plug it back into the shelf to close it.
3. Main control panel: (The panel is installed on the instrument tray as shown in the figure below)

1 2 3 4 5 6 7 8

17 16 15 14 13 12 11 10 9

NO.	Name	No.	Name
1	Setting	10	Chair Down-lifting
2	Flush	11	Memory position 3
3	Water supply	12	Memory position 2
4	Heating	13	Memory position 1
5	Spitting Position	14	Memory position
6	Reset	15	View Lamp
7	Chair Up-lifting	16	Oral Lamp
8	Backrest Forward Leaning	17	Lock

9	Backrest Back Tilting		

Connect the power source, water source and gas source of the equipment, and adjust the dental comprehensive treatment machine to a suitable position, so that the machine is on standby.

1, Three-purpose spray gun: after the gun is taken off, press the corresponding water (gas) button to spray water (gas), and press the atomizing button at the same time.

2. Strong and weak dental pumps: pull strong and weak dental pumps out of shelves and close them when insert them back to shelves .

3. Main control panel: (as shown above, the panel is installed on the instrument tray)

* Set button 1

(1) Water supply and water supply setting

Press the setting button for 5 seconds till the indicator light to enter setting .

Press the water supply button 3 to start feeding water; when the water in the cup reaches the required amount of water, release the water supply button and stop the water supply.

Press the setting button again, the indicator will be off and the setting is completed. The computer has made a new memory. When you use it later, just tap the water supply.

The key will automatically feed the water to the water in the cup. (If the water pressure suddenly changes a lot or when the cup size is changed, please press The steps described re-adjust the amount of water supplied.)

This setting can be saved after power off.

(2)Flush time setting

Press the setting button for 5 seconds to set the indicator light to enter the setting state.

Press the flush button 2, the specific time is as follows:

Press the first time and make a sound.

Press the second time and make two sound.

Press the third time and ring three times.

Press the fourth time and ring four times. (Normally open)

The number of prompts respectively indicates the flush time mode (the time is changed from short to long).

After the setting is completed, press the SET button again, and the setting indicator is off, indicating that the flushing time has been saved. (In the process of watering, press the flush button.

Stopping and stopping).

This setting can be saved after power off.

(3) Restore factory settings

Press and hold the setting button for 15 seconds, the setting indicator lights, and the dental chair starts to move itself after long buzzer sounds. At this time, release the setting button,
dental chair will go the highest seat, the front of the backrest and the seat is the lowest. After the last position of the backrest, the buzzer will automatically find the double high and low low.

carry out.

The setting indicator is off, indicating that the memory bit has been saved.

This setting can be saved after power off

（4）Memory setting

Tap this key to enter three different doctor memory positions. During the memory operation, the memory position indicator on the control panel corresponds to the blue display.

The memory bits are set as follows:

A+ (1, 2, 3) is three memory positions

B+ (1, 2, 3) is three memory bits

C+ (1, 2, 3) is three memory bits

Press the setting button lightly for 5 seconds, the setting indicator will light up to enter the setting state. At this time, you can adjust the height of the electric dental chair by pressing the seat up button, seat down button, backrest back button, and backrest forward button. Example: First press the memory position selection key to switch the doctor position, the doctor indicator on the control panel a is always on, lightly press and hold the chair up button and the chair down button, press P1 memory position one after the state is adjusted. The other memory bits can be deduced by analogy. After setting, you can tap the setting button to exit the setting. The indicator light is off, indicating that the memory bit has been saved.

* Flushing spittoon 2

Tap the flush button once to start flushing. The flush icon on the control panel will be displayed in blue until it stops automatically at the preset time.

The color returns to white; during the flushing process, if you press this button again, the flushing stops.

Flushing preset time setting: press and hold the SET button for 4 to 5 seconds, and let go when the setting indicator on the control panel turns blue.

Press the red button in turn, there are four time modes (the setting button has been introduced above)

* Water supply button 3 (with solenoid valve and heating device)

Press the water supply button lightly to start water supply. The water supply icon on the control

panel will be displayed in blue until it stops automatically at the preset time.

The color returns to white; during the water supply process, if you press this button lightly again, the water supply will stop.

Water supply preset time setting: lightly press the setting button for 4 to 5 seconds, let go when the setting indicator on the control panel turns blue, press

Hold down the water supply button, let go after the required time is reached, the setting is completed, and then press the set button to exit.

* Heating key 4

Press the heating button lightly, the heater starts to heat, the heating icon on the control panel is displayed in blue, when the temperature reaches the set, the heater stops Stop heating, the color of the icon will return to white; during the heating process, if you press the key lightly, heating will stop.

* Spitting key 5:

Press this button lightly, the backrest of the electric dental chair is tilted forward to the extreme position, at the same time the dental lamp is turned off, the flushing is turned on, and the control panel The phlegm position and flush button are displayed in blue. After the spitting is completed, you only need to press this button again, and the back of the electric dental chair will move to the previous treatment position.When it is in place, the dental light will be turned on, the flushing will be turned off, and the dental light button on the control panel will be displayed in blue; press any direction key once to stop it immediately action.

* Reset button 6:

Press the reset button lightly, the electric dental chair immediately runs to the initial state, the dental lamp and the film viewing lamp are automatically turned off; the seat is lowered to the lowest Position, the backrest is tilted forward to the extreme position to facilitate the patient to go up and down; press any direction key during operation to stop the movement immediately Made.

* Seat up key 7:

Press this key lightly, the electric dental chair will move in the direction indicated by the arrow (up), and the upward icon on the control panel will be displayed in blue. Meet the needs

Position, release this button, the electric dental chair will stop running immediately, and the control panel icon will be displayed in white (if you keep pressing this button, the dental chair

When the chair rises to the limit position, it will stop automatically.).

* Backrest forward key 8:

Press and hold this button, the backrest of the electric dental chair will move in the direction indicated by the arrow (front), and the back-up icon on the control panel will be displayed in blue.When the desired position is reached, release this button, the backrest of the electric dental chair will stop running immediately, and the control panel icon will display in white (if you keep pressing Hold this key, the dental chair will stop automatically when the backrest reaches the limit position.)

* Lean back key 9:

Press and hold this button, the backrest of the electric dental chair will move in the direction (rear) shown by the arrow, and the back down icon on the control panel will be displayed in blue.

When the desired position is reached, release this button, the backrest of the electric dental chair will stop running immediately, and the control panel icon will display in white (if you keep pressing Hold this button, the dental chair will stop automatically when the backrest reaches the limit position.)

* Seat down button 10:

Press and hold this button, the electric dental chair will run in the direction indicated by the arrow (down), and the down icon on the control panel will be displayed in blue. achieve

When the desired position is required, release this key, the electric dental chair will stop running immediately, and the control panel icon will be displayed in white (if you keep pressing this key,

The dental chair will stop automatically when it descends to the extreme position.

* Memory keys 11, 12, 13:

Tap the corresponding 3 keys to enter three different doctor memory positions. The memory position indicator on the control panel during memory operation The indicator light corresponds to the blue display.

* Doctor's position key 14:

Tap this key to select back and forth among the three doctor positions "A", "B", and "C".

* Film viewing light button 15

Lightly press the movie viewer button to turn on the movie viewer, and the movie viewer icon on the control panel will be displayed in blue. Tap the button to turn off the movie viewer.

The film light, the color of the icon returns to white.

* Dental light key 16

Tap the dental lamp button to turn on the dental lamp, the dental lamp icon on the control panel will be displayed in blue, and then tap the button to turn it off Dental lamp, the icon color returns to white.

* Lock motor key 17

Lightly press this button, the control panel icon will be displayed in blue, the motor status is the seat up and down buttons, the backrest forward and backward buttons stop operation

Function, lock the motor; press this key again to unlock the motor state, the motor state is the seat up and down button, the backrest is tilted forward and backward Back key to restore operation function.

4、Water and air switch (see the picture

on the right)

Left: Water switch

Right side: Water purification bottle gas switch

（Located in front of the box）

* Water transfer switch Press the water transfer switch button to use an external water source, pull out the button to use pure water bottle water.

* Water purification bottle gas switch Turn on the water purification bottle gas switch to inflate the water purification bottle with pressure.

5、Assistant control (see picture below)

1 2 3 4 5

1 control panel (functions the same as the main control panel)

2 Three way syringe holder

3 Strong suction seat

4 Weak suction seat

5 Reserve the light curing base

6、Pure water bottle:

There is a pure water bottle in the box of this equipment, which is used by the three-purpose gun and mobile phone. First switch to the pure water bottle water source through the water switch, then turn off the water bottle control air switch and turn off the water bottle, add about 600ml of pure water to the water bottle, install the water bottle and screw it tightly, turn on the water purification bottle air switch, and then use the gun and mobile phone for three times Use pure water. Turn off the water cup control gas switch, and switch to an external water source through the water switch. At this time, the three-purpose gun and mobile phone use the external water source.

Precautions:

In order to ensure that the control air pressure of the water cup is within the range of 0.18～0.2Mpa,

There is a pressure reducing valve in the equipment box, which is reduced when the equipment leaves the factory.

The pressure of the pressure valve has been adjusted. Non-professionals should not adjust this valve. (See picture on the right)

7、Foot controller (see picture below)

1	**UP-Seat up**
2	**BD-lean back**
3	**BU- Backrest forward**
4	**DN- Seat down**
5	**Chip blowing switch**
6	**W water supply**
7	**A air supply**

8、High and low speed phones:

Pull the high-speed mobile phone out of the shelf, place the water and air switch on the right and step on the pedal, and the phone is in the air supply state; place the water and air switch on the left and step on the pedal, and the

phone is at the same time water supply and air supply. In the spray working state, adjust the corresponding water control valve knob to adjust the spray size of the mobile phone. The water control knob is at the lower right of the instrument panel; when you step on the chip blowing button, the phone only has the chip blowing function. The working gas of the mobile phone is adjusted by the knob of the gas regulating valve, which is located at the bottom of the diaphragm valve just below the instrument tray. The operation method of low-speed mobile phones is the same as that of high-speed mobile phones.

Precautions:

* When adjusting the water regulating valve and the gas regulating valve, the water and gas should be adjusted gradually from small to large to achieve the best atomization effect. Do not start the phone without load or overvoltage, otherwise it will affect the life of the phone. Please do not adjust the working pressure of the worm gear to the maximum, so as not to affect the bearing life.

9、Operating instructions for the instrument tray (see the figure below)

The instrument panel adopts a full air control system. When any mobile phone is selected, its central control valve will automatically open to provide power air and cooling water. The schematic diagram of each valve switch is as follows:

1 2 3 4 5

6 7 8 9

10 11 12 13

1	Pressure meter	8	Low speed handpiece water adjustor
2	Voltmeter	9	Atomizer water regulating valve
3	Holder box	10	Air reducer

4	Instrument tray handle air lock valve	11	Air adjuster 1
5	Touch screen	12	Air adjuster 2
6	Handpiece air adjuster 1	13	Air adjuster 3
7	Handpiece air adjuster 2		

Work performance

9.1 Pressure meter

Display the current working pressure of the handpiece；

9.2 Voltmeter

Display the voltage of the current power supply；

9.3 Holder Box

There is a rack valve core in the rack box, and there is an M4 screw on the back to adjust the working pressure of the handpiece.

The working air pressure of the machine decreases to off, and increases counterclockwise. Non-professionals should not adjust at will；

9.4 Instrument tray handle airlock

Here the switch is in the normally open state, the spring arm is self-locking, and the worktable is fixed at the selected height. When adjusting the height of the workbench, press Switch button, after adjusting the workbench to the selected position, release the button。

9.5 Touch screen

After turning on the power, operate the dental chair function (the specific operation has been described above);

9.6 High-speed mobile phone water regulating valve

6. 7 This is the adjustment of the atomization size of the water for two high-speed mobile phones. When rotating clockwise, the atomization of the cooling water of the mobile phone is reduced to off, and counterclockwise is increased;

9.7 Low-speed handpiece water regulating valve

9 This is the adjustment of the atomization size of the low-speed mobile phone water. When rotating clockwise, the atomization of the mobile phone cooling water is reduced to off, and counterclockwise is increased;

9.8 Atomizer water regulating valve

10 is the adjustment of the atomization size of the cooling water of the light curing machine. When the atomization cooling water is turned clockwise, the atomization cooling water is reduced to off, and it is increased in the counterclockwise direction.

9.9 Return gas cylinder

Collect the return water mist in the mobile phone tube;

9.10 Air control valve

The size of the three sets of mobile phone cooling water is adjusted. When rotating clockwise, the cooling water of the mobile phone is reduced to off, and counterclockwise is increased.

7. Maintenance

1. Air filter pressure reducing valve

In order to ensure the stable, clean and dry gas pressure in the equipment, the pressure reducing valve adopts glass fiber filter paper for air filtering, and an air filtering pressure reducing valve is provided at the air inlet in the external ground box。

Schematic diagram of air reducer Schematic diagram of hanger spool

Precautions:

A. After the moisture-containing air passes through the filter pressure reducing valve, the filtered moisture will accumulate and settle in the filter cup. Over time, it will affect the filtering effect. Under normal circumstances, there is one of the following conditions to drain the air filter pressure relief valve. (Unscrew the knob at the bottom of the filter cup to discharge)

* The use time is more than one week;
* The accumulated water in the filter cup exceeds 3/4 volume (including 3/4);
* The water in the filter cup changes color.

B. The filter element should be cleaned once a month. Remove the filter element and wash it with an ultrasonic cleaner or a neutral detergent.

2. Water filter

In order to ensure that the water input to the equipment is clean, a PP material filter element is used for filtering, and a water filter is installed in the external ground box.

Precautions:

The filter element of the filter is cleaned once a month (depending on the water quality and frequency of use). Remove the filter element and wash it with an ultrasonic cleaner or a neutral detergent.

3、Spittoon

The spittoon must be cleaned regularly, and the filter should be cleaned once a day to prevent clogging of the drain.

4、Pylon valve

The O-rings of the pylon spool are easy to wear parts and will wear out or age over time. When the pylon

spool can no longer be adjusted, the O-rings need to be replaced.

5、Film viewer

The film viewer is used to view X-ray film. After a long time of use, the lamp tube will be damaged, and it needs to be replaced at this time. The specific method is: first cut off the power, then unscrew the screw on the cover of the film viewer, remove the broken U-shaped energy-saving lamp, replace it with a new U-shaped energy-saving lamp, close the cover and install the screws When in use, just turn on the side switch of the film viewer screen.

Note: This film viewer lamp uses 24V voltage, and the power supply should be cut off before maintenance; the film viewer is a high-end electronic product, and bumps should be avoided;

The structure design of the film viewer is scientific and compact. Non-professionals should not disassemble and assemble it by themselves; keep the film viewer dry at all times.

6、Dental chair

The dental chair is an intermittent working equipment, and the short-term continuous operation should not exceed 1 minute. The treatment machine should be cleaned and kept tidy every day, and the cushion should be treated with wax spray regularly. Neutral detergent should be used for cleaning, and attention should be paid to whether the detergent damages the surface of the treatment machine during normal use。

7、Three-way syringe

Use a brush to scrub the surface, and then wipe it with medical alcohol. Put it into a high-temperature and high-pressure disinfection oven for disinfection (the temperature of the disinfection oven should be at135℃), packed in a special sterile bag, and time stamped.

8. Dental lamp

The maintenance of the dental lamp should be carried out at room temperature, and wipe it gently with a soft cloth dampened with clean water. The surface of the lamp film cannot be wiped, only the dust can be blown off with compressor air.

9. Strong (weak) saliva suction device

After each use, a certain amount of clean water should be sucked to ensure the smooth flow of the pipeline.

10. Pure water bottle

Clean the purified water bottle at least once a day.

11. Clean the surface of the body

The cabinet is cleaned with a damp cloth and neutral detergent to ensure that the leather surface is smooth and elastic and not corroded; PU parts and ABS parts are cleaned with a soft cloth dipped in soapy water; metal baking paint parts are cleaned with a soft cloth dipped in soapy water Wipe with car wax;

八. Troubleshooting

Failure phenomenon	cause of issue	elimination methods
1、Motor is weak	1、 Poor needle	Recalibration

	2、poor bearing	
	3、 Not enough work pressure	Check air pressure
2、 The motor is not turning smoothly	1、 Poor needle	Test bur
	2、 poor bearing	
3、 Unstable working pressure	1、 Filter blocking	Clean
	2、 Intake pipe kinking	Inspection pipeline
	3、 Gas source is not turned on	Open gas
4、 Bearing durability is poor	1、 Poor lubrication	Refer to the handpiece manual
	2、 Poor needle	
	3、 Excessive cutting	
	4、 handpiece is moisture	The filter should be drained once a day
5、 handpiece without fog	1、 Head pipe blocking	Refer to the handpiece manual
	2、 Improper adjustment of water fine-tuning	
	3、 Foot control water source is not open	Open gas
6、 handpiece water contains bubbles	1、 High speed head gasket	Refer to the handpiece manual
	2、 Tube rupture	Check replacement
7、 Handpiece water spray is poorly atomized	1、 High speed head nozzle blocking	Refer to the handpiece manual
	2、 Improper adjustment of water micro-regulator	Readjust the water adjusted valve
8、 handpiece connector leaking	1、 High speed head gasket	Refer to the handpiece manual
	2、 Excessive water in the air filter	The filter is discharged once a day
9、 The three-way syringe does not produce water	1、 Clog water pipes	Block the nozzle while pressing the water outlet button to remove debris
	2、 Unconverted water switch	Turn on the water source switch
10、 The three-way syringe contains water when it is jetted	1、 Excessive water in the air filter	The filter is discharged once a day
	2、 Valve core failure	
	3、 Nozzle is not properly installed	

11、Air leak when the handpiece is not working	1、 The normally open valve of the holder is not adjusted to the normal position	Adjust the normally open valve to the normal position
	2、 The main control valve chip has been broken	Replacement chip
12、 Dental chair does not move	1、 Power is not activated	Turn on the power
	2、 Fuse damage	Replacement bulb
	3、 Control board program error	Reset control program
	4、 The foot switch does not return air to lock the control box	Check if the foot switch is back
13、 Work light does not work or does not light	1、 Power is not turned on	Turn on the power
	2、 Lamp damage	Replacement bulb
	3、 Fuse damage	Replacement Fuse
14、 The dental chair lifts or the backrest does not move enough.	1、 Improper setting of dental chair limit position	Reset limit position
15、 Weak suction does not suck or sucks strong	1、 The tip is blocked	Cleaning filter
	2、 Normally closed valve is not adjusted to normal position	Adjust the normally closed valve to the normal position
	3、 Normally closed valve spool can not be played	Repair or replacement
	4、 Suction valve can not be opened	Repair the suction valve or replace it
	5、 Pipe folding pipe	Dredge pipe
16、 The water cup is not washed out	1、 Suction valve can not be opened	Replace the suction valve
	2、 No gas or no water	Check the air and water source
	3、 Button failure	Replacement valve
17、 The water heater is not heated	1、 No voltage to enter	Check line or switch
	2、 The water heater has been burned	Replace the water heater
18、 handpiece stays too long	1、 The foot switch is too slow	Repair or replace the foot switch
	2、 Slightly folded pipe	Check and clear
19、 Two of the three handpiece are not working properly, and the other one does not turn or water.	1、 Normally open valve is not adjusted to normal position	Adjust the normally open valve to the normal position

	2、 Normally open valve spool can not afford	Repair or replacement
	3、 The main control valve chip has been broken	Replacement chip
20、 Pick up a handpiece and hang another handpece at work.	1、 handpiece holder misplacement	Replacement position

1、The equipment nameplate is marked with the following:

⚠ Note the accompanying documentation for the device

Type B application part

2、The outer packaging wooden box is marked with the following：

Avoid heavy pressure Avoid rain Place up Fragile, handle with care Avoid sun exposure

3、Waterproof rating IPX1

4、Grounding sign

5、Check the instructions

J. Contraindications, precautions, warnings, and instructions

(1) You should read and understand all the contents in the manual before you can operate it;
(2) Follow all warnings and instructions on the instrument during operation;
(3) The power socket line should be configured according to the standard, and the grounding wire must be firm;
(4) Never open the water heater switch when there is no water supply;
(5) The instrument tray shall not be stacked with heavy objects;
(6) The air pressure of the treatment machine has been set at the factory, and non-professionals are not allowed to adjust at will;
(7) The dental chair's action limit is locked, and non-professionals are not allowed to adjust at will;
(8) The water and gas power main switch should be turned off when leaving work;
(9) The foot switch must be set to the water in the state of water to discharge water;
(10) A unit or individual clinic using the device must be equipped with or connected to an amalgam separation device (connected to the drain connector of the device) in the dental waste discharge system;
(11) During maintenance and repair, the water and electricity source must be drained after draining the water and gas, and the water and electricity source is connected before use;
(12) Put the handle and nozzle of the three-way syringe into the disinfection bag before disinfection, and then sterilize at 134 ° C (2 bar) with high pressure steam, the disinfection time is not shorter than 3 minutes;

Read the manufacturer's instructions before cleaning and disinfecting high speed turbine drills (high speed handpiece) and low speed pneumatic motors (low speed handpiece);
The outer casing is cleaned with a damp cloth and a neutral detergent to ensure that the leather surface is smooth, elastic and non-corrosive; the PU parts and ABS parts are cleaned with a soft cloth dampened

with soapy water; wipe the metal with a soft cloth dampened with soapy water or with a car spray wax
Baking part
Take special care when handling fiber optic phones to avoid damaging the illuminated end and to ensure that the head does not come into contact with the treated mixture, maintain a certain distance or use a transparent sheet within the first 5 seconds of treatment;
(16) Any traces left on the tool by the mixture must be removed immediately, the fiber optic phone is removed and cleaned with a cloth dipped in alcohol;
(17) Do not aim the light of the fiber-optic phone at the patient's eyes! The light emitted may cause harm to some patients, such as those with cataracts. Generally speaking, fiber does not cause permanent damage, but may induce temporary blindness;
The dental chair has a rated load of 140kg. If it is overloaded, it will not work properly. If it is used together with external equipment for planting work, the dental chair should be disconnected every time. To avoid personal injury due to malfunction and accidental touch of the control button;
Only remove the stylus after the high-speed handpiece and the low-speed handpiece have completely stopped, otherwise the chuck will be damaged and the bur will fall out and cause personal injury;
(20) Only use high quality burs and bolts of appropriate size;
(21) Check the damage of the chuck before starting work to determine whether the needle is securely stuck in the phone;
(22) After replacing the high-speed handpiece stylus, the stylus should be pulled out to confirm that it is installed in place;
(23) The diameter of the needle should be between 1.59 and 1.60 mm (ISO 1797 Class 3 standard), and the maximum length is 25 mm (ISO 6360-1 standard);
(24) High-speed handpiece can only be used if stylus or repair tools are installed;
(25) Do not press the release button of the bur when the tool is in use. The friction between the button and the air motor impeller may cause the head to overheat and may cause burnout;
The tissue in the patient's mouth (tongue, cheeks, lips, etc.) must be protected by a suitable method (using a mirror, etc.) to avoid touching the button;
(27) Do not touch the light bulb directly with your hand. After the bulb has cooled down, wear protective gloves and replace it to avoid burns.
(28) It is strictly forbidden to touch the PC board and the electronic components of the manufacturer by hand or metal equipment;
(29) Users should regularly maintain and replace aging-resistant accessories (such as dental handpieces);
(30) The screen of the viewing light is made of organic materials. When reading the film, avoid scratching the surface with hard objects such as the nib. Otherwise, the scratches will be difficult to eliminate, which will affect the reading afterwards. It is forbidden to use the viewing light in places where the humidity is lower than the required ambient humidity.
Note: Always turn off the power before servicing. If it is not used for a long time, check the viewing lamp at least once a month.
(31) If you need to construct materials for waterway, please contact us.

K. Transportation and storage environment requirements

a. Ambient temperature range: 5 ° C -40 ° C;

b. Relative humidity range: relative humidity is not more than 80%

c. Atmospheric pressure range: 86KPa ~ 106KPa.

Rainproof during transportation, anti-large vibration, pay attention to light handling.

The packaged equipment is stored in a well-ventilated room with a relative humidity of no more than 80%,no corrosive gases.

Parts List

No.	Name	Quantity	Replacement cycle	Replacement / use method
1	4mm Allen wrench	1	-	For fixing the dental light screw
2	Φ5×20mm，F5AL250VFuse	4	When damaged	Used to replace switching power supply insurance
3	Leveling screw	4	Chassis is not normal	Used to adjust the chassis level

L. Waste disposal instructions

1. The waste discharge system of the treatment machine is equipped with a solid collector. The collector can intercept any solid waste with a diameter of 2 mm;
2. The treatment body must be disposed of in the waste discharge system in accordance with local environmental protection requirements.
3. Disposal of wastewater and waste must comply with local environmental protection requirements.
4. The dental treatment machine must be equipped with or connected to an amalgam separation device in the waste discharge system (connected to the drain connection of the equipment);
5. Do not dispose of this device as domestic waste!
6. The product must be fully treated (cleaned/disinfected/sterilized) before disassembly/disposal.
7. Description of electromagnetic compatibility risks:

The dental integrated treatment machine designed and manufactured by the company meets the requirements of IEC60601-1-2:2001, so that the maintenance can achieve the intended operation of the company's equipment in a compatible electromagnetic environment.

8. Declaration of hazardous substances

Part Name	Toxic or harmful substances or elements					
	(Pb)	(Hg)	(Cd)	(Cr6+)	(PBB)	(PBDE)
Power cord with plug: Plug wire	×	O	O	O	O	O
switch	×	O	O	O	O	O
transformer	×	O	O	O	O	O
Fuse	×	O	O	O	O	O
Over temperature	×	O	O	O	O	O
Motor	×	O	O	O	O	O
PCB	×	O	O	O	O	O

○ mean Indicates it is toxic

The content of harmful substances in all homogeneous materials of this part is below the limit requirement stipulated in SJ/T 11363-2006 "Limited Requirements for Toxic and Hazardous Substances in Electronic Information Products".

×: Indicates that the content of the toxic and hazardous substance in at least one of the homogeneous materials of the part exceeds the limit requirement specified in SJ/T 11363-2006.

Parts with lead instructions

1. With plug power cord: plug wire / power switch Most connectors metal shell, terminals and other lead, lead and lead.

2. The internal connection point of the transformer uses a high-temperature solder with a lead content of 85% or more.

3. Fuse internal resistance lead

4. Over temperature protector internal resistance lead

5. The internal resistance of the motor contains lead.

6. PCB surface pads contain lead.

M. Electromagnetic compatibility

Notice:

- Dental unit KS-D109 meets the requirements of YY0505 standard electromagnetic compatibility.
- Users should install and use the electromagnetic compatibility information provided in the random file.
- Portable and mobile RF communication equipment may affect the performance of the dental unit, avoiding strong electromagnetic interference when used, such as near cell phones, microwave ovens, etc.
- The instructions for the guide and the manufacturer are detailed in the annex.

- Warning:

- The dental unit KS-D109 should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed that it will function properly in its configuration.
- In addition to the cable sold by the manufacturer of the dental unit KS-D109 as a spare part for internal components, the use of extra-standard accessories and cables may result in an increase in the emission or immunity of the dental unit KS-D109.

Cable information:

No.	Name	Cable length (m)	Whether to block	Remarks
1	POWER CABLE	1.5	NO	
2	FOOT PEDAL CABLE	1.5	NO	

Annex:

Guide and manufacturer's statement – electromagnetic emissions

The dental unit KS-DLX301 is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Emission test	**Compliance**	**Electromagnetic environment – guide**
Radio frequency emission GB 4824	Group 1	The dental unit KS-DLX301 uses RF energy for its internal function only. Therefore, its RF emissions are low and there is little possibility of interference with nearby electronic equipment.
Radio frequency emission GB 4824	Class B	The dental unit KS-DLX301 is suitable for use in all facilities, including domestic facilities and direct connection to residential low-voltage power supply networks.
Harmonic emission GB 17625.1	Class A	
Voltage fluctuation / flicker emission GB 17625.2	conform	

Guide and manufacturer's statement – electromagnetic immunity			
The dental unit KS-DLX301 is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guide**
Electrostatic discharge GB/T 17626.2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	The ground should be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst GB/T 17626.4	±2kV Power cord	±2kV Power cord	The network power supply should have the quality used in a typical commercial or hospital environment.
Surge GB/T 17626.5	±1 kV Wire-to-line ±2 kV Line to ground	±1 kV Wire-to-line ±2 kV Line to ground	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage dip, short in terruption and volta ge change on the p ower input line GB/T 17626.11	<5 % UT for 0.5 cycles (on the UT, >95% sag) 40 % UT for 5 cycles (on the UT, 60% sag) 70% UT for 25 cycles (on the UT, a 30% sag) <5 % UT for 5s (on the UT, >95% sag)	<5 % UT for 0.5 cycles (on the UT, >95% sag) 40 % UT for 5 cycles (on the UT, 60% sag) 70% UT for 25 cycles (on the UT, a 30% sag) <5 % UT for 5s (on the UT, >95% sag)	The network power supply should have the quality used in a typical commercial or hospital environment. If the user of the dental unit needs continuous operation during a power outage, it is

			recommended that the dental unit be powered by an uninterruptible power supply or battery.
Power frequency magnetic field （50/60Hz） GB/T 17626.8	3A/m	3A/m,50Hz	The power frequency magnetic field should have the characteristics of the power frequency magnetic field in a typical place in a typical commercial or hospital environment.
Note: UT refers to the AC network voltage before the test voltage is applied.			

Guide and manufacturer's statement – electromagnetic immunity

The dental unit KS-D109 is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity test	IEC 60601Test Level	Compliance level	Electromagnetic environment – guide
Radio frequency conduction GB/T 17626.6	3 V(effective value) 150 kHz～80 MHz	3V(effective value)	Portable and mobile RF communications equipment should not be used closer to any part of the dental unit KS-D109, including cables, than the recommended isolation distance. This distance is calculated by a formula corresponding to the transmitter frequency. Recommended isolation distance $d = 1.2\sqrt{P}$
Radio frequency radiation GB/T 17626.3	3V/m 80 MHz～2.5 GHz	3V/m	$d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz In the formula: P = in watts (W) based on the transmitter's maximum rated output power provided by the transmitter manufacturer; d—Recommended isolation distance in meters (m). The field strength of a fixed RF transmitter is determined by survey a to the electromagnetic field, and each frequency range b should be lower than the compliance level. Interference may occur near devices marked with the following symbols. 

Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band is used.
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human bodies.

[a] Stationary transmitters, such as base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, are not theoretically predictable in terms of field strength. In order to assess the electromagnetic environment of a fixed RF transmitter, the survey of the electromagnetic field should be considered. If the measured field strength of the dental unit is higher than the applicable RF compliance level above, the dental unit should be observed to verify that it is functioning properly. Additional measures may be necessary if abnormal performance is observed, such as reorienting the direction or position of the dental unit.

[b] The field strength should be less than 3V/m over the entire frequency range from 150kHz to 80MHz.

Recommended isolation distance between portable and mobile RF communication equipment and dental unit

The dental unit KS-DLX301 is expected to be used in an electromagnetic environment where radio frequency disturbances are controlled. Depending on the maximum rated output power of the communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication device (transmitter) and the dental unit KS-DLX 303 as recommended below.

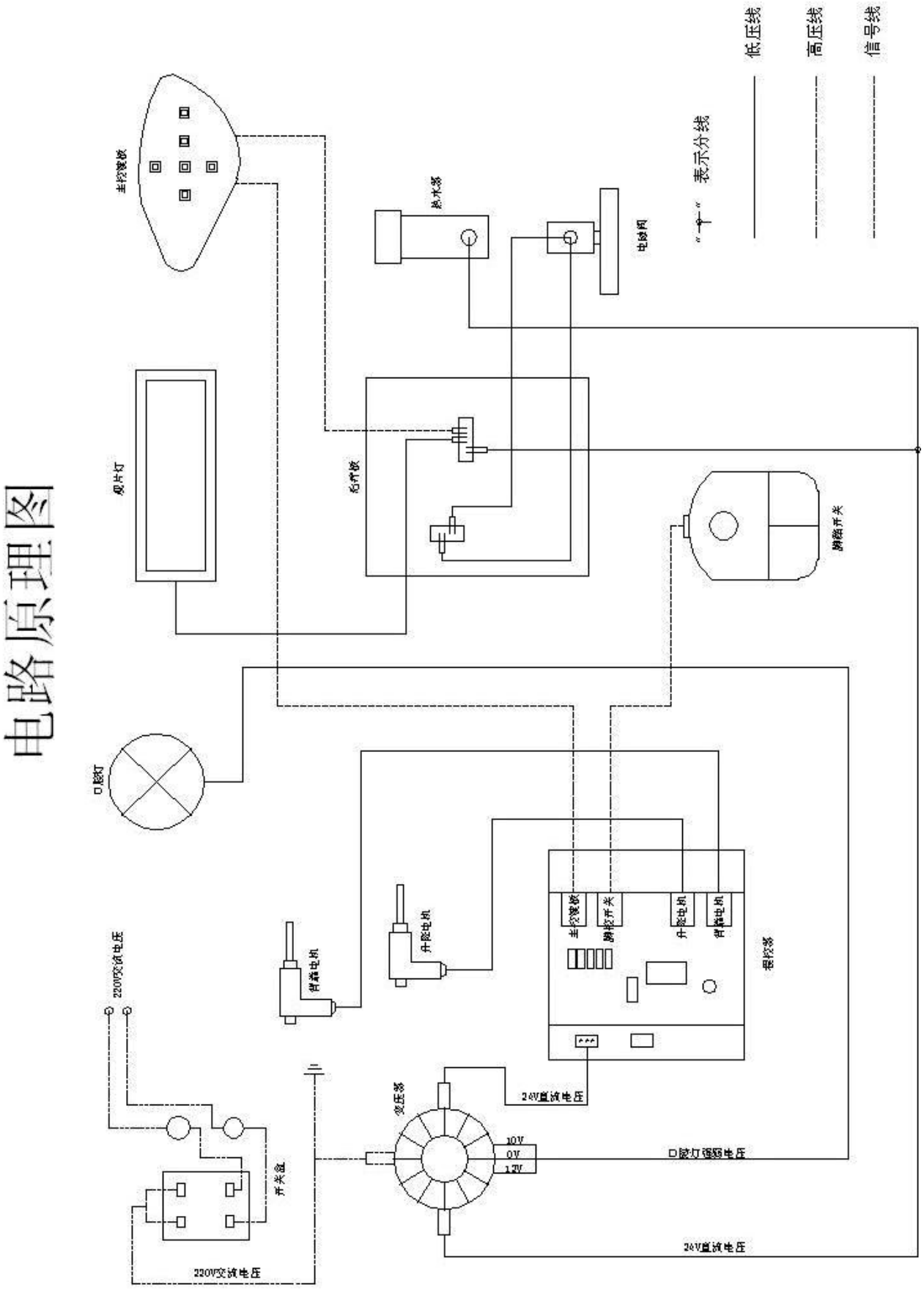
Rated maximum output power of the transmitter W	Corresponding distance /m corresponding to different frequencies of the transmitter		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ～ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ～ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the transmission provided by the transmitter manufacturer. Maximum rated output power in watts (W).

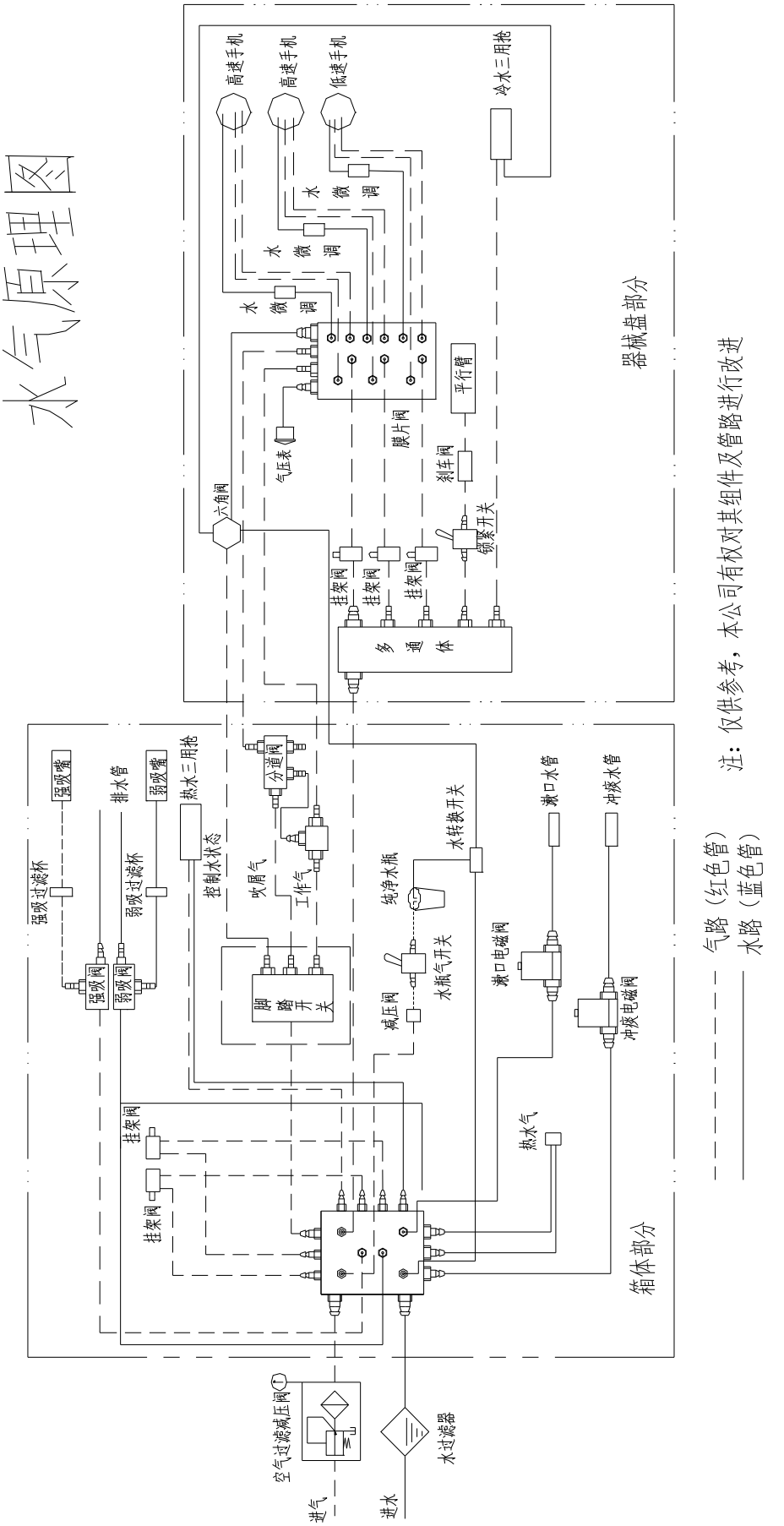
Note 1: At the 80MHz and 800MHz frequency points, the formula for the higher frequency band is used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and the human body.

Circuit diagram and water vapor schematic



水气原理图


高速手机
高速手机
低速手机
冷水三用抢
水微调
水微调
水微调
平行臂
气压表
膜片阀
刹车阀
六角阀
锁紧开关
挂架阀
挂架阀
挂架阀
多通体
器械盘部分
强吸过滤杯
强吸嘴
排水管
弱吸嘴
热水三用抢
分道阀
控制水状态
吹屑气
工作气
水转换开关
漱口水管
冲液水管
纯净水瓶
脚踏开关
减压阀
水瓶气开关
漱口电磁阀
冲液电磁阀
强吸阀
弱吸阀
弱吸过滤杯
挂架阀
挂架阀
热水气
箱体部分
空气过滤减压阀
水过滤器
进气
进水
气路（红色管）
水路（蓝色管）
注：仅供参考，本公司有权对其组件及管路进行改进

Name Dental Comprehensive Treatment Machine

Model：KS-D109

Technical Requirement Number：

Production License Number：

Product Registration Certificate Number：

Date of production see product label

Product validity： 5 years

Date of the prepared instruction： January 5, 2019

Production/Registration Name: Foshan City Kaso Medical Equipment Co., Ltd.

Production/Registration Address: 4th Floor, No.2Workshop Building, Donghua Industrial Zone, Shakeng, Luocun, Shishan Town, Nanhai District, Foshan City (Residence Declared)

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