Test Laboratuvarları

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DENEY RAPORU

Test Report

KD-22-1675-R1-N1-2
06-22

Müşteri *Client*	:	HPOTECH MEDİKAL ve TEKNİK ÇÖZÜMLER SANAYİ ve TİCARET A.Ş.
Adres *Address*	:	FERHATPAŞA MAH. 31.SK. NO:49 ATAŞEHİR / İSTANBUL
İmalatçı *Manufacturer*	:	HPOTECH MEDİKAL ve TEKNİK ÇÖZÜMLER SANAYİ ve TİCARET A.Ş.
Deney Numunesi *Test Sample*	:	TKBO-221
Marka *Trade Mark*	:	HPOTECH
Deney Metodu *Test Method*	:	TS EN 60601-1:2009 + A1:2014 + AC:2011 + A12:2015 + A1/AC:2014 (IEC 60601-1:2005/AMD2:2020)
Deney Tarihi *Date of Test*	:	10.06.2022
Toplam Sayfa Sayısı *Total Number of Pages*	:	47
Basım Tarihi *Date of Issue*	:	27.06.2022

Deney ve / veya ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri (talep halinde) ve deney metotları, bu raporun tamamlayıcı kısmı olan takip eden sayfalarda verilmiştir.
The test and / or measurements results, the uncertainties (if required) with confidence probability and test methods are given on the following pages which are part of this report.

Mühür *Seal*	**Deney Sorumlusu** *Person in Charge of Test*	**Bölüm Müdürü** *Department Manager*
	Samet KANGI	Ata Gürül ARSLANLI

Rapor detaylarını karekod ile kontrol edebilirsiniz.
You can check the report details via QR code.

İçindekiler **Sayfa**
Contents Page

1. Numunelerin Tanımı *Definition of the Samples* — Tek Kişilik Hiperbarik Oksijen Tedavi Ünitesi

1.1 TKBO 221– HYPERBARIC OXYGEN CHAMBER **(22-1675-R1-N1)**

Numune Kabul Tarihi *Date of Receive*		:	Test was performed on manufacturer's field.(10.06.2022)
Numune Seri No *Serial No*		:	TKBO 221
Tip *Type*		:	TKBO 221
Kutup Sayısı *Number of Poles*		:	Mono Phase
Beyan Gerilimi *Rated Voltage*	U_n	:	220 VAC
Beyan Akımı *Rated Current*	I_n	:	10 A
Beyan Frekans *Rated Frequency*	f_n	:	50 Hz
Beyan Koruma Derecesi *Rated Degree of Protection*	IP	:	20
Numune Boyutları *Dimensions of the Sample*	mm	:	-
Numune Ağırlığı *Weight of the Sample*	kg	:	-
Sınıf *Class*		:	Class I
Cihaz – Malzeme Listesi *Device – Component List*		:	Bknz. Firma Dökümanları *See Documentary of Client*

2. Deney Sonuçları *Test Results* : Deney sonuçları, müşteri tarafından laboratuvara teslim edilen ve sadece deneyi yapılan numuneye aittir.
The test results only belong to the tested sample(s) delivered to the laboratory by client.

Numune *Sample*	**Uygulanan Deney** *Applied Test*	**Sonuç** *Result*
TKBO 221	TS EN 60601-1:2009 + A1:2014 + AC:2011 + A12:2015 + A1/AC:2014 (IEC 60601-1:2005/AMD2:2020)	**OLUMLU** *PASSED*

3. Çevre Şartları *Environmental Conditions*

3.1 Ortam Sıcaklığı *Ambient Temperature* : (23±3) °C

3.2 Ortam Nemi *Ambient Moisture* : (40±3) %Rh

4. Deney Metodundan Sapma, Ekleme ve Çıkarmalar *Deviations, Additions & Cutbacks from the Test Method* : Deneyler; standart deney metoduna göre uygulanmıştır.
Tests were made according to the clauses of the relevant standards.

5. Şartnamelere Uygunluk (Gerekli Hallerde) *Conformity to Specifications (If Necessary)* : –

6.	**Dağıtım Bilgileri** *Distrubition Information*	:	HPOTECH MEDİKAL ve TEKNİK ÇÖZÜMLER SANAYİ ve TİCARET A.Ş
7.	**Açıklama** *Explanation*	:	Müşteri isteği ile testler firmanın adresinde yapılmıştır. Firma isteği ile rapor içeriğindeki testler yapılmıştır.
8.	**Ölçüm Belirsizliği** *Uncertainty of Measurement*	:	

9. Deney Uygulamaları:
Test Applications

IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Test specification:	
Standard.....:	IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)
Test procedure .....:	Type Test
Non-standard test method.....:	
Test Report Form No. .....:	IEC60601_1P
Test Report Form Originator.....:	UL(US)
Master TRF.....:	2019-10-11

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 NCBs that own these marks.

TKBO–221

Dizayn Standart	: EN 13445	Üretim Tarihi	: 03.2022
Sertifika	: HPOTECH DECLARATION	Max. Çalisma Sicakligi	: 40 C
Tanim	: Tek Kisilik Hiperbarik Tedavi Kabini	Max. Çalisma Basinci	: 1.0 Bar
		Dizayn Basinci	: 1.0 Bar
Seri Numarasi	: TKBO–221	Test Basinci	: 1.43 Bar
Akiskan	: Oksijen	Emniyet Valfi Set Degeri	: 1.1 Bar
Test Tarihi	: 03.2022		
Kapasite	: 1 kisilik (1.05 m3)		
Is Numarasi	: 2022–0146		

CE 1785

HPOTECH MEDİKAL VE TEKNİK ÇÖZÜMLER SANAYİ VE TİCARET A.Ş
Address:Ferhatpasa Mah. 31.Sk. No:49
Atasehir / ISTANBUL
PN : +90 (0)506 118 94 05

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	Permanently installed
Device type (component/sub-assembly/ equipment/ system):	Equipment
Intended use (Including type of patient, application location) :	See Clause 1.1
Mode of operation ..... :	Continuous
Supply connection	Non-detachable cord
Accessories and detachable parts included..... :	-
Other options include ..... :	-
Testing	
Date of receipt of test item(s)..... :	Test was performed on manufacturer's field.
Dates tests performed..... :	10.06.2022
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:

Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "K" of TRF for IEC for 60601-1 3rd edition with Amendment 1.

"(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.

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

INSULATION DIAGRAM

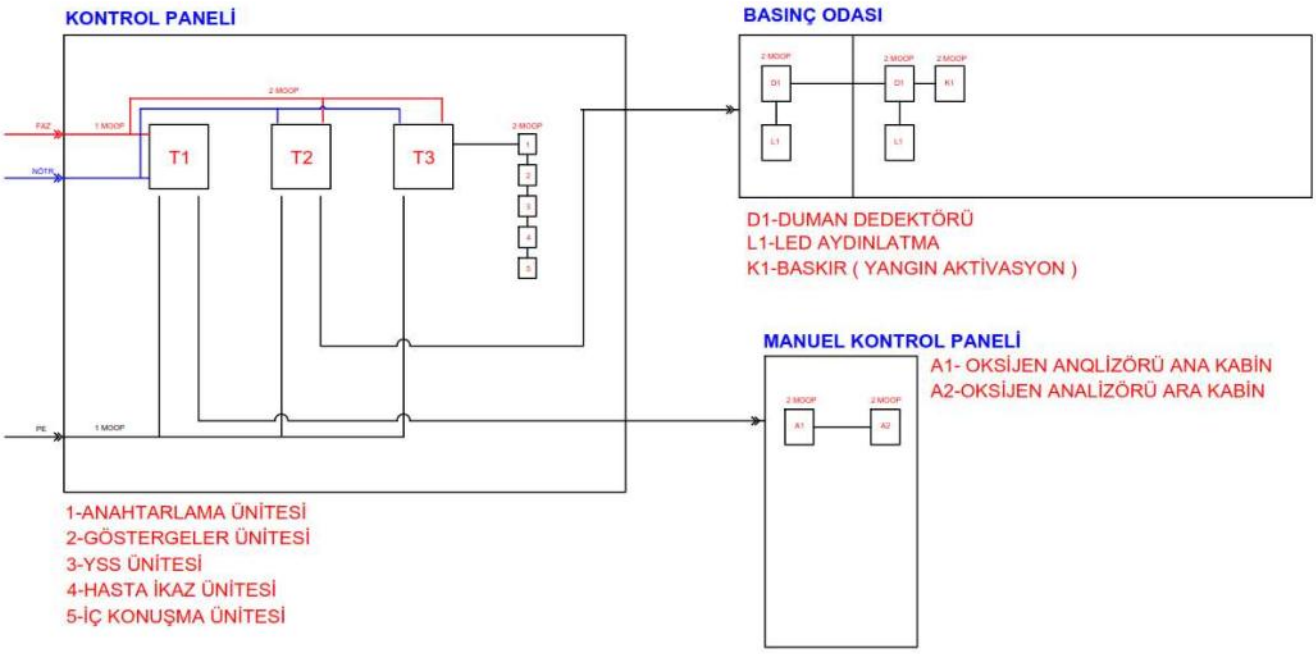


TABLE: INSULATION DIAGRAM		P
Pollution degree ..... :	2	—
Overvoltage category..... :	II	—
Altitude..... :	48m	—
Additional details on parts considered as applied parts ..... :	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V_{rms}	V_{pk}					
-	1MOOP	IIIb	220	-	2,5	1,1	12	12	Panel socket
-	2MOOP	IIIb	-	24VDC	1	0,8	10	10	Valve
-	2MOOP	IIIb	-	24VDC	1	0,8	13	7	Chamber socket1
	1MOOP	IIIb	220	-	2,5	1,1	11	9.3	Omron power supply Input Socket
	1MOOP	IIIb	220	-	2,5	1,1	7	5.5	Mervesan power supply Input Socket
	1MOOP	IIIb	220	-	2,5	1,1	15.5	13.6	MCB L-N

Supplementary Information:

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 PLAN Document: TD.01.91 Rev.00 11.07.2020	P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.	See TD.01.92 Rev.07 25.02.2022	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.		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.	RM File Reference to Essential performance: TD.01.92 Rev.07 25.02.2022	P
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		P
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		P
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE.....:	See Appended Table 4.3	P
	- RISK CONTROL measures implemented		P
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		P
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE..... :	2 Years	P
4.5	Alternative RISK CONTROL methods utilized:	See TD.01.92 Rev.07 25.02.2022	P
	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)	RMF Reference to specific risks: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	P

	Alternative means based scientific data or clinical opinion or comparative studies .....:		**P**
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.....:**	See Appended Insulation Diagram Table	**P**
	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)**	RMF Reference to specific RISKS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**P**
	Assessment identified the APPLIED PART TYPE requirements.....:	Type B	**P**
4.7	**ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2.....:**		**P**
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested ..... : **(ISO 14971 Cl. 4.2-4.4)**	RISK ANALYSIS reference: (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 TD.01.92 Rev.07 25.02.2022	**P**
4.8	**All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ....:**		**P**
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		**P**
	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)**	RMF Reference to specific RISKS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**P**
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION .. :	See Table 8.10 b.	**P**
	Components determined to be acceptable where used as a MEANS OF PROTECTION..... :	RMF Reference to specific RISKS: TD.01.92 Rev.07 25.02.2022	**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**
4.9	**A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately.....:**	~~See appended Table 8.10 b~~ No high-integrity characteristic component.	**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)**	~~RMF Reference to specific RISKS:~~ ~~(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:	~~See Table 8.10 b~~	**N/A**
4.10	**Power supply**		**P**
4.10.1	**ME EQUIPMENT is suitable for connection to indicated power source** (select applicable).....:	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 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**
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		**P**
5.9.1	**APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS..... :**		**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 ..... :**	No conductive parts.	**N/A**
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL ..... :		**N/A**
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	**CLASS I ME EQUIPMENT, externally powered**		**P**
	CLASS II ME EQUIPMENT, externally powered	Class I	**N/A**
	INTERNALLY POWERED ME EQUIPMENT	Class I	**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	Type B	**N/A**
	TYPE CF APPLIED PART	Type B	**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 ..... :**	IP20 Verified by test	**P**
6.4	**ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use..... :**		**N/A**
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**		**P**
6.6	**CONTINUOUS or Non-CONTINUOUS OPERATION ..... :**	Continuous operation	**P**

8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		**P**
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		**N/A**

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 .....:**		**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 .....:		**P**
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	Inspected visually.	**P**
	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**
8.6.3	**PROTECTIVE EARTH CONNECTION not used for a moving part,**	No moving parts.	**N/A**
	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)**	~~RMF Reference to proof of reliability:~~ ~~(ISO 14971 Cl.__)~~	**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..... :	See appended Table 8.6.4 & Clause 8.7	**P**
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		**P**
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		P
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		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
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		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)		P

	– 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		N/A
	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		N/A
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 :	See appended Table 8.7	P
	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 100µA in NORMAL CONDITION and 500µA 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..... :	See appended Table 8.7	P
	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 ..... :	See appended Table 8.7	P
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements ..... :	See appended Table 8.7	P
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
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).....:**	Refer to Insulation Diagram	**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**	No declaration by manufacturer.	**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 appended Table 8.9.2	**N/A**
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**		**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)..... :**	See appended Table 8.9.3.2	**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 ..... :	See appended Table 8.9.3.3	**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**
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**

9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		**P**
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) ..... :		**—**
	- 83 dBA (when halving the cumulative exposure time) (dBA) ..... :	30.5 dB: Ambient 42.5 dB: Operation	**—**
	– 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)**	RMF Reference to specific RISKS: (ISO 14971 Cl.4.2-4.4)	**P**
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	Not hand-held equipment.	**N/A**
	– 2.5 m/s² for a cumulative time of 8 h during a 24 h period (m/s²)..... :		**N/A**
	– Accelerations for different times, inversely proportional to square root of time (m/s²) ..... :		**N/A**

10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		**P**
10.1	**X-Radiation**		**P**
10.1.1	**The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT ..... :**	See Table 10.1.1	**P**
	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)**	~~RMF Reference to specific RISKS:~~ ~~(ISO 14971 Cl.__)~~	**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)	~~RMF Reference to specific RISKS:~~ ~~(ISO 14971 Cl.__)~~	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.		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)	~~RMF Reference to specific RISKS:~~ ~~(ISO 14971 Cl.__)~~	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)	~~RMF Reference to specific RISKS:~~ ~~(ISO 14971 Cl.__)~~	N/A
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)	~~RMF Reference to specific RISKS:~~ ~~(ISO 14971 Cl.__)~~	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	The temperature did not exceed.	P
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No operating thermal cut-outs in normal condition.	N/A
	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 RISK: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	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..... :	There is no such applied parts.	N/A

	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	~~RMF Reference to specific RISKS: (ISO 14971 Cl.__)~~	**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 :**	Masks present.	**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 ..... :		**—**
	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: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**P**
	APPLIED PARTS surface temperature of equal to or less than 41°C		**P**
	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 ..... :	~~RMF Reference to specific RISKS:~~	**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)	~~RMF Reference to specific RISKS: (ISO 14971 Cl.__)~~	**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)**	~~See appended Table 11.1.3d and RMF Reference to specific RISKS: (ISO 14971 Cl.__)~~	**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)	~~RMF Reference to specific RISKS: (ISO 14971 Cl.__)~~	**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: (ISO 14971 Cl.__)~~	**N/A**

	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE.....:	~~RMF Reference to specific RISKS:~~	**N/A**
11.1.4	**GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL**		**N/A**
11.2	**Fire prevention**		**N/A**
11.2.1	**ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3**		**N/A**

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: (ISO 14971 Cl.4.2-6.5)	**P**
12.2	**RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING ..... :**	See documents.	**P**
12.3	**MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. ..... :**		**N/A**
12.4	**Protection against hazardous output**		**P**
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)**	RMF Reference to specific RISKS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**P**
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)**	RMF Reference to specific RISKS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**P**
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)**	RMF Reference to specific RISKS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**P**
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)**	RMF Reference to specific RISKS: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**P**
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..... :	~~See IEC 60601-1-3 Report~~	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)	~~RMF Reference to specific RISKS:~~ (ISO 14971 Cl.__)	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)	~~RMF Reference to specific RISKS:~~ (ISO 14971 Cl.__)	N/A
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)	~~RMF Reference to specific RISKS:~~ (ISO 14971 Cl.__)	N/A

14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		N/A
14.1	Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or	The ME equipment does not have software. Substances are marked with N/A	P
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK.....:		N/A
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)	~~RMF Reference to specific RISKS:~~ ~~ISO 14971 Cl.)~~	N/A
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		N/A
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 62304:2006 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS		N/A
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304 .....:	~~Software Class:~~	N/A
	Software development process applied according to Clause 5 of IEC 62304 .....:		N/A
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 .....:		N/A
	Software development process Configuration Management applied according to Clause 8 of IEC 62304.....:		N/A
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304 .....:		N/A

14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process .....:		N/A
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan		N/A
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/A
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/A
14.6	RISK MANAGEMENT PROCESS		P
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/A
	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)	~~RMF Reference to specific HAZARDS:~~ ~~(ISO 14971 Cl.)~~	N/A
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/A
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure .....: (ISO 14971 Cl. 6.1)	~~RMF Reference to specific RISKS:~~ ~~(ISO 14971 Cl.)~~	N/A

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/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems .....: (ISO 14971 Cl. 6.3)		N/A
14.9	Design is broken up into sub systems and descriptive data on design environment documented ..... :		N/A
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/A
	– milestone(s) when VERIFICATION is to be performed for each function		N/A
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N/A
	– selection and utilization of VERIFICATION tools		N/A
	– coverage criteria for VERIFICATION		N/A
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented		N/A
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE .....:		N/A
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented		N/A
	The person with overall responsibility for PEMS VALIDATION is independent		N/A
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)	~~RMF Reference to specific RISK CONTROLS:~~ ~~(ISO 14971 Cl.)~~	N/A
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		N/A
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304..... :	~~Software Class:~~	N/A

	Software Process for Software changes applied according to Clause 5 of IEC 62304.... :		N/A
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304 ..... :		N/A
	Configuration management of software changes applied per Clause 8 of IEC 62304 .... :		N/A
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304.... :		N/A
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/A
	a) Purpose of the PEMS connection to an IT-NETWORK		N/A
	b) required characteristics of the IT-NETWORK		N/A
	c) required configuration of the IT-NETWORK		N/A
	d) technical specifications of the network connection, including security specifications		N/A
	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/A
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)	~~RMF Reference to specific hazardous situations:~~ ~~(ISO 14971 Cl. __)~~	N/A
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		N/A
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties		N/A
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS		N/A
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis		N/A
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment		N/A

15	**CONSTRUCTION OF ME EQUIPMENT**		**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**		**N/A**
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~~	**N/A**
	No unacceptable RISK resulted		**N/A**
15.3.4.2	**Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test .....:**	~~See Appended Table 15.3~~	**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 ..... :**	~~See Appended Table 15.3~~	**N/A**
	No damage resulting in an unacceptable RISK sustained		**N/A**
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**		**N/A**
	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°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C..... :		**N/A**
	No damage resulting in an unacceptable RISK		**N/A**
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**

17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		**P**
	RISKS associated confirmed by review..... :		**P**
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :		**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: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	**P**
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems	See IEC 60601-1-2 Report Report No: 22-1675-R1-N1-1	**P**

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	Mentioned in TD.01.91 Rev.00 11.07.2020	—	Risk Management Process (excluding production and post-production)	P
3.2	Mentioned in TD.01.91 Rev.00 11.07.2020	—	Adequate Resources	P
3.2	Mentioned in TD.01.91 Rev.00 11.07.2020	—	Assignment of qualified personnel	P
3.2	Mentioned in TD.01.91 Rev.00 11.07.2020	—	Policy for determining criteria for risk acceptability	P
3.3	—		Qualification of personnel	
3.4a	—			
3.4b	—			
3.4c	—			
3.4d	—			
3.4e	—			
3.5	—			
4.1	—		Mentioned in TD.01.91 Rev.00 11.07.2020 has the relevant steps of ISO 14971 for applicable parts.	
4.2	—			
4.3	—			
4.4	—			
5	—			
6.2	—			
6.3	—			
6.4	—			
6.5	—			
6.6a	—			
6.6b	—			
6.7	—			
7	—			
8	—			

Supplementary Information: RMF document was inspected.

Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.

4.3	TABLE: ESSENTIAL PERFORMANCE	P

List of ESSENTIAL PERFORMANCE functions	MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)	Remarks
Clause 03.04	User Manual Doc. No:TD.01.122 Rev.00 25.02.2022	Clearly detailed.

Supplementary Information: **Manufacturer documentations were inspected.**

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 (W or VA)	Power factor (cos φ)
Normal Condition	226V	50	0.5	122VA	0.579

Supplementary Information:

5.9.2	TABLE: Determination of ACCESSIBLE parts	P

Location	Determination method (NOTE1)	Comments
Electrical Area	Test Finger, Visual	No Access

Supplementary information:

[1)] NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.

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)
Cord PE terminal – Inside Panel Screw	25A/10sec.	1.125	45	200
Cord PE terminal – Panel Enclosure	25A/10sec.	1.4	56	200
Cord PE terminal – Bed Profile	25A/10sec.	1.625	65	200
Cord PE terminal – Panel	25A/10sec.	2.05	82	200
Cord PE terminal – Hyperbaric Tunel Enclosure	25A/10sec.	1.625	63	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

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)		—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
After termal stability(Maximum measured values.)					
P(N)-N(C)		**220**	**50**	**35.8**	**The maximum recorded values are mentioned in the table for A,B and cleaning.**
P(N)-N(O)		**220**	**50**	**42.5**	
P(R)-N(C)		**220**	**50**	**67.7**	
Fig. 14 - Touch Current (TC)		—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
After termal stability(Maximum measured values.)					
P(N)-N(C)-E(C)		**220**	**50**	**1.5**	**The maximum recorded values are mentioned in the table for A,B and cleaning.**
P(N)-N(C)-E(O)		**220**	**50**	**32.5**	
P(N)-N(O)-E(C)		**220**	**50**	**1.2**	
P(R)-N(C)-E(C)		**220**	**50**	**1.4**	
Fig. 15 - Patient Leakage Current (P)		—	—	—	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)
After termal stability(Maximum measured values.)					
Bed					
P(N)-N(C)-E(C)		**220**	**50**	**0,1AC+0,2DC**	**The maximum recorded values are mentioned in the table for A,B and cleaning.**
P(N)-N(C)-E(O)		**220**	**50**	**0,1AC+0,3DC**	
P(N)-N(O)-E(C)		**220**	**50**	**0,1AC+0,2DC**	
P(R)-N(C)-E(C)		**220**	**50**	**0,1AC+0,2DC**	
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)		—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)		—	—	—	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)

Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
Fig. 19 – Patient Auxiliary Current	—	—	—	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)
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	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)
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	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)
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA

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	—	—	—	Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC

Supplementary information: **The patient mask was not used in the tests.**

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).

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

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.		
After Thermal Stability					
LN – Bed Profil	1MOOP	242	-	1500	No
LN – Control Panel	2MOOP	242	-	3000	No
LN – Bed	2MOPP	242	-	4000	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).

10.1.1	TABLE: Measurement of X - radiation	P

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/ / Front surface during temperature rise test.	0,15 µSv/h	
2/ /		
3/ /		
4/ /		
5/ /		
6/ /		
7/ /		
8/ /		
9/ /		
10/ /		

Supplementary information:

[1)] Measurements made at 5 cm from any surface to which 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. ..... :	TKBO 221					
Test ambient (°C) ..... :	26					
Test supply voltage/frequency (V/Hz)[4] . :	220/50					

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
TKBO 221	1	Panel Button	48	28	Not exceeded
	2	Panel Enclosure	74	27	Not exceeded
	3	Bed	43	22	Not exceeded
	4	Emergency Stop	48	26.5	Not exceeded
	5	Screen	48	30.2	Not exceeded
	6	Chamber Enclosure	48	22.6	Not exceeded
	7	Screen Button	48	28.7	Not exceeded
	8	On/Off Button	60	26.6	Not exceeded
	9	Relay	Informative	35	Not exceeded
	10	Schneider MCB Latch	Informative	32	Not exceeded
	11	Schneider MCB Body	Informative	27	Not exceeded
	12	Omron Power Supply	Informative	40.2	Not exceeded
	13	Mervesan Power Supply	Informative	43.4	Not exceeded

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.

Information from Risk Management, as applicable:

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	P
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	N/A
15.3.4.1	Drop Test (hand-held)	Free fall height (m) =	N/A
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) =	N/A
Supplementary information: [1)] As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field).			

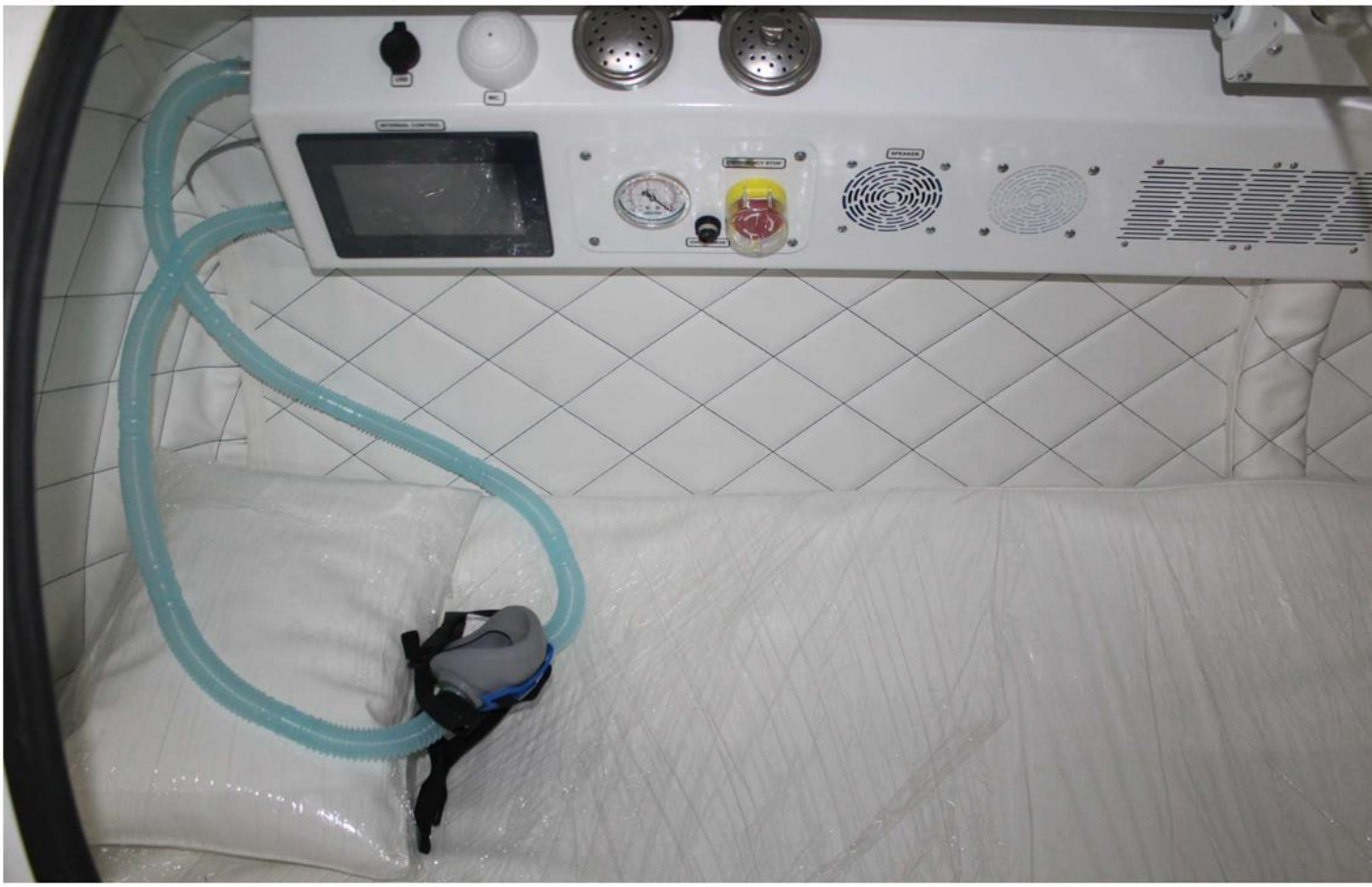
10. Deney ve Ölçüm Bilgileri:
Test and Measuring Arrangement

Cihaz *Device*	İmalatçı *Manufacturer*	Seri No. / Kod *Serial No / Code*	Sertifika No *Certificate No*	Kalibrasyon Bitiş Tarihi *Calibration Due Date*
Temperature&Humidity Meter	CEM	LC349	6216	January/2023
Digital Caliper	ACCUD	LC365	6212	January/2023
Ruler	MAS	LC443	200602	October/2023
Dielectric Tester	SAKO	LC31	176205	September/2022
Medical Safety Analyzer	FLUKE ESA620	LC91	146401	July/2022
Desibelmeter	TES	LC44	19390	September/2022
Elimko Data Logger	E-680	LC5	20SC2103	December/2022
Multimeter	FLUKE 115	LC1	179201	September/2022
Newtonmeter	NK-500	LC204	2138245	September/2022
Gauge Stick	LVT	LC166	20KD2645	July/2022
Jointed Test Finger	-	LC205	-	No need to calibrate
Test Finger	-	LC206	-	No need to calibrate

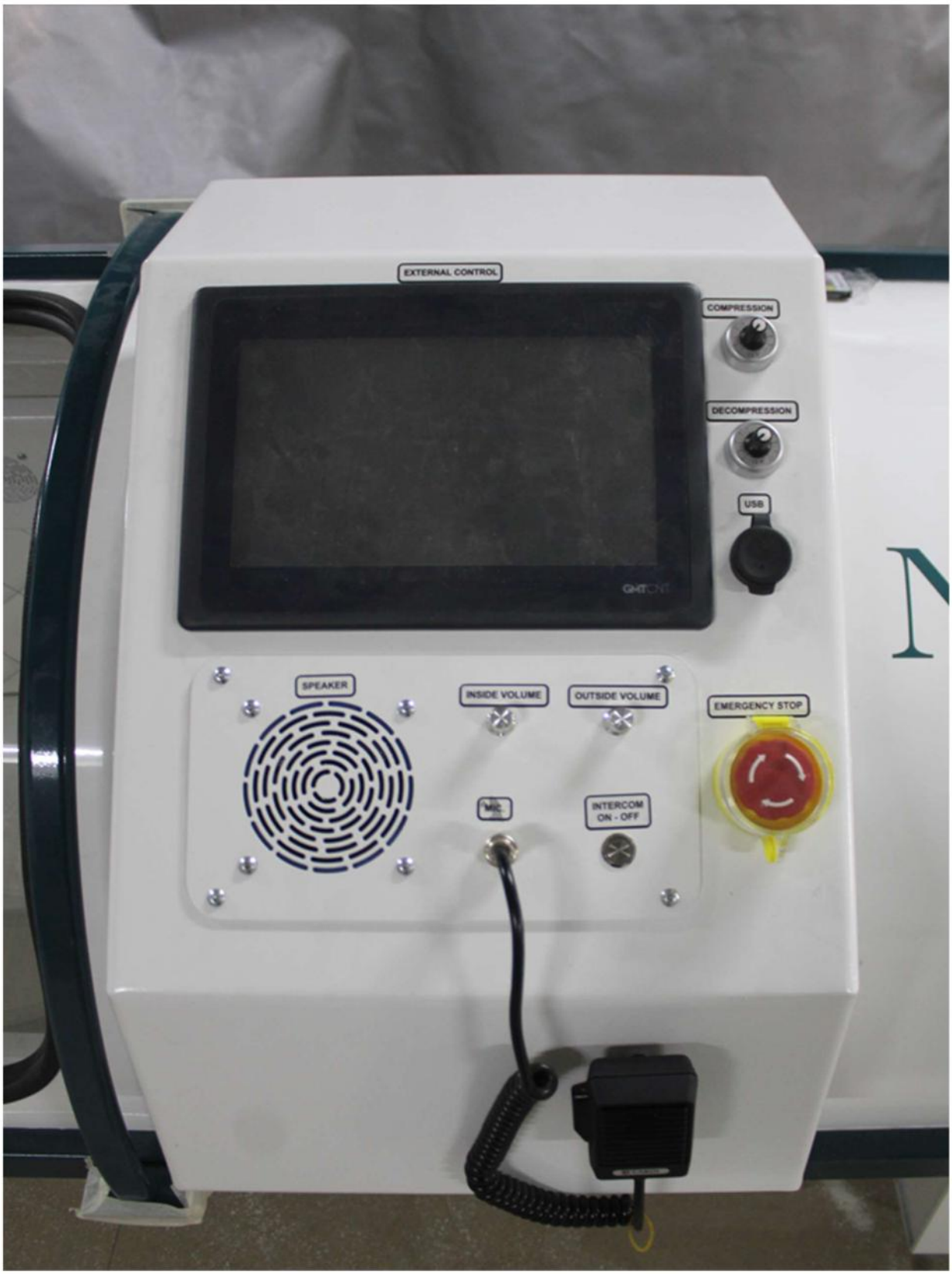
11. Deney Fotoğrafları:
Test Photographs

Photograph1: Hyperbaric Chamber

Photograph2: Hyperbaric Chamber



Photograph3: Hyperbaric chamber bed



Photograph4: Control Panel

12. Firma Dokümanları:
Documentary of Client

hpo tech

TKBO-1 KRİTİK KOMPONENT LİSTESİ

BİLEŞEN DETAYLARI	İMALATÇI /MARKA DETAYLARI	MODEL NUMARASI	BİLEŞENE AİT TEKNİK ÖZELLİKLER	BİLEŞENİN BELGELENDİRİLDİĞİ STANDARDI	İLGİLİ BELGENİN SERTİFİKA NOSU
ALÜMİNYUM	SEYKOÇ	5 mm.	5454-H111	EN 485-2	223412001M00011
AKRİLİK	CASTPLUS+ŞEKİL	20 mm.	Kırılma İndisi 1.49	TS EN ISO 7823-1	182449-TSE-01/01
EMNİYET VENTİLİ	YKS	YKS-349	1.1Bar	(PED) 2014/68 / AB	2737
MANOMETRE	TEKMAR ÇİVATA	PAKKENS	KL 2,5	EN 837-1	001029-TSE-10/01
VAKUMETRE	HİDROPAKS	DASTERM	KL 2,5 (-1 manometre)	TS EN 13190	14.0.30.4.16.001/ TSE-63800
HAVA FİLTRESİ-GİRİŞ-ÇIKIŞ	AAG MAKİNA	AF.700-701	Debi: 700 lt/min. Çalışma Basıncı: 7 Bar	EN IS 12100:2010	17-IS-0492-TAT-21-MAD-2876
SICAKLIK VE NEM SENSÖRÜ	ENDA	ENDA ESHT-102-W50	125 gr. Montajlı tip	TS EN 61326-1: 2013 EN 60529 standardına göre IP65	Seri No: 221318033
BASINÇ SENSÖRÜ	WIRCON	BT-100	0-1 BAR		SeriNo: 211021008
OKSİJEN SENSÖRÜ	ENVİTECH-	OOM102	Ø29	ISO 80601-2-55	G1 021697 0017
MONİTÖRLER	GMT	GMT CNT TSG-070-101	7''+ 10''	EN61000-6-4:2007 EN61000-6-2:2005	HMI-TSG-CE-UYGUNLUK BEYANI
BIBS REGÜLATÖRÜ	HİPEROXY	BİBS REGÜLATÖRÜ	GİRİŞ-ÇIKIŞ	EN 14931 EN ISO 10524-1 EN 738-1 EN 738-1 A/1	DC-1006-01

HPOTECH MEDİKAL VE TEKNİK ÇÖZÜMLER SAN. VE TİC. A.Ş.

ADRES: FERHATPAŞA MAH. 31. SOK. NO:49 ATAŞEHİR / İSTANBUL Tel: +905061189405

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TKBO-1 KRİTİK KOMPONENT LİSTESİ

GÜÇ KAYNAĞI	MERVESAN	MT-60-12	12 Volt 5 Amper	-	
GÜÇ KAYNAĞI	OMRON	S8VK-C12024	Switching Power Supply	EN 61204-3 :2000 EN62368-1: 2014 EN IEC 63000: 2018	OMSQ-G05130203F
GÜÇ KAYNAĞI	ILED	S-12V10A	12V10A	En 55032:classA	LCS201223033AE
EMI filtre	SCHAFFNER	FN 2070-10-06	250V 10A50/60Hz	IEC/EN60939	

Innovative Medical Solutions

HPOTECH MEDİKAL VE TEKNİK ÇÖZÜMLER SAN. VE TİC. A.Ş.

ADRES: FERHATPAŞA MAH. 31. SOK. NO:49 ATAŞEHİR / İSTANBUL Tel: +905061189405

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No. OMSQ-G05130203F

Original

OMRON

EU DECLARATION OF CONFORMITY

1. **Product Models/Products:**
   S8VK-C series
2. **Name and address of the manufacturer:**
   OMRON Corporation
   Shiokoji Horikawa, Shimogyo-ku Kyoto, 600-8530 Japan
3. **This declaration of conformity is issued under the sole responsibility of the manufacturer.**
4. **Objects of the declaration:**
   S8VK-C series, Switching Power Supply
5. **The objects of the declaration described above are in conformity with the relevant Union harmonisation legislation:**
   2014/30/EU EMC Directive
   2014/35/EU Low Voltage Directive
   2011/65/EU RoHS Directive
6. **References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:**
   EMC Directive : EN 61204-3: 2000 Class A High severity levels
   Low Voltage Directive : EN62368-1: 2014 and EN62477-1: 2012 + A11: 2014
   RoHS Directive : EN IEC 63000: 2018

Signed and on behalf of : OMRON Corporation
Place and date of issue : Kyoto, Japan 20th August.2021

Signature:
Name: Tsunetoshi Oba
Function: Industrial Automation Company, Components Division Manager

Name and address of contact in EU
OMRON Europe B.V.
Quality & Environment Department
Attn: J.J.P.W. Vogelaar, European Quality & Environment Manager
Zilverenberg 2, 5234 GM, 's-Hertogenbosch, The Netherlands

Attestation of Compliance

Reference No.	:	LCS201124021BS
Applicant	:	ILED ELECTRONICS LIMITED
Address	:	1-2F, Building A4, Quanbao Industry Zone Park, Guangming Road No.36, Shiyan Town, Baoan District, Shenzhen, Guangdong, China 518108
Product	:	LED STRIP LIGHT
Trade Mark	:	FIO-LED, IW - LED IND. LTD., iled
Model(s)	:	Refer to Annex 1
Parameters	:	DC12V, 4,8W/m, Max. 5m, IP20, ta45°C
Tested according to	:	EN 60598-2-21:2015; EN 60598-1:2015+A1:2018; EN 62471:2008; EN 62493:2015; EN IEC 62031:2020

The submitted products have been tested by us with the listed standards.

This Attestation of Compliance is issued according to the council Directive 2014/35/EU, Referred to as the Low Voltage Directive. It confirms that the listed product complies with all essential requirements of the LVD Directive and applies only to the sample and its technical documentation submitted to Shenzhen Southern LCS Compliance Testing Laboratory Ltd. for testing.

After preparation of the necessary technical documentation as well as the EC conformity declaration the required CE marking can be affixed on the product.Other relevant Directives have to be observed.

CE

Manager

APPROVED

Date of issue: December 25, 2020

Shenzhen Southern LCS Compliance Testing Laboratory Ltd.
101-201, No.39 Building, Xialang Industrial Zone, Heshuikou Community, Matian Street, Guangming District, Shenzhen, China
Tel: (86)0755-29871520 Fax: (86)0755-29871521
Http://www.lcs-cert.com Email: webmaster@lcs-cert.com

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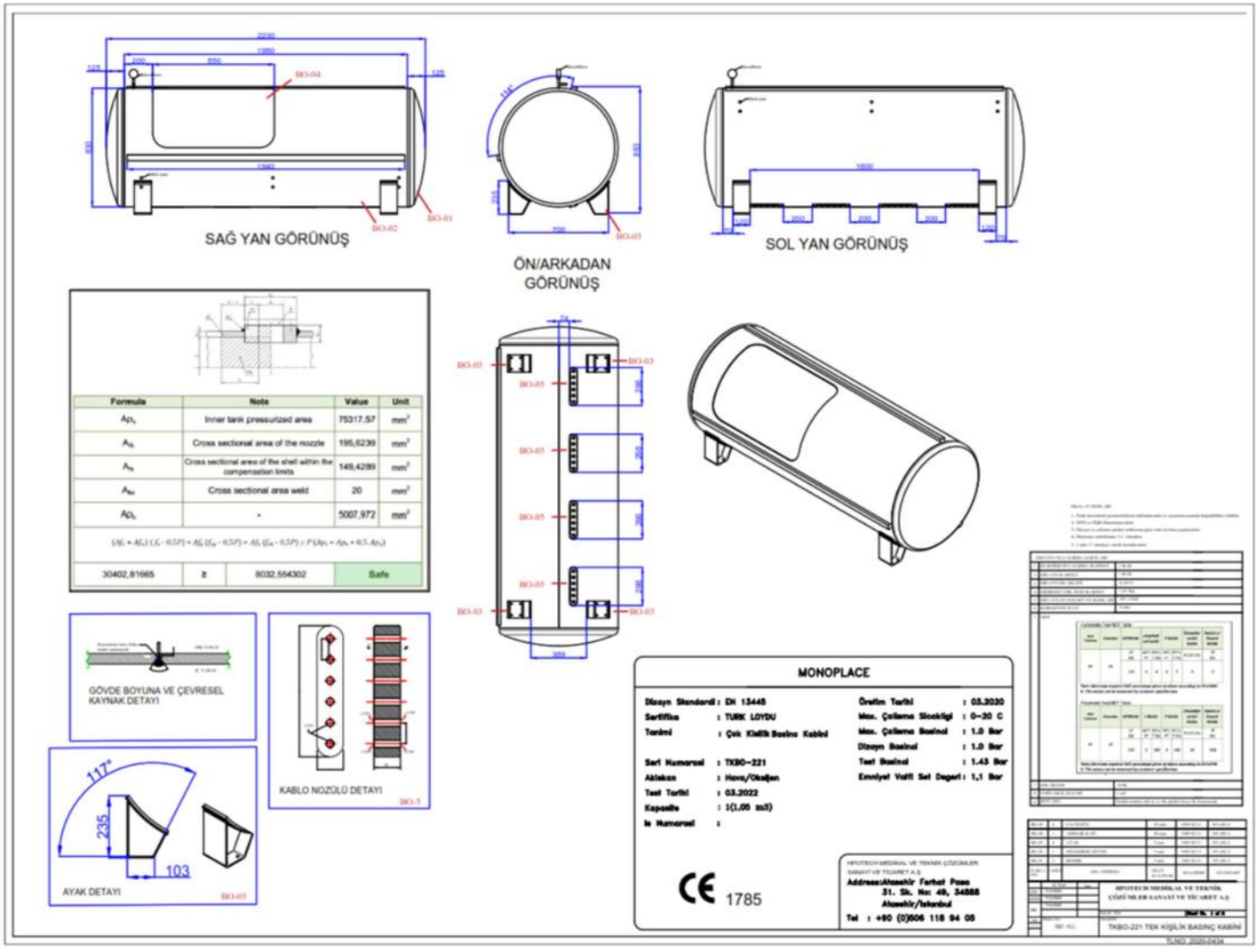
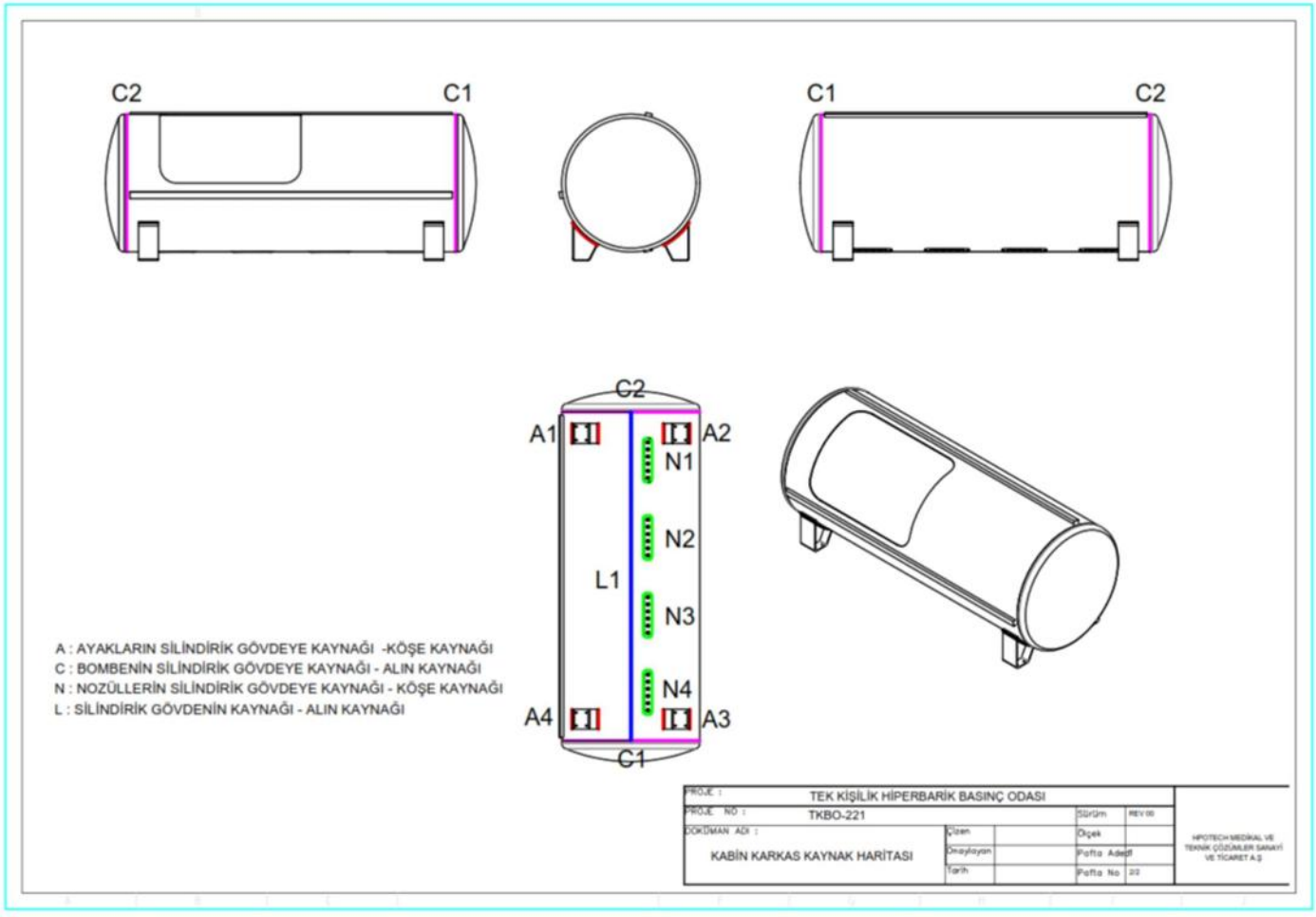
Scan,Query authenticity



Formula	Note	Value	Unit
Ap_b	Inner tank pressurized area	75317,57	mm^2
A_{nb}	Cross sectional area of the nozzle	195,0239	mm^2
A_{sb}	Cross sectional area of the shell within the compensation limits	149,4289	mm^2
A_{wb}	Cross sectional area weld	20	mm^2
Ap_b	-	5007,972	mm^2
$(A_b + A_{fb}) \cdot (f_r - 0,5 \cdot f) + A_{fb} \cdot (f_{rn} - 0,5 \cdot f) + A_{fb} \cdot (f_{rn} - 0,5 \cdot f) \geq F \cdot (A_{pb} + A_{pn} + 0,5 \cdot A_{wb})$			
30402,81665	≥	8032,554302	Safe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C : BOMBENİN SİLİNDİRİK GÖVDEYE KAYNAĞI - ALIN KAYNAĞI
N : NOZÜLLERİN SİLİNDİRİK GÖVDEYE KAYNAĞI - KÖŞE KAYNAĞI
L : SİLİNDİRİK GÖVDENİN KAYNAĞI - ALIN KAYNAĞI
PROJE : TEK KİŞİLİK HİPERBARİK BASINÇ ODASI
PROJE NO : TKBO-221
Sürüm REV 00
DOKÜMAN ADI : KABİN KARKAS KAYNAK HARİTASI
Çizen
Onaylayan
Tarih
Ölçek
Pafta Adedi
Pafta No 2/2
HİPOTECH MEDİKAL VE TEKNİK ÇÖZÜMLER SANAYİ VE TİCARET A.Ş.