

8.10 TABLE: List of critical components					
Component/ Part No.	Manufacturer / Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹
Dental unit					
Enclosure, instruments table	Manufacturer AS	Abc123	Casted Aluminium, Min. 3.3mm thick	IEC 60601-1	Tested in equipment
Enclosure, lamp arm	Manufacturer AS	Def456	Aluminium Pipe, Min 4.5mm thick	IEC 60601-1	Tested in equipment
Enclosure, plastic parts	Sabic Innovative Plastics	Cycoloy HC1238	60°C, V-0 for min. 1.2mm (all colours), measured min thickness: 1.5mm	UL 746, UL 94, C22.2 No. 0.17	cURus (E45329)
Mains Power Board, P/N: rs-003, rev. 03					
PCB material	Suntak Multilayer PCB	JJ-02	125°C, V-0	UL 796	UR (E207844)
Mains terminals (P1- P6)	JST	LP45	20/24A (UL/IEC), 300/500V, AWG 22-14, 2.5mm ² , 105°C, V-0	IEC 60947-7-1 UL 1059	VDE, UR E123456
Primary fuse before mains switch (F1) 230V	Littelfuse	215	T5.0AH, 250V, 5x20mm	IEC 60127-2 ANSI/UL 248-1/ ANSI/UL 248-14	VDE 40013521 UR E10480 CSA LR1422-30
Primary fuse after mains switch (F2) 230V	Littelfuse	215	T2.0AH, 250V, 5x20 mm	IEC 60127-2 ANSI/UL 248-1/ ANSI/UL 248-14	VDE 40013521 UR E10480 CSA LR1422-30
Primary fuse before mains switch (F1) 115V	Littelfuse	215	T10.0AH, 250V, 5x20mm	IEC 60127-2 ANSI/UL 248-1/ ANSI/UL 248-14	VDE 40013521 UR E10480 CSA LR1422-30
Primary fuse after mains switch (F2) 115V	Littelfuse	215	T4.0AH, 250V, 5x20 mm	IEC 60127-2 ANSI/UL 248-1/ ANSI/UL 248-14	VDE 40013521 UR E10480 CSA LR1422-30
Mains switch	Switch king	88.XX.8	16(8)A/250Vac, 125/55°C, 5E4, IP40	IEC 61058-1 UL 1054	ENEC03,IMQ UR E112233
Secondary fuses (F3-F5)	Bussmann	S512	T4AH, 250V, 5x20 mm	IEC 60127-2 ANSI/UL 248-1/ ANSI/UL 248-14	VDE 40011926 UR E19180
PTC device (R1)	Bourns Inc.	MF-R600	30V, 6A, 125°C	IEC 60730-1	TÜV Certificate number R020057213
Fuse holders (F1-F5)	Schurter	OGN- 0031.8201 (holder) OGN-0853.0551 (cover)	10.0A, 250Vac, 85°C, V- 0	IEC 60127- 6:1994+A1+A2 UL 512	UR E39328 VDE 40001042
EMC filter (FL1)	Schurter	5500.2019	6.5A, 125/250V, 50/60Hz, 25/85/21	IEC 60939 UL 1283 CSA-C22.2 No. 8	VDE 40004673 UR E72928 ENEC10

Capacitor (C12, C13)	Murata	KH102M	250Vac, Y2, V-0, 125°C, 1xMOPP	IEC 60384-14 EN 60384-14	UR 37921 VDE (40002796) VDE (40002796)
Relays (RL1, RL2)	Omron	G5V-2 H1	24VDC/1A, 125VAC/0.5A, 70°C, V-2, FI only	UL508 CSA C22.2 No 14	UR E41515 CSA LR31928
Secondary terminals (P8-P12)	Molex	5045/XX	250V, 3A, 125°C, V-0	UL 1977	UR E29179
Secondary terminals (P13-P16)	Phoenix Contact	MCV1.5G6.81	160V, 8A, 95°C, V-0	ANSI/UL 486A-486B CSA-C22.2 No. 158	UR E60425 CSA LR13631
Internal primary wirings (Mains Power Board – Mains switch)	Kabelflex	H05VV-F	300/500V, 5x1.0mm ² 70°C, PVC Dielectric strength test: 4000V	HD 21.5 S3 clause 4 + /A1:1999 +/A2:2001	<HAR>
Shrinkable tubing primary wirings	Link solutions APS	FRZH heat shrinkable tubing	VW-1, 135°C	UL224	UR (E361238) CSA (220127)
Secondary wiring	Wiring experts	UL style 1007 / 1569	AWG 20-24, 80°C, PVC, VW-1	UL 758	UR (E112233)
Mains isolation transformer	Isolation trafo	ASP-4040	2 x 0-115V 50Hz, Temperature class A Sec1: 6A/0-24V Sec2: 6A/0-12-17V	UL 2601 IEC 60601-1	UR E111222 Tested in equipment
- Core insulation	Dupont	Polyester film Mylar A	3 rounds, each=0.05mm thick, min 50% overlap, total insulation=2 layers 105°C, VTM-2	UL94 ISO 9773	UR E93687
- Primary winding	Dahrentrad AB	Damid 200	Polyesterimide enameled copper wire, grade 2 Temp=200°C	UL1446	UR E101843
- Primary to secondary insulation	Dupont	Polyester film Mylar A	6 rounds, each=0.05mm thick, min 50% overlap, total insulation=5 layers Temp=105°C VTM-2	UL94 ISO 9773	UR E93687
-Termination wire	Nexans	Style 1569	300 VAC, Class A, 30 AWG - 2 AWG	UL 758	UR E214778 UR E157822
-Sleeving/ Tubing	Unichem Co, Ltd	UNIVP-300	105°C, VW-1, 1.0 mm	ANSI UL224	UR E157822
- Self resetting thermal fuse	Thermik	S01	250V, 7.2A, 110°C	UL873 UL60730-1 EN 60730-1 EN 60730-2-9	UR E130346 VDE 40022282

- Tape	Dupont	Polyester film Mylar A	0.05mm, 105°C	UL94 ISO 9773	UR E93687
- Potting compound	Stevenson	RX 121	PUR, 150°C, V-0, min thickness 3.0 mm	UL 746, UL 94	UR E111111
Foot Control					
Plastic enclosure	LG Chem	HF-380	5VA for min 1.5mm, V-0 for min 3.0mm, measured=3,2 mm, 85°C, ABS	IEC 60695-11-10	UR E234567
Plug	Binran	Series 66	500V, 85°C, IP40, metal	IEC 60601-1	Tested in equipment
Cable	VX Cables	Style 2464	300V/80°C, 2m, VW-1	UL 758	UR E191919
Console Controller Board, P/N: xx-xxxx, rev. 02					
PCB material	Suntak Multilayer PCB	JJ-02	125°C, V-0	UL 796	UR E207844
Secondary terminals (P1-P8)	Molex	5045/XX	250V, 3A, V-0	UL 1977	UR E29179
Instrument Controller Board, P/N: yy-yyyy, rev. 06					
PCB material	Suntak Multilayer PCB	JJ-02	125°C, V-0	UL 796	UR E207844
Secondary terminals (P1-P5)	Molex	5045/XX	250V,3A,V-0	UL 1977	UR E29179
Instrument board Display, P/N: zz-zzzz, rev. 02					
PCB material	Suntak Multilayer PCB	JJ-02	125°C, V-0	UL 796	UR E207844
Secondary terminals (P1-P7)	Molex	5045/XX	250V,3A,V-0	UL 1977	UR E29179
Water system					
Main magnet valve	Axbloy	601	0-6bar, 24Vdc, 8W, -10°C to +100°C	IEC 60601-1	Tested in equipment
Water filter regulator	Filter clo	58TT79	Max 13bar input, 0-12 bar output, filtration: 50µm	IEC 60601-1	Tested in equipment
Manometer	Mano Work	97687	0-12bar	IEC 60601-1	Tested in equipment
Fountain valves (x2)	Axbloy	605	0-6bar, 24Vdc, 4W, -10°C to +90°C	IEC 60601-1	Tested in equipment
Fountain valve	Axbloy	603	0-6bar, 24Vdc, 8W, -10°C to +100°C	IEC 60601-1	Tested in equipment
Water tubes (green)	Tube masters	65987	20bar, 60°C, HB, 6/3.9mm	UL 746	UR E140250
Water tubes (transparent)	Tube masters	65955	20bar, 60°C, HB, 6/3.9mm	UL 746	UR E140250

Water couplings	Couplings Work	Fittings Series A Fittings Series B Fittings Series C	60bar, 18bar, 12bar	IEC 60601-1	Tested in equipment
Amalgam separator	Meta pro	MXP22	24Vac, 2A, 250mbar, Class A	IEC 60601-1	Tested in equipment
Air system					
Main magnet valve	Axbloy	6598	0-6bar, 24Vdc, 8W, 100°C, IP65	IEC 60601-1	Tested in equipment
Air filter regulator	Mano Work	9369852	Max 13bar input, 0-12 bar output	IEC 60601-1	Tested in equipment
Manometer	Mano Work	123456	0-12bar	IEC 60601-1	Tested in equipment
Water valve (3 provided)	Axbloy	6692	0-6bar, 24Vdc, 4W, 100°C, IP65	IEC 60601-1	Tested in equipment
Air valve (6 provided)	Axbloy	6896A	0-6bar, 24Vdc, 8W, 100°C, IP65	IEC 60601-1	Tested in equipment
Air tubes (blue)	Tube masters	65236	23bar, -40°C to +60°C, 6/3.8mm	Tested in equipment	Tested in equipment
Air tubes (yellow)	Tube masters	65689	23bar, -40°C to +60°C, 6/3.8mm	Tested in equipment	Tested in equipment
Air couplings	Couplings Work	Fittings Series A Fittings Series B Fittings Series C	60bar, 18bar, 12bar	IEC 60601-1	Tested in equipment
Selective valve	Valve exp	6987	24Vdc, 75mA, max 200mbar, IP20	IEC 60601-1	Tested in equipment
Suction system					
Connector, suction	Binder	Series 680	500V, 85°C, IP40, metal	IEC 60601-1	Tested in equipment
Plug, suction	Binder	Series 680	500V, 85°C, IP40, metal	IEC 60601-1	Tested in equipment
Cord, suction	Restox	Style 2464	300V/80°C, 2m, VW-1	UL 758	UR E1564789
Suction arm	Raybax	TT234	Casted Aluminium, 2.0mm min thickness	IEC 60601-1	Tested in equipment
Suction nozzle	Stevia	NN78	PUR/155°C	IEC 60601-1	Tested in equipment
Suction hose	Sivling	VRT543	EVA/65°C	IEC 60601-1	Tested in equipment
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				
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹	
Y1 capacitors (Mains Power Board) (IC1-IC4)	Murata	KX DE1B3KX221K (C39) DE1B3KX471K (C98)	Y1, 125°C, 220pF (C39), 470pF (C98)	IEC 60384-14	VDE, Semko, Nemko, Fimko, IMQ	
Optical isolators (Mains Power Board) (IC10, IC11)	Analog Devices	ADuM2401 ARWZ	125°C, 7.7mm ext. cr./cl., 2 MOPP @ 125Vac	IEC 60601-1 2nd ed IEC 60601-1 3rd ed (cl. 8.5.5.1, 8.8.3, 8.9.1.15, 8.9.3.3)	CSA (205078)	
Supplementary information: 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.						