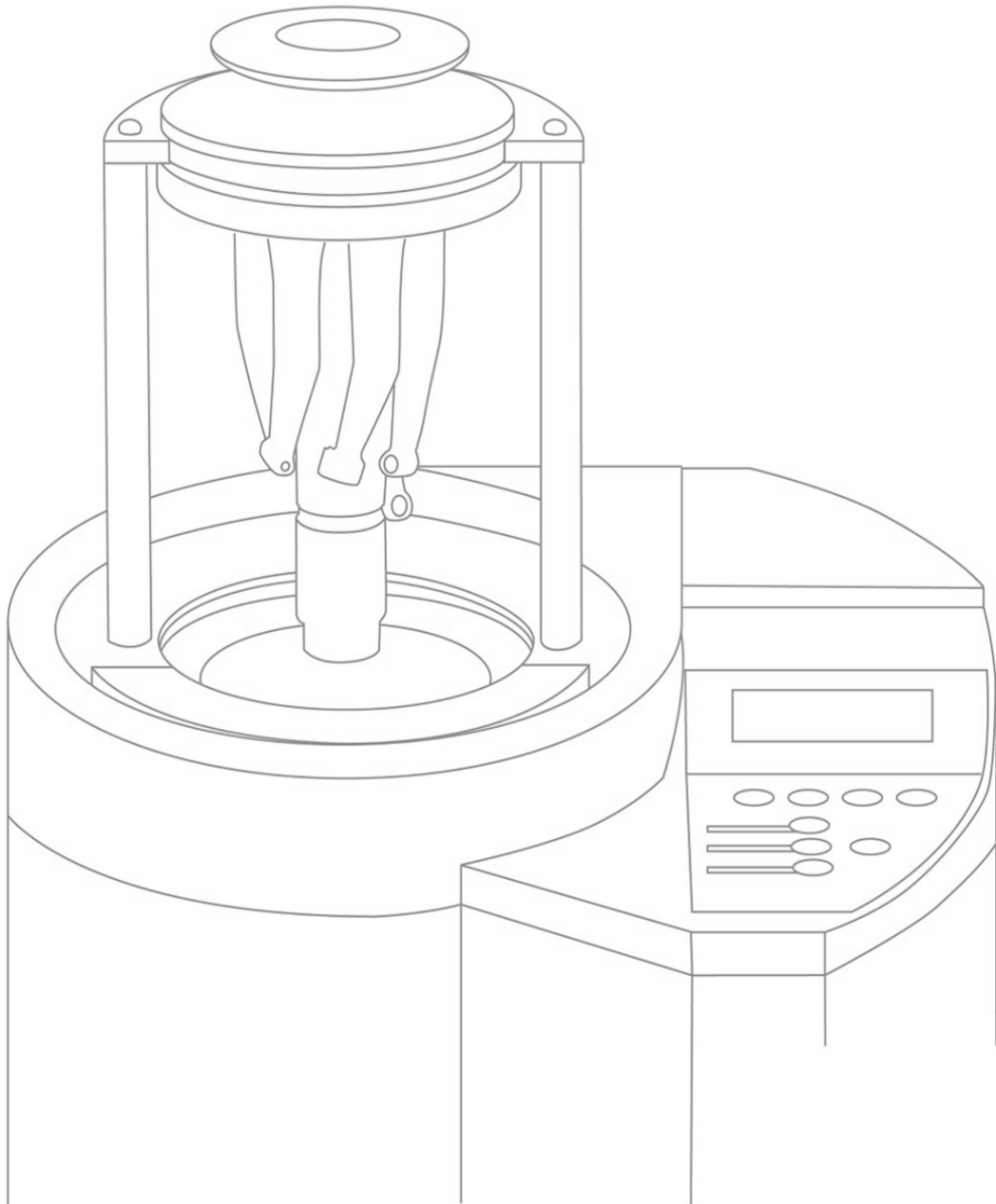


DAC UNIVERSAL

PRE-PURCHASE INFORMATION



CONTENT

1.	DAC UNIVERSAL.....	3
1.1.	Installation Information	3
1.1.1	Dimensions of Usable Space	3
1.1.2	Weight	3
1.1.3	Water Supply.....	4
1.1.4	Electricity Supply	4
1.1.5	Ambient Temperature, Altitude Pressure and Humidity	4
1.1.6	Compressed Air	4
1.2.	Additional Information	4
1.2.1	Service / Repair Spare Parts/Installation.....	4
1.2.2	Water & Steam Generation in the Sterilizer Chamber	5
1.2.3	Drained Water.....	5
1.2.4	Quality Information Requirements	6

1. DAC UNIVERSAL

The DAC UNIVERSAL is specially designed for the treatment of dental instruments – both wrapped and unwrapped. The DAC UNIVERSAL is a combination autoclave that cleans, lubricates and sterilizes handpieces, turbines and solid instruments.

The DAC UNIVERSAL comply to ISO/EN 15883-5 for cleaning and EN 13060 type S for steam sterilization of:

- *SIRONA T1 CLASSIC S40L*
- *SIRONA T2 REVO RH40*
- *SIRONA Endo 6:1*
- *SIRONA T2 CONTROL S*
- *SIRONA T2 Racer S*
- *SIRONA T1 LINE C200L*
- *Dental rotating instruments, which are comparable concerning weight, materials, surface, construction principle, gaps and geometry.*

- *EMS Universal Piezon handpiece EN-041A*
- *Other dental ultra sonic scalers which are comparable concerning weight, materials, surface, construction principle, gaps and geometry.*

- *Solid dental instruments suitable for steam sterilization (use of basket lid)*
- *Wrapped dental instruments (use of wrapped lid)*

1.1. Installation Information

1.1.1 Dimensions of Usable Space

- Total height of machine (open): 53 cm
- Total height of machine (closed): 35 cm
- When closed the autoclave is 35 cm x 36 cm (H x W).
- Recommended minimum space to the wall: 10 cm.
- Furthermore, there must be enough space to allow the autoclave to open (upright).
- The minimum height should be 70 cm, to prevent any bodily harm when opening the lid.

1.1.2 Weight

- Weight of DAC UNIVERSAL including handle and oil bottle: 23 kg
- Weight of DAC UNIVERSAL including handle with 6 instruments, oil bottle and full water tank: 25 kg
- The weight per support area when the reservoir is filled with water and the chamber contains a maximum load: 227635 N/m²
- The weight per support area during a pressure test: 227635 N/m²

1.1.3 Water Supply

- Recommended quality of the water used during the process: Demineralized or distilled water below 3 $\mu\text{S/cm}$.

1.1.4 Electricity Supply

- The DAC UNIVERSAL is a multiple-voltage machine, which means that it can operate at any voltage level between 90-120V or 190-240V.
- Type of electricity supply: AC
- Frequency: 50/60Hz
- Power supply: 1100W

1.1.5 Ambient Temperature, Altitude Pressure and Humidity

- Allowed range for the ambient temperature 16 °C – 26 °C.
- Allowed humidity maximum: 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C.

1.1.6 Compressed Air

- The maximum and minimum pressure: 5-8 bars
- The flow at minimum pressure: 150 l/min
- Quality information/requirement:
 - Air Quality according to ISO8573-1
 - Residual water max. content: 0.88 g/m³ (Class 3 according to ISO8573-1)
 - Residual oil max. content: 0.01 mg/m³ (Class 1 according to ISO8573-1)
 - Residual dust max content: 0.1 mg/m³ (Class 1 according to ISO8573-1)

1.2. Additional Information

1.2.1 Service / Repair Spare Parts/Installation

The service/repair spare parts list and tools information are available. All dealers have technical personnel, who is trained by Sirona Dental A/S for installation and repair if necessary. Sirona Dental A/S guarantees the supply of spare parts for the autoclaves for 7 years from the date of purchase.

1.2.2 Water & Steam Generation in the Sterilizer Chamber

Cleaning

Cold wash: below 45 °C

Hot rinse: Up to 107 °C

Sterilization

Gentle program: 121 °C at 2.1 bar (abs) for 15 minutes

Standard program: 134 °C at 3.2 bar (abs) for 3 minutes

Prion program: 134 °C at 3.2 bar (abs) for 18 minutes

The maximum water consumption used in a cycle: 800 ml

1.2.3 Drained Water

The sterilizer is designed so that the temperature of water or vapour drained to an external drainage system does not exceed 100 °C and the max. flow is 5 l/min.

The total heat in joule transmitted by the sterilizer to the surrounding air during an hour of continuous operation with the sterilization cycle giving the highest emission of heat, based on an ambient temperature of 23 ± 3 °C: 1495 kJ.

The mean and peak sound levels generated by the sterilizer, expressed as an A-weighted sound power level, when measured in accordance with EN ISO 3746:

Mean 47 dBA

Peak 58 dBA

1.2.4 Quality Information Requirements

Quality information requirements are stored by the manufacturer in a document called *Fulfillment of Essential Requirements Annex I According to Council Directive 93/42/EEC of 14 June 1993 And Medical Device Directive 2007/47/EC*.

Type test

Type test	Sterilization cycle type S		
	Wrapped load	Solid Load	Handpieces
Air leakage	x	x	x
Dynamic chamber	x		
Empty chamber	x	x	x
Solid load, unwrapped		x	x
Solid load, single wrapped	x		
Dryness, solid load, unwrapped		x	x
Dryness, solid load, single wrapped	x		
Non-condensable gasses	x	x	x
Microbiological test MBI	x	x	x

For EC Declaration of Conformity, please refer to www.sironahygiene.com.

The DAC UNIVERSAL is manufactured according to the directives and other harmonized standards listed below:

Directive / Norm		Date	Edition	Title
Directive	93/42/EEC	1993-06-14		Medical Devices directive (MDD)
Directive	2007/47/EC	2010-03-21		Medical Directive Amendment
Directive	97/23/EC	1997-05-29		The Pressure Equipment Directive (PED)
Directive	2006/95/EC	2006-12-12		Low Voltage Directive (LVD)
DS/EN	13060 + A2	2010-04-28	3	Small Steam Sterilizers
DS/EN	13445-1	2009-09-11	4	Unfired pressure vessels – Part 1: General
DS/EN ISO	13485	2012-02-28	3	Medical devices – Quality Management systems – Requirements for regulatory purposes.
DS/EN ISO	14971	2009-09-30	4	Medical devices - Application of risk management to medical devices
DS/EN ISO	15883-1	2009-07-13	2	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
DS/CEN ISO/TS	15883-5	2005-12-01	1	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy
DS/EN	60601-1-2	2007-09-28	3	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility (EMC) - Requirements and tests
IEC	61010-1	2001-12-07	2	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC	61010-2-40	2006-01	1	Safety requirement electrical equipment for Laboratory use
DS/EN	62304	2006-09-12	1	Medical device software - Software life-cycle processes
DS/EN	62366	2008-02-19	1	Application of usability engineering to medical devices
DS/EN ISO	9001	2008-12-09	4	Quality management system - Requirements