

### Proposer

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Date Quick Scan .... :2013-06-17

### Previous Verification:

Previous Verification performed:    X No     Yes, date:

### Description Technology – technical documentation

The BacTerminator Dental includes several water treatment steps to ensure clean water to the dental unit water line:

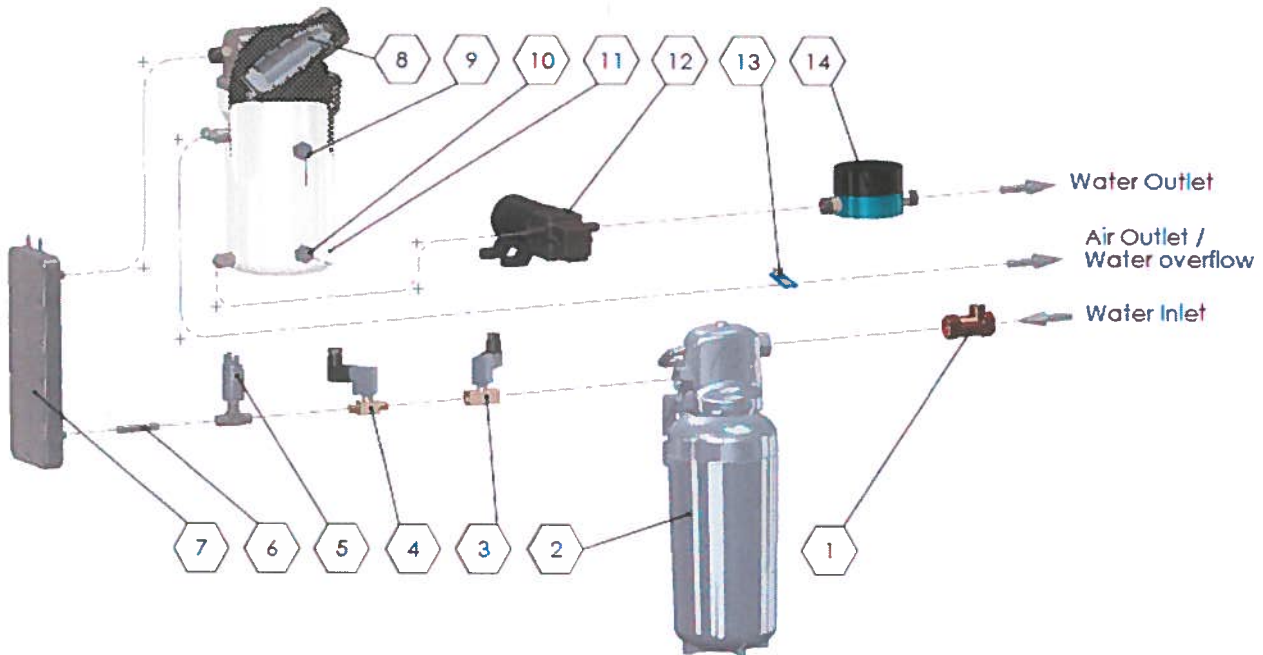
- Pre-filtering - a 100 micron filter stops all major particles
- Softening - An ion exchanger removes all scaling from the system, meaning the dental unit will no longer clog up with scaling
- Carbon filter - removes old chlorine and odour from the incoming water
- Fine filtering - a 1 micron filter removes finer particles
- Chlorination - In-line electrolysis produces an adjustable amount of chlorine that disinfects the water
- Bio Reaction Zone - A specially designed feature that seize all microorganisms large enough not to be immediately killed by the chlorine, thus ensuring that no living microorganisms are sent into the dental unit water line.

The chlorinated water emerging from the BacTerminator Dental will prevent growth of bacteria in the dental unit water line, and thus also ensure the patient's health.

The unit is to be used for dental unit water lines or similar applications for following purposes:

- Prevention of live bacteria and microorganisms in the water.
- Removal of particles and prevention of scale build up in the water line.

The unit has a residual and preventive effect on growth of bacteria and microorganisms in connected subsequent equipment.

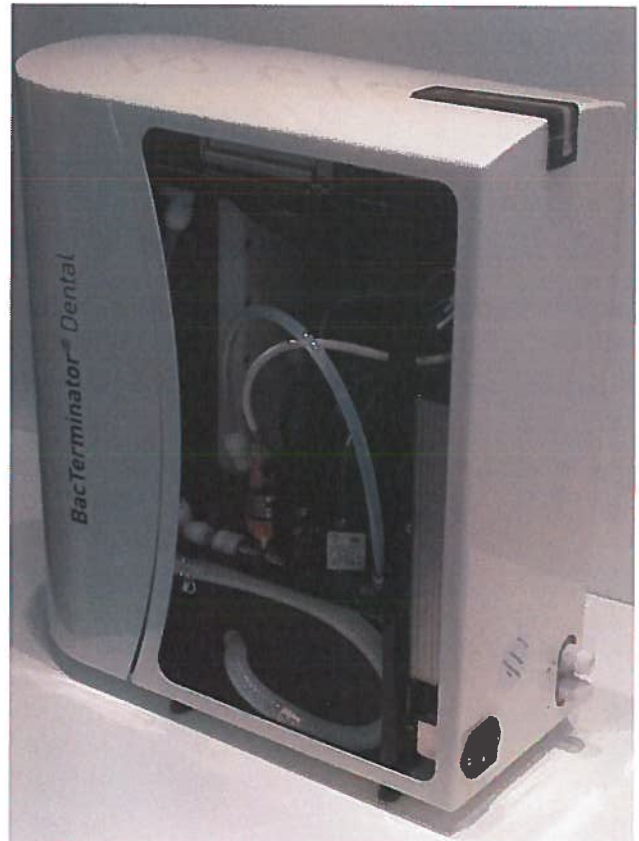


**Process diagram:**

- 1: DS EN/6117 Approved non-return valve
- 2: Head and cartridge for filter/softener
- 3&4: Solenoid valves
- 5: Pressure switch
- 6: Optional flow restriction
- 7: BacTerminator disinfection chamber
- 8: BioReductionZone
- 9: Water tank with 20mm air gap
- 10: Level sensors
- 11: Pump
- 12: Pulsation dampener
- 13: Leak detector

The product will be produced according to ISO 13485 and CE-mark as Medical device.

The technology of the BacTerminator has been tested by VKI in February 1998 using 8 different types of bacteria at a flow of 4 l/min. The test showed that at an effect of 25A/8,4V or above, no bacteria growth was possible.<sup>1</sup>



<sup>1</sup> VKI-case no. 10924

**Intended application of the technology**

Matrix:

Cleaning of water of drinking water quality according to WHO's guidelines.

Purpose:

The unit is to be used for dental unit water lines or similar applications for following purposes:

- Prevention of live bacteria and microorganisms in the water.
- Removal of particles and prevention of scale build up in the water line.

The unit has a residual and preventive effect on growth of bacteria and microorganisms in connected subsequent equipment.

**Initial performance claim**

The test is performed to validate the following vendor claims:

1. BacTerminator produce a minimum of 0.5 mg/l of free chlorine when the requirements to the concentration of chloride and the conductivity in the incoming water are fulfilled.
2. Removal or killing of pathogenic bacteria (*Legionella*) to undetectable levels (< 1/100 ml), and heterotrophic plate count (incubated at 37 °C in 48 hours) < 1 CFU/ml in the outlet water of BacTerminator® Dental (ingoing to the dental unit).
3. Outgoing water (from the dental unit) has a heterotrophic plate count < 500 CFU /ml and < 100 CFU Legionella/L.<sup>2</sup>
4. No biofilm is generated in new dental chair piping systems.
5. Existing biofilm is removed from old dental chair piping systems.

The operational conditions shall be in accordance with:

- The inlet water shall be of a quality fulfilling WHO's guidelines for drinking-water quality. The pH is lowered in the treatment unit by approximately one pH unit in the outlet water.
- Conductivity and chlorine shall be 200-1500µS/cm and 10-250mg/l according to the unit manual.

**Performance requirements**

- Water in: 1-1½L/min depending on restriction and water pressure
- Water out: 1-3L/min @ 2-2½bar

Description/principles clear .....	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No:
Declared performances described.....	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No:
Innovative technology .....	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No:
Ready-to-market .....	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No:
Prototype in advanced stage of development.....	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No:

<sup>2</sup> Requirement according to DS 2451-12

**Remarks out of Quick Scan to be considered:**

The BacTerminator Dental also has some key environmental aspects which set it apart from other disinfection devices used:

No chemicals are added to create the disinfection. All other devices on the market for disinfection of water add at least one chemical to the water. These products do therefore have a much higher risk profile than the BacTerminator Dental. As the risk for handling the chemicals and the risk of adding too much of the chemicals have to be added to the risk profile. When using the BacTerminator Dental the necessary disinfection agents are created in the device, and are created in controlled doses. Do the creation of the disinfection agents no chemical handling is necessary when using the BacTerminator Dental.

The use of resources during operation of the BacTerminator Dental is limited to the electricity used to power the device and the filters used. The BacTerminator will use approximately 20 Watt when in use, less than 5 Watt on standby and a maximum of 200 Watt. And 2 filter carriages and 1 sterile filter an year, depending on the water quality. And NO chemicals!

Most of the parts are reusable. Approximately 75% of the parts used to produce a BacTerminator are reusable when the device is decommissioned. The remaining 25% can be incinerated or are electronics.

The BacTerminator Dental has Longevity of minimum 5 years. This lifetime is based on regular service and preemptive maintenance as necessary. The BacTerminator Dental is not designed to become obsolete, and even though new and more efficient technology may become available, the BacTerminator Dental will still perform its basic function - disinfecting water.

The technology is suitable for verification under the EU ETV pilot programme.

**Verification body:**

Name ..... : Peter Fritzel

Date ..... : 18-07-2013

Signature ..... : 

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**DS Certificering A/S**

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