

QUICK SCAN REPORT	Technology name:	BacTerminator® Dental
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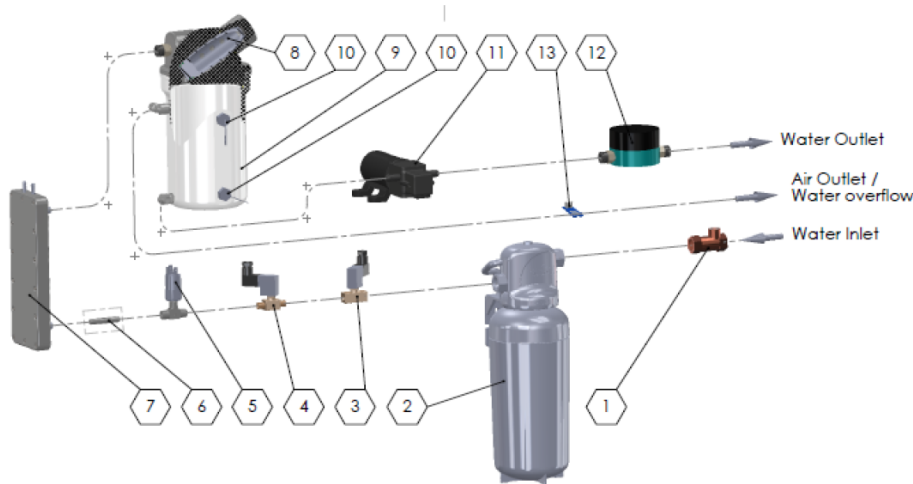
Verification body		Proposer	
Name:	DS Certification	Name:	Adept Water Technologies A/S
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Quick scan		Previous quick scan					
Date:	07052013	Yes		Date:		No	X

<p>Technology description</p> <p>The BacTerminator Dental includes several water treatment steps to ensure clean water to the dental unit water line:</p> <ol style="list-style-type: none"> 1. <i>Pre-filtering - a 100 micron filter stops all major particles</i> 2. <i>Softening - An ion exchanger removes all scaling from the system, meaning the dental unit will no longer clog up with scaling</i> 3. <i>Carbon filter - removes old chlorine and odor from the incoming water</i> 4. <i>Fine filtering - a 1 micron filter removes finer particles</i> 5. <i>Chlorination - In-line electrolysis produces an adjustable amount of chlorine that disinfects the water</i> 6. <i>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.</i> <p><i>The lightly 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.</i></p> <p>Intended Use</p> <p>This product has the following intended use:</p> <p>The unit is to be used for dental unit water lines or similar applications for following purposes:</p> <ul style="list-style-type: none"> • prevention of live bacteria and microorganisms in the water. • removal of particles and prevention of scale build up in the water line. <p>The treated water will not be harmful to the health of patients or dentists.</p> <p>The unit has a residual and preventive effect on growth of bacteria and microorganisms in connected subsequent equipment.</p>

Operational conditions:

The inlet water shall be of a quality fulfilling WHO's guidelines for drinking-water quality regarding chemistry. The pH is lowered in the treatment unit to by one pH unit in the outlet water. Conductivity and chlorine shall be sufficient for production of a free chlorine concentration in the outlet water of 0.5-1.0 ppm.



Process diagram:

- 1: DS EN/6117 Approved non-return valve
- 2: Head and cartridge for filter/softener)100 µm filter + carbon filter + ion exchange filter (removal of Ca⁺⁺), 1 µm filter
- 3&4: Solenoid valves
- 5: Pressure switch
- 6: Optional flow restriction
- 7: BacTerminator disinfection chamber
- 8: BioReductionZone (Hollow fibre membrane filter 0,2 µm
- 9: Water tank with 20mm air gap
- 10: Level sensors
- 11: Pump
- 12: Pulsation dampener
- 13: Leak detector

Technology ready to market			Technology in last development phase			
Yes	X	No	Yes	X	No	
Performance claims						
Matrice(s):	Water for Dental Unit Water lines					
Purpose(s):	Treatment of water including in-line disinfection of water by electrolysis. The system uses the natural chloride and conductivity in the water to produce disinfectants, i.e. HOCl and OCl ⁻ .					
Vendor claim(s):	Removal or killing of pathogenic bacteria (<i>Pseudomonas aeruginosa</i> and <i>Legionella</i>) to undetectable levels (respectively < 1 CFU/L and < 100 CFU/L), and heterotrophic plate count (incubated at 37 °C in 48 hours) < 500 CFU/ml in the					

	<p>outlet water.</p> <p>No biofilm is generated in new dental chair piping systems.</p> <p>Existing biofilm is removed from old dental chair piping systems. This is done according to the system is able to produce 0,5 – 1.0 ppm free chlorine measured at the outlet of the system.</p>
Definitions	
Matrix:	Public drinking water -The inlet water shall be of a quality fulfilling WHO's guidelines for drinking-water quality regarding chemistry.
Purpose:	The unit is a medical device for use in connection with the Dental Inlet Water Line. The BacTerminator Dental will offer immediate improvement of water quality.
Initial performance claims	<p>Removal or killing of pathogenic bacteria (<i>Legionella</i> and <i>Pseudomonas aeruginosa</i>) to undetectable levels (< 1/ liter), and heterotrophic plate count (incubated at 36 °C in 48 hours) < 200 CFU/ml in the outlet water.</p> <p>No biofilm is generated in new dental chair piping systems.</p> <p>Existing biofilm is removed from old dental chair piping systems.</p> <p>This is done according to the system is able to produce 0,5 – 1 ppm free chlorine measured at the outlet of the system.</p>
Previous tests performed No	
Test body:	
Test reports provided to the verification body:	

Evaluation by verification body

Technology description clear				Performance claims clear			
Yes	X	No		Yes	X	No	

Existing test data							
Tests performed				Test body qualified			
Yes		No	X	Yes		No	
Test report available				Test report qualified			
Yes		No	X	Yes		No	
Test methods available				Test methods adequate			
Yes		No	X	Yes		No	
Raw data available				QA of raw data adequate			
Yes		No	X	Yes		No	
Performance claims sustained				Performance claims relevant			
Yes		No	X	Yes		No	

Conclusions quick scan (incl. estimated cost range for a verification)

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

[budget information not disclosed]

Date	Name	Signature
2013.05.13	Peter Fritzel	Original signed by Peter Fritzel

DS Certificering A/S

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