Statement of Verification

EU Environmental Technology
Verification pilot programme

Technology:	BacTerminator® Dental
Registration number:	VN20160010
Date of issue:	21. January

Verification Body		**Proposer**	
Name:	ETA-Danmark A/S	Name:	Adept Water Technologies
Contact:	Thomas Bruun	Contact:	Michael Reidtz Wick
Address	Göteborg Plads 1 DK-2150 Nordhavn	Address:	Ellekær 6 DK-2730 Herlev
Telephone:	+45 72 24 59 00	Telephone:	+45 88 70 85 26
E-mail:	tb@etadanmark.dk	E-mail:	mrw@adeptwatertech.com
Web:	www.etadanmark.dk	Web:	www.adept-dental-water.com

Signed, 10 February 2016.

Verification responsible
Thomas Bruun

Managing Director
Michael Reidtz Wick

DANAK
Reg. Nr. 9099

This EU-ETV verification statement summarizes the results from verification of the BacTerminator® Dental, produced by Adept Water Technologies A/S in Herlev, Denmark.

The EU Environmental Technology Verification (ETV) pilot programme is a programme, which is voluntary. It aims to establish a framework for independent, qualified, third-party assessment of the performance of eco-innovative technologies, to facilitate their entry into the market. The programme has been active since 2011.

A Danish ETV programme was established in 2008 as a partnership between five Danish technological service centres, which provides experts and test facilities for the verification procedure. The partners are DHI, Danish Technological Institute, FORCE Technology, AgroTech and DELTA.

ETA-Danmark A/S is a subsidiary in Danish Standard, and is the Danish verification body for Environmental Technology Verification. ETA-Danmark is accredited by the Danish Accreditation body, DANAK, according to EN 17020 for performing environmental technology verifications. This is based on the cooperation with the DANETV-partners.

The statement of verification is available on the ETV Registry at the following webpage http://iet.jrc.ec.europa.eu/etv/verified-technologies

1. Technology description

The description of the technology is based on information from Adept Water Technologies.
BacTerminator® Dental (BDT) applies on-site generation of chlorine from sodium chloride-salt in an electrolytic cell (Figure 1). The BDT is designed specifically for use in dental clinics and is produced according to ISO 13485 regarding medical devices. The product is CE-marked as medical device. The BDT includes several treatment steps to ensure pure and safe water to the dental unit:

- Pre-filtering - a 100 micron filter retains large particles
- Softening - an ion exchanger prevents scaling from the system to ensure the dental unit will not clog due to scaling
- Carbon filter - removes any existing chlorine and odour from the incoming water
- Fine filtering - a 1 micron filter removes fine particles
- Chlorination - In-line electrolysis on mixed metal oxide electrodes produces an adjustable amount of oxidants (chlorine, hypochlorous acid and hypochlorite, thereby disinfecting the water
- Bio Reaction Zone – a chamber ensuring that the bacteria are in contact with the oxidants for a sufficient period of time.

Figure 1: The BacTerminator® Dental (Photo provided by Adept Water Technologies)

2. Application

2.1. Matrix

The matrix is drinking water to be used in chairs in dental clinics.

2.2. Purpose

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

- Prevention of bacteria and other 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 other microorganisms in connected downstream equipment.

2.3. Conditions of operation and use

The performance claims are based on the following operational conditions:

- The quality of the inlet water must fulfil WHO's guidelines for drinking-water quality.
- The pH in the treatment unit is reduced by approximately one pH unit in the outlet water.
- Conductivity must be 200-1500 µS/cm, and chloride must be 10-250 mg/L.
- Water in: 1-1½ L/min. The BDT is restricting this water flow, which otherwise would depend on water tap dimension and water pressure.
- Water out: 1-3 L/min at 2-2.5 bar. The outlet water flow depends on the pump and the back pressure.

2.4. Verification parameter definition summary

The selected performance claims for BDT unit were:

1. Production 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*) and heterotrophic plate count (HPC 37, incubated at 37°C for 48 hours) in the outlet water of the BDT.
3. Legionella count and HPC 37 in outgoing water from the dental chair
4. Degree of generated biofilm in new surrogate dental chair piping systems.
5. Degree of removal of existing biofilm from old surrogate dental chair piping systems.
6. Formation of halogenated by-products such as trihalomethanes and haloacetic acids: below USEPA's limits for drinking water.
7. Free chlorine content in outlet water of BDT.
8. Level of heavy metals in outlet water: no leaching of metals.

3. Test and analysis design

The Technical specification ISO/TS 11080 "*Dentistry – Essential characteristics of test methods for evaluation of treatment methods intended to improve or maintain the microbiological quality of dental unit procedural water*", dated 2009-06-01, describes in details how to test dental chair disinfection technologies such as the BDT. The technical specification evaluates the two following aspects:

- Removal of biofilm from surfaces within the dental unit water delivery system
- Prevention or inhibition of biofilm formation on surfaces within the dental unit water delivery system.

The test design was therefore based on ISO/TS 11080. The standard only focuses on HPC at 37°C, while *Legionella* was included in this verification. Tap water containing *Legionella* and bacteria cultures were used for the challenge tests.

3.1. Existing and new data

A test for heavy metals was performed by Eurofins Product testing A/S, Denmark. The metals contained in the mixed metal oxide electrodes of the BDT were below the analytical detection limit, during an exposure time of 17 days. The test was found to convincingly demonstrate that the electrodes do not leach the electrode metals in detectable concentrations, even after extended contact time.

3.2. Laboratory or field conditions

Surrogate dental chairs were constructed by Adept and operated at DHI's laboratory facilities in Hørsholm, Denmark. The microbiological analysis was performed as agar plate culturing of water sampled in colony forming units (CFU) per millilitre. The test design included the operation of the BDT on a new surrogate dental chair with no biofilm (Phase 1), and on a surrogate dental chair with pre-grown biofilm (Phase 2). Phase 1 was carried out from 28 April to 7 October 2014, and Phase 2 from 7 October 2014 to 31 March 2015 (Figure 2).

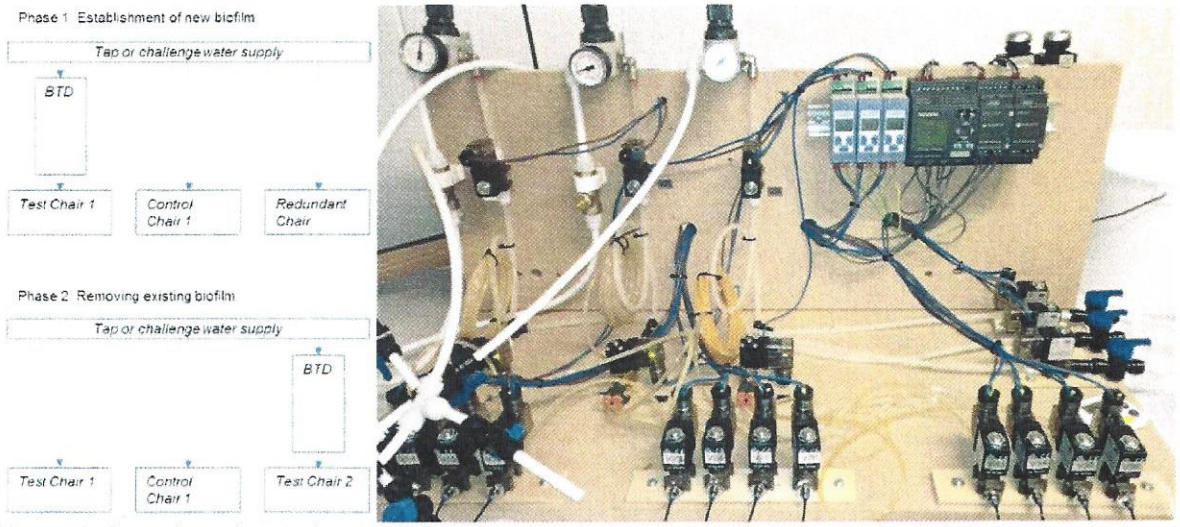

Figure 2: Overview of test phases and test setup

3.3. Matrix compositions

During continuous operation, the test setup was fed with tap water. During challenge tests, water from hot water systems known to contain *Legionella* was applied, or tap water spiked with bacteria culture.

3.4. Test and analysis parameters

The following tests parameters were investigated (Table 1):

Table 1: Test and analysis parameters overview

Bacteria	Free chlorine and by-products
Biofilm development in new surrogate dental chair with BDT	Free chlorine after the BDT
Biofilm in old surrogate dental chair after installation of BDT	Free chlorine after the surrogate dental chair.
Biofilm in chair without BDT– control measurement	Chlorinated by-products after the surrogate chair
Level of heterotrophic plate count after BDT	**Operational parameters**
Level of heterotrophic plate count without BDT– control measurement	Water flow through the system
Level of *Legionella* after BDT	**Environmental parameters**
Level of *Legionella* without BDT– control measurement	Power consumption during operation and outside working hours (standby).
Level of heterotrophic plate count after surrogate dental chair with BDT	
Level of heterotrophic plate count after surrogate dental chair without BDT– control measurement	
Level of *Legionella* after surrogate dental chair with BDT.	
Level of *Legionella* after surrogate dental chair without BDT– control measurement	

3.5. Tests and analysis methods summary

Analyses were performed at the test laboratory and at external laboratories. The choice of methods for each parameter are summarised in the section below.

3.6. Parameters measured

The following parameters were analysed during the test (Table 2):

Table 2: Overview of parameters analysed

Parameter	Method / device	*Legionella* source	Water source	Output water from BDT	Outgoing water dental chair	Tube sample dental chair
Bacteria in water phase	HPC 37, HPC R2A	X	X	X	X	
Bacteria on surface	HPC R2A					X
Legionella	Plate count	X		X	X	
Free chlorine, chloride, hardness	Photometric equipment		X	X	X	
Temperature, pH, conductivity	Regular online devices	X	X	X		
Drinking water parameters	Regular methods		X		X	
Total Trihalomethanes (TTHM) haloacetic acids	GC-MS				X	
Heavy metals (determined by the composition of the electrode material)*	ICP-MS			X		

4. Verification results

4.1. Performance parameters

Biofilm formation (Phase 1)

Biofilm was sampled from the inner surfaces of the tubes downstream the BDT. The criterion (detection limit) for biofilm formation was determined to be 43 CFU/cm². **The biofilm formed in test chair 1 was below the detection limit. In contrast, significant biofilm formation was detected in both control chairs** (Table 3).

Table 3: Biofilm formation in test phase 1, as HPC on R2A agar at 22 °C, sampled from tubes (CFU/cm²)

Date of sampling	Test chair 1	Control chair 1	Control chair 2
2014-04-22	3	10	n.a.
2014-05-05	1	3 400	n.a.
2014-07-18	7	6 300	n.a.
2014-09-24	18	122 000	50 200

n.a. = not analysed

Biofilm removal (Phase 2)

In phase 2, biofilm was sampled from the inner surfaces of the tubes downstream the BDT. **The biofilm in test chair 2 decreased by two orders of magnitude, and was more than two orders of magnitude lower than in control chair 1.** The formation of biofilm in test chair 1 increased by 2-3 orders of magnitude in phase 2 after the BTD was removed from the chair (Table 4).

Table 4: Biofilm formation in test phase 2, as HPC on R2A agar at 22 °C, sampled from tubes (CFU/cm²)

Date of sampling	Test chair 1	Control chair 1	Test chair 2
2014-10-09	n.a.	68 500	66
2014-11-20*	9 930	81 900	396

* Average of 2-5 samples taken from different tubes n.a. = not analysed

Reduction of Bacteria in water

The reduction of bacteria across the BDT during *Legionella* challenge is shown in Table 5. In several instances, the quantifiable $\log_{10}$ reduction was limited by the measurement range of the analytical methods. For each sampling occasion, the measured free chlorine concentration and the corresponding CT-value (product of chlorine concentration and contact time) are stated.

Table 5: Reduction of Legionella (ISO 6222:2000, uncertainty 0.3 $\log_{10}$) and HPC at 37 °C (DS 3029:2001, uncertainty 0.3 $\log_{10}$) across the BDT during Legionella challenges in test phases 1 and 2, free chlorine concentration and CT-value.

Free Cl_2 mg/l	CT-value mg*min/L	HPC in 1/ml	HPC out 1/ml	HPC reduction $\log_{10}$	Legion. in 1/ml	Legion. out 1/ml	Legion. reduction $\log_{10}$
0.6	0.4	300	4	1.9	80	< 10	> 0.9
3.3	2.0	1400	< 1	> 3.1			
4.45	2.8	> 2000	3	> 2.8	40000	< 10	> 3.6
2.3	1.4	230	5	1.7			
1.26	0.8	> 2000	7	> 2.5	> 1000000	< 10	> 5.0
1.86	1.2	> 2000	9	> 2.3	40000	< 10	> 3.6
1.49	0.9	> 2000	11	> 2.3	> 1000000	< 10	> 5.0
0.15	0.1	3700	650	0.8			
2.77	1.7	450	5	2.0	13000	< 10	> 3.1

It is concluded that the BDT removed Legionella that were added to the test system to below the detection limit when the CT-value was ≥0.4 mg · min /L. This corresponded to a free chlorine concentration about 0.6 mg/L. The BDT removed Heterotrophic Plate Count (HPC) at 37 °C in water to 11 CFU/ml or less. **At CT-values ≥ 0.4 mg · min/L, the reductions were 1.7 to >3.1 $\log_{10}$ units.**

On one challenge test occasion with addition of Legionella, the observed CT-value was low (0.1 mg · min/L, at 0.15 mg/L free chlorine), for unknown reasons. On that sampling occasion, the reduction of HPC was 0.8 log. "*Suspected Legionella*" were detected in the outlet that day. Due to an oversight

by the analytical laboratory (lack of confirmation), the *Legionella* results from that sampling day are especially uncertain.

Free chlorine concentration

The measured concentrations of free chlorine and the applied power setting on the BDT are reported in Table 6. **In all cases within the acceptable range of conductivity (200-1500 µS/cm) and chloride (10-250 mg/L), the BTD produced above 0.5 mg/l of free chlorine, while the concentration was also below the WHO drinking water level of 5 mg/l.**

Table 6: Average free chlorine measured in the outlet of the BDT. Standard deviations (±) and number of replicates (n) are stated in brackets. BDT power setting is shown in square brackets. The acceptable range of feed water conductivity and chloride stated by Adept Water Technologies is highlighted in grey.

Target Conductivity / Target Chloride	Very low 5 mg Cl⁻/L	Low 10 mg Cl⁻/L	Medium 75 mg Cl⁻/L	High 250 mg Cl⁻/L
Very low (100 µS/cm)	0.86 (±0.051, n=3) [15]			
Low (200 µS/cm)		1.11 (±0.049, n=2) [12]	>2 (n=2, n=1) [12;5]	
Medium (800 µS/cm)		0.73 (±0.006, n=2) [12]	1.89 (±0.028, n=2) [5]	
High (1500 µS/cm)		0.77 (±0.090, n=2) [15]		1.6 (n=1) [2]
Very High (2000 µS/cm)	0.43 (±0.017, n=3) [15]			24.1* (±1.273, n=15)

* Maximum chlorine production test at 1824 µS/cm and 234 mg/L chloride (both measured)

Chlorination by-products

Halogenated by-products were analysed in two samples. **The concentration of Total Trihalomethanes (TTHM) varied between 18 and 57 µg/L. This is below the US drinking water directive requirements (sum < 80 µg/L) and EU requirements (sum < 100 µg/L). The highest sum of concentrations of haloacetic acids was 27 µg/L, which is below the US limit of 60 µg/L for five haloacetic acids (HAA5).** The highest detected TTHM concentrations coincided with a relatively high free chlorine concentration of 1.8 mg/L in the outlet of the BTD.

4.2. Operational parameters

During operation of the BDT, the water flow through the system and general water quality parameters were measured.

4.3 Environmental parameters

It was found that the electrodes do not leach the electrode metals to the water in detectable concentrations, after extended contact time (17 days). Electricity usage during operation was 2.6-5 W, and 1.5 W outside working hours. The consumption per 7 hours working day with connection to one dental unit was calculated to be 0.03-0.04 kWh.

4.4. Additional parameters

The user manual and other descriptions were considered complete, including health and safety aspects. No critical issues were identified with regard to resource use. On decommissioning, the unit will be electronic waste, and should be handled in accordance with local regulations.

5. Additional information

Chlorine production is adjusted manually by changing the power setting on the BacTerminator® Dental. This is done by a plumber during installation of the equipment, and during maintenance. The required power setting depends on the tap water quality entering the unit. Details on the chlorine concentration and the power setting of the unit are found in the BDT user manual.

6. Quality assurance and deviations

The verification was carried out according to the Quality Assurance plan described in the verification protocol. There were no deviations from the verification protocol. During testing, internal and external audits were carried out by DHI and ETA Danmark, respectively.