Adept Water Technologies A/S

BacTerminator® Dental

Verification Report
November 2015

Approved by
Peter Fritzel (Verification responsible, ETA Danmark)
Peter Schneider (Head of department, DHI)

Adept Water Technologies A/S

BacTerminator® Dental

Prepared for Adept Water technologies A/S

Represented by Michael R. Wick

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Archiving: All standard project files (documents, *etc.*) are archived at ETA Danmark. Any other project files (set-up files, forcing data, model output, *etc.*) are archived with the institute performing the tests or analysis.

1 Introduction

Environmental technology verification (ETV) is an independent (third party) assessment of the performance of a technology or a product for a specified application under defined conditions and quality assurance.

The objective of this verification is to evaluate the performance of the BacTerminator® Dental, a technology based on a combination of filtration and disinfection by electrolysis of water to dental chairs.

This verification was performed under the EU ETV Pilot Programme, together with the Chinese ETV Pilot Programme.

This Verification Report and the verification of the technology are based on the Specific Verification Protocol (Appendix D), Test Plan (Appendix F), and Test report for the Adept Water Technology BacTerminator® Dental [1].

1.1 Name of technology

BacTerminator® Dental, produced by Adept Water Technologies A/S.

1.2 Name and contact of proposer

Adept Water Technologies
Ellekær 6
2730 Herlev
Denmark

Contact:
Michael Reidtz Wick, email: mrw@adeptwatertech.com, phone: +45 8870 8526, mobile: +45 5164 3636

Website: www.adept-dental-water.com

1.3 Name of Verification Body and responsible of verification

EU ETV:
ETA Danmark A/S[1]
Göteborg Plads 1
2150 Nordhavn
Denmark

Person responsible for verification:
Peter Fritzel (PF), email: pf@etadanmark.dk, phone +45 7224 5900

Appointed verification expert (verification protocol phase):
Mette Tjener Andersson (MTA), DANETV

Appointed verification expert (verification report phase):
Gerald Heinicke (GHE), DANETV, e-mail: ghe@dhigroup.com, phone: +45 4516 9268

[1] During time of verification DS Certification has changed name to ETA Danmark.

China ETV:
Chinese Society for Environmental Sciences (中国环境科学学会)
No.54 Honglian Nan Cun
Haidian District
Beijing 100082.
P.R.China

Person responsible for verification:
Wang Rui (WR) 王睿 (Name in Chinese), email: wangrui797@163.com, phone: +86 010 62210466.

1.4 Verification organisation, including experts

The verification was conducted by ETA Danmark A/S in cooperation with Danish Centre for Verification of Climate and Environmental Technologies, DANETV.

The verification was planned and conducted to satisfy the requirements of the ETV scheme established by the European Union (EU ETV Pilot Programme) [2].

The verification was coordinated and supervised by ETA Danmark, assisted by an appointed DANETV verification expert.

In addition, the verification was planned and conducted to satisfy the requirement of the Chinese ETV scheme.

The tests were carried out by DHI DANETV test centre. The proposer built the test setup, helped with the decision on the correct chlorine production level (power setting) on the BacTerminator® Dental, and carried out service (change of filters) during the test phase.

Internal and external experts were assigned to provide independent expert review of the planning, conducting and reporting of the verification and tests:

- Internal technical experts:
    - Gerald Heinicke (GHE), DANETV, e-mail: ghe@dhigroup.com (verification protocol phase)
    - Bodil Mose Pedersen (BOP), DANETV, e-mail: bop@dhigroup.com (verification report phase)
    - Yi Bin (YB), 易斌 (Name in Chinese), Chinese Society for Environmental Sciences (CSES), email: nibiy@sina.com
    - Liu Ping (LP), 刘平 (Name in Chinese), Chinese Society for Environmental Sciences (CSES), email: liup3000@163.com
- External technical experts:
    - Lars D. M. Ottosen (LDMO), Aarhus University, Institute for Biological and Chemical Engineering, email: ldmo@eng.au.dk (verification protocol phase)
    - Mette Tjener Andersson, Niras (MEA), email: mea@niras.dk, (verification report phase)
    - Lin Shaobin (LSB), 林少彬 (Name in Chinese), Chinese Center for Disease Control and Prevention (CDC), email: 13501260565@163.com

The tasks assigned to each expert are given in more detail in section 5, Quality assurance.

The relationships between the organisations related to this verification and test are given in Figure 1.1 .

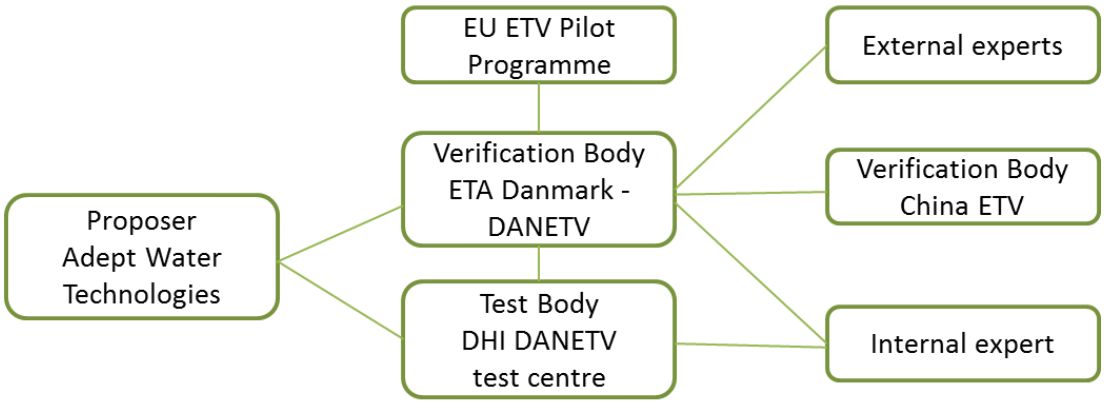

Figure 1.1 Organisation of the verification and test

The principles of operation of the DANETV verification process are given in Table 1.1. Verification and testing are divided between the verification body and the test body.

Table 1-1 Simplified overview of the verification process

Phase	Responsible	Document
Preliminary phase	Verification body	Quick Scan
		Contract
		Specific verification protocol
Testing phase	Test body	Test plan
		Test report
Assessment phase	Verification body	Verification report
		Statement of Verification

Quality assurance is carried out by an expert group of internal and external technical experts. Two audits of the test system were performed, starting with an internal audit by the test body followed by an external audit by the DANETV verification body under ETA Danmark. Reference for the verification process is the EU ETV General Verification Protocol [2] and ETA Danmark's internal procedure [3].

After completion of the verification, an EU Statement of Verification will be issued by the Danish verification body. Based on the verification report and the EU Statement of Verification, a China ETV Statement of Verification will be issued.

1.5 Deviations from the verification protocol

There were no content deviations from the verification protocol. The project was delayed by more than one year, compared to the verification schedule in the verification protocol. This was mainly due to problems in obtaining tap water with a reliable content of *Legionella*. The delay did not affect the conclusions of the verification.

2 Description of technology and application

2.1 Summary description of the technology

The description of the technology is based on information from Adept Water Technologies.

The technology behind BacTerminator® Dental (in this report abbreviated BDT in some tables) is based on on-site generation of disinfectants in an electrolytic cell. Oxidant inactivating the microorganisms is produced from NaCl-salt (Figure 2.1).

The BacTerminator® Dental is designed specifically for use in dental clinics and is produced according to ISO 13485 regarding medical devices and is CE-marked as medical device.

Figure 2.1 The BacTerminator® Dental (Photo provided by Adept)

The BacTerminator® Dental includes several water treatment steps to ensure clean water to the dental unit water line (Figure 2.2):

- Pre-filtering - a 100 micron filter stops all major particles
- Softening - a ion exchanger removes all scaling from the system to ensure the dental unit will not clog up with scaling
- Carbon filter - removes chlorine and odour from the incoming water
- Fine filtering - a 1 micron filter removes fine particles

- Chlorination - an in-line electrolysis produces an adjustable amount of oxidants (chlorine, hypochlorous acid (HOCl) and hypochlorite (OCl-) disinfecting the water
- Bio Reaction Zone – a chamber ensuring that the bacteria are in contact with the oxidants for a sufficient period of time.

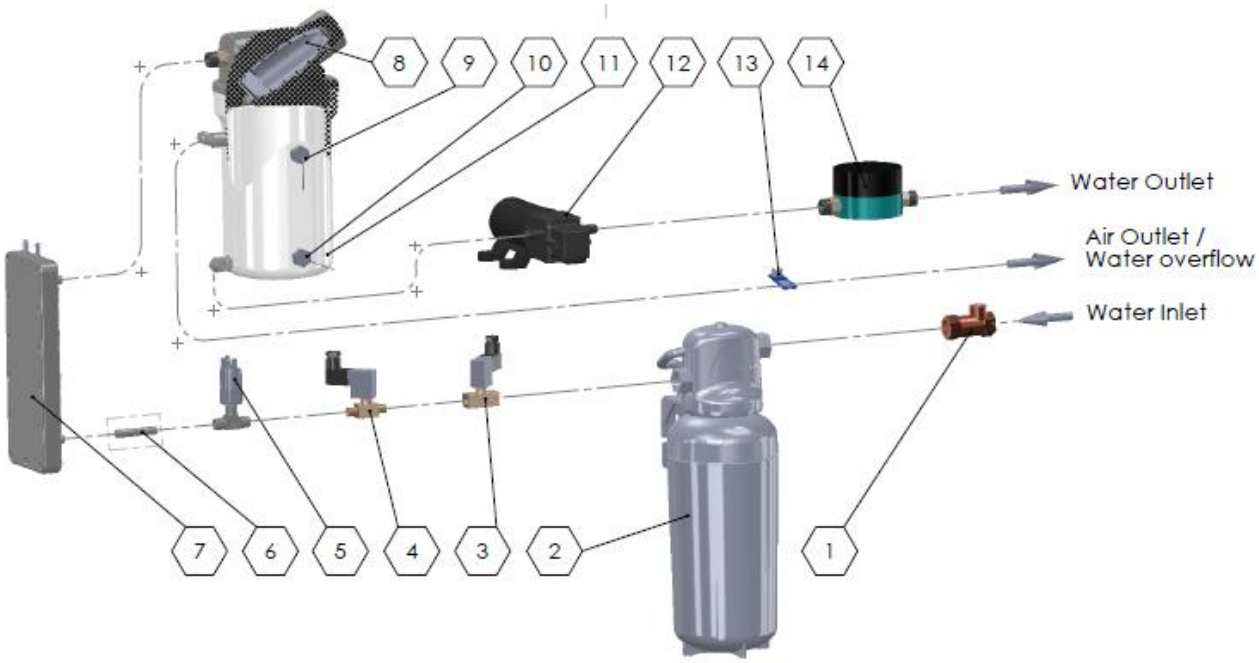

Figure 2.2 Process diagram: 1: DS EN/6117 Approved non-return valve; 2: Head and cartridge for filter/softener; 3 & 4: Solenoid valves; 5: Pressure switch; 6: Optional flow restriction; 7: BacTerminator® disinfection chamber; 8: Bio Reaction Zone; 9: Water tank with 20mm air gap; 10: Level sensors; 11: Pump; 12: Pulsation dampener; 13: Leak detector

2.2 Intended application

The intended application of the product for verification is defined in terms of the matrix and the purpose. The BacTerminator® Dental is a combination of filtration and disinfection by electrolysis of water to dental chairs.

2.2.1 Matrix

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

2.2.2 Purpose

The unit is to be used for dental unit 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 microorganisms in connected subsequent equipment.

2.2.3 Technologies

BacTerminator® Dental is based on on-site generation of chlorine in an electrolytic cell.

2.2.4 Technical conditions

The proposer stated the following operational conditions as prerequisites for the operation of the BacTerminator® Dental:

- 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 concentration 10-250mg/L.
- Water in: max. 1-1.5 L/min. The BacTerminator® Dental is restricting this water flow, which otherwise would depend on water tap dimension and water pressure.
- Water out: max. 1-3 L/min at 2-2.5 bar. The outlet water flow depends on pump and back pressure.

2.3 Verification parameter definition

The original claims from the proposer were all found to be relevant and valid. In addition to the claims from the proposer were included two claims regarding free chlorine and formed chlorinated by-products (Appendix D).

The selected performance claims for a BacTerminator® Dental unit are:

1. BacTerminator® produces 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.
4. No biofilm is generated in new dental chair piping systems. (The test body specified the level of biofilm acceptable as equal to "no biofilm growth").
5. Existing biofilm is removed from old dental chair piping systems. (The test body specified the level of biofilm acceptable as equal to "no biofilm growth").
6. No formation of halogenated by-products such as trihalomethanes and haloacetic acids. Concentrations are kept below USEPA's limits for drinking water.
7. Free chlorine content in outlet water of BacTerminator® Dental < 50 mg/L.
8. Level of heavy metals in outlet water is below drinking water quality criteria.

3 Existing data

A test for heavy metals was performed by Eurofins Product testing A/S, Denmark, and reported on 4 November 2013. The test showed that the metals contained in the mixed metal oxide (MMO) electrodes of the Bac-Terminator® Dental were below the detection limit, during an exposure time of 17 days. The results are described in Appendix J of the test report [1].

The test was reviewed on 13 March 2014 and found to convincingly demonstrate that the electrodes do not leach the electrode metals in detectable concentrations after extended contact time.

3.1 Accepted existing data

The abovementioned data were accepted.

4 Evaluation

Detailed descriptions of the test design and test results are found in the Test Plan (Appendix F) and the Test Report [1].

4.1 Calculation of verification performance parameters

The following parameters were evaluated, as described in the specific verification protocol.

4.1.1 Bacteria

The following parameters were identified:

Claim 4 & 5
- Biofilm development in new surrogate dental chair with chair with BacTerminator® Dental
- Biofilm in old surrogate dental chair after installation of BacTerminator® Dental
- Biofilm in surrogate dental chair without BacTerminator® Dental – control measurement

Claim 2
- Level of heterotrophic plate count after BacTerminator® Dental
- Level of heterotrophic plate count without BacTerminator® Dental – control measurement
- Level of *Legionella* after BacTerminator® Dental
- Level of *Legionella* without BacTerminator® Dental – control measurement

Claim 3
- Level of heterotrophic plate count after surrogate dental chair with BacTerminator® Dental
- Level of heterotrophic plate count after surrogate dental chair without BacTerminator® Dental – control measurement
- Level of *Legionella* after surrogate dental chair with BacTerminator® Dental.
- Level of *Legionella* after surrogate dental chair without BacTerminator® Dental – control measurement

These levels from surrogate dental chairs with BacTerminator® Dental were compared to values from the control measurements.

4.1.2 Free chlorine

The average and standard deviation of measurements for free chlorine were determined at:

Claim 1 & 7
- The sampling point just after the BacTerminator® Dental
- The sampling point after the surrogate dental chair.

Contact time[2] (mg of free Cl_2 * min) was calculated based on water flow and free chlorine concentration. The relation between contact time and bacterial (heterotrophic plate count and *Legionella*) reduction was investigated.

4.1.3 Chlorination by-products

The average and standard deviation of measurements for chlorination by-products as trihalomethanes and haloacetic acids were determined at the sampling point after the surrogate dental chair (related to Claim 6).

[2] In water treatment, this parameter is commonly known as the *Ct-value* (*i.e.* the integral of the free chlorine concentration over time).

4.2 Evaluation of test quality

4.2.1 Control data

The BacTerminator® Dental operated without any problems during the entire test period. There were some minor problems with flow measurements and clogging of the sampling tips in the test system.

Control of the tests system:
The test system was controlled by flow measurements and control of the water quality data [1].

Control analyses of measured vs. nominal concentrations were carried out for chloride and free chlorine. The measured concentrations were found to be within the required tolerances.

The repeatability of Heterotrophic plate count (HPC) on R2A agar was determined, and was well within the requirements.

Performance evaluation audit:
There were no online measurements to be controlled as part of a performance evaluation audit.

Control of analysis performed at external laboratory
All external analyses were carried out under accreditation, which requires participation in proficiency tests.

Control of the data quality and integrity
Spread sheets used for the calculations were subject to control on a sample basis (spot validation of at least 5% of the data).

4.2.2 Audits

An internal test system audit was performed by Bodil Mose Pedersen from DHI on 9 July 2014. The verification body ETA Danmark, represented by Peter Fritzel, performed a test system audit on 9 October 2014.

Conclusions from the internal audit (Bodil Mose Pedersen): "No non-conformities expecting to influence the test results were identified."

Conclusions from the audit of ETA Danmark (Peter Fritzel): "There is consistency with the test plan, and handling of samples is carried out in a safe manner."

4.2.3 Deviations

There were 6 deviations to the test plan. None of these are considered to have any significant impact on the test. See section 3.4 of the test report, and Appendix I (the letter I, not 1) to the test report.

There were no amendments to the test plan.

4.3 Verification results (verified performance claim)

4.3.1 Performance parameters

The following results were obtained during the test, related to the performance parameters and the proposer's claims.

4.3.1.1 Bacteria

Claim 4: No biofilm is generated in new dental chair piping systems.

In test phase 1 (28 April to 7 October 2014), test chair 1 received chlorinated water from the BacTerminator® Dental, while control chairs 1 & 2 received tap water.

First flush as an indication of biofilm presence

The enumeration of bacteria in the first flush is only an indication of biofilm formed on the surfaces. This analysis was carried out to ensure, that there was enough biofilm formed for the test.

HPC on R2A agar in the first flush water samples of control chair 1 in test phase 1 was between 20,500 CFU/ml and 90,900 CFU/ml (Table 4.1), indicating biofilm formation in accordance with the requirements (10^4 - 10^6 CFU/ml) as described in ISO 11080 /9/.

HPC-R2A was a factor 4 to 10 times higher in the first flush of control chair 1, when compared to test chair 1. The analytical repeatability (standard deviation within the day) was determined to 0.064 $\log_{10}$ units, corresponding to 16 %. The difference was therefore considered significant.

One sample taken from control chair 2 also indicated the presence of biofilm. The other HPC parameter (at 37 °C) in the first flush trial suffered from too low dilutions during analysis, *i.e.* most results were larger than the upper limit of the analytical range (data not shown).

Table 4-1 HPC on R2A agar at 22 °C in tests phase 1. Concentrations in first flush from test chair 1 and control chairs 1 & 2.

Date of sampling	Test chair 1 (CFU/ml)	Control chair 1 (CFU/ml)	Control chair 2 (CFU/ml)
2014-04-22	2 730	20 500	n.a.
2014-05-05	24 500	90 900	n.a.
2014-07-09	7 240	68 600	n.a.
2014-09-24	12 800	52 500	11 800

Biofilm as measured on the inner surface of the tubing

Biofilm was sampled from the inner surfaces of the tubes downstream the BacTerminator® Dental (Table 4.2). The criterion of biofilm formation was determined to be 43 CFU/cm², prior to the start of the test (see Appendix E of the Test report). The biofilm formed in test chair 1 was below 43 CFU/cm². In contrast, significant biofilm formation was detected in both control chairs.

Table 4-2 Biofilm formation in test phase 1, as HPC on R2A incubated at 22 °C, in tubes connected to valves 1-5 (test chair 1), 2-5 (control 1) and 3-5 (control 2). Average of duplicate analyses, except test chair 1 on 24 September (single analysis). All values in 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

Claim 5: Existing biofilm is removed from old dental chair piping systems.

In test phase 2 (7 October 2014 to 31 March 2015), control chair 2 was converted to test chair 2, and received chlorinated water from the BacTerminator® Dental. Test 1chair and control chair 1 received tap water.

First flush as an indication of biofilm presence

The enumeration of bacteria in the first flush is only an indication of biofilm formed on the surfaces. This analysis was carried out to ensure, that there was enough biofilm formed for the test.

The results of the analyses of the first flush in phase 2 are shown in Table 4.3. The HPC-R2A in the first flush of control chair 1 in phase 2 was between 5,600 CFU/ml and 17,100 CFU/ml, remaining at a level indicating biofilm presence.

It is concluded that the HPC concentrations in the control chairs (including test chair 1) indicate biofilm formation in phase 2, as described in ISO11080 /32/, and that the BTD reduces the bacteria concentration.

Table 4-3 HPC on R2A agar at 22 °C in tests phase 2. Concentrations in first flush from test chair 1 (now a control), and control chair 1 and test chair 2 (*i.e.* previous control chair 2).

Date of sampling	Test chair 1 (CFU/ml)	Control chair 1 (CFU /ml)	Test chair 2 (CFU /ml)
2014-10-09	n.a.	17 100	10 850
2014-10-28	n.a.	15 300	5 750
2014-11-20	40 500	5 640	4 750

n.a. = not analysed

Biofilm as measured on the inner surface of the tubing

Also in phase 2, biofilm was sampled from the inner surfaces of the tubes downstream the BacTerminator® Dental (Table 4.4). The formation of biofilm in test chair 2 was 2 orders of magnitude lower than at the end of phase 1, and more than 2 orders of magnitude lower than in control chair 1. However, the biofilm did not decrease to below the detection limit of 43 CFU/cm^2. The formation of biofilm in test chair 1 increased 2 to 3 orders of magnitude in phase 2 after the BTD was removed from the chair.

Table 4-4. Biofilm formation in test phase 2, as HPC on R2A incubated at 22 °C, in tubes connected to valves 1-5 (test chair 1), 2-5 (control 1) and 3-5 (test chair 2). Average of duplicate analyses, unless indicated otherwise. All values in CFU/cm^2.

Date of sampling	Valve	Test chair 1	Control chair 1	Test chair 2
2014-10-09	1-5, 2-5, 3-5	n.a.	68 500	66
2014-11-20	1-5, 2-5, 3-5	9 250	50 000	434
	1-6	10 600		
	*2-3		71 000	
	*2-4		124 000	
	2-6		82 000	
	3-3			148
	3-4			675
	3-5			434
	3-6			289
Average 20 Nov		*9 930*	*81 900*	*396*

* single analysis n.a. = not analysed

Claim 2 & 3: Removing or killing Legionella pneumophila and HPC (37 °C), Concentration of Legionella and HPC in outgoing water

During the test, Legionella from four sources were added to the test system. These included hot tap water from two buildings in the Copenhagen area (Rigshospitalet and Ryparken), known to contain *Legionella*, and two *Legionella* cultures.

Reduction of *Legionella*

The results of the Legionella challenges are shown in Table 4.5 (Phase 1) and Table 4.6 (Phase 2). On two sampling dates (2014-11-20 and 2015-01-28), the confirmation of *Legionella* was not carried out, due to an oversight by the external laboratory. Therefore, these results are reported as "suspected *Legionella",* and shown in parenthesis in the tables. For these sampling

days, it cannot be stated with certainty, that the suspected Legionella detected were the added *Legionella pneumophilae*.

"Suspected" *Legionella* (>100/L) were detected in the BacTerminator® Dental outlet on one occasion, coinciding with a low contact time (*i.e.* Ct-value) of 0.1 mg · min /L. The low contact time was due to a low concentration of 0.15 mg/L free chlorine, which is below the minimum of 0.5 mg/L stated by Adept Water Technologies. The reason for the low chlorine concentration that day is unknown, but may be related to flow and retention times. It is therefore important that the chlorine production level is set correctly in relation to the inlet water quality. On this sampling day, the confirmation of *Legionella* was not carried out, due to an oversight by the external laboratory – thus the "suspected *Legionella*". The results from that sampling day are therefore especially uncertain.

Table 4-5 Phase 1 results from *Legionella* analyses during challenge with water containing *Legionella*. Results in brackets are "suspected" *Legionella* (due to oversight by the external laboratory). Unit: CFU/L

Date	Inlet BDT	Outlet BDT	Outlet test chair 1	Inlet control chair 1&2	Outlet control chair 1	Outlet control chair 2
2014-04-22	80	< 10	< 10	100	< 10	n.a.
2014-05-05	< 10	< 10	< 10	< 10	< 10	n.a.
**2014-07-09	40 000	< 10	< 10	*****40 000	100 000	n.a.
***2014-07-09	(> 100)	< 10	< 10	(> 100)	(> 100)	n.a.
**2014-09-24	40 000	< 10	< 10	*****40 000	90 000	70 000
****2014-09-24	> 1 000 000	< 10	< 10	*****> 1 000 000	> 1 000 000	(> 100)

* Challenge water from Ryparken ** Challenge water from Rigshospitalet *** *Legionella* culture obtained from Rigshospitalet **** NCTC 12821 suspension (culture) ***** Same sample and analysis as for inlet BTD n.a. = not analysed

Table 4-6 Phase 2 results from *Legionella* analyses during challenge with water containing *Legionella*.. Results in brackets are "suspected" *Legionella* (due to oversight by the external laboratory). Unit: CFU/L

Date	Inlet BDT	Outlet BDT	Outlet test chair 1	Inlet test chair 1 & control chair 1	Outlet control chair 1	Outlet test chair 2
****2014-10-14	> 1 000 000	< 10	n.a	*****> 1 000 000	> 1 000 000	7 000
****2014-11-20	(> 100)	< 10	< 10	*****(> 100)	(> 100)	550
****2015-01-28	(> 100)	(> 100)	(> 100)	*****(> 100)	(> 100)	90 000
**2015-03-31	13 000	< 10	n.a	*****13 000	6 000	< 10

** Challenge water from Rigshospitalet **** NCTC 12821 suspension (culture)
***** Same sample and analysis as for inlet BTD n.a. = not analysed

The reduction of *Legionella* across the BacTerminator® Dental as a function of the contact time during *Legionella* challenge is shown in Figure 4.1. Contact time estimation was based on the measured free chlorine concentration and the minimum residence time, which was calculated from the measured (maximum) flow of 1385 ml/min and a total BacTerminator® Dental tank volume.

At contact times of at least 0.4 mg · min/L, all reductions were larger than the values shown in the figure, because the concentrations in the outlet were below the detection limit. On most occasions, a high inlet concentration allowed the quantification of reductions >3 $\log_{10}$ units to >5 $\log_{10}$ units. On one occasion, the measured reduction was >0.9 $\log_{10}$ units, due to a low *Legionella* concentration in the inlet.

It is concluded that the BacTerminator® Dental removed the *Legionella* to below the detection limit (Claim 2) when the contact time was sufficient (in this case 0.4 mg · min /L). This corresponded to a free chlorine concentration about 0.6 mg/L.

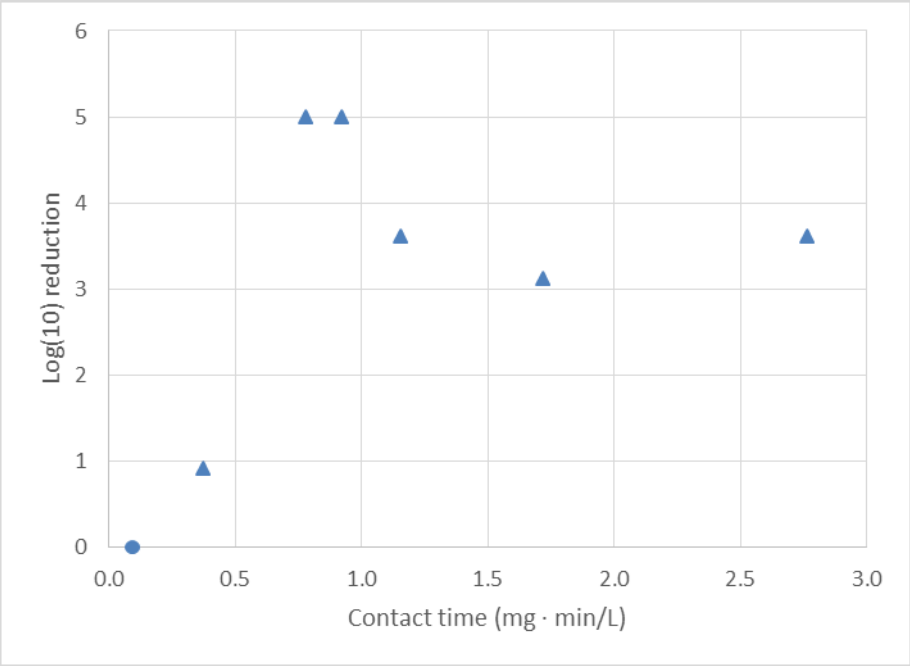

Figure 4.1 Reduction of *Legionella* across the BacTerminator® Dental during *Legionella* challenges in test phases 1 and 2, as a function of the contact time (Ct-value). Upward pointing triangles illustrate that the reduction is larger than indicated by the y-axis value.

Legionella was not detected in test chair 1 during phase 1. There was no significant reduction across the control chair 1 (Table 4.5).

Phase 2 (Table 4.6) represents the installation of a BacTerminator® Dental on an existing dental unit, as the test chair 2 was transformed from a control chair receiving untreated water to a test chair receiving BTD treated water on the 8 October 2014.

On 14 October 2014, the concentration of *Legionella* in test chair 2 was more than 2 $\log_{10}$ units lower than the concentration in control chair 1 showing that the change to BTD treated water had reduced the concentration. The detection of *Legionella* in outlet test chair 2 on subsequent sampling dates in phase 2 was considered to be caused by cross contamination via the discharge container for the tubes. Prior to the last *Legionella* challenge test on 31 March 2015, the test chair 2 outlet tube was replaced and separated from the common discharge container. The following results showed no *Legionella* in the outlet of test chair 2, compared to 6000 *Legionella*/L in the control chair [1].

Reduction of HPC (37 °C)

The reduction (removal or inactivation) from the feed water of the HPC at 37 °C by the BTD is shown in Table 4.7 (Phase 1) and Table 4.8 (Phase 2). The HPC was reduced to 11 CFU/ml or less, except on 28 January 2015 coinciding with a low contact time (0.1 mg •min/L, at 0.15 mg/L free chlorine).

Table 4-7 Heterotrophic plate counts at 37 °C in phase 1. Unit: CFU/ml

Date	Inlet BDT	Outlet BDT	Outlet test chair 1	Inlet control chair 1	Outlet control chair 1	Outlet control chair 2
2014-04-22	300	4	2	690	820	n.a.
2014-05-05	1 400	< 1	40	1 300	> 2 000	n.a.
**2014-07-09	> 2 000	3	14	*> 2 000	> 2 000	n.a.
***2014-07-09	230	5	19	*230	890	n.a.
**2014-09-24	> 2 000	7	13	*> 2 000	> 2 000	> 2 000
****2014-09-24	> 2 000	9	100	*> 2 000	> 2 000	> 2 000

* Same sample and analysis as for inlet BTD ** Challenge water from Rigshospitalet
*** DHI tap water added *Legionella* culture obtained from Rigshospitalet
**** DHI tap water added NCTC 12821 suspension (culture) n.a. = not analysed

Table 4-8 Heterotrophic plate counts at 37 °C in phase 2. Unit: CFU/ml.

Date	Inlet BDT	Outlet BDT	Outlet test chair 1	Outlet control chair 1	Outlet test chair 2
2014-10-14	> 2000	11	n.a.	> 2000	11
2015-01-28	3700	650	3200	4400	130
**2015-03-31	450	5	n.a.	60	< 1

** Challenge water from Rigshospitalet n.a. = not analysed

The reduction of HPC across the BTD during *Legionella* challenge as a function of the contact time is shown in Figure 4.2. At contact times ≥ 0.4 mg min/L, the reductions were 1.7 to >3.1 log_{10} units. On 28 January 2015, the reduction was 0.8 log units, coinciding with a low contact time (0.1 mg · min/L, at 0.15 mg/L free chlorine)[3]. The contact time calculation was based on the free chlorine concentration and the measured maximum flow through the unit.

It is concluded that the BTD removes HPC at 37 °C to 11 CFU/ml or less at reduction rates of 1.7 log_{10} units to > 3.1 log_{10} units at contact times ≥0.4 mg · min /L.

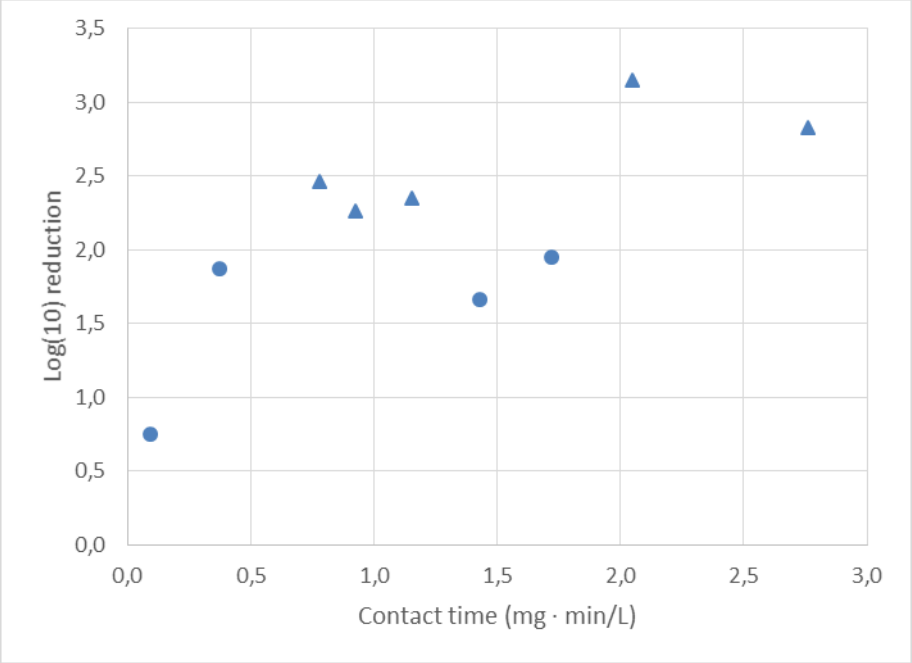

Figure 4.2 Reduction of HPC across the BTD during *Legionella* challenge as a function of the contact time. Triangles illustrate that the reduction is larger than indicated by the y-axis.

The heterotrophic plate counts from test chair 1 in phase 1 were between 2 CFU/ml and 100 CFU/ml (Table 4.7). For comparison, the heterotrophic plate count was > 2000 CFU/ml in the outlet of the control chairs. HPC in the outlet from test chair 2 in phase 2 was 11, 130 and < 1 CFU/ml. The high HPC concentration coincided with a low chlorine concentration (0.15 mg/L).

It is concluded that the heterotrophic plate counts were between 2 and 100 CFU/ml in the outlet of the test chairs, as claimed, under the condition that the contact time (Ct-value) of free chlorine was at least 0.4 mg min/L.

4.3.1.2 Free chlorine concentration

Claim 1: BacTerminator® produces 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.

[3] As mentioned above, in section "Reduction of Legionella"

The intensity of chlorine production by the BacTerminator® Dental was adjusted manually, by changing the power setting. The power setting ranged from level no. 2 in high chloride test water to the maximum level no. 15 in low chloride test water. The measured average concentrations of free chlorine are reported in Table 4.9. The acceptable range of feed water conductivity and chloride stated by Adept is highlighted in grey.

Table 4-9 Average free chlorine measured in the outlet of the BDT. BacTerminator® Dental power setting shown in parenthesis. Standard deviations are stated in the test report [1].

Target Conductivity/ Target Chloride	Very low 5 mg/L	Low 10 mg/L	Medium 75 mg/L	High 250 mg/L
Very low (100 µS/cm)	0.86 (15)			
Low (200 µS/cm)		1.11 (12)	>2 (5 & 12)	
Medium (800 µS/cm)		0.73 (12)	1.89 (5)	
High (1500 µS/cm)		0.77 (15)		1.6 (2)
Very High (2000 µS/cm)	0.43 (15)			24.1* (15)

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

Claim 7: Free chlorine content in outlet water of BacTerminator® Dental < 50 mg/L.

A test with the BacTerminator® Dental at maximum setting (*i.e.* 15) was carried out at measured conductivity of 1824 µS/cm and 234 mg/L chloride, and resulted in 24.1 mg/L free chlorine (Table 4.9).

4.3.1.3 Chlorination by-products

Claim 6: No formation of halogenated by-products such as trihalomethanes and haloacetic acids. Concentrations are kept below USEPA's limits for drinking water

Halogenated by-products were analysed in samples taken on 9 July and 24 September 2014.

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) [4].

Total Trihalomethanes (TTHM) varied between 18 and 57 µg/L. This is below the US drinking water directive requirements (sum < 80 µg/L) [4] and EU requirements (sum < 100 µg/L) [5].

On 9 July 2014, TTHM was higher than the current Danish drinking water requirements (sum < 25 µg/L) [6]. The TTHM concentration on 9 July coincided with a relatively high free chlorine concentration of 1.8 mg/L in the outlet of the BTD compared to the free chlorine concentration of 0.48 mg/L on 24 September. Note that the formation of trihalomethanes not only depends on free chlorine in the water, but also on the presence and character of Natural Organic Matter (NOM).

4.3.2 Operational parameters

During operation of the BacTerminator® Dental the water flow through the system was recorded. The results are reported in Appendix C to the test report [1].

Water temperature (°C), pH, hardness (°dH), and conductivity (µS/cm) were measured on both sides of BacTerminator® Dental (Appendix B to the test report). The quality of in and out going water was analysed for general drinking water parameters. The water quality was within the guidelines of WHO [7], as well as the European drinking water requirements [5].

4.3.3 Environmental parameters

4.3.3.1 Heavy metals from the electrode material

Claim 8: Level of heavy metals in outlet water is below drinking water quality criteria

A test for heavy metals was performed by Eurofins (external lab) and reported on 4 November 2013. The test showed that the metals contained in the mixed metal oxide (MMO) electrodes of the BacTerminator® Dental were below the detection limit, during an exposure time of 17 days.

The test was reviewed on 13 March 2014 and found to convincingly demonstrate that the electrodes do not leach the electrode metals in detectable concentrations after extended contact time.

4.3.3.2 Power consumption

The power consumption was measured from Thursday 1st May to Monday 5 May, and on 21 November 2014. A summary of the results are shown in Table 4.10.

Table 4-10: Measured hourly and measured or calculated daily energy consumption in May and November 2014. The consumption per litre is estimated on the basis of an estimated volume of 17.4 L per 3 dental units.

	1-2 May 2014	21 November 2014
Measured consumption per hour during operation (kWh)	0.0026	0.0050
Measured consumption per hour outside working hours (kWh)	0.0015	0.0015
Estimated consumption per 7 hours working day with connection to 1 dental unit (kWh)	0.0315	0.0370
Estimated consumption per litre with connection to 1 dental unit (kWh)	0.0054	0.0064
Measured consumption per 7 hours working day with connection to 3 dental units (kWh)	0.0438	0.0604
Estimated consumption per litre with connection to 3 dental unit (kWh)	0.0025	0.0035

4.3.4 Additional parameters

4.3.4.1 User manual

The verification criterion for the user manual is that the manual describes the use of the equipment adequately and is understandable for the typical test coordinator and test technician. This criterion was assessed through evaluation of a number of specific points of importance (Table 4.11).

A description is complete if all essential steps are described, if they are illustrated by a figure or a photo, where relevant, and if the descriptions are understandable without reference to other guidance.

Adept Water technologies has provided:

- Service Manual. BacTerminator Dental. Installation - Operation – Service. I 800 rev. 05 (46 pages)

Instruction for Use. Original Instruction: 130039 rev. 04UK. Date of Issue: 20150630 (2 pages)

Table 4-11 Criteria for evaluation of user manual

Parameter	Complete description	Summary description	No description	Not relevant
Product				
Principle of operation	x			
Intended use	x			
Performance expected	x			
Limitations	x			
Preparations				
Unpacking			x	
Transport		x		
Assembling	x			
Installation	x			
Function test		x		
Operation				
Steps of operation	x			
Points of caution	x			
Accessories	x			
Maintenance	x			
Trouble shooting	x			
Safety				
Chemicals	x			
Power	x			

It is concluded that the user manual is complete and useful.

4.3.4.2 Required resources

The capital investment and the resources for operation and maintenance could be seen as the sustainability of the product and will be itemized based on a determined design [8], see Table 4.12 for the items included.

Table 4-12 List of capital cost items and operation and maintenance cost items per product unit

Item type	Item	Number	None
Capital			
Site preparation	Flush upstream water system if necessary and make sure that the included return-valve complies with local regulations regarding back-flow prevention	Included in "installation" by plumber, see below.	
Buildings and land			None
Equipment	BacTerminator® Dental	1	
Utility connections	Power 230 V Drinking water system Sewer system	1 1 1	
Installation	To be installed by plumber	1 day	
Start-up/training	By plumber during installation		
Permits			None
Operation and maintenance			
Materials, including chemicals	Filters* Chlorine, chloride and hardness measurement strips.	approx. 4 filters yearly On demand	
Utilities, including water and energy	Electric power	See section on power consumption	
Labor	Filter change* Measuring water quality with strips	Once/twice a year On demand	
Waste management	Used filters*	approx. 4 filters yearly	
Permit compliance			None

*See details in Table 4-13

The following information regarding resource use was provided by Adept Water Technologies:

Resources used during production of the equipment in the BacTerminator® Dental
The BacTerminator Dental is made from parts sourced from around the world: The aluminium cabinet is manufactured in Denmark with materials from the world market. Plastic parts are similarly moulded in Denmark. Power supplies, electrodes and electronic parts are from the Far East, the pumps are from USA and the plastic fittings and tubing are typically, but not exclusively made in the EU. Adept has quality standards as to the functionality and purity/approvals of the subassemblies, but not as to how the raw materials are produced.

As to transport, the subassemblies are mainly transported by road from the local suppliers. Power supplies are transported by sea and then by road. Electrodes are transported by air.

Longevity of the equipment
The expected lifetime of BacTerminator Dental is 5+ years. Lifetime is based on regular service and pre-emptive maintenance as necessary (Table 4-13.

Table 4-13 Preemptive replacements. The following parts should be replaced regularly (information provided by proposer.

Item No.	Item	Interval
130025	Pre-filter	Min. every 6 months
130032	Biorecation Zone Filter	1 year
130056	Air filter for overflow	1 year
130083	Valves	3 years
130069	Chamber	3 years
130167	Pump	3 years

Robustness/vulnerability to changing conditions of use or maintenance
If the pre-filter (softener) is not changed after the alarm has indicated, that it needs to be changed, then calcium ions will result in scale build-up on the electrodes, which will decrease the efficiency in chlorine production and eventually completely stop functioning. It is however often possible to remove the calcium from the electrodes with e.g. citric acid, so the electrodes can be used again. If no chlorine is produced due to scale-build up on the electrodes, then the Bio Reaction Zone Filter will clog faster due to bacterial growth in the filter. The amount of bio-film and the planktonic bacteria in the dental unit waterlines will increase.

The carbon filter inside the pre-filter can also be used up and thus not prevent odour from “old” chlorine in the water, or prevent small organic molecules from entering the dental unit water-lines.

If the Bio Reaction Zone Filter is not changed then the filter will clog from build-up of particles in the water. That would result in no water coming through to the handpieces on the dental unit.

If valves are not changed then the valves will clog, resulting in either no water coming through or a water leakage. If the pump is not changed, it can leak water or not be able to pump water through the BacTerminator Dental unit.

Reusability, recyclability (fully or in part), End of life decommissioning and disposal
On decommissioning, the unit is to be considered electronic waste, and handled in accordance with local regulations. Adept will in any case offer to receive the unit for recycling. Adept do not expect that they can recondition and recycle many parts of a well-used equipment, but an elec-trode chamber and the power supplies/electronics may serve as spare parts.

4.4 Recommendation for the Statement of Verification

4.4.1 Technology description

The description of the technology is based on information from Adept Water Technologies.

BacTerminator® Dental applies on-site generation of chlorine from sodium chloride-salt in an electrolytic cell. The BacTerminator® Dental 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 BacTerminator® Dental 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 - an in-line electrolysis produces an adjustable amount of oxidants (chlorine, hypochlorous acid (HOCl) and hypochlorite (OCl^-), 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 4.3 The BacTerminator® Dental (Photo provided by Adept)

4.4.2 Application

4.4.2.1 Matrix

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

4.4.2.2 Purpose

The unit is to be used for dental unit 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.

4.4.2.3 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 and chloride must be 200-1500µS/cm and 10-250 mg/L.
- Water in: 1-1½L/min. The BacTerminator® Dental is restricting this water flow, which otherwise would depend on water tap dimension and water pressure.
- Water out: 1-3L/min at 2-2.5 bar. The outlet water flow depends on the pump and the back pressure.

4.4.2.4 Verification parameter definition summary

The selected performance claims for BacTerminator® Dental unit are:

1. BacTerminator® 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, incubated at 37 °C for 48 hours) in the outlet water of BacTerminator® Dental.
3. *Legionella* and Heterotrophic plate count in outgoing water (from the dental unit).
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.
7. Free chlorine content in outlet water of BacTerminator® Dental.
8. Level of heavy metals in outlet water.

4.4.3 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* [9] describes in details how to test dental chair disinfection technologies such as BacTerminator® Dental. 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* is included in this verification. Tap water containing *Legionella* and bacteria cultures were used for the challenge tests.

4.4.3.1 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 (MMO) electrodes of the BacTerminator® Dental 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.**

4.4.3.2 Laboratory or field conditions

Surrogate dental chairs were constructed by Adept and operated at DHI´s laboratory facilities at 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 BacTerminator® Dental on a new surrogate dental chair with no biofilm (Phase 1), and on a surrogate dental chair with pre-grown biofilm (Phase 2), see Figure 4.4. Phase 1 was carried out from 28 April to 7 October 2014, and Phase 2 from 7 October 2014 to 31 March 2015.

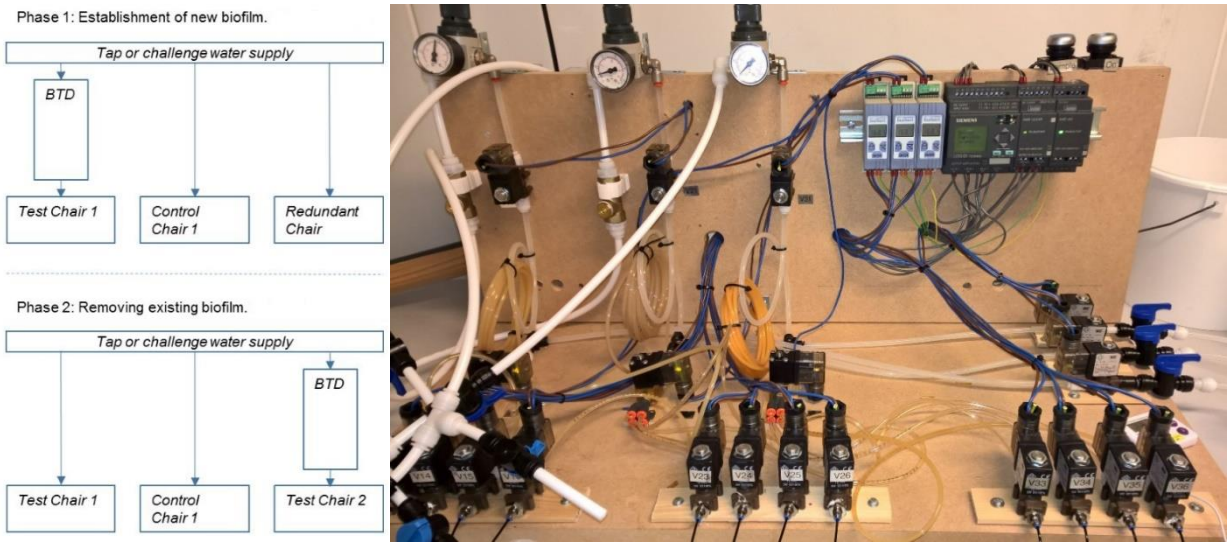

Figure 4.4 Overview of test phases and test setup

4.4.3.3 Matrix compositions

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

4.4.3.4 Test and analysis parameters

The following tests parameters were investigated (Table 4.13).

Table 4-14 Test and analysis parameters overview

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

4.4.3.5 Test 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.

4.4.3.6 Parameters measured

Table 4.14 gives an overview of the parameters analysed during the test.

Table 4-15 Overview of parameters analysed

Parameter	Method / device	*Legionella* source	Water source	Output water from BacTerminator® Dental	Outgoing water from dental unit	Tube sample from dental unit
Bacteria in water phase	HPC 36, 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		

4.4.4 Verification results

4.4.4.1 Performance parameters

<u>Biofilm formation (Phase 1)</u>

Biofilm was sampled from the inner surfaces of the tubes downstream the BacTerminator® Dental (Table 4.15). The criterion (detection limit) for biofilm formation was determined to be 43 CFU/cm^2. **The biofilm formed in test chair 1 was below the detection limit. In contrast, significant biofilm formation was detected in both control chairs.**

Table 4-16 Biofilm formation in test phase 1, as HPC on R2A incubated at 22 °C, sampled from tubes. All values in 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 BacTerminator® Dental (Table 4.16). **The biofilm in test chair 2 decreased by two orders of, 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 4-17. Biofilm formation in tubes in test phase 2, as HPC on R2A agar incubated at 22 °C. All values in 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 BacTerminator® Dental as a function of the contact time during *Legionella* challenge is shown in Figure 4.5.

It is concluded that the BacTerminator® Dental removed *Legionella* that were added to the test system to below the detection limit when the contact time (Ct-value) was ≥0.4 mg · min /L. This corresponded to a free chlorine concentration about 0.6 mg/L. On one challenge test occasion, "suspected *Legionella*" were detected in the outlet, coinciding with a low contact time (0.1 mg · min/L, at 0.15 mg/L free chlorine). Due to an oversight by the analytical laboratory, the Legionella results from that sampling day are especially uncertain.

The BacTerminator® Dental removed Heterotrophic Plate Count (HPC) at 37 °C in water to 11 CFU/ml or less. **At contact times ≥ 0.4 mg · min/L, the reductions were 1.7 to >3.1 log_{10} units.** On one occasion, the reduction was 0.8 log units, coinciding with a low contact time (0.1 mg · min/L, at 0.15 mg/L free chlorine).

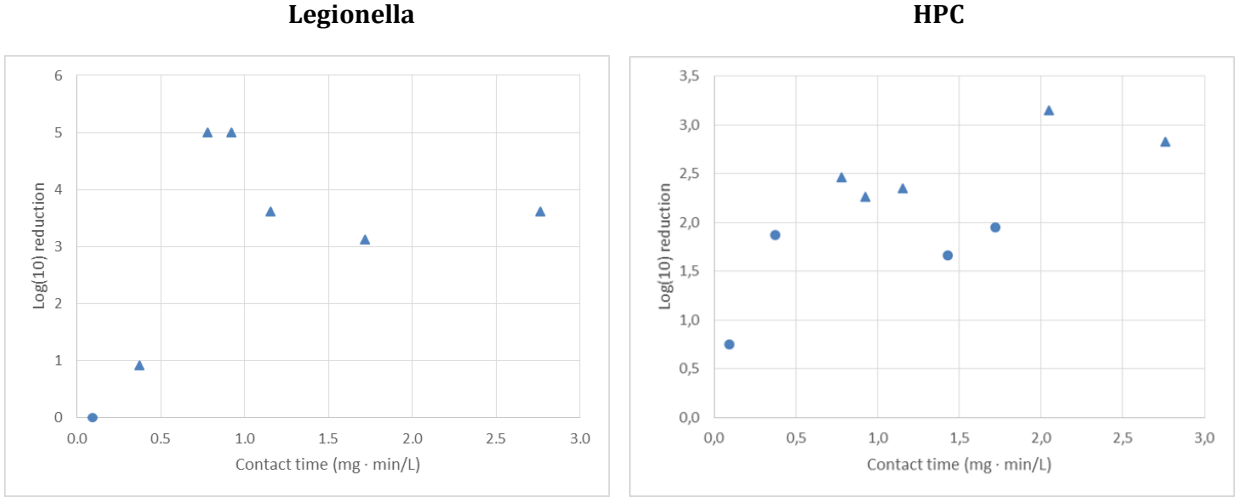

Figure 4.5 Reduction of Legionella and Heterotrophic Plate Count (HPC) at 37 °C across the BacTerminator® Dental during Legionella challenges in test phases 1 and 2, as a function of the contact time (Ct-value). Triangles illustrate that the reduction is larger than indicated by the y-axis value.

Free chlorine concentration

The measured concentrations of free chlorine and the applied power setting on the BacTerminator® Dental are reported in Table 4.17. The acceptable range of feed water conductivity and chloride stated by Adept is highlighted in grey. **In all cases within the acceptable range of conductivity and chloride the BTD produces above 0.5 mg/l, while the concentration is also below the WHO drinking water level of 5 mg/l.**

Table 4-18 Average free chlorine measured in the outlet of the BacTerminator® Dental. BacTerminator® Dental power setting shown in parenthesis. Standard deviations are stated in the test report.

Target Conductivity/ Target Chloride	Very low 5 mg/L	Low 10 mg/L	Medium 75 mg/L	High 250 mg/L
Very low (100 µS/cm)	0.86 (15)			
Low (200 µS/cm)		1.11 (12)	>2 (5 & 12)	
Medium (800 µS/cm)		0.73 (12)	1.89	
High (1500 µS/cm)		0.77 (15)		1.6 (2)
Very High (2000 µS/cm)	0.43 (15)			24.1* (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)**.

4.4.4.2 Operational parameters

During operation of the BacTerminator® Dental, the water flow through the system and general water quality parameters were measured. The results are reported in the test report.

4.4.4.3 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.

4.4.4.4 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.

4.4.5 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 Adept's user manual.

4.4.6 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 extern audits were carried out by DHI and ETA Danmark, respectively.

5 Quality assurance

The staff and the experts responsible for quality assurance as well as the different quality assurance tasks can be seen in Table 5.1. The reviews were prepared using the DANETV review report template. An audit of the test was performed by the DANETV verification body.

Table 5-1 QA plan for the verification

	Internal expert	Verification body DANETV		Verification body China ETV + external expert	Proposer	External expert
Initials	GHE/BOP	MTA/GHE	PF		Adept	LDMO
Tasks						
Specific verification protocol	Review (GHE)			Review	Review	Review
Test plan		Review (MTA)	Approve	Review + approve	Review + approve	
Test system at test site			Audit	Review audit report		
Test report		Review (GHE)		Review	Review	
Verification report	Review (BOP)			Review	Review	Review
Statement of Verification					Acceptance	Review

Internal review of the verification protocol was conducted by Gerald Heinicke (GHE) from DANETV and a test system audit was conducted following general audit procedures by certified auditor Peter Fritzel (PF) from ETA Danmark. Internal review of the verification report was conducted by Bodil Mose Pedersen (BOP). External review of the verification report was conducted by Mette Tjener Andersson, Niras (MEA).

The verification protocol and the verification report require external review according to EU ETV pilot programme GVP [2]. External review was performed by Lars D. M. Ottosen (LDMO), Aarhus University, Institute for Biological and Chemical Engineering.

The verification body reviewed and approved the test plan and review the test report. The review of the test plan was performed by Mette Tjener Andersson (MTA). The review of the test report was performed by Gerald Heinicke (GHE). Approvals were given by Peter Fritzel (PF).

China ETV and their external expert, Lin Shaobin (LSB), Chinese Center for Disease Control and Prevention, reviewed the test plan and verification report. Approvals were given by Ren Guanping (RGP).

6 References

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APPENDICES

APPENDIX A

Terms and definitions

The terms and definitions used by the verification body are derived from the EU ETV GVP, ISO 9001 and ISO 17020.

Term	DANETV	Comments on the DANETV approach
Accreditation	Meaning as assigned to it by Regulation (EC) No 765/2008.	EC No 765/2008 is on setting out the requirements for accreditation and market surveillance relating to the marketing of products.
Additional parameter	Other effects that will be described but are considered secondary.	None
Amendment	Is a change to a specific verification protocol or a test plan done before the verification or test step is performed.	None
Application	The use of a product specified with respect to matrix, purpose (target and effect) and limitations.	The application must be defined with a precision that allows the user of a product verification to judge whether his needs are comparable to the verification conditions.
CFU	Colony forming unit	A microorganism or aggregate of microorganisms that forms a colony during analysis
Contact time	Product of chlorine concentration and time, expressed as [mg · min/L]	In water treatment applications, this parameter is commonly called Ct-value.
GC-MS	Gas chromatography mass spectrometry	
DANETV	Danish centre for verification of environmental technologies.	None
Deviation	Is a change to a specific verification protocol or a test plan done during the verification or test step performance.	None
Evaluation	Evaluation of test data for a technology product for performance and data quality.	None
Experts	Independent persons qualified on a technology in verification.	These experts may be technical experts, QA experts for other ETV systems or regulatory experts.
General verification protocol (GVP)	Description of the principles and general procedure to be followed by the EU ETV pilot programme when verifying an individual environmental technology.	None
HPC	Heterotrophic plate count.	

Term	DANETV	Comments on the DANETV approach
HPC 36	Heterotrophic plate count according to ISO 6222 Water quality - Enumeration of culturable micro-organisms - Colony count by inoculation in a nutrient agar culture medium. The agar is yeast extract agar, pour plate inoculation (mixed with fluid agar) and incubation at 36 °C +/- 2 °C in 48 hours.	
HPC R2A	The agar is an R2A agar, spread plate inoculation (applied on the surface of the agar) and incubation at 21 °C +/- 1 °C in 14 days.	
ICP-MS	Inductively coupled plasma mass spectrometry	
Matrix	The type of material that the technology is intended for.	Matrices could be soil, drinking water, ground water, degreasing bath, exhaust gas condensate etc.
Operational parameter	Measurable parameters that define the application and the verification and test conditions. Operational parameters could be production capacity, concentrations of non-target compounds in matrix etc.	None
(Initial) performance claim	Technical specifications of product claimed by the proposer. Must state the conditions of use under which the claim is applicable and mention any relevant assumption made.	The claims of the proposer must be included in the ETV proposal. The initial claims can be developed as part of the quick scan.
Performance parameters (revised performance claims)	A set of quantified technical specifications representative of the technical performance and potential environmental impacts of a technology in a specified application and under specified conditions of testing or use (operational parameters).	The performance parameters must be established considering the application(s) of the product, the requirements of society (legislative regulations), customers (needs) and initial performance claims of the proposer.
Procedure	Detailed description of the use of a standard or a method within one body.	The procedure specifies implementing a standard or a method in terms of e.g.: equipment used.
Proposer	Any legal entity or natural, which can be the technology manufacturer or an authorised representative of the manufacturer of the technology. If the manufacturers of the technology concerned agree, the proposer can be another stakeholder undertaking a specific verification programme involving several technologies.	Can be vendor or producer.
Purpose	The measurable property that is affected by the product and how it is affected.	The purpose could be reduction of nitrate concentration, separation of volatile organic compounds, reduction of energy use (MW/kg) etc.

Term	DANETV	Comments on the DANETV approach
(Specific) verification protocol	Protocol describing the specific verification of a technology as developed applying the principles and procedures of the EU GVP and the quality manual of the verification body.	None
Standard	Generic document established by consensus and approved by a recognised standardization body that provides rules, guidelines or characteristics for tests or analysis.	None
Test/testing	Determination of the performance of a product for measurement/parameters defined for the application.	None
Test performance audit	Quantitative evaluation of a measurement system as used in a specific test.	*E.g.* evaluation of laboratory control data for a relevant period (precision under repeatability conditions, trueness), evaluation of data from laboratory participation in proficiency test and control of calibration of online measurement devises.
Test system audit	Qualitative on-site evaluation of test, sampling and/or measurement systems associated with a specific test.	E.g. evaluation of the testing done against the requirements of the specific verification protocol, the test plan and the quality manual of the test body.
Test system control	Control of the test system as used in a specific test.	E.g. test of stock solutions, evaluation of stability of operational and/or on-line analytical equipment, test of blanks and reference technology tests.
TTHM	Total trihalomethanes	
Verification	Provision of objective evidence that the technical design of a given environmental technology ensures the fulfilment of a given performance claim in a specified application, taking any measurement uncertainty and relevant assumptions into consideration.	None

APPENDIX B

Quick Scan

QUICK SCAN REPORT	Technology name:	BacTerminator® Dental

Verification body		**Proposer**	
Name:	DS Certification	Name:	Adept Water Technologies A/S
Contact:	Peter Fritzel	Contact:	Michael Wick
Address:	Kollegievej 6 2920 Charlottenlund Denmark	Address:	Diplomvej 378 2800 Kgs. Lyngby
Telephone:	+45 7224 5900	Telephone:	+45 8870 8525
E-mail	pf@dscert.dk	E-mail	mrw@adeptwatertech.com

Quick scan		Previous quick scan					
Date:	07052013	Yes		Date:		No	X

Technology description

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

1. *Pre-filtering - a 100 micron filter stops all major particles*
2. *Softening - An ion exchanger removes all scaling from the system, meaning the dental unit will no longer clog up with scaling*
3. *Carbon filter - removes old chlorine and odor from the incoming water*
4. *Fine filtering - a 1 micron filter removes finer particles*
5. *Chlorination - In-line electrolysis produces an adjustable amount of chlorine that disinfects the water*
6. *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 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.

Intended Use

This product has the following intended use:

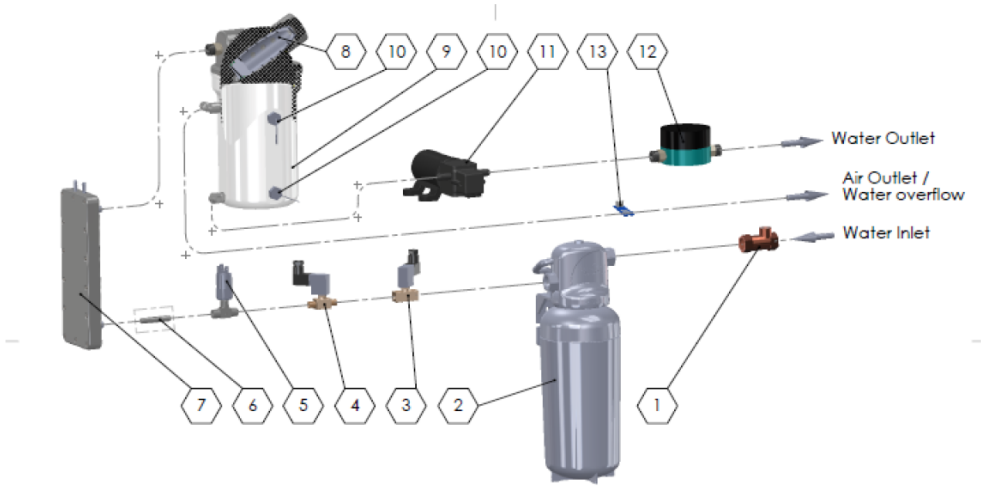
The unit is to be used for dental unit water lines or similar applications for following purposes:

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

The treated water will not be harmful to the health of patients or dentists.

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

Operational conditions:
The inlet water shall be of a quality fulfilling WHOs 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 (*Pseudomonas aeruginosa* and *Legionella*) 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						

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

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Kollegievej 6
DK 2920 Charlottenlund
Tlf.: +45 7224 5902
Runetoften 14, 1. sal
DK 8210 Aarhus V

APPENDIX C

Proposal

ETV

Verification Proposal

DS CERTIFICERING

Project No.: 011987-02

Date: 18-07-2013

Proposer

Name ..... :Adept Water Technologies A/S

Contact ..... :Michael Wick

Address ..... :Diplomvej 378; DK-2800 Lyngby

Telephone..... :+45 88 70 85 25

Telefax..... :

Email..... :MRW@adeptwatertech.com

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:

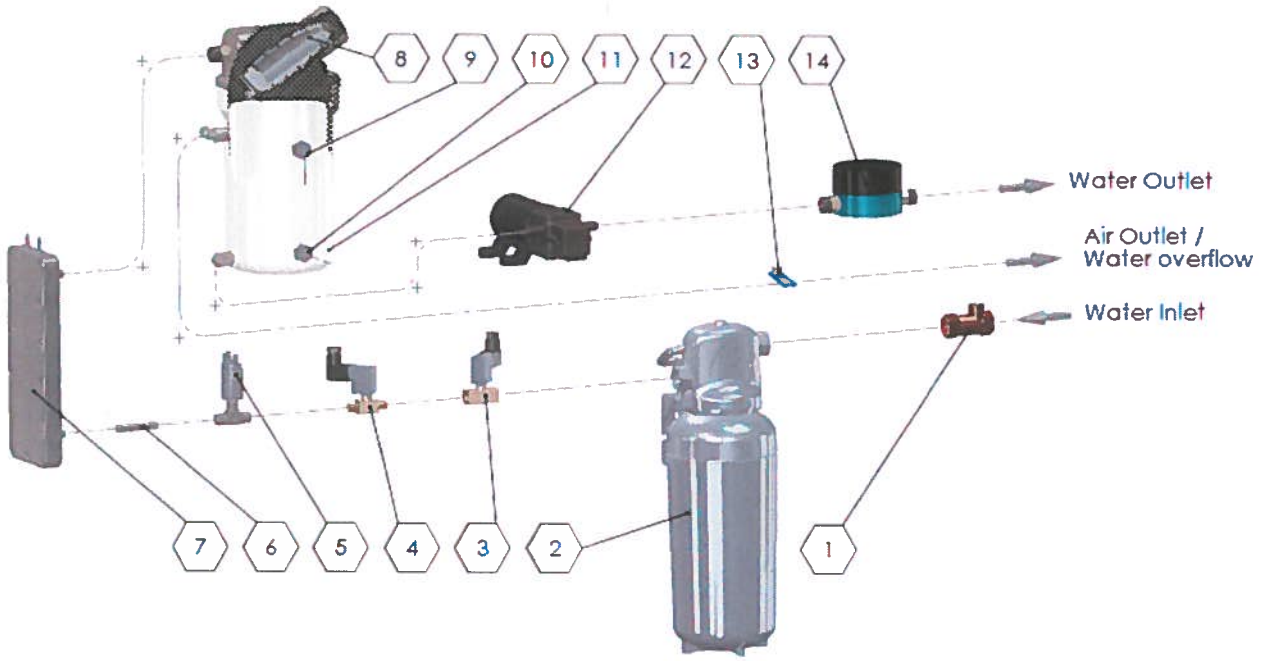
- Pre-filtering - a 100 micron filter stops all major particles
- Softening - An ion exchanger removes all scaling from the system, meaning the dental unit will no longer clog up with scaling
- Carbon filter - removes old chlorine and odour from the incoming water
- Fine filtering - a 1 micron filter 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.[1]

[1] 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.[2]
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 WHOs 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 .....:	☒Yes	☐No:
Declared performances described.....:	☒Yes	☐No:
Innovative technology .....:	☒Yes	☐No:
Ready-to-market	☒Yes	☐No:
Prototype in advanced stage of development.....:	☒Yes	☐No:

[2] 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 marked to disinfection of water adds 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 ..... : Peter Fritzel

Email ..... :pf@dscert.dk

DS Certificering A/S

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DK 2920 Charlottenlund
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DK 8210 Aarhus V

APPENDIX D

Specific verification protocol

Adept Water Technologies A/S

BacTerminator® Dental

Specific Verification Protocol
September 2013

Approved by
Morten Rungø (Head of projects, DHI)
Peter Fritzel (Verification responsible, DS Certificering)

30-09-2013

X 

Approved by

Signed by: Morten Rungø

Adept Water Technologies A/S

BacTerminator® Dental

Prepared for Adept Water technologies A/S

Represented by Michael R. Wick

Project No	011987-02
Classification	Restricted

Authors	Mette Tjener Andersson

Contents

Figures

Tables

Appendices

Archiving: All standard project files (documents, etc) are archived at DS Certificering. Any other project files (set-up files, forcing data, model output, etc) are archived with the institute performing the tests or analysis.

1 Introduction

Environmental technology verification (ETV) is an independent (third party) assessment of the performance of a technology or a product for a specified application under defined conditions and quality assurance.

The objective of this verification is to evaluate the performance of the BacTerminator® Dental, a technology based on a combination of filtration and disinfection by electrolysis of water to dental chairs.

This verification is performed under the EU ETV Pilot Programme. The verification is performed together with the Chinese ETV Pilot Programme.

1.1 Name of technology

BacTerminator® Dental, produced by Adept Water Technologies A/S.

1.2 Name and contact of proposer

Adept Water Technologies
Diplomvej 378
2800 Kgs. Lyngby
Denmark

Contact:
Michael Reidtz Wick, email: mrw@adeptwatertech.com, phone: +45 8870 8526, mobile: +45 5164 3636

Website: www.adept-dental-water.com

1.3 Name of verification body/persons responsible for verification

EU ETV:
DS Certificering A/S
Kollegievej 6
2920 Charlottenlund
Denmark

Person responsible for verification:
Peter Fritzel (PF), email: pf@dscert.dk, phone +45 7224 5900

Appointed verification expert:
Mette Tjener Andersson (MTA), DANETV, e-mail: mta@dhigroup.com, phone: +45 4516 9148

China ETV:
Chinese Society for Environmental Sciences (中国环境科学学会)
No.54 Honglian Nan Cun
Haidian District
Beijing 100082.
P.R.China

Person responsible for verification:
Wang Rui (WR) 王睿 (Name in Chinese), email: wangrui797@163.com, phone: +86 010 62210466.

1.4 Verification organisation, including experts

The verification will be conducted by DS Certificering A/S in cooperation with Danish Centre for Verification of Climate and Environmental Technologies, DANETV.

The verification is planned and conducted to satisfy the requirements of the ETV scheme established by the European Union (EU ETV Pilot Programme) [1].

The verification will be coordinated and supervised by DS Certification, assisted by an appointed DANETV verification expert.

In addition, the verification will be planned and conducted to satisfy the requirement of the Chinese ETV scheme. Therefore this specific verification protocol will be reviewed by China ETV before implementation.

Tests will be coordinated and supervised by DHI DANETV test centre with the participation of the proposer, Adept Water Technologies.

An internal and an external expert are assigned to provide independent expert review of the planning, conducting and reporting of the verification and tests:

- Internal technical experts:
    - Dr. Gerald Heinicke (GHE), DANETV, e-mail: ghe@dhigroup.com
    - Yi Bin (YB), 易斌 (Name in Chinese), Chinese Society for Environmental Sciences (CSES), email: nibiy@sina.com
    - Liu Ping (LP), 刘平 (Name in Chinese), Chinese Society for Environmental Sciences (CSES), email: liup3000@163.com
- External technical experts:
    - Lars D. M. Ottosen (LDMO), Danish Technological Institute, email ldmo@ti.dk
    - Lin Shaobin (LSB), 林少彬 (Name in Chinese), Chinese Center for Disease Control and Prevention (CDC), email: 13501260565@163.com

The tasks assigned to each expert are given in more detail in section 8 Quality assurance.

The relationships between the organisations related to this verification and test are given in Figure 1-1 .

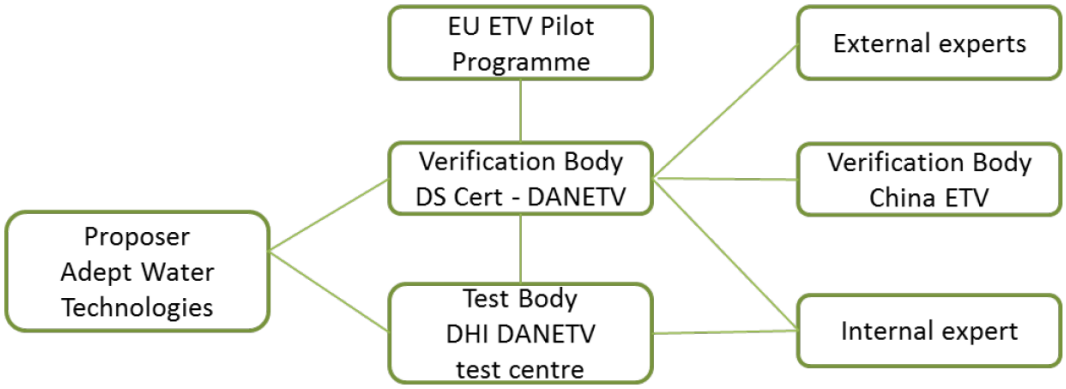

Figure 1-1 Organisation of the verification and test

1.5 Verification process

The principles of operation of the DANETV verification process are given in Table 1 1. As it can be seen, verification and testing are divided between the verification body and the test body.

Table 1-1 Simplified overview of the verification process

Phase	Responsible	Document
Preliminary phase	Verification body	Quick Scan
		Contract
		Specific verification protocol
Testing phase	Test body	Test plan
		Test report
Assessment phase	Verification body	Verification report
		Statement of Verification

Quality assurance is carried out by an expert group of internal and external technical experts. Two audits of the test system will be performed, starting with an internal audit by the test body followed by an external audit by the DANETV verification body under DS Certification. Reference for the verification process is the EU ETV General Verification Protocol [1] and DS Certificering's internal procedure [2]. A Statement of Verification will be issued by the DANETV verification body after completion of the verification. The final verification report will include the other documents prepared as appendices.

After completion of the verification, an EU Statement of Verification will be issued by the Danish verification body. Based on the verification report and the EU Statement of Verification, a China ETV Statement of Verification will be issued.

2 Overall description of the technology type

The technology behind BacTerminator® Dental is based on on-site generation of disinfectants in an electrolytic cell. Oxidant inactivating the microorganisms is produced from NaCl-salt. The salt can either be salt in the water or added salt. The overall reaction is:

$$NaCl + H_2O \rightarrow NaOCl + H_2$$

Oxidation reactions are carried out at the anode, where two chloride ions (Cl^-) are stripped of one electron each to produce chlorine gas:

$$2Cl^- \rightarrow Cl_2 + 2e^-$$

Depending on the electrolytic cell it is also possible to produce oxidants other than chlorine, which can provide enhanced inactivation of microorganisms. The chlorine gas can react with water and form the strong oxidant "hypochlorous acid" (HOCl):

$$Cl_2 + H_2O \rightarrow HOCl + H^+ + Cl^-$$

The chlorine production is balanced by water reduction reaction taking place at the cathode:

$$2H_2O + 2e^- \rightarrow 2OH^- + H_2$$

The hydroxide ions produced then react with the hypochlorous acid (HOCl) producing the oxidant hypochlorite (OCl^-):

$$HOCl + OH^- \rightarrow H_2O + OCl^-$$

Prior to the electrolytic cell units are often installed for filtration and water softening, *i.e.* removal of $CaCO_3$, to prevent scaling. Hydrogen ventilation may be needed to prevent build-up of hydrogen gas in the system.

3 Description of the specific technology for verification

The description of the technology is based on information from Adept Water Technologies.

The BacTerminator® Dental is designed specifically for use in dental clinics and is produced according to ISO 13485 regarding medical devices and is CE-marked as medical device.

Figure 3-1 Demo of the BacTerminator® Dental

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 - a ion exchanger removes all scaling from the system to ensure the dental unit will not clog up with scaling
- Carbon filter - removes old chlorine and odour from the incoming water
- Fine filtering - a 1 micron filter removes fine particles
- Chlorination - an in-line electrolysis produces an adjustable amount of oxidants (chlorine, hypochlorous acid (HOCl) and hypochlorite (OCl-) disinfecting the water
- Bio Reaction Zone – a chamber ensuring that the bacteria are in contact with the oxidants for a sufficient period of time.

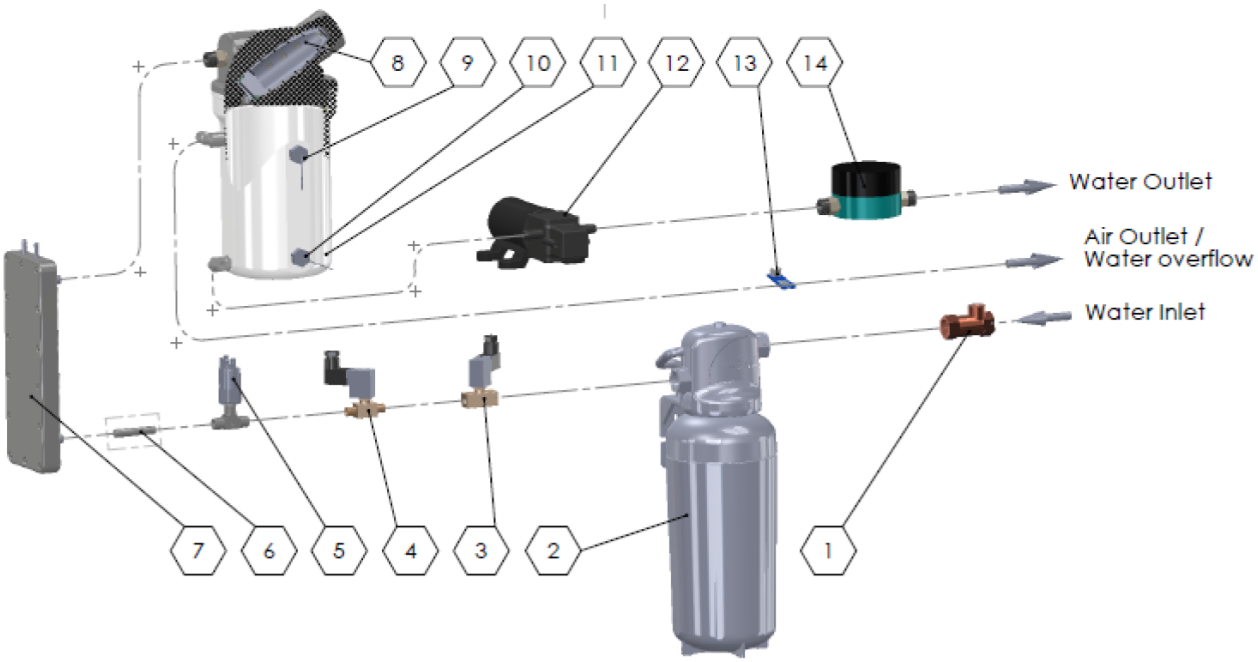

Figure 3-2 Process diagram: 1: DS EN/6117 Approved non-return valve; 2: Head and cartridge for filter/softener; 3 & 4: Solenoid valves; 5: Pressure switch; 6: Optional flow restriction; 7: BacTerminator disinfection chamber; 8: Bio Reaction Zone; 9: Water tank with 20mm air gap; 10: Level sensors; 11: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

3.1 Application and performance parameter definitions

The intended application of the product for verification is defined in terms of the matrix and the purpose. The BacTerminator® Dental is a combination of filtration and disinfection by electrolysis of water to dental chairs.

3.1.1 Matrix/matrices

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

3.1.2 Purpose(s)

The unit is to be used for dental unit 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 microorganisms in connected subsequent equipment.

3.1.3 Exclusions

The effect of the technology is only verified under operational conditions as specified by Adept Water Technologies, e.g. in the user manual, and not under any extreme conditions.

3.2 Performance parameters for verification

The performance parameters for the verification comprise parameters that e.g. describe the treated water quality, regulatory requirements, parameters that assess equipment performance

etc. Performance or quality parameters may include chemical, physical and biological parameters.

The proposer has specified the performance claims for a BacTerminator® Dental unit as follows:

1. BacTerminator produces 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 inactivation of pathogenic bacteria (*Legionella*) to undetectable levels (< 1/100 ml), and heterotrophic plate count (HPC, incubated at 37 °C in 48 hours) < 1 CFU/ml in the outlet water of BacTerminator® Dental (*i.e.* feed to the dental unit).

3. Outgoing water (from the dental unit) has a HPC < 500 CFU /ml and < 100 CFU *Legionella*/L.

4. No biofilm is generated in new dental chair piping systems.

5. Existing biofilm is removed from old dental chair piping systems.

These claims are based on the following operational conditions:

- The inlet water shall be of a quality fulfilling WHO's guidelines for drinking-water quality.
- The pH is reduced in the treatment unit by approximately one pH unit in the outlet water.
- The conductivity is 200-1500µS/cm and the content of chloride is 10-250mg/l in the feed water, according to the unit manual.
- Water flow rate in: 1-1½L/min. The BacTerminator® Dental is restricting this water flow, which otherwise would depend on water tap dimension and water pressure.
- Water flow rate out: 1-3L/min @ 2-2½bar. The outlet water flow depends on pump and back pressure.

3.2.1 Regulatory requirements

A water cleaning device as the BacTerminator® Dental can be seen as a device for drinking water or as a medical device. Since national regulations for drinking water vary between countries, Adept Water Technologies has chosen to produce the units as medical devices under ISO 13485 *Medical devices -- Quality management systems -- Requirements for regulatory purposes* and to have their units CE-marked as medical device.

A Danish Standard (DS 2451-12) exists on *Infection control in the health care sector – Part 12: Requirements for procedures in dental clinics* [4]. In the standard, the following criteria are listed with regards to bacteria in the dental chair water:

1. Water in dental units must have a heterotrophic plate count (HPC) < 500 CFU /ml at 37°C.

2. Water from dental units should not contain pathogenic or potentially pathogenic microorganisms.

3. A CFU above 100 CFU *Legionella pneumophila*/L must not be detected in water from dental units.

4. A method must be established to ensure low HPC and minimal occurrence of pathogenic or potentially pathogenic microorganisms.

5. The water quality, measured as HPC, and the indicator bacteria *Legionella pneumophila* must be controlled at least every 12 month.

6. Sampling, transport, growing and identification of bacteria must be done by an accredited laboratory. (Note: When sampling, a minimum of 100 ml water is taken from airotor or ultrasonic tooth cleaner.)

7. The dental unit must be secured against back suction.

Of main interest with regards to the effect of the BacTerminator® Dental are the criteria 1 to 3.

In the US, the criterion is a HPC < 500 CFU/ml, though they recommend a value < 200 CFU/ml. From 1995, manufacturers have been asked to provide equipment with the ability to deliver treated water with < 200 CFU/mL of unfiltered output from waterlines [5]. Other sources also recommend water from dental unit waterlines to contain < 200 CFU/mL [6, 7].

For comparison, the drinking water criteria at the water tap in Denmark are a HPC <200 CFU/ml at 22 °C and 20 CFU/ml at 37°C [8]. The EU criteria for bottled drinking water are 100 CFU/ml at 22 °C and 20 CFU/ml at 37°C [9]. From WHO, there are no specific HPC limit for drinking water.

The BacTerminator® Dental produces free chlorine. The chlorine not used for oxidation will stay in the outlet water. In Denmark there is no criterion for free chlorine content in drinking water. It is however specified that the content must be as low as possible, ensuring fulfilment of the microbiological criteria [8]. WHO has set a drinking water guideline value to 5 mg free chlorine/litre [10]. Since water in the dental chair is not used for regular drinking water, the WHO guideline does not have to be fulfilled; a maximum of 50 mg free chlorine/l is seen as relevant for dental chair water.

For disinfection by-products there are several guideline values, for example by WHO, US EPA, and the EU Drinking Water Directive. The US National Primary Drinking Water Regulations state the maximum content levels for Total Trihalomethanes (TTHMs, 80 µg/l) and Haloacetic acids (HAA5, 60 µg/l) as well as for some specific substances [11]. EU has a limit only for total trihalomethanes (TTHMs, 100 µg/l) [9].

3.2.2 Application based needs

During chlorination processes there is a possibility of formation of trihalomethanes and other chlorinated by-products, due to the chlorine reacting with organic matter in the water. Adept Water Technologies has included a carbon filter in their BacTerminator® Dental to remove organic matter.

A US EPA verification protocol for verification testing for inactivation of microbiological contaminants [12] (with a specific chapter is focusing on on-site generation of halogen disinfectants for inactivation of microbiological contaminants) specifies the water analysis to include the following parameters: general drinking water parameters, free available and total available chlorine, chlorite, chlorate and bromate, disinfection by-products as trihalomethanes and haloacetic acids etc.

The electrode is constructed of metals and heavy metals. It has to be ensured that these are not to be found in concentrations above drinking water quality criteria according to [8].

3.2.3 State of the art performance

Competing products

Trustwater™ markets a product, Ecasol™, similar to the BacTerminator® Dental [13]. The technology is based on generation of activated solutions by passing a dilute NaCl-solution through a Flow-through Electrolytic Membrane, segregating the ions formed and producing Ecasol™, a charged disinfectant solution. The positively charged Ecasol™ has a redox value in excess of 600mV, is pH neutral and consists of a mixture of oxidants (mainly hypochlorous acid) in a physically excited state that is capable of penetrating biofilms and is highly microbicidal. In contrast to the BacTerminator® Dental, a salt is added to Ecasol™.

Trustwater™ has the following claims for Ecasol™:

- It is 100 times more effective than Sodium Hypochlorite
- It does not taint the water
- It is fully effective against biofilm removal
- It is not subject to pH effects
- It is not easily neutralised by organic materials
- It effectively destroys cryptosporidium and other protozoa.

Trustwater™ has performed a test of the Ecasol™ at Dublin Dental Hospital's 103 dental chair units [14]. Mains water of varying quality was treated by specifically selected automated filtration units to provide dental unit chairs with water of a consistent chemical composition. This water was then automatically disinfected using an electrochemically activated solution Ecasol™ (2.5 ppm) prior to distribution to chairs. Microbiological quality of the dental unit water line supply and the output water was monitored weekly by culture on R2A agar for 10 sentinel chairs for a 100-weeks period. Dental unit water lines were tested for the presence of biofilm by scanning electron microscopy. The results showed a chemical composition of processed mains water consistently better than potable water standards. Dental unit water line supply water and output water aerobic heterotrophic bacterial counts averaged <1 and 18.1 CFU/mL, respectively, from the 10 chairs compared to 88 CFU/mL for unprocessed mains water. This correlated with the absence of biofilm in the water lines. No adverse effects due to Ecasol™ treatment of supply water were observed for water lines or chairs instruments.

Blue Safety also manufactures a similar product, though again salt needs to be added [15]. They do not give a detailed list of their claims, but on the homepage the following relevant statements can be found:

- 100 times more effective than sodium hypochlorite (NaOCl)
- An effect is promised after 4-8 weeks after installation (control sample)
- Effective against pathogen microorganisms (*e.g. Legionella* and *Pseudomonas*), virus, algae, fungi and biofilm
- Safe material and no corrosion, while pH is 7.

Other studies and similar products

With regards to biofilm reduction a study was performed on 28 dental unit water lines evaluating three disinfection products, based on sodium hypochlorite/citric acid, ethanol/chlorhexidine and hydrogen peroxide/silver ions [16]. After a test period of 8 weeks all three methods showed > 99 % reduction of the baseline (from 1.04-1.45 log CFU/cm^2) to below detection limit.

There are many disinfection technologies on the market using electrolysis for generation of chlorine. These are designed for treatment of drinking water, utility water, wastewater and swimming pool water. Some of these claim that their technologies do not form disinfection by-products [17] such as trihalomethanes. One vendor specifies that the technology is less suitable for *Legionella* protection [17]. Another vendor specifies that with their technology, a free chlorine concentration of 0.5 ppm is required for protection against *Legionella* [18].

3.2.4 Selected performance parameters

The claims from the proposer are all found to be relevant and valid. In addition to the five claims from the proposer are two claims regarding free chlorine and formed chlorinated by-products.

The selected performance claims for a BacTerminator® Dental unit are:

1. BacTerminator produces 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.

4. No biofilm is generated in new dental chair piping systems. (The test body must specify the level of biofilm acceptable as equal to ”no biofilm growth”).

5. Existing biofilm is removed from old dental chair piping systems. (The test body must specify the level of biofilm acceptable as equal to ”no biofilm growth”).

6. No formation of halogenated by-products such as trihalomethanes and haloacetic acids. Concentrations are kept below USEPA’s limits for drinking water.

7. Free chlorine content in outlet water of BacTerminator® Dental < 50 mg/L.

8. Level of heavy metals in outlet water is below drinking water quality criteria.

These 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 and chloride must be 200-1500µS/cm and 10-250mg/l (according to the unit manual).
- Water in: 1-1½L/min. The BacTerminator® Dental is restricting this water flow, which otherwise would depend on water tap dimension and water pressure.
- Water out: 1-3L/min @ 2-2½bar. The outlet water flow depends on pump and back pressure.

3.3 Operational parameters

During operation of the BacTerminator® Dental the following parameters shall be noted:

- Water flow (L/min)
- Power consumption (kWh)
- Water temperature (°C), pH, hardness (°dH), conductivity (µS/cm), these shall be measured on both sides of BacTerminator® Dental

The quality of in and out going water shall be analysed for general drinking water parameters.

3.4 Additional parameters

Besides the performance parameters obtained by testing, a compilation of parameters describing the ease of understanding the user manual, the required resources, as well as the occupational health and environmental issues of the product were included in the verification.

4 Existing data

No existing test data has been provided by Adept Water Technologies for evaluation under this verification.

5 Requirements for test design and data quality

Based on the application and performance parameters identification the requirements for the test design have been set. A detailed test plan will be prepared separately based on the specification of the test requirements presented below.

The test must be planned and performed in accordance with the EU ETV General Verification Protocol [1].

5.1 Test design

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 [19] describes in details how to set up a test of dental chair disinfection technologies such as BacTerminator® Dental. 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 detailed test design, to be described in a test plan from DHI, must therefore be based on ISO/TS 11080.

ISO/TS 11080 only focuses on HPC, while for this verification also *Legionella* must be included, due to the selected performance parameters.

According to ISO/TS 11080 it is possible to use either tap water or a challenge suspension. Due to health risks when handling *Legionella* it is preferred to use tap water containing *Legionella*. This is done by identifying a hot water source with *Legionella* and by using this source for contamination of DHI tap water. The biofilm in the tubing system is created by leaving the surrogate chair at room temperature and in periods leaving the water stagnant in the tubes. The biofilm creation can be measured indicative by measuring CFU-level in the outlet water. ISO/TS 11080 specifies a HPC range in the dental chair system of 10^4-10^6 CFU/ml when testing removal of biofilm. Due to the decision of using tap water as bacteria source it can be difficult to reach a sufficiently high CFU-level. After measurement of CFU-level, the test body must consult the verification body and Adept Water Technologies to decide whether microbial suspension is needed and how it can be done with minimum risk. The actual biofilm on tube surface must, in addition to the CFU in water indicator, be measured before start of testing.

It is anticipated that 3-4 samples are needed during establishment of the biofilm in the dental chair and the same number of samples shall be taken to follow the removal of biofilm.

According to ISO/TS 11080 the test can be performed in an actual dental chair or in a surrogate chair. For this verification test surrogate dental chairs will be constructed and placed in a laboratory.

The microbiological testing will be performed as agar plate culturing of water sampled in colony forming units (CFU) per millilitre. In addition to the requirements of ISO/TS 11080, *Legionella* analyses must be performed.

Adept Water Technologies have claimed that the BacTerminator® Dental ensures no biofilm formation in new dental chairs and removal of biofilm in current dental chairs. Therefore the test needs to include test on a newly built surrogate dental chair with no biofilm, and on a surrogate dental chair with pre-grown biofilm.

5.2 Reference analysis and measurements

As reference analyse to the agar plate culturing, samples of the tube for the surrogate dental chair must be analysed for assessing biofilm on the surface.

Table 5-1 gives an overview of the required parameters to be analysed during the test.

Table 5-1 Overview of parameters to be analysed

Parameter	Analyse method / device	*Legionella* source	Water source	Output water from Bac-Terminator® Dental	Outgoing water from dental unit	Tube sample from dental unit
Bacteria in water phase	HPC 36, HPC R2A	X	X	X	X	
Bacteria on surface (biofilm)	HPC R2A, Direct microscopic count					X
Legionella	Plate count	X		X	X	
Free chlorine	Hach Lange photometric equipment, chlorine sticks		X	X	X	
Temperature, pH, hardness, conductivity	Regular online devises	X	X	X		
Drinking water parameters[1]	Regular methods		X		X	
Trihalomethanes, haloacetic acids	GM-MS				X	
Heavy metals (determined by the composition of the electrode material)	ICP-MS				X	

5.3 Data management

Data storage, transfer and control must be in accordance with the requirements of the DHI DANETV test centre quality manual [20], enabling full control and retrieval of documents and records. The filing and archiving requirements of the DHI quality manual must be followed; i.e. 10 years archiving.

The actual data handling must be specified further in the test plan.

5.4 Quality assurance

The quality assurance of the tests must include 1) control of the test system (in this case the set-up with BacTerminator® Dental and surrogate dental chair), 2) the on-line measurement equipment (performance evaluation audit), 3) control of analysis performed at external laboratory (results from proficiency tests) and 4) control of the data quality and integrity.

The test plan and the test report will be subject to review by an internal expert. Furthermore, the test plan and test report must be subject to review by the person responsible for the verification (in this case both DANETV and China ETV) and Adept Water Technologies. The test plan must be approved by the verification bodies and Adept Water Technologies prior to initiating tests.

[1] E.g. according to Normal control at the laboratory Eurofins: www.eurofins.dk/media/3224791/drikkevandspakker_2013.pdf

A test system audit will be performed during the verification testing by a certified auditor from the DANETV verification body.

All analyses must be performed under ISO 17025 accreditation. If this is not the case, detailed explanation for the deviation must be given.

5.5 Test report requirements

The test data provided in the test report must follow the principles of template of the DHI DANETV test centre quality manual [20], with data and records from the tests presented.

6 Evaluation

6.1 Calculation of performance parameters

Bacteria

For the parameters bacteria (heterotrophic plate count), *Legionella* and biofilm graphs must be drawn. The following parameters must be identified:

- Biofilm development in new chair with BacTerminator® Dental
- Biofilm in old chair after installation of BacTerminator® Dental
- Biofilm in chair without BacTerminator® Dental – control measurement
- Level of heterotrophic plate count after BacTerminator® Dental
- Level of heterotrophic plate count without BacTerminator® Dental – control measurement
- Level of *Legionella* after BacTerminator® Dental
- Level of *Legionella* without BacTerminator® Dental – control measurement
- Level of heterotrophic plate count after surrogate dental chair with BacTerminator® Dental
- Level of heterotrophic plate count after surrogate dental chair without BacTerminator® Dental – control measurement
- Level of *Legionella* after surrogate dental chair with BacTerminator® Dental.
- Level of *Legionella* after surrogate dental chair without BacTerminator® Dental – control measurement

These levels from chairs with BacTerminator® Dental must be compared to values from the control measurements.

Free chlorine
The average and standard deviation of measurements for free chlorine must be determined at:

- The sampling point just after the BacTerminator® Dental
- The sampling point after the surrogate dental chair.

Contact time (in mg free Cl_2 * min) is calculated based on water flow and free chlorine concentration. Plot relation between contact time and bacterial (heterotrophic plate count and *Legionella*) reduction.

Chlorinated by-products
The average and standard deviation of measurements for chlorinated by-products as trihalomethanes and haloacetic acids must be determined at:

- The sampling point after the surrogate dental chair.

6.2 Evaluation of test quality

The test data provided in the test report will be evaluated against the requirements set in this protocol and the objectives set in the test plan. Focus will be specifically on the planned 1) control of the test system, 2) performance evaluation audit (e.g. for online measurements), 3) con-

trol of analysis performed at external laboratory (results from proficiency tests) and 4) control of the data quality and integrity.

Spread sheets used for the calculations will be subject to control on a sample basis (spot validation of at least 5% of the data).

6.3 Additional parameter summary

6.3.1 User manual

The verification criterion for the user manual is that the manual describes the use of the equipment adequately and is understandable for the typical test coordinator and test technician. This criterion is assessed through evaluation of a number of specific points of importance, see Table 6-1 for the parameters to be included.

A description is complete if all essential steps are described, if they are illustrated by a figure or a photo, where relevant, and if the descriptions are understandable without reference to other guidance.

Table 6-1 Criteria for evaluation of user manual

Parameter	Complete description	Summary description	No description	Not relevant
Product				
Principle of operation				
Intended use				
Performance expected				
Limitations				
Preparations				
Unpacking				
Transport				
Assembling				
Installation				
Function test				
Operation				
Steps of operation				
Points of caution				
Accessories				
Maintenance				
Trouble shooting				
Safety				
Chemicals				
Power				

6.3.2 Required resources

The capital investment and the resources for operation and maintenance could be seen as the sustainability of the product and will be itemized based on a determined design [21], see Table 6-2 for the items that will be included.

Table 6-2 List of capital cost items and operation and maintenance cost items per product unit

Item type	Item	Number	None
Capital			
Site preparation			
Buildings and land			

Item type	Item	Number	None
Equipment			
Utility connections			
Installation			
Start up/training			
Permits			
Operation and maintenance			
Materials, including chemicals			
Utilities, including water and energy			
Labor			
Waste management			
Permit compliance			

The design basis will be described and the cost items relevant for the BacTerminator® Dental will be listed. Note that the actual cost for each item is not compiled and reported.

Evaluation will also be done on the following subjects:

- Resources used during production of the equipment in the BacTerminator® Dental
- Longevity of the equipment
- Robustness/vulnerability to changing conditions of use or maintenance
- Reusability, recyclability (fully or in part)
- End of life decommissioning and disposal.

Information on these subjects will be obtained from Adept Water Technologies and from the test body's experiences with the BacTerminator® Dental during the planned tests.

6.3.3 Occupational health and environmental impact

The risks for occupational health and for the environment associated with the use of the products will be identified. A list of chemicals classified as toxic (T) or very toxic (Tx) for human health and/or environmentally hazardous (N) (in accordance with the directive on classification of dangerous substances [22]) will be compiled. The information will be given as amount used per product unit (sample), see Table 6-3 for format.

Table 6-3 Compilation of classified chemicals used during product operation

Compound	CAS number	Classification	Amount used per product unit

Additional risks from installing, operating and maintaining the product will be evaluated, compiled and reported, if relevant. In particular, risks for human health associated with power supply and danger of infections will be considered.

7 Verification schedule

The verification is initiated in the summer of 2013. A detailed schedule is given in Table 7-1. The time schedule should be seen as tentative, especially since the time required for formation of biofilm in the surrogate dental chair is unknown.

Table 7-1 Verification schedule

Task	Verification Body DANETV	Verification Body China ETV	Test Body
Specific verification protocol	June 2013		
Review of specific verification protocol		July 2013	
Handle external + proposer review of specific verification protocol	Aug 2013		
Testing, incl. test planning, testing and reporting			Oct 2013- Feb 2014
Review of test plan	Oct 2013	Oct 2013	
Test system audit	~ Dec 2013		
Assessment and verification reporting	March 2014		
Review of test report and verification report		April 2014	
Handle external and proposer's review of verification report	April-May 2014		
Issuing of Statement of Verification	May 2014	June 2014	

8 Quality assurance

The staff and the experts responsible for quality assurance as well as the different quality assurance tasks can be seen in Table 8-1. All relevant reviews will be prepared using the DANETV review report template [20]. An audit of the test will be performed by the DANETV verification body.

Table 8-1 QA plan for the verification

	Internal expert	Verification body DANETV		Verification body China ETV + external expert	Proposer	External expert
Initials	GHE	MTA	PF		Adept	LDMO
Tasks						
Specific verification protocol	Review			Review	Review	Review
Test plan		Review	Approve	Review + approve	Review + approve	
Test system at test site			Audit	Review audit report		
Test report		Review		Review	Review	
Verification report	Review			Review	Review	Review
Statement of Verification					Acceptance	Review

Internal review is conducted by Gerald Heinicke (GHE) from DANETV and a test system audit is conducted following general audit procedures by certified auditor Peter Fritzel (PF) from DS Certificering.

The verification protocol and the verification report require external review according to EU ETV pilot programme GVP [1]. External review will be performed by Lars D. M. Ottosen (LDMO), Danish Technological Institute.

The verification body will review and approve the test plan and review the test report. The review will be performed by Mette Tjener Andersson (MTA), while the approval will be given by Peter Fritzel (PF).

China ETV and their external expert, Lin Shaobin (LSB), Chinese Center for Disease Control and Prevention, will review the documents and will also approve the test plan before start of testing.

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APPENDICES

APPENDIX A

Terms and definitions

The terms and definitions used by the verification body are derived from the EU ETV GVP, ISO 9001 and ISO 17020.

Term	DANETV	Comments on the DANETV approach
Accreditation	Meaning as assigned to it by Regulation (EC) No 765/2008.	EC No 765/2008 is on setting out the requirements for accreditation and market surveillance relating to the marketing of products.
Additional parameter	Other effects that will be described but are considered secondary.	None
Amendment	Is a change to a specific verification protocol or a test plan done before the verification or test step is performed.	None
Application	The use of a product specified with respect to matrix, purpose (target and effect) and limitations.	The application must be defined with a precision that allows the user of a product verification to judge whether his needs are comparable to the verification conditions.
CFU	Colony forming unit.	
GC-MS	Gas chromatography mass spectrometry	
DANETV	Danish centre for verification of environmental technologies.	None
Deviation	Is a change to a specific verification protocol or a test plan done during the verification or test step performance.	None
Evaluation	Evaluation of test data for a technology product for performance and data quality.	None
Experts	Independent persons qualified on a technology in verification.	These experts may be technical experts, QA experts for other ETV systems or regulatory experts.
General verification protocol (GVP)	Description of the principles and general procedure to be followed by the EU ETV pilot programme when verifying an individual environmental technology.	None
HPC	Heterotrophic plate count.	
HPC 36	Heterotrophic plate count according to ISO 6222 Water quality - Enumeration of culturable micro-organisms - Colony count by inoculation in a nutrient agar culture medium. The agar is yeast extract agar, pour plate inoculation (mixed with fluid agar) and incubation at 36 °C +/- 2 °C in 48 hours.	

Term	DANETV	Comments on the DANETV approach
HPC R2A	The agar is an R2A agar, spread plate inoculation (applied on the surface of the agar) and incubation at 21 °C +/- 1 °C in 14 days.	
ICP-MS	Inductively coupled plasma mass spectrometry	
Matrix	The type of material that the technology is intended for.	Matrices could be soil, drinking water, ground water, degreasing bath, exhaust gas condensate etc.
Operational parameter	Measurable parameters that define the application and the verification and test conditions. Operational parameters could be production capacity, concentrations of non-target compounds in matrix etc.	None
(Initial) performance claim	Technical specifications of product claimed by the proposer. Must state the conditions of use under which the claim is applicable and mention any relevant assumption made.	The claims of the proposer must be included in the ETV proposal. The initial claims can be developed as part of the quick scan.
Performance parameters (revised performance claims)	A set of quantified technical specifications representative of the technical performance and potential environmental impacts of a technology in a specified application and under specified conditions of testing or use (operational parameters).	The performance parameters must be established considering the application(s) of the product, the requirements of society (legislative regulations), customers (needs) and initial performance claims of the proposer.
Procedure	Detailed description of the use of a standard or a method within one body.	The procedure specifies implementing a standard or a method in terms of e.g.: equipment used.
Proposer	Any legal entity or natural, which can be the technology manufacturer or an authorised representative of the manufacturer of the technology. If the manufacturers of the technology concerned agree, the proposer can be another stakeholder undertaking a specific verification programme involving several technologies.	Can be vendor or producer.
Purpose	The measurable property that is affected by the product and how it is affected.	The purpose could be reduction of nitrate concentration, separation of volatile organic compounds, reduction of energy use (MW/kg) etc.
(Specific) verification protocol	Protocol describing the specific verification of a technology as developed applying the principles and procedures of the EU GVP and the quality manual of the verification body.	None
Standard	Generic document established by consensus and approved by a recognised standardization body that provides rules, guidelines or charac-	None

Term	DANETV	Comments on the DANETV approach
	teristics for tests or analysis.	
Test/testing	Determination of the performance of a product for measurement/parameters defined for the application.	None
Test performance audit	Quantitative evaluation of a measurement system as used in a specific test.	E.g. evaluation of laboratory control data for a relevant period (precision under repeatability conditions, trueness), evaluation of data from laboratory participation in proficiency test and control of calibration of online measurement devises.
Test system audit	Qualitative on-site evaluation of test, sampling and/or measurement systems associated with a specific test.	E.g. evaluation of the testing done against the requirements of the specific verification protocol, the test plan and the quality manual of the test body.
Test system control	Control of the test system as used in a specific test.	E.g. test of stock solutions, evaluation of stability of operational and/or on-line analytical equipment, test of blanks and reference technology tests.
TTHM	Total trihalomethanes	
Verification	Provision of objective evidence that the technical design of a given environmental technology ensures the fulfilment of a given performance claim in a specified application, taking any measurement uncertainty and relevant assumptions into consideration.	None

APPENDIX E

Amendment and deviation report for verification

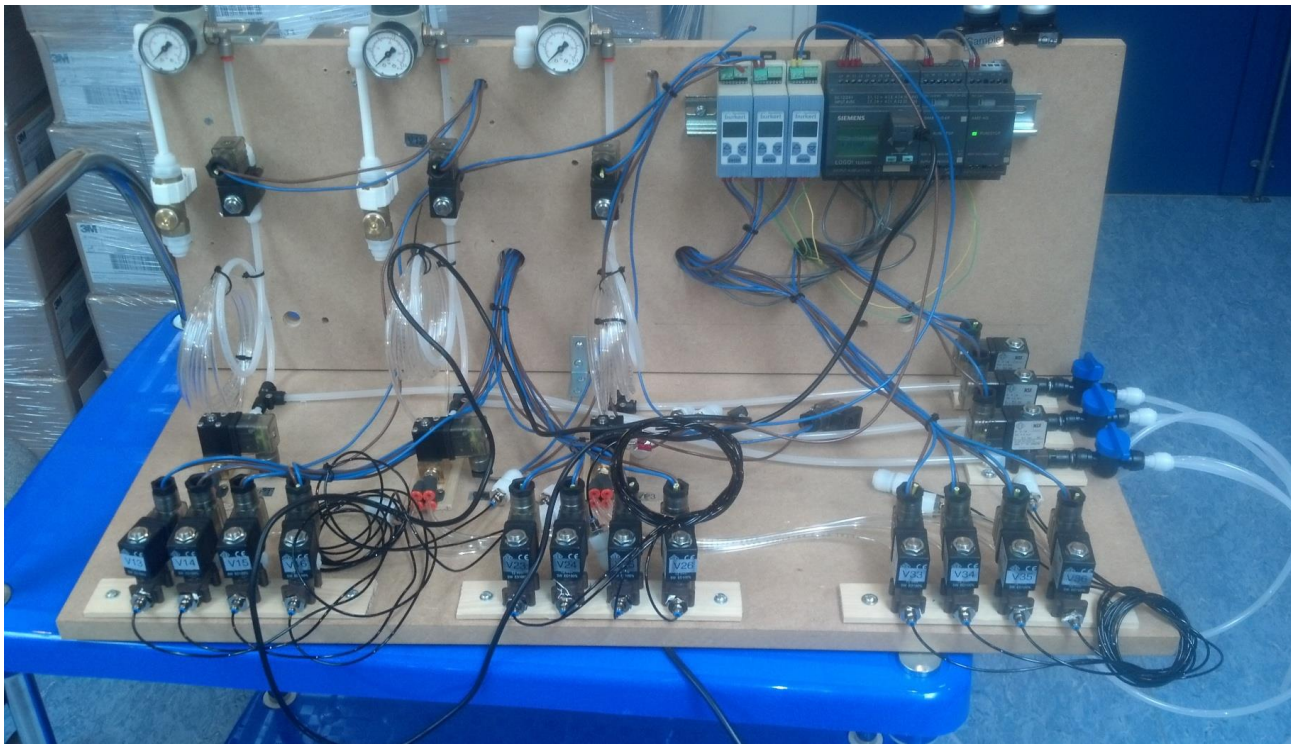
There were no amendments to or deviation from the specific verification protocol.

APPENDIX F

Test Plan

BacTerminator ® Dental

Environmental Technology Verification Test Plan



Adept Water Technologies A/S

DHI DANETV Test Plan

December 2013

This report has been prepared under the DHI Business Management System certified by DNV to comply with
Quality Management ISO 9001
Quality Management System certified according to DS/EN ISO 9001 by Det Norske Veritas, Business Assurance, Danmark A/S
Insert the logos for allowed certifications in cells above, logos can be found here.

Approved by
04-12-2013 X Approved by Signed by: Morten Rungø

BacTerminator ® Dental

Environmental Technology Verification Test Protocol

Prepared for	Adept Water Technologies A/S
Represented by	Michael Reidtz Wick, CEO

Test set-up

Project manager	Claus Jørgensen

Project number	11814507
Approval date	4 December 2013
Revision	Final version 1.0
Classification	Open

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FIGURES

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APPENDICES

1 Introduction

1.1 Verification protocol reference

This test protocol is based on the specific verification protocol for BacTerminator® Dental issued by DS Cert and DANETV, September 30, 2013. /1/

1.2 Name and contact of proposer

Adept Water Technologies A/S, Diplomvej 378, 2800 Lyngby, Denmark

Michael Reidtz Wick, +45 88708526, mw@adeptwatertech.com and

Poul Fogh, pf@adeptwatertech.com

1.3 Name of test body/test responsible

DHI DANETV Test Centre, Agern Alle 5, 2970 Hørsholm, Denmark

Test responsible will be Claus Jørgensen, DHI.

1.4 Test object

The test object is the BacTerminator ® Dental (BTD).

2 Test Design

2.1 Test site

2.1.1 Types of test sites

The test site is the DHI laboratory

2.1.2 Addresses

Agern Alle 5, DK-2970 Hørsholm

2.1.3 Descriptions

The test will be performed in the DHI laboratory. Preparations and analyses will be performed in the Microbiology lab and the surrogate dental units will be located in room O2-D11, which is temperature regulated.

2.1.4 Special needs

Safe handling of *Legionella pneumophilae*.

Ventilation of the location of the surrogate dental units due to risk of hydrogen evolution.

2.2 Tests

2.2.1 Performance claims and operational conditions

2.2.1.1 Performance claims:

1. BacTerminator produces 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.

4. No biofilm is generated in new dental chair piping systems. (The test body must specify the level of biofilm acceptable as equal to ”no biofilm growth”.)

5. Existing biofilm is removed from old dental chair piping systems. (The test body must specify the level of biofilm acceptable as equal to ”no biofilm growth”.)

6. No formation of halogenated by-products such as trihalomethanes and haloacetic acids. Concentrations are kept below USEPA’s limits for drinking water.

7. Free chlorine content in outlet water of BacTerminator® Dental < 50 mg/L.

8. Level of heavy metals in the BTD outlet water is below the EU drinking water quality criteria.

2.2.1.2 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 and chloride must be 200-1500µS/cm and 10-250mg/l (according to the unit manual).
- Water in: 1-1½L/min. The BacTerminator® Dental is restricting this water flow, which otherwise would depend on water tap dimension and water pressure.
- Water out: 1-3L/min @ 2-2½bar. The outlet water flow depends on pump and back pressure.

2.2.2 Test staff

Laboratory technicians are Mette Albrechtsen and Jørgen Hansen, DHI.

2.2.3 Test equipment

Three surrogate dental chairs, in the following called chairs, were developed by the proposer in cooperation with the test responsible.

The chairs mimic dental chairs with respect to tube lengths and materials, valves and mouth pieces.

The simulated chair has a cup holder and 4 instruments:

- Cup holder (approx 1200 mL/min)
- Tri function instrument (approx. 125 mL/min)
- Primary instrument (approx. 70 mL/min)
- Secondary instrument (approx. 70 mL/min)
- Ultrasonic instrument (approx. 30 mL/min)

A picture of the chairs is shown in Figure 2-1

A schematic is shown in Figure 2-2.

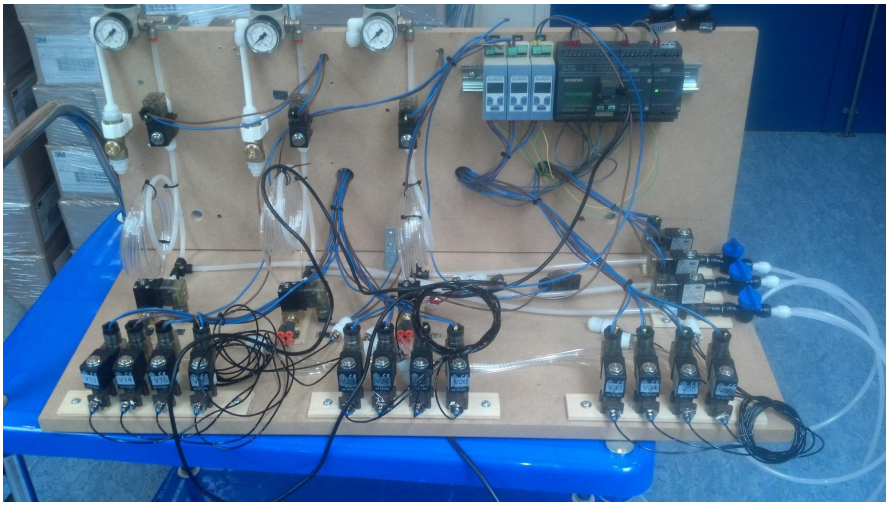

Figure 2-1: The test equipment.

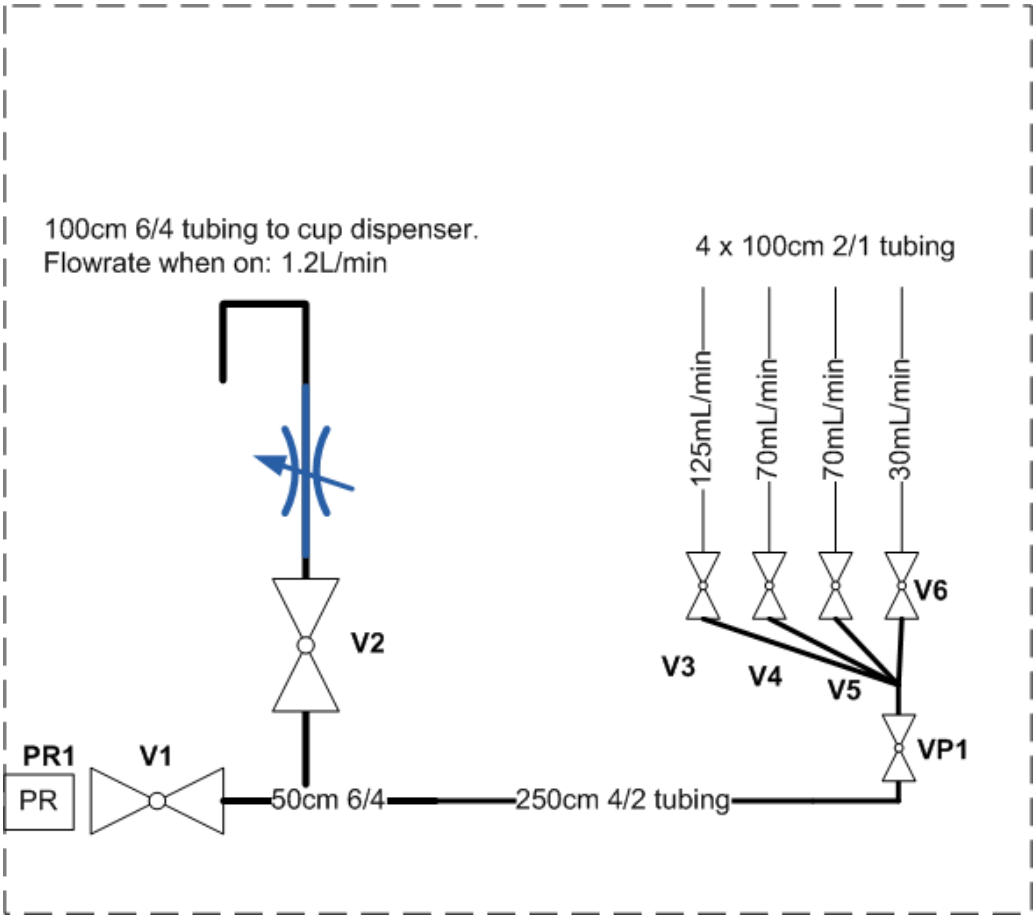

Figure 2-2: Design of the surrogate dental chairs

A list of construction materials is shown in Table 2-1

Table 2-1: List of materials

	Function/size	Material
Non-return valve	Back-flow prevention	Brass, PTFE, AISI 316
8/6 tubing	8 mm outer/6 mm inner diameter. Before non-return valve	Polyethylene (PE)
6/4 tubing	6 mm outer/4 mm inner diameter	Linear low-density polyethylene (LLDPE)
4/2	4 mm outer/1 mm inner diameter	Polyamid 12 (Nylon 12, PA12)
2/1	2 mm outer/1 mm inner diameter	Polyurethane (PU)
PR	Pressure regulator	Unknown
V1-V6	Valves	Gold plated copper, Viton, polyphenylene sulfid (PPS), AISI 300 and AISI 400
VP1	Proportional valve	Brass and or Polyoxymethylene (POM)
Fittings	Fittings	Nickel plated brass and or POM

The surrogate chairs are controlled by PLCs. The PLCs are configured to simulate treatment of one patient every half hour. Table 2-2 shows the events during a half hour period. on a weekly basis as shown in Table 2-3. The operation may be changed when the test system is running.

During the test phase, the surrogate chairs will be kept in the dark, to avoid algae growth in the tubing.

Table 2-2: PLC configuration for operation of the surrogate chairs. The table shows events occurring every half hour corresponding to treatment of 1 patient.

Valve	Events in each ½ hour cycle	Description	Duty cycle (%)
V1	Open	Main valve open at all times	100
V2	Open 7 s, at time 29 min and 53 s	Drinking cup filled at the end of every half hour	0.4
V3	Open 15 s, at the end of each 5 minute interval	Tri-function instrument. Used 15 s every 5 minutes	5.0
V4	Open 60 s, at time 12 min	Primary instrument. Used for 60 s 12 min into the treatment	3.3
V5	Open 15 s, at time 19 min	Secondary instrument. Used 15 s 19 min into the treatment	0.9
V6	Open 7 minutes, at time 22 min	Ultrasonic instrument. Used 7 min 22 min into the treatment	25.5

Table 2-3: Weekly operation of the chairs. The green colour indicates the active period

Day\time	9-10	10-11	11-12	12-13	13-14	14-15	15-16	16-17	17-18
Mon									
Tue									
Wed									
Thu									
Fri									
Sat									
Sun									

The sampling points will be as shown in Table 2-4.

Table 2-4: Sampling points

ID	Name used in text	Description
BTD-I	BTD inlet	Drinking water or challenge water going into the BTD
BTD-O	BTD outlet	Treated water after the BTD
Chair-O	Chair outlet	Water leaving the chair from the ultrasonic instrument.
Biofilm	Biofilm	Pieces cut out of the 4/2 tube before VP1

2.2.4 Test method

2.2.4.1 Claim 1: Production of chlorine

The testing of free chlorine production by the BDT will be carried out initially using tap water and demineralised water with addition of varied amounts of chloride and other ions to regulate the conductivity to high, medium and low levels. Conductivity will be varied between 100 µS/cm and 2000 µS/cm and chloride between 5 mg/l and 500 mg/l.

1. Conductivity and chloride is measured in tap water.
2. A sodium chloride stock solution is prepared at a concentration of 5 g chloride/L.
3. A mixture of tap water and chloride stock with a concentration of 500 mg/l is produced.
4. The conductivity and the chloride concentration of the mixture are determined.
5. If the conductivity is below 2000 µS/cm, a stock solution of Na_2SO_4 with a suitable concentration is prepared. The conductivity of this solution is determined.

6. Based on the measured conductivities and chloride concentrations, mixtures of deionised water, tap water and stock solutions are prepared in 20 L batches according to Table 2-5.

7. All mixtures are analysed for pH, temperature, conductivity and chloride. Free chlorine will be analysed in the combination of very low conductivity and very low chloride concentration, as well as in the very high / very high combination.

8. The BTD settings for production of approximately 0.5 mg/L is determined for selected mixtures based on information from the proposer and tested by treating 5 to 10 L of water.

9. Each mixture is pumped through the BTD at a rate of approximately 1 l/min in the order indicated in Table 2-5. After 8 litres, outlet samples are taken and immediately analysed for free chlorine and pH. The very low / very low combination will be analysed twice to determine carry over effects from test to test

Table 2-5: Variation of conductivity and chloride for testing of claim 1. Numbers give the order in which the test shall be conducted.

Conductivity/Chloride	Very low 5 mg/l	Low 10 mg/l	Medium 75 mg/l	High 250 mg/l	Very high 500 mg/l
Very low (100 µS/cm)	1/14				12
Low (200 µS/cm)		3	6	9	
Medium (800 µS/cm)		4	7	10	
High (1500 µS/cm)		5	8	11	
Very High (2000 µS/cm)	2				13

The test temperature will be room temperature.

2.2.4.2 Claims 2-8: Water treatment

The guidelines in ISO/TS 11080:2009 /2/ (Test methods for water treatment in dentistry) will be followed to the extent possible within the practical and economic constraints of this project.

The tests are carried out using 3 chairs; see the description in section 2.2.3.

The test is run in two phases. Claims 2, 3, 4, 6, 7 and 8 are verified in phase 1. Claim 5 is verified in phase 2.

The chairs/The BTD are all challenged with drinking water during the entire test period, and on occasions with a Legionella challenge solution, hence, all chairs are treated equally with the exception of the BTD. The challenge solution will be pumped from a sterilized 50 litre stirred container into the BTD.

In phase 1, Chair 1 is connected to the BTD. Another chair is a control chair. The difference observed between the control chair and chair 1 verifies the effect of BTD on new dental chairs, i.e. preventing biofilm formation. Chair 2 receives water of the same quality and quantity during phase 1 as the control chair. Chair 2 and the control chair are therefore considered to be identical with respect to biofilm, *Legionella* and HPC at the end of phase 1.

In phase 2, the BTD is moved from chair 1 to chair 2. In this phase, the difference observed between chair 2 and the control chair verifies the effect of BTD on old dental chairs, i.e. biofilm removal.

ISO/TS 11080 suggests that a minimum of two surrogate chairs are tested. In this test setup, two chairs are tested, although not simultaneously and not from the same point of departure. However, the end point and the claim for the two are the same: no biofilm.Biofilm will build up in the control chair and in chair 2 during the challenge. The size of the biofilm will depend on the time and the growth rate of the biofilm. The time to build up a sufficient biofilm is unknown, but preliminary tests show that biofilm is detectable in tubes within a month.

The time schedule shown in Table 2-6 is therefore tentative. The period between sampling will depend on the results of previous measurements.

The test temperature will be in the range of 28 °C ± 2 °C.

All tubes will be disinfected prior to the test.

Table 2-6: Analytical plan and tentative time schedule

Time (day)	Test chair 1	Control chair	Test chair 2
	Phase 1 • Testing of Claim 2 and 3: Removal or killing of pathogenic bacteria and heterotrophic plate count • Testing of Claim 4: No biofilm is generated in new dental chair piping systems • Testing of Claim 6: No formation of halogenated by-products • Testing of Claim 7: Free chlorine < 50 mg/L • Testing of Claim 8: Heavy metals below WHO drinking water quality criteria		
	Test chair Connected to BacTerminator® Dental	Control chair	Challenged but not analysed initially
1	Legionella challenge Water quality (Ch,M1,Chl) and biofilm	Legionella challenge Water quality (Ch,M1,Chl) and biofilm	Legionella challenge
8	DW Legionella challenge Water quality (M1, Chl) and biofilm	DW Legionella challenge Water quality (M1, Chl) and biofilm	Legionella challenge
21	Legionella challenge Water quality (M1, Chl) and biofilm	Legionella challenge Water quality (M1, Chl) and biofilm	Legionella challenge
42	Legionella challenge Water quality (Ch,M1,Chl) and biofilm	Legionella challenge Water quality (Ch,M1,Chl) and biofilm	Legionella challenge Water quality (M1) and biofilm
	Phase 2 • Testing of Claim 5: Existing biofilm is removed from old dental chair piping systems		
Time (day)	**Test chair 1**	**Control chair**	**Test chair 2**

42			Connected to BacTerminator® Dental
63	-	DW Legionella challenge Water quality (M1, Chl) and biofilm	DW Legionella challenge Water quality (M1, Chl) and biofilm
84	-	Water quality (M2, Chl, HM) and biofilm	Water quality (M2, Chl, HM) and biofilm
105	Water quality (M1) and biofilm	Water quality (M1,Ch, Chl,) and biofilm	Water quality (M1,Ch, Chl) and biofilm

Performance parameters:

DW: Drinking water analysis: Normal control as required by Danish legislation. Sampling time before legionella challenge. Sampling point: inlet and outlet BTD.

M1: Microbiology: HPC 36, HPC R2A, Legionella. Sampling time: HPC 36 and HPC R2A on *first flush in the morning. HPC 36 and Legionella during Legionella challenge. Sampling points: HPC R2A and HPC 36 *first flush: outlet chair. HPC 36 and Legionella inlet BTD, outlet BTD and outlet Chair.

M2: Microbiology: HPC 36, HPC R2A. Sampling time: *first flush in the morning. Sampling point: outlet Chair.

Biofilm. Total number of bacteria HPC R2A. Sampling time: Before Legionella challenge. Sampling point: Distal end of tube.

Ch: Chemical parameters. Trihalomethanes, haloacetic acids. Sampling time: before Legionella challenge. Sampling points: Inlet and outlet BTD.

Chl: Chlorine. Sampling time: Before and after Legionella challenge. Sampling points: inlet BTD, outlet BTD and outlet Chair.

HM: Heavy metals. Identified based on an on-going study carried out by the proposer. If the on-going study is of a sufficient quality, then the heavy metal analyses will not be carried out.

Operational parameters:

Temperature, pH, conductivity, chloride and hardness. Sampling time: prior and during Legionella challenge. Sampling points: inlet and outlet BTD.

Flow: Mouth piece, mouth rinsing water (Water delivered by the chair to be used by the patient after treatment).

Legionella challenge solution: is water containing a documented concentration of *Legionella*.

**Volume of the first flush sample to be calculated from tube diameters and lengths*

Challenge by Legionella

Hot water collected from a hot water system with a documented content of *Legionella.*

Alternatively a laboratory culture may be used.

Challenge by heterotrophic bacteria for biofilm formation

Tap water will be used as challenge water to mimic a real situation. However, the recommended /2/ levels of 10^4 to 10^6 CFU/ml in the effluent procedural water may not be reached when using high quality drinking water. Should this be the case, it will be discussed with DS Certification and the Client whether a prepared challenge water will be necessary.

If a prepared microbial suspension is considered necessary, the following organisms will be used: *Pseudomonas fluorescens Migula* strain P17 (ATCC 49642) and *Aquaspirillum sp*. Strain

NOX (ATCC 49643). Both are isolated from a water distribution system in the Netherlands. In addition a source of easy assimilable organic carbon will be added.

2.2.5 Type and number of samples

The sampling schedule is shown in the analytical plan (see Table 2-6).

The total number of analyses is shown in Table 2-7 and Table 2-8:

Table 2-7: Number of samples for Claim 1

Parameter	# of analyses
Chlorine inlet BTD	2
Chlorine outlet BTD	14
pH in	14
pH out	14
Temperature	14
Conductivity	14
Chloride	14
Flow	14

Table 2-8: Number of samples for Claims 2 through 8:

Parameter\sampling day	1	8	21	42	63	84	105	sum
Biofilm	4	4	4	6	4	4	6	32
HPC R2A	4	4	4	6	4	3	5	30
HPC36	8	8	8	12	8	6	12	62
Legionella	5	5	5	7	4	2	7	35
Trihalomethanes	4	0	0	4	2	0	2	12
Haloacetic acids	4	0	0	4	2	0	2	12
Chlorine	10	10	10	10	8	8	8	64
Operational excl. flow	3	3	3	3	3	3	3	21
Flow	4	4	4	4	4	4	6	30
Drinking water analysis	0	4	0	0	4	0	0	8

2.2.6 Operational conditions

For claim 1, the conductivity wil be varied between 100 µS/cm and 2000 µS/cm and chloride between 5 mg/l and 500 mg/l.

For the remaining tests, the conductivity and the chloride concentration will be as in the water quality at DHI and the water quality in the challenge water. If not between 200 µS/cm and 1500 µS/cm and chloride between 10 and 250 mg/l, the water quality will be adjusted.

2.2.7 Technology maintenance

A logbook of performed maintenance will be kept.

2.2.8 Health, safety and wastes

Room O2-D11 has ventilation. Gentle point ventilation will be applied above the BTD, to remove any possible emitted hydrogen.

3 Analysis and Measurements

3.1 Analytical laboratory

The measurements will be carried out in the DHI laboratory (not accredited) or by an external accredited laboratory to be selected, as stated for each of the analytical methods.

3.2 Analytical parameters and methods

3.2.1 Claim 1: Production of chlorine

3.2.1.1 Chloride

Chloride is determined at DHI according to DHI SOP 30/290:05 using the Hach-Lange analysis kit LCK 311. Quality control samples of 0 mg/l, 5 mg/l, 10 mg/l, 75 mg/l, 250 mg/l, and 500 mg/l of Cl^- are produced from deionized water and dried NaCl and analysed. A deviation of 10 % is accepted.

Results, including quality control results, are recorded manually and inserted into a spread sheet. The manually recorded results are scanned and filed on the share point at the end of the test. The spread sheet is filed on the internal DHI share point site.

3.2.1.2 Chlorine

Chlorine is determined at DHI according to DHI SOP 30/290:05 using the Hach-Lange analysis kit LCK 410.

Chlorine is also determined with chlorine sticks (Adept catalogue no.130043).

Temperature will be measured using a traceable calibrated thermometer according to DHI SOP 30/251:13 and pH will be measured according to DHI SOP 30/217:15.

Results, including quality control results, are recorded manually.

3.2.2 Claim 2 to 8: Water treatment

3.2.2.1 Legionella pneumophilae

DS 3029:2001. Environmental quality - Enumeration of Legionella - Concentration and colony count on solid medium - Spread plate method. External accredited laboratory.

The accredited analytical reports are filed on share point. The results are inserted into a spread sheet, which is filed on the share point

3.2.2.2 Heterotrophic plate count, HPC 36

DS/EN ISO 6222:2000. Water quality - Enumeration of culturable micro-organisms - Colony count by inoculation in a nutrient agar culture medium (ISO 6222:1999). External accredited laboratory.

3.2.2.3 Heterotrophic plate count (R2A)

Spreadplate method using R2A agar with an incubation time of 2 weeks at 15 °C according to DHI SOP 30/816:03. The low nutrient agar and the long incubation time give low selectivity and a high plate count.

3.2.2.4 Biofilm

The biofilm is analysed according to DHI SOP 30/822:01.

Two pieces of tube with the same length in the distal end of the tube (Ø = 4 mm) are cut open in the longitudinal direction. The inside of the tube is swept with a sterile cotton bud to collect the attached bacteria. The cotton bud is then transferred to 1 ml 0.2 µm sterile peptone buffer and vortexed vigorously for 1 minute. The peptone buffer is subsequently examined by HPC R2A (DHI SOP 30/816:03).

To determine a limit of detection of the biofilm assay, 10 pieces of a colonized tube are swabbed three times, each time with a clean cotton bud. Each tube is analysed in duplicate based on the third cotton bud. The limit of detection (LD) and limit of quantification (LQ) is determined according the following formulas /3/:

$$\mathrm{LD} = 3 \cdot \mathrm{Sw}$$

and

$$\mathrm{LQ} = 3 \cdot \mathrm{LD}$$

where

$S_w^2 = (d_1^2 + d_2^2 + d_3^2 + \ldots d_n^2)/2\mathrm{n}$, and

d is the difference between the duplicate analyses.

The LQ is used as criterion for presence or absence of biofilm. The LQ is determined before the initiation of the test.

3.2.2.5 Free chlorine

Analysed on Hach Lange photometric equipment, using LCK410 Free Chlorine cuvette test, 0.05-2.0 mg/L Cl_2 according to DHI SOP 30/290:05.

3.2.2.6 Trihalomethanes, haloacetic acids, heavy metals

Analysed by the external accredited laboratory.

3.2.2.7 Normal drinking water control

The analyses include the following parameters:

Colour, clarity, taste, temperature, conductivity, pH, Non Volatile Organic Carbon, Ammonium, Nitrite, Nitrate, Chloride, Fluoride, Iron, Manganese, Total-P and Sulfate.

Analysed by the external accredited laboratory.

3.2.2.8 Temperature, flow, hardness, pH and power consumption.

Temperature is determined with a traceable calibrated thermosensor according to DHI SOP 30/215:13.

Flow is determined by collection in volumetric beakers.

Hardness is determined with Hach Lange photometric equipment using LCK327 Water Hardness cuvette test 1-20° according to DHI SOP 30/290:05.

pH is measured with pH electrodes according to DHI SOP 30/217:15.

Power consumption is determined using aPowerKwHDetective (SL-energiteknik, Sønderborg, Denmark)

3.3 Analytical and measurement performance requirements

Chloride and chlorine analyses are checked by analysing quality control samples. For chloride, a dried sodium chloride solution is used. For chlorine, Hach Lange chlorine standard samples (LCA 310) are analysed. A deviation of 25 % between result and nominal concentration of the standard is accepted.

For HPC on R2A, at least 1 sample is analysed in duplicate on each sampling occasion. The relative difference between the duplicates should be in compliance with the requirements for accredited HPC 22 °C in drinking water /3/.

The extraction efficiency of the biofilm from 2 tubes is controlled on each sample occasion by extracting the swapped tube in 1 ml peptone buffer and subsequently the buffer by HPC R2A. The result should not be higher than the detection limit.

The Hach-Lange determination of hardness is controlled by analysing the drinking water samples sent to Eurofins for normal drinking water analysis.

Performance requirements are not set for temperature, pH, flow and power consumption. For temperature, traceable calibrated thermo sensors are used. pH-meters are calibrated with traceable buffers. The volumetric beakers used for flow determination are compared to weight on traceable calibrated balances. Power consumption is determined with a traceable calibrated meter.

The remaining analyses should comply with the criteria for LD and expanded uncertainty for drinking water as described in the Danish Order No. 900 of 17 August 2011 on quality requirements for environmental analyses: https://www.retsinformation.dk/Forms/R0710.aspx?id=138231.

3.4 Preservation and storage of samples

Samples for microbial analyses should be stored at 5 °C ± 3 °C and analysed within 24 hours.

Samples for chlorine, temperature and pH should be analysed immediately.

Samples for chloride, conductivity and hardness should be stored at room temperature or lower and analysed within 1 week.

The samples analysed by the external accredited laboratory are preserved/stored as required by the laboratory.

3.5 Data management

3.5.1 Claim 1: Production of chlorine

The results of the chlorine measurements will be presented in tabular form as Table 2-5.

3.5.2 Claim 2 to 8: Water treatment

Results of the chlorine analyses of samples from the outlet of the BTD and outlet of the chairs will be presented in graphs or in tabular form, including average and standard deviations.

When possible, contact time (in mg free Cl_2 * min) will be calculated and plotted against bacterial reduction.

Temporal variation will be shown for the following parameters and sampling points:

- Biofilm development in new chair with BacTerminator® Dental
- Biofilm in old chair after installation of BacTerminator® Dental
- Biofilm in chair without BacTerminator® Dental – control measurement
- Heterotrophic plate count after BacTerminator® Dental
- Heterotrophic plate count without BacTerminator® Dental – control measurement
- *Legionella* after BacTerminator® Dental
- *Legionella* without BacTerminator® Dental – control measurement
- Heterotrophic plate count after surrogate dental chair with BacTerminator® Dental
- Heterotrophic plate count after surrogate dental chair without BacTerminator® Dental – control measurement
- *Legionella* after surrogate dental chair with BacTerminator® Dental
- *Legionella* after surrogate dental chair without BacTerminator® Dental – control measurement.

Other performance parameters will be presented in tabular form.

Operational parameters will be presented as ranges or in more detail in the report, if appropriate and all data will be presented in an appendix.

3.6 Data storage, transfer and control

All data generated and all other records and information relevant to the quality and integrity of the study will be retained. Manually recorded results will be scanned and filed on share point (11814507) after termination of the study and stored for at least 10 years. Manually recorded results and results from the external lab will be transferred to spread sheets and filed on share point (11814507). At least 10 % of the experimental data transferred to the spread sheet will be controlled.

4 Quality Assurance

4.1 Test plan review

This test plan has been subject to internal review according to the DHI quality system. The test plan was reviewed by Gerald Heinicke. The test plan will be reviewed and approved by the proposer, DS Certificering and China ETV

4.2 Performance control – analysis and measurements

The results of the performance control analyses are compared to the performance requirements described in section 3.3.

For the analyses performed by Eurofins, the current LD and expanded uncertainties are obtained from Eurofins and compared to the drinking water requirements in /3/.

4.3 Test system control

For testing of claim 1:

The concentration of chlorine and chloride in the test samples are verified by analysis as described in section 2.2.4.1.

For testing of claim 2-8:

The chair connected to BTD is compared to a non-connected control chair, which has been subjected to the same treatment.

The flow is determined.

The chlorine and pH measurements assure that the BTD is working as intended.

The inflowing drinking water is tested for absence of chlorine.

4.4 Data integrity check procedures

The calculation of all results produced by DHI is quality controlled by a second pair of eyes.

No less than 10 % of the data transferred to spread sheets will be quality controlled by a second pair of eyes.

4.5 Test system audits

The test is audited during the critical phases by Bodil Mose Petersen, DHI.

Two critical phases were identified:

- Production of chlorine
- Water treatment during *Legionella* challenge.

4.6 Test report review

The test report will be reviewed by internal expert Gerald Heinicke, DHI.

The test report will also be reviewed by the proposer, DS Certificering and China ETV.

5 Test Report

The test report will be in accordance with the general verification protocol and contain the following sections:

1 Introduction

1.1 Name and contact of proposer

1.2 Name of test sub-body/test responsible

1.3 Reference to test plan and specific verification protocol

1.4 Summary amendment and deviations to test plan

2 Test Design

3 Test Results

3.1 Test data summary

3.2 Test performance observation

3.3 Test quality assurance summary, incl. audit result

3.4 Details on amendments to and deviations from test plan

4 References

List of figures and list of tables

APPENDIX A – Terms and Definitions

APPENDIX B – Test Data Report

APPENDIX C – Test Plan Amendment and Deviation Reports (if relevant).

5.1 Amendment report

Any amendments to the test plan prior to initiation of the test will be documented and sent to the verification body and the proposer for approval.

5.2 Deviations report

Any deviation to the test plan during the test will be documented and sent to the verification body and the proposer for approval.

6 References

/1/ Adept Water Technologies A/S, BacTerminator® Dental, Specific Verification Protocol. 30 September 2013

/2/ ISO/TS 11080 Dentistry – Essential characteristics of test methods for evaluation of treatment methods intended to improve or maintain the micro-biological quality of dental unit procedural water. First edition. 01-06-2009.

/3/ Danish Order No. 900 of 17 August 2011 on quality requirements for environmental analyses : https://www.retsinformation.dk/Forms/R0710.aspx?id=138231

APPENDICES

APPENDIX A – Terms and Definitions

A Terms and Definitions

Term	Definition	Comments
Accreditation	Meaning as assigned to it by Regulation (EC) No 765/2008	EC No 765/2008 is on setting out the requirements for accreditation and market surveillance relating to the marketing of products
Amendment	A change to a specific verification protocol or a test plan done before the verification or test step is performed	None
Analytical laboratory	Independent analytical laboratory used to analyse test samples	The test centre may use an analytical laboratory as subcontractor
Application	The use of a technology specified with respect to matrix, purpose (target and effect) and limitations	The application must be defined with a precision that allows the user of a technology verification to judge whether his needs are comparable to the verification conditions
BTD	BacTerminator ® Dental	The test object
Challenge solution	A solution containing a documented concentration of the target (Legionella) and pumped through the BTD	None
DANETV	Danish centre for verification of environmental technologies	None
Deviation	A change to a specific verification protocol or a test plan done during the verification or test step performance	None
Environmental technologies	Environmental technologies are all technologies whose use is less environmentally harmful than relevant alternatives	The term technology covers a variety of products, processes, systems and services
Evaluation	Evaluation of test data for a technology for performance and data quality	None
General verification protocol (GVP)	Description of the principles and general procedure to be followed by the ETV pilot programme when verifying an individual environmental technology.	None

Term	Definition	Comments
Innovative environmental technologies	Environmental technologies presenting a novelty in terms of design, raw materials involved, production process, use, recyclability or final disposal, when compared with relevant alternatives.	None
LLDPE	Linear low-density polyethylene	
Matrix	The type of material that the technology is intended for	Matrices could be soil, drinking water, ground water, degreasing bath, exhaust gas condensate etc.
Method	Action described by e.g. generic document that provides rules, guidelines or characteristics for tests or analysis	An in-house method may be used in the absence of a standard, if prepared in compliance with the format and contents required for standards, see e.g. see Appendix D
Operational parameter	Measurable parameters that define the application and the verification and test conditions.	Operational parameters could be flow, pH, temperature, production capacity, concentrations of non-target compounds in matrix, etc.
(Initial) performance claim	Proposer claimed technical specifications of technology. Shall state the conditions of use, under which the claim is applicable, and mention any relevant assumption made.	The proposer claims shall be included in the ETV proposal. The initial claims can be developed as part of the quick scan.
PA12	Polyamid 12 (Nylon 12)	
PLC	Programmable logic controller	
PE	Polyethylene	
Performance parameters (revised performance claims)	A set of quantified technical specifications representative of the technical performance and potential environmental impacts of a technology in a specified application and under specified conditions of testing or use (operational parameters).	The performance parameters must be established considering the application(s) of the technology, the requirements of society (legislative regulations), customers (needs) and proposer initial performance claims.
POM	Polyoxymethylene	
Potential environmental impacts	Estimated environmental effects or pressure on the environment, resulting directly or indirectly from the use of a technology under specified conditions	None

Term	Definition	Comments
	of testing or use.	
PPS	Polyphenylene sulfid	
Procedure	Detailed description of the use of a standard or a method within one body	The procedure specifies implementing a standard or a method in terms of e.g.: equipment used
Product	Ready to market or prototype stage product/technology, process, system or service based upon an environmental technology	Technology is used instead of the term product
Proposer	Any legal entity or natural person, which can be the technology manufacturer or an authorised representative of the technology manufacturer. If the technology manufacturer in question agrees, the proposer can be another stakeholder undertaking a specific verification programme involving several technologies.	Can be vendor or producer
PTFE	Polytetrafluoroethylene	
Purpose	The measurable property that is affected by the technology and how it is affected.	The purpose could be reduction of nitrate concentration, separation of volatile organic compounds, reduction of energy use (MW/kg), etc.
Ready to market technology	Technology available on the market or at least available at a stage where no substantial change affecting performance will be implemented before introducing the technology on the market (e.g. full-scale or pilot scale with direct and clear scale-up instructions).	None
Specific verification protocol	Protocol describing the specific verification of a technology as developed applying the principles and procedures of the EU GVP.	None
Standard	Generic document established by consensus and approved by a recognised standardization body that provides rules, guidelines or characteristics for tests or analysis.	None

Term	Definition	Comments
Test body	Unit that plans and performs test.	None
Verification body	Unit that plans and performs verification.	None
Test/testing	Determination of the performance of a technology for measurement/parameters defined for the application.	None
Test performance audit	Quantitative evaluation of a measurement system as used in a specific test.	E.g. evaluation of laboratory control data for a relevant period (precision under repeatability conditions, trueness), evaluation of data from laboratory participation in proficiency test and control of calibration of online measurement devises.
Test system audit	Qualitative on-site evaluation of test, sampling and/or measurement systems associated with a specific test.	E.g. evaluation of the testing done against the requirements of the specific verification protocol, the test plan and the quality manual of the test body.
Test system control	Control of the test system as used in a specific test.	E.g. test of stock solutions, evaluation of stability of operational and/or on-line analytical equipment, test of blanks and reference technology tests.
Vendor	The party delivering the technology to the customer. Here referred to as the proposer.	Can be the producer.
Verification	Provision of objective evidence that the technical design of a given environmental technology ensures the fulfilment of a given performance claim in a specified application, taking any measurement uncertainty and relevant assumptions into consideration.	None

APPENDIX B – References Methods

B Reference Methods

Not applicable.

APPENDIX C – In-house Test Methods

C In-house Test Methods

Not applicable.

APPENDIX D – In-house Analytical Methods and Measurements

D In-house Analytical Methods and Measurements

The following in-house analytical methods are used

DHI SOP 30/212:15. Apparatur. Ledningsevnemålere (Conductivity meters)

DHI SOP 30/217. Apparatur. pH-metre (pH meters)

DHI SOP 30/251:13. Apparatur: Thermosensorer. (Thermosensors)

DHI SOP 30/290:05: Apparatur. Hach-Lange

DHI SOP 30/816:03. Vandanalyse. Kimtal på R2A. (Heterotrophic plate count on R2A.)

DHI SOP 30/822:01. Vandanalyse. Biofilm

APPENDIX E – Data Reporting Forms

E Data Reporting Forms

Claim 1

Date	
Technician	

	Cond µS/cm	Chloride mg/l	Chlorine mg/L
Tap water			
Mixture of tap water and chloride stock with aditional ions			

	Cond µS/cm	Chloride mg/l	Temp. °C	pH in	pH out	Chlorine before test mg/L	Chlorine after BTD mg/L
Solution 1							
Solution 2							
Solution 3							
Solution 4							
Solution 5							
Solution 6							
Solution 7							
Solution 8							
Solution 9							
Solution 10							
Solution 11							
Solution 12							
Solution 13							
Solution 14							
Chlorine stand 1	Koncentration:		Batch:				
Chlorine stand 2	Koncentration:						
Chlorine stand 3	Koncentration:						

pH meter used:	
Themometer used:	
Pipettes used:	

11814507

Claims 2 to 8

Chair no	
Parameter	
Unit	

Date and time	Inlet to BTD	Outlet BTD	Outlet Chair	Technician	QC

Used equipment: