Adept Water Technologies A/S

BacTerminator® Dental

Specific Verification Protocol
September 2013

Approved by
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Signed by: Morten Rungø

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 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 .

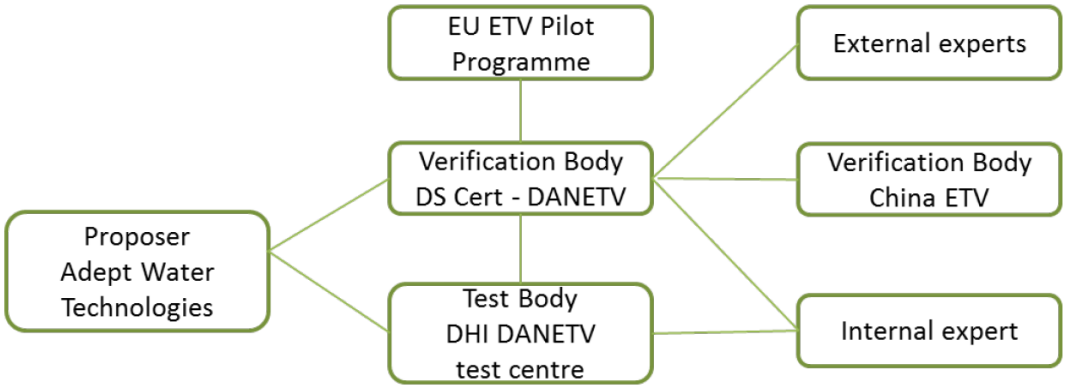

Figure 1-1 Organisation of the verification and test

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.

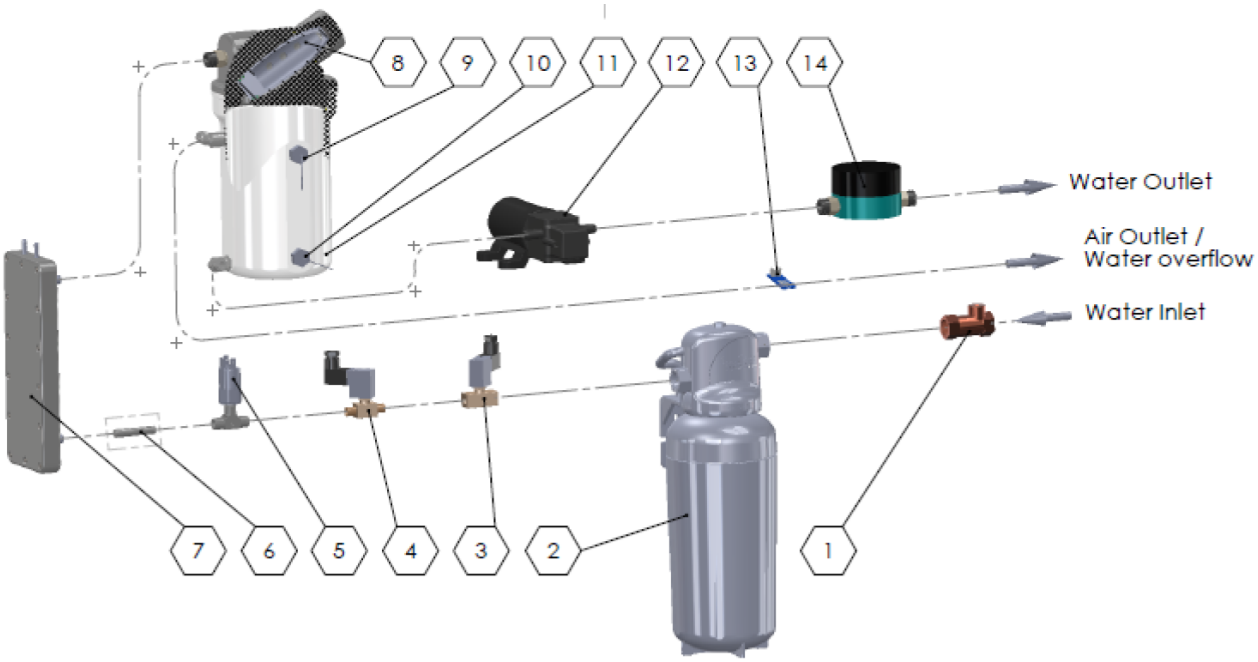

Figure 3-2 Process diagram: 1: DS EN/6117 Approved non-return valve; 2: Head and cartridge for filter/softener; 3 & 4: Solenoid valves; 5: Pressure switch; 6: Optional flow restriction; 7: BacTerminator disinfection chamber; 8: Bio Reaction Zone; 9: Water tank with 20mm air gap; 10: Level sensors; 11: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