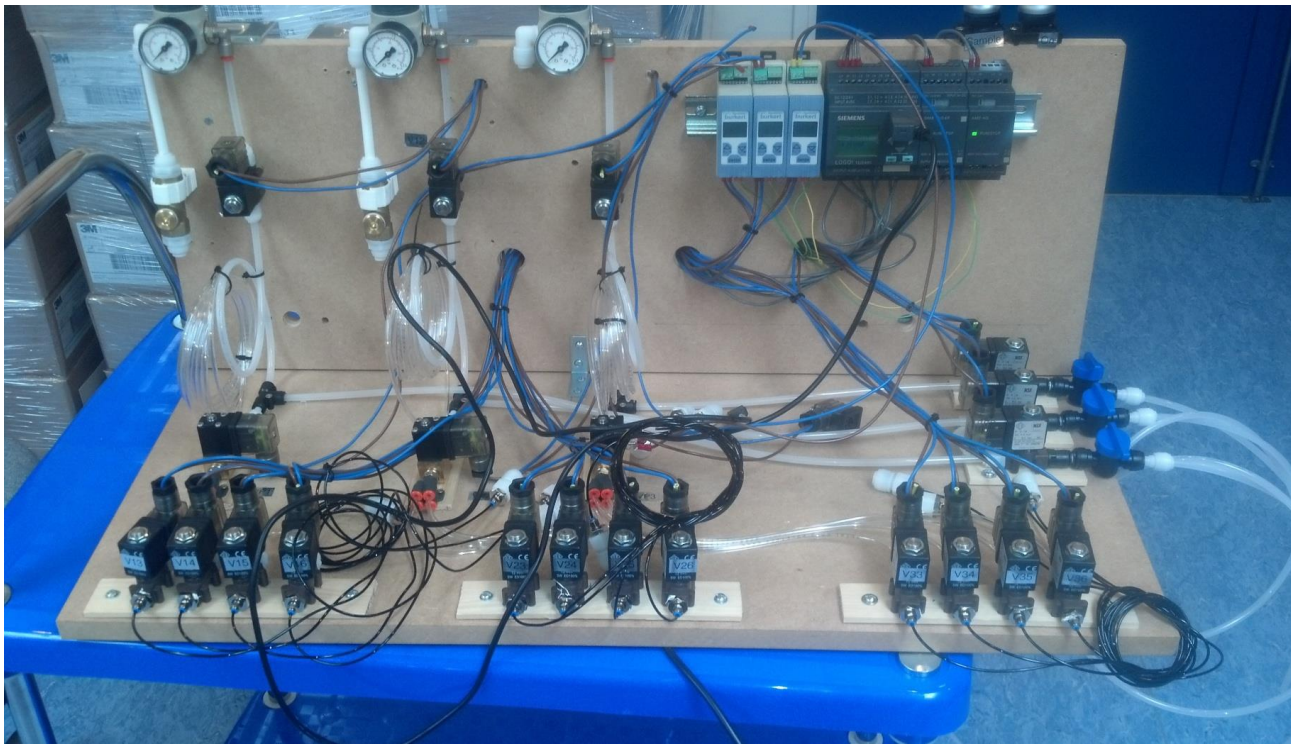
BacTerminator ® Dental

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
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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

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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.

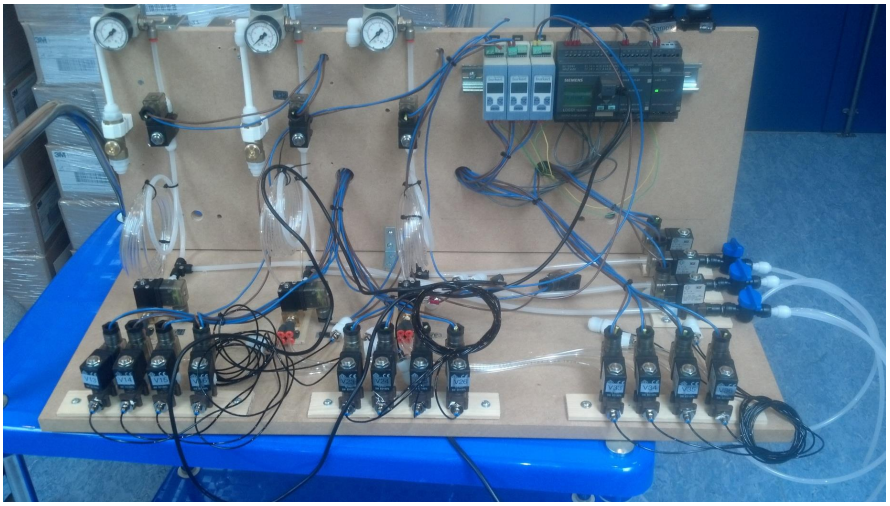

Figure 2-1: The test equipment.

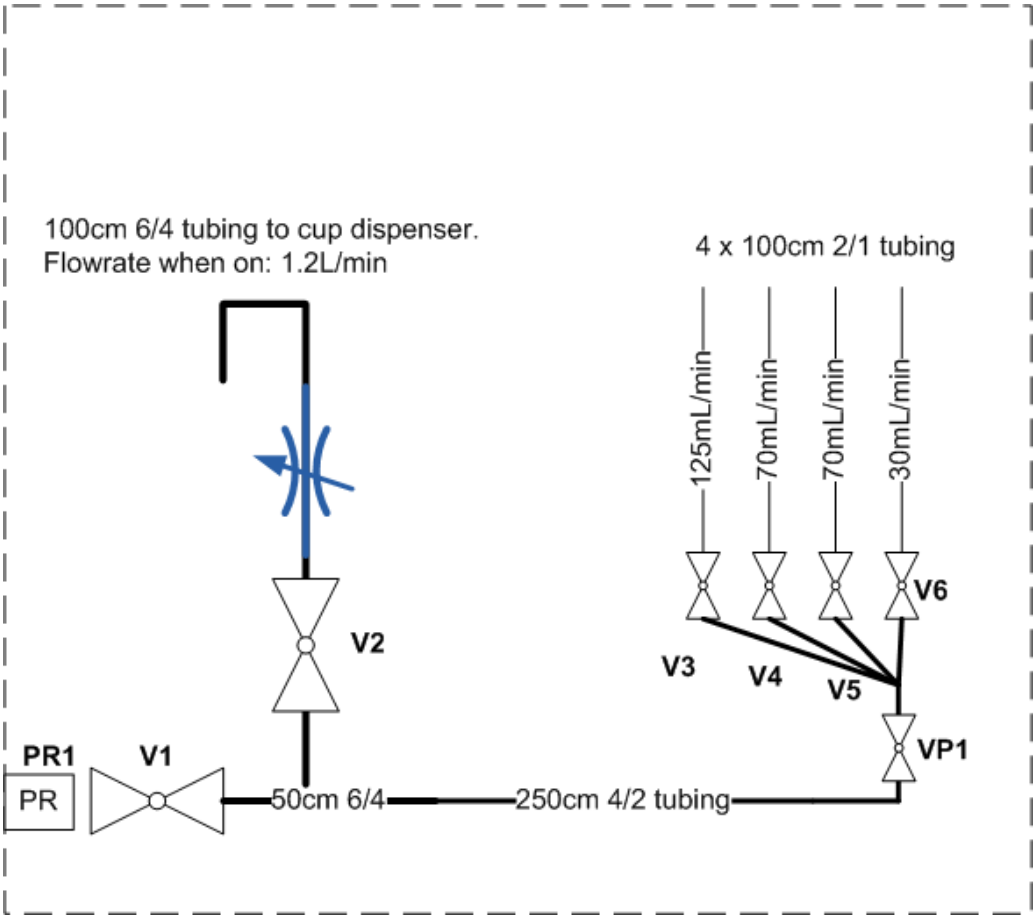

Figure 2-2: Design of the surrogate dental chairs

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: