Ultrasonic Cleaner Periodic Testing advice

How to comply with HTM01-05 when using Walker Electronics Ltd ultrasonic cleaners

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your solution in ultrasonics . . .

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why test your ultrasonic cleaner?...

All Primary Care Dental Practices should be working at or above the essential quality requirement of *Health Service Technical Memorandum 01-05: Decontamination in primary care dental practices* - called HTM01-05 for short in this document.

HTM01-05 states "Patients deserve to be treated in a safe and clean environment with consistent standards of care every time they receive treatment. It is essential that the risk of person-to-person transmission of infections be minimised as much as possible."

HTM01-05 14.1 states "The ultrasonic cleaner/irrigator should be maintained and serviced in accordance with the manufacturer's instructions." HTM01-05 14.2 states "Manufacturer's guidance on validation should be followed."

This document sets out the procedure which **MUST** be followed when commissioning, testing and validating Walker Electronics Ltd ultrasonic cleaners. It is a combination of advice by Walker Electronics Ltd and HTM01-05.

commissioning before first use...

When commissioning a NEW ultrasonic cleaner before first use on-site, the following tests **MUST** be completed.

- The Walker Electronics Ltd Load check strip test (Pages 6-9)
- The Walker Electronics Ltd DentaCheck Protein Residue test (Pages 10-12)
- The Foil Ablation test (See note on page 5 – Pages 14 to 16)

For the protein residue test, Browne's Test Soil Ref. 2304 **MUST** be used. This is available from Walker Electronics Limited.

The testing schedule…

Daily Test	Description	Performed by	Reference
Drain machine at end of day/session.	Remove all contaminated water from tank. Wipe with a WELsan wipe and leave to air dry. DO NOT use corrosive chemicals or alcohol.	User or operator	Walker Electronics Ltd
Cleaning efficacy.	Visual inspection all items cleaned. Ensure there are no visual contaminants.	User or operator	Walker Electronics Ltd
Weekly Test	Description		
Protein Residue test (using Walker Electronics Ltd DentaCheck residual protein test pages 10-12).	Confirms that the cleaning process retains the capability of removing proteins from loads.	User or operator	Walker Electronics Ltd
Cleaning efficacy test (using Walker Electronics Ltd load check holder and strips pages 6-9).	Confirms that the ultrasonic cleaner can remove artificial soil.	User or operator	Walker Electronics Ltd
Quarterly Test	Description		
Cleaning efficacy test (using the Walker Electronics Load check holder and strips pages 6-9)	Confirms that the ultrasonic cleaner can remove artificial soil.	CP(D) or service engineer	BS EN ISO 15583:1
Ultrasonic activity test (see note on page 5).	Foil ablation test. Refer to instruction on pages 14 to 16 of this leaflet.	CP(D) or service engineer	BS EN ISO 15583:1
Protein Residue Test (using Walker Electronics Ltd DentaCheck residual protein test pages 10-12).	Confirms that the cleaning process retains the capability of removing proteins from loads.	CP(D) or service engineer	BS EN ISO 15583:1
Annual Test	Description		
Completion of ALL validation tests above		Return to Walker Electronics Ltd	As above

Definitions as per HTM01-05…

User

This person has day-to-day responsibility for the management of the decontamination equipment and processes. A likely overlap may mean that this role is duplicated, but the responsibility must be demonstrated. An important function of the User is to ensure that anyone operating and testing decontamination equipment (that is, an Operator) is suitably trained and competent. The User should seek advice from manufacturers or the service engineer on how to carry out the testing of equipment and daily tasks.

Operator

This is the person with authority to operate decontamination equipment. This person will also carry out daily and weekly periodic tests.

CP (D) - Competent Person (Decontamination)

This person is responsible for the servicing, testing and maintaining of the decontamination within in practice. The competent person may be either directly employed by the practice or provide a service by the PCT or a third party.

Service Engineer

A person provided under a service level agreement or contract who is certified by the service agent or Walker Electronics Ltd to be competent to both service and test specified decontamination equipment. This person may, among other duties, perform validation tests in accordance with EN standards cited in HTM01-05. The service engineer may give an opinion on the outcomes of validation testing as well as providing data to an Authorising Engineer (Decontamination) or Authorised Person (Decontamination) for validation approval.

Understanding the Foil Ablation test…

On a multi transducer tank the foil ablation test, protein residue test and the soil test will all provide a different, but accurate assessment of the ultrasonic cleaners' ability to remove protein.

On a single transducer tank, it is Walker Electronics Ltd opinion that the weekly load test and the weekly protein residue test will determine the cleaning efficiency of the ultrasonic cleaner. If there were a fault that leads to a failure of the protein residue test or load check strip test, this fault would also have led to a failure of the foil ablation test.

Walker Electronics Ltd are therefore of the opinion that the foil ablation test provides little or no benefit in assessing the efficacy of an ultrasonic cleaner WITH A SINGLE TRANSDUCER and therefore advises that this test should be omitted from the service schedule of its model QC and Q105 units.

About Load Test Strips…

Walker Electronics Ltd load check strips are a consistent, reproducible and reliable way of keeping check on the cleaning efficiency of your ultrasonic bath.

They are used in conjunction with the load check holder and can be used with no risk of adding blood borne contaminants as they contain two sources of protein, lipids and polysaccharides derived from eggs and porcine.
Specially formulated to mimic the cleaning efficacy soil tests for surgical instruments as described in HTM01-05.

The strips have many benefits including:

- Safe to handle
- Reproducible testing
- Easy to interpret results
- Bench marked performance suitable for validation
- Mimics occluded surfaces to present a realistic challenge

Use these strips on a weekly basis to validate the cleaning efficiency of your Walker Electronics Ltd Ultrasonic Cleaner.

The following equipment will be required:

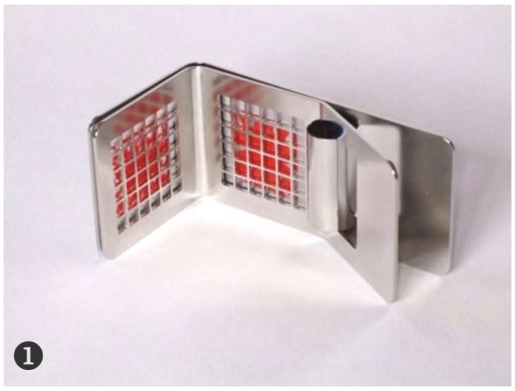
1. Walker Electronics Load Check Holder
2. 1 or 2 Walker Electronics Limited Load Check Strips.
3. 1 or 2 Sachets of WELzyme green.

Load Test Strips instruction…

Method.

1. Fill the bath with clean water and 1 or 2 sachets of WELzyme green. See leaflet enclosed with WELzyme green for dosing instructions. The fluid temperature must be in excess of 20°C but less than 45°C.

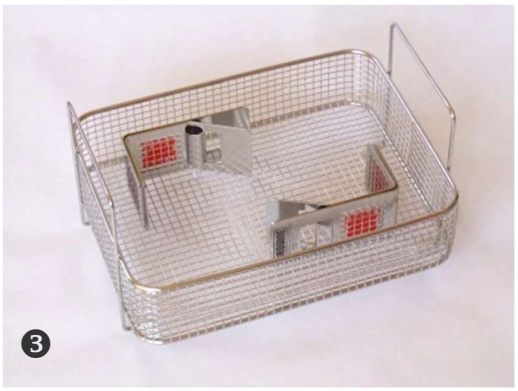
2. Degas the solution by running the unit through a 3 minute cycle or allow the machine to perform its automatic degas cycle.



3. Ensure that your hands and the load check holder are dry.

4. Place 1 check strip in the holder ensuring it is centrally located and not protruding from either side (1).

5. For the model QC and Q105, place the holder in the middle of the basket as shown (2). For the models 80T, T105, 80H and H105 place one holder at each end of the basket as shown (3)



6. After running a complete cycle (see important notes), remove the holder from the basket and carefully remove the check strip. Rinse the strip under potable water to remove any loosened soil. Caution should be used as the holder may be hot and any residual soil from the strip may stain.

IMPORTANT notes...

Place the holder in a vertical position as shown as placing it horizontally may affect the result.

The suggested time of 6 minutes SHOULD be the time for your normal cycle length for the 80T and 80H.
In the case of the QC, Q105, T105 and H105 the default cycle length is 3 minutes and this should be the length of the initial soil test cycle. Should the test fail at 3 minutes, the test time should be increased in 1 minute increments until a pass result is achieved. Consult Walker Electronics Ltd if the test fails after 6 minutes.

The time taken to achieve a soil test pass result should then be used as your normal cycle length.

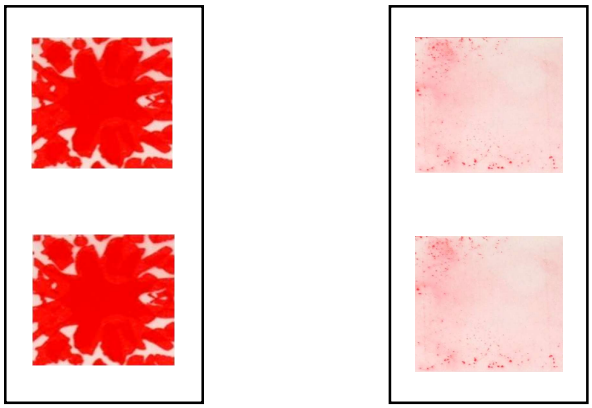
The test can be affected by many factors. The most common reasons for test failures are incorrect solution or dilution especially in hard water areas, trapped air in the water, and incorrect storage of test strips.

STORE THE STRIPS BELOW 20°C PREFEREABLE REFRIGERATE

Both the load check indicator strips and the load check holder are available by calling Walker Electronics Ltd on 01636 892410 or ordering online at walkerelectronics.co.uk

Interpreting Load Strip Test results…

Inspect the check strip for evidence of soil by placing it against a white background.



FAIL

PASS

If more than 2% of the soil remains on the strip, cleaning should be considered inadequate and department procedures should be followed in respect of failed cleaning efficacy testing.

DentaCheck Protein Residue test …

The DentaCheck protein residue test is a rapid test that can detect residual proteins left behind on the surfaces of hard to clean dental and surgical instruments. An easy-to-read colour change gives results within 10 seconds. DentaCheck exceeds current guidelines for protein testing as published in HTM01-05 (page 60 section14.4)
Gloves must be worn when using the residual protein test.

The following equipment will be required:

1. 1 x DentaCheck protein residue test.
2. A used instrument that has been recently ultrasonically cleaned and rinsed.
3. 1 or 2 Sachets of WELzyme green (see dosing inside packaging)

Method.

1. Clean the instruments in the ultrasonic cleaner using WELzyme green and the normal cycle length determined by the Load Check Strip test (pages 7-9). Thoroughly rinse the instruments in clean water as traces of cleaning fluid can give a false positive result! If the object to be tested is already wet, swab the object focusing on hinges or crevices which may be contaminated. If the object to be tested is dry, simply wet the swab with sterile water before you swab the areas of interest.

2. Unscrew the cap.

3. Swirl the swab in the brown reagent for 5 seconds.

4. Visually inspect the reagent for colour change. If the reagent has turned any shade of blue, protein has been detected. The darker the blue colour, the more protein detected. If the reagent remains brown, protein residue **has not** been detected.

Interpreting the DentaCheck results…

The colour of the solution will indicate the level of protein residue on surface. By regarding the color of the solution, an estimate of surface cleanliness can be made.

Brown = PASS

The solution colour remains unchanged. No protein detected. No further action required.

Shades of Blue = FAIL

Colour change detected. Protein residue is present. The darker the blue colour, the more protein has been detected.

DentaCheck tests are available by calling Walker Electronics Ltd on 01636 892410 or ordering online at walkerelectronics.co.uk

Wand Meters…

HTM 01-05 states:

"Ultrasonic energy meters are now available to monitor efficiency and operating frequency of ultrasonic baths. They are much quicker and more convenient than the classic foil ablation test but should be used with care. Precise positioning of the wand will need to be noted in order to make the test repeatable."

Walker Electronics Ltd purchased and tested an ultrasonic activity meter from a reputable manufacturer. The activity meter that was tested did not give a meaningful reading as the power was represented in a 0 to 100% format with no explanation of what 100% was. The frequency that the activity meter stated was also suspect, as the calibrated external frequency counter connected to the circuit produced a different result.

As HTM01-05 states, precise positioning of the wand is essential to its accuracy. It is not possible under normal surgery conditions to position the wand with enough accuracy to obtain a consistently reliable result.

For the above reasons
Walker Electronics Ltd strongly advises
AGAINST the use of wand meters in
ANY of our Ultrasonic Cleaners.

Performing a Foil Ablation test…

Ultrasonic activity test or Foil Ablation as described in HTM01-05.

The ultrasonic activity can be investigated by the erosion pattern created on aluminium foil exposed to ultrasonic energy in the tank. In theory, the activity test should result in a uniform pattern on each of the foil strips. In reality, there will ALWAYS be 'hot spots' and 'cold spots' of ultrasonic energy throughout the tank.

A roll of test foil to the specification recommended by HTM 01-05 is available by calling Walker Electronics Ltd on 01636 892410 or ordering online at www.walkerelectronics.co.uk.

The following equipment will be required:

1. Walker Electronics Limited Aluminium foil for ultrasonic cleaner testing as specified in HTM01-05 (20mm Wide x 0.018mm thick)
2. Adhesive tape (for example autoclave indicator tape or masking tape).
3. A watch or clock with a second hand.
4. A rule or tape measure.

Method.

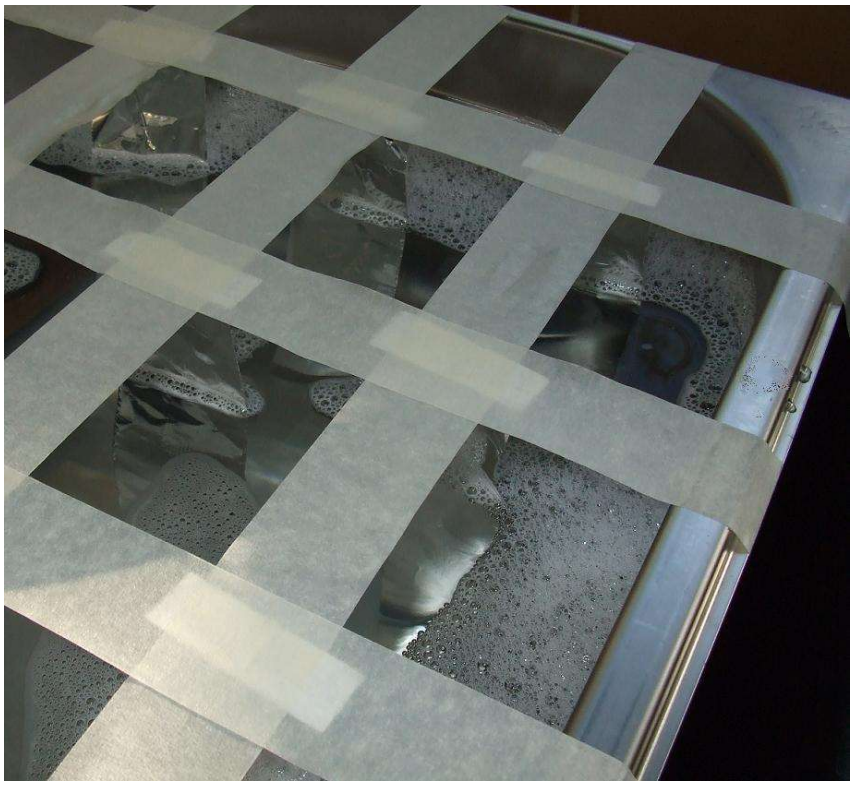
1. Remove the basket or instrument tray. Cut strips of aluminium foil in lengths 120 mm longer than the bath is deep. Roll up one end of the foil so that the foil is now as long as the bath is deep.

2. Ensure that:

- ✓ the water in the tank is at the fill level indicated by the ridge.
- ✓ the water contains 1 or 2 sachets of WELzyme green (see dosing instructions in the WELzyme green box)
- ✓ the temperature of the water in the tank is more than 20°C but less than 45°C.

3. Degas the solution by running the unit through a 3 minute cycle or allow the machine to perform its automatic degas cycle.

4. Using strips of adhesive tape across the top of the bath, suspend nine strips of the prepared foil in the bath in a 3 x 3 grid. Ensure that the rolled bottom end of each foil strip is no more than 10 mm above, but not touching, the bottom of the bath.



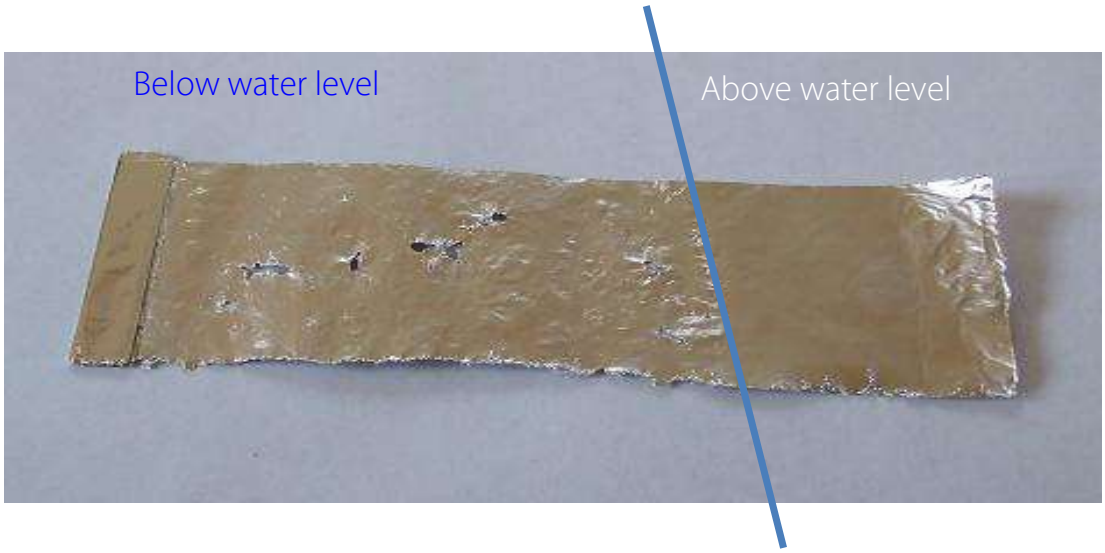
5. Operate the bath for a 6 minute cycle.

6. Remove the strips from the bath, blot-dry and examine. The strips can be filed conveniently by sticking them to a sheet of plain paper using a transparent adhesive tape.

7. Drain the bath and clean to remove debris of eroded aluminium foil.

Interpreting the foil ablation test results…

When the foil strips are inspected, the areas that show maximum erosion should be at similar positions on all nine foils and each should be eroded to a similar extent.



On re-testing the extent of erosion, the erosion pattern should remain consistent. If the zones of erosion are markedly different on the nine foils, it indicates poor uniformity of cleaning. Poor uniformity of cleaning may be due to failure of one or more of the transducers that produce the ultrasonic vibration in the base of the bath.

A significant change between tests indicates a deterioration or failure in the transducers. If there is no erosion, this indicates complete failure. In the event of any of these findings, withdraw the ultrasonic cleaner from use and send it for repair or replace it.

	Walker Electronics Ltd QC and Q105 ultrasonic baths.	Walker Electronics Ltd 80T, T105, 80H and H105 ultrasonic baths.
Daily	Visual inspection of instruments.	Visual inspection of instruments.
Weekly	Load check strip test. DentaCheck Protein residue test.	Load check strip test. DentaCheck Protein residue test.
Quarterly	Same as weekly tests.	Same as weekly tests PLUS the Foil ablation test.
Yearly	Return to Walker Electronics Ltd for validation.	Return to Walker Electronics Ltd for validation.

blank for your notes…

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ultrasonic cleaner periodic testing advice version 13.

In accordance with its policy of progressive product design, Walker Electronics Limited reserves the right to change product specifications without prior notice.

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