

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?...

HTM01-05 is the standard that all primary care dental practices must be working towards.

HTM 01-05 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."

A testing protocol for ultrasonic cleaners is an important part of HTM01-05.

This leaflet sets out the procedure which Walker Electronics Ltd advise **must be** carried out on their range of ultrasonic cleaners.

It is a combination of advice by Walker Electronics Ltd and HTM01-05.

HTM01-05 testing schedule...

Daily Test	Description	Performed by	Reference
Drain machine at end of day/session.	Remove all contaminated water from tank. Wipe with mild disinfectant and cloth, rinse and dry thoroughly. 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 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 the load check holder and strips pages 6-9).	Confirms that the ultrasonic cleaner is capable of removing artificial soil.	User or operator	Walker Electronics Ltd
Quarterly Test	Description		
Cleaning efficacy test (using the load check holder and strips pages 6-9)	Confirms that the ultrasonic cleaner is capable of removing 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 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		CP(D) or service engineer or 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 OR foil ablation test alone 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 soil test, this fault would also have led to a failure of the foil ablation test. Conversely, if there were a fault that leads to a failure of the foil ablation test this fault would also have led to a failure of the protein residue test or soil 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 can 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 HTM 01-05.

The strips have many benefits including:

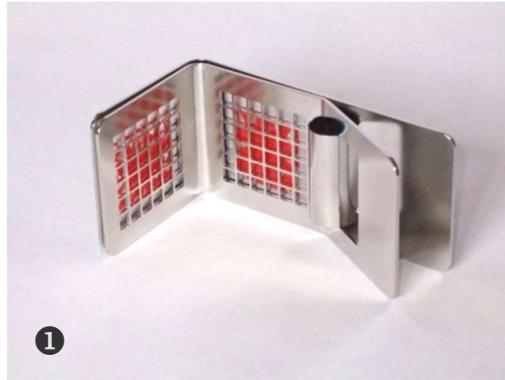
- Safe to handle
- Reproducible testing
- Easy to interpret results
- Bench marked performance suitable for validation
- Mimics occluded surfaces to present a realistic challenge

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

Load Test Strips instruction...

1. Fill the bath with satisfactory potable (drinking) water and your normal detergent at the recommended dilution and to the recommended level. The fluid temperature must be in excess of 20°C.

2. Degas the solution by running the unit through 1 cycle as advised by the equipment manufacturer.

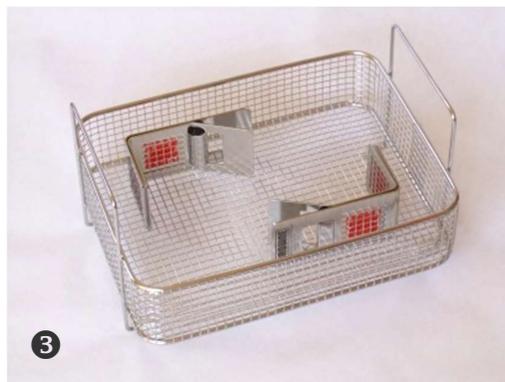


3. Ensure that your hands and the load check holder is dry.

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 test time.

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

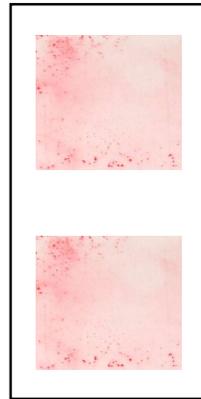
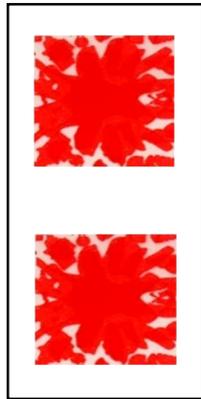
The test can be affected by many factors. The most common reasons for test failures are incorrect solution or dilution especially in hard water areas, trapped air in the water, and incorrect storage of test strips.

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 www.walkerelectronics.co.uk

interpreting Load Strip Test results...

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



X
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 has the ability to detect residual proteins left behind on the surfaces of hard to clean dental and surgical instruments. An easy to read colour change gives you your final results within 10 seconds.

This protein test is based on a dye-binding solution used in clinical chemistry and can detect protein residues within 1ug sensitivity, therefore incubation is not required.

DentaCheck meets and exceeds current guidelines for protein testing, as published in HTM01-05 (page 60 section 14.4)

Gloves must be worn when using the residual protein test

1. **Rinse your instruments before testing 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 a 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 www.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 ultrasonic cleaner manufacturer. The activity meter that we 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 was producing 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 advise
AGAINST the use of wand meters in
ANY of their baths.**

performing a Foil Ablation test...

Ultrasonic activity test or Foil Ablation as described in HTM 01-05

The ultrasonic activity can be investigated by the erosion pattern created on aluminium foil exposed in the tank for a short period. This activity may not be uniform throughout the tank. Validation tests will determine the pattern variation at defined positions and the time required to produce this pattern.

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. aluminium foil provided for ultrasonic cleaner testing
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

The following method should be used:

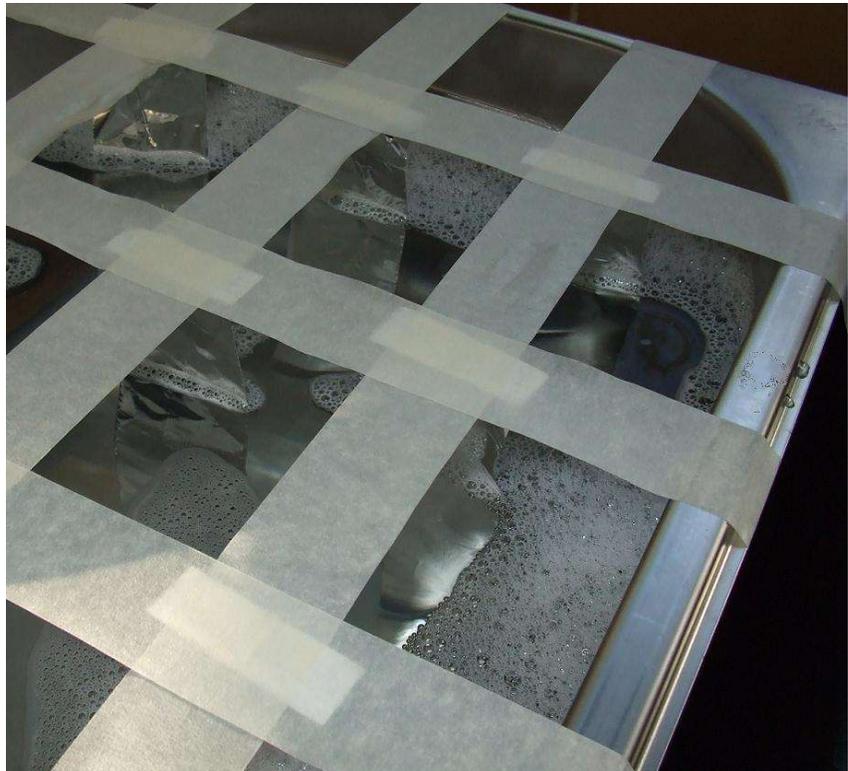
1. Cut strips of aluminium foil in lengths 120 mm longer than the bath is deep. Roll up one end of the foil so that the foil is now as long as the bath is deep.

2. Ensure that:

- ✓ the water in the tank is at the required level
- ✓ the required amount of any chemical additive specified by the manufacturer has been added
- ✓ the water in the tank is at the specified operating temperature.

3. Carry out the manufacturer's recommended start-up procedure. This will normally include a period of operation to eliminate dissolved gases from the solution in the bath (the degassing procedure).

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.



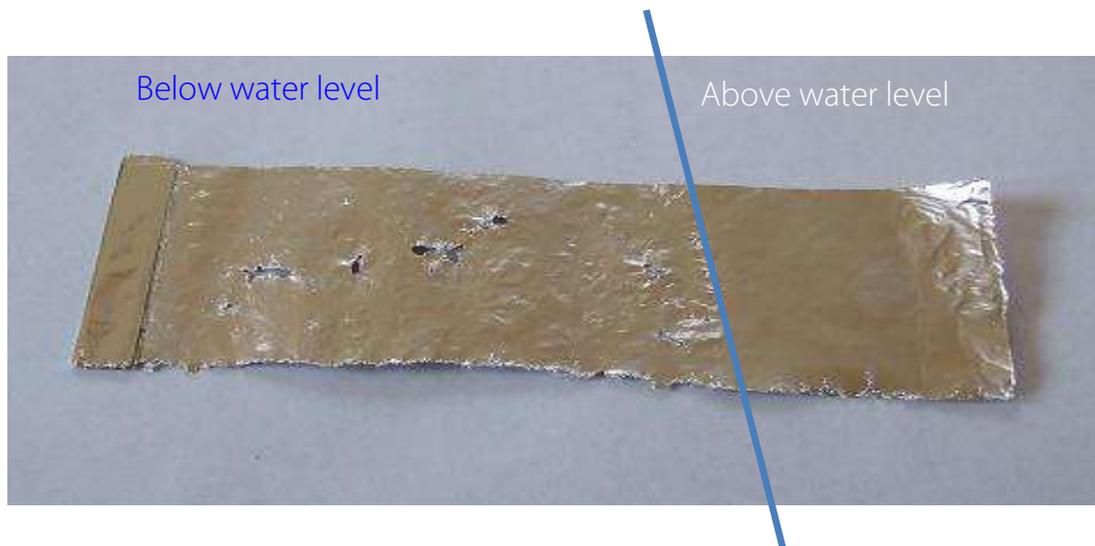
5. Operate the bath for the predetermined exposure time. This varies typically between 30 seconds and 10 minutes depending on the power rating of the ultrasonic transducers.

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 might 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.

Period	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 strip test Protein residue test	Load strip test Protein residue test
Quarterly	Same as weekly tests	Same as weekly tests AND Foil ablation test
Yearly	Return to Walker Electronics Ltd for validation	Return to Walker Electronics Ltd for validation

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