Ultrawave

Precision ultrasonic cleaning equipment

hygea d3ntal®

Operator Instruction Manual

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Contents

Important Information

Safety Instructions

The primary concern of Ultrawave is that this equipment is operated and maintained with the safety of the patient and staff in mind. To assure safe and reliable operation:

Read and understand this manual before attempting to install or operate the hygea d3ntal.

Ensure that the relevant personnel are informed on the contents of this manual.

> ⚠ **Equipment Alert**
>
> - Always ensure the liquid is above the level sensor when in operation.
> - Do not operate the hygea d3ntal without water and ensure that the bath contains waterbased solutions before use
> - Do not place parts or containers directly on the bottom of the cleaning tank; always use a basket to support items. Failure to comply may cause damage to the transducers and will void your warranty
> - Do not place hands or fingers in the bath. Doing so may cause discomfort and possible skin irritation. Avoid contact with solutions
> - Do not move the hygea d3ntal when it contains water
> - Do not put hot water above 40°C into the hygea d3ntal
> - Never use solvents or flammable solutions. Doing so may cause a fire or explosion and will void your warranty
> - Do not use mineral acids. These could damage your bath
> - Do not use solutions containing chlorine bleach.
> - Only a certified service technician should disassemble the hygea d3ntal should it be needed.

Safety Instructions

⚠ Caution to avoid electrical shock:

Do unplug from power source before filling or emptying the bath.

Do keep the control panel and area around the hygea d3ntal clean and dry – wipe up any ultrasonic solution which spills over the tank brim.

Do not operate the ultrasonic cleaner without an earthed mains cable.

Do not immerse the ultrasonic cleaner in water.

Subjecting the hygea d3ntal to improper treatment or misuse will invalidate the warranty.

Electromagnetic Interference

The hygea d3ntal is designed and built to minimise electromagnetic interference with other devices. However, if interference is noticed between another device and this product:

Remove interfering device from room.

Plug the hygea d3ntal into an isolated circuit.

Increase separation between ultrasonic and interfering device.

Contact Ultrawave if interference persists.

Safety Symbols

|	
⚠	**Danger** Indicates an imminently hazardous situation which will result in serious or fatal injury. This symbol is used only in the most extreme conditions.
⚠	**Caution** Indicates a potentially hazardous situation which may result in minor or moderate injury. It may also be used to alert against unsafe practices.
⚠	**Equipment Alert** Indicates a potentially hazardous situation which could result in equipment damage.

Shipping Symbols
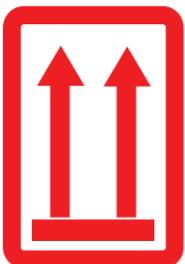
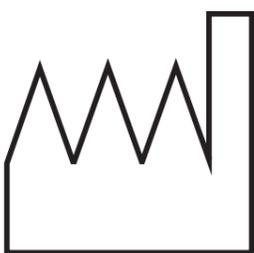| Symbol	Meaning	Symbol	Meaning
↑↑	Proper shipping orientation	☔	Keep dry
⚟	Fragile	REF	Catalogue Number
🏭	Date of Manufacture	SN	Serial Number
🏭	Manufacturer		

Transportation / Storage Conditions

Ambient Temperature Range	-20°C to +45°C
Relative Humidity	10% to 90% (non-condensing)
Atmospheric Pressure	49.6 kPa to 106.4 kPa

Unpacking Your hygea d3ntal

Check your hygea d3ntal and its carton carefully for any internal or external damage. If you find damage, contact Ultrawave or your supplier immediately.

Parts/Accessories Included with the hygea d3ntal	QTY
Three Tier Basket Carrier	1
Instrument Cassettes	2
Basket Tray	2
Basket Clip	1
Lid	1
Hose Connector	1
Drain Hose	1
Power Cable	1
Quick Guide	1
Sonozyme 3 Sachets	6
Wireless USB Dongle	1

For additional accessories please visit the ultrawave website

www.ultrawave.co.uk

PC Set Up

Please check your PC has these minimum system requirements available:

- Windows 7 or above
- 2GB RAM
- USB 2.0 Port

Installing the Ultrawave Cycle Validation Software

To download the Ultrawave Cycle Validation Software for the hygea d3ntal please go to the URL:

www.ultrawave.co.uk/pages/validation-software

Note: Please ensure that you have user rights to install the software. If not please contact your network or IT administrator.

1. Click on the download link
2. Once the software has downloaded click on the .msi file to run and install

Drivers

If the software does not run correctly please also download the drivers zip file from the URL above and unpack and install these onto your computer.

Machine Set Up - Positioning the hygea d3ntal

- The hygea d3ntal may be positioned on a table or a counter top and should be positioned within reach of a standard earthed electrical outlet. The label located on the back of the hygea d3ntal will identify correct power requirements.

- The hygea d3ntal must be positioned no more than 1**5 metres away** from the wireless USB dongle with **direct line of sight** in order to ensure the validation data can be received.
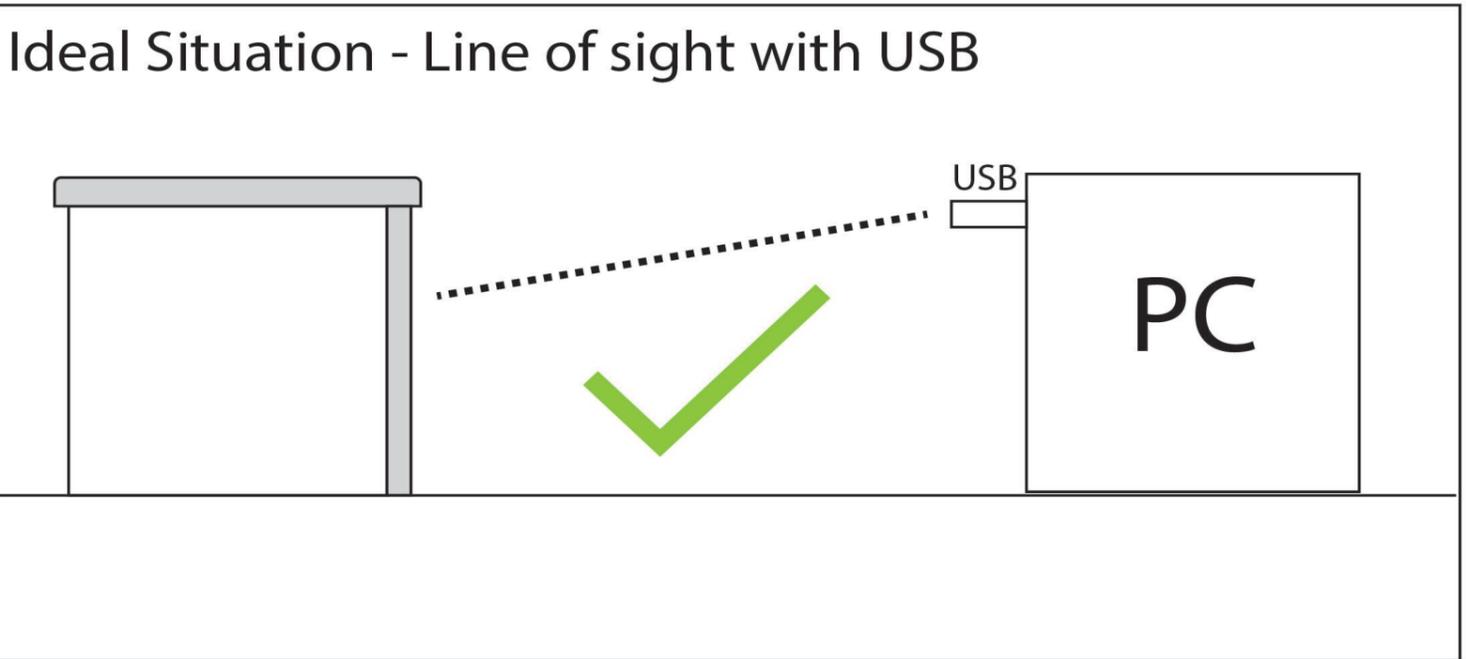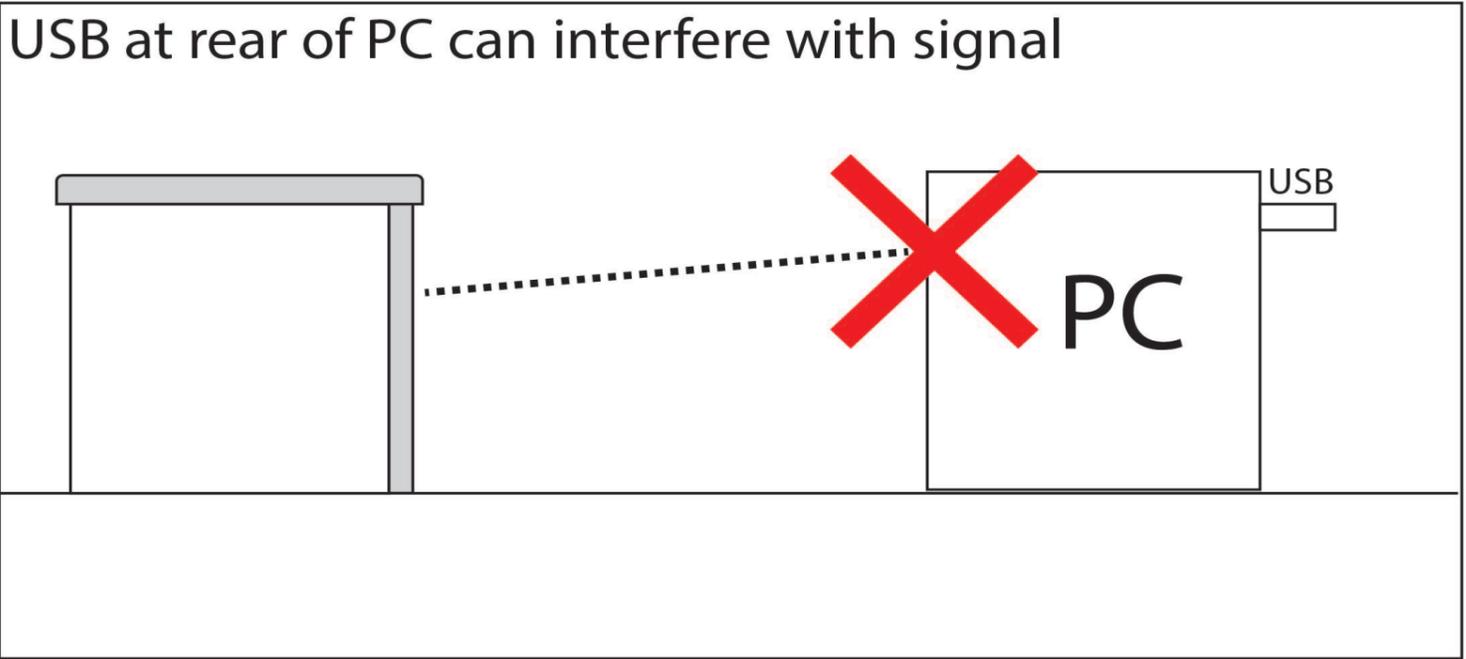

The hygea d3ntal relies on low power radio waves to transmit validation data, therefore it can be susceptible to interference. Please ensure all radio interference is kept to a minimum within the vicinity of the unit.

If connection is interrupted during a cycle then it will backup the validation data to the hygea d3ntal's internal memory. If this occurs please ensure that connection is re-established as soon as possible to ensure records are sent to the PC and no permanent loss occurs.

Positioning the hygea d3ntal (cont)

Please see the below tips for positioning of the hygea d3ntal:

Line of sight blocked

May reduce the quality of the signal

USB at rear of PC can interfere with signal

PC

USB

Ideal Situation - Line of sight with USB

USB

PC
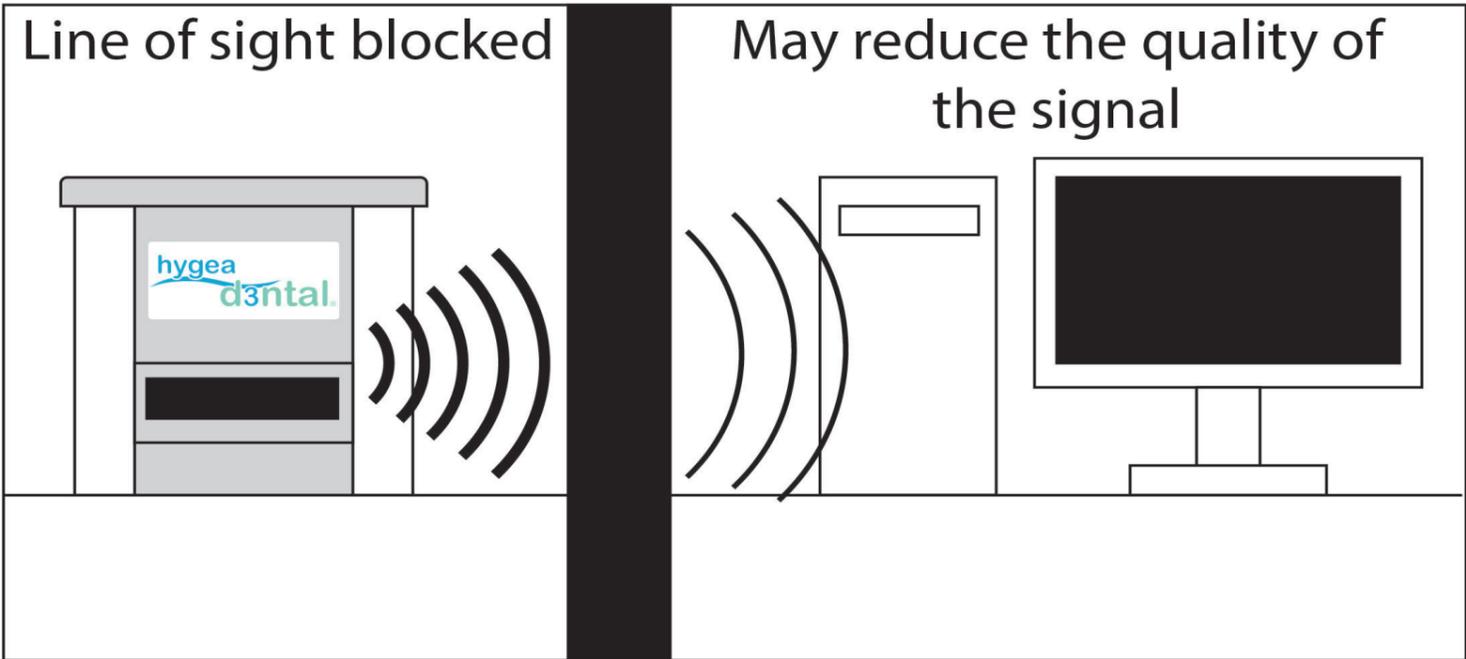
To Record the Saved Data

1. Always ensure the USB dongle is inserted into a PC or tablet prior to turning the hygea d3ntal power on. Once the power is on please ensure the following screen is observed:

```
INITIALISING                    <
COMMUNICATIONS                  <
      ↵    UW Ultrawave    menu
```

2. The hygea d3ntal will then scan and find the USB Dongle - Please ensure it is no more than 15 metres away.

```
SCANNING FOR                    <
USB DONGLE                      <
      ↵    UW Ultrawave    menu
```

3. If the USB is found the following screen will be displayed.

```
USB DONGLE                      <
FOUND                           <
      ↵    UW Ultrawave    menu
```

4. If any validation records are stored within the hygea d3ntal these will then be transferred to the PC at the end of each cycle.

```
SENDING RECORD                  <
1 OF 1                          <
      ↵    UW Ultrawave    menu
```

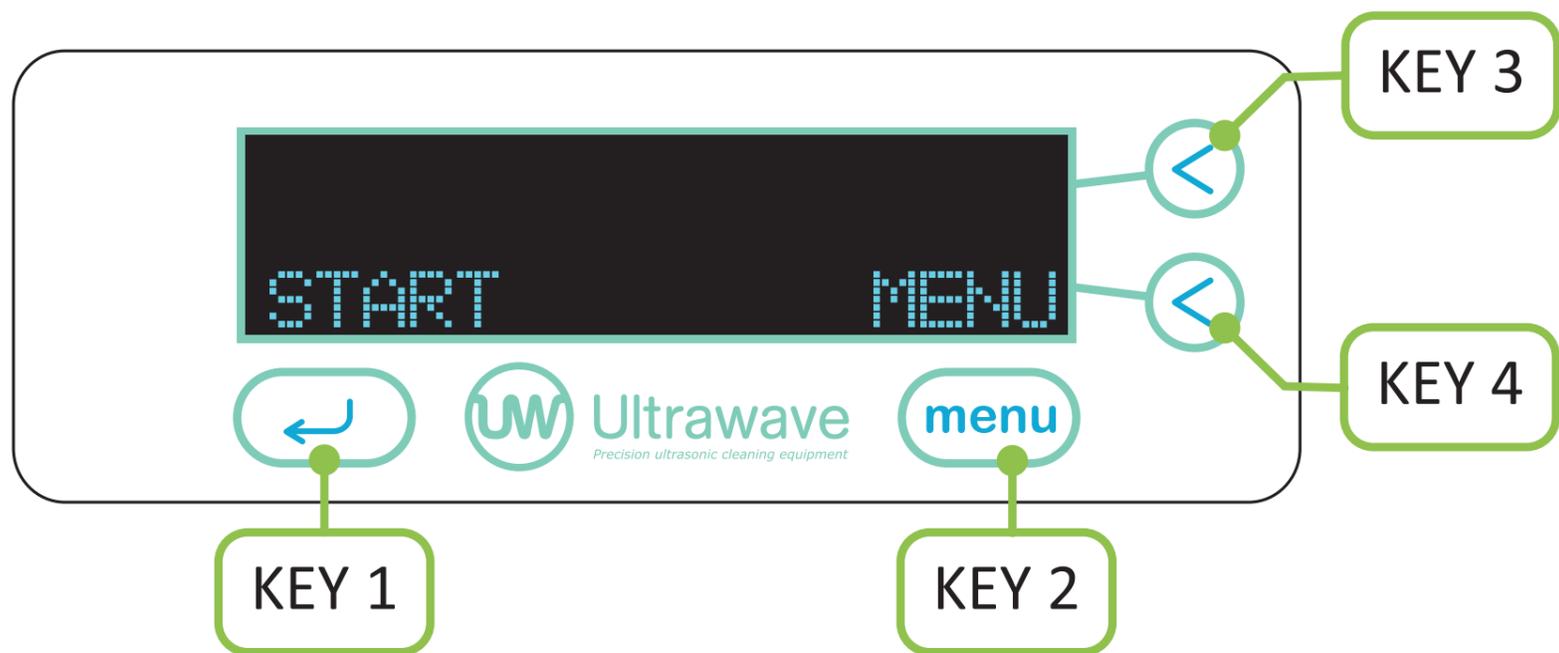5. The hygea d3ntal is now ready to use and will store data.

Failed Connection

If a connection is not found when following steps 1-3 above, the following screen will be displayed:

If this occurs please refer back to the machine setup section on page 7.

Controls & Indicators

The different keys perform the following functions:

KEY 1:   Starts and ends the ultrasonic cycle

KEY 2:   Menu – Scroll through the menu

KEY 3:   Up/On/Yes – Adjust the settings in the options menu

KEY 4:   Down/Off/No – Adjust the settings in the options menu

Connecting to Services

Connecting the Drain Assembly

1. Screw the hose connector into the drain valve at the rear of the hygea d3ntal.
2. Locate the hygea d3ntal close to a drain or sink and within easy reach of a standard earthed electrical outlet. Do not place on a circuit which could become overloaded.
3. Connect one end of the drain hose to the hose connector, and locate the other end over a drain or sink. Cut and shorten hose if required.
4. Connect the power cord into a suitable outlet.
5. Ensure that the power plug and the switch are accessible.
6. Make sure the drain valve is closed.

Drain Valve (Closed)

Hose Connector
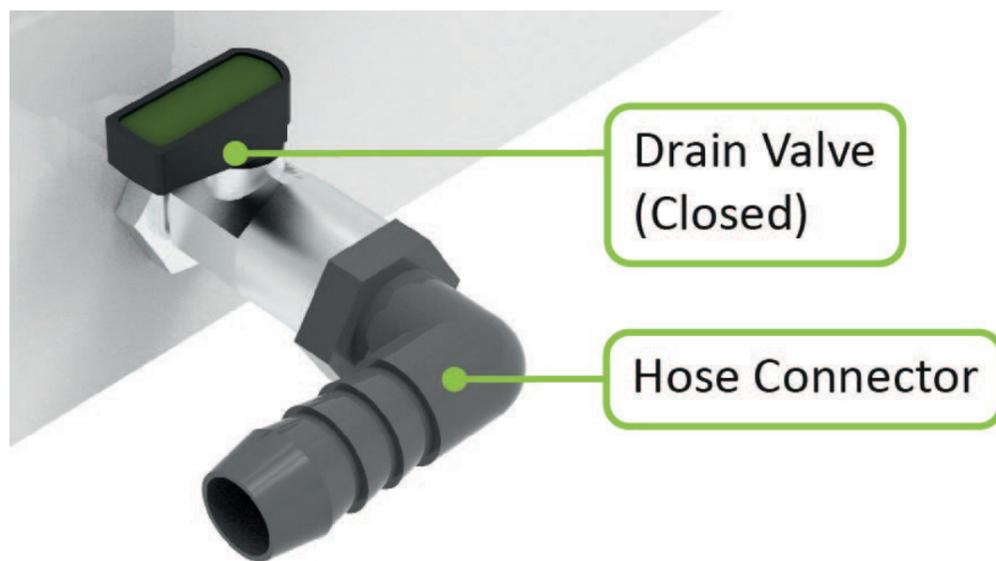
Connecting the Power Cord

1. Plug the power cord into the main power connection located on the back of your unit

2. Ensure your hygea d3ntal ultrasonic cleaner is plugged into a 240 VAC fully earthed outlet.
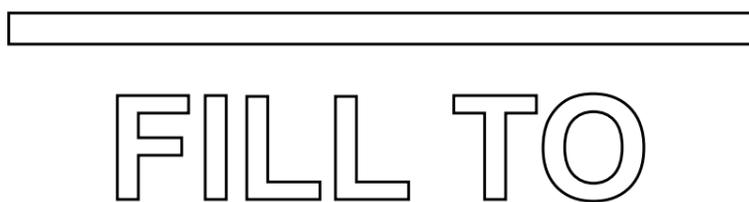

On/Off Switch

240V
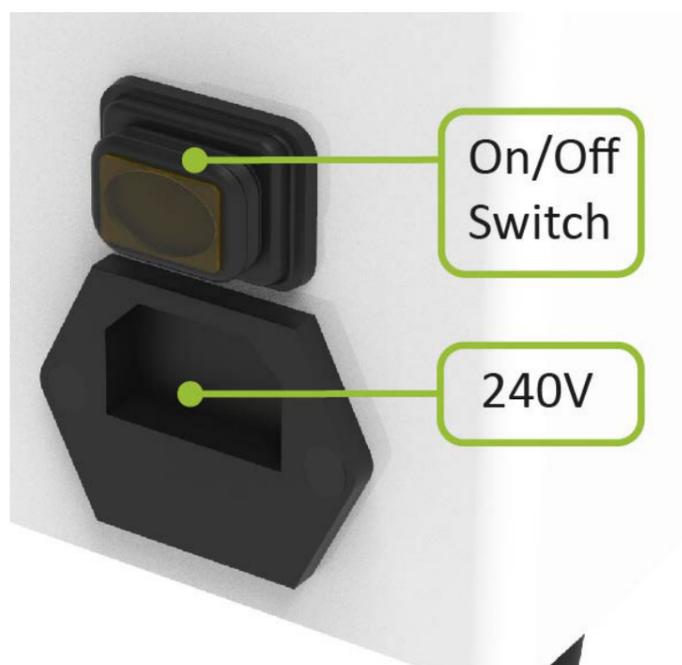
Operation

Before Operating the hygea d3ntal

1. Pour cold water into the bath until the level reaches the 'FILL TO' line (A).

2. Add 1 sachet of Sonozyme 3 (B).

3. Place the lid on top of the hygea d3ntal.

4. Turn on the hygea d3ntal via the switch at the rear, just above the power cord. The switch will then illuminate.

5. Run degas cycle.

A

FILL TO

B

Equipment Alert

If the liquid level is too low, i.e below the Fill To line. You will not be able to run a cycle until the tank is properly filled. The following warning will be displayed.

Sonozyme 3

Sonozyme 3 is the recommended detergent to be used with the hygea d3ntal. As the detergent is an essential part of the cleaning process a reminder screen will be displayed each time the liquid falls below the liquid level sensor or when the hygea d3ntal is switched on.

Note: Selecting NO will not prevent the use of the hygea d3ntal this is purely a reminder.

```
SONOZYME          YES    <
ADDED?            NO     <
       ↵  UW Ultrawave  menu
```

Degas

- A degas cycle will allow optimum ultrasonic activity by removing gases present in the ordinary tap water.

- The time needed to degas the liquid will vary depending on the amount of gas present in the liquid.

- A degas cycle of 5 to 10 minutes is recommended.

```
DEGAS             YES    <
                  NO     <
       ↵  UW Ultrawave  menu
```

Running a Degas Cycle

1. If the liquid falls below the Liquid Level Sensor, or if new liquid has been added or changed, the option to degas your hygea d3ntal will appear.

2. Prior to starting the degas cycle, remove all instruments and make sure the unit is filled with liquid and the required dose of Sonozyme 3.

3. Place the lid on the hygea d3ntal.

4. Select the < YES key to start the degas cycle. The screen below will display.

5. Wait 5 to 10 minutes.

6. Press the ↵ key SKIP to end the degas cycle. Your degas cycle will NOT automatically stop when degassing has completed.
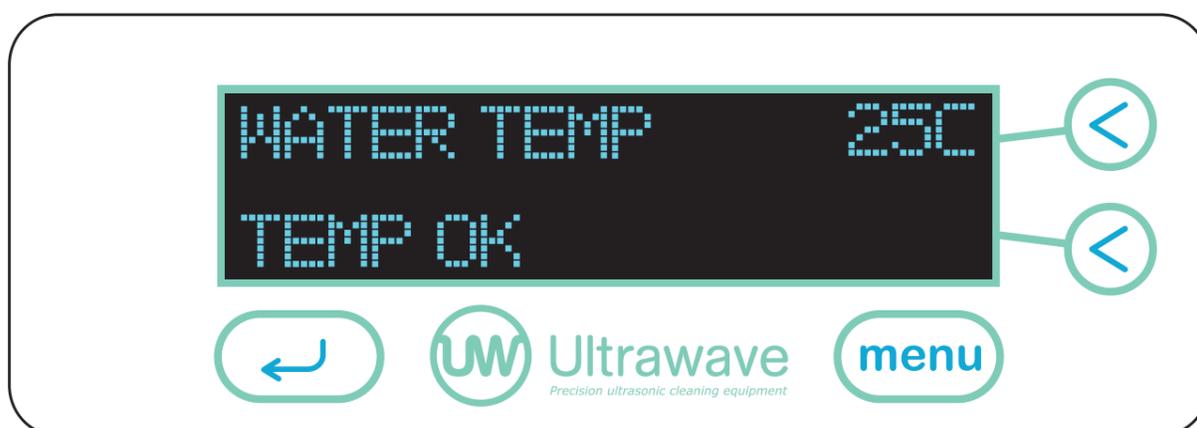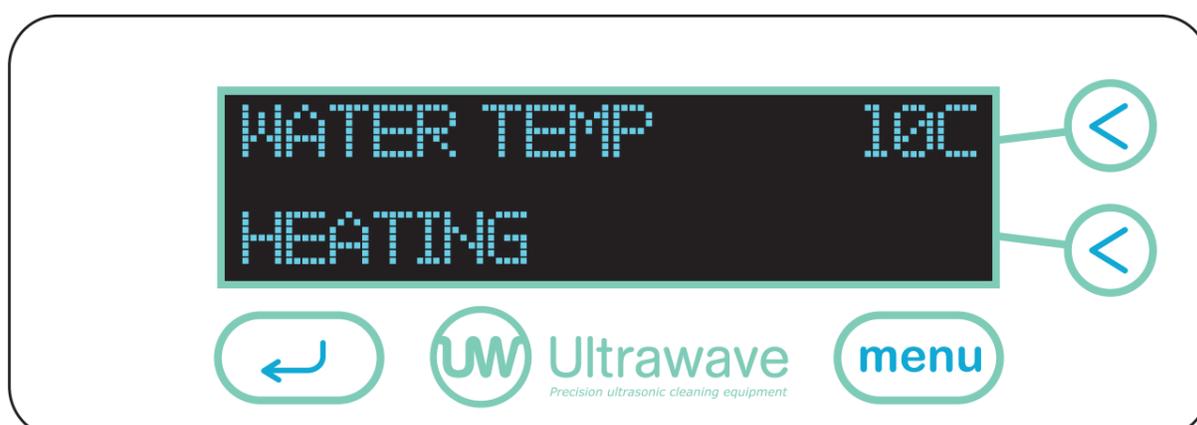
Process Locking Lid

- The hygea d3ntal is fitted with a lid sensors to prevent cycle interruption. The cycle will abort and the operator will be notified should the cycle be interrupted.

- A cycle cannot be started without the lid in place. The following screen will be displayed if the lid is not in place.
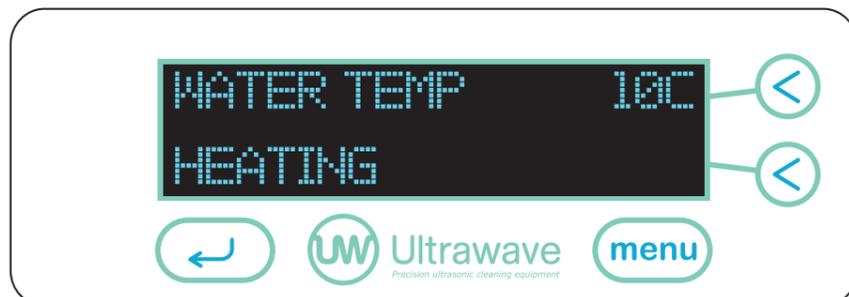

- Once the lid is in place, the screen will alternate with either of the following displays giving a water temperature status.

OR

Preparing To Run A Cycle

```
START                    MENU
```
↵   Ultrawave   menu

```
WATER TEMP        10C
HEATING
```
↵   Ultrawave   menu

```
WATER TEMP        25C
TEMP OK
```
↵   Ultrawave   menu

1. Place instruments to be cleaned in the three tier basket carrier and use the clip to secure the basket trays.

2. Insert basket carrier into the hygea d3ntal.

3. Check the bath for the required level of water and Sonozyme 3.

4. Place the lid on the hygea d3ntal prior to starting the cycle.

5. The hygea d3ntal is now ready for use. Press the ↵ key START to begin the cleaning cycle.

Note: The hygea d3ntal cleaning cycle time has been factory preset to 10 minutes.

Some instruments may take longer or shorter to clean effectively depending on the level of contamination. To adjust the cycle time refer to 'adjusting the cycle time' section.

Caution
Always rinse and inspect your instruments to ensure all debris has been removed prior to sterilisation.

⚠ Equipment Alert
Heating the water in the bath will aid the cleaning process. When cleaning surgical instruments, it is recommended to limit the temperature to 40°C. This will avoid the coagulation of protein and other bio burden which could then bake onto the instruments.

During Operation

- The time set by the operator will be displayed and will count down as the cycle continues.

- The temperature displayed is the actual liquid temperature and the default is 25°C, if flashing this indicates the liquid is heating up.

- The operator can abort the cycle at any time by pressing the ⏎ key ABORT.

- If the temperature reaches 50°C the hygea d3ntal is too hot. The hygea d3ntal will automatically abort the cycle and you will receive an ABORT - OVER TEMP message. (refer to the troubleshooting).

Successful Completion of Cycle

1. On successful completion of the cycle, the below message will display until the operator presses OK.

2. Remove the basket from the bath, rinse and inspect after cleaning.

3. Your hygea d3ntal remembers the set parameters from the previous cycle. If the operator wants to run the same cycle press OK. It is not necessary to run through the menu each time.

4. Your hygea d3ntal is factory set to run a 10 minute cycle.

Basket Draining

The lid can be inverted and the basket placed on top to catch excess liquid.

Programming Options

The following parameters can be adjusted (Temperature, Cycle Time, Power Level, Leap). Your hygea d3ntal remembers the set parameters from the previous cycle.

1. To access the options menu and scroll through the various changeable parameters, press the MENU key, when the main screen below is displayed.

2. To scroll through the menu, press the MENU button.

3. When you exit the Programming Options, **DO NOT SWITCH THE MACHINE OFF**; you must start a cycle for the new settings to be saved. Once saved, the new settings will be used each time the machine is switched on.

Setting the Temperature

Your hygea d3ntal is fitted with a thermostat and heaters to ensure the temperature of the liquid is maintained at the set temperature. The heaters will switch on if the cleaning liquid temperature is lower than the set temperature.

1. Your hygea d3ntal enables the user to set the desired temperature of the cleaning liquid between 20°C and 40°C.

2. As a safety feature, the heaters and ultrasonics in your hygea d3ntal will only operate when the bath is full of liquid.

3. Use the + and - buttons to accurately set the desired temperature.

4. When the desired temperature has been selected, use the MENU key to move to the next screen.

During normal operation, ultrasonic energy will heat the cleaning liquid by up to 15°C per hour. Your hygea d3ntal cannot cool the cleaning liquid. If the liquid temperature becomes too hot, you must either let it cool down or refill the bath with cooler water.

Setting the Cycle Time

• Your hygea d3ntal enables the user to set the cycle time from 1 minute up to 99 minutes. The factory preset cycle time is 10 minutes.

1. Press the MENU button and the TIME screen below will appear.

2. Use the < + and < - keys to increase or decrease the desired cycle time.

3. When the desired cycle time has been selected, use the MENU key to move to the next screen, or press the ⏎ key to go back to the START screen.

Setting the Power Level

- Your hygea d3ntal allows the user to adjust the power level of the ultrasonic activity. This allows the cleaning cycle to be accurately tailored to the specific cleaning application if required.

- Your hygea d3ntal is factory preset to a power level of 100%.

1. Press the MENU button and scroll to the POWER screen as shown below.

2. Use the < + and < - keys to adjust the power level between 70 and 100%.

3. When the desired power level has been selected, use the MENU key to move to the next screen, or press the ⏎ key to go back to the START screen.

4. Start a cycle to store the desired Power.

FREQUENCY LEAP

Frequency LEAP technology provides more homogeneous ultrasonic cleaning activity throughout the whole bath.

Using advanced software and generators, the hygea d3ntal uses Frequency LEAP to create a pseudo-random leaping action between a wide frequency range, reducing standing waves and improving the cleaning action.

Your hygea d3ntal has a factory preset with the LEAP function ON. The ON setting means that Frequency LEAP is automatically selected when the unit is turned on.

Setting the Frequency Leap

1. Press the MENU button and scroll to the LEAP screen as shown below.

2. Use the < ON and < OFF keys to set the LEAP function ON or OFF.

3. When the desired setting has been selected, use the MENU key to move to the next screen, or press the ↵ key to go back to the START screen.

4. Start a cycle to store the desired LEAP function setting.

Advanced Menu Options

This menu allows advanced settings to be specified and displays usage history of your hygea d3ntal.

1. To access the Advanced Menu press and hold keys 3 and 4 together. The below screen will appear.

2. In order to scroll through the settings available in the Advanced Menu, press the MENU key.

3. Press the MENU key to move to the next screen.

The first screen shows the unique serial number of your hygea d3ntal ultrasonic bath and the version of software. [The software version implemented on your bath may be different to that shown].
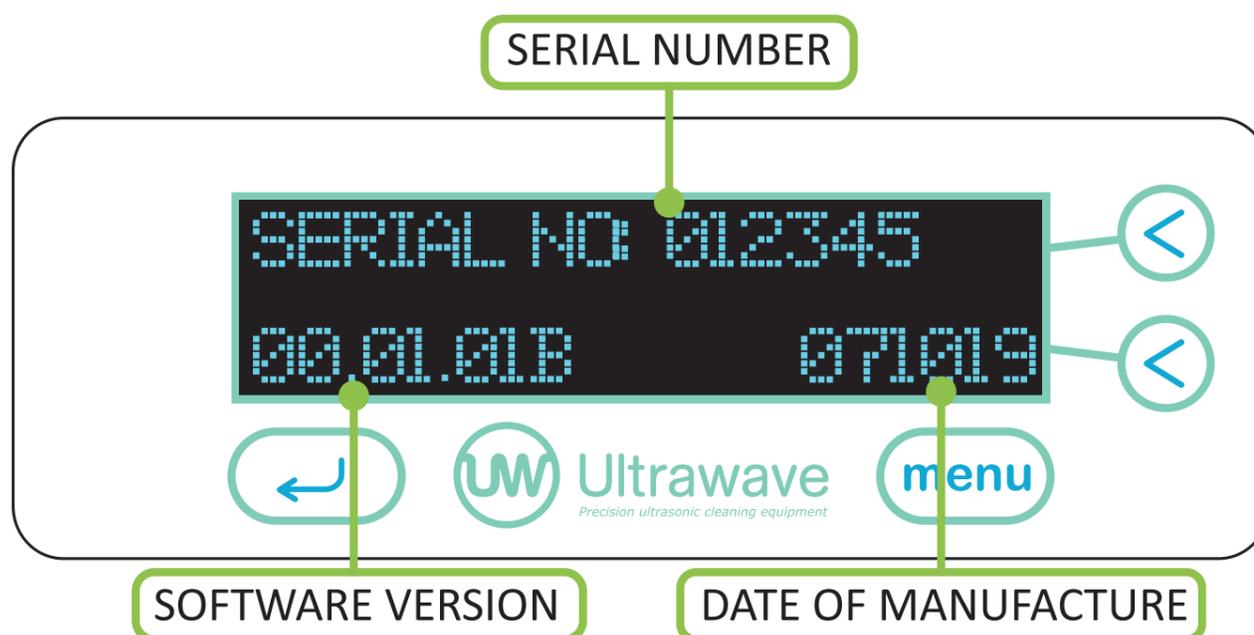
Note: The Serial Number is also located on the label at the back of the hygea d3ntal.

Setting the Time and Date

1. To set the date and time press the SET button.

2. The figures will flash and and you can use the + or - to adjust date or time. Press MENU to move to the next figure.

> ⚠ IMPORTANT: Please ensure the time and date are correct before using the hygea d3ntal as these will be used on the validation records.
>
> The hygea d3ntal will not automatically update for daylight savings time.

Total Usage

This screen shows the total time your hygea d3ntal ultrasonic bath has been in use in days, hours and minutes; i.e. the sum of all the cleaning cycle times since new.

```
TIME USED
2 5 27
```

This example shows that the bath has been in use for a total of 2 days, 5 hours and 27 minutes.

Total Cycles

The cycle count shows all cycles which have begun and includes those cycles that have not been completed i.e. those cycles aborted by the operator or because the liquid level was low.

```
CYCLE COUNT
00012
```

• This example shows the hygea d3ntal has started a total of 12 cycles since new.

Sleep Mode

The hygea d3ntal can be set to low power mode to minimise energy consumption when not in use. During sleep mode the hygea d3ntal uses less than 10 Watts of power per hour.

- The hygea d3ntal is factory preset with sleep mode off.

- Pressing + or - will increment the time in 5 minute intervals with a maximum of 60 mins.

- By setting Sleep Mode to ON, the screen illumination will power down and display SLEEP, and the heaters will cease to maintain the liquid temperature.

> **IMPORTANT:** Please ensure the liquid is above the level sensor before performaing the validation cycle.
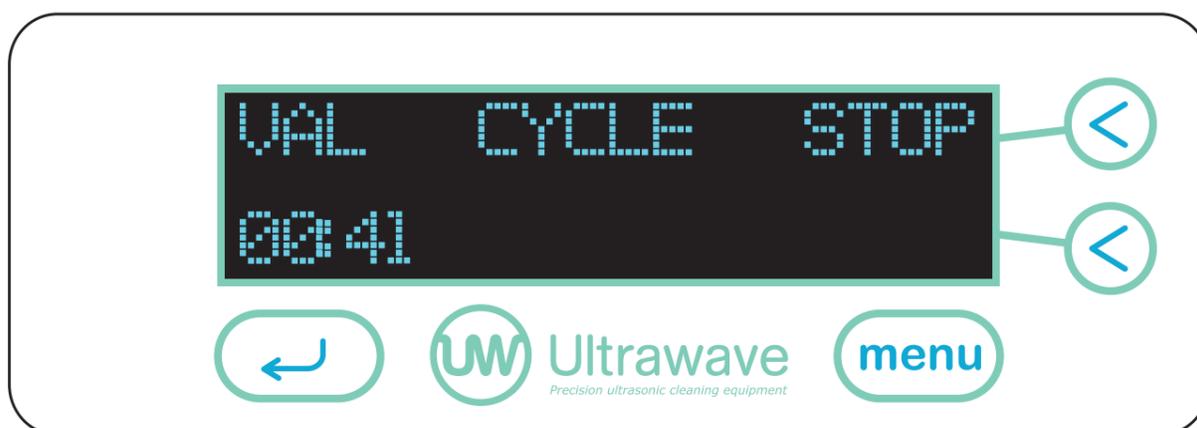
Validation Cycle

```
VALIDATION CYCLE      <
01:00            RUN  <
        ↵  UW Ultrawave   menu
```

To run a validation cycle press RUN, the ultrasonics will operate for 60 seconds and a countdown will be displayed to indicate the remaining time.

Once the timer reaches 0 seconds the ultrasonics will switch off automatically. The hygea d3ntal will operate without the lid in the validation mode.

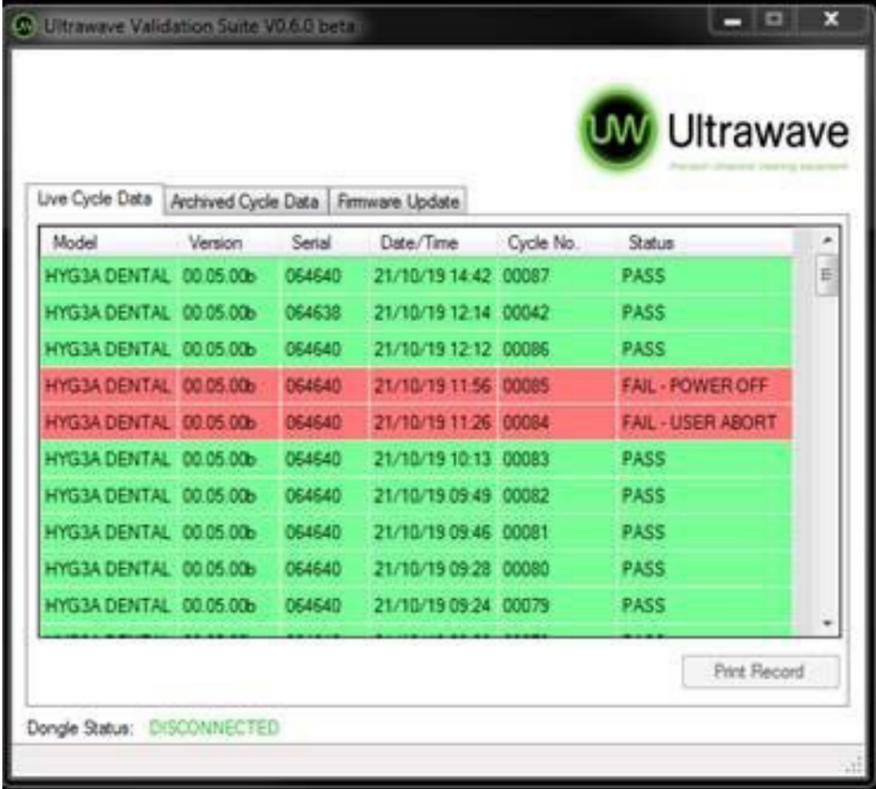To stop the validation at any time press STOP.

```
VAL   CYCLE   STOP   <
00:41                <
        ↵  UW Ultrawave   menu
```

To advance to the next screen press MENU. To exit the advanced menu press the ↵ Key.

```
ADVANCED MENU         <
EXIT            MENU  <
        ↵  UW Ultrawave   menu
```

Using The Ultrawave Cycle Validation Software

1. Open the validation suite by double clicking on the icon.

2. By default the 'live cycle data' screen will appear first. (Please note this screen will only show data from the last 7 days).

3. If you need to print a record please highlight the relevant row by clicking once and press 'print record'

4. If you need to open a validation record please double click on the relevant row to see a more detailed view:

Recalling Cycle Data (Greater than 7 days old)

1. Please click on the 'archived cycle data' tab as below:
2. Use the 'Show Records From' and 'To' to select your required date and click 'GO'

3. The relevant records will now be shown. These can be printed or displayed as previously shown.
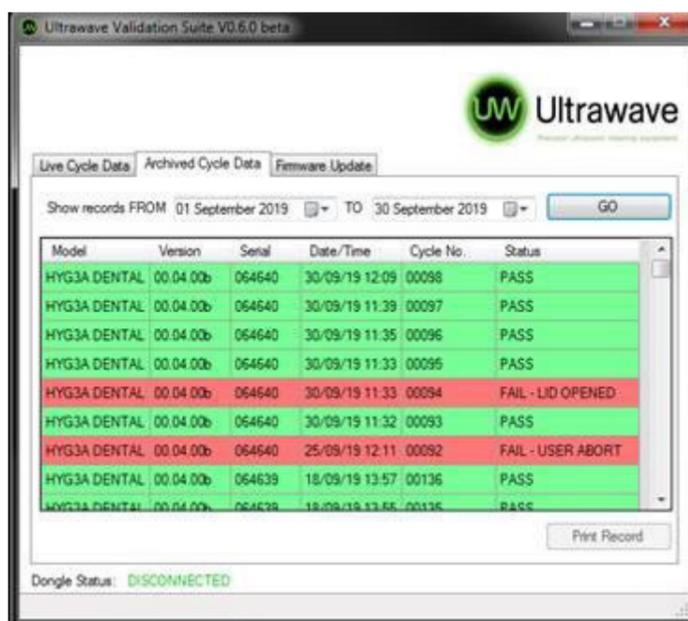
Firmware Updates

1. If there are updates for your unit you will be notified via email and these can be downloaded from the Ultrawave website. To ensure you receive these updates please register your device at:

www.ultrawave.co.uk/pages/warranty-registration

2. Download the firmware update onto your PC in a safe location.

3. Click the 'Load File' in the Ultrawave Validation Software and navigate to the firmware file location.

4. Click on the firmware file and press 'Open'.

5. This will now install the updated firmware.

6. Switch on the hygea d3ntal ultrasonic bath.

7. Follow the hygea d3ntal on screen instructions which will install the updates.

8. The downloading screen will appear. Please do not switch the power off during this process.

```
DOWNLOADING ...

5%
```
<

<

↵   UW Ultrawave   menu
Precision ultrasonic cleaning equipment

```
RE-PROGRAMMING

DO NOT POWER OFF
```
<

<

↵   UW Ultrawave   menu
Precision ultrasonic cleaning equipment
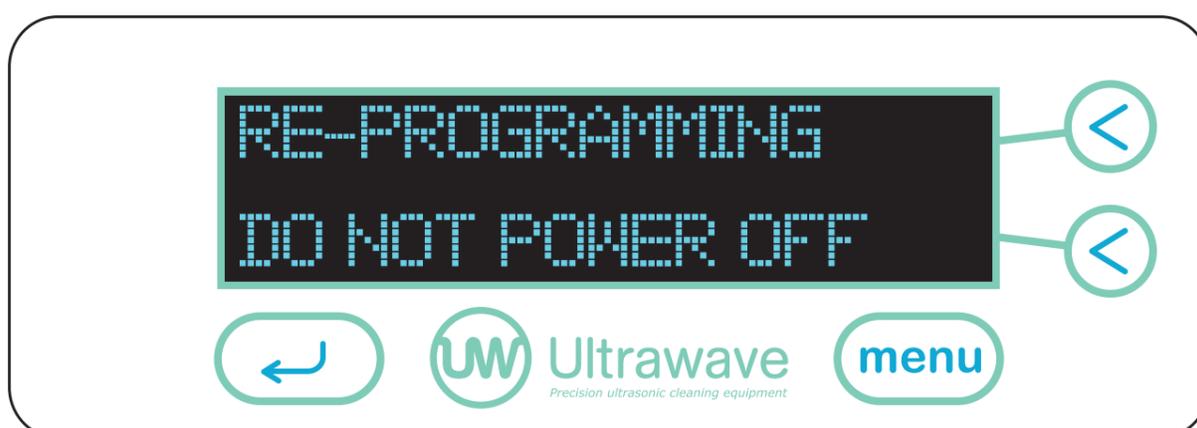
9. Once the update is complete the hygea d3ntal will return to the start menu.

```
START          MENU
```
<

<

↵   UW Ultrawave   menu
Precision ultrasonic cleaning equipment

Periodic Testing and Validation

It is a requirement of decontamination guidelines that the hygea d3ntal is periodically tested and validated to ensure optimum performance as outlined in HTM01-05 and HTM2030.

The following pages outline Ultrawave (the manufacturer's) guidelines for the periodic testing of the hygea d3ntal. The frequency and nature of these tests are recommended as the minimum protocols that should be followed in order to ensure optimum performance of the hygea d3ntal and to adhere to applicable regulations and guidelines.
In some cases, more frequent testing schedules may be stipulated.

Weekly tests (carried out by the operator)

Cleaning efficacy test using the Brownes STF Load Check Indicator strips and holders (available from Ultrawave).

Monthly tests (carried out by the operator)

Ultrasonic activity test using the Hygea Ultrasonic Activity Meter (available from Ultrawave). If there is no access to the Activity Meter, this test should be replaced by the aluminium foil ablation test.

Quarterly tests (carried out by the operator/Estates department)

Ultrasonic activity test using the aluminium foil ablation test (available from Ultrawave).

Annual Validation Tests (carried out by Ultrawave approved engineer)

A combination of tests ensuring correct and accurate operation of all components of the hygea d3ntal (including automatic control tests, cleaning efficacy, ultrasonic activity tests, PAT test, diagnostic test etc.)

Note: Each test should also include the test(s) itemised above as the less frequent tests. Eg. When conducting the quarterly test, the weekly and monthly tests should also be carried out as part of the same routine.

Contact the Ultrawave Service department (0845 330 4238 or service@ultrawave.co.uk) to discuss Service Contract and periodic testing options packages.

All components needed to carry out periodic testing, including a complete Validation Kit can be purchased from Ultrawave.

Specifications

Operating Environment

Ambient Temperature	5°C to 40°C (41°F -104°F)
Maximum relative humidity	80% R.H. in room temperatures up to 31°C (88°F) decreasing linearly to 50% R.H. at 40°C (104°F)
Altitude above sea level	Up to 2000m
Operating Environment	Indoor use only

Electrical Requirements

Connect to a 230VAC 50Hz fully earthed supply via a 3 pin plug. It can be dangerous to operate an ultrasonic bath without an earthed connection.

The power plug is fitted with a 5A fuse. NEVER FIT A FUSE OF A HIGHER RATING. Ensure that excess power cable is stored neatly

230V Electrical Details

Power supply:	230VAC @ 50Hz
Ultrasonic Frequency:	32 to 38 kHz
Heater Range:	5°C to 55°C
Pollution Degree:	2
Installation Category:	II

Note: Supply voltage fluctuations are not to exceed ±10% of the nominal supply voltage

Standards

BS EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control and laboratory use
EN 60601-1-2:2015	EMC Compliance (EC medical devices emissions Group 1 Class A)
EN 61326:2013	EMC Compliance (EC emissions Group 1 Class A)

NOTE: If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Ultrasonic Cleaning Bath is intended for use in the electromagnetic environment specified below. The customer or the user of the Ultrasonic Cleaning Bath should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnectic environment - guidance
Mains Port Conducted Emissions EN 55011:2007	Group 1 Class B	The Ultrasonic Cleaning Bath uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated Emissions EN 55011:2007	Group 1 Class A	The Ultrasonic Cleaning Bath is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Mains Harmonics EN 61000-3-2:2006	Class A	
Voltage Fluctuations EN 61000-3-3:1995 + A1:2009 + A2:2009	Complies	

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Ultrasonic Cleaning Bath

The Ultrasonic Cleaning Bath is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The Customer or the user of the Ultrasonic Cleaning Bath can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ultrasonic Cleaning Bath below, according to the maximum output power of the communications equipment.

Radiated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz d = 1.2 x $\sqrt{P}$	80 MHz to 800 MHz d = 1.2 x $\sqrt{P}$	800 MHz to 2.5 GHz d = 2.3 x $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.37
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

The transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, er frequency applies.

NOTE 2: These guidlines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures and people.

# Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Ultrasonic Cleaning Bath is intended for use in the electromagnetic environment specified below. The customer or the user of the Ultrasonic Cleaning Bath should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge EN 61000-4-2:1995	±2 / 4 / 6kV Contact ±2 / 4 / 8kV Air	±2 / 4 / 6kV Contact ±2 / 4 / 8kV Air	The floor should be in wood, concrete or ceramic tile. If the floor is covered with synthetic material, relative humidity should be at least 30%
EFT/Burst EN 61000-4-4:2004	±2 kV L, N, E	±2 kV L, N, E	The quality of the power supply should be that one of a typical commercial or clinical environment.
Surge Immunity EN 61000-4-5:2006	±0.5 / 1 / 2kV L-E &N-E ±0.5 / 1kV L-N	±0.5 / 1 / 2kV L-E &N-E ±0.5 / 1kV L-N	The quality of the power supply should be that one of a typical commercial or clinical environment.
Magnetic Field Immunity EN 61000-4-5:2006	3A/m	3A/m	Power frequency magnetic fields should have characteristic levels of a typical commercial or clinical environment.
Dips & Interruptions EN 61000-4-11:2004	- 100% ±0.5 cyc, - 60% 5 cyc, - 30% 25 cyc, - 100% 250 cyc	- 100% ±0.5 cyc, - 60% 5 cyc, - 30% 25 cyc, - 100% 250 cyc	The quality of the power supply should be that one of a typical commercial or clinical environment. If the user requests a continuous functioning during power supply interruptions, it is r ecommended a backup power supply unit (UPS) or battery.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Ultrasonic Cleaning Bath is intended for use in the electromagnetic environment specified below. The customer or the user of the Ultrasonic Cleaning Bath should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Radiated Field Immunity EN 61000-4-3:2006	3V/m, 80% 1kHz AM, 80MHz-2.5GHz	3V/m, 80% 1kHz AM, 80MHz 2.5GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Ultrasonic Cleaning Bath, including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800MHz to 2.5 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m).
Conducted RF Immunity EN 61000-4-6:2007	3V, 80% 1kHz AM, 0.15-80MHz	3V, 80% 1kHz AM, 0.15-80MHz	
NOTE 1: At 80MHz and 800 MHz, the higher frequency applies. **NOTE 2:** These guidlines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures and people.			
A Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic sitesurvey should be considered. If the measured field strength in the location in which the Ultrasonic Cleaning Bath should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientation or relocation of the Ultrasonic Cleaning Bath. Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.			

Dimensions

Tank External Dimensions (mm)				Tank Internal Dimensions (mm)			Carrier Internal Dimensions (mm)		
A	B	C	D	E	F	G	X	Y	Z
345	285	320	265	280	230	150	230	180	90
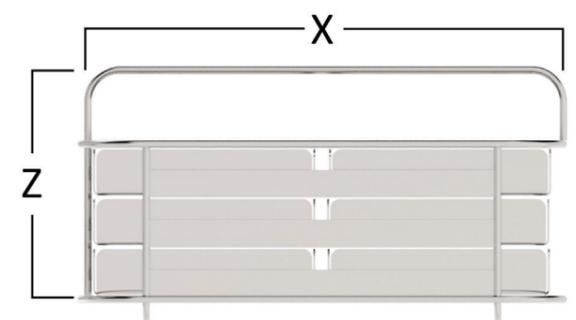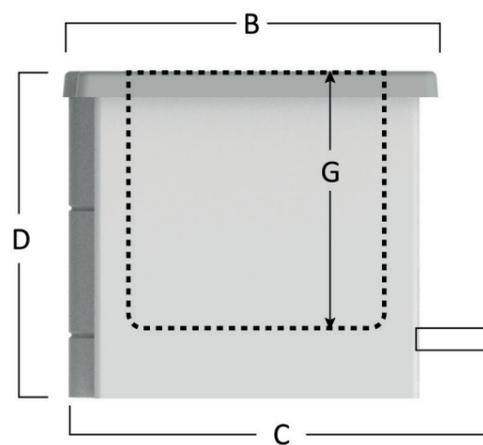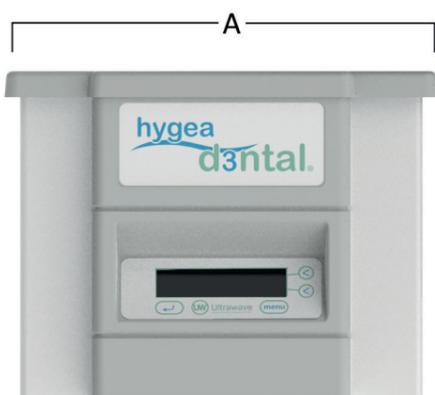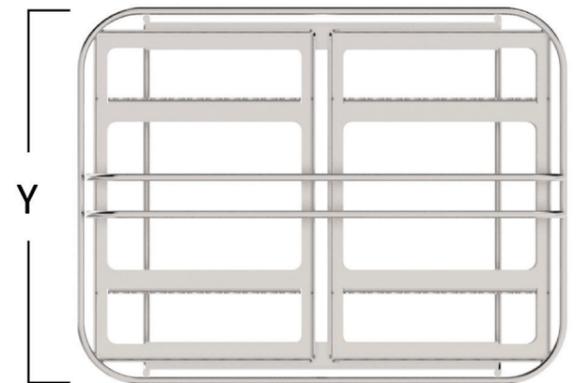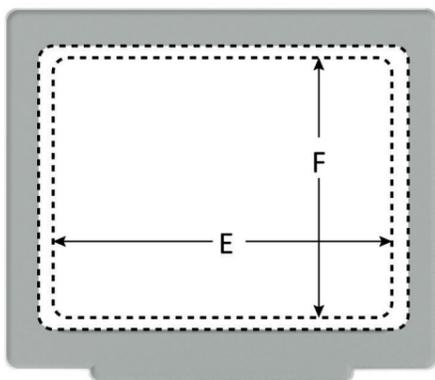
Working Capacity	Tank Capacity max.	Total Power (W)	Ultrasonic Power (W)	Heating Power (W)
9.5L	10L	400	100W	300W

Maintenance / Troubleshooting

It is important to keep your bath clean. Not only will contaminated liquid reduce the performance of the bath, it may also damage it. Change the cleaning liquid after each clinical session.

Before cleaning the hygea d3ntal always switch off and disconnect it from the power supply and allow it to cool down to less than 40°C. Clean by wiping with a damp soapy cloth and rinse.

The base of the bath generates the ultrasonic activity by vibrating at very high speeds. If any contaminants are in contact with the bath, they act as an abrasive, causing wear on the metal surface. In extreme cases, the bath will develop holes and start to leak.

Troubleshooting and Cycle Abort Messages

- If the hygea d3ntal fails to turn on (no display is shown). Check that it is plugged in, that mains power is present and the switch at the rear is in on.

- If a cycle is aborted, by the operator or by the hygea d3ntal, the reason for the failure will be displayed.

USER CYCLE ABORT

If the user aborts the cycle, the following screens will be displayed. Press OK to clear.
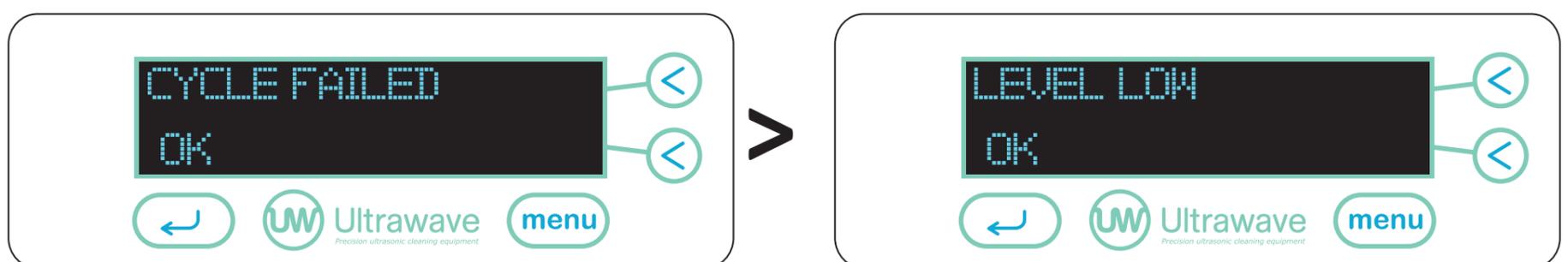
NOTE: This will record the abort in the validation software.
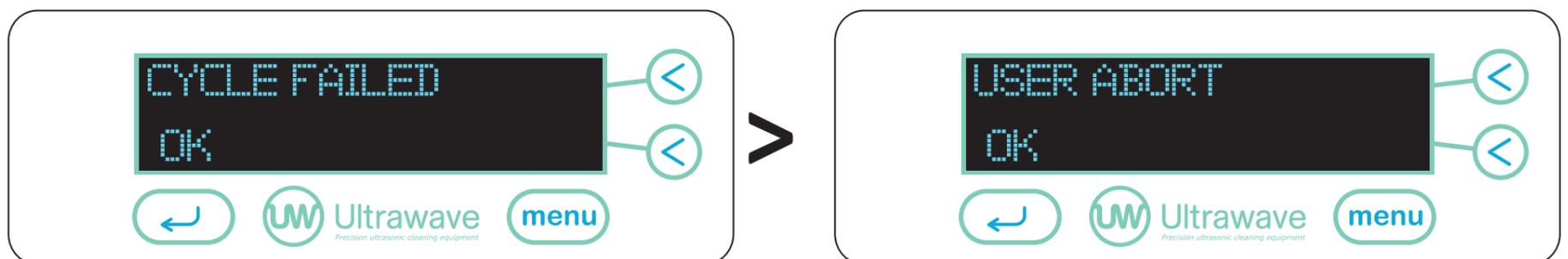
ABORT LEVEL LOW

If the liquid drops below the required level during operation, the cleaning cycle will stop and the following screens will appear.

If the unit is not running at the time a 'Fill Tank' message will appear instead of an abort.

NOTE: This will record the abort in the validation software.

Solutions:

- Fill the hygea d3ntal with water so that it is above the liquid level sensor inside the bath.

- If you are using normal water ensure that Sonozyme has been added.

- If the water in your area is hard, slightly more Sonozyme 3 may be required.
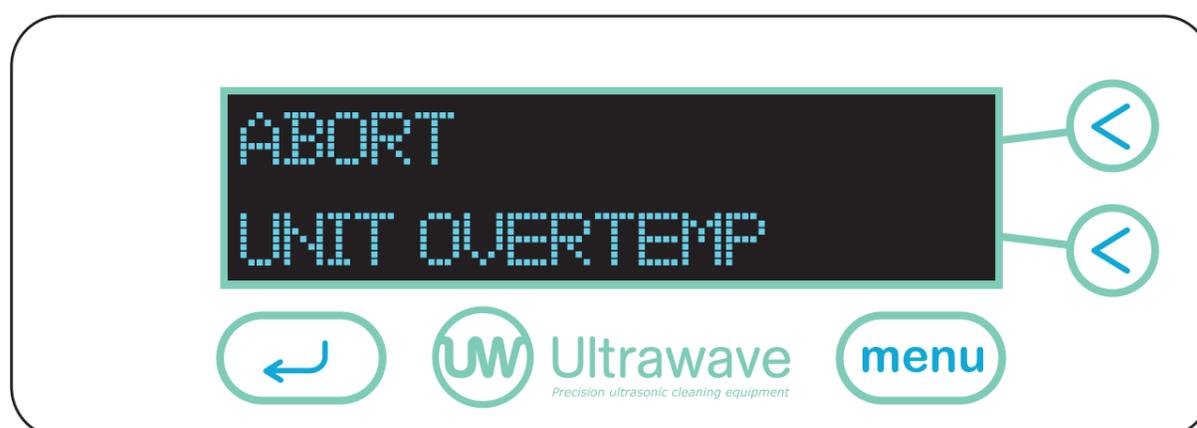
ABORT HEATER OVER TEMP

If the internal heater exceeds its allowed maximum temperature, the following screens will be displayed.

- Switch the unit off, top up the liquid above the level sensor and switch the unit back on.

ABORT (UNIT OVER TEMP)

If the unit overheats due to prolonged use, the following screen will appear.

Solutions:

- The hygea d3ntal has detected that the ultrasonic generator on the unit has operated above the rated temperature and has disabled the ultrasonic function.

- This also disables a cycle from starting The most likely cause is the liquid evaporating when the level sensor is switched off.

- Switch the hygea d3ntal off, allow the unit to cool for a few minutes, top up the liquid above the level sensor and switch the unit back on.

ABORT LID OPENED

To ensure that the operator is aware in the event of cycle disruption, the following screen will be displayed if the lid is removed during a cleaning cycle.
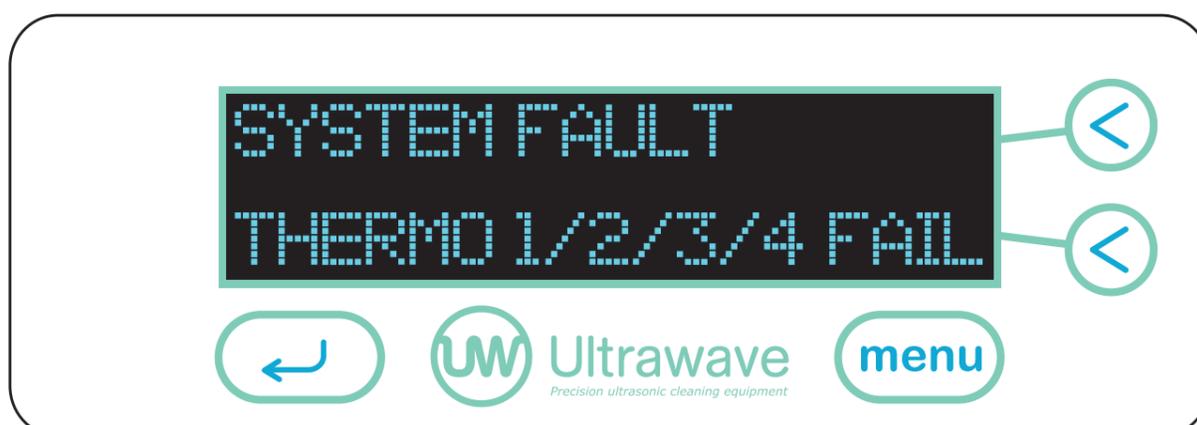

Solutions:

Re-apply the lid and restart the cleaning cycle.

SYSTEM FAULTS

If the hygea d3ntal experiences a technical fault the following message (or similar) will be displayed:

ADDITIONAL FAULTS THAT MAY OCCUR

- HEATER TEMP
- UNIT TEMP
- SONICS FAIL
- CYCLE MEM FULL

Solutions:

Switch off the mains power for at least 2 minutes and power on. If the problem persists please contact your local distributor.

Warranty

The warranty on the hygea d3ntal ultrasonic bath applies to defects appearing within 36 months of the date of sale, or 6000 hours usage (whichever comes first) because of faulty material or manufacture. Genuine defective items returned to Ultrawave or its agent's premises will be replaced or repaired free of charge at their discretion.

The warranty is extended to 5 years on the ultrasonic transducer bonding process. If the transducers or bonding material are exposed to liquid or cleaning chemicals, the warranty will be invalidated. The warranty does not apply to:

- normal wear and tear
- damage caused by misuse
- non-observance of maintenance, service or connection instructions
- damage caused by the use of toxic, flammable, acidic, caustic or corrosive chemicals or liquids not recommended by Ultrawave.

The user should familiarise themselves with this instruction booklet before operating the equipment and should apply to Ultrawave or its agent for advice on cleaning techniques or chemicals. Ultrawave will not be responsible for damage or injury caused by incorrect use. Statutory rights are not affected.

WEEE Compliance

Ultrawave is complying with the WEEE regulations by contracting-our obligations to a Producer Compliance scheme. Once it is deemed that this hygea d3ntal is no longer effective, please contact Ultrawave to arrange collection by our compliance scheme provider, who will pick up the machine from your premises.

Returning Equipment to Ultrawave

All equipment being returned to Ultrawave for service, repair or other reason **MUST BE FULLY DECONTAMINATED** prior to return and include a certificate of decontamination.

Failure to do so may result in additional charges or the equipment being returned to the user/sender at Ultrawave's discretion.

Ultrasonic baths which have been used in medical/healthcare applications should be decontaminated/packaged in accordance with MHRA guideline document DB2003(5) 'Management of Medical Devices prior to Repair, Service or Investigation'. This can be found at www.mhra.gov.uk.

This policy is designed to protect the health and safety of Ultrawave employees, reducing the risk of potential injury or infection.

More information on decontamination guidelines, as well as copies of decontamination certificates can be found at www.ultrawave.co.uk.

If you require further information, please call the Ultrawave Service Department on +44 (0) 845 330 4238 or email service@ultrawave.co.uk.

hygea d3ntal Accessories

The following items are available from Ultrawave or its agents for use with the hygea d3ntal.	
	Sonozyme 3 detergent Enzymatic detergent packaged in boxes of 120 "tear and dose" sachets.
	Hygea d3ntal carrier system The carrier system provides users with the ability to clean up to 60 instruments at once. A choice of mesh trays or cassettes can be selected.
	Ultraclean M2 detergent A non-enzymatic detergent packaged in boxes of 6 x 1 Litre bottles.
	Hygea Ultrasonic Validation Kit A complete Validation kit, providing all the material required for weekly, monthly and periodic testing.
	Hygea Ultrasonic Activity Meter An Activity Meter which indicates the level of ultrasonic activity in the tank. Ideal for monthly performance measurement.

Compliance with the Control of Noise at Work Regulations

The Control of Noise at Work Regulations 2005 (the Noise Regulations[1]) came into force for all industry sectors in Great Britain on 6 April 2006. The Control of Noise at Work Regulations 2005 replaces the Noise at Work Regulations 1989.

The aim of the Noise Regulations is to ensure that workers' hearing is protected from
excessive noise at their place of work, which could cause them to lose their hearing and /or to suffer from tinnitus (permanent ringing in the ears).

The level at which employers much provide hearing protection and hearing protection zones is now 85 decibels (daily or weekly average exposure) and the level at which
employers must assess the risk to workers' health and provide them with information and training is now 80 decibels. There is also an exposure limit value of 87 decibels,
taking account of any reduction in exposure provided by hearing protection, above which workers must not be exposed.

To help you calculate your workers' exposure, Ultrawave publish the noise generated by your ultrasonic cleaner on the Certificate of Test. The figure is that experienced by a worker standing in the operating position.

The full test of the Control of Noise at Work Regulations 2005[2] and the full text of the Noise at Work Regulations 1989[2] can be viewed online.

Guidance on the 2005 Regulations can be found in the free HSE leaflet 'Noise at Work' (INDG362 (rev 1)[4] and in HSE's priced book 'Controlling Noise at Work'

[1]   http://www.hse.gov.uk/noise/regulations.htm
[2]   http://www.opsi.gov.uk/si/si2005/20051643.htm
[3]   http://www.opsi.gov.uk/si/si1989/Uksi_19891790_en_1.htm
[4]   http://www.hse/gov/uk/pubns/indg362.pdf
[5]   http://www.hsebookds.co.uk

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Ultrawave baths are manufactured in the United Kingdom and
conform to exacting standards