

Hygea 6427



Operator Instruction Manual



Contents

Contents	1
Safety instructions	2
Instal ^l ation	3
Quick guide	4
Connecting Hollow Instruments	5
Operator instructions	7
Starting a cycle	11
The cleaning cycle does not start	14
Cycle abort messages	15
Draining the tank	18
Changing printer paper	19
Maintenance & Cleaning	21
Periodic testing and validation	22
Validation Testing Reminder	23
Hygea 6427 Cycle validation	24
Using the Ultrawave Cycle Validation Software	25
Hygea 6427 good practice	30
Detergent	31
Cleaning the Hygea 6427	31
Compliance with the Control of Noise at Work regulations	32
Temperatures of touchable hot surfaces	33
Warranty	34
WEEE Compliance	34
Troubleshooting	35
Returning equipment to Ultrawave	36
Hygea 6427 Accessories	36
Notes	38



Safety instructions

Electrical

Connect to a 220-240 VAC fully earthed supply via a 3pin plug. It can be dangerous to operate an ultrasonic bath without an earth connected.

The mains plug is fitted with a 5A fuse. **NEVER FIT A FUSE OF A HIGHER RATING.**

Ensure that excess mains cable is stored neatly.

General use

Ensure that the bath contains liquid before you switch it on.

Always fill with cold water. This will ensure that the **Hygea 6427** always runs its automatic de-gas cycle (see pg 29 for the importance of degassing).

Do not place fingers or other parts of the body in the bath.

Always use a basket to support items to be cleaned. Not doing so may damage the bath and invalidate your warranty.

Care should be taken when operating the bath at higher temperatures as external surfaces may become hot.

For best cleaning results use a detergent, at a suitable dose, recommended for use in ultrasonic cleaning baths. Never use toxic, flammable, acidic, caustic or corrosive solutions in the bath.

Refer to the **Hygea 6427** Operator Instructions manual for full guidance on the correct use of the bath.

The user should familiarise themselves with this *Operator Instructions* manual before operating the equipment and should apply to Ultrawave or its agent for advice on cleaning techniques or detergents. Ultrawave will not be responsible for damage or injury caused by incorrect use of the equipment.

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Installation

The following parts and accessories are included with the **Hygea 6427** ultrasonic bath:

- 1 x Hygea 6427 ultrasonic bath
- 1 x basket with irrigation ports
- 1 x MC card
- 1 x memory card to USB card reader
- 1 x Hygea 6427 accessory Kit
- 1 x hose tail
- 1 x 2m length of drain hose
- 1 x Certificate of Test
- 1 x Declaration of Conformity
- 1 x Warranty registration card
- 1 x Hygea 6427 Administrator instruction manual
- 1 x Hygea 6427 Operator instruction manual

How to install?

The **Hygea 6427** should be installed on a benchtop (or stand if provided) located close to a drain or sink.

Screw the hose connector into the drain valve located on the rear of the unit.

Connect the drain hose as shown below.

Locate the unit close to a drain or sink. Connect one end of the drain hose to the hose connector, and locate the other end over a drain or sink.



Connect the mains lead into a suitable mains socket. Your **Hygea 6427** is now ready to use.



Quick guide

Pour cold water into the bath so that it reaches the minimum tank fill line (but does not go over the maximum fill line).

Add the required dose of detergent (see pg 30).

In order to save the cycle data to the MC card, ensure that the MC card is installed in the port prior to turning the machine on.

Switch on the machine via the switch at the rear of the unit, on the left hand side, above the electrical mains lead.

If the water is below the minimum temperature, the **Hygea 6427** will automatically start degassing and heating the liquid.

Once the water is heated to the minimum operating temperature, the **Hygea 6427** is ready to use, although an extra degas cycle may be required.

Select your operator identification.

Press the "ENTER" key to start the cleaning cycle.

REMEMBER

- Always keep the bath full of liquid when in operation.
- Do not put hot water into the bath.
- Always use the baskets to support items to be cleaned.
- Never expose hands to cleaning solutions.
- Never use toxic, flammable, acidic, caustic or corrosive solutions.
- Never breathe the fumes from strong solutions.
- Rinse the instruments in clean water once the cycle is complete.

IMPORTANT: Once the cleaning cycle has finished, remove the cleaned items and rinse them in clean running water.

Subjecting the bath to improper treatment or misuse will invalidate the warranty.



Connecting Hollow Instruments

The **Hygea 6427** is supplied with an accessory kit, which allows hollow lumen instruments to be connected to the manifold to allow the internal surfaces of the instruments to be cleaned.

All tubing connections are made via small stainless steel clips.

To use these, press the small stainless clip in towards the pipe and pull the connector straight up, the connector is then pushed into the other receptacle.

1. The tubes can be connected to the manifold by inserting the connections into the luers located on the manifold.



2. Connect the basket by inserting the connector into the luer located on the top of the tank.



3. Connect the other end of this hose to the manifold located on the basket.





4. The instruments can be connected by inserting the correct size connector into the tube and then connecting the hollow instrument.



5. The instrument and hose can then be connected to the manifold.

Important: The tubes must be connected whenever the Hygea 6427 is in use; not doing so may cause the pump to burn out. This may invalidate your warranty.



Operator instructions

Ensure your **Hygea 6427** ultrasonic bath is plugged into a 220-240V fully earthed supply.

Once plugged in, switch on your **Hygea 6427** via the power on/off at the rear of the unit.



When the **Hygea 6427** is first switched on, the following screen will appear for approximately 5 seconds.



While this screen is displayed, the buttons are inoperative. This is normal as the **Hygea 6427** is running through its start-up routine and checking all internal systems are working correctly.

The top line of the display indicates the **Hygea 6427** serial number. This uniquely identifies the machine.

After 5 seconds, the **Hygea 6427** is ready for use.



The **Hygea 6427** is fitted with a liquid temperature sensor. If this temperature is below the minimum set cleaning temperature (20°C), the following screen will display.



The **Hygea 6427** will automatically start heating and degassing the liquid.

When the liquid reaches the required temperature, the following screen will be displayed and the **Hygea 6427** will be ready to use. (The actual min. and max. temperatures may be different from those indicated below.)



Press the "Accept" button to continue.



Step 1 – Selecting the operator

The following screen will be displayed:



Press the "Up" and "Down" buttons to scroll through the list of operators. The "<" symbol will move up and down the list, indicating which name is selected.

Press the "Next" button to show the next group of four names. Up to 20 names can be stored in the operator list. When the correct operator is selected, press the "Accept" button.

Step 2 – Starting the process

Once the operator is selected, the following screen will be displayed:

Welcome	NURSE A	
Set Temp 25.C	Bath Temp 24.C	
Cycle Time	5 Mins	
S	tart	
en	iter)	esc

To begin the cleaning cycle, press the "Start" button.



After first switching the bath on, or after emptying and refilling the tank, the following screen displays to confirm that detergent has been added:



Press the "Start" button to confirm that the liquid contains detergent. (See page 30 for information about detergents).

The **Hygea 6427** will then begin the cleaning cycle. During the cycle, the lid will lock and cannot be opened until the cycle is completed or aborted.



Starting a cycle

The **Hygea 6427** is factory pre-set with a total cycle time of 15 minutes. This consists of 3 consecutive cycle stages of 5 minutes and the countdown will display from 5 minutes.

During this cycle, the irrigation pump will operate three times, once at the beginning of each cycle stage.

The default pump cycle time is set to 1 minute. Under these parameters, the pump will run during the 1^{st} , 6^{th} and 11^{th} minutes. If the pump time is set to 2 minutes, the pump will run during the 1^{st} and 2^{nd} , 6^{th} and 7^{th} and 11^{th} minutes.

While the pump is in operation, the word "pump" will display on screen:



When the pump is not in operation, the following screen will display: The default ultrasonic cycle time of the **Hygea 6427** is 15 min. The following screen will appear.

Operator		
Cycle No. Time Rem 5:00	01234 Bath Temp 26.C	
Cycle I Abort	Running Cycle	
(en	ter)	esc

The cycle can be aborted at any time by the operator, by pressing the "Abort Cycle" button and the cycle time can be changed in Administrator mode. Please refer to pg 11 of the *Administrator Instruction* manual for information on setting the cycle time.



On successful completion of the cycle, the following message will be displayed and the data recorded.



If the print option is chosen, then at the end of each cycle, the integral printer in the **Hygea 6427** will print a ticket showing the details of that cycle:

*Ultrawave	*
Version: V3-00. Model: HYGEA 6427 Serial- No: 056204 Time: 15.30 Date: 01/12/17 Hops A	
Op: 01 Nurse A Cycle-No: 01234	
Set-Parameters: Min-Temp: Set-Temp: Max-Temp: Cycle-Time:	20.C 25.C 40.C 15.M
Cycle-Parameters: Cycle-Start-Temp: Min-Temp: Max-Temp: Cycle-Finish-Temp:	25.C 25.C 26.C 26.C
Cycle-Time: Ultrasonic-Action: *Cycle PASS*	5.00M PASS

Once the ticket is printed, simply tear off and store as necessary.



If the cycle validation mode is set to save to the MC card (either as well as or instead of the hard copy ticket), a digital record can be saved to the supplied MC card.

Note: in order for the data to save to the card, the MC card must be inserted into the MC port on the control panel before your **Hygea 6427** is switched on.



The digital cycle traceability will save the information of each cycle (as shown on the ticket on page 12) to the MC card.

This information can then be transferred to a PC and an electronic copy saved, using the Ultrawave Cycle Validation software supplied on the MC Card. It is recommended that the MC Card is removed and the information transferred to the PC at the end of each clinical session (twice a day).

When the data recording is complete, the following screen is displayed:



To print another copy, press the "Yes" button. This can be done as many times as needed.

If a copy of the print-out is not required, press the "ESC" button.

The lid will then unlock, allowing removal of the instrument trays.



The cleaning cycle does not start

If the screen displays a "Low Fluid" warning as below, the bath will not operate until the unit is filled to the correct level and the detergent dose added.



If the screen shows a "Lid Open" warning, the cycle will not start until the lid has been closed.





Cycle abort messages

If the cycle aborts, the reason will be displayed. The print-out will record a process fail and give the reason, and an audible warning will sound to signal a process fail. To turn off the audible warning, press and hold the "ENTER" button at the bottom of the screen until the warning stops.

If the operator aborts the cleaning cycle, the following screen will be displayed:



If the fluid level drops below the required level during operation, the cleaning cycle will stop and the following screen will be displayed:



Important: The operator must acknowledge this by pressing and holding the "**ENTER**" button to complete the aborted cycle.



If the lid is opened during operation, the cleaning cycle will stop and the following screen will be displayed:



It is important that you do not turn off the main electricity supply to your **Hygea 6427** when it is running a cycle.

The **Hygea 6427** recognizes when the main electricity supply fails during a cycle and prints a report (and/or creates a record on the MC card) when the machine is next switched back on.

The cycle will be recorded as an aborted cycle.

If the cycle fails due to a power failure, the following screen is displayed when the power is restored:



Important: the operator must acknowledge this by pressing and holding the "ENTER" button to complete the aborted cycle.

If the MC Card is not present, and "MC Card Only" is selected as the validation mode, then you will not be able to run another cycle until an MC card is inserted. A message of "Please insert MC Card" will appear on the above screen.



If the liquid temperature rises above the pre-set maximum during operation, the cleaning cycle will stop and the following screen will be displayed:



If the liquid temperature drops below the pre-set minimum temperature during operations, the cleaning cycle will stop and the following screen will display:



If the ultrasonic power drops below a certain point during a cycle, the cycle will stop and the following screen will be displayed:



If the cycle aborts, the reason will be displayed and an audible alarm will sound to signal a process fail. In all instances of an aborted cycle, a "Cycle Aborted" ticket will be printed to invalidate the cycle.

Important: the operator must acknowledge this by pressing and holding the "**ENTER**" button to complete the aborted cycle.



Draining the tank

The tank is drained via the tap on the right hand side of the unit.



DRAIN TAP SHOWN CLOSED

Step 1 – Ensure that the drain is either directly over a sink or is connected to a tube, which is placed into a sink.

Step 2 – Turn the tap until open.



DRAIN TAP SHOWN OPEN

Step 3 – Allow the liquid to drain.

- **Step 4 –** Close the tap when the tank is completely drained
- **Step 5** Wipe the inside of the tank to remove debris and/or residual fluid.



Changing printer paper

When the paper roll is coming to an end, a red stripe will appear on the paper indicating that new paper rolls need to be ordered.

Use the paper feed button to feed through the last few centimetres of paper and fit a new roll.

Step 1 – Open the printer paper tray by pulling the clear cover towards you as shown below:



Step 2 – Remove the empty paper.

Step 3 – Insert a new thermal paper roll as shown in the below picture:





Step 4 –The paper must unroll from the top for easy feeding.



Step 5 – Close the cover

Step 6 – Close the printer paper tray.



Step 7 – Feed a small amount of paper through the printer by pressing the paper advance button on the right hand side of the printer or the paper button on the panel. The **Hygea 6427** is now ready to use.



Maintenance & Cleaning

- There are no user serviceable parts inside the machine.
- The **Hygea 6427** should be subject to a routine maintenance programme by Ultrawave service technicians. Please contact Ultrawave for details.
- Do not use cleaning solvents of any kind on any part of the machine.
- This unit should not be hosed down.
- Use only proprietary stainless steel cleaners for all metallic surfaces.

Daily activities:

- The liquid level sensor located inside the cleaning chamber should be wiped clean every day. If contamination is allowed to build up, the **Hygea 6427** may give a false alarm.
- All internal surfaces of the **Hygea 6427** should be manually cleaned and disinfected daily.
- Cleaning and disinfection processes may be regulated by the CSSD/HSDU manager or AP so check with these before attempting manual disinfection.
- Check hoses for any signs of visible blockages or damage and replace as necessary

Weekly activities:

 Disinfection of the chamber and internal pipe-work may be achieved by adding up to 50g of soluble Sodium Dichloroisocyanurate (NaDCC) to the tank before starting a 15 cleaning cycle. It is important not to process any instruments while disinfecting the Hygea 6427.

Please refer to the manufacturer's data sheet for correct use of the NaDCC instructions (e.g. HydraChem BIOSPOT or ECOLAB Actichlor)

Monthly activities:

• Remove the instrument manifolds from the basket. Remove the two metal end stops and run a tube brush through the manifold. Refit the two end stops and mount the manifolds back on the basket.



Periodic testing and validation

It is a requirement of decontamination guidelines that the **Hygea 6427** ultrasonic bath 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 6427** ultrasonic bath. 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 bath and to adhere to applicable regulations and guidelines. In some cases, more frequent testing schedules may be stipulated.

1. Weekly tests (carried out by the operator)

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

2. Weekly 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.

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

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

4. Annual Validation Tests (carried out by Ultrawave approved engineer)

A combination of tests ensuring correct and accurate operation of all components of the **Hygea 6427** (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 to discuss Service Contract and periodic testing options packages:

Tel: +44 (0) 29 2083 7337

Email: <u>service@ultrawave.co.uk</u>

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

Visit our website: <u>www.ultrawave.co.uk</u>



Validation Testing Reminder

The **Hygea 6427** ultrasonic bath is installed with software which provides a reminder when the annual Validation Testing is due.

This Validation Testing should occur at least once every 12 months. Therefore after, 11 months in operation, a reminder will appear on the LCD display warning that the annual validation testing is due.

The Validation Testing reminder will display as below:



When this reminder appears, simply contact Ultrawave or its agent to schedule this Validation Testing. It is a requirement of National guidelines and recommendations that this complete Validation Testing is done at least once every 12 months.



Hygea 6427 Cycle validation

The **Hygea 6427** provides validation and traceability of every cleaning cycle. Validation can be achieved by two means:

- Hard copy print out to integral printer
- Digital copy to supplied MC Card

Screen 1 in Administrator mode, allows the Administrator to specify what means of Validation is required (see pg. 4 of the Administrator Instruction Manual for more information).

If the hard copy print out is chosen, then at the end of each cycle, the integral printer in the **Hygea 6427**, will print a ticket showing the details of that cycle:

*U	*Ultrawave*						
Version: V3-00. Model: HYGEA 6427 Serial- No: 056204 Time: 15.30 Date: 01/12/17							
	Hosp A						
Op: 01 Cycle-No:	Nurse. A 01234						
Set-Paramet Min-Temp: Set-Temp: Max-Temp: Cycle-Time:	ers:	20.C 25.C 40.C 15.M					
Cycle-Parameters: Cycle-Start-Temp: 25.C Min-Temp: 25.C Max-Temp: 26.C Cycle-Finish-Temp: 26.C							
Cycle-Time:		10.00M					
Ultrasonic-A	ction:	DAGO					
*	Cycle PASS*	PA55					

Once the ticket is printed, simply tear off and store as necessary.



Using the Ultrawave Cycle Validation Software

If the MC card Validation mode is selected, cycle information is saved to the inserted MC card and data can be saved in an electronic format. The following pages explain how to use the MC card and the Ultrawave Cycle Validation Software.

1. Setting the Validation Mode

This is done in Screen 1 of the *Administrator Instruction* menu (see pg. 4). In order to enable digital cycle validation set the Validation Mode to MC Card only or Printer & MC Card.

2. Inserting the MC Card

In order for data to save to the MC card, the card must be inserted into the port located on the left hand side of the control panel before your **Hygea 6427** is switched on.



The digital cycle traceability will save the information of each cycle (as shown on the ticket on page 23) to the MC card. This information can then be transferred to a PC and an electronic copy saved, using the Ultrawave Cycle Validation software supplied on the MC Card.

If the MC card is not inserted, then a message will display on the screen in Operator mode "MC Card not present". If MC Card only is selected as the Validation mode, and the MC card not present, then the cycle will not run.

If no MC card is available, then the chosen Validation Mode will have to be amended in the Administrator mode menu.



3. Installing the Ultrawave Cycle Validation Software

Ultrawave recommend that the cycle data saved on the MC Card is transferred to a PC at the end of every clinical session (twice a day).

The supplied MC Card is already installed with the Ultrawave Cycle Validation Software. Cycle data should be saved to this where it can be stored as a digital record.

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

Also ensure that 'Microsoft .Net 3.5 Framework' is installed as well as the associated updates.

In order to install the Software, the MC Card should be inserted into the PC using the USB card reader. Insert the MC Card into the applicable port on the reader and then insert the reader into a USB port on your PC.



When the MC Card is first inserted, the Autorun program should start, allowing installation of the Cycle Validation Software.

If the Autorun software does not start, simply go into My Computer, find the applicable drive containing the MC card and run Setup.exe.

Follow on the on screen prompts to install the Ultrawave Cycle Validation software.



4. Using the Ultrawave Cycle Validation Software

When the Cycle Validation Software is installed and opened the below screen will display:

Ultrawave Ltd.
Data Suite
Version 1.0.0.0
Telephone: +44 (0) 845 330 4236
+44 (0) 2920 837337
Fax: +44 (0) 845 330 4236

There are two options available:

- 1. View the Cycle Results stored on the PC (this allows the operator to see previous cycle data that has already been saved to the program)
- 2. Copy Cycle Results from MC Card (this allows the operator to copy the data from the MC Card to the PC)

If option 1 is chosen, and data is already saved to the PC, the data will display in the below format.



If you wish to copy new cycle data to the software, click on the Copy Cycle Results from MC Card button. You will need to ensure that the MC card is inserted into the card reader and this inserted into the USB port on your PC.

When the button is pressed, a pop up will display asking if you wish to delete the cycle data off the MC card. Ultrawave recommend that this data is deleted to prevent duplication.

When the data is stored in the programme, the individual cycle information results can be viewed. Select one cycle by clicking the tick box in the Cycle column on the left hand side.



W	Ultra	awave	B Li Coperate	Number scation 1 or Name	Los Cycle Co	Date cation2 mplete
Cycle	Serial Number	Date	Location1	Location2	Operator Name	Cycle complete
	000000	25/05/13	HIGH ST DENTAL		01 ALICE 8	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE B	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE B	PASS
	000000	25/05/13	HIGH ST DENTAL		01 ALICE 8	PASS
	000000	25/05/13	HIGH ST DENTAL		01 ALICE 8	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE 8	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE B	FAILED
2	000000	25/25/11	HIGH ST DENTAL		OT ALLER B	1965.5
	000000	25/05/13	HIGH ST DENTAL		01 ALICE B	PASS
	000000	25/05/13	HIGH ST DENTAL		01 ALICE B	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE 8	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE 8	FAILED
	000000	25/05/13	HIGH ST DENTAL		OT ALICE B	PASS

Then press the View Single Cycle Result button to see a ticket showing the data associated with this cycle.

icle Report		- Manber	1/53	Date
Ultrawave	•	ame	Cycle Co	mplete
Version: Model: Serial-No:	V2-00 H1250Vp	ocation2	Operator Name	Cycle complete
Time: Date: HIGH ST DENTA	13:50 25/05/13		OF ALICE B	FALLED
Op: 01 Cvcle-No:	ALICE B 00026		OT ALICE B	FALLED
Set Parameters: Min Temp	20.c		OT ALICE B	PASS
Set Temp Măx Temp Cycle Time	40.C 10:00M		OT ALICE B OT ALICE B	FALED
Cycle Parameters: Cycle Start Temp Min Temp Max Temp Cycle Finish Temp Cycle Time	26.C 29.C 26.C 29.C 10:00M			
Ultrasonic Activit	y: PASS			lose
* Cycle: PASS	•			

If required, this can then be printed by pressing the print button.

It is also possible to print data from multiple cycles. This can be done by clicking on multiple cycles in the left hand column.

W		awav	Operati	ocation1 or Name	Loc Cycle Co	ation2 nplete
Cycle	Serial Number	Date	Location1	Location2	Operator Name	Cycle complete
	000000	25/05/13	HERE TT DENTIL		OT ALARE &	19635
2	000000	25/05/17	MIGH ST DENTIN		IN ALLEY #	FAILED
	300000	25/05/13	HIGH ST DENTAL		DI ALICE B	
2	100000	25/05/13	HIGH ST DENTAL		STALES &	
	COLORED	25/05/12	HEAT ST DENTAL		OT ALLES &	19655
	000000	25/05/13	HIGH ST DENTAL		07 ALICE B	PASS
	000000	25/05/13	HIGH ST DENTAL		01 ALICE B	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE B	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE B	FAILED
	000000	25/05/13	HIGH ST DENTAL		OT ALICE B	PASS

In order to print the data from multiple cycles, click the Print Cycle Results button. The following print preview page will then display from which a hard copy of the cycle data can be printed:



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	CONTRACTOR OF CONTRACTOR	distanting	Allow Annual	
	Variation Science Market Roomers Market Roomers Market Science Market Roomers	Nacional Si-Si Nacional Municipal Nacional Si Si Si Nacional Si Si Si Nacional Si Si Si Si Nacional Si Si Si Si Si Nacional Si Si Si Si Si Si Si Si Nacional Si	Name 10 - 10 Manata Anno 10 Manata Maria - 10 Maria - 1	
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The Ultrawave Cycle Validation Software allows the operator to search for individual cycle data.

In order to use the Search function, simply type the search field in the applicable search box located in the top right of the screen.

W	Ultra Precision utraso	awav	e Li Operation	ocation1 or Name	Los Cycle Co	ation2
Cycle	Serial Number	Date	Location1	Location2	Operator Name	Cycle
	000000	25/05/13	HIGH ST DENTAL		OT ALICE B	PASS
	000000	25/05/1	HIGH ST DENTAL		01 ALICE B	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE B	FAILED
	000000	25/05/13	HIGH ST DENTAL		01 ALICE 8	FAILED
		22/05/13	HIGH ST DENTAL		UT ALICE B	PASS :
	View Single Cycle Result		Print Cycl Results	le	c	lose

The following fields can be used to search for cycle data:

- Serial Number of the machine
- Location/Clinic/Practice
- Operator name
- Date
- Cycle complete (PASS or FAIL)

When you have finished using the Cycle Validation Software simply press the Close button and then Exit and the cycle date.



Hygea 6427 good practice

The need to degas: In order to allow optimum ultrasonic activity, the gases present in ordinary tap water need to be driven out of the cleaning solution.

The time needed to degas the liquid varies depending on the amount of gas present in the liquid and the quantity of water in the tank. Ultrawave recommends a degas period of at least 10 minutes.

During the degas cycle, you will see bubbles of gas forming on the inside of the bath, and slowly rising to the surface. Degassing is complete when you can no longer see these bubbles.

Another indication of increased "cold-boiling" at the liquid surface indicates that the liquid is degassed.

Once the liquid is degassed, the bath is immediately useable and will run the cleaning cycle.

The effect of heat: Heating the liquid in the bath will aid the cleaning process.

Normally a temperature of between 30 to 60°C is sufficient to accelerate the process. However, when cleaning medical instruments, the **maximum temperature should be set to 40°C**. Setting the Max above 40°C may cause proteins to coagulate and "bake on" to the instruments.

Ultrasonic activity itself will heat up the liquid at a rate of approximately 10-15°C per hour if in continuous use.

Baskets: Instruments should be placed in a Hygea 6427 basket

Cleaning time: The **Hygea 6427** cycle time is pre-set to 10 minutes. This is changeable by the machine administrator. Independent tests have shown that this is adequate for all but the most heavily soiled instruments.

If the instruments are not clean at the end of a cycle, then repeat the cleaning cycle, or increase the cycle time as explained on page 13 of the *Administrator manual*.

Rinsing: After the instruments are removed from the **Hygea 6427** they should be rinsed with clean running water prior to the next stage in the decontamination process.

Rinsing the instruments ensures that any contaminants present in the water at the end of the cycle do not re-adhere to the instruments when the baskets are removed from the **Hygea 6427**.

Portable Appliance Testing should be conducted with water in the bath.



Detergent

In order to provide the best cleaning results, a cleaning detergent must be used with the ultrasonic bath.

Ultrawave recommend the Ultraclean M2 for use in the Hygea 6427.

Ultraclean M2 is a general purpose, non-enzymatic detergent suitable for use on all medical instruments.

Packaged in a 1 litre bottle, between 640ml and 1600ml of **Ultraclean M2** should be added to the **Hygea 6427** every time the bath is refilled. It is recommended that this occurs twice daily.

The Safety Data Sheets for these detergents are available on the Ultrawave website <u>www.ultrawave.co.uk</u>. [Visit the Downloads section of the Product Support area of the site]

For more information, contact us via e-mail at <u>sales@ultrawave.co.uk</u> or call on

+44 (0) 29 2083 7337

Cleaning the Hygea 6427

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 regularly.

Your cleaning process will determine how often to change the liquid – the more soiled your items, the more often you will need to change the liquid. Change the cleaning liquid at least daily.

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. Portable Appliance Testing should be conducted with water in the bath.

There are no user serviceable parts inside. All service and repair should be referred to qualified Ultrawave approved engineers only.

Service contracts for your **Hygea 6427** ultrasonic bath are available from Ultrawave or its agents.

Contact our Service Department on:

Tel: +44 (0) 29 2083 7337

Email: service@ultrawave.co.uk



Compliance with the Control of Noise at Work regulations

The Control of Noise at Work Regulations 2005 (the <u>Noise Regulations</u>^[1]) came into force for all industry sectors in Great Britain on 6 April 2006. The Control of Noise at Work Regulations 2005 replace 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 must 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 Ltd 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 text of the <u>Control of Noise at Work Regulations 2005^[2]</u> and the full text of the <u>Noise at Work Regulations 1989^[3]</u> can be viewed online.

Guidance on the 2005 Regulations can be found in the free HSE leaflet <u>'Noise at</u> <u>Work'(INDG362 (rev 1)</u>^[4] and in HSE's priced book 'Controlling Noise at Work' (L108) (ISBN 0 7176 6164 4) available from <u>HSE Books</u>^[5] or from bookshops.

- ^[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.hsebooks.co.uk



Temperatures of touchable hot surfaces

BS EN 13202:2000 gives the recommended maximum surface temperatures for different materials at various exposure times (see below)

Your **Hygea 6427** ultrasonic bath can be set so that the cleaning fluid is up to 60°C. This means that parts of your ultrasonic cleaner will be above the recommended maximum temperature. If you do operate your ultrasonic cleaner at temperatures above the recommended maximum, then Ultrawave Ltd advise that you conduct a risk assessment, and if appropriate fix a "Caution – Hot" warning label to your machine.

The following limit values are based on the harmonized standards –

- BS EN 13202:2000 Ergonomics of the thermal environment Temperatures of touchable hot surfaces Guidance for establishing surface temperature limit values in production standards with the aid of -
- EN 563: 1994 Safety of machinery Temperatures of touchable surfaces Ergonomics data to establish temperature limit values for hot surfaces.

Materials/time-temp*	1 sec	4 sec	10 sec	10 min	8 hr
uncoated metal	65°C	58°C	55°C	48°C	43°C
painted metal	83°C	64°C	55°C	48°C	43°C
enamelled metals	74°C	60°C	56°C	48°C	43°C
ceramics, glass, stone	80°C	70°C	66°C	48°C	43°C
plastics	85°C	74°C	70°C	48°C	43°C
wood	110°C	93°C	89°C	48°C	43°C

Time	Contact	Part
1 sec	accidental contact	Outer case, tank flange
4 sec	parts held for short periods	knobs, switches
10 sec	parts continuously held in normal use	handles
10 min	prolonged use	handles
8 hr	continuous use	handles



Warranty

The warranty on the Ultrawave **Hygea 6427** ultrasonic bath applies to defects appearing within 12 months of the date of sale 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 two years on transducer assemblies and to 5 years on the bonding process. If the transducers or bonding material are exposed to liquid or cleaning chemical, 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 fluids 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.

To confirm the warranty of your **Hygea 6427**, complete the enclosed warranty card and return to Ultrawave or send an e-mail with the details of the machine including the serial number to <u>sales@ultrawave.co.uk</u>. Statutory rights are not affected.

WEEE Compliance

Ultrawave are complying with the WEEE regulations by contracting-out our obligations to a Producer Compliance scheme. Once it is deemed that this **Hygea 6427** is no longer effective, please contact us to arrange collection by our compliance scheme provider, who will pick up the machine from your premises.



Troubleshooting

Ultrawave have a dedicated Service team who are able to resolve any problems that occur with your **Hygea 6427**. However, on many occasions, it is possible that the problem can be rectified by the operator.

The unit fails to turn on (no display is shown)	Check that the unit is plugged in and that mains electricity is present.
The screen displays: "FLUID LEVEL LOW OR NO DETERGENT"	Fill the Hygea 6427 with water so that it is between the MIN and MAX level indicated inside the tank. If you are using "pure" water (eg. De-I or RO) ensure that the detergent has been added.
The screen displays: "LID OPEN Please Close Lid""	Close the lid. If the lid is already closed, there may be a problem with the lid sensor. Attempt to run another cycle to see if the problem reoccurs.
The screen displays: "SONICS LOW"	The Hygea 6427 is fitted with an ultrasonic power feedback circuit, which monitors the ultrasonic activity in the bath during a cleaning cycle. If the ultrasonic power drops below a certain level, the cycle will abort and this message will display. This is not necessarily caused by a problem with the machine. If this message displays, run another cycle to see if the problem persists.
The screen displays:	Drain and refill with fresh cold water
"OVER TEMP"	The Hygea 6427 is fitted with a temperature sensor that automatically sets off an audible alarm if the liquid gets too hot. Ultrasonic activity itself will heat up the liquid at a rate of approximately 10-15°C per hour. If the Hygea 6427 is operated continuously, it may eventually set off the audible alarm because the liquid is too hot.
The screen displays: "UNDER TEMP"	The cleaning solution is not yet at the minimum temperature. Wait until the cleaning solution has reached the minimum operating temperature.
The screen displays: "NO MC CARD PRESENT"	If the Validation Mode selected is to write to the MC Card, then the Hygea 6427 will detect if the card is present. If the MC Card is not present, and "MC Card Only" is selected as the

If any of these problems persist, the Ultrawave Service Department can be contacted on +44 (0) 29 2083 7337 or <u>service@ultrawave.co.uk</u>.

There are no user serviceable parts inside the Hygea 6427.



Returning equipment to Ultrawave

All equipment being returned for any 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.

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

Ultrasonic baths which have been used in medical/healthcare applications should be decontaminated/packaged in accordance with the <u>Health and Social Care Act 2008</u>.

"How to Decontaminate" Guidance is given on the <u>decontamination</u> page on the Ultrawave website

If you require further information, please call the Ultrawave After Sales Department on +44 (0) 29 2083 7337 or email <u>service@ultrawave.co.uk</u>.

Hygea 6427 Accessories

The following items are available from Ultrawave or its agents for use with the **Hygea 6427**.



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.





Hygea Accessory Kit

The **Hygea 6427** is supplied complete with an accessory kit which contains the fittings to connect to hollow instruments to the machine's irrigation ports.



Aluminium foil

Aluminium foil for quarterly validation of the **Hygea 6427**.



Brownes STF Load check indicator test strips and holders

Brownes strips and holders for weekly testing of the **Hygea 6427.**



Service Contracts and Validation Testing

Ultrawave can offer full Service and Validation packages for the the **Hygea 6427**, to ensure the machine is performing at the optimum level and the testing requirements as stipulated in guidelines and recommendations are met.

For information on any of these products or services, contact Ultrawave on:Tel:+44 (0) 29 2083 7337Email:sales@ultrawave.co.uk



Notes

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Ultrawave baths are manufactured in the United Kingdom.

Ultrawave baths are manufactured to exacting standards and conform to international standards.