Bioquell | QUBE

Aseptic Processing Workstation

USER MANUAL

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Revisions

Rev	Description	Date	C.R.No.	Orig.	Chkd.	Apprd
1	FIRST ISSUE	30th July 2013	-	JL	PM	ORC
2	Screen navigation, glove & sleeve replacement added; Board replaceable fuses added; Section 3.3.1 moved to 4.3.2; alarm conditions/actions added to table; errors corrected.	9th Sept 2013	CR2455	JL	PM	ORC
3	Updated alarm table; ADMIN functions, date & time, time zone moved to supervisor access; Fig 27 corrected; updated screenshots; new pressure setpoints function button; connector part nos. for Air Sampler added; errors corrected; service schedule updated.	23 Jan 2014	CR2560 CR2541	JL	PM	ORC
4	Addition of US sterilant labelling notes; Environmental Monitoring Level 4 option; 3.1 advice on positioning unit added; Fig 20 updated; 3.1.2 advice on power covers added; 3.3 bottle fill, storage and documents amended; 4.3.2 Rev 2 bottle holder change; 4.5.2 info moved to product leaflet 5.3.1 advice corrected; 6.3 information amended; 8.2 amended; 8.3 removed. 9 volt free corrected	12 May 2015	CR2689 CR2629	ORC	JH	PGB
5	Aeration cut-back added, p42. Maintenance period clarified. Alarms 40,41,72, 73 & 119 added. QRTP & QBPM added. Additional info and trouble shooting on cross-sensitivity of H_2O_2 sensor. P70	12 Aug 15	CR2889	ORC	GK	PGB
6	Section 6.3 removed, 6.2 covers all service information.	25 Sep 15	CR2971	ORC	GK	PGB

Bioquell designs, manufactures and supplies as a service a broad range of bio-decontamination solutions for:

- rooms
- systems and processes
- laboratory equipment
- biomedical equipment

For further information and contact details refer to website www.Bioquell.com

It is essential that the safety and operating instructions described in this manual are observed.
These are the original instructions

The Bioquell QUBE is only to be used by personnel who have been trained by Bioquell or their agents on its safe use. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

These instructions assume the equipment has been installed in accordance with the procedure detailed within TD069-IM-001.

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United States of America only:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/TV technician for help.

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1 SAFETY

1.1 Safety Information relating to Hydrogen Peroxide and HPV Cycles

Safety instructions that must be observed when operating or servicing the Bioquell QUBE or handling the Hydrogen Peroxide bottles are listed below.

Danger and Warning signs  are used where there is a potential hazard to personnel.

The mandatory symbol  is used to describe other safety precautions that should be followed before operating the equipment.

**SAFETY OBSERVANCE IS ESSENTIAL WHEN USING THIS EQUIPMENT.
READ THIS SECTION CAREFULLY BEFORE USING THE EQUIPMENT**

DANGER – CHEMICAL INJURY HAZARD

	HANDLING HYDROGEN PEROXIDE Wear personal protective equipment including Eye protection, single use neoprene or vinyl gloves and protective clothing.
	HYDROGEN PEROXIDE LIQUID can cause burns and blistering to the skin and tissue damage to the eyes when in contact. HYDROGEN PEROXIDE VAPOUR can cause irritation to eyes, nose, throat, lungs and skin and breathing difficulties and coughing. IN ALL CASES SEEK MEDICAL ADVICE.

ACTION TO BE TAKEN ON EXPOSURE TO HYDROGEN PEROXIDE	
EYES	Irrigate with sterile water for at least 10 minutes.
LUNGS	Remove casualty immediately to fresh air, rest and keep warm.
SKIN	Drench with water. If spilled on clothing remove immediately and wash thoroughly.
MOUTH	Rinse thoroughly with water and give plenty to drink. Do not induce vomiting.

	SPILLAGES Mop up with plenty of water and run to waste, diluting at least 20:1. Always ensure wipes used to mop up spillages are rinsed with cold water before being put in waste bins; there is a risk of spontaneous combustion if thrown directly in waste bin containing other materials.
	HANDLING HYDROGEN PEROXIDE BOTTLE Wear protective gloves. Inspect outer bag containing peroxide bottle for signs of liquid before opening. If any liquid is present in the bag DO NOT OPEN. Discard safely. If no signs of liquid in the bag open carefully and remove bottle. Keep bottle upright at all times. Handle bottle in accordance with safety data supplied on bottle label and packaging.
	BEFORE RUNNING A CYCLE Check that all doors and front access windows are closed and seals inflated.
	DURING A CYCLE • Do not attempt to open the QUBE before the end of the cycle or to open a QUBE door unless the door switch is illuminated GREEN. • Observe warnings and alarms displayed on the control panel. • Do not attempt to disengage or remove the Hydrogen Peroxide liquid bottle.
	AT THE END OF AERATION Check that the vapour concentration is at, or below, the country's Occupational Exposure Limit (OEL) (Long-term exposure limit is 1ppm and short-term is 2ppm in the UK). In USA: the Permitted Exposure Limit (PEL) has a Threshold Limit Value (TLV) of 1ppm for eight hours exposure a day.
	IF THE CYCLE ABORTS DURING GASSING OR AERATION Check that the vapour concentration is at, or below, the OEL before opening the QUBE. If above the OEL run an "AERATION ONLY" cycle in accordance with the operating instructions until the safe concentration level is reached.
	VISIBLE LIQUIDS in the enclosure must be treated as concentrated Hydrogen Peroxide. Observe Hydrogen Peroxide handling precautions and remove liquid by diluting with water at least 20:1 and wiping up.
	EXTERNAL DISCHARGE of vapours by ventilation from the enclosure to atmosphere during the aeration period must avoid leakage of Hydrogen Peroxide vapours within the building.

1.1.1 Consumable H_2O_2 bottle labelling symbols explained

	CHEMICAL INJURY HAZARD	Hydrogen Peroxide liquid is hazardous – corrosive
	CHEMICAL INJURY HAZARD	Hydrogen Peroxide liquid is harmful and is an oxidizing agent
	RFID	This product contains an RFID tag

Note: Further information relating to safety for the Hydrogen Peroxide is available from on the MSDS provided with the consumable.

1.2 General Safety Information relating to the QUBE

WARNING – EQUIPMENT DAMAGE

	The QUBE system, once installed, only requires moving forward to enable cleaning of all sides. If the equipment is to be moved across a threshold or any substantial distance then it should be completely disassembled and re-assembled by trained personnel to ensure safe operation once re-positioned. Cables must not, at any time, be trailed causing a trip hazard. Ensure supporting feet (x2) are retracted prior to moving any QUBE system. The weight of the QUBE system is dependent upon the configuration; however, local manual handling regulations must be adhered to. To prevent damage to the QUBE do not manoeuvre by handling the front screen, glove ports or gas strut covers.
	Avoid moving the QUBE system (or any part thereof) once a cycle has been started.
	Prior to switching on the QUBE system ensure all doors are closed.
	Operate the equipment strictly in accordance with the Operating Instructions.

	Major repairs or adjustments to the Bioquell QUBE should only be made by a Bioquell Service Provider or those trained to perform such procedures by Bioquell. Non-routine maintenance performed by unqualified personnel or installation of unauthorised parts could cause personal injury or result in damage.
	The equipment must be serviced in accordance with the Maintenance Schedule to maintain safe performance. Potential hazards or failure of performance may occur if the equipment is not serviced by trained and authorised personnel. Contact your Bioquell Service Provider to schedule preventative maintenance or for emergency repairs.
	Use of traditional alcohol sprays and wipes must be avoided to prevent damage to the sensitive electrical components within the QUBE system especially the Hydrogen Peroxide sensor.
	Use of paper or other abrasive cloths could potentially damage the QUBE front screen during cleaning.
	Do not cover the top of the QMTD as this could potentially block the filter.

DANGER – PERSONAL INJURY HAZARD

	The Bioquell QHPV module weighs approx. 280 kg (617 lbs); the QEXT module approx. 240Kg (529.1 lbs) and the QMTD module approx. 64 kg (141 lbs). Local manual handling regulations and SOPs must be adhered to when moving this equipment to prevent personal injury. Assisted mechanical devices will be required if moving over a threshold or for any distance.
	Take care when moving the Bioquell QUBE on inclined surfaces.
	Park the Bioquell QUBE on flat surfaces only. Secure by extending the support feet to stop the unit moving.
	Do not tilt the unit over as toppling may occur.
	The Bioquell QUBE contains electrical connections. Always disconnect the power supply before gaining access to electrical and pneumatic systems for inspection or maintenance. Access to these systems should be restricted to trained personnel; failure to do so may cause an ELECTRICAL INJURY HAZARD.

1.3 Warning Labels within the QUBE

ELECTRICAL INJURY HAZARD

Only trained personnel should be accessing the electrical system

2 DESCRIPTION OF QUBE SYSTEM

2.1 Purpose of System

The Bioquell QUBE is an aseptic processing workstation with integrated HPV decontamination system. This system can be used for various applications including: sterility testing; pharmacy compounding, aseptic material transfer and others that require an aseptic environment. It is a modular system that is configurable to the Client's needs.

The QUBE is loaded via the front access window. Dependent upon the application, the QUBE may be supplied with Bioquell "SafeSort[1]", internal racking and rails. There is a Product Description Sheet for each of the optional accessories available from Bioquell.

All replacement or serviceable parts are accessible from the front of the QUBE; thereby allowing it to be positioned against a wall. Key access is required to components that may present a hazard.

2.2 QUBE Modules

The QUBE system is modular incorporating a QUBE Hydrogen Peroxide Vapour (QHPV) Module and additional modules dependent upon ordered configuration:

- QUBE Extension Module (QEXT) (max.2)
- QUBE Side Door Module (QSDM)
- QUBE Material Transfer Device (QMTD)
- QUBE Open Connection Module (QOCM)
- QUBE Closed Connection Module (QCCM)
- QUBE Rapid Transfer Port (QRTP)
- QUBE Blank Plate Module (QBPM)

As standard the QHPV Module is supplied without integrated continuous particle monitoring or active air sampling systems (unless ordered as part of the configuration). However, it is fitted with the connections for these systems including having a "Dummy cone" in place.

Figure 1 depicts one typical configuration of a QUBE system. The QUBE is available as a 1-chamber, 2-chamber or 3-chamber system of various configurations.

[1] *Bioquell SafeSort is a prescription decontamination system designed for gassing components and used in hospital pharmacy applications.*

Figure 1: Typical Configuration of QUBE System

2.2.1 QUBE Hydrogen Peroxide Vapour Module - QHPV

This chamber incorporates the HPV decontamination system and controls including the touch screen. Each QUBE system incorporates a QHPV module. The complete system is controlled via a Control Panel from the QHPV Module. Figure 2 depicts the main features of this module.

2.2.2 QUBE Extension Module - QEXT

This module can be positioned either left, right or both sides of the QHPV chamber. It enables the Operator to continue to 'work' on one load whilst simultaneously decontaminating another load. If the system is configured with more than one QEXT module then one may be used as an accumulator to store a load whilst one is being processed and one being gassed.

2.2.3 QUBE Side Door Module – QSDM

This module is positioned either on the left hand end, or right hand end, or both ends of the chambers. It can be used to transfer the load between QUBE modules, while providing a physical separation between modules allowing the QHPV unit to run cycles on its own.

2.2.4 QUBE Material Transfer Device - QMTD

This module is positioned either on the left hand end, right hand end, or both ends of the chambers. It can be used to transfer the load into and/or out of the QUBE system.

2.2.5 QUBE Open Connection Module – QOCM

The QOCM allows for a large open aperture between QEXT modules only, thus making them into a 4-glove device.

2.2.6 QUBE End Modules

The end panels for the QUBE system where a QMTD is not fitted can be one of the following:

QUBE Closed Connection Module – QCCM
This is a solid end panel

QUBE Rapid Transfer Port – QRTP
This end panel has a 190mm diameter RTP fitted to it. There is a left and a right hand version ensuring that the RTP always hinges to the back.

QUBE Blank Plate Module – QBPM
The end panel has a circular blank 3mm thick stainless steel sheet, through which penetrations can be made to suit application.

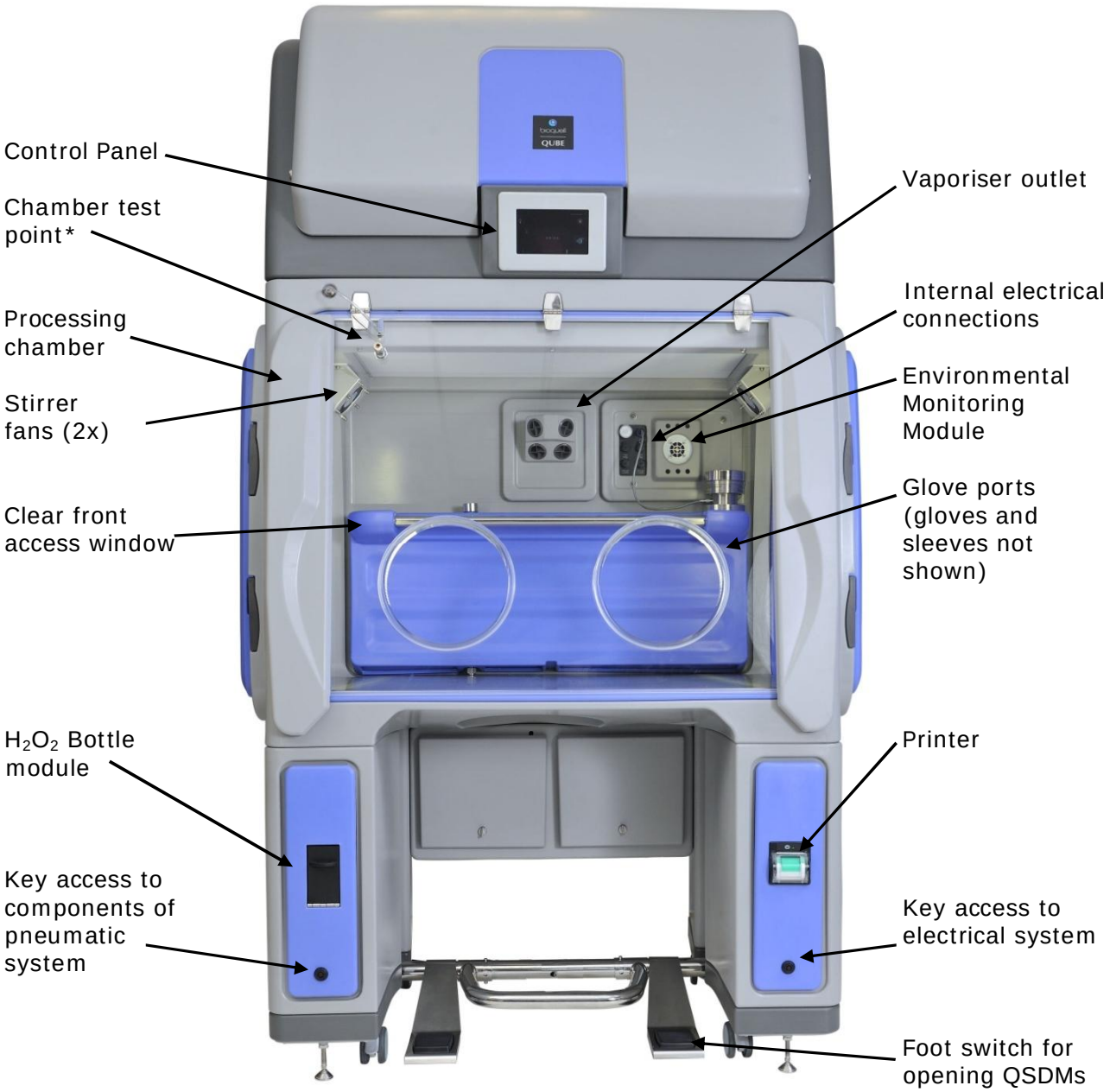


Figure 2: QHPV Module

* Mating part is Bioquell part number H03020720 and has a 5/16” (8mm) Hose barb outlet.

2.3 Optional Sub-systems

The following sub-systems are not integrated into the QUBE as standard but available to order as part of the configuration:

2.3.1 Glove Tester

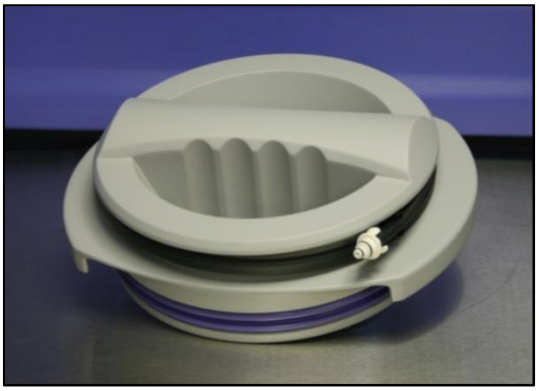


Figure 3: Glove Tester

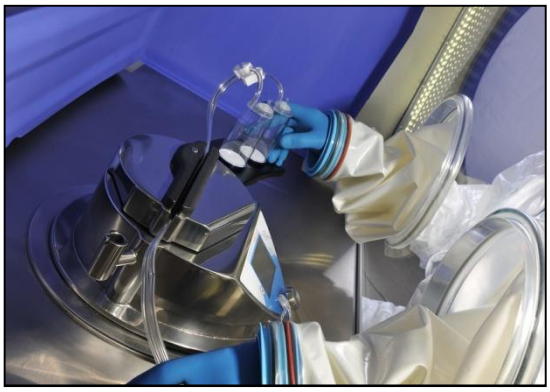
The Glove Tester (Part No.TD069-5900) is an accessory that can be supplied with the QUBE system to enable the leak testing of sleeves and gloves.

A glove test cannot be performed on a QUBE module which is being decontaminated.

For information on how to use the glove tester refer to Instructional Leaflet TD069-5900_PDS (supplied with glove tester).

2.3.2 Sterility Test Pump

The QUBE system has been designed to work with the Merck Millipore SteriTest Symbio Flex or Equinox Isofit Pump for sterility testing applications. The “SteriTest” unit is fully integrated into the chamber moulding.



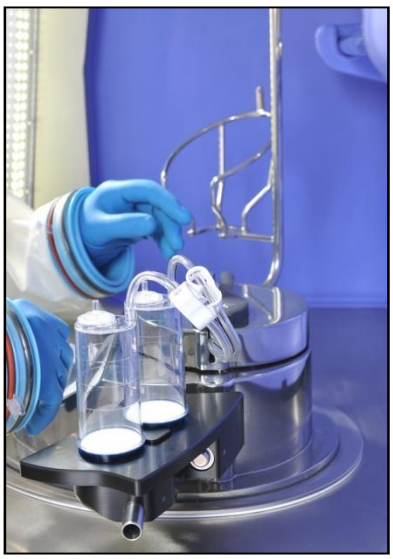


Figure 4: Sterility test unit in use (Equinox shown)

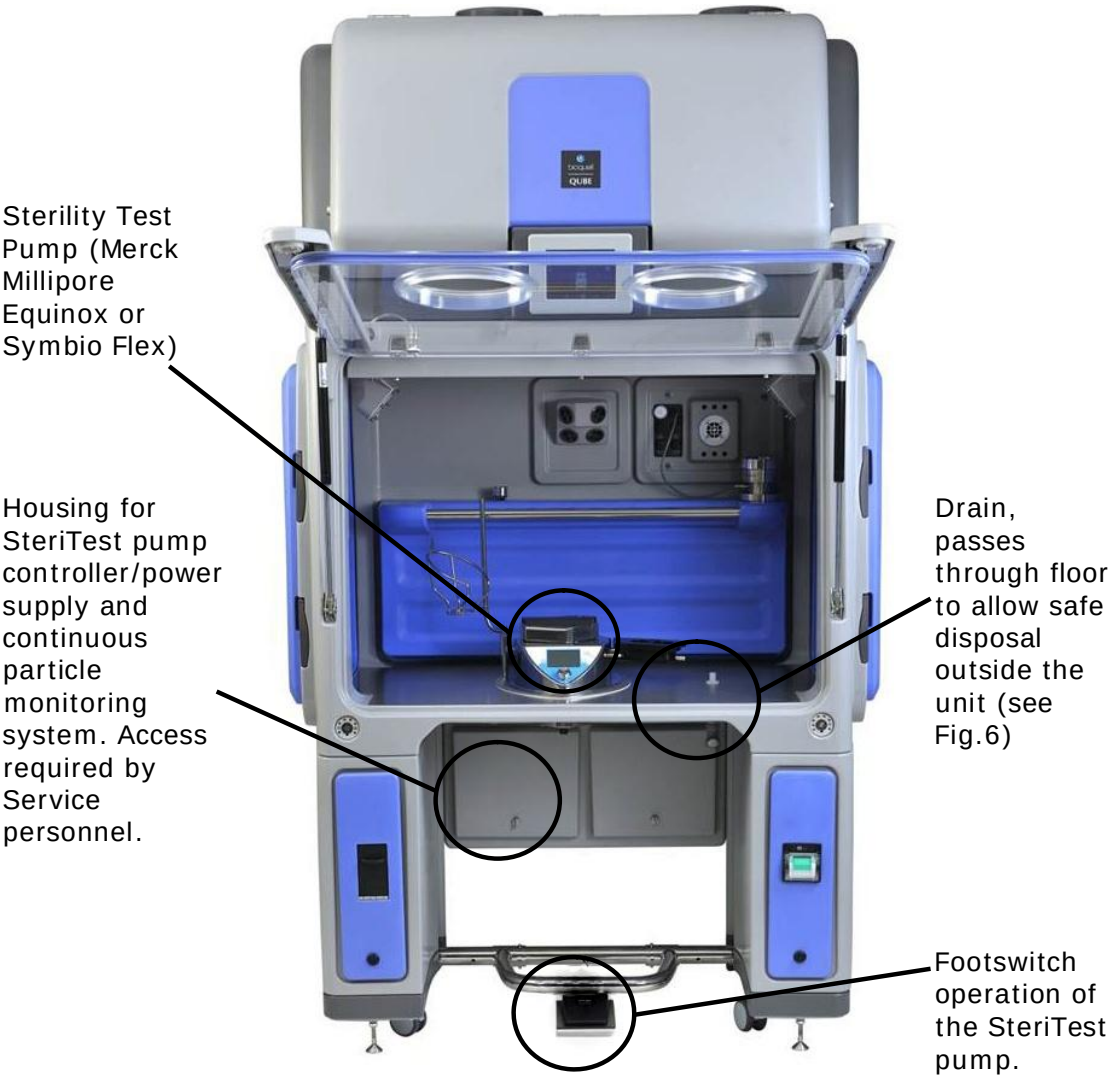


Figure 5: SteriTest unit installed

Prior to use of SteriTest unit ensure tubing is connected to drain. Connect tubing as shown in Figure 6.

Figure 6: Push-in connection

For details on how to use the “SteriTest” pump refer to the Manufacturer’s Instructions (supplied if part of ordered configuration).

To remove the drain connection press release button and pull out, as shown in Figure 7.

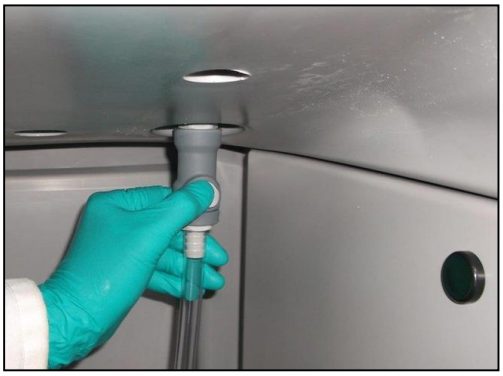


Figure 7: Removal of drain tubing

It is advisable to execute the scheduled maintenance of the “SteriTest” unit whilst the QUBE is being serviced. Contact Merck Millipore for scheduling the Servicing of this unit (refer to Section 6.2 for contact details).

The QUBE may also be supplied with the “SteriTest” pump drain only if a client-supplied free standing SteriTest pump is installed.

Racking has been designed by Bioquell for this application. This racking is available in kit form; refer to TD069-6200_PDS for how to assemble.

2.3.3 Integrated Environmental Monitoring

2.3.3.1 Level 1 Environmental Monitoring Package

As *standard* the QUBE QHPV and QEXT chambers have been designed to allow for Level 1 Environmental Monitoring to be performed. Level 1 Environmental Monitoring consists of:

- Periodic particle monitoring checks using a portable particle counter connected to the pre-fitted tube and supplied ISO-Kinetic cone. A blanking cone is also supplied, to be fitted instead of the ISO-Kinetic cone when sampling is not taking place. The particle monitor is not supplied by Bioquell.
- An integral connector inside the chamber can be used to connect to an Active Air Sampler (see Fig. 21, Item 2), and a coupler is provided (see Fig. 12) on the QUBE’s right leg to enable connection to the air sampler’s power device. The Active Air Sampler and power device and settle plates are not supplied by Bioquell.
- Settle plates and other alternative monitoring methods may be adequate, as shown in Figure 8.

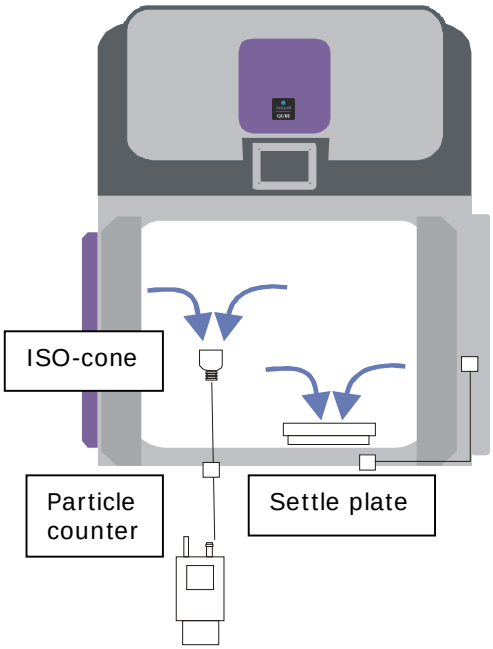


Figure 8: Level 1 Environmental Monitoring System Diagram

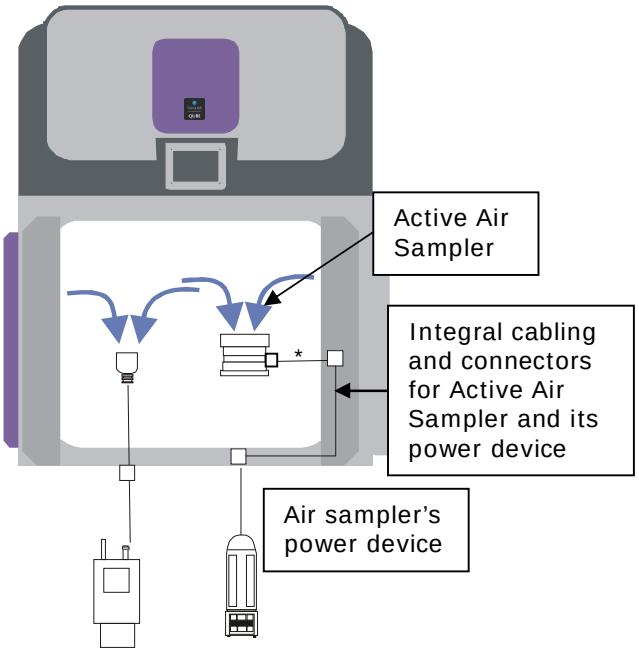


Figure 9: Level 1 Environmental Monitoring System Diagram

ISO-Kinetic cone, blanking cone and integral cable and connectors for Active Air Sampler are supplied with units. The connectors are specifically for the SAS Isolator 180 Sampler. If not using a Bioquell-supplied Sampler then a LEMO connector (LEMO Part No. FGL.2K.302.CLLC55Z) must be fitted to the Sampler. Cable between sampler and chamber marked with * can be supplied separately (Bioquell Part No. TD069-0621)

ISO-Kinetic cone

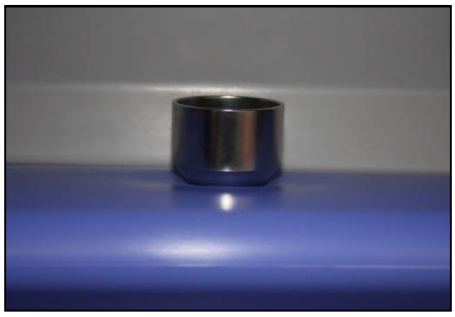


Figure 10: ISO-Kinetic Cone

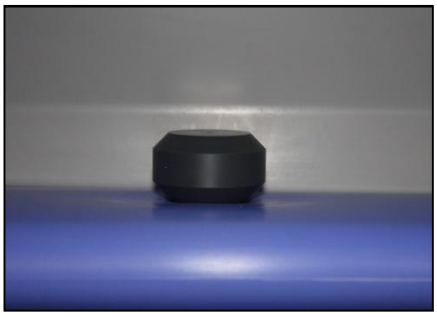
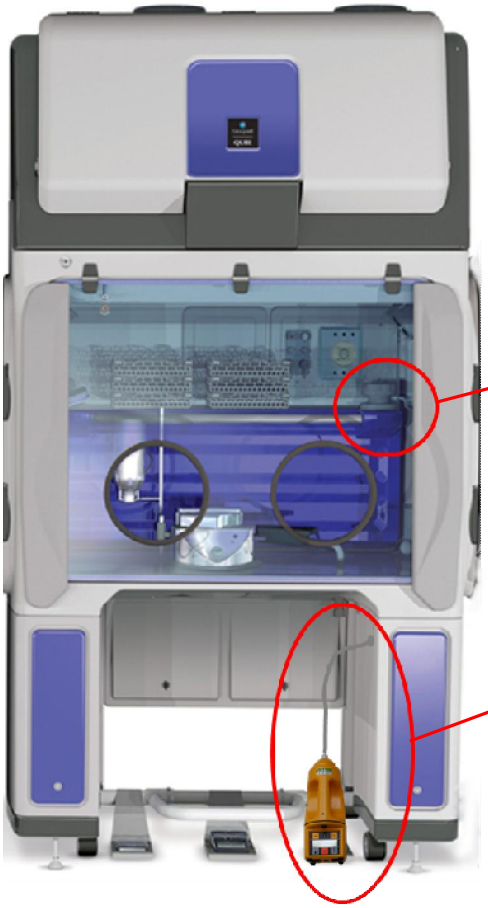


Figure 11: Blanking Cone

Connecting the Active Air Sampler



Active Air Sampler, location shown, is plugged into the dedicated connector within the chamber (refer to Fig. 21, Item 2)

Keyed bulkhead coupler supplied on QUBE right leg for attaching the sampler's power device.

Figure 12: Connecting Active Air Sampler

2.3.3.2 Level 2 Environmental Monitoring Package

The QUBE QHPV and/or QEXT chambers are *optionally* supplied with an Active Air Sampler (See Figure 13) to enable Level 2 Environmental Monitoring; the air sampler is powered and controlled through the QUBE's touch screen.

Figure 13: Active Air Sampler

The Active Air Sampler has a stainless steel head. It is permanently placed within the QUBE and attached through a dedicated DC supply connector; labelled thus:

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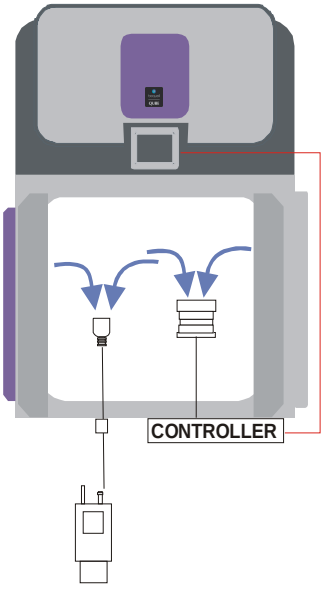


Figure 14: Level 2 Environmental Monitoring System Diagram

As Level 1, when particle monitoring is to be performed the blanking ISO-Kinetic cone fitted to the QUBE should be replaced with the supplied ISO-Kinetic cone.

2.3.3.3 Level 3 Environmental Monitoring Package

The QUBE is *optionally* supplied with an Active Air Sampler and a proprietary integrated continuous particle monitoring system with integrated vacuum pump. An ISO-kinetic cone is fitted to the QUBE chamber.

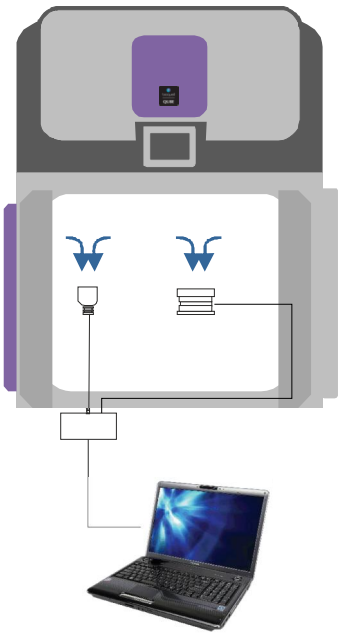


Figure 15: Level 3 Environmental Monitoring System

Sample air is fed continuously to the particle counter monitoring unit via tubing from the ISO-Kinetic cone. See Figure 15.

Pharmagraph enVigil-PnP logging software is supplied to output and record results to a PC; the PC is not supplied by Bioquell. Up to 2 chambers can be run from one software license. Refer to manufacturer's instructions for use.

2.3.3.4 Level 4 Environmental Monitoring Package

The QUBE is *optionally* supplied with a proprietary integrated continuous particle monitoring system with integrated vacuum pump. An ISO-kinetic cone is fitted to the QUBE chamber. Pharmagraph enVigil-PnP logging software is supplied and record results to a PC. The PC is not supplied by Bioquell.

An integral connector inside the chamber can be used to connect to an Active Air Sampler (see Fig. 20, Item 2), and a coupler is provided (see Fig. 12) on the QUBE's right leg to enable connection to the air sampler's power device. The Active Air Sampler and power device and settle plates are not supplied by Bioquell.

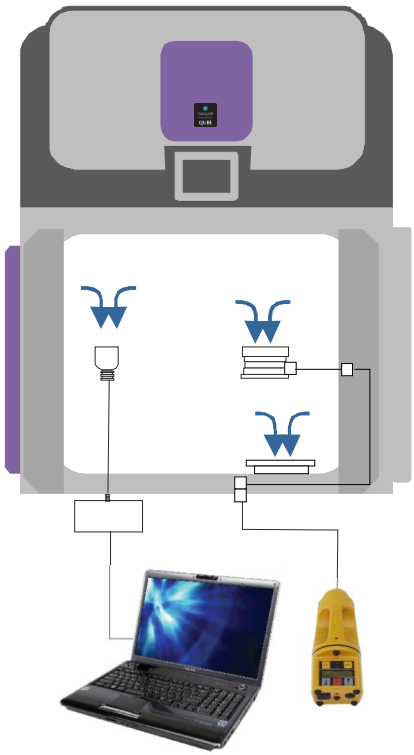


Figure 16: Level 4 Environmental Monitoring System

2.3.4 'Tri-Clover' or Sanitary Connection Port to Chamber

Figure 17: Tri-Clover Clamp

The QUBE may be supplied with an optional 1" Tri-Clover fitting in the base of the chamber to enable fluids to be supplied to the chamber without breaking the integrity of the chamber.

2.3.5 Ducted Extract

A dedicated ducted extract system is offered such that the system air is exhausted via attachment to an HVAC system (ducted to outside the building).

A by-pass valve diverts room airflow to the exhaust duct during a leak test or decontamination cycle. This ensures that room HVAC flows remain balanced and the pressure within the room remains controllable. Refer to 5.3.1 on how to configure the QUBE when not in use while continuing to allow air to be extracted from the room.

2.3.6 Additional Printer

On QUBE systems where a QMTD transfer hatch is fitted to a QEXT there is an option for an additional printer on the QMTD Module. This prints a short report every time the door is opened to confirm the period held in aseptic conditions.

2.4 Configurations

The QUBE system is configurable with up to 3 modules (QHPV and QEXT) and 2 QMTDs. Contact Bioquell for available configurations.

2.5 Control Panel

The Control Panel has been developed using intuitive icons to simplify the User interface. For an explanation of the icons, graphics and colour schemes refer to Section 4.1.1.

2.6 Lighting

Chamber lighting is provided in all modules of the QUBE system. The white lighting intensity is User adjustable via the control panel. All module light levels are adjusted together but can be switched off individually. During processing mode the chambers have white lighting, and during a HPV cycle they are blue.

2.7 Modes of Operation

The Bioquell QUBE can be used in two modes of operation. Refer to Section 4.3 for information on how to operate the QUBE.

2.7.1 Processing Mode

In processing mode the QUBE provides a unidirectional airflow working zone that meets the classification requirements of ISO 14644-1 Class 5 (equivalent to EU cGMP Grade A and US FED STD 209E Class 100). Air handling may be via a recirculation or ducted system (dependent upon Client requirements).

The QHPV & QEXT modules include integrated air handling to stabilize the chamber thermal conditions and to allow for pressure control. The chamber pressure can be controlled from -60Pa to +75Pa.

2.7.2 Bio-decontamination Mode

The QHPV, when used in this mode and in conjunction with appropriate validation as necessary, provides assurance of bio-decontamination to a 6-log microbial reduction of the load.

Either the QHPV module or a complete QUBE system may be decontaminated.

The HPV Cycle is a four stage process:
• 'Conditioning' when the Hydrogen Peroxide vaporiser increases to operating temperature, and the instruments warm-up and stabilise.

• 'Gassing' when the Hydrogen Peroxide liquid is vaporised and is distributed around the chamber(s), dew point is reached and micro condensation forms on surfaces.

• 'Dwell' when the Hydrogen Peroxide Vapour is either maintained at a constant level or the vapour is distributed without additional vapour addition.

• 'Aeration' when the Hydrogen Peroxide Vapour is catalytically converted to water vapour and oxygen.

3 QUBE CONNECTIONS & SET-UP

3.1 Position

It is important that the Qube is not positioned in direct sunlight, or near sources of heat or cooling such as autoclaves or heating/cooling vents. This may cause heat build-up in the unit or compromise the decontamination cycles.

3.2 Electrical Connections

The following section describes the connections to and from the QUBE system – these can vary dependent upon auxiliary equipment supplied.

It is recommended that only trained personnel should be employed if the QUBE system requires moving any substantial distance as this would require electrical disconnection. Thus, this section is primarily concerned with providing information on how to connect auxiliary equipment to the QUBE. It is expected, however, that occasionally the QUBE system is moved forwards to enable cleaning of the rear faces.

The primary means for power isolation is via the ON/OFF switch on the rear of the QHPV and QEXT modules. If, due to the QUBE being positioned against a wall, this is not accessible then a secondary means of power isolation is required via a wall socket which is accessible. Wherever possible the unit should be positioned such that the primary means of isolation is accessible.

WARNING – To avoid risk of electric shock the equipment must only be connected to a supply main with protective earth.

Do not replace the mains cord with an inadequately rated one.

3.2.1 External Electrical Connections

The electrical connections are positioned on the rear of the right hand QHPV module leg.

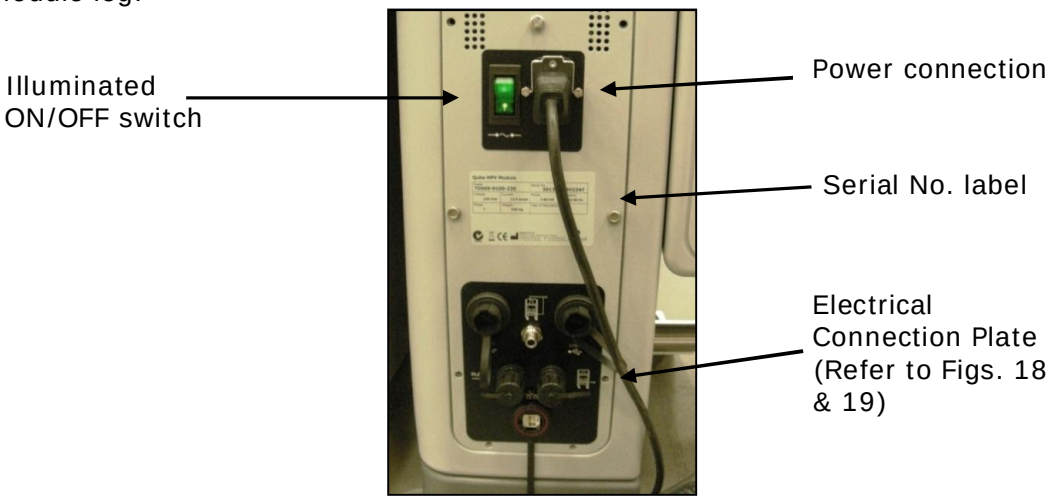


Figure 18: Electrical Connections (230V version shown)

Each module (QHPV & QEXT) is independently supplied with power. The QMTD is supplied with power by the QHPV module.

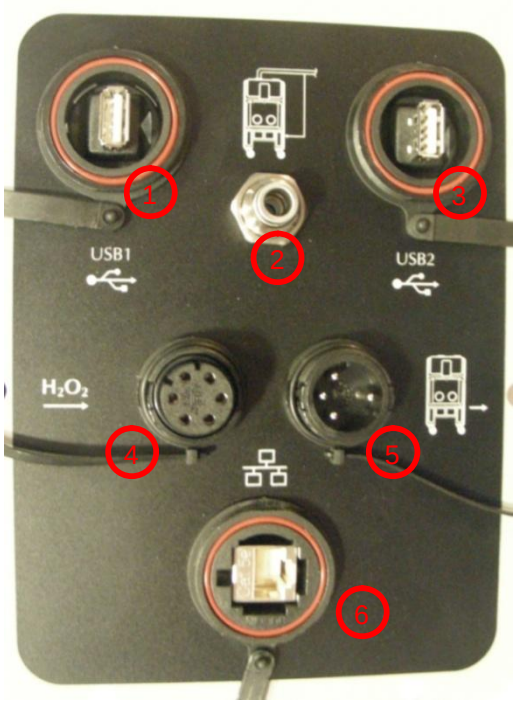


Figure 19: Electrical connection plate (QHPV)

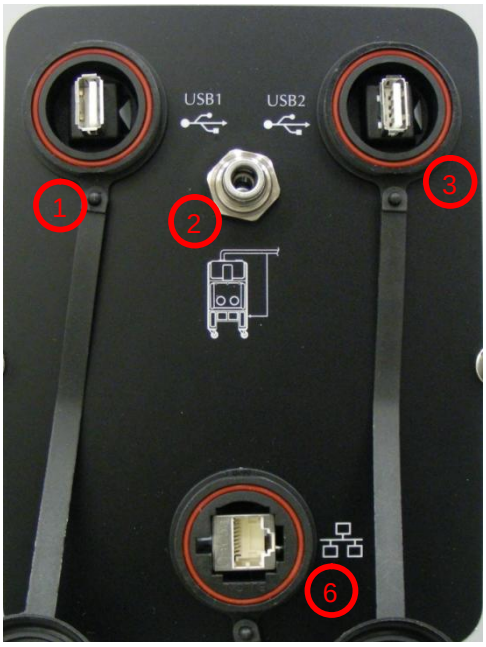


Figure 20: Electrical connection plate (QEXT)

The connection for the Glove Tester is located on the side of the QUBE left leg.

The connection for the viable monitor is located on the side of the QUBE right leg.

Item	Elec. Ref.	Description
1	USB1	Link to internal USB connections for equipment being used inside the chamber.
2	SP01	Duct pressure monitoring switch connection (ducted option)
3	USB2	Link to internal USB connections for equipment being used inside the chamber.
4	-	A digital input has been provided for interfacing to a room gas monitoring system by way of an external voltfree contact. For this specification the input is present when the external voltfree contact is closed. Item 4 provides the connection to the room gas monitoring system. The equipment used must have a Bulgin connector PX0800 with insert SA3243.
5	-	Alarm status volt-free output.
6	ENET	Ethernet connection.

3.2.2 Internal Electrical Connections

Figure 21: Internal Connections

> WARNING: For the two accessory outlets (labelled 5 & 6) the total power must not exceed 200W for the pair. Keep the covers on tight when not in use to prevent electric shock when cleaning or pressure leaks. Output voltage is the same as the unit's supply.

Item	Description	Required mating connector
1	Filter for chamber pressure monitor.	N/A
2	Connection for active air sampler.	Bulgin PX0410/04P/4550 (insertion tool 13027/1)
3	Mini B USB for connection to USB1.	Mating USB Mini B (Bulgin PX0441 or PX0442)
4	Mini B USB for connection to USB2.	Mating USB Mini B (Bulgin PX0441 or PX0442)
5	Accessory outlet (≤200W) 230V/120V/100V.	Bulgin PX0410/03P/5560 (insertion tool 13027/2)
6	Accessory outlet (≤200W) 230V/120V/100V.	Bulgin PX0410/03P/5560 (insertion tool 13027/2)

3.3 Door Control

The QUBE doors are fitted with pneumatic inflatable seals for security and robustness. When the QUBE is powered up the door seal will automatically inflate when the door is closed.
To open a connecting door, depress the footswitch located below it on the handle side; this deflates the seal, enabling the door to be opened.

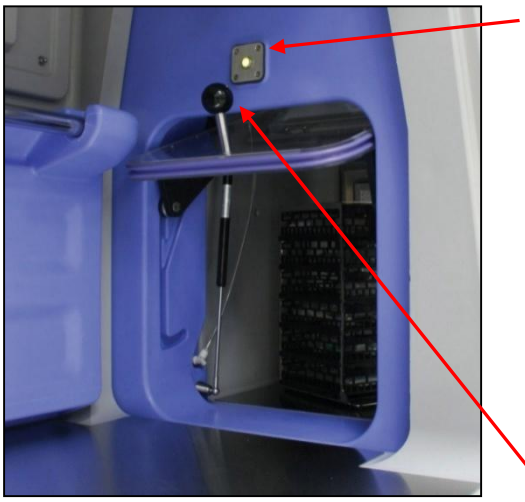


Figure 22: Side door

- Not illuminated – The door is disabled and cannot be opened.
- Continuous green – The door is enabled and can be opened.
- Flashing red – There is an alarm on the door sealing.
- Flashing green – Informing the user that an action is required; either open the door prior to the start of a complete system decontamination or shut at the end of the complete system cycle.

For safety reasons all doors are interlocked by the control software, thereby ensuring that when a decontamination cycle is being run the relevant doors cannot be opened.

When in Processing Mode:

- Only one door at a time of a QMTD module can be open.
- There will be a clean up time of 2 minutes after opening the QMTD external door before the internal door can be opened again.
- Two internal doors of any module can never be open at the same time.
- The internal doors of a QHPV module can only be opened if the QHPV module is aseptic.
- The front door of a QHPV module can be opened by a user with operator or above access rights only if the inner doors are locked.
- Where there is an open connection between QEXT modules, the doors at either end of the module cannot be open at the same time.
- The front door of a QEXT module can only be opened by a user with supervisor or above access rights.

3.4 Hydrogen Peroxide Supply

The QUBE has been designed to use only Bioquell approved 35% w/w Hydrogen Peroxide in 150ml bottles. Note the usable volume is 140ml.

Each bottle contains a Radio Frequency Identification (RFID) tag which enables the bottle's batch number, volume of Hydrogen Peroxide remaining and expiry date to be read automatically by the QUBE.

Hydrogen Peroxide must never be stored in direct sunlight. It must be stored at 25°C or below. All Bioquell Hydrogen Peroxide bottles are vented to prevent build-up of gas. Each consumable bottle must be kept upright.

WARNING – Personal Protective Equipment must be used when handling consumable bottles which contain Hydrogen Peroxide. As a minimum Bioquell suggest wearing suitable gloves and eye protection.

WARNING – Once opened, the bottles are no longer leak tight and so should be stored upright.

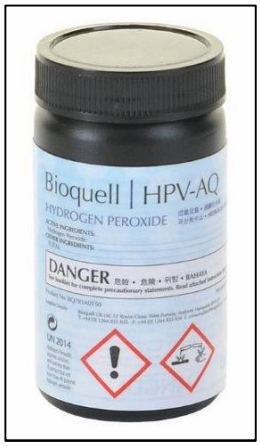


Figure 23: QUBE consumable bottle

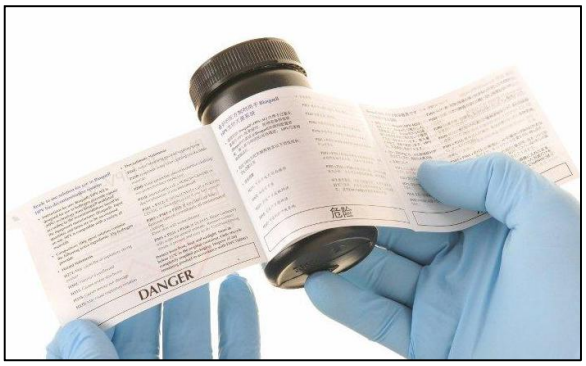


Figure 24: QUBE bottle labelling

Each consumable bottle has a multi-language booklet label attached with detail translated into languages relevant to the territory supplied. A Material Safety Data Sheet (MSDS), Certificate of Analysis and supplemental labelling, as applicable, is available in the language(s) relevant to the territory and is on the Bioquell web site.

Figure 25: Bottle showing register

Figure 26: Bottle with cap removed

The bottle, as depicted in Figure 25, incorporates a register feature to ensure the Operator has correctly aligned the RFID tag with the reader within the QUBE.

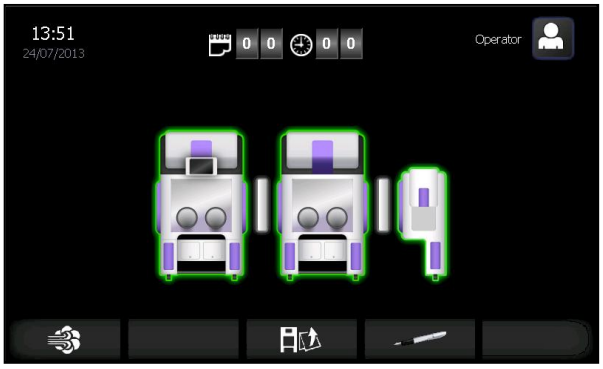
Each QUBE bottle is equipped with a semi-permeable membrane which provides adequate sealing and ventilation of the bottle. Disposal and/or recycling of the QUBE bottle must be in accordance with local regulations due to the contents being hazardous waste.

Refer to section 4.3.2 for details on how to load the consumable bottles when the QUBE is to run a decontamination cycle.

4 QUBE OPERATION

When initially powered, after booting up, the QUBE splash screen with the Bioquell logo will appear.

Press anywhere on screen to proceed to the start page once loaded.



The system automatically detects the configuration of equipment and displays this in icon form.

The time displayed in the top centre is the time since the aseptic hold was established in days and hours.

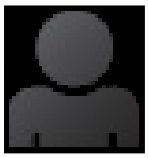
The time and date displayed in the top left hand corner is the present time and date.

4.1 The Control Panel Explained

4.1.1 Icons

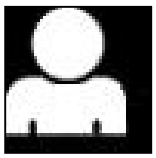
The Control Panel has been developed using custom-designed icons to communicate functions. A quick reference guide is provided on the following pages.

Access Level



Logged off

Supervisor



Operator – Logged on

Administrator

Access rights for each level is detailed in section 5.4.3.1

Modules

QHPV

QMTD (Left)

QEXT

QMTD (Right)

The outline colour of each module represents its condition; GREEN meaning aseptic; AMBER not aseptic; BLUE when in cycle; RED during alarm conditions.

Administrative Functions

Back button

Print currently loaded cycle recipe parameters

Confirmation

Delete recipe

Save data

Load cycle recipe

Administration

Setup Functions

	Date & Time		Time zone
	Manage users		Edit users
	Light ON		Light OFF
	Open front access window (from home page)		Open access window (from information page)
	Load Hydrogen Peroxide / Unlock Bottle Module		Active Air Sampler

Cycle-related Functions

	Airflow (m^3/hr)		Chamber Pressure (Pa)
	Relative Humidity (%)		Chamber Temperature (ºC)
	H_2O_2 concentration		
	Glove test start		Glove test stop
	Glove test		Cycle

Cycle recipes

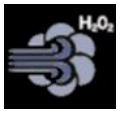
Process stop

A white icon depicts the currently selected module (shown on Info Page)

A grey icon depicts modules that are not currently selected (shown on Info Page)

Phase Icons

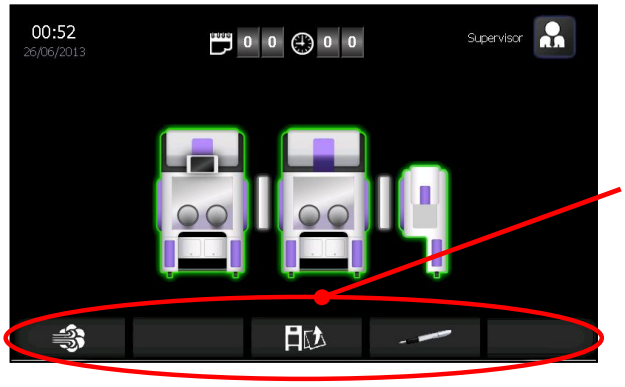
Conditioning



Gassing

Gassing dwell

Aeration



Navigation Bar

Keys within this bar enable access to additional screens and functions.

By pressing the module icon at any time the following information screen is displayed:

Information Page

The information displayed represents the chamber pressure, airflow, temperature, relative humidity and Hydrogen Peroxide concentration.

At any time the  button returns to the Home Page.

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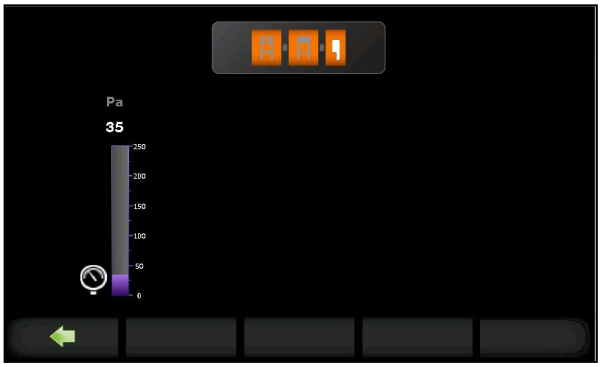
A similar page will display the pressure status of the QMTD, if selected:



At any time press the  button to toggle the light ON and OFF for the selected module (not during cycle).

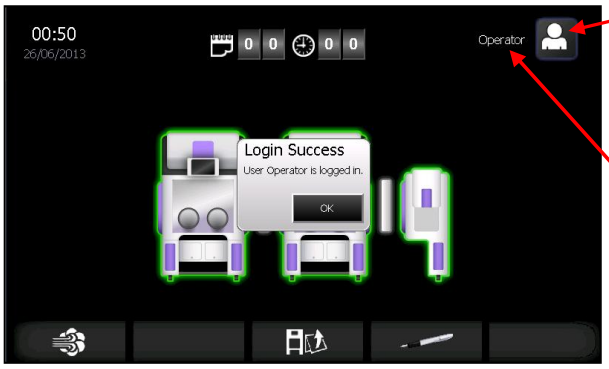
4.2 Logging ON

Initially  "No User" is displayed in the top right of the screen.

Press the  icon to log on.

Use the drop down arrow to select the User.

Enter password and click OK.



Icon displays access level (refer to Screen Navigation, Section 11, for access levels for different functions)

User Name

If the details have been entered correctly then the "Login Success" box is displayed.

Click OK.

If details have been entered incorrectly the “Login Failure” box will be displayed.

Click OK to return to the Login screen.

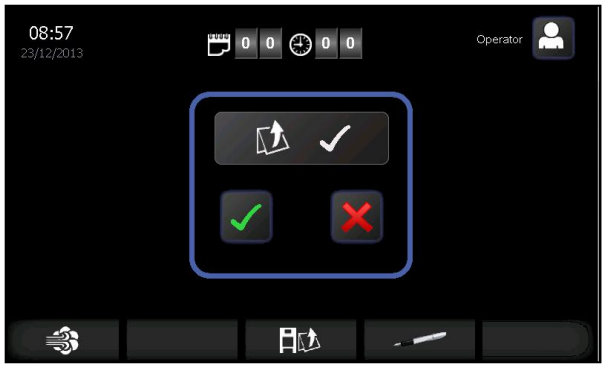
For more details on password management refer to Section 5.4.3.

4.2.1 Loading the QHPV chamber

This section outlines how to use the control panel to open the QHPV front access window.

> WARNING – By opening the front access window the chamber will no longer be aseptic and a decontamination cycle will need to be run to re-establish aseptic conditions.

On the Home Page press the  button. This button is only visible if the front access window can be opened (unlocked).



Press green ✓ to confirm that you want to open the window.

Alternatively, press the red ✗ to cancel the request.

Once the seal is deflated, as indicated by the chamber lights turning off, gently push the front window for it to release, and then allow it to open up.

The load can then be placed within the QUBE. The front access window is shut by pushing on the glove ports until closed. The seal will automatically re-inflate once the front access window is closed.

> WARNING – Do not attempt to close the front access window by pushing on the sides of the window as this could cause damage.

Use of racking, rails and SafeSort is optional and dependent upon the application. Contact Bioquell if a specific item is required.

4.2.2 Opening Doors

To open either of the side doors to enable the load to be transferred into a QEXT Module or QMTD or out of the QUBE system, press the foot switch below the door on the handle side to deflate the seal and then pull up the handle.

The doors can only be opened if it is safe to do so. The door indicator is illuminated green when they can be unlocked and flashes green when they can be opened.

4.3 Bio-decontamination Mode

Load the items to be gassed into the QHPV chamber as described in Section 4.2.1, ensuring good gassing presentation (occluded surface area of load is minimised). Specialist rails, racking and accessories are available from Bioquell for this purpose.

4.3.1 Preparing to Start a Cycle

Ensure sleeves are in correct position prior to starting a cycle; for positive pressure cycles refer to Figures 27 & 28 below. For negative pressure cycles fully extend the gloves and hang off internal racking or if not present use hanging rail (TD069-6300)

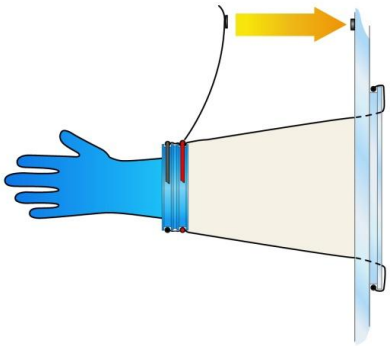


Figure 27: Attached by magnet to front window

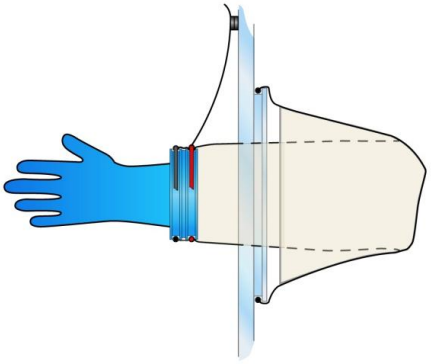
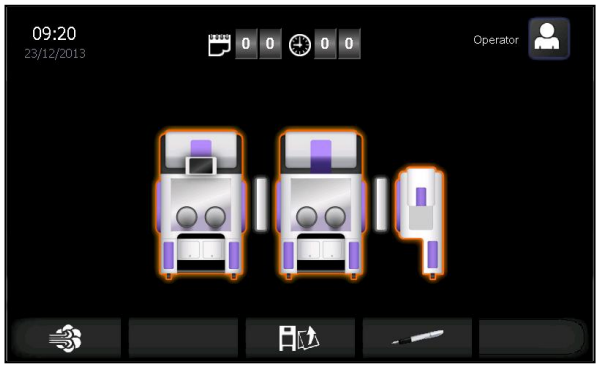


Figure 28: Correct position for gassing

The Operator must be LOGGED ON to run a gassing cycle. Refer to section 5.4.3 for information on managing users of the system.

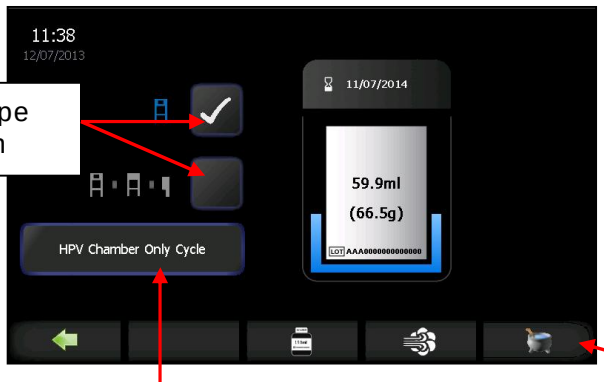


Home Page

This page depicts the system configuration.

Select the cycle button,  on the navigation bar.

The Cycle Start Page is displayed.



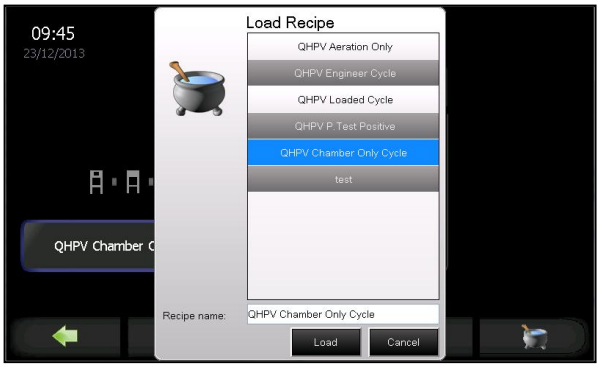
Cycle type selection

Cycle Start Page

Supervisor or above access level is required to change the type of cycle, i.e. complete system or HPV only cycle, after which an Operator can choose and run a cycle. After a complete system cycle it automatically reverts back to a HPV only cycle.

Cycle recipes (refer to Section 4.4)

The cycle name of the currently loaded cycle is displayed here. Press to view/ select from the list of cycles.



Select cycle recipe from the list shown.

Press “Load”.

Note:. The cycle used should be validated for the presentation and load being bio-decontaminated.

APPLICABLE TO USA ONLY The QUBE must be operated in accordance with the Bioquell Hydrogen Peroxide sterilant labelling. It is Federal offence to use pesticides in a manner inconsistent with their labelling.

4.3.2 Loading a Hydrogen Peroxide Bottle

If attempting to start a gassing cycle and there is either no bottle loaded, insufficient Hydrogen Peroxide within the bottle or it has expired, then the  button will not be visible.

Figure 29: Opening bottle module door

The bottle module door can only be opened manually if there is no bottle loaded. Otherwise, unlock by selecting the bottle changing function, 

, on the touch screen.

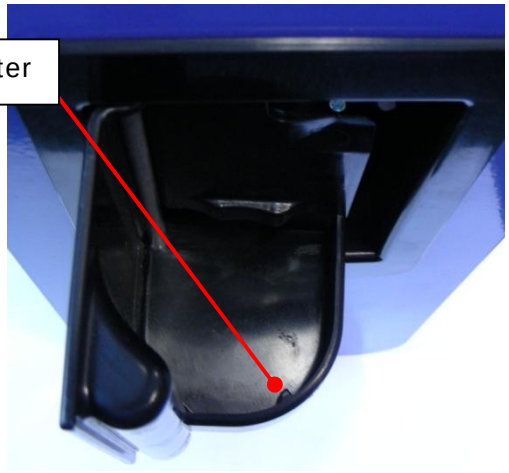


Figure 30: Location of bottle register

Unscrew the cap and keep safe.

 Failure to remove cap will damage equipment. Then, carefully place the H_2O_2 bottle upright into the holder ensuring the RFID symbol  on the bottle is at the back of the module then the bottle should locate on the register (as shown in Figure 24); slight rotation may be necessary until it drops down.

This ensures that once installed the RFID tag on the bottle is aligned correctly with the reader within the QUBE unit.

If there is insufficient Hydrogen Peroxide for the cycle the bottle must be changed.

To change the bottle press the 

button (only visible if bottle already loaded) and follow the actions depicted by the on-screen animation. The animation sequence depicted is dependent upon whether a bottle was installed to start with or not.

The following images assume the Hydrogen Peroxide is to be replenished; thus includes first removing the bottle:

1

Waiting for the bottle module to unlock

2

Bottle module ready to open

3

Operator to open the bottle module door

4

Bottle module door opened

5

Operator to remove existing bottle, if present, and discard in accordance with local regulations

6

Bottle module door open

7

To load new bottle Operator to:
Unscrew bottle cap by rotating counter-clockwise.

8

Operator to remove cap and keep.

9

Rotate the bottle to ensure the RFID symbol is to the right and then it will drop into place. Refer to Figure 30.

10

Operator to place bottle within bottle module.

11

Bottle loaded.

12

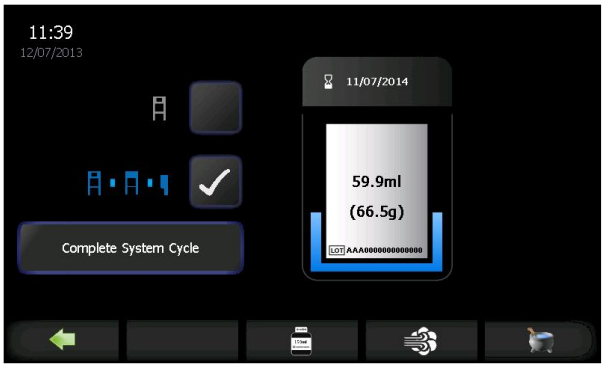
Operator to close bottle module by pushing gently. If the door cannot be closed because the bottle is protruding, rotate the bottle until it drops down and the bottle module door can be closed, or remove the lid.

Note: If the Hydrogen Peroxide is not going to be used for more than 3 days it is recommended that the bottle is removed, cap replaced and it is stored in a refrigerator or cool dark place.

The coloured surround to the bottle icon is a level indicator showing how much Peroxide is in the bottle. It is coloured blue if there is sufficient peroxide and amber if there is insufficient peroxide for the currently selected cycle.

A representation of the volume of Hydrogen Peroxide left in the bottle is displayed in the centre of the bottle icon, in ml and g. The Lot No. of the peroxide is shown at the bottom of the bottle and the expiry date at the top. If the date has expired the icon will flash amber.

4.3.3 Running a Cycle



To run the selected cycle press the  button.

Press the ✓ to start the currently loaded cycle.

Or, press ✗ to cancel the request.

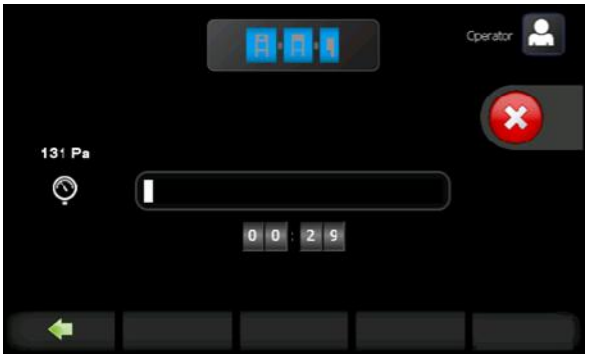
When confirmation is received the timer will automatically start and display the phase count down, as shown in the following screens.

4.3.4 Cycle Phases

The progress bar colour displayed is an indication of the cycle phase (white while pressurising and green during actual pressure decay test; blue for conditioning and gassing phases; amber for the aeration phase). Progress of the coloured bar indicates the time to complete the phase. The progress bar turns green at the end of aeration.

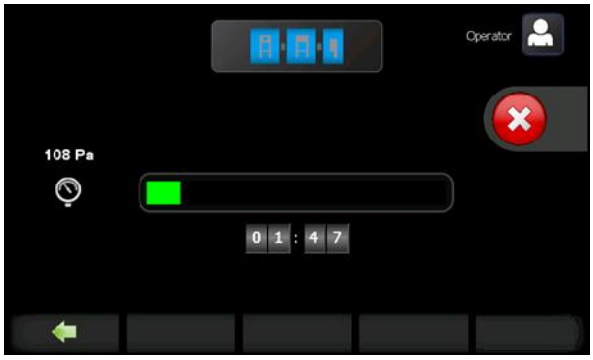
4.3.4.1 Pressure test (optional)

The pressure test, for checking QUBE leak integrity, can be done as a stand-alone test, or it can be at the beginning of a cycle. The chamber is pressurised to a set pressure. The pressure change is monitored and if it changes more than a set value within a given time the system shuts down.



The unit will initially build-up pressure to the set point, only the pressure will be displayed.

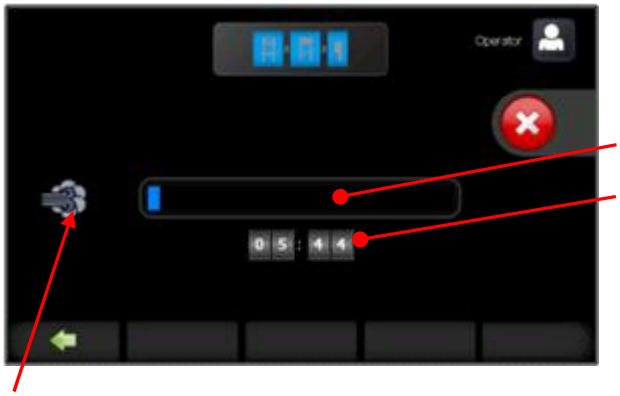
When the pressure has been reached, the unit goes through a stabilisation phase, when a white slider and a countdown will also be displayed.



The green slider represents the leak test in progress with the countdown time displayed.

4.3.4.2 Conditioning Phase

When the unit starts conditioning the system initialises, configures itself, and the vaporiser gets up to its operating temperature.



Progress bar

Phase countdown (Conditioning takes 7 minutes)

Conditioning phase icon

4.3.4.3 Gassing Phase

Liquid from the bottle is pumped onto a vaporiser. Air then passes around the vaporiser where it picks up the H_2O_2 vapour for distribution.
The air circulation system has been designed to distribute the hot vapour evenly throughout the chamber(s) being bio-decontaminated.

The screen depicted during gassing phase of cycle.

4.3.4.4 Gassing Dwell Phase

On completion of the dwell phase the cycle automatically proceeds to the aeration phase.

By pressing on the small blue icon for the module being gassed the critical parameters may be viewed. The white icon depicts the currently selected module.

These parameters may be viewed at any time during a cycle.

Press  to return to Home Page.

4.3.4.5 Aeration Phase and Aeration Only Cycle

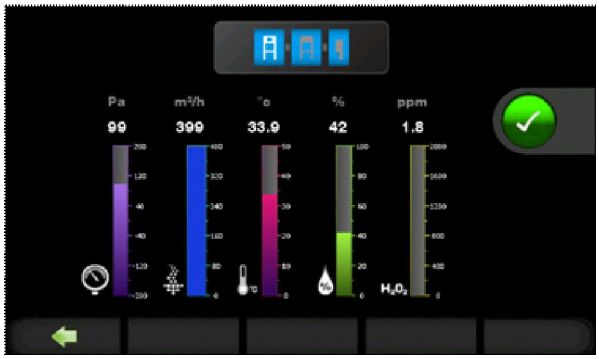
A catalyst within the QUBE converts the Hydrogen Peroxide (H_2O_2) Vapour into Water Vapour and Oxygen.

An 'Aeration only' cycle can be loaded and run just like a complete cycle. This cycle only runs the aeration phase. It ought to be run if the QUBE has alarmed mid cycle and the Hydrogen Peroxide requires removing.

4.3.4.6 End of cycle

On completion of Aeration the Operator is prompted to confirm the end of the cycle. At the end of a successful cycle, i.e. the Hydrogen Peroxide concentration is below the preset level (a preset cycle parameter) the  replaces the  and is visible on any page (as shown on the Information Page below). The Hydrogen Peroxide level in the chamber should be checked periodically at the end of the cycle by an independent low level Hydrogen Peroxide measuring device. There is a test point on the window to enable the sample to be taken. Note the concentration level indicated on the screen will be higher than a low level measurement due to the lag on the sensor.

During this period the Aeration flow rate is cut back. This allows it to be left running in this state for an extended period, for example over night, and ensures there is no additional increase in chamber temperature.



Press the  to end the cycle.

A confirmation box will appear:

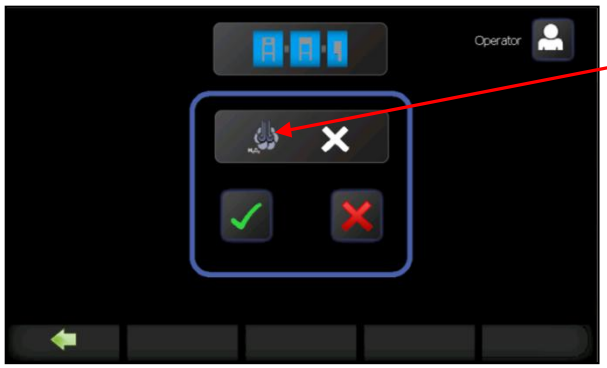
Press the ✓ to confirm.

Once confirmed the screen will revert to the Home Page.

4.3.5 Aborting a cycle

At any time a cycle can be aborted by pressing the  button, as shown on the following screen. Alarm number 127 will be displayed.

A confirmation screen will appear:



Dwell phase icon (the appropriate icon will be displayed dependent upon the phase).

Press the ✓ to confirm, or, press ✗ to cancel the request.

Once confirmed, the screen will revert to the Home Page with the associated alarm displayed.

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4.3.6 Printouts

4.3.6.1 Cycle Printout (QHPV)

The following information will be included on the cycle printout:

HEADER:

- Time and Date
- Software versions
- Serial Number (of QUBE system)
- Cycle count
- Calibration due date

DECONTAMINATION INFORMATION:

- H_2O_2 Lot Number

CYCLE INFORMATION:

- Cycle Name
- Cycle parameters
- Current time and phase status (i.e. Conditioning, Gassing, Gassing Dwell, Aeration and Complete) including parameters (i.e. chamber pressure, temperature and RH; peak H_2O_2.)
- Operator Name
- Signature Box

ALARMS AND WARNINGS:

- Alarm details if cycle failed

4.3.6.2 Product Transfer Printout (QMTD Option)

If part of the configured system, the User can print a load data exit report, including:

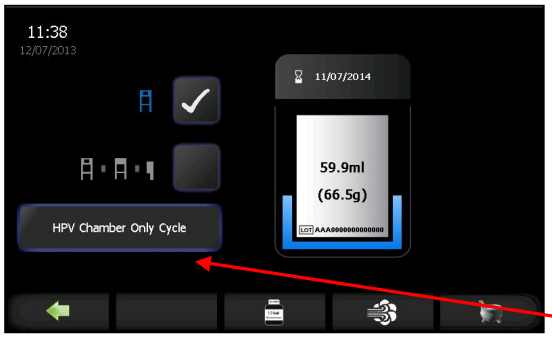
- References from the QUBE plus time and date record
- Aseptic hold status of the processing modules
- Space for entering signature
- Space for manually entering load reference

4.4 Cycle Recipes

There are two sets of recipes: one set for a single QHPV module and one set for the complete QUBE system.

4.4.1 Viewing Recipes

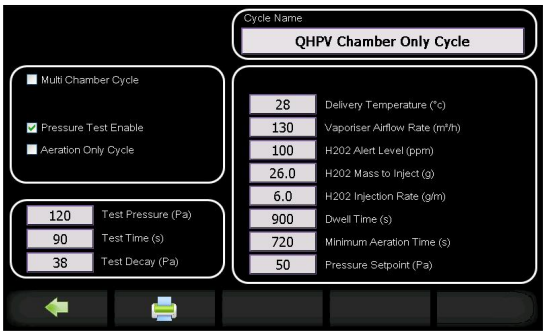
For QHPV only cycles those with Operator or above access level may view the cycle parameters. For full system cycles those with Supervisor or above access level may view them.



Select the recipe as described in 4.3.1.

Press the  to view the stored parameters for the selected recipe.

Press this button to view the list of stored cycle recipes.



This list of recipe parameters can also be printed by pressing  .

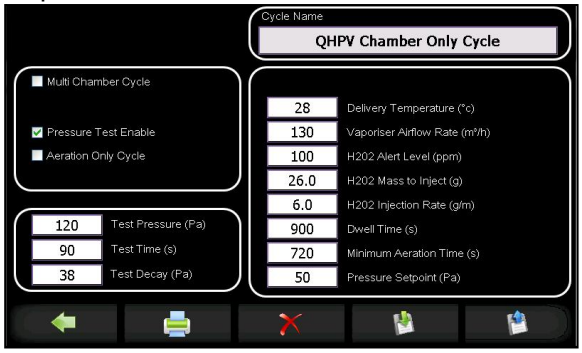
4.4.2 Pre-Loaded Recipes

The Qube comes with four pre-programmed QHPV and system cycles:

1. Aeration only – This runs Aeration only for one hour, and is for use after an alarm
2. Pre validated cycle – QHPV Loaded Cycle, standard pre-validated cycle for a typical QHPV load. System Empty Cycle, standard pre-validated cycle for an empty system to start aseptic hold.
3. Engineering Cycle – This cycle is for the Service technician to use when checking the unit.
4. P. Test Positive – This is the standard 1% positive pressure decay test

4.4.3 Creation and Editing Recipes

From the Cycle Start Page press the  to view the parameters of the loaded recipe.

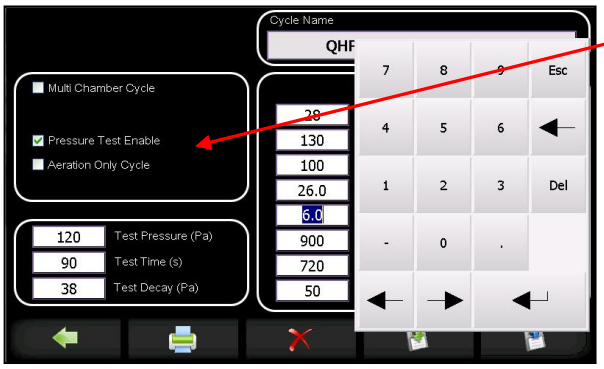


Those with ADMINISTRATOR access may edit the stored recipe parameters and create new recipes.

The following table details the recipe parameters that can be altered:

Description	Units	Limits
Multi chamber	-	ON/OFF
Pressure Test Only	-	ON/OFF
Pressure Test Enable	-	ON/OFF
Aeration Only Cycle	-	ON/OFF
Parametric gassing	-	ON/OFF
Cycle Name	-	24 characters
Test Pressure	Pa	-240 - +240
Test Time	s	0 - 9999
Test Decay	Pa	1 - 200
Recirc Flow Rate	%	0 - 100
Delivery Temperature	ºC	15 - 45
Vaporiser Airflow Rate	m^3/h	5 - 400
H2O2 Alert Level	ppm	0 - 1000
H2O2 Mass to Inject	g	5 - 166
H2O2 Injection Rate	g/min	1.5 - 6.0
Dwell Time	s	120 - 9999
Minimum Aeration Time	s	300 - 9999
Pressure Setpoint	Pa	-100 to +100

To create new or edit existing recipes:



For new cycles start by removing all the ticks in the left hand box. Then choose the type of cycle and edit the parameters to the values required via the numerical keypad. (If Multi Chamber Cycle is not ticked it will be a QHPV only cycle)

When all values have been entered press the  button, rename the recipe (if required), then load it by depressing the  button.

A recipe can also be deleted by pressing  . A confirmation box will appear.

Applicable to USA only : The QUBE must be operated in accordance with the Bioquell Hydrogen Peroxide sterilant labelling. It is Federal offence to use pesticides in a manner inconsistent with their labelling.

4.5 Pressure Testing

4.5.1 Chamber Leak Test

A monitoring chamber leak test may be performed at negative or positive pressure on the QHPV chamber only or the complete QUBE system.

The chamber leak test may form part of the loaded cycle or may be a separate user-selectable cycle. Refer to Section 4.4 for loading cycles.

The cycle is run in the same way as a decontamination cycle (as discussed in Section 4.3.4).

If unsuccessful an alarm icon will appear in the navigation bar and the QUBE system will end the sequence. Refer to Section 7.1.1 for an explanation of the alarm screen.

On successful completion of a separate test use the  button to return to the Home Page.

4.5.2 Glove Leak Testing (optional)

The operation of the Glove Tester (TD069-5900) is described in separate instructions TD069-5900_PDS, supplied with the tester.

4.6 Operation of the Sterility Test Pump (optional)

Refer to Manufacturer's instructions for the correct operational procedure. This is supplied separately from this Manual.

4.7 Operation of Active Air Sampler

The active air sampler, part of the Level 2 and Level 3 Environmental Monitoring Options, (as shown in Figs. 14 and 15) should be permanently placed within the QUBE and is connected through a dedicated connector (Item 2 in Fig. 21). Refer to Manufacturer's instructions for the correct operational procedure.
The power device (shown in Fig. 12) is only required for use with customer supplied air samplers.

Air is aspirated at a fixed speed for period of time through a cover. The resulting laminar air flow is directed onto the agar surface of a "Contact Plate".

Figure 28: Removal of aspirating head

Remove the aspirating head by unscrewing from the body.

Remove cover from Contact Plate.

Figure 29: Contact Plate

Place Contact Plate into sampling unit – using standard 90mm Contact Plates; held in place by the sprung tab.

Replace aspirating head.

To operate, navigate to the Information Page for the relevant chamber.

Start the timer by pressing the  button (visible only when configuration includes Level 2 Environmental Monitoring Option).

The sampler, supplied by Bioquell (TD069-0620), has a sampling rate of 180 litres/min and runs for a set period of 5 minutes 33 seconds.

When the sampling cycle is completed, the plate is removed and incubated. The organisms are then visible to the naked eye and can be counted for an assessment of the level of contamination (colony forming units).

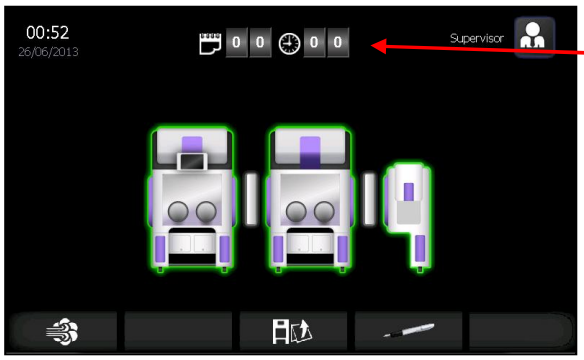
The manufacturer recommends that re-calibration of the Active Air Sampler is performed every 6–12 months and also if the air sampler has potentially been damaged or the flow rate has been compromised.

4.8 Aseptic Hold

The Aseptic Hold period is the validated time that aseptic conditions can be maintained after a decontamination cycle of the complete system has been run. This period must be validated for each installation, and Bioquell can assist in this process.

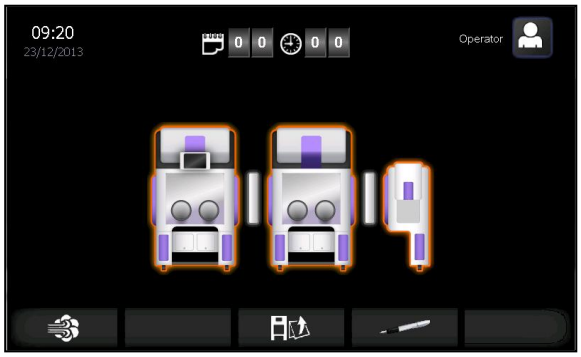
The display shows the user the time elapsed since the aseptic hold was established by the completion of a successful decontamination cycle.

The timer starts when a complete system decontamination has finished and ends when there has been a system breach: a pressure or airflow alarm, the front door has been opened or the timer ends (which is set in the Administration screen). The aseptic hold period is only applicable to QEXT modules.



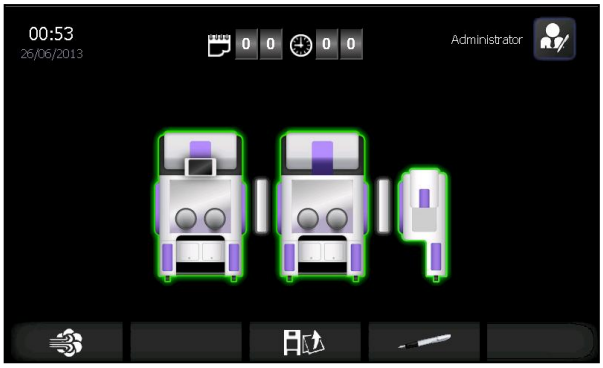
Aseptic hold period displayed here (days and hours).

In case of power failure the QUBE system has been designed to ensure that the seals remain inflated, to maintain containment, but aseptic hold will end as pressure and airflow will be out of specification.



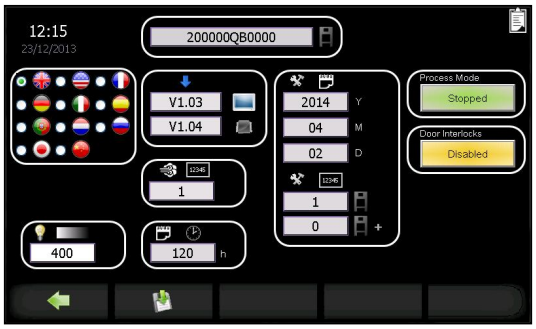
The amber coloured surround to the modules means the aseptic hold has been breached.

5 SYSTEM ADMINISTRATION

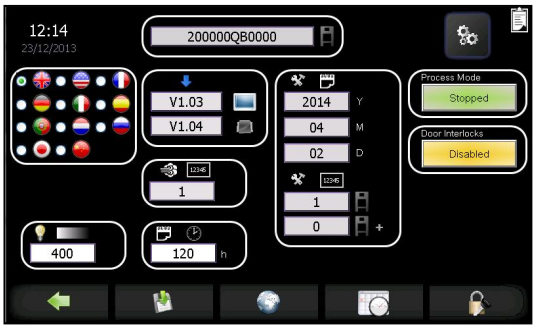


From the Home Page press the  button to display the Administration Page.

The  button is only visible when LOGGED ON and once pressed displays the following screens (dependent upon access level):



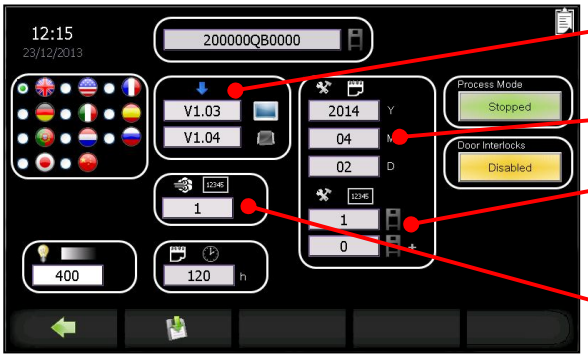
Operator access level screen



Administrator access level screen

Only the white boxes (language and light level) are editable by an Operator. Other options require higher level access, i.e. change date and time, manage passwords and user access, and view system information.

5.1 System Information (only viewable)



Software versions for the HMI (top) and controller (bottom).

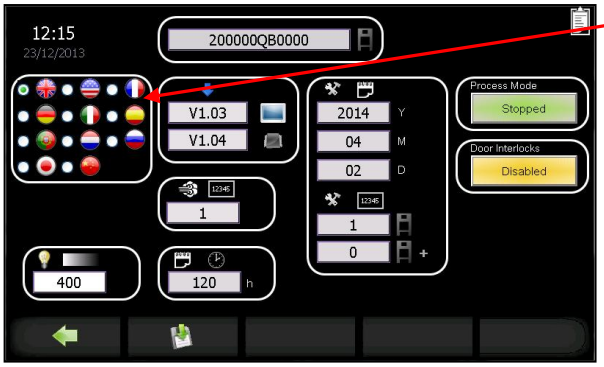
Service due date

Number of cycles since last service on QHPV unit only (top) and system (bottom).

Total cycle count (all cycles).

5.2 OPERATOR editable functions

5.2.1 Set Language

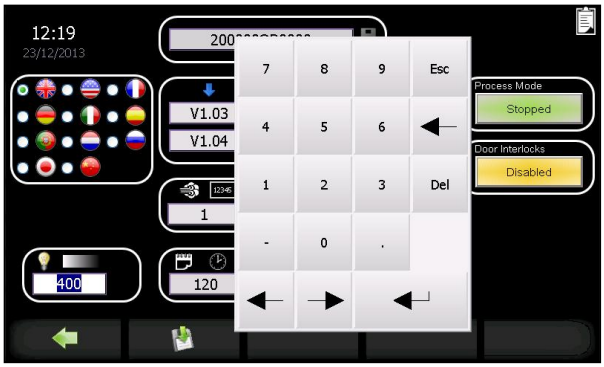


Press the applicable radio button for the required screen language.

Press  to make changes permanent.

5.2.2 Adjust Chamber light intensity

Any user may adjust the white light intensity for ease of use for the whole system.



A standard numerical keypad is displayed.

Enter a value between 0 and 400 and press  to accept.

When the light level is acceptable press the  button to make the change permanent and  to return to the Home Page.

5.3 SUPERVISOR editable functions

The following functions are editable by those with SUPERVISOR access rights.

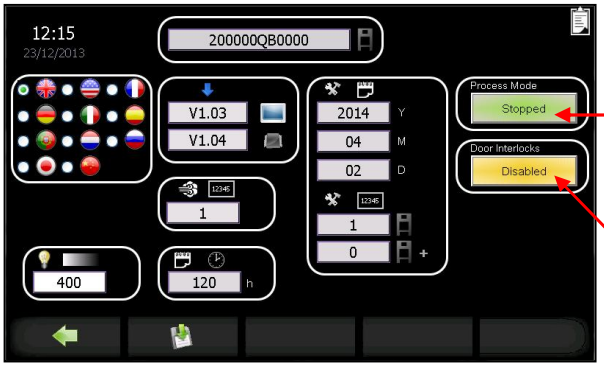
5.3.1 Suspending Processing Mode - system use not required

If the QUBE is not required to be used for a prolonged period, and thus the fans need not run, it is recommended that the QUBE is turned off at the power button on the back of the unit when it is in Process Mode.

If the QUBE is ducted and extract out of the room must be maintained, then an administrator can switch the processing mode status button to 'Stopped', (see following screen). Then all internal doors must be left open, to do this first disable

the door interlocks (see following screen) and at least one glove is to be removed, this is to stop a pressure build-up in the chamber.

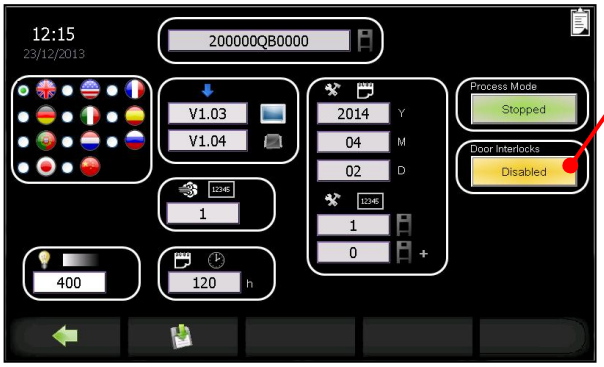
When the unit is to be used again, a decontamination cycle of the whole system should be run, and this will set the system back into normal operation.



'Process Mode' button shows 'Running' for normal running, 'Stopped' for when not in use.

'Door Interlocks' button shows 'Enabled' for normal running, 'Disabled' to allow internal doors to be opened

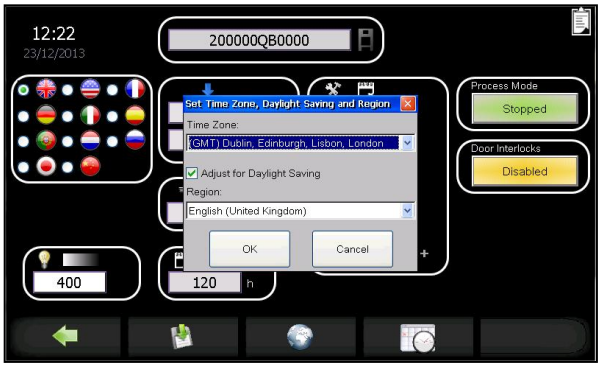
5.3.2 Door Interlocks



Press 'Door Interlocks' button to 'Disabled' to allow any door to be opened thus overriding the door interlock logic.

5.3.3 Set Time Zone

The QUBE control system incorporates a real time clock. The time zone and region is settable.

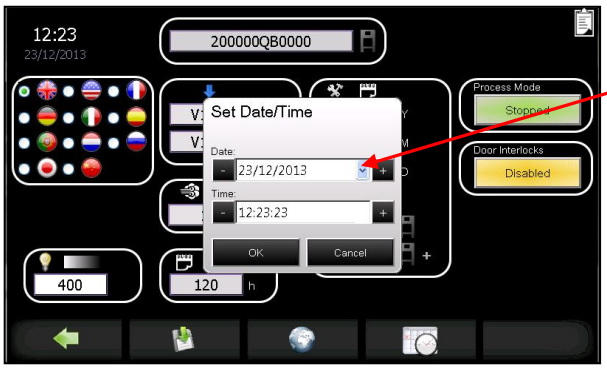


Press the  button.

The pop-up box that appears enables the User, via the drop down arrows and scroll bar, to select the appropriate time zone and region.

Click OK to accept.

5.3.4 Date and Time



To set the date, press the  button.

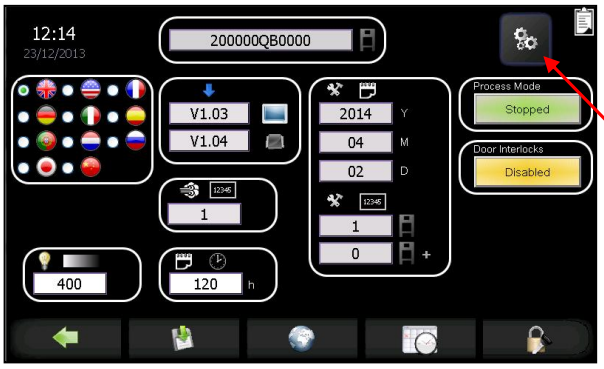
Use the "-" or "+" buttons or press the drop down arrow to access the calendar.

Use the "-" or "+" buttons to increase or decrease the time in minutes.

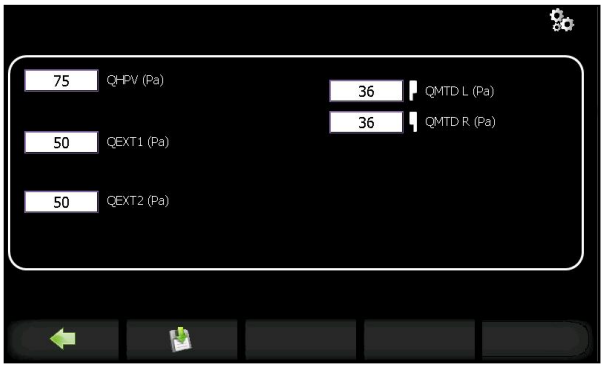
Click OK to accept.

5.4 ADMINISTRATOR editable functions

5.4.1 Pressure Setpoints



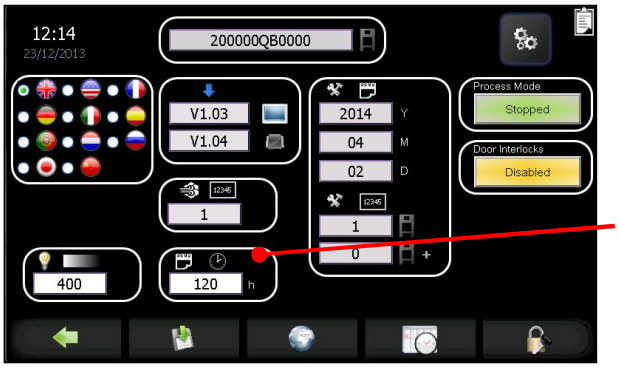
Press to enable editing of module pressure setpoints. Button is not visible at Operator and Supervisor access levels.



Edit to set the pressure regime of individual modules.

Ranges:
-60 to +75Pa (for QHPV, QEXT1, QEXT2)
0 to +100Pa (for QMTDL and QMTDR)

5.4.2 Maximum Aseptic Hold Period



To alter the maximum aseptic hold period (in hours) after gassing press the white box and enter new time into keypad.

5.4.3 Manage Users

This access level is required to edit passwords and user access levels.

Press the  button to access the functions.

The list of Users is displayed.

At any time the User can return to the Administration Page by selecting ‘Close’.

5.4.3.1 Adding New Users

In the displayed boxes enter the User’s name and password.

The ‘Description’ box may be left blank or a reference may be added.

The password chosen must be unique to each individual, and contain a minimum of 3 and a maximum of 24 alphanumeric characters. *Note: More characters may be entered but only the first 24 characters will be displayed*.

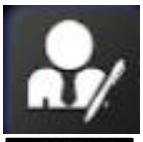
Select ‘Next’ to proceed to the next screen or ‘Cancel’ to return to the Administration Page.

Select the access level the new User is to be given.

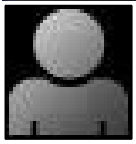
There are three user groups that a person can be put in; these are listed below:

OPERATOR — Someone in this group can start and stop a pre-programmed recipe; run the glove tester; open QHPV door; adjust chamber light intensity; start active air sampler; load Hydrogen Peroxide.

SUPERVISOR — As for OPERATOR plus the ability to change cycle type plus additional administrative functions described in 5.3.



ADMINISTRATOR — As for SUPERVISOR plus the ability to edit recipes and additional administrative functions described in section 5.4.



NO USER — No user is logged in. Access to the Home Page and Information Page is permitted, but all navigation keys are disabled.

Note: 'NO USER' is not selectable.

5.4.3.2 Changing Access Level

Select the person's name for which access level is to be changed.

Select 'Edit'.

Enter the User's details.

Select 'Next'.

Select access level to which the User is to be assigned.

Then select 'Finish'.

5.4.3.3 Deleting Users

Select the name of the User to be removed.

Select 'Remove'.

A prompt box appears. Select 'YES' to remove the User or 'NO' to return to the previous screen.

6 PREVENTATIVE & SCHEDULED MAINTENANCE

6.1 Operator Maintenance

6.1.1 Cleaning

The QUBE exterior surfaces are manufactured from Polypropylene, ABS/PC, painted Polyurethane, Epoxy coated Aluminium Alloy and Stainless Steel.

To keep the QUBE exterior surfaces clean the following procedure is recommended:

1. Using a mild detergent solution (non abrasive) wipe the external surfaces with a damp cloth taking care not to wet the control panel. All electrical connections should be capped.
2. Rinse cloth and wipe thoroughly.
3. Dry surfaces with a lint-free clean cloth.

If cleaning near the mains power input then the QUBE should be switched off; otherwise power can be left on.

Compatibility of different cleaning solutions with the QUBE materials of construction cannot be guaranteed.

For internal cleaning Bioquell recommend use of KLERWIPE-CR (wipes), Biocides A, B, C or D, from www.shieldmedicare.com.

Ensure all internal electrical connections are capped when cleaning the chamber interior.

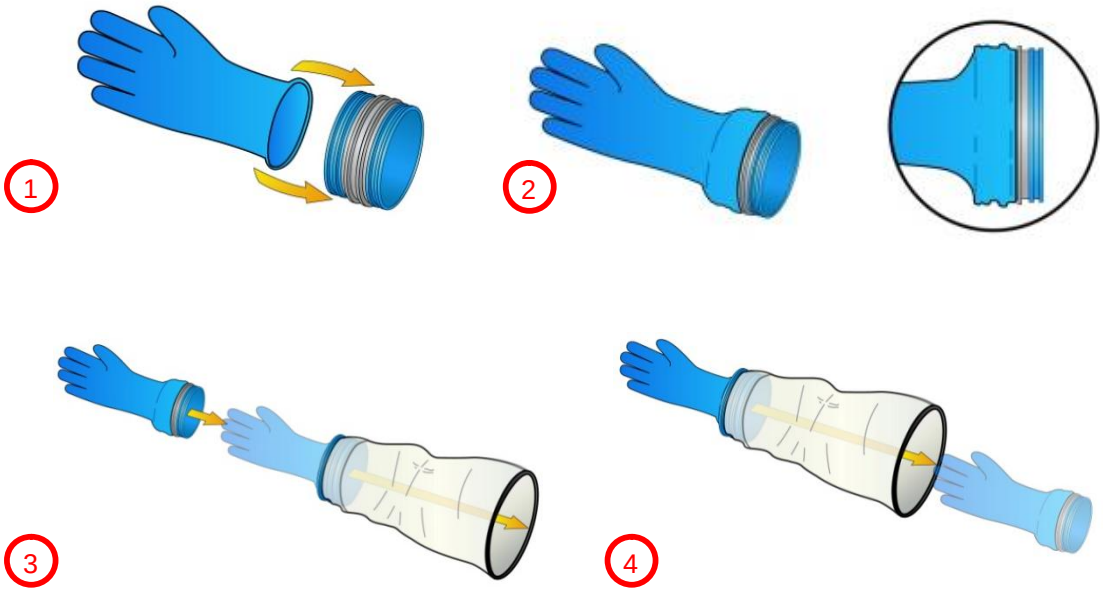
WARNINGS – The control panel screen will be damaged if cleaned with a solvent containing solution.

Never use solutions containing Chlorine such as bleach on Stainless Steel.

Do not use alcohol or similar cleaning agents as it will adversely affect the Hydrogen Peroxide Sensor

6.1.2 Replacing Gloves

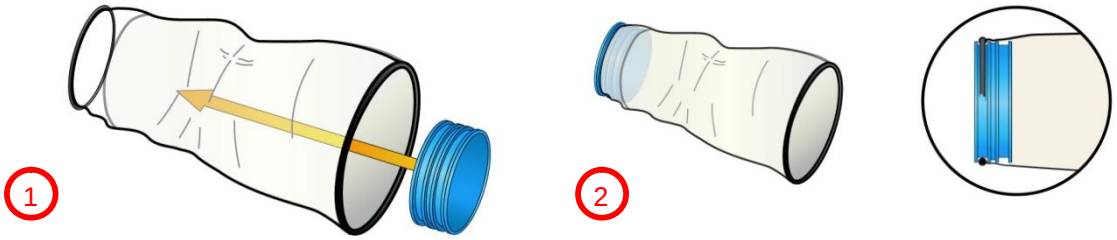
Follow the procedure described in the images below to change the safe change gloves. Within the QUBE decontaminate the cuffs and sealed pack of sterile gloves.
This allows for the old glove and cuff to be ejected out of the QUBE while maintaining aseptic conditions:

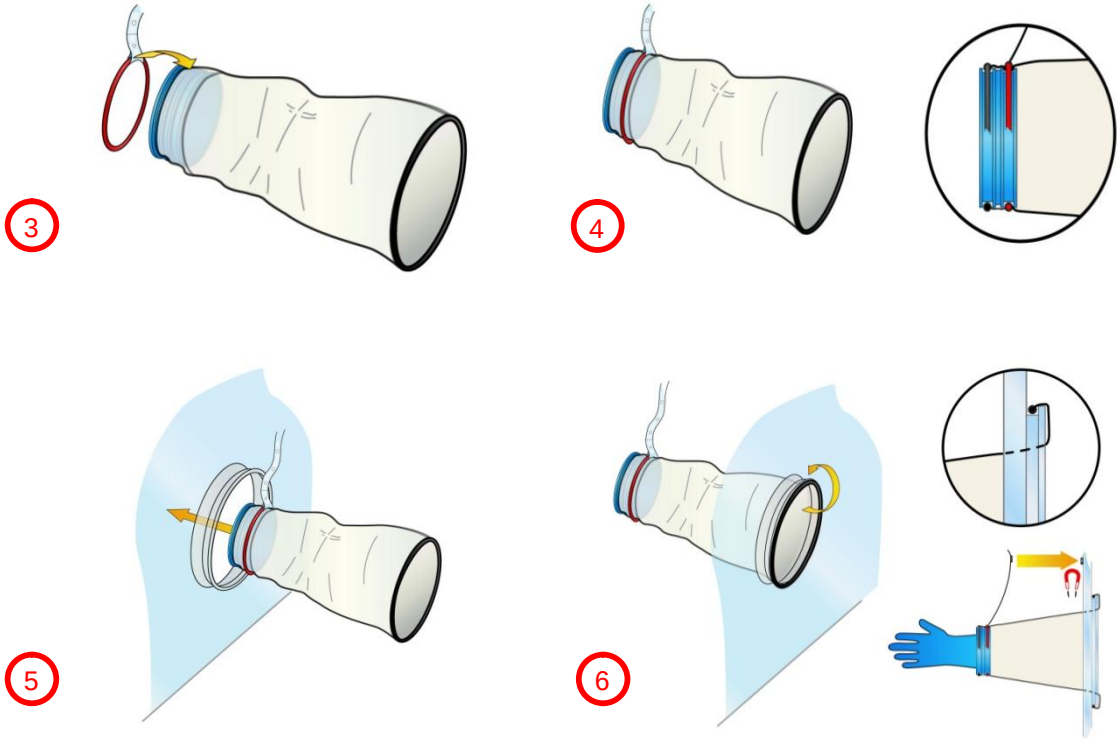


NOTE: Ensure only Hydrogen Peroxide compatible gloves are used (BQ Part No H07990534).

6.1.3 Fitting New Sleeves

Follow the procedure described in the images below:





6.1.4 Changing the Printer Paper

The paper required for the printer is available from Bioquell (BQ Part No. 7050-00003).

To change the printer paper, proceed as follows:

Open the printer cover by gently lifting the green part.

Replace with a new roll of paper ensuring correct orientation (as shown).

Push cover closed. The printer is now ready to use.

6.2 Scheduled Maintenance

For GMP compliance sensor calibration and functional checks may be performed on a 6-monthly basis, depending on application assessment. Otherwise scheduled Routine maintenance should be performed on an annual basis with a Major Service every 4 years.

Only genuine replacement parts supplied by a Bioquell-trained Service Provider must be used to ensure safe operation.

Servicing of optionally supplied sub-systems, i.e. Sterility Test Pump, environmental monitoring particle counter ought to be performed by the equipment supplier during the QUBE scheduled service visit.

The following web link details all the Merck /EMD Millipore offices around the globe to arrange servicing of the Sterility Test Pump:
http://www.millipore.com/offices/cp3/officeshome

The following web link provides the contact details for Pharmagraph global agents to arrange servicing of the Particle Monitoring System:
http://www.pharmagraph.co.uk/agents/locations-worldwide/agents/12-13

7 TROUBLESHOOTING

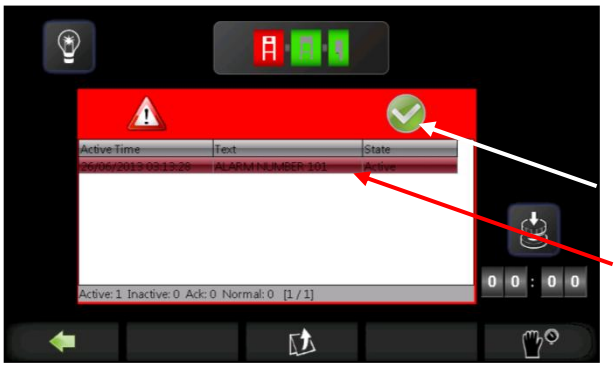
7.1 Alarms & Warnings

If there is an active alarm the  is visible and an audible warning is given. If there is an active unacknowledged alarm then it will flash. The associated alarm reference number is displayed on screen and also printed.

7.1.1 Alarm Screen

The module with the active alarm will be coloured red.

Depressing the  button toggles the alarm view.



The screen will display the alarm number and the associated module (via the red icon).

When the  button is depressed the alarm is acknowledged.

The alarm number.

The alarm will only be removed if the alarm condition is not present.

Press the  button to hide the alarm screen.

If a cycle aborts during a decontamination cycle, run an 'Aeration Only' cycle to remove the HPV, see section 4.3.4.5.
The number of potential alarms is dependent upon the configuration installed.

QHPV active alarms abort all decontamination cycles.

Module alarms abort system decontamination cycles.

Many of the alarms have common actions:

No.	Module	Description	Condition	*Action	User Action
1	QMTD_L	Door timeout	Unable to achieve locking or unlocking of door in time available.	2 Removes air from seal	Open and shut door, check seal for leaks
2	QMTD_L	Door open	Door is open when it should be locked closed.	2	Close QMTD door
3	QMTD_L	Air inlet valve fault	If valve not in position and transition monitor time expired.	2	Contact Bioquell
4	QMTD_L	Air exhaust valve fault	If valve not in position and transition monitor time expired.	2	Contact Bioquell
5	QMTD_L	Hatch pressure sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
6	QMTD_L	Hatch pressure low	If in Processing Mode and pressure below alarm low limit and mask time expired.	No Action	Identify and resolve any leaks
7	QMTD_L	Hatch pressure high	If in Processing Mode and pressure below alarm high limit and mask time expired.	No Action	Identify and resolve any leaks
9	QMTD_R	Door timeout	Unable to achieve locking or unlocking of door in time available.	2 Removes air from seal	Open and shut door, check seal for leaks
10	QMTD_R	Door open	Door is open when it should be locked closed.	2	Close QMTD Door
11	QMTD_R	Air inlet valve fault	If valve not in position and transition monitor time expired.	2	Contact Bioquell
12	QMTD_R	Air exhaust valve fault	If valve not in position and transition monitor time expired.	2	Contact Bioquell
13	QMTD_R	Hatch pressure sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
14	QMTD_R	Hatch pressure low	If in Processing Mode and pressure below alarm low limit and mask time expired.	No Action	Identify and resolve any leaks
15	QMTD_R	Hatch pressure high	If in Processing Mode and pressure below alarm high limit and mask time expired.	No Action	Identify and resolve any leaks

No.	Module	Description	Condition	*Action	User Action
17	QEXT1	Air inlet valve fault	If valve not in position and transition monitor time expired.	2	Contact Bioquell
18	QEXT1	Air exhaust valve fault	If valve not in position and transition monitor time expired.	2	Contact Bioquell
19	QEXT1	Particle counter divert valve fault	If Level 3 monitoring option enabled and valve not in position and transition monitor time expired.	2	Contact Bioquell
20	QEXT1	Active air sampler fault	If Level 2 monitoring option enabled and no signal received from Air Sampler.	Turns sampler off	Check air sampler is plugged in, check dish is fitted
21	QEXT1	Extract duct pressure fault	If option enabled and pressure higher than pressure switch setting.	2	Check duct fan operation. Check tube from duct to back of unit.
22	QEXT1	EMM fan rotation fault	No tacho feedback signal received from EMM fan.	2	Contact Bioquell
23	QEXT1	Centre door timeout	Unable to achieve locking or unlocking of door in time available.	2	Open and shut door, check seal for leaks
24	QEXT1	Centre door open	Door is open when it should be closed.	2,3	Close Centre door
25	QEXT1	QSDM door timeout	Unable to achieve locking or unlocking of door in time available.	2	Open and shut door, check seal for leaks
26	QEXT1	QSDM door Open	Door is open when it should be locked closed.	2	Close Side door
27	QEXT1	Chamber pressure sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
28	QEXT1	Return airflow pressure sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
29	QEXT1	EMM humidity sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
30	QEXT1	EMM chamber temperature sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
31	QEXT1	EMM_H2O2 sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
32	QEXT1	Chamber pressure low	Actual pressure lower than setpoint minus offset.	2,3	Identify and resolve any leaks
33	QEXT1	Chamber pressure high	Actual pressure higher than setpoint plus offset.	2,3	Identify and remove any blockages

No.	Module	Description	Condition	*Action	User Action
34	QEXT1	Return airflow low	Actual airflow is lower than setpoint minus offset.	2,3	Remove back filter cover and inspect for any obstructions
35	QEXT1	Return airflow high	Actual airflow is higher than setpoint plus offset.	2,3	Contact Bioquell
37	QEXT1	Chamber humidity high	If in Process mode and RH level above alarm limit and mask time expired.	Warning only	Reduce humidity in room
39	QEXT1	Chamber temperature high	If in Process mode and Temperature above alarm limit and mask time expired.	Warning only	Reduce room temperature
40	QEXT1	Left-hand recirculation fan rotation fault	If system cycle, no tacho feedback signal has been received from LH chamber recirculation (stirrer) fan. If option enabled.	2	Contact Bioquell
41	QEXT1	Right-hand recirculation fan rotation fault	If system cycle, no tacho feedback signal has been received from RH chamber recirculation (stirrer) fan. If option enabled.	2	Contact Bioquell
42	QEXT1	Module connection fault	Communication cable between QHPV and QEXT not connected.	2	Contact Bioquell
43	QEXT1	PPM level not achieved	If in cycle and H_2O_2 Alert level cycle parameter not achieved by end of gassing.	2	Re-run the cycle
44	QEXT1	QSDM door closed	If in multi chamber cycle and door closed.	2	Open door, re-run cycle
45	QEXT1	RH level not achieved	If in cycle and RH Alert limit not achieved by end of gassing.	2	Re-run cycle
49	QEXT2	Air inlet valve fault	If valve not in position and transition monitor time expired.	2	Contact Bioquell
50	QEXT2	Air exhaust valve fault	If valve not in position and transition monitor time expired.	2	Contact Bioquell
51	QEXT2	Particle counter divert valve fault	If Level 3 monitoring option enabled and valve not in position and transition monitor time expired.	2	Contact Bioquell
52	QEXT2	Active air sampler fault	If Level 2 monitoring option enabled and no signal received from Air Sampler.	Turns sampler off	Check air sampler is plugged in, check dish is fitted
53	QEXT2	Extract duct pressure fault	If option enabled and pressure higher than pressure switch setting.	2	Check duct fan operation. Check tube from duct to back of unit
54	QEXT2	EMM fan rotation fault	No tacho feedback signal received from EMM fan.	2	Contact Bioquell

No.	Module	Description	Condition	*Action	User Action
55	QEXT2	Centre door timeout	Unable to achieve locking or unlocking of door in time available.	2	Open and shut door, check seal for leaks
56	QEXT2	Centre door open	Door is open when it should be closed.	2,3	Close centre door
57	QEXT2	QSDM door timeout	Unable to achieve locking or unlocking of door in time available.	2	Open and shut door, check seal for leaks
58	QEXT2	QSDM door open	Door is open when it should be locked closed.	2	Close side door
59	QEXT2	Chamber pressure sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
60	QEXT2	Return airflow pressure sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
61	QEXT2	EMM humidity sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
62	QEXT2	EMM chamber temperature sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
63	QEXT2	EMM_H2O2 sensor error	Always active, if 4-20mA signal <3mA.	2	Contact Bioquell
64	QEXT2	Chamber pressure low	Actual pressure lower than setpoint minus offset.	2,3	Identify and resolve any leaks
65	QEXT2	Chamber pressure high	Actual pressure higher than setpoint plus offset.	2,3	Identify and resolve any blockages
66	QEXT2	Return airflow low	Actual airflow is lower than setpoint minus offset.	2,3	Remove back filter cover and inspect for any obstructions
67	QEXT2	Return airflow high	Actual airflow is higher than setpoint plus offset.	2,3	Contact Bioquell
69	QEXT2	Chamber humidity high	If in Process mode and RH level above alarm limit and mask time expired.	No Action	Reduce humidity in room
71	QEXT2	Chamber temperature high	If in Process mode and temperature above alarm limit and mask time expired.	Warning only	Reduce room temperature
72	QEXT2	Left-hand recirculation fan rotation fault	If system cycle, no tacho feedback signal has been received from LH chamber recirculation (stirrer) fan. If option enabled.	2	Contact Bioquell
73	QEXT2	Right-hand recirculation fan rotation fault	If system cycle, no tacho feedback signal has been received from RH chamber recirculation (stirrer) fan. If option enabled.	2	Contact Bioquell

No.	Module	Description	Condition	*Action	User Action
74	QEXT2	Module connection fault	Communication cable between QHPV and QEXT not connected.	2	Contact Bioquell
75	QEXT2	PPM level not achieved	If in cycle and H_2O_2 Alert level cycle parameter not achieved by end of gassing.	2	Re-run the cycle
76	QEXT2	QSDM door closed	If in multi chamber cycle and door closed.	2	Open door and re-run cycle
77	QEXT2	RH level not achieved	If in cycle and RH Alert limit not achieved by end of gassing.	2	Re-run cycle
81	QHPV	RFID reader error	RFID reader disconnected.	1,2	Contact Bioquell
82	QHPV	Compressed air fault	Always active, if pressure less than limit and mask time expired.	1,2	Contact Bioquell
83	QHPV	Centre door timeout	Unable to achieve locking or unlocking of door in time available	1,2	Open and shut door, check seal for leaks
84	QHPV	Centre door open	When the door is open when it should be closed.	1,2	Close centre door
85	QHPV	QSDM left door timeout	Unable to achieve locking or unlocking of door in time available.	1,2	Open and shut door, check seal for leaks
86	QHPV	QSDM left door open	When the door is open when it should be closed.	1,2	Close door
87	QHPV	QSDM right door timeout	Unable to achieve locking or unlocking of door in time available.	1,2	Open and shut door, check seal for leaks
88	QHPV	QSDM right door open	When the door is open when it should be closed.	1,2	Close door
89	QHPV	Bottle module timeout	H_2O_2 liquid extraction needle has not extended or retracted within allowed time.	1,2	Acknowledge alarm, it will then retry.
91	QHPV	Chamber pressure sensor error	Always active, if 4-20mA signal <3mA.	1,2	Contact Bioquell
92	QHPV	Return airflow pressure sensor error	Always active, if 4-20mA signal <3mA.	1,2	Contact Bioquell
93	QHPV	EMM humidity sensor error	Always active, if 4-20mA signal <3mA.	1,2	Contact Bioquell
94	QHPV	EMM chamber temperature sensor error	Always active, if 4-20mA signal <3mA.	1,2	Contact Bioquell
95	QHPV	EMM H2O2 sensor error	Always active, if 4-20mA signal <3mA.	1,2	Contact Bioquell

No.	Module	Description	Condition	*Action	User Action
96	QHPV	Glove pressure sensor error	Always active, if 4-20mA signal <3mA.	1,2	Contact Bioquell
97	QHPV	Air divert valve fault	If valve not in position and transition monitor time expired.	1,2	Contact Bioquell
98	QHPV	Air inlet valve fault	If valve not in position and transition monitor time expired.	1,2	Contact Bioquell
99	QHPV	Air exhaust valve fault	If valve not in position and transition monitor time expired.	1,2	Contact Bioquell
100	QHPV	Particle counter divert valve fault	If Level 3 monitoring option enabled and valve not in position and transition monitor time expired.	1,2	Contact Bioquell
101	QHPV	Active air sampler fault	If Level 2 monitoring option enabled and no signal received from Air Sampler.	Turns sampler off	Check air sampler is plugged in, check dish is fitted
102	QHPV	Left-hand recirculation fan rotation fault	If QHPV only cycle, no tacho feedback signal has been received from LH recirculation fan.	1	Contact Bioquell
103	QHPV	Right-hand recirculation fan rotation fault	No tacho feedback signal has been received from RH recirculation fan.	1	Contact Bioquell
104	QHPV	EMM fan rotation fault	There is no feedback from the EMM fan tacho.	1,2	Contact Bioquell
105	QHPV	Room H2O2 ppm high	Always active if option enabled.	1,2	Evacuate room, re-enter with handheld H_2O_2 sensor
106	QHPV	Extract duct pressure fault	If option enabled and pressure higher than pressure switch setting.	1,2	Check duct fan is operating and tube from duct to back of unit
107	QHPV	H2O2 pump rotation fault	Always active. There is no feedback signal from pump rotation sensor.	1,2	Contact Bioquell
108	QHPV	Chamber pressure low	If in Process Mode or in cycle and actual pressure lower than setpoint minus offset.	1,2 Prevents opening of inner door(s)	Identify and resolve any leaks. Re-run cycle
109	QHPV	Chamber pressure high	If in Process Mode or in cycle and actual pressure higher than setpoint plus offset.	1,2 Prevents opening of inner door(s)	Identify and remove any blockages. Re-run cycle.

No.	Module	Description	Condition	*Action	User Action
110	QHPV	Return airflow low	If in Process Mode or in cycle and actual airflow lower than low alarm limit.	1,2 Prevents opening of inner door(s)	Remove back filter cover and inspect for any obstructions. Re-run cycle.
111	QHPV	Return airflow high	If in Process Mode or in cycle and actual airflow higher than high alarm limit.	1,2 Prevents opening of inner door(s)	Re-run cycle. Contact Bioquell
113	QHPV	Chamber humidity high	If in Process mode and RH level above alarm limit and mask time expired.	Warning only	Reduce humidity in room
115	QHPV	Chamber temperature high	If in Process mode and Temperature above alarm limit and mask time expired.	Warning only	Reduce room temperature
118	QHPV	Air heater temperature low	In cycle air heater temperature lower than alarm low limit.	1,2	Contact Bioquell
119	QHPV	Air heater temperature high	In cycle air heater temperature greater than 49.0°C	1,2	Contact Bioquell
120	QHPV	Vaporiser temperature low	In cycle actual temperature lower than alarm low limit. Not active in Aeration.	1,2	Contact Bioquell
121	QHPV	Vaporiser temperature high	In cycle actual temperature higher than alarm high limit. Not active in Aeration.	1,2	Contact Bioquell
122	QHPV	HMI communication error	Communications have been lost between the HMI and the control system for >30s.	1,2	Contact Bioquell
123	QHPV	Glove tester seal timeout	Glove tester seal pressure can not reach set point within time.	Removes air from Seal	Check connection to leg and re-try
124	QHPV	Pressure test – Test pressure not achieved	Unable to reach initial test pressure when pressurising with fan.	1,2	Locate leak and resolve
125	QHPV	Pressure test – Test start pressure not achieved	Unable to maintain the test pressure when stabilising with the pressure control valves.	1,2	Locate leak and resolve
126	QHPV	Pressure test – Pressure decay test failed	Pressure decay exceeds test parameters.	1,2	Locate leak and resolve
127	QHPV	Cycle aborted by user	User has aborted the cycle through the UMI.	1,2	No action
128	QHPV	PPM level not achieved	If in cycle and H_2O_2 Alert level cycle parameter not achieved by end of gassing.	1,2	Re-run the cycle
129	QHPV	Sterilant injection fault	Unit detected a period of no Peroxide during gassing.	1,2	Contact Bioquell
130	QHPV	QSDM left-hand door closed	If in multi chamber cycle and door closed.	2	Open door, re-run cycle

No.	Module	Description	Condition	*Action	User Action
131	QHPV	QSDM right-hand door closed	If in multi chamber cycle and door closed.	2	Open door, re-run cycle
132	QHPV	RH level not achieved	If in cycle and RH Alert limit not achieved by end of gassing.	1,2	Re-run cycle
133	QHPV	QMTD left-hand recirculation fault	If QMTD present and in multi chamber cycle and over pressure switch is made.	2	Contact Bioquell
134	QHPV	QMTD right-hand recirculation fault	If QMTD present and in multi chamber cycle and over pressure switch is made.	2	Contact Bioquell

* Action: 1 - Aborts QHPV-only decontamination cycles
2 - Aborts full-system decontamination cycles
3 - Ends aseptic hold

Advice on what to do in the event of an alarm is available from Bioquell UK or your local Bioquell agent.

Contact details: csts@bioquell.com; or Tel: +44(0)1264 835835.
When contacting Bioquell please quote the alarm number.

7.2 Troubleshooting

Fault	User Action	Further Action
No power to QUBE system	Check power lead is properly connected. Check power is switched ON at mains. Check QUBE power switch is ON.	Contact Bioquell Service Provider.
Lights not working	Check mains power indicator is illuminated. Check front access window is shut.	Contact Bioquell Service Provider to replace light strip.
System not movable	Check castor locks have been released and that stays are not down. Check castors are not fouled by debris or cables. Check if castors seized or damaged.	Release as necessary. Clear as necessary. Contact Bioquell Service Provider.
Printer does not operate	Check correct paper has been used. Check green light on printer is lit. Check paper feed.	Replace paper roll if necessary. The green light will flash. Press paper advance key on printer. Check paper was the correct side up. An appropriately trained person may check all control cable connections. Contact Bioquell service provider.
Rejected password	Re-enter password in accordance with Manual instructions. Re-set password by administrator.	Contact person with administrator's rights.
Cycle time extended	If the cycle time increases, check that alcohols, IPA or other hydrocarbons are not present in the atmosphere, being used to clean the Qube or being used to wipe items prior to being placed in the Qube	Use low level sensor to verify the end of the cycle, see section 4.3.4.6 (The Hydrogen Peroxide sensor is adversely affected by hydrocarbons, resulting in sluggish response and a zero offset of the ppm reading)

8 PARTS LIST

8.1 Consumables

Part Description	Part Number
Printer paper	7050-00003
Gloves (for a pair of gloves)	H07990534
Biological Indicators (100pk)	TD078-1000-100-XX[2]
Chemical Indicators (100pk)	TD078-5000-100-XX
150ml bottles of Hydrogen Peroxide	BQ783-*X*-0150[3]

8.2 Replacement Parts

This list is not exhaustive but includes spare parts that a Client may require:

Part Description	Part Number
Main door inflatable seal	TD069-1182
Inflatable seal pass-through	TD069-4114
Sleeve	H07990525
Environmental Monitoring Module EMM2	TD060-3500
Antisurge T4A HBC, 250V Fuses (F1, F3, F4, F5)	Board mounted
Antisurge T12A HBC, 250V Fuse (F2)	Board mounted
Antisurge T10A HBC, 250V Fuse (F6, F7)	Board mounted
Window test point mating part	H03020720

[2] Where XX denotes the region, i.e. EU for Europe, AM for the Americas or AP for Asia Pacific
[3] Where *X* denotes the country of purchase. Please contact your local Bioquell office or agent.

9 SPECIFICATION

The following specification relates generally to the QUBE system.

Unit Dimensions (WxHxD): QHPV & QEXT modules		
	Overall External	1360 x 2335 x 843 mm (53.5“ x 91.9“ x 33.2“)
	Inside Chamber	1100 x 750 x 540 mm[4] (43.3“ x 29.5“ x 23.6“)
QMTD module	External	660 x 1750 x 800 mm (25.9 x 68.9 x 31.5”)
	Usable space	440 x 495 x 365 mm (17.3 x 19.5 x 14.4”)
Unit Weight:	QHPV QEXT QMTD	280 kg (617.3 lbs) 240 kg (529.1 lbs) 64 kg (141 lbs)
Air Quality:		ISO 14644-1 Class 5 (EC GMP Annex 1 Grade A; US Class 100)
Filtration:	Chamber boundary	99.995% (EN 1822:2009 H14)
	Inlet /Exhaust	99.95% (EN 1822:2009 H13)
Airflow System:		Unidirectional
Downflow air velocity:	At glove working height and working zone	0.35m/s +/- 0.1
Exhaust airflow rate:		100-120 m^3/hr (approx. 20%)
Chamber Pressure:		User selectable between -60Pa to +75Pa
Chamber Lighting:	Processing mode:	Warm white. User adjustable from 0 to 1000 Lux at working surface
	Bio-decontamination mode	Blue
Decontamination Method:		Hydrogen Peroxide Vapour Micro-condensation
Aeration Method:		Integrated Catalyst
Cycle Time:		≈30 mins[5] (QHPV only)
H_2O_2 Liquid Supply:		• Bioquell Hydrogen Peroxide sterilant only • 35% w/w (stored at 4°C to 25°C)[6]
Materials of Construction:	External surfaces:	• Polypropylene (PP) • Acrylonitrile Butadiene Styrene / Polycarbonate Mix (ABS/PC) • Clear cast acrylic • Polyurethane (PU) Painted • Aluminium Alloy (Epoxy coated) • Stainless Steel • Cast acrylic • Polyester Labels
	Internal chamber surfaces:	• Polypropylene (PP) • Acrylonitrile Butadiene Styrene / Polycarbonate Mix (ABS/PC) • Polyurethane (PU) • Stainless Steel Flooring (316 grade) • Polyester Labels
Door Sealing System:		• Silicone inflatable seals with integrity monitoring

[4] Chamber shape may affect equipment location. For full chamber size & shape please contact Bioquell

[5] Dependent upon loading and absorbency of chamber contents. Time to decontaminate the complete QUBE system depends upon load condition and configuration.

[6] For a full Hydrogen Peroxide Specification please contact Bioquell or its agents

Decontamination Starting Environmental Limiting Conditions:	Temperature Limits:		16°C – 26°C (60.8°F – 78.8°F)
	Relative Humidity Limits:		30 – 70% RH
Operating Environmental Conditions:	Temperature: Relative Humidity:		5°C – 40°C[7] (41°F – 105°F) 80% Max
Control System:			Embedded microprocessor control
Data Printer:			Thermal print record
Internal Chamber Connections (QHPV + QEXT):	Electrical		• (2x) Mini USB 'B' type • (2x) AC Power (200W max) • DC Power for Viable Monitor
	Air		• ISO-Cone for particle monitoring
External Connections: (items marked * refer to QHPV only)			• Mains power supply input • (2x) USB 'A' Type (connected to chamber) • Remote Room HPV Monitor[8] • Alarm status signal digital (volt-free) output (requires voltage from external equipment) • Ethernet Data Output • Viable monitor controller input (external version) • Pressure feedback from exhaust duct (option)
	Gas/Vapour		• Low level HPV measurement point • Glove/Sleeve leak test point (option)
Power Requirements[9]:	230V AC:	QHPV QEXT	Single phase, 50/60 Hz (7.8 A max) Single phase, 50/60 Hz (5 A max)
	120V AC:	QHPV QEXT	Single phase, 50/60 Hz (15 A max) Single phase, 50/60 Hz (7.8 A max)
	100V AC:	QHPV QEXT	Single phase, 50/60 Hz (TBA A max) Single phase, 50/60 Hz (TBA A max)
Power Supply:			Installation category II
Power Consumption[9] QHPV Only:	Bio-decontamination mode:	QHPV QEXT	1.8kW 1.15kW (230V), 0.94kW (120V)
Packaged Dimensions: (W x H x D)	Chamber:		1470 x 2050 x 1020 mm (57.8 x 80.7 x 40.1 inches)
	Legs:		1420 x 920 x 970 mm (55.9 x 36.2 x 38.2 inches)
Packaged Gross Weight:			409.5 kg (902.8 lbs)
Noise at 1m:	Normal operation		54 dB(A)

[7] System safe to operate but efficacy cannot be guaranteed.

[8] HPV room monitoring equipment. Contact Bioquell for details.

[9] Additional power will be required for additional modules. The current and power quoted are for 2 QMTDs fitted to a QHPV unit, a SteriTest pump, particle counter fitted and working and all internal sockets fully loaded in the module.

Options:		• Product configurations using additional QUBE system modules • Integrated Merck Millipore® Isofit Equinox or Symbio Flex Sterility Test Pump • Environmental Monitoring Packages inc. Viable Monitoring and Continuous Particle Monitoring • Load Transfer Trolley • Height adjustable ergonomic lab chair • In-Chamber USB Camera • Externally ducted version with constant room air extract by-pass valve & skid mounted extract fan • Glove & sleeve leak tester with integrated pneumatic supply and control through touch screen • QUBE Prescription Decontamination System

10 EC DECLARATION OF CONFORMITY

EC DECLARATION OF CONFORMITY FOR ATTACHMENT OF 'CE' MARK

CE

We, the manufacturer: BIOQUELL UK Limited.
52 Royce Close,
West Portway
Andover, England
SP10 3TS
Tel: +44 (0) 1264 - 835835
Fax: +44 (0) 1264 - 835836

declare under our sole responsibility that the appliance:

Bioquell | QUBE

Serial Number as stated on the unit's rating plate

complies with the Essential Requirements of the R&TTE Directive 1999/5/EC and the Machinery Directive 2006/42/EC by means of the following harmonised standards:

EN 12100:2010

EN 61326-1:2006 & EN 301489-3 (V1.4.1)
Tested by:
TRaC, 74-78 Condor Close, Three Legged Cross, Wimborne, Dorset, BH21 6SU
Certificate Nos.: TRA-012752-38-00A (Emissions); TRA-012752-38-01A (Immunity)

Other harmonised Standard used:
EN 61010: 2010

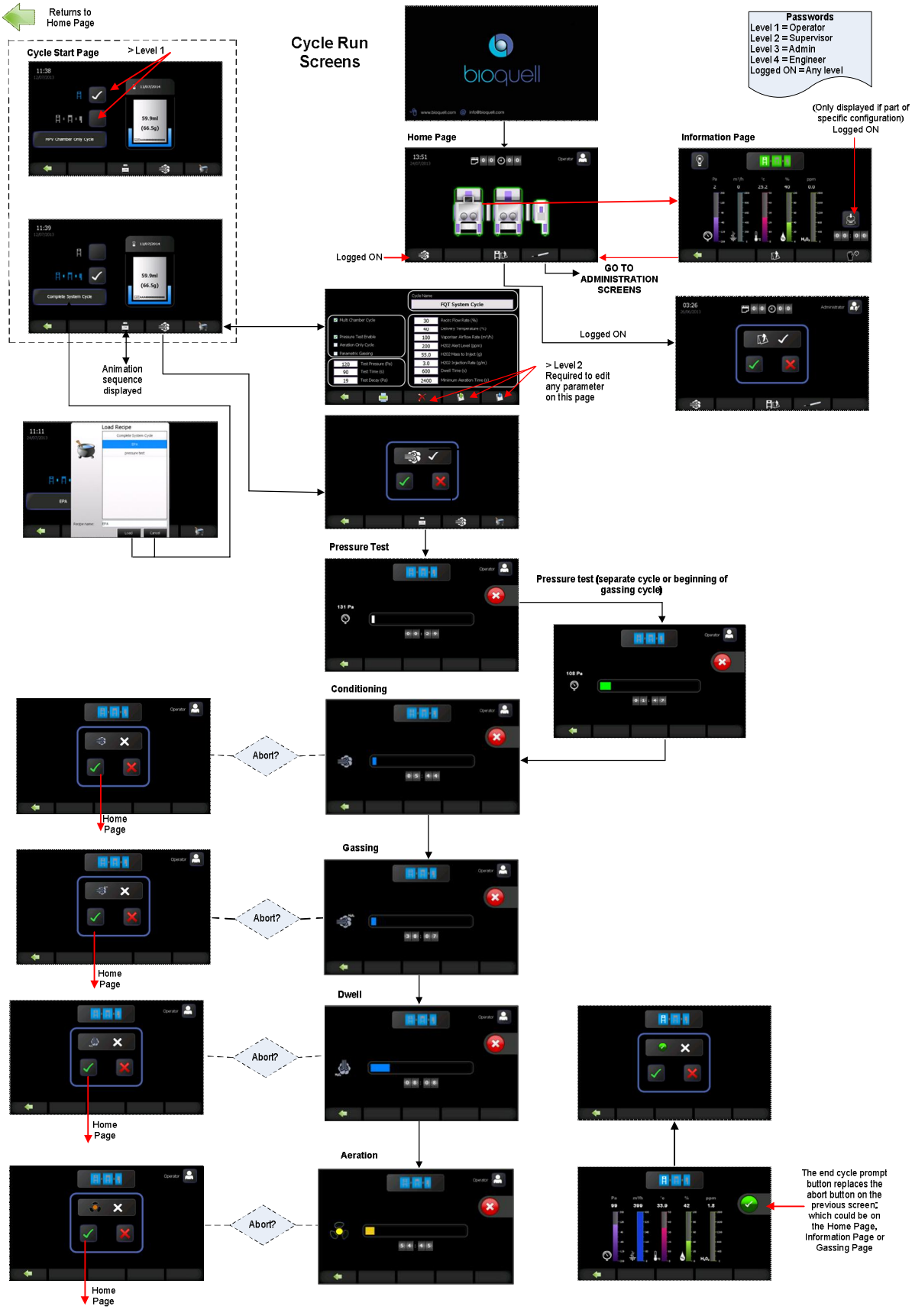
A copy of the Technical File for this equipment is available from:
O.R.Cumberlege
At Bioquell UK Limited, 52 Royce Close, West Portway, Andover, England

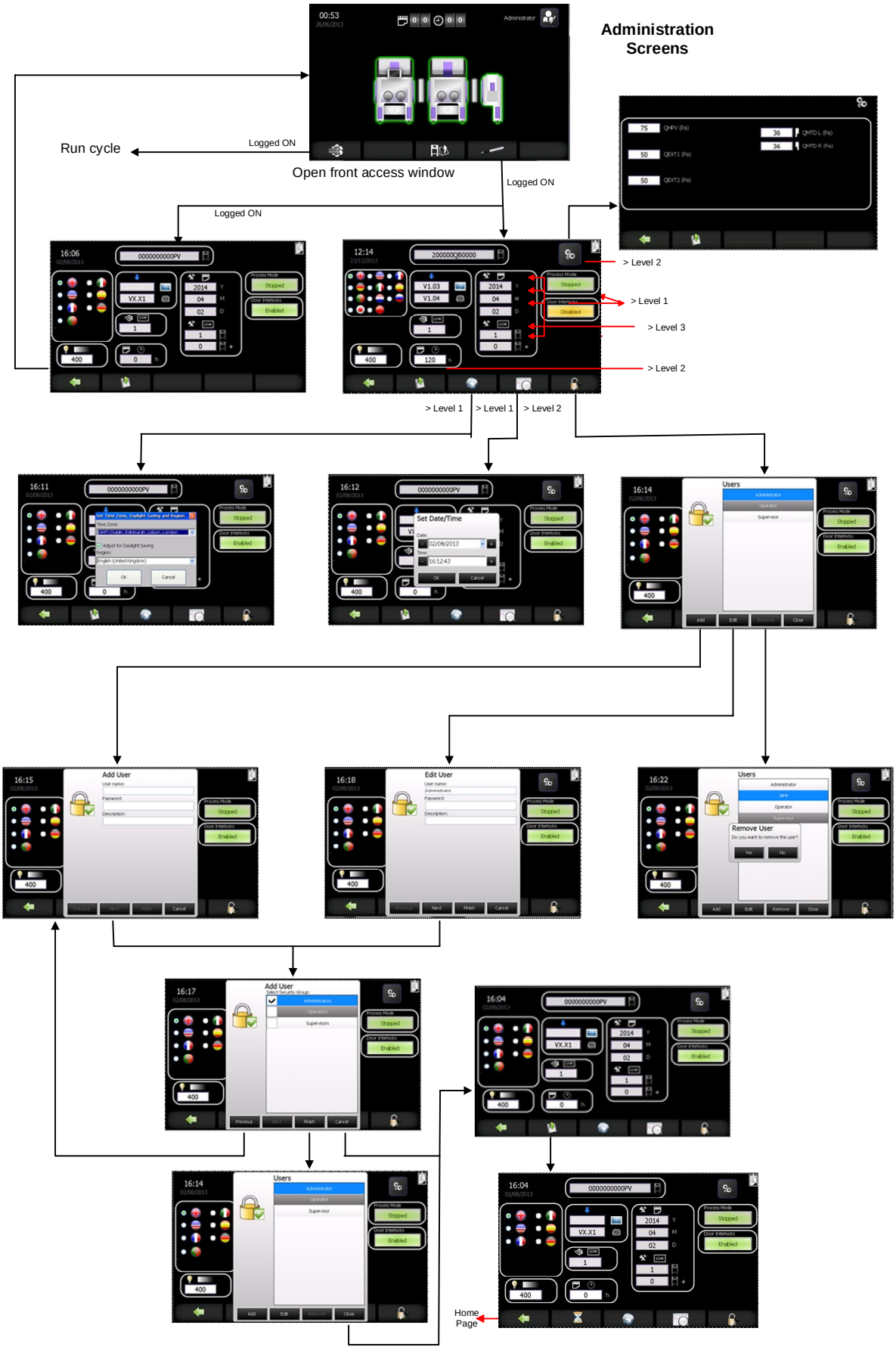
Authorised signatory of manufacturer:

O.R.Cumberlege
Director

30th July 2013

11 SCREEN NAVIGATION




Administration Screens
Run cycle
Logged ON
Open front access window
Logged ON
Logged ON
> Level 2
> Level 1
> Level 3
> Level 2
> Level 1
> Level 1
> Level 2
Add User
Edit User
Users
Remove User
Set Date/Time
Home Page

12 GLOSSARY

The following provides a list of terms/acronyms used within this document:

(c)GMP	(current) Good Manufacturing Practice (term used in Pharmaceutical and Medical Device industries that are regulated against in many countries)
DOP	Dispersed Oil Particulate (used for filter integrity testing)
HEPA	High Efficiency Particulate Air (filter)
HPV	Hydrogen Peroxide Vapour
QHPV	QUBE HPV Module
QEXT	QUBE Extension Module
QMTD	QUBE Material Transfer Device
QSDM	QUBE Side Door Module
QOCM	QUBE Open Connection Module
QCCM	QUBE Closed Connection Module
EMM	Environmental Monitoring Module (a Bioquell replaceable component within the QUBE that incorporates the sensors to monitor the temperature, Relative Humidity and H_2O_2 concentration within the chamber)
HVAC	Heating, Ventilation & Air Conditioning
MSDS	Material Safety Data Sheet
RFID	Radio Frequency Identification (the QUBE system uses RFID tags on the Hydrogen Peroxide consumable bottles and an RFID reader is incorporated in the QUBE)
USB	Universal Serial Bus

13 DEFAULT PASSWORDS

Access to these passwords should be limited to the necessary personnel and at the appropriate level of seniority and training.

It is advised that this page is removed from the manual and stored in a safe place.

Name	Password
ADMINISTRATORS	ADMIN
SUPERVISORS	SUPER
OPERATORS	OPER

The passwords can be changed or deleted with people's name and their own password.

It is strongly advised that these names and passwords are changed to actual people.

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For further information on Bioquell's technology:

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