TopicalWound™ OXYGEN

Hyper-Box System

User Manual

1 Table of Contents

2 Preface

Application

This documentation applies to the product described as:

- **Hyper-Box *System***

You will find this description on the nameplate on the rear of the device.

Firmware version

This documentation applies to the software version:

- **SW Version 3.0 (or greater)**

Subject to technical modification without prior warning.

Key to symbols used in this manual	
Keys, Hyper-Box labels and information in the display:	Keys, such as ***Enter***, Hyper-Box Labels, such as ***Air IN***, and information in the display, such as ***Change Settings?***, are shown in bold, italic type.

These products are covered by various USA and International Patents that can be found at: www.aotinc.net/patents

3 Intended Use

3.1 Intended Use

The **Hyper-Box** System is intended to be used for the treatment of acute and chronic wounds, such as;

- skin ulcerations due to diabetes, venous stasis, post surgical infections and gangrenous lesions
- decubitus ulcers
- amputations/infected stumps
- skin grafts
- burns
- frostbite

The device can be used in hospitals, nursing homes, clinics, as well as at the patient's home as an adjunct to standard wound therapy.

Warning!

Inadequate cleaning and disinfection of the ***Hyper-Box*** *Therapy* controller after use may lead to transmission of infectious disease.

Inadequate room ventilation, or Inappropriate venting of oxygen from the ***Hyper-Box*** *System* could lead to fire or explosion.

Never smoke or use a naked flame in the presence of oxygen.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Do not modify this equipment without authorization of the manufacturer.

Do not use in the presence of acute thrombophlebitis or DVT.

Caution

USA federal law restricts this device to sale or use by or on the order of a physician.

The ***Hyper-Box*** *System* should be operated by trained personnel under the direction of a qualified medical practitioner.

4 Technical Data

4.1 Configuration

4.1.1 Pneumatics

Input flow	> 10 L/min
Input Pressure	5 – 60 Psi (0.3 – 4 Bar)
Therapy Pressure	0 – 50 mbar

4.1.2 Special functions: Automatic stand-by mode

4.1.3 Expected Service Life: 10 Years

4.1.4 Monitoring

- Operating time
- Operating pressure
- Therapy pressure too high
- Internal temperature too high
- Therapy complete

4.1.5 Physical data

W x L x H of Single-Use Hyper-Box Chamber	9 x 18 x 30 inches (23 x 46 x 76 cm)
W x L x H of Controller Unit	8 x 9 x 5 inches (20 x 23 x 13 cm)
Total weight of Hyper-box Controller	6.4 lbs (2.9 kg)

4.1.6 Rating

Operational Temperature	50 to 104°F (10 to 40°C)
Operational Humidity	< 80 % RH
IP Rating (Protection against vertically falling water drops when controller is tilted up to 15°)	IP21
Storage and transport conditions	14 to 140°F (-10 to 60°C) at 5 to 95 % RH

4.2 Power supply

Input voltage to Power supply	100 - 230 VAC 50 - 60Hz
Output voltage to Power supply	12 VDC
Power consumption	< 10VA

4.3 Compliance and approvals

CE 0050

The ***Hyper-Box*** *System* complies with the requirements of directive 93/42/EEC concerning Medical Devices and therefore bears the CE mark.

The ***Hyper-Box*** *System* is classified as protection class II, Type BF, steady state.

The ***Hyper-Box*** *System* complies with the following International standards:

IEC 60601-1 - Electrical Safety
IEC 60601-1-2 - Electromagnetic Compatibility
CAN/CSA-C22.2 No. 0-M91 - General Requirements – Canadian Electrical Code, Part II
CSA Std. C22.2 No. 0.4-M2004 - Bonding and Grounding of Electrical Equipment (Protective Grounding)
CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment Part 1: General Requirements for Safety
CAN/CSA-C22.2 No. 601.1S1-94 - Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90--Medical Electrical Equipment--Part 1: General Requirements for Safety
CSA 601.1 Amendment 2:1998 UL Std No. 0601 1, 1. - Medical Electrical Equipment Part 1: General Requirements for Safety.

4.4 Manufacturer's declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The ***Hyper-Box*** *System* is intended for use in the electromagnetic environment specified below. The customer or the user of the Hyper-Box controller should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***Hyper-Box*** controller uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ***Hyper-Box*** controller is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The ***Hyper-Box*** controller is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Hyper-Box*** controller should assure that it is used in such an environment.			
Immunity tests	**EN 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 secs.	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 secs.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Hyper-Box controller requires continued operation during power mains interruptions, it is recommended that the Hyper-Box with O2 controller be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: U_T is the AC mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The ***Hyper-Box*** controller is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Hyper-Box*** controller should assure that it is used in such an environment.			
Immunity tests	**EN 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Hyper-Box controller, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms	d = 1.2 x root P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 x root P 80 MHz to 800 MHz d = 2.3 x root P 800 MHz to 2.5 GHz
			Where *P* is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Fixed strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Hyper-Box controller is used exceeds the applicable RF compliance level above, the Hyper-Box controller should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Hyper-Box controller. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the ***Hyper-Box*** controller

The ***Hyper-Box*** controller is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***Hyper-Box*** controller can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***Hyper-Box*** controller as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (P) W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d= 1.2 x root P	**80 MHz to 800 MHz** d= 1.2 x root P	**800 MHz to 2.5 GHz** 2.3 x root P
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be calculated using the equation applicable to the frequency of the transmitter. *P* is the maximum output power rating of the transmitter in watts (W) as declared by the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance fort he higher frequency range applies
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

4.5 Device labels and symbols

The following labels and symbols can be found on the ***Hyper-Box*** *System*:

Power switch:
On/Off

Navigation and value setting button
Up

Navigation and value setting button
Down

Enter button: change menu level, apply changed value and acknowledge of alarms

DC Power Supply input:
12 VDC/800mA

Serial number

Caution

No smoking!

Do not use oil or grease!

Single Use - Do Not Reuse

CE number

Applied part type BF, according to EN 60601-1

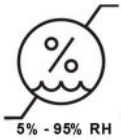

Double Insulated

CSA & UL Approval

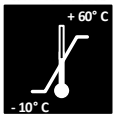

Recycle: Electronic Equipment


Consult instructions for use


Manufacturer



Humidity Limitation



Temperature Limitation


Do Not Use if Package is Damaged


Keep dry


Fragile; Handle with care


This Way Up

5 Safety Instructions

5.1 Symbol for warnings cautions and notes

This triangular hazard symbol is used to draw your attention specifically to the remaining dangers associated with proper use and to emphasize important technical requirements.

Warnings, Cautions or Instructions, to prevent potential injury or damage.

5.2 Personnel

Caution

The ***Hyper-Box*** *System* should only be operated by personnel with suitable training under the order of a physician.

5.3 Basic safety information and warnings

Warning!

The ***Hyper-Box*** *System* should only be used with medical grade oxygen from a Cylinder, Piping system, Liquid Oxygen System or Concentrator.

If utilizing a Liquid Oxygen System (LOX) with the device, follow all rules pertaining to the safe handling of liquid oxygen, as detailed in Appendix B

Only use clean, oil-free DISS hoses and connections to connect the ***Oxygen Source*** to the Hyper-Box controller.

Inadequate room ventilation, or inappropriate venting of oxygen from the ***Hyper-Box*** *System* could lead to fire or explosion.

Never smoke or use an open flame in the presence of oxygen.

To disinfect the ***Hyper-Box*** Controller - we recommend use of the specified cleaners detailed in section 9 - ***Care and Maintenance***, of this manual.

If the ***Hyper-Box*** *System* is damaged in any way, or the supply of oxygen can no longer be guaranteed - stop treatment with the device immediately.

5.4 Potential Risks

Potential risks associated with the use of this device may include:

- infection, if proper cleaning is not performed
- burn, if caution is not taken with the liquid oxygen or electrical fittings
- tissue damage, if instructions for use are not followed

6 Preparing for Use

6.1 Personnel

Caution The ***Hyper-Box*** *System* should only be operated by personnel with suitable training under the order of a physician.

6.2 *Hyper-Box Therapy* Single-Use Chamber

Warning!

The chamber is for single use only. **Do not** reuse, reprocess or disinfect. Reuse, reprocessing or disinfection may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient harm or illness. Reuse, reprocessing or disinfection may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to harm or illness to the patient.

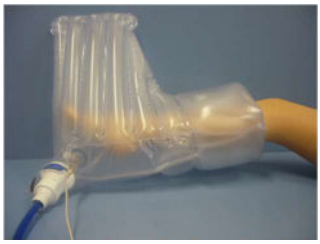
After use, dispose of product and packaging in accordance with administrative and/or local government policy.

Warning!

Powering off the unit by pressing the On/Off button or removing the Quick Connect hose, will relieve cuff pressure if required to remove patient's limb from the Single Use Chamber at any time during Therapy.

6.3 Items supplied with the *Hyper-Box Therapy* Single-Use Chamber and *Hyper-Box System*

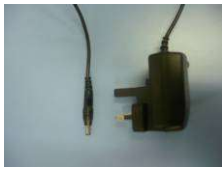
Single Use Chamber



Hyper-Box Controller

DISS Oxygen line

Power supply



Aeroneb Solo Humidifier and Cable

Interface Quick Connect Hose

User manual

6.4 Set up and assembly

The set up and assembly is detailed below.

6.5 Pre-Cleaning

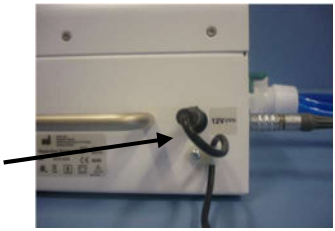
Prior to use the external surfaces of the ***Hyper-Box*** controller and accessories should be cleaned and disinfected with an effective intermediate level disinfectant as referenced is section 9.

6.6 Connecting the Power supply

Take the Power supply, Select and affix the appropriate power plug provided. Connect the 12 DC output to the DC socket on the rear of the ***Hyper-Box*** controller.

⚠ Ensure to attach the DC Power cable to the P-Clip.

DC Power supply cable and input connector

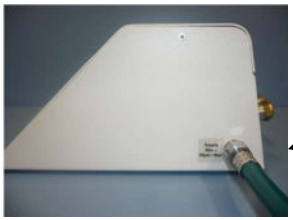


6.6.1 Power Supply Input voltage

The power supply should be connected to any 100 -240 VAC 50/60 Hz outlet.

6.7 Connecting the DISS Oxygen hose to the controller unit

Connect the DISS oxygen hose to the DISS connector located on the Side of the controller unit



DISS O2 Connector

Warning!

The ***Hyper-Box*** *System* should only be used with medical grade oxygen from a Cylinder, Piping system, Liquid Oxygen System or Concentrator

Do not obstruct the vent port on the ***Hyper-Box*** *System* controller.

Use only in a well-ventilated room. Inadequate room ventilation, or inappropriate venting of oxygen from the ***Hyper-Box*** *System* could lead to fire or explosion.

Never smoke or use an open flame in the presence of oxygen.

If utilizing a Liquid Oxygen System (LOX) with the device, follow all rules pertaining to the safe handling of liquid oxygen, as detailed in Appendix B

Only use clean, oil-free DISS hoses and connections to connect the Oxygen Source to the ***Hyper-Box*** controller.

6.8 Connecting the DISS Oxygen hose to a Liquid Oxygen (LOX) system, High Pressure Cylinder

Installation instructions:

1. Connect the alternate end of the DISS oxygen hose to the regulator/flowmeter outlet on the oxygen cylinder or LOX system.
2. Slowly open the main valve on the oxygen cylinder or LOX system.
3. Set the flowmeter to 10 lpm

6.9 Connecting the DISS Oxygen hose to the hospital's piped medical gas supply or Concentrator

Installation instructions:

1. Connect the DISS oxygen hose to the DISS oxygen outlet of the flowmeter connected to the piped wall supply or Concentrator.
2. Set the flowmeter to 10 lpm.

6.10 Setting up the AeroNeb Solo Humidifier

Take the AeroNeb humidifier and connect the interface cable. Then connect the interface cable to the humidifier output on the rear of the controller.

Humidifier cable and connector

Unpack the Single-Use chamber assembly and install the humidifier into the Single-Use chamber as shown below:

It is recommended to keep humidifier facing upright during treatments.

Fill the AeroNeb cup with sterile demineralized (distilled) water.

Caution

The Use of fluids other than sterile distilled water for humidification may cause damage to the humidifier and ***Hyper-Box*** *System*

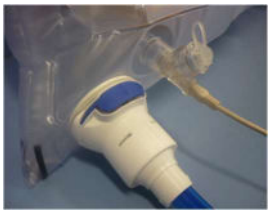
After each treatment, dispose of the unused water utilizing standard procedures

The AeroNeb Humidifier is Single Patient Use and should be disposed of between patients.

6.11 Connecting the Single-Use chamber to the controller

Take the Interface Hose and connect the Quick connect plug to the Quick connect socket on the Controller unit (the smaller plug). Connect the Other end of the Hose to the Quick connect socket on the Single-use chamber as shown (larger plug)

The Quick connect plug and sockets are keyed to guarantee correct orientation and connection.



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7 Applying the Therapy

7.1 Basic description

The ***Hyper-Box*** *System* is intended as adjunctive therapy to standard wound care for acute or chronic wounds. Wounds should be cleaned, and debrided if required, per standard wound care protocols, prior to commencing treatment with this device.

The ***Hyper-Box*** controller regulates the humidified oxygen pressure and the duration of treatment inside the Single-Use extremity chamber in accordance with the physician's orders.

The Single-Use chamber should be disposed of between treatments.

7.2 Preparing the wound

It is recommended to remove all bandages, dressings, creams and ointments from the wound prior to treatment, unless they are gas permeable.

7.3 Recommended Treatment duration

The minimum recommended treatment durations are:

- 60 – 90 mins. once a day, five days per week

7.4 Infected wounds

It is recommended that all infected wounds (including those infected with antibiotic-resistant strains, such as MRSA) be treated utilizing the institutions' standard operating procedures in conjunction with the therapy.

7.5 Applying the therapy utilizing the Single Use Chamber

1. Set the desired therapy pressure and duration as prescribed by the physician as detailed in section 8 of this manual.
2. Press the **"Power On**" button for 2 seconds
3. Select **"Inflate Bag**" by pressing the enter key on the controller unit. The deflated chamber will slowly inflate and become ridged. "**Inflating Bag**" will be displayed during this process.
4. Insert the patient's limb through the patient inlet, making sure that the chamber inner sides do not come in contact with the wound.
5. Select **"Inflate Cuff**" by pressing the enter key on the controller unit. The deflated patient cuff will inflate around the patient's limb and create a seal. "**Inflating Cuff**" will be displayed during this process.
6. Select **"Start Therapy**" by pressing the enter key on the controller unit. The therapy will now be applied to the patient per the physician's orders.

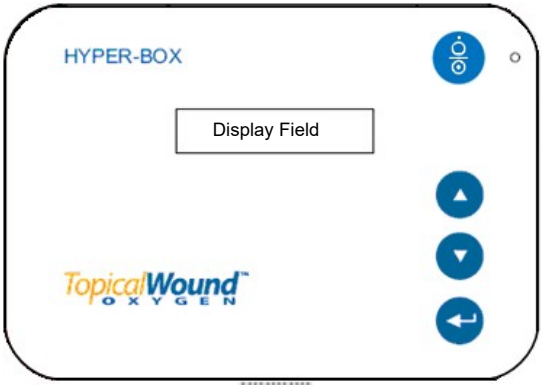
7. The therapy can be paused if required by pressing the enter key during the pressurizing cycle of the therapy. "**Therapy Paused Up to continue**" will be displayed. To resume the treatment press the "**Up"** button to continue.
8. The therapy will automatically stop once the set treatment duration has completed and the Patient Cuff will deflate.
9. Remove the patient's limb from the chamber.
10. Dispose of the single use chamber.

7.6 Aftercare

After treatment, the wound should be dressed utilizing the desired dressings as recommended by the clinician and following standard wound care procedures.

8 Controller Unit Operation

8.1 Description of operating controls



Display Field	The display field provides information on the monitoring values for the ***Hyper-Box*** *System* and is used to enter setting values
LED	The LED provides a visual alarm
On/Off 	Use the ***On/Off*** switch to switch the device on, or power down to the stand-by mode.
Navigation button ***UP*** 	Use the navigation button ***Up*** to scroll up a menu
Navigation button ***DOWN*** 	Use the navigation button ***Down*** to scroll down a menu
Enter 	The ***Enter*** button is used to move between menu levels and to acknowledge alarms.

8.2 Personnel

Caution

The ***Hyper-Box*** *System* should only be operated by personnel with suitable training under the order of a physician.

8.3 Switching the device on/off

Check that all cables and tubes are correctly installed.

Start the device by pressing the ***On/Off*** button

8.4 The start screen

When the ***Hyper-Box*** is switched on using the ***On/Off*** button, the welcome screen appears. After two seconds the message **"Inflate Bag"** is displayed.

The buzzer will bleep upon switch on.

8.5 Operating Screens

The message **"Inflate Bag"** is displayed.

Press the ***Enter*** key to inflate the chamber.

The message **"Inflating Bag"** is displayed.

The message **"Inflate Cuff"** is then displayed.

Press the ***Enter*** key to inflate the patient cuff.

The message **"Inflating Cuff"** is displayed.

.

The message **"Start Therapy?"** is then displayed

Press ***Enter*** to commence the therapy.

During the therapy the **cyclical therapy pressure** and a countdown of **therapy time** is displayed'

Pressing the ***On/Off*** key will cause the therapy to stop and patient cuff to deflate.

8.6 Pausing Therapy

To pause the treatment press the ***Enter*** key during the pressurizing cycle of the therapy.

To resume treatment press the **Up** button.

8.7 Therapy Complete screen

After completion of the therapy, the message **"Therapy Complete"** is displayed.

The buzzer will sound until the unit is switched off

8.8 The monitoring and settings menu

The monitoring and settings menu displays a number of selectable or monitored parameters. These include:

1. The therapy pressure in mbar
2. The therapy duration in minutes
3. The accumulative therapy hours

You can scroll through these menus, or select another display value, by pressing the navigation buttons ***Up*** and ***Down***.

8.9 Changing Settings for Therapy Pressure and Duration, and for viewing Running hours

You can set the therapy pressure and duration as prescribed by the physician as follows;

Start the device by pressing the ***On/Off*** button, The welcome screen appears. After two seconds the ***Inflate Bag*** message is displayed.

Press the ***Up*** and ***Down*** arrow together to progress into the settings and calibration menu.

Use the ***Up*** and ***Down*** arrow to adjust prescribed therapy pressure and then press ***Enter***.

Use the ***Up*** and ***Down*** arrow to adjust prescribed therapy duration and then press ***Enter***.

These values are now stored in memory and will be retained until changed using this process.

The accumulative therapy running hours are now displayed

You can now exit by pressing the ***On/Off*** button,

If you wish to zero the pressure transducers, press the ***Up*** arrow instead of the ***On/Off*** button,

Make sure the Quick connect tubing is disconnected and press *Enter*. The pressure transducers are now zeroed.

You should now exit by Pressing the ***On/Off*** button,

8.10 The alarm screen

If an alarm is triggered, a corresponding message will appear in the display.

Alarms are divided into two priority classes:

- High priority alarm
- Medium priority alarm

8.10.1 Alarm Messages

An alarm is displayed when a certain alarm condition is met. The alarm display ends as soon as the alarm condition no longer exists.

‘**Check for leaks**’ Alarm

If the set pressure in the system is not reached within 3 minutes ‘**Check for leaks**’ message will be displayed.

Check the following:

1. Oxygen hose is connected and gas supply is switched on.
2. The interface hose is connected to controller and single use chamber.
3. The cuff is inflated and there is no leak around the limb.
4. The humidifier is inserted into the single use chamber.
5. Replace the single use chamber.

Once the issue is resolved restarting the unit will resume normal operation.

Loss of Pressure

If system pressure drops significantly during use the unit will automatically shut off.

Check the following:

1. The gas supply is switched off.
2. The interface hose has not got disconnected connected from the controller or single use chamber.
3. The humidifier has come out or not inserted fully.
4. The limb was removed from the single use chamber during therapy.
5. The single use chamber has a leak. Replace the single use chamber.

Once the issue is resolved restarting the unit will resume normal operation.

8.10.2 Warnings

Warning!

All alarms should be responded to in timely manner. Ignoring any alarm may interfere with the functionality of the device and could result in patient injury.

9 Care and Cleaning

9.1 Personnel

Caution

The ***Hyper-Box*** *System* should only be operated and maintained by personnel with suitable training on the order of a physician.

9.2 Guidelines for care and maintenance

To ensure the safe and effective functionality of the ***Hyper-Box*** controller it is important that the device is cleaned and maintained according to these instructions. Only use spare parts and accessories recommended by the manufacturer.

Caution

Guidelines and maintenance instructions provided by the manufacturer should be followed.

Inadequate cleaning and disinfection of the ***Hyper-Box*** controller and its accessories after use may lead to transmission of infectious disease.

Always observe and follow the manufacturer's instructions for use for the cleaning/disinfectant substance.

9.3 Limitations on Reprocessing:

Due to the product design and the materials used, no definite limit to the maximum number of performable Cleaning and Disinfection processing cycles can be specified. The service life of the medical device is determined by their function and careful handling.

9.4 Cleaning and Disinfection

Dispose of the Single-Use chamber after use.

After each treatment, dispose of the unused water utilizing standard procedures

The AeroNeb Humidifier is Single Patient Use and should be disposed of between patients.

The external surfaces of the ***Hyper-Box*** controller and accessories should be cleaned and disinfected after every use with an effective intermediate level disinfectant.

Even antibiotic-resistant organisms, such as MRSA, are effectively destroyed by the intermediate level disinfectants listed below.

Clean and Disinfect all external surfaces of the Controller, including gas connections and hose, Quick Connect Interface hose, Humidifier cable and plug, Power supply and power cord.

The following intermediate level cleaner/disinfectants (or equivalents) are recommended for this purpose:

Alpha Guard GF

Dr. Deppe Laborities GmbH, Germany

Bacillol 30 Tissue Wipes

BODE Chemie GmbH, Germany

Professional AMPHYL® II Disinfectant Deodorant Spray

Reckitt Benckiser Inc., USA.

Cleaning and Disinfection Instructions

9.5 Transport

No particular requirements.
It is recommended that instruments are reprocessed as soon as is reasonably practical following use.

9.6 Preparation for Cleaning:

Disconnect reusable chamber from the Quick Connect Hose and the Humidifier and dispose of Chamber.
Disconnect Quick connect Hose from Controller unit.
Disconnect the Humidifier cable from the controller.
Unplug the power supply unit.

9.7 Disinfection with Amphyl II Deodorant Spray

Professional AMPHYL® II Disinfectant Deodorant Spray kills microorganisms on environmental surfaces.
To Disinfect: Hold can upright 6" to 8" from surface. Spray precleaned surfaces 2 to 3 seconds until covered with mist. Spray Controller unit, Quick connect hose, power supply and cord, Humidifier cable and Oxygen hose.
Allow to stand for 10 minutes to air dry.

9.8 Disinfection with AlphGuard Solution:

Disinfectant (AlphGuard Solution) must be used in accordance with the manufacturer's labeled instructions. Gloves should be worn.

Application Procedure:

1. Select appropriate concentration per the table below, such as 1.5% (15 mL AlphaGuard / 1L water).

Concentration	Exposure Time (Minutes)
1.50%	15
1.00%	30
0.50%	60
0.25%	240

2. Mix AlphaGuard with water in a bottle per the concentration ratio desired.

3. Use a cloth or paper towel to apply solution to all external surfaces of the Controller unit. Also apply solution to the external surfaces of the Quick connect hose, power supply and cord, humidifier cable and Oxygen hose.

4. Observe required exposure time to achieve disinfection.

9.9 Disinfection with Bacillol 30 Tissue Wipes:

Disinfectant (Bacillol 30 Tissue Wipes) must be used in accordance with the manufacturer's labeled instructions. Gloves should be worn.

Application Procedure:

1. Thoroughly wipe all external surfaces of the Controller unit, including; the Quick connect hose, power supply and cord, Humidifier cable, Gas connections and Oxygen hose with the Bacillol 30 Tissues.

2. Make sure to completely wet all surfaces to achieve best disinfection results.

3. Dispose of used tissues after use.

4. Allow for 30 min exposure time to guarantee disinfection.

9.10 Inspection and Functional Testing:

Optically inspect for cleanliness.
Repeat cleaning and Disinfection procedure if necessary. Prior to use perform functional testing and setup according to Section 6 of the User Manual.

9.11 Packaging:

A standard packaging material may be used.

9.12 Storage:

Store disinfected device in a dry, clean, and dust-free environment at moderate temperatures of between 5°C to 40°C.

10 Preventive Maintenance

10.1 Scheduled Preventive Maintenance

Refer to Hyper-box Service Manual (P/N G00316) for further information on Preventative Maintenance and Technical Service instructions.

Interval	Part	Procedure
After Each Patient Therapy	Single-Use Chamber	After each therapy dispose of the Single-Use chamber following standard local procedures. The chamber is for single use only. **Do not** reuse, reprocess or disinfect.
After Each Patient Treatment	Humidifier	After each treatment, dispose of the unused water utilizing standard procedures. The AeroNeb Humidifier is Single Patient Use and should be disposed of between patients.
Annually	Exhaust Muffler	Replace the chamber vent muffler (G00141)

10.2 Manufacturer's address

AOTI Ltd.,
Unit 20, Glenrock Business Park,
Ballybane,
Galway. Ireland.

10.3 Technical support & customer service

AOTI Ltd.,
Unit 20, Glenrock Business Park,
Ballybane,
Galway. Ireland.
customerservice@aotinc.net

10.4 Address for orders

AOTI Ltd.,
Unit 20, Glenrock Business Park,
Ballybane,
Galway. Ireland.
customerservice@aotinc.net
Tel.: +353 9166 0310

11 Accessories and Spare Parts

11.1 Accessories and spare parts

Item	Order number
Hyper-Box *System*	G00001-2
Alpha Guard disinfectant/cleaner	G00005
Single-use Chambers (Case of 20) **Medium**	G00020
Single-use Chambers (Case of 20) **Large**	G00061
Humidifier	G00113
Humidifier Cable	G00114
Quick Connect Interface Hose	G00126
Muffler Sintered Bronze, 1/4",	G00141
Oxygen Supply Hose ISO, DISS Nut - DISS Handtight (White)	G00191
Oxygen Supply Hose US, DISS Nut - DISS Handtight (Green).	G00192
Power Supply, 100 - 240 VAC, O/P 12v, Euro	G00250
Power Supply, 100 - 240 VAC, O/P 12v, US/Japan	G00251
Power Supply, 100 - 240 VAC, O/P 12v, UK	G00252
Service Manual	G00316
Professional AMPHYL® II Disinfectant Deodorant Spray, Box of 12.	G00335
Bacillol 30 Tissue Wipes	G00336

12 Disposal

The operator is responsible for the disposal of the device. The operator must either …

- Deliver the device, free of charge and duty paid, to the manufacturer for disposal or
- Surrender the device to a licensed private or public collection company or
- Competently recycle the parts/dispose of them properly.

Where an operator chooses to dispose of the device himself, the disposal regulations are specified for each country and laid down in the appropriate laws and regulations. Please consult the responsible authorities for instructions on what is required.

With this in mind, all waste is to be recycled or disposed of:

- Without any risk to human health
- Without employing procedures or methods which cause damage to the environment - in particular water, air, earth, flora and fauna
- Without causing any noise or odour nuisance
- Without detriment to the surroundings or landscape.

13 Appendix A: Abbreviations and Glossary

A	
A	Ampere
AC	Alternating Current
AT	Ampere Slow Blow (fuse)
B	
Bar	1 bar = 14.50 psi
C	
°C	Degrees Celsius Converting Celsius (C) to Fahrenheit (F): F = 9*C/5 + 32
D	
dBA	Decibels measured with a filter
DC	Direct Current
F	
°F	Degrees Fahrenheit Converting Fahrenheit (F) to Celsius (C): C = (F-32)*5/9
H	
Hz	Hertz (1 Hz = 1 s^{-1})
I	
IP	Safety class according to ISO standards
L	
L	Litres
Lbs	Pounds
Lpm	Litres per minute of flow
M	
Max., max.	Maximum
Min	Minute
min.	Minimum
mmHG	Millimetres of mercury pressure
P	
psi	Pressure pounds per square inch (1 bar = 14.50 psi)
R	
RH	Relative humidity
T	
TF	Technical fault
V	
V	Volt
VA	Apparent power of device
VAC	Volt Alternating Current
VDC	Volt Direct Current

14 Appendix B: LOX Use

PATIENT USER TRAINING CARD

USE OF MEDICAL LIQUID OXYGEN VESSELS IN THE HOME

1

Read the ***User Instruction Manual*** carefully before operating your liquid oxygen vessels and equipment.

Pay special attention to information where the hazard symbol is shown.

2

Materials burn much more vigorously in oxygen than air.

Never smoke (or let someone else smoke near you) whilst using your oxygen equipment.

Do not use your oxygen vessels near open fires or naked flames.

3

Only use your liquid oxygen vessels and equipment in a ***well ventilated area.***

Keep internal doors open whilst your oxygen vessels are in use.

4

Never place your oxygen vessels near curtains or cover them with clothing as this will restrict air circulation.

Materials become ***oxygen enriched*** if any leak occurs with no ventilation.

Never use or carry the portable oxygen vessel under any clothing.

5

Follow the advice Your Service Provider has given you where to safely store and use your liquid oxygen vessel.

Use and store your liquid oxygen base unit ***upright***.

Use the portable unit only as shown in the Instruction Manual.

6

Do not use oils or grease with your liquid oxygen vessels or equipment.

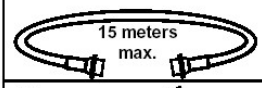
Ensure that your hands are ***clean*** when using the vessels.

Only use authorised creams and moisturisers when using your medical oxygen.

7

Attach the oxygen tubing to the outlet connector on the liquid oxygen vessel.

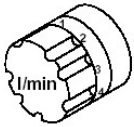
Ensure that the length of the tubing does not exceed 15 metres



8

To turn on your liquid oxygen vessel, turn the oxygen flow control valve anticlockwise.

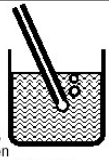
9



Set the flow control valve to the flowrate ***prescribed by your Doctor***

Check for any leaks on the tubing connection after selecting the correct flowrate.

10

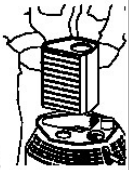


Check for flow by placing the end of the tubing in a glass of water and watch for bubbles.

If no bubbles appear, check a flow has been selected and there are no leaks.

If a flow is still not evident, contact your Service Provider.

11



When transfilling the portable unit, ***never leave it unattended*** until the unit is full.

If the unit will not disconnect easily, ***never*** use force to remove it. ***Wait*** a few moments to allow it to thaw and then try again.

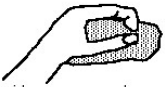
12

Never touch any cold parts on either vessel or allow liquid oxygen to come into contact with your skin.

This could cause a serious burn.

Immerse affected parts in tepid water if you receive a cold burn.

13



Use only a clean damp cloth to clean your liquid oxygen vessels or any associated equipment.

Only use mild non-abrasive cleaning materials.

Allow the liquid oxygen vessels to dry after wiping down.

14

Select zero on the oxygen flow control valve after use.

Keep closed when the liquid oxygen vessel is not in use.

15

If either liquid oxygen vessel fails for any reason call your Service Provider immediately.

Never try and repair any fault unless specifically instructed by your Service Provider