Hyper-Box
Topical Wound Oxygen System

User Manual

1 Table of Contents

2 Preface

Application

This documentation applies to the product described as:

- **Hyper-Box Topical Wound Oxygen (TWO_2) System**

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

Firmware version

This documentation applies to the firmware version:

- **SW Version 1.0 (or greater)**

Second edition of this user manual: Rev C - January 2008

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.

3 Intended Use

The Hyper-Box *Topical Wound Oxygen*[tm] 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 Hyper-Box *Topical Wound Oxygen*[tm] controller regulates the oxygen pressure and the duration of treatment inside the extremity chamber in accordance with the physician's orders.

Warning!

Inadequate cleaning and disinfection or sterilization of the Hyper-Box *Topical Wound Oxygen*[tm] system after use may lead to transmission of infectious disease.

Inadequate room ventilation, or Inappropriate venting of oxygen from the Hyper-Box *Topical Wound Oxygen*[tm] System could lead to fire or explosion.

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

Do not use in the presence of acute

Caution

Federal law restricts this device to sale by or on the order of a physician.

The Hyper-Box *Topical Wound Oxygen*[tm] 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	5 -10 L/min 100 % oxygen
		Input Pressure	0 – 60 Psi (0 – 4 Bar)
		Therapy Pressure	0 – 50 mb
4.1.2	Special functions	Automatic stand-by mode	
4.1.3	Monitoring	Operating time	
		Operating pressure	
4.1.4	Alarms, warnings	Check seals	
		Therapy pressure too high	
		Internal temperature too high	
		Therapy complete	
4.1.5	Physical data	W x L x H of Reusable Hyper-Box Chamber	14 x 14 x 22 inches (35 x 35 x 56 cm)
		W x L x H of Single-Use Hyper-Box Chamber	12 x 14 x 20 inches (30 x 35 x 51 cm)
		W x L x H of Controller Units	8 x 13 x 3 inches (20 x 33 x 8 cm)
		Total weight of Reusable Hyper-Box System	48 lbs (21 kg)
		Total weight of Single-Use Hyper-Box System	15 lbs (7 kg)
4.1.6	Rating	Operational Temperature	50 to 104°F (10 to 40°C)
		Operational Humidity	< 80 % RH
		Storage and transport conditions	14 to 140°F (-10 to 60°C) at 5 to 95 % RH

4.2 Power supply

Input voltage	115 VAC ~50z 230 VAC ~50/60Hz
Power consumption	< 25VA
Fuse Rating	1A slow-blow

4.3 Compliance and approvals

CE 0050

The ***Hyper-Box*** *Topical Wound Oxygen*[tm] *system* complies with the requirements of directive 93/42/EEC concerning Medical Devices and therefore bears the CE mark.

The **Hyper-Box** Topical Wound Oxygen[tm] system is classified as protection class I, Type BF, steady state.

The ***Hyper-Box*** *Topical Wound Oxygen*[tm] *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 with O2 controller is intended for use in the electromagnetic environment specified below. The customer or the user of the Hyper-Box with O2 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 with O2 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 with O2 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 with O2 controller is intended for use in the electromagnetic environment specified below. The customer or the user of the Hyper-Box with O2 controller should assure that it is used in such an environment.			
Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 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 with O2 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 with O2 controller is intended for use in the electromagnetic environment specified below. The customer or the user of the Hyper-Box with O2 controller should assure that it is used in such an environment.			
Immunity tests	**IEC 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 with O2 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 with O2 controller is used exceeds the applicable RF compliance level above, the Hyper-Box with O2 controller should b observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Hyper-Box with O2 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 with O2 controller

The Hyper-Box with O2 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 with O2 controller can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hyper-Box with O2 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*** *Topical Wound Oxygen*^{tm} 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

AC Input
115V~60Hz

Mains input: 115V~60Hz

AC Input
230V~50/60Hz

Mains input: 230V~50/60Hz

SN: YYYY-XXXX

Serial number

Warning: observe accompanying documents.

No smoking!

Do not use oil or grease!

CE0050

CE number

Applied part type BF, according to EN 60601-1

CSA & UL Approval

Dispose of Safely

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 emphasise important technical requirements.

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

5.2 Personnel

Caution

The ***Hyper-Box*** *Topical Wound Oxygen*[tm] system should only be operated by personnel with suitable training

5.3 Basic safety information and warnings

Warning!

The ***Hyper-Box*** *Topical Wound Oxygen*[tm] system should only be used with medical grade 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 *Topical Wound Oxygen*[tm] controller.

Inadequate room ventilation, or Inappropriate venting of oxygen from the Hyper-Box *Topical Wound Oxygen*[tm] System could lead to fire or explosion.

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

To sterilize the ***Hyper-Box*** *Topical Wound Oxygen*[tm] Reusable Chamber or Controller. Use only the specified cleaners detailed in section 11 - ***Care and Maintenance***, of this manual.

6 Preparing for Use

6.1 Personnel

Caution

The ***Hyper-Box*** *Topical Wound Oxygen*[tm] system should only be operated by personnel with suitable training

6.2 Items supplied with the *Hyper-Box Topical Wound Oxygen*[tm] Reusable Chamber and Controller system

Reusable Chamber and Controller

DISS Oxygen Hose

Power cord

User manual

6.3 Set up and assembly

The set up and assembly is the same when utilizing either the Reusable or Single-Use Chamber with the Controller unit, except for steps 6.10 and 6.11.

6.4 Connecting the Mains supply

You can find the AC power connection on the right side of the ***Hyper-Box*** *Topical Wound Oxygen*[tm] controller.

6.4.1 Input voltage

The *Topical Wound Oxygen*[tm] ***Hyper-Box*** should be connected to a grounded 115 VAC, 60 Hz, or 230 VAC 50/60 Hz mains outlet.

6.4.2 Mains power cord

Only use the grounded three-pin power cord provided with the device.

6.5 Connecting the Oxygen hose to the controller unit

Connect the DISS oxygen hose to the DISS connector located on the right-hand side of the controller unit

DISS O2 Connector

Warning!

The *Hyper-Box Topical Wound Oxygen*^{tm} system should only be used with medical grade oxygen.

Do not obstruct the vent port on the Hyper-Box *Topical Wound Oxygen*^{tm} system controller.

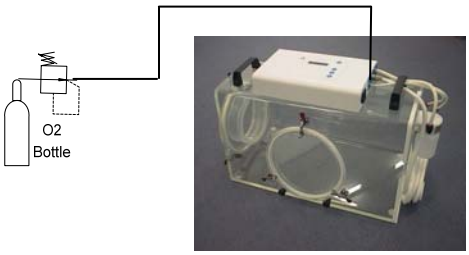
Use only in a well ventilated room. Inadequate room ventilation, or Inappropriate venting of oxygen from the Hyper-Box *Topical Wound Oxygen*^{tm} System could lead to fire or explosion.

Never smoke or use a naked 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 *Topical Wound Oxygen*^{tm} controller.

6.6 Connecting the Oxygen hose to a Liquid Oxygen (LOX) system or a 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.

6.7 Connecting the Oxygen hose to the hospital's piped medical gas supply

Installation instructions:

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

6.8 Setting up the Humidifier

Take a new Single-Use humidifier jar from the Hyper-Box Topical Wound Oxygen™ system and fill it to ¾ full with sterile, demineralised (distilled) water. Then screw it to the humidifier jar connector.

Caution

The use of fluids other than sterile distilled water for humidfication may cause damage to the Hyperbox system.

After each treatment, dispose of the water and jar utilizing standard hospital procedures

6.9 Connecting the patient sleeves on the Reusable chamber

Remove the patient ring from the Reusable Hyper-Box chamber. Select the correct sleeve size for the patient as detailed below:

Sleeve

Patient Ring

Sleeve	Limb Size
Paediatric sleeve	< 9 inches
Small sleeve	> 9 < 10 Inches
Medium sleeve	>10 < 13.5 Inches
Large sleeve	> 13.5 < 15 Inches
X-Large sleeve	> 15 Inches

Stretch the larger end of the sleeve over the patient inlet ring

7 Applying the Therapy

7.1 Basic description

The *Hyper-Box Topical Wound Oxygen*[tm] system is intended as adjunctive therapy to standard wound care for acute or chronic wounds..

The Hyper-Box *Topical Wound Oxygen*[tm] controller regulates the humidified oxygen pressure and the duration of treatment inside the extremity chamber in accordance with the physician's orders.

The reusable chamber must be cleaned and sterilized between patients to alleviate any potential cross infection risks.

7.2 Preparing the wound

It is recommended to remove all bandages, dressings, creams and ointments from the wound prior to treatment.

Wounds should be cleaned, and debrided if required, per standard wound care protocols, prior to commencing treatment with this device

7.3 Recommended Treatment duration

Recommended treatment durations are :

Out-patient:

- 60 – 90 mins. once a day

In-patient or home-patient:

- 3 hours once a day or 90 mins twice a day

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 Reusable Chamber

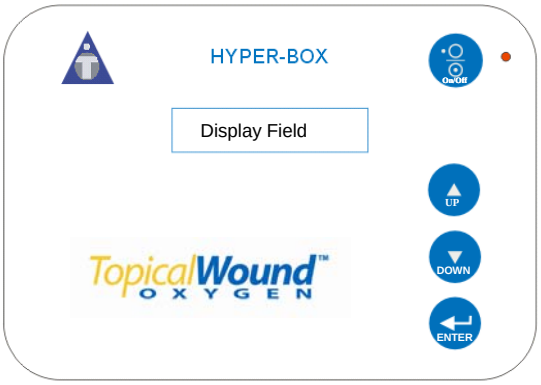
1. Set the desired therapy pressure and duration as prescribed by the physician as detailed in section 8 of this manual.
2. Insert the patient's limb through the Patient Ring, making sure to stretch the sleeve such that it does not come in contact with the wound.
3. Position the limb in the chamber and close all three red clamps.
4. Check that the side access door is completely closed.
5. When the ***Hyper-Box*** is switched on using the ***Power*** button, the welcome screen appears. After two seconds an information screen is displayed, followed two seconds later by the first monitoring menu screen (time and pressure).
6. The monitoring and settings menu displays specific Hyper-Box values. Toggle through to the "**Start/Stop?"** display by pressing the navigation buttons ***Down***.
7. Select **"Start**" by pressing the enter key on the controller unit. The therapy will now be applied to the patient per the physician's orders.
8. The therapy will automatically stop once the set treatment duration has completed.
9. Remove the Patient Ring from the chamber and the patient's limb from the sleeve.

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 *Topical Wound Oxygen*™ ***Hyper-Box*** 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*** *Topical Wound Oxygen™* system should only be operated by personnel with suitable training

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 chamber selection screen is displayed.

8.5 Reusable Chamber Selected

The preset therapy pressure and duration time is now displayed

Toggle through to the "**Start/Stop?"** display by pressing the navigation buttons ***Down***.

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

While the therapy , pressing the ***Enter*** key will cause the therapy to stop

8.6 Therapy Complete screen

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

8.7 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 mb
2. The therapy duration in minutes
3. The devices running hours
4. Various alarm messages

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

8.8 Changing Settings for therapy Pressure and Duration

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

Start the device by pressing the ***Power*** button. The welcome screen appears. After two seconds the chamber selection screen is displayed.

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

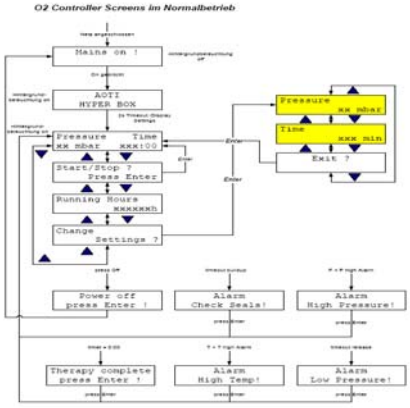
Use the ***Up*** and ***Down*** arrow to adjust prescribed therapy pressure and then press ***Enter***.

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.

8.9 Running hours

The running hours can be viewed by using the ***Up*** and ***Down*** arrow to toggle to the running hours display.



8.10 The alarm screen

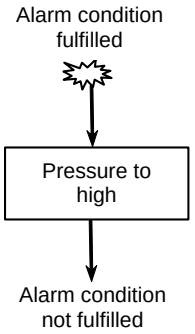
If an alarm is triggered, a corresponding message will appear in the display.

Alarms are divided into two priority classes:

- High priority alarm
- Medium priority alarm

8.10.1 High Priority Alarms

A high priority alarm is generated when a certain alarm condition is met. The alarm ends as soon as the alarm condition no longer exists. The alarm can be silenced for two minutes by pressing the ***Enter*** button. If the alarm condition is still present once these two minutes have elapsed, the alarm will resume.



Two minutes silence after pressing the ***Enter*** button.

High priority alarm conditions

Alarm condition	Reset Criteria	Reaction of device
High Pressure alarm		
Therapy Pressure exceeds set alarm value	Therapy Pressure within limits	Switch to stand-by and vents chamber to atmosphere

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.

Medium priority alarm conditions	Alarm condition	Reset Criteria/ Corrective action	Reaction of device
Check seal	The therapy pressure in the chamber has not been reached within 90 seconds	Check all patient connections, tubes and cuff for leakage	Controller vents chamber to atmosphere

Informational Messages	Alarm condition	Reset Criteria/ Corrective action	Reaction of device
Therapy complete	Preset therapy duration has elapsed	Once the Enter button has been pressed, the settings screen appears	None.

8.10.3 Exiting the alarm menu

Once the alarm condition is no longer active, the current settings screen returns to the display.

9 Care and Maintenance

9.1 Personnel

Caution

The ***Hyper-Box*** *Topical Wound Oxygen*[tm] system should only be operated and maintained by personnel with suitable training

9.2 Guidelines for care and maintenance

To ensure the safe and effective functionality of the *Topical Wound Oxygen*[tm] ***Hyper-Box*** 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.

This is particularly important for the cleaning and sterilization of reusable products.

Inadequate cleaning and disinfection or sterilization of the Hyper-Box *Topical Wound Oxygen*[tm] system after use may lead to transmission of infectious disease.

Alternative cleaning/disinfectant substances to those recommended may cause damage to the acrylic material of the reusable Hyper-Box chamber.

Always observe the manufacturers instructions for use for the cleaning/disinfectant substance

9.3 Cleaning and Disinfection

The surfaces of the Hyper-Box Reusable chamber and the controller should be cleaned and disinfected after every use with an effective high level disinfectant.

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

The sleeves on the reusable chamber are single patient use and should be replaced between patients.

Clean and Disinfect all internal and external surfaces of the reusable chamber and the external surfaces of the controller, including gas connections, hoses and mains power cord.

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

Alpha Guard GF

Dr. Deppe Laborities GmbH, Germany

T36® Disinfectant

Alda Pharmaceuticals Corp., Canada

Professional AMPHYL® Disinfectant Cleaner

Reckitt Benckiser Inc., USA.

9.3.1 Manufacturer's address

AOTI Ltd.
Qualtech House
Parkmore Business Park West
Galway, Ireland

9.3.2 Technical support service

AOTI Ltd.
Qualtech House
Parkmore Business Park West
Galway, Ireland
service@aotinc.net

10 Accessories and Spare Parts

10.1 Address for orders

AOTI Ltd.
Qualtech House
Parkmore Business Park West
Galway, Ireland
sales@aotinc.net

10.2 Accessories and spare parts

Article	Order number
Hyper-Box System 230 VAC	G00001
Hyper-Box System 115 VAC	G00002
Hyper-Box Reusable Chamber	G00004
Alpha Guard disinfectant/cleaner- bottle	G00005
Alpha Guard disinfectant/cleaner- case/12	G00131
Sleeves Single-Use	
Paediatric sleeve	G00006
Small sleeve	G00007
Medium sleeve	G00008
Large sleeve	G00009
X-Large sleeve	G00010
Sleeves Reusable	
Paediatric sleeve	G00011
Small sleeve	G00012
Medium sleeve	G00013
Large sleeve	G00014
X-Large sleeve	G00015
Chamber door- patient	G00016
Chamber door- closed	G00017
Humidifier Jar Kit	G00021
Oxygen Sup Hose- DISS-DISS- US	G00167
Oxygen Sup Hose- DISS-DISS	G00059

11 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.

Caution

During self-disposal - please note that some of the electronic components in the device carry AC mains voltage. Before you open the device, always disconnect the mains plug (risk of electrocution).

12 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

13 Appendix B: Liquid Oxygen Safety

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.

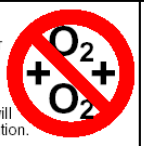
Do not use your oxygen vessels near open fires or naked flames.

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.

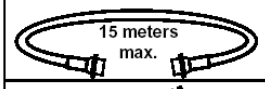
Ensure that your hands are ***clean*** when using the vessels.

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.

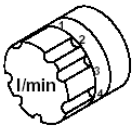
Ensure that the length of the tubing does not exceed 15 metres



8

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

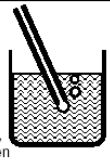
9



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

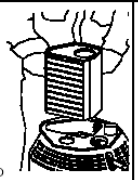


Check for flow by placing the end of the tubing in a glass of water and watch for bubbles.

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.

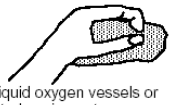
12

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