Hyper-Box System

Instructions For Use

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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 3.2.10 (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:	Buttons, such as ***Enter,*** Hyper-Box Labels, such as ***Therapy***, and information in the display, such as ***Start Therapy?*** 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 mains supply with protective earth.

Do not modify this equipment without authorization of the manufacturer.

Caution **Rx Only**

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.

Contra-indications:

Do not use in the presence of acute thrombophlebitis or deep vein thrombosis (DVT).

Warning!

To ensure safe operation of the **Hyper-Box System** only use equipment supplied by the manufacturer or equipment outlined in the instructions for use.

Do not attempt to connect the **Hyper-Box System** to any other equipment not described in the instructions for use.

Caution!

The **Hyper-Box System** is a medical device, not a toy. Keep away from children, pets and pests as they can damage the device and potentially affect performance.

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	10 – 50 mbar
4.1.2	Expected Service Life	10 Years	
4.1.3	Monitoring	Operating time Operating pressure Therapy pressure too high Internal temperature too high Therapy complete	
4.1.4	Physical data	W x L x H of Single-use Chamber, Medium, Case 20	13 x 18 x 8 inches (33 x 46 x 20 cm)
		W x L x H of Single-use Chamber, Large, Case 20	14 x 18 x 9.5 inches (36 x 46 x 24 cm)
		W x L x H of Controller Unit	8.3 x 9 x 5 inches (21 x 23 x 12 cm)
		Total weight of Hyper-Box Controller	6.4 lbs (2.9 kg)
		Total weight of Hyper-Box System	11 lbs (5 kg)
4.1.5	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 (Hyper-Box Controller)	14 to 140°F (-10 to 60°C) at 5 to 95 % RH

4.2 Power supply

Input voltage	100 - 240 VAC 50 - 60Hz
Output voltage	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

Caution

Although the **Hyper-Box System** is compliant with the current EMC regulations applicable, the device may be susceptible to EMC radiation from medical emitters such as electrocautery, MRI, electrosurgery and diathermy devices and action should be taken to avoid exposure.

4.4 Date of Manufacture

Date of Manufacture is indicated by a Serial / Lot Number.

Serial Number denotes the Date of Manufacture in the format YYYY.
The first 4 digits of Serial Number indicate the Year of Manufacture.

Lot Number denotes the Date of Manufacture in the format YYYYMMDD.
The first 8 digits of Lot Number indicate the Date of Manufacture.

4.5 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	30 A/m	30 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	6 V rms 150 kHz to 80 MHz	3 V rms	d = 1.2 x root P
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 3 V/m 2.7 GHz to 6 GHz	3 V/m / 10 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 for 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.			

4.6 Device labels and symbols

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

Power switch: On/Off

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

Navigation and value setting button ***Up***

Navigation and value setting button ***Down***

CE Number

Manufacturer

Applied part type BF, according to EN 60601-1

Double Insulated

DC Power Supply input: 12 VDC/1000mA

Recycle: Electronic Equipment

Serial Number

Medical Device

Unique Device Identifier

Catalogue Number

Lot Number

Medical device contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR)

Refer to Instructions for Use

No Smoking!

Single-use - Do Not Reuse

Do Not Use if Package is Damaged

Caution

Keep dry

Fragile; Handle with care

This Way Up

Humidity Limitation

Temperature Limitation

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 or Concentrator.

If utilizing an Oxygen Concentrator with the device, follow all rules pertaining to the safe use, as detailed in Appendix A.

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 sections 9 and 10 - ***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.

The **Hyper-Box System** contains metal alloys; stainless steel and hastelloy which contain cobalt CAS No. 7440-48-4, and brass which contains lead; CAS No. 7439-92-1.
Defined as a CMR 1B and 1A according to the European Commission in a concentration above 0.1% weight by weight.

5.4 Potential Risks

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

- Infection - if proper cleaning is not performed before each use
- Burn/fire hazard - if caution is not taken with adequate ventilation or smoking/use of flame in presence of oxygen
  Electrical shock – if caution is not taken with electrical fittings

5.5 Potential side-effects

No known side-effects associated with the use of this device.

5.6 Potential clinical benefits

Potential clinical benefits associated with the use of this device may include:

- increased healing rate
- wound reduction/wound closure
- reduced hospitalizations
- reduced amputations
- reduced pain

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.

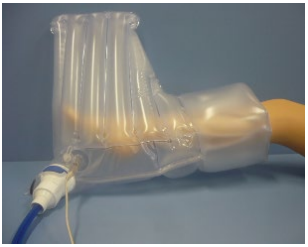
The Single-use Chamber is the only accessible part which comes into contact with the patient and as such is classified as an applied part (Type BF).

Warning!

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

6.3 Hyper-Box System Items

Hyper-Box Controller

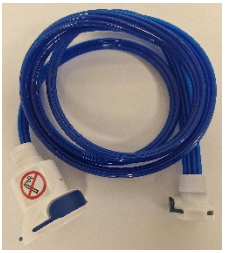


Single-use Chamber

DISS Oxygen Hose

Power supply

Humidifier and Cable



Quick Connect Interface Hose

Instructions For Use

Humidifier Plug (Qty. 2)

6.4 Set up and assembly

The set up and assembly is detailed below.

6.5 Pre-Cleaning

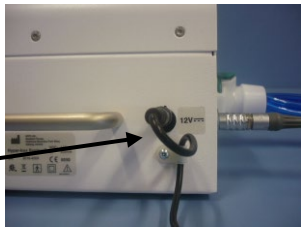
Prior to use the external surfaces of the Hyper-Box controller and accessories should be cleaned and disinfected with an effective intermediate level disinfectant as referenced is section 9.

6.6 Connecting the Power supply

Take the Power supply and 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 Oxygen Hose Connector

Warning!

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

Do not obstruct the vent port or Power Source 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 an Oxygen Concentrator with the device, follow all rules pertaining to the safe use, as detailed in Appendix A.

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

To prevent any risk of strangulation or asphyxiation from the tubing or cables, store excess length of tubing or cable in an appropriate and safe manner.

6.8 Connecting the DISS Oxygen hose to a High-Pressure Gas Cylinder

Connection instructions:

1. Connect the alternate end of the DISS oxygen hose to the regulator/flowmeter outlet on the oxygen cylinder.
2. Slowly open the main valve on the oxygen gas cylinder.
3. Set the flowmeter to ≥10 L/min

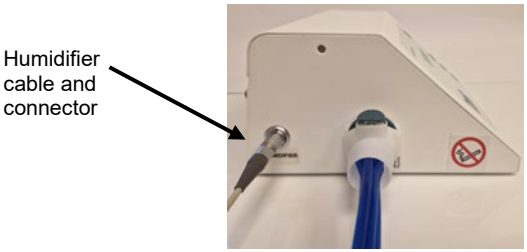
6.9 Connecting the DISS Oxygen hose to the hospital's piped medical gas supply or Oxygen Concentrator

Connection instructions:

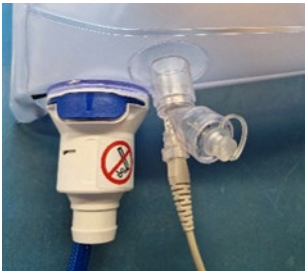
1. Connect the DISS oxygen hose to the DISS oxygen outlet of the flowmeter connected to the piped wall supply or Oxygen Concentrator.
2. Set the flowmeter to ≥10 L/min.

6.10 Setting up the Humidifier

Take the humidifier and connect the humidifier cable. Then connect the humidifier cable plug to the humidifier output port on the side of the controller.



Unpack the Single-use Chamber assembly and install the humidifier into the Humidifier port in the Single-use Chamber as shown below:



It is recommended to keep humidifier facing upright during treatments as shown.

Fill the Humidifier cup using the 5ml Sterile water vial supplied with the Single-use Chamber.
(**Note:** If you are NOT using humidification, plug the humidifier port on the chamber with the Humidifier Plug supplied).

Caution

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

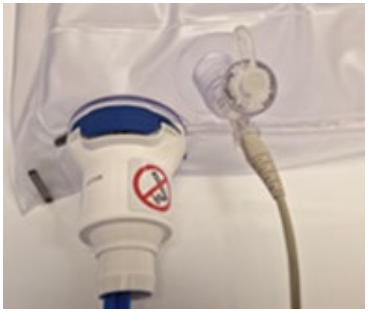
After each treatment, dispose of the unused water utilizing standard procedures.

The 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 (the smaller plug) to the Quick connect socket on the Controller unit. 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.



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 oxygen pressure and the duration of treatment inside the Single-use Chamber in accordance with the physician's orders.

The Single-use Chamber is Single-use only and 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 (Controller Unit Operation) of this manual.
2. Switch on the oxygen concentrator or flow meter to ensure ≥ 10 L/min oxygen is supplied to the controller.
3. Press the ***'Power On'*** button for 3 seconds, the unit will turn on and ***'Start Therapy?'*** will be displayed.
4. Insert the lower limb to be treated into the Single-use Chamber and pull the Chamber upward until the limb is as far into the Chamber as it will go. The Chamber Cuff must make contact with skin and remain clear of any dressings or clothing.
5. Press the ***'Enter'*** button on the controller unit to start the therapy. ***'Inflating Ribs'*** will be displayed, and the chamber Ribs will inflate. Once the Ribs inflate the Cuff will automatically inflate around the patient's limb and create a seal. ***'Inflating Cuff'*** will be displayed during this process.
6. Once the Cuff is inflated Therapy will start, and oxygen will be supplied into the Single-use Chamber. The display will show the therapy pressure increasing and decreasing and the therapy time counting down from the set time.

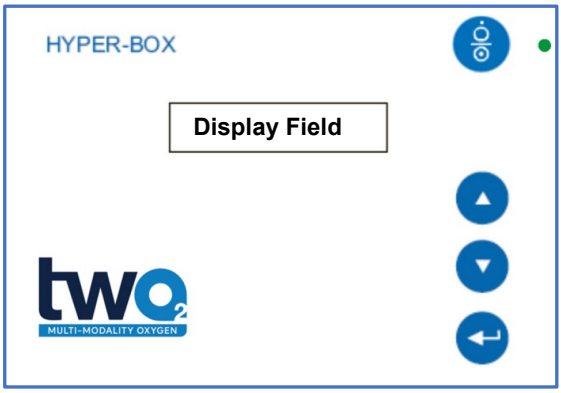
7. The therapy will now be applied to the patient per the physician's orders.
8. The therapy will automatically stop once the set treatment duration has completed. **'*Therapy finished'*** will be displayed, the end of therapy audible alarm will sound, and the LED will flash.
9. Remove the patient's limb from the Single-use Chamber.
10. Disconnect the quick connect hose and remove the humidifier or humidifier plug from the Single-use Chamber.
11. 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 view setting values.

LED — The Green LED provides a visual alarm.

On/Off — Use the ***On/Off*** button to switch the device on or off.

UP button Navigation — Use the navigation button ***Up*** to scroll up a menu.

DOWN button Navigation — 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 controller is switched on using the ***On/Off*** button, the welcome screen appears. After three seconds the message ***'Start Therapy?'*** is displayed.

The audible buzzer will beep upon switch on. Pressing the **'Enter'** button will start the therapy.

8.5 Operating Screens

The message ***'Inflating Ribs'*** is displayed and the Ribs will start to inflate.

Once the Ribs are inflated the Cuff automatically starts to inflate and the message ***'Inflating Cuff'*** will be displayed.

Once the Cuff is inflated the Therapy automatically starts and oxygen is supplied to the Single-use Chamber.

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

Pressing the ***On/Off*** button will cause the therapy to stop and the patient cuff will automatically deflate. The Cuff can also be deflated by opening the Cuff valve.

8.6 Therapy Complete screen

After completion of the therapy, the message ***'Therapy Complete'*** is displayed. The Green LED will flash and the audible buzzer will beep intermittently until the unit is switched off by pressing the ***On/Off*** button.

8.7 The monitoring and settings menu

The monitoring and settings menu displays the selectable and monitored parameters. To access this menu switch on the controller by pressing the ***'On/Off'*** button.

After three seconds the ***'Start Therapy?'*** message is displayed. Pressing the ***'Up'*** and ***'Down'*** buttons simultaneously will access the monitoring and settings menu.

These include:

1. **Set Therapy time.** The therapy duration in minutes is displayed. The therapy duration can be set as prescribed by the physician (30 to 360 min).
2. **Set Therapy Pressure.** The therapy pressure in mbar is displayed. The therapy pressure can be set as prescribed by the physician (15 to 50 mbar).
3. **Total Therapy.** The accumulative therapy time for the controller in hours and minutes is displayed.
4. **Patient Therapy.** The accumulative therapy time for the patient in hours and minutes is displayed.
5. **Auto-zero**. This function allows an auto-zero of the pressure transducers to be performed.

Scroll through the menus by pressing the ***'Enter'*** button.

8.8 Changing Settings for Therapy Pressure and Duration, viewing Total running hours, Patient therapy time and Auto-zero

To change the settings, access the monitoring and settings menu as described above. The first menu displayed will be the **Set Therapy time** menu.

Set Therapy time: Press the ***'Up'*** button to increase the therapy time or press the ***'Down'*** button to decrease the therapy set time**.** The therapy time value is now stored in memory and will be retained until changed using this process. Press ***Enter*** to move to the ***Set Therapy Pressure*** menu.

Set Therapy Pressure: Press the ***'Up'*** button to increase the therapy pressure or press the ***'Down'*** button to decrease the therapy set pressure. The therapy pressure value is now stored in memory and will be retained until changed using this process. Press ***'Enter'*** to move to the ***Total Therapy*** menu.

Total Therapy: The total accumulative therapy running hours for the controller unit is displayed in hours and minutes. Press ***'Enter'*** to move to the ***Patient Therapy*** menu.

Patient Therapy: The total accumulative patient therapy running hours is displayed. To reset the ***Patient Therapy*** time to zero for a new patient press the ***'Up'*** and ***'Down'*** buttons simultaneously, the hours and minutes will be reset to zero. To bypass press the ***'Enter'*** button and move to the **Auto-zero** menu.

Auto-zero: The Auto-zero menu will be displayed. To perform an auto-zero press the ***'Up'*** button. The prompt 'Disconnect tubes' will be displayed. Disconnect the Quick Connect hose from the side of the controller and press ***'Enter'***. The auto-zero values will be displayed, and the Auto-zero is now complete. To bypass the Auto-zero function press the ***'Enter'*** button.

Pressing the ***'Enter'*** button will exit the settings menu and return to Start Therapy.

8.9 The alarm screen

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

8.9.1 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 kinks**' Alarm

If an obstruction is encountered during the the Single-use chamber Cuff inflation or the Cuff dosen't inflate fully the ***'Check for kinks <– to continue'*** message will be displayed.

Check the following:

1. Oxygen hose is connected, and gas supply is ≥ 10 L/min.
2. The interface hose is connected to controller and Single-use Chamber.
3. The Cuff line in the chamber from the 6-port connector to the Cuff is not kinked.
4. The Cuff valve is fully closed.
5. Press the ***'Enter'*** button to restart the CUFF inflation. This can be repeated unlimited times.

‘**Check for leaks**’ Alarm

If the set pressure in the system is not reached within 4 minutes ***‘Check for leaks <− to continue’*** message will be displayed and the audible alarm will be sounding.

Check the following:

1. Oxygen hose is connected, and gas supply is ≥ 10 L/min.
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 or humidifier plug is inserted into the Single-use Chamber.
5. Press the ***‘Enter’*** button to restart the Chamber inflation. This can be repeated unlimited times.
6. Replace the Single-use Chamber.

Loss of Pressure

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

Check the following:

1. The gas supply is switched off.
2. The interface hose has got disconnected from the controller or single-use chamber.
3. The humidifier or humidifier plug 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.

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.

Do not perform maintenance while the **Hyper-Box System** is in operation.

Maintenance shall only be performed by authorised personnel.

Do not modify the **Hyper-Box System** in any way, as it may affect the performance and functionality of the device.

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 sterile water utilizing standard procedures.

The 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:

Bacillol 30 Tissue Wipes

BODE Chemie GmbH, Germany

Professional AMPHYL® II Disinfectant Deodorant Spray

Reckitt Benckiser Inc., USA.

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 the Quick Connect Hose and the Humidifier (or humidifier plug) from the Single-use Chamber.
Dispose of the Single-use Chamber.
Disconnect Quick Connect Hose from the Controller.
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 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.

9.9 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 this Manual.

9.10 Packaging:

A standard packaging material may be used.

9.11 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 G00319) 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 sterile water utilizing standard procedures. The Humidifier is Single Patient Use and should be disposed of between patients.
Annually	Exhaust Muffler	Replace the controller exhaust muffler (G00141).

10.2 Manufacturer's address

AOTI Ltd.,
Unit 20, Glenrock Business Park,
Ballybane, Galway.
Ireland. H91 N23C

10.3 Technical support & customer service

AOTI Ltd.,
Unit 20, Glenrock Business Park,
Ballybane, Galway.
Ireland. H91 N23C
customerservice@aotinc.net

10.4 Address for orders

AOTI Ltd.,
Unit 20, Glenrock Business Park,
Ballybane, Galway.
Ireland. H91 N23C
sales@aotinc.net

10.5 Note

Do not conduct any unauthorized repair or replacement of components.

Please contact the manufacturer or local distributor should any assistance be required for the use or maintenance of the device.

11 Accessories and Spare Parts

11.1 Accessories and spare parts

Item	Order number
Hyper-Box System	G00001-2
Single-use Chambers, Medium (Case of 20)	G00020
Single-use Chambers, Large (Case of 20)	G00061
Humidifier	G00113
Humidifier Cable	G00114
Quick Connect Interface Hose	G00126
Muffler Sintered Bronze, 1/4"	G00141
Oxygen Supply Hose US, DISS Nut DISS Handtight (Green)	G00192
Power Supply, 100 - 240 VAC, O/P 12v, US	G00251
Humidifier Plug	G00334
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, 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.

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: Oxygen Concentrator Use

1 Read the **Instructions For Use** carefully before operating your oxygen concentrator.

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 concentrator near open fires or naked flames.

3 Only use your oxygen concentrator and equipment in a well ventilated area.

Keep internal doors open whilst your oxygen concentrator is in use.

4 Never place your oxygen concentrator near curtains or cover it with clothing as this will restrict air circulation.

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

5 Follow the advice your safety provider has given you where to safely store and use your oxygen concentrator.

Use and store your oxygen concentrator upright.
Use it only as shown in the **IFU**.

6 Do not use oil, grease or petroleum-based or other flammable products with the oxygen carrying accessories or the oxygen concentrator.

Oxygen accelerates the combustion of flammable substances.

7 Attach the oxygen hose to the DISS outlet connector on the oxygen concentrator.
Only use the oxygen supply hose provided with the equipment.

8 Clean the cabinet, control panel and power cord only with a mild household cleaner applied with a damp (not wet) cloth or sponge, and then wipe all surfaces dry.

Do not allow any liquid to get inside the concentrator.

9 If the oxygen concentrator fails for any reason, call your Service Provider immediately.

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

Visit **www.AOTInc.net** for more information.