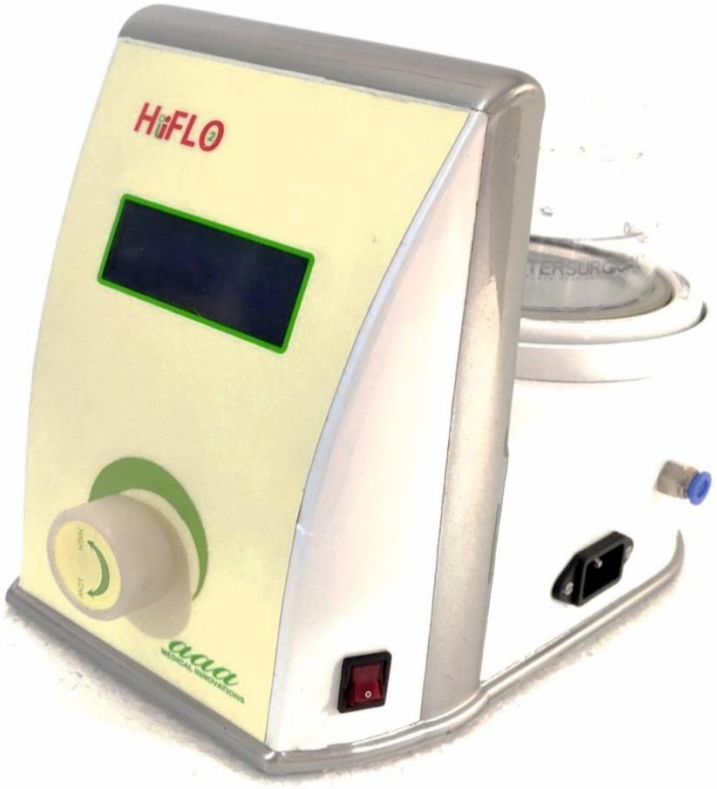
HiFLO 2

Humidified High Flow Nasal Oxygen Therapy Device

User Manual



aaa MEDICAL INNOVATIONS

HiFLO

1. OVERVIEW

Overview

The HiFLO is a humidifier with flow controller that delivers warmed and humidified respiratory gases to the patient with a flow rate from 5 LPM to 70 LPM. The gas delivered is composed of oxygen.

1.1 Intended use:

The HiFLO is intended to deliver warmed and humidified respiratory gases to spontaneously breathing patients with a flow rate from 5 LPM to 70 LPM and is capable of providing high flow therapy. The device can be used in the emergency room, operating room, anaesthesia, outpatient department, Intensive care unit, inpatient department and other diagnostic
and treatment rooms. This device can also be used for homecare.

1.2 Cautions, Precautions and Warnings:

The Precautions, cautions and warnings indicate that the personal safety of the patient or the unit may be involved. **Disregarding precautions, cautions and warnings could result in injury to patient &\or malfunction or damage to the unit. Use the HiFLO unit only after reading cautions, precautions and warnings.**

Cautions:

C1: Nasal delivery of respiratory gases generates flow-dependent positive airway pressure (PAP). This must be taken into account where PAP could have adverse effects on a patient.

C2: If a patient begins to feel ill or are experiencing discomfort while using this device, consult the physician immediately.

C3: The use of Oxygen requires that special care be taken to reduce the risk of fire. Accordingly, for safety it is necessary that all sources of ignition be kept away from the unit and preferably out of the room in which it is being used.

C4: Do not allow smoking or open flames within 10 feet of this device while oxygen is connected and while device in use.

C5: Do not use cleaning agents other than those specified in the user manual. Do not use alcohol, isopropyl alcohol, ethylene chloride or petroleum-based cleaners on the cases, connectors and accessories.

C6: Do not use the unit when the room temperature exceeds 30°C (86°F) or is below 10°C (50°F) as the unit may not perform

satisfactorily or may malfunction. Humidity output will be compromised below 18°C (64°F) and above 28°C (82°F).

C7: Do not use power supplies, power cables or accessories other than those specified in the user manual. The use of non-specified power supplies, power cables or accessories may create a safety hazard and/or impair equipment performance.

C8: The power cord connector should be connected securely to the unit. Avoid unnecessary removal of the power cord from the unit. If removal is necessary, hold the connector during removal. Avoid pulling on the power cord.

C9: Please make sure that the heated breathing circuit connector is properly connected to the unit.

C10: Do not drive, drag or place objects over cord / pipe / tube in either powered or storage condition. Doing so may lead to damaged cord / pipe / tube and may experience inferior performance, malfunction or damage.

C11: It is the responsibility of the end user to maintain optimal Distilled water level at all times as instructed on humidified chamber.

C12: The output Oxygen Flow may be affected if any of the oxygen carrying path is disturbed, including oxygen inlet pipe, humidifier jar inlet pipe, humidifier jar, heated breathing tube or interface.

Precautions:

P1: Avoid use of the HiFLO in presence of pollutants, smoke or fumes. Do not use the HiFLO in presence of flammable anaesthetics mixture, cleaning agents or other chemical vapours.

P2: Ensure that the HiFLO is switched on before connecting Oxygen.

P3: Oxygen must only be added through the special oxygen inlet port on the side of the unit. To ensure that oxygen enters the unit correctly, the oxygen inlet port must be fitted properly to the unit.

P4: When finished, turn off the oxygen source. Remove the output of the oxygen source from the oxygen inlet port on the side if the unit. The oxygen flow must be turned off when the unit is not operating, so that oxygen does not build up inside the unit or the surrounding.

P5: Never leave the HiFLO in an environment which can reach high temperatures, such as an unoccupied car or closed chamber in high temperature environments. This could damage the device.

P6: HiFLO should be placed in a position where ventilation around the unit is not restricted.

P7: Humidifier chamber, Heated breathing circuit & interface are intended for single use and using them for longer than the specified time can result in serious injury and\or damage to the unit. (Humidifier chamber has to be changed every 24 hours of usage)

P8: Ensure that the Mains power cord is attached to proper mains supply socket.

P9: To avoid danger of choking or strangulation hazard, keep cords away from children and pets.

P10: The humidifier chamber is to be check periodically for fluid leak and if found, immediately change the humidifier jar.

P11: Please switch off the unit before removal of humidifier (chamber) from the unit. Also switch off the unit during filling of distilled water in humidifier chamber.

P12: To avoid burns:

- the unit should only be used with interfaces, water chambers and heated breathing tubes / circuits specified in the user manual.
- using the humidifier jar, heated breathing tube or interface for longer than the specified time can result in serious injury including infection.

P13: Never operate the unit if:

- it has been dropped or damaged,
- it has a damaged power cord or plug,
- it has been dropped into water or if the unit has been soiled with water.

P14: Please ensure that the device is not positioned at an angle greater than 10° from the horizontal plane. Failure to do so may cause the device to overbalance and/or may lead to water spilling out from the chamber.

P15: Continuous monitoring of oxygen saturation of the patient is required while using this device.

P16: The device should only be operated by trained personnel under guidance of a physician

P17: When the device is used with a supply of oxygen, please pay attention to the following:

- Inspect the oxygen tube and ensure it is free of folds or kinks.
- Keep device away from sources of ignition and/or open fumes.

P18: Do not smoke near the device.

P19: Oxygen concentration and flow of delivered gas should only be determined by a physician or trained medical professional.

- Oxygen supply shall be standard dry and clean compressed oxygen for medical applications. The minimum oxygen concentration required is 99.5% .
- Shut off the oxygen supply before turning off the device.

- Oxygen leakage may cause serious accidents.
- If an oxygen leak is discovered, shut off the supply of oxygen and contact
- authorized personnel for repair

P20: The operator or responsible department should contact "AAA medical innovations" representative:

- for assistance, if needed, in setting up, using or maintaining the device, or;
- to report unexpected operation or events.

P21: After using the device, store it away from pets and out of the reach of children. Keep the storage environment clean and free from dust.

P22: Any liquid spilt or dropped into the device may cause damage to the device or injury to patient and/or end user.

P23: Ensure that the chamber is not tilted in any orientation to avoid water entering the breathing circuit.

Warnings:

W1: The unit is not intended for life support.

W2: HuFLO2 delivers high flow oxygen gas, which accelerates combustion.

W3: A spontaneous and violent ignition may occur if oil, grease or greasy substances come in contact with oxygen under pressure. These substances must be kept away from all oxygen equipment and HuFLO 2 .

W4: Do not submerse the HuFLO2 and any of its accessories in liquid.

W5: Do not expose to water or precipitation. Do not operate in exposed rain. This could lead to electrical shock and/or damage.

W6: Do not block the flow of the gas through the unit, breathing tube, and other tubes / pipes and interface.

W7: Do not wrap electrical cord, tube / pipe, breathing circuit & oxygen tube around the device while in use or even during storage.

W8: Ensure that the inlet Oxygen pressure is between 50 & 60 PSI. Pressure higher or lower than this may cause unit to malfunction or damage.

W9: Use of unit is not recommended without distilled water filled humidifier chamber. Do not use saline in humidifier chamber. Using saline for humidification is not recommended.

W10: Do not use unit with leak in humidifier chamber.

W11: Do not attempt changing the humidifier chamber, while the unit is switched on.

W12: Do not disassemble the HiFLO or any of the accessories or attempt any maintenance other than tasks described in the user manual; disassembly creates a hazard of electrical shock and will void your warranty. Do not remove the tamper evident label. For events other than those described in the manual, contact your equipment provider for servicing by authorized personnel.

W13: Never operate the unit if:

- the heated breathing tube or interface has been damaged with holes, tears or kinks,
- it is not working properly,
- the case screws have ever been loosened.

W14: Never block the air openings of the unit or place it on a soft surface such as a bed or couch/sofa, where the inlet area may be blocked. Keep the air openings free of lint, hair etc.

W15: Do not store or use the unit where it can fall or be pulled into water. If water has entered the unit enclosure, disconnect the power cord and discontinue use.

W16: To avoid choking, or inhalation of a foreign object, never drop or insert any object into any opening or tube or connector.

W17: T-sens HuFlO Circuits are for single use only. Do not keep T-sens HuFLO circuit in any liquid

W18: Display warnings:

- Check O2 supply & start oxygen flow
  - Confirm the input Oxygen supply is connected and is having pressure in prescribed range of 50 psi to 60 psi.
  - Check the front flow setting knob, if the flow setting knob is kept on zero setting then also same message may appear

- Check T-sens HuFLO circuit
  - Check & confirm that the T-sens HuFLO circuit (heated breathing circuit) connector is properly connected to connector on the unit

1.3 Safety Instructions

- Do not use the device in the presence of a flammable substances.
  Doing so could lead to fire or explosion.

- Do not use the device for any purpose other than what is specified in the manual.
  Doing so may cause damage to the device or injury to patient and/or end user.
- Do not block or obstruct the air and oxygen inlets or the delivery gas outlet.
  Blockage or obstruction may lead to device malfunction and/or injury to patient
  and/or end user.
- Do not use any parts or accessories other than those listed in this manual.
- Do not place liquid containers on or near the top of the device.
- Do not attempt to disassemble, repair or modify the unit. Doing so may cause
  damage to the device or injury to patient and/or end user.
- Do not blow into the air inlet or outlet too avoid contamination of the device,
- Do not fill water chamber beyond the maximum water level indicated on the
  chamber. Doing so may cause water to spill into the breathing circuit. If water level
  exceeds the maximum, please replace the chamber with a new one.
- Do not pour water with a temperature of over 37°C or below 10°C into the chamber.
- Do not kink or block the water supply tube.
- Do not apply excessive force to the device.
- Do not drop or subject the device to strong impacts or shocks.
- Avoid exposing the device to direct sunlight and/or high temperatures.
- Do not allow children to tamper with or operate the device.
- Do not immerse the machine in liquid/water.
- Do not use organic solvents to clean the surface of the device.
- Do not use the device if it is not working properly, stop using the device and have a qualified technician or engineer inspect the device before attempting to use it again.
- Do not attempt to service the device while it is in use. Doing so may cause damage
  to the device or injury to patient and/or end user.
- To prevent burns, do not touch the heater plate when the device is running and
  do not touch for 30min after running.
- To prevent burns, do not touch the bottom of the chamber when it is hot.

- Do not use the device when room temperature is below 18°C or above 28°C.
- Do not use the power cord or the power plug if it is damaged, and do not plug the
  power cord into a loose electrical outlet/socket. Doing so may lead to electric shock.

Keep power cord away from heated or hot surfaces as this may damage the power

cord. Use of a damaged power cord may lead to electric shock or serious device
malfunction.

- Do not plug the power plug into the electrical outlet with wet hands. Doing so
  may lead to electric shock.
- Do not wash the machine with water, or splash water to the power source. Doing
  so may lead to electric shock or serious device malfunction.
- If the machine is not being used for a long period of time, it is recommended that
  the device is unplugged/ disconnected from the electrical outlet.
- To unplug the power plug from the electrical outlet, do not drag the power cord.
  Unplug by pulling the power plug. Dragging the power cord may lead to electric
  shock or serious device malfunction.
- Be sure to turn off the power and unplug the power plug from the electrical outlet
  before installing, moving, or servicing the device. Failure to do so may lead to
  electric shock or serious device malfunction.
- Do not excessively stretch, bend or apply excessive force to cables and hoses.

NOTE: The device should be maintained and serviced only by qualified or trained Personnel.

1.4 Safety Classification

• Type of protection against electric shocks: Class II double insulated.

• Degree of protection against electric shock: Type BF applied parts (Patients will come
in direct contact with high flow nasal cannula during treatment.)

• Degree of protection against harmful ingress of particulate matter and water: IP 21.

• Degree of safety of application in the presence of a flammable anaesthetic mixture

with air or oxygen or nitrous oxide: Equipment is not suitable for use in the presence
of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

- Mode of operation: Continuous operation.

1.5 Environmental Conditions

This device should not be exposed to excessive vibration, dust, corrosive or explosive
gases. During device operation it should be placed in a horizontal position. Suitable
environmental conditions for operation are:

- Ambient temperature: 18 ~ 28°C;
- Relative humidity: 15% ~ 93% RH, non-condensing;
- Atmospheric pressure: 86 ~ 106kPa;
- Altitude: up to 2000m above sea level.

- Storage and transportation conditions: -20°C ~ 50°C, 15% ~ 93% RH, non-condensing,

1.6 Environmental Protection

At the end of service life, the device and its accessories should be disposed of and decommissioned
in accordance with local laws and regulations.
Contact the appropriate local authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories.ction

2. PRODUCT FEATURE

Dual Temperature Control: This device allows the operator to set flow of oxygen from 8-70 LPM and
is equipped with two highly sensitive temperature sensors to monitor unit & patient end temperature.
The device also has a number of temperature protection settings to ensure patient
safety.

Flow Rate Control

This device allows the operator to set the flow rate from 8LPM to 70LPM. The device monitors the flow rate with a built-in highly sensitive flow rate sensor.

Display and Control Interface

The device is equipped with a LCD display monitor and control flow knob to make the device easier to control, and to provide clear display of functions and data.

Alarms

The device has an auditory alarm function to alert patient or end user when an alarm
condition occurs. The auditory alarm is accompanied by information
displayed on the LCD display

2.1 HiFLO main unit

HiFLO

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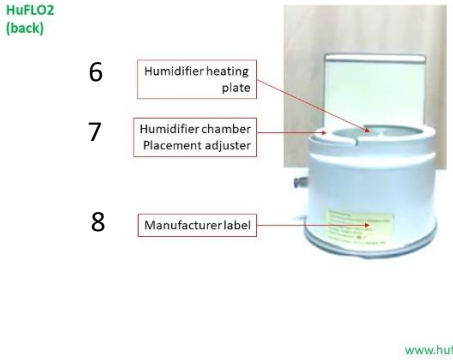
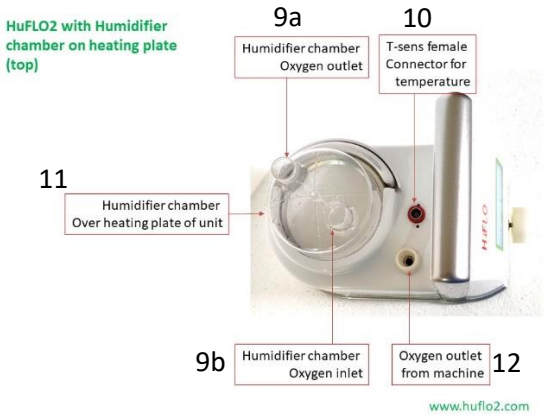
Power Input	100-240V AC , 50/60Hz, Single phase
Power	150Watts
Flow Rate Range (Adult Mode)	5～70L/min
Working Pressure	50～60 psi
Output Temperature Range	33～37°C
Humidification Output	＞12mg/L @ 31～36°C
Sound Pressure Level	＜50 dB(A)
Dimensions	280 mm x 190 mm x 240 mm
Net Weight	1.8±0.2kg
Expected Service Life of the Unit	5 years





1	LCD Dislplay For Flow, Temperature & Warnings
2	Flow Control Nobe
3	Oxygen Pressure Tubing Inlet Port
4	Power Cable Connector
5	Unit On/Off Switch
6	Humidifier Heating Plate
7	Humidifier Chamber Locking Plate (Placement Adjuster)
8	Manufacturer Label
9a	Humidifier Chamber Oxygen Outlet
9b	Humidifier Chamber Oxygen Inlet
10	T-Sens Female Connector
11	Humidifier Chamber Over Heating Plate
12	Oxygen Outlet From Unit (Machine)

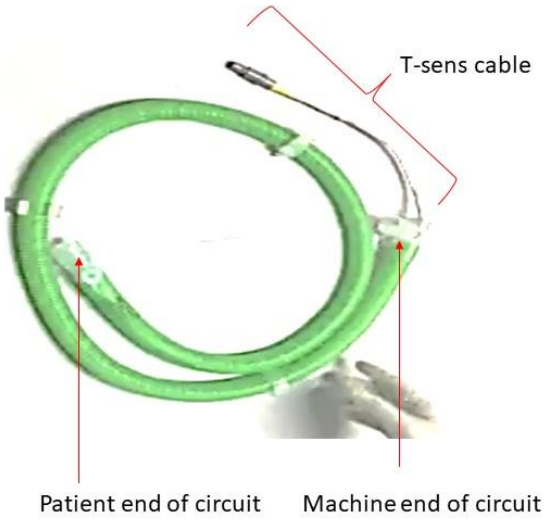
2.2 Accessories Description

T-sens HuFLO Circuit (circuit with heater wire and distal end temperature sensor)

This is an unique circuit compatible with HuFLO unit. This circuit is having heater wire to maintain temperature of breathing gas traveling through circuit. A specific temperature sensor is kept at the patient end of circuit which provides continuous measurement of temperature of the breathing gas at patient end of circuit.

T-sens HuFLO circuit is only circuit compatible with The HuFLO unit

It is a single use circuit.



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T-sens HuFLO Circuit (circuit with heater wire and distal end temperature sensor

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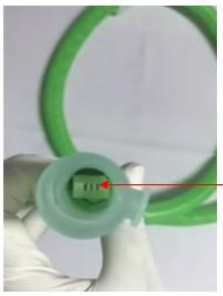
T-sens HuFLO circuit is only circuit compatible with HuFLO unit

Length: 1.6 meter

It is a single use circuit.



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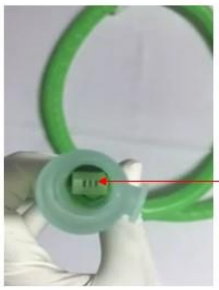
T-sens HuFLO Circuit (circuit with heater wire and distal end temperature sensor

This is an unique circuit compatible with HuFLO unit. This circuit is having heater wire to maintain temperature of breathing gas traveling through circuit. A specific temperature sensor is kept at the patient end of circuit which provides continuous measurement of temperature of the breathing gas at the patient end of circuit.

T-sens HuFLO circuit is only circuit compatible with HuFLO unit

Length: 1.6 meter

It is a single use circuit.



Temperature Sensor at the Patient of the circuit

T-sens connector male

T-sens cable

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Humidifier Chamber
(Intersurgical make)

The dual float auto fill chamber offers the clinician a constant water level within the chamber, therefore minimizing any change of compliance within the breathing system. This dual float auto fill chamber provides an efficient method of ensuring the chamber is filled to a constant water level at all times and is supplied complete with fill set.

Its single use humidifier chamber

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(Intersurgical make)

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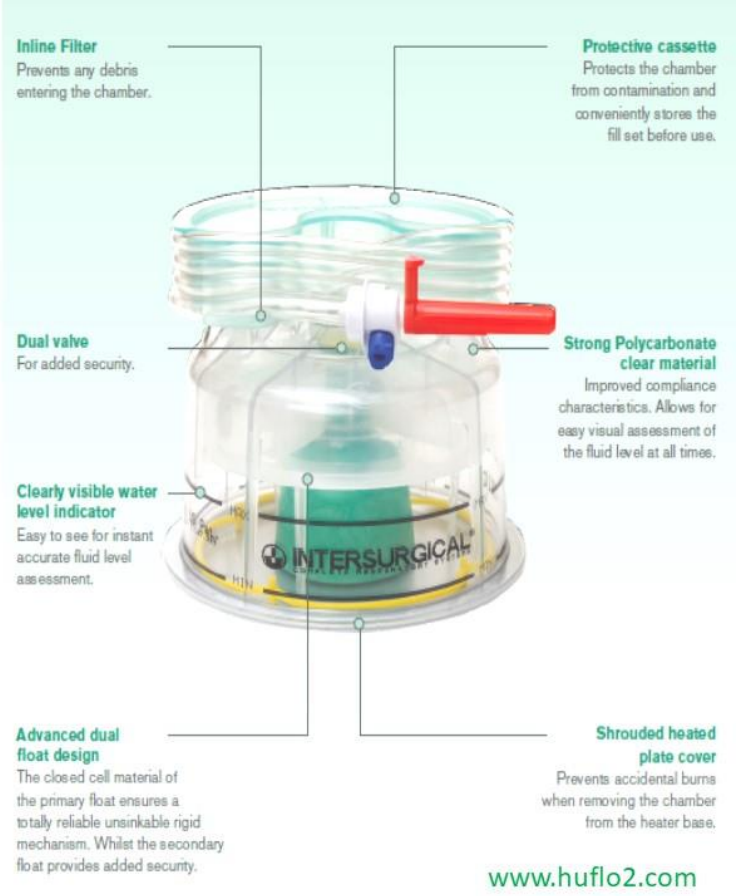
Its single use humidifier chamber



Oxygen Pressure tubing

HuFLo2 is supplied with 5 meter long blue color high pressure tubing for oxygen supply

Length 5 metres

Material: Poly Urethane

Diameter

ID: 6 mm

OD: 8 mm

Strength (pressure tolerance)

10-15 bar capacity approximately

Connection:

Unit end is to be attached to unit port for oxygen inlet

Other end is to be attached to wall out let of central oxygen supply through oxygen wall outlet connector

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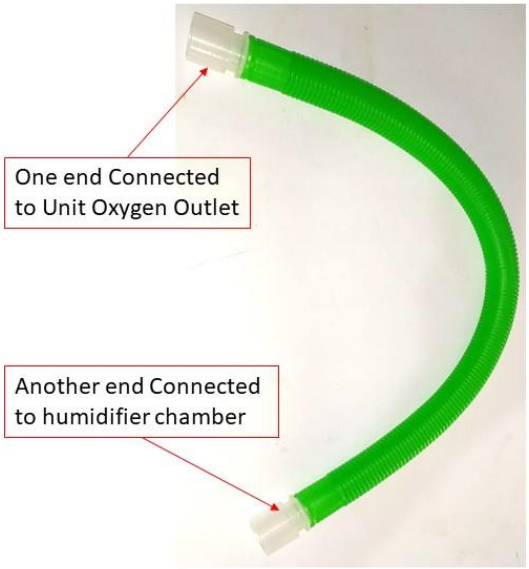
Humidifier chamber inlet connecting tube

This tube connects Unit Oxygen outlet to humidifier chamber inlet.



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2.3 Package Contents

Product	Number
HuFLO2 main unit	1
T-sens HuFLO circuit	1
Oxygen Pressure tubing (5mts)	1
Humidifier Chamber	1
Connecting tube from machine to humidifier chamber to	1
High Flow Nasal Cannula	1
Power cable	1
Warning leaflet	1

3. OPERATING INSTRUCTION: LOG ON WWW.HUFLO2.COM GO TO SET UP VIDEO

3.1 Pre start check List:

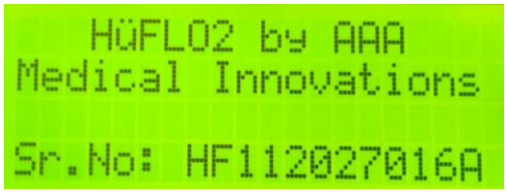
- Check oxygen supply pressure: 60psi
- Check oxygen tubing connection from unit to oxygen outlet
- Check connection of power cable from unit to main electric switch
- Check proper position of humidifier chamber on heating plate
- Check water level upto maximum mark in humidifier chamber
- Check proper connection of connecting circuit of unit oxygen outlet to humidifier chamber inlet
- Check T-sens male-female sockets are properly connected
- Check proper connection and position of T-sens HuFLO circuit to humidifier chamber
- Check User interface (Nasal Cannula) attachment at distal end of T-sens HuFLO circuit.

3.2 Starting Unit:

After ensuring safety as described in manual and completing pre start check list.

Press ON\OFF switch to start machine.

On start of unit, LCD displays serial number of unit



After few seconds , LCD displays following message if flow nobe is in neutral position.

By Rotating the flow nobe anti clock direction, oxygen flow starts and display shows oxygen flow rate. To increase flow, further rotate the flow nobe anti clock direction. Start oxygen flow with 5-8 litres per minute and wait for 3-5 minutes for proper heating and humidification. Once gas temperature rises to 33-35 degree centigrade, apply nasal cannula to patient. Slowly & Gradually increases the oxygen flow to desired level for better patient tolerance and comfort. Once unit is properly functioning, display shows following message

3.3 Trouble shooting

1. Display showing Check T-sens HuFLO circuit

suggest disconnection of T-sens HuFLO circuit connection from t-sens male -female connection. Check t-sens male -female connection and connect it properly.

3.4 Turning off the unit:

Disconnect O2 supply, before power off the HuFLOw2. Ensure neutral position of flow control nobe before turning off the unit

4. MAINTAINANCE:

For any repair or change of components, please contact AAA medical innovations or local
authorized supplier.

AAA medical innovations will provide device related documents to assist service personnel in
parts repair.

Installers and operators must follow the instructions of installation, operation, inspection
and maintenance. They must be authorized by AAA medical innovations.

Inspections and maintenance must be performed in accordance with the recommended
schedule. In any of the following circumstances. AAA Medical innovations will not be responsible
for the safety and reliability of the device performance:

* Modifying, or repairing the machines without any authority from AAA medical innovations.
* Unauthorized components are used
* Electrical power source is not compatible with local regulations
* Use of device is not in accordance with the instruction manual

It is recommended that users obtain the following information before performing
maintenance or repairs:

* Nature and scope of maintenance or repairs conducted
* Changes in the scope of maintenance
* Maintenance date
* Name of staff or company providing the maintenance service
* Signature from the Maintenance operator

5. 5. WARRANTY ERIOD

Do not attempt to disassemble the device without authorization. The warranty period
is 1 year from the date of purchase (Billing Date). Warranty is for manufacturing defect of HuFLO main unit only. No warranty on HuFLO2 accessories.

During the warranty period, the warranty will be void under the following conditions:

1) An error caused by operating the unit in any unprescribed conditions or applications.
2) Damage caused by using an improper power supply, improper installation or
operations not listed in this manual.
3) Damage caused by installation, modification or repair from unauthorized service engineers.
4) Damage caused by natural disasters such as fire, earthquake, power surge, lightning,
flood, etc.

When the machine develops a fault, please contact your supplier or "AAA medical innovations" for
maintenance.

6. CONTACT US

" AAA medical innovations"
12, Durganagar Society,
Behind Tube Company,
Old Padra Road . www.huflo2.com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