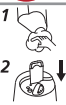
CAIRE®

HELiOS™ Reservoirs

User Manual (English)

User Controls & System Status Indicators

ISO 7000; Graphical symbols for use on equipment—Index and synopsis	
	Storage or operating temperature range. Reg. # 0632
	Storage humidity range Reg. # 2620
	Keep away from rain, keep dry. Reg. # 0626
	Name and address of manufacturer. Reg. # 3082
	Caution, consult accompanying documents. Reg. # 0434A
REF	Catalog Number. Reg. # 2493
SN	Serial Number. Reg. # 2498
	This way up. Reg. # 0623
	Fragile, handle with care. Reg. # 0621
ISO 7010: Graphical symbols—Safety colors and safety signs—Registered safety signs	
	Frostbite may occur on contact with cold liquid or gaseous oxygen, or frosted parts. Warning low temperature. To warn of low temperature or freezing conditions. Reg. # W010
	The instruction manual must be read. Reg. # M002
	Keep away from open flame, fire, sparks. Open ignition source and smoking prohibited. Reg. # P003
	Do not smoke near unit or while operating unit. Reg. # P002
	Type BF applied part (degree of protection against electric shock). Reg. # 5333
	Warning. Reg. # W001
Council Directive 93/42/EEC; concerning medical devices	
EC REP	Authorized representative in the European Community
CE ####	If the product unique device identifier (UDI) label has the CE#### symbol on it, the device complies with the requirements of Directive 93/42/EEC concerning medical devices. The CE#### symbol indicates notified body number.
0029	This device complies with the requirements of Directive 2010/35/EU concerning medical devices. It bears the pi marking as shown.
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road	
	Non-toxic gas.
	Hazard Oxidizing substances: fire intensifying risk.
UN1073 OXYGEN, REFRIGERATED LIQUID	Refrigerated Liquid, USP; Produced by Air Liquefaction
Internal Symbols	
	Keep unit well ventilated at all times
	Keep away from flammable materials, oil and grease.
	Wipe connector with clean dry cloth before filling.
IEC 60417: Graphical Symbols for use on equipment	
	Do not cover unit. These units normally vent oxygen. No. 5641
21 CFR 801.15: Code of Federal Regulations Title 21	
RX ONLY	Federal law restricts this device to sale by or on the order of a physician.
Council Directive 2012/19/EU: waste electrical and electronic equipment (WEEE)	
	WEEE
IEC 60601-1: Medical electrical equipment Part 1 General requirements for basic safety and essential performance	
IPX1	Drip Proof

This product may be covered by one or more patents, US and international. Please visit our website below for the listing of applicable patents. Pat.: www.caireinc.com/corporate/patents/.

Specifications

- Mode of Operation: Continuous Flow
- Type of Protection Against Electrical Shock: Internally Powered Equipment
- Degree of Protection Against Electrical Shock: Type BF Applied Part
- IPX1 Classification According to the Degree of Protection Against Ingress of Water: Drip Proof
- Equipment not suitable for use in the presence of flammable mixtures

Product Specifications

	HELiOS U36	HELiOS U46	HELiOS 36	HELiOS 46
LOX capacity	85 lb (38,6 kg)	110 lb (49,9 kg)	85 lb (38,6 kg)	110 lb (49,9 kg)
Gaseous equivalent capacity	29,069 L	37,916 L	29,069 L	37,916 L
Weight, filled	138 lb (62,6 kg)	170 lb (77,1 kg)	138 lb (62,6 kg)	170 lb (77,1 kg)
Weight, empty	53 lb (24 kg)	60 lb (27,2 kg)	53 lb (24 kg)	60 lb (27,2 kg)
Height	33.5 in. (851 mm)	37.5 in. (952 mm)	33.5 in. (851 mm)	37.5 in. (952 mm)
Diameter	15.4 in. (391 mm)	15.4 in. (391 mm)	15.4 in. (391 mm)	15.4 in. (391 mm)
Typical use time at 2 LPM demand mode	10 days 21 hrs	13 days 21 hrs	10 days 21 hrs	13 days 21 hrs
Operating pressure	22 psi (152 kPa)	22 psi (152 kPa)	22 psi (152 kPa)	22 psi (152 kPa)
Normal evaporation rate	1.2 lb/ day (0,54 kg/ day)	1.2 lb/ day (0,54 kg/ day)	1.2 lb/ day (0,54 kg/day)	1.2 lb/ day (0,54 kg/day)
Standard flow control range	Maximum flow 10 LPM	Maximum flow 10 LPM	Maximum flow 10 LPM	Maximum flow 10 LPM
Flow Rate Accuracy	Please see Flow Table in the HELiOS Technical Service Manual, PN 14883289			

Warning Information

Important: Read this manual thoroughly before operating the HELiOS.
RX Only.

WARNING: THIS DEVICE IS NOT INTENDED FOR LIFE SUSTAINING USE.

WARNING: IF YOU FEEL THE EQUIPMENT IS NOT OPERATING PROPERLY, CALL YOUR HEALTH CARE PROVIDER. DO NOT ATTEMPT TO REPAIR OR ADJUST THE UNIT YOURSELF.

WARNING: DO NOT MODIFY THIS EQUIPMENT WITHOUT AUTHORIZATION FROM THE MANUFACTURER.

WARNING: IF CONTINUITY OF OXYGEN SUPPLY IS REQUIRED, ENSURE THAT AN ADEQUATE SUPPLY OF OXYGEN AND/OR A SECONDARY OXYGEN SUPPLY IS AVAILABLE AT ALL TIMES DURING THERAPY.

WARNING: PATIENT OR OTHERS MAY BE ENTANGLED IN CANNULA OR OTHER TUBING CAUSING ASPHYXIATION.

WARNING: DO NOT ALLOW SMOKING, CANDLES, OR OPEN FLAMES WITHIN 10 FEET (3 METERS) OF THE DEVICE, OR CLOSER THAN 8 INCHES (20 CM) FROM ANY SOURCE OF IGNITION.

WARNING: KEEP YOUR UNIT IN A WELL-VENTILATED AREA.

WARNING: DO NOT STORE LIQUID OXYGEN EQUIPMENT IN A CLOSET, CAR TRUNK, OR OTHER CONFINED AREA. DO NOT PLACE BLANKETS, DRAPERIES, OR OTHER FABRICS OVER EQUIPMENT.

WARNING: THIS PRODUCT CAN EXPOSE YOU TO CHEMICALS INCLUDING NICKEL, WHICH IS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER. FOR MORE INFORMATION, GO TO WWW.P65WARNINGS.CA.GOV.

WARNING: IN THE EVENT THERE IS A SERIOUS INCIDENT OCCURRING WITH THIS DEVICE, THE USER SHOULD IMMEDIATELY REPORT THE INCIDENT TO THE PROVIDER AND/OR THE MANUFACTURER. A SERIOUS INCIDENT IS DEFINED AS AN INJURY, DEATH, OR POTENTIAL TO CAUSE INJURY/DEATH SHOULD THERE BE A REOCCURRENCE OF THE INCIDENT. THE USER CAN ALSO REPORT THE INCIDENT TO THE COMPETENT AUTHORITY IN THE COUNTRY WHERE THE INCIDENT OCCURRED.

Caution: Use the HELiOS Reservoir only as directed by your doctor.

Caution: The unit contains liquid oxygen which is extremely cold, almost 300°F (-184°C). Exposure to such a low temperature can cause severe frostbite.

Caution: Liquid and gaseous oxygen, though non-flammable, cause other materials to burn faster than normal. This hazard, along with the low temperature of liquid oxygen, warrants certain safety precautions.

Caution: Keep flammable materials away from this equipment. Aerosol sprays, oils and grease, including facial creams and petroleum jelly, ignite easily and may burn rapidly in the presence of oxygen.

Caution: Smoking while wearing an oxygen cannula can cause facial burns and possibly result in death.

Removing the cannula and placing it on clothing, bedding, sofas, or other cushion material will cause a flash fire when exposed to a cigarette, heat source, spark or flame.

If you smoke please: (1) turn off the portable, (2) take off the cannula, and (3) leave the room where the device is located.

Caution: In the event of an accidental tip-over, immediately but cautiously return the unit into an upright position if possible. If any liquid oxygen is escaping, leave the area immediately and call your healthcare provider. Do not attempt to move the unit or stop the liquid oxygen from escaping.

Note: Do not touch frosted parts of any unit.

Note: Do not store or operate the portable coupled to the HELiOS Reservoir.

Note: Do not allow untrained personnel to handle or operate this device.

Note: Use of this device is prohibited on commercial passenger and cargo air flights by the Federal Aviation Administration.

Intended Use

The CAIRE HELiOS Reservoir is intended for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.

Introduction

HELiOS Universal Reservoir shown.
Universal & Standard reservoirs are available
in 36 and 46 liter models.

A liquid oxygen system is designed to provide supplementary oxygen as prescribed by a physician. Your liquid oxygen system includes a HELiOS reservoir. This user manual contains the instructions for using the HELiOS reservoir.

The Helios reservoir is intended for the administration of supplemental oxygen to the patient in the end user's home and can also be used in institutions such as nursing homes or sub-acute care facilities. The device is not intended for life support nor does it provide any patient monitoring capabilities. It is recommended to have an alternate source of supplemental oxygen in the event of mechanical failure.

The device is used by COPD patients or those with diminished breathing capacity. The device is prescribed to the patient. The device is sold to a provider that is trained to operate and service the Helios reservoir. The provider trains the user." Your liquid oxygen system may also contain a portable unit to provide an ambulatory source of oxygen for an extended period of time. Refer to the user manual supplied with your portable unit for information on its operation.

The HELiOS reservoir is filled with liquid oxygen by your health care provider. It is designed to store the liquid oxygen for the purposes of filling a portable unit, and breathing directly from the reservoir for stationary use.

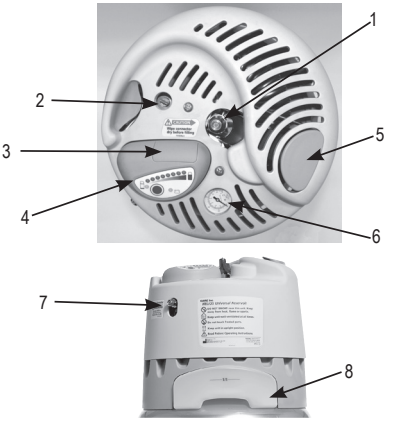
The HELiOS reservoir stores liquid oxygen that can be used to fill a portable liquid oxygen tank. HELiOS Universal reservoirs can fill any CAIRE top fill (TF) portable with a compatible fill connector. HELiOS Standard reservoirs can only fill the HELiOS H300 Plus and H850 Marathon portable units (see Standard and Universal Reservoirs section for model identification).

The HELiOS reservoir is also designed for stationary use. Continuous oxygen flow from 0-10 LPM can be taken directly from the reservoir with the attachment of an external flow control valve.

Another method of stationary use is to connect a HELiOS H300 or H850 portable unit to the HELiOS reservoir using an oxygen supply line. When the portable is connected to the reservoir in this manner, the reservoir supplies gas oxygen to the portable and allows you to breathe from the portable as a conserving (demand) device without filling it.

Controls

1. Portable Fill Connector
2. Vent Valve
3. Battery Housing
4. Contents Indicator
5. Portable Release Button
6. Pressure Gauge
7. DISS Connection (Breathing Oxygen Supply)
8. Moisture Container



Standard & Universal Reservoirs

HELiOS Reservoirs are available in both Standard (H36, H46) and Universal (U36, U46) models. The easiest way to identify which reservoir you have is by looking at the fill connector. Universal reservoirs have a higher fill connector whose pop-off assembly is curved upward. Reference the below figure to identify the model of your reservoir.

HELiOS Standard reservoirs will only fill the HELiOS H300 and H850 portable units.

HELiOS Universal reservoirs will fill any CAIRE top-fill (TF) portable unit that has a compatible female fill connector. A compatible female fill connector is shown on this page.

Universal reservoir

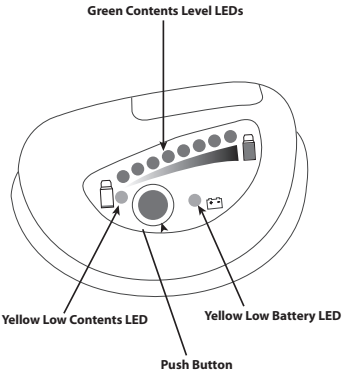
Standard reservoir

PB-Style portable fill connector

Operating Instructions – Level Verification

1. Press the blue button on the contents indicator.
2. Read the LED lights to indicate the liquid contents level.
   - If you get a green contents level light, there is sufficient oxygen in the reservoir to fill your portable unit.
   - If the yellow low contents light appears, the reservoir is empty or nearing empty. Contact your heath care provider immediately.
   - If the yellow low battery light appears, inform your healthcare provider the next time your HELiOS reservoir is filled.

NOTE: The HELiOS reservoir will continue to fill and deliver oxygen when the low battery light is on as long as there is oxygen in the tank.



HELiOS contents indicator

WARNING: REMOVE THE BATTERY FROM THE HELIOS RESERVOIR IF THE RESERVOIR IS NOT LIKELY TO BE USED FOR SOME TIME.

Operating Instructions – Filling a Portable

1. Verify the level of liquid oxygen in the unit (see Operating Instructions — Level Verification).
2. Clean and dry the fill connectors on both the HELiOS reservoir and the portable unit. Wipe gently using a clean, dry, lint-free cloth.

WARNING: THE FILL CONNECTORS MUST BE CLEAN AND DRY WITH A LINT-FREE CLOTH ON BOTH THE STATIONARY AND PORTABLE UNITS TO PREVENT FREEZING AND POSSIBLE EQUIPMENT FAILURE.

WARNING: SHOULD LEAKAGE BE EXCESSIVE TO THE POINT THAT A STREAM OF LIQUID IS PRESENT, LEAVE THE AREA AND CALL YOUR HEALTH CARE PROVIDER IMMEDIATELY.

WARNING: DO NOT DEPRESS OR DISTURB THE METAL POPPET ON THE FILL CONNECTOR WHEN DRYING IT. THIS CAN CAUSE LEAKAGE OF LIQUID OXYGEN.

Caution: Should there be any liquid leakage from the HELiOS reservoir after separating the units, set the portable aside, ensuring it remains vertical, leave the room and call your health care provider immediately.

3. Turn the flow control knob on the portable unit to the off (0) position.
4. Follow the filling instructions provided for your portable unit.

Operating Instructions – Breathing Directly from the Reservoir

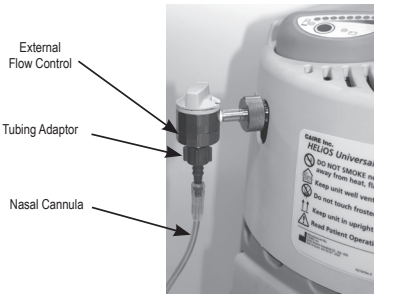
Note: Use the duration charts available at www.caire-medical.com as a guideline to determine the length of time your HELiOS reservoir will operate continuously at a given flow rate.

1. Verify the level of liquid oxygen in the unit (see Operating Instructions — Level Verification).
2. Use the following chart as a guideline to the recommended tubing length.

FLOW SETTING	MAXIMUM (RECOMMENDED) TUBING LENGTH*
(LPM)	**22-psig**
1-6	100 Ft. (30.5 m)
8	100 Ft. (30.5 m)
10	50 Ft. (15.2 m)

*Length is oxygen tubing only. Does *not* include a 7 Ft. cannula.

3. Attach an external flow control valve (FCV) to the DISS connection of the reservoir. Make sure to tighten the nut until no hissing sound is heard.

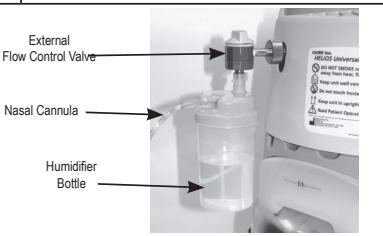


Attachment of external flow control valve

4. *If a humidifier bottle will not be used:*
   - Attach a tubing adaptor to the bottom of the external flow control valve.
   - Attach your nasal cannula or oxygen tubing to the tubing adaptor.

   If a humidifier bottle will be used:
   - Attach a humidifier bottle to the bottom on the external flow control valve.
   - Fill the humidifier bottle with distilled water to the proper level as indicated by the humidifier's instructions.
   - Attach your nasal cannula or oxygen tubing to the connector on the humidifier bottle.

Caution: To ensure proper flow rates, verify that all fittings are tight and leak free.



Attachment of a humidifier bottle to the external flow control valve.

5. Turn the knob on the external flow control valve until your prescribed continuous flow rate (numeric in LPM) is displayed in the window and a positive detent is felt.

NOTE: The knob should not be set higher than the maximum flow rate prescribed by a physician.

NOTE: Out-of-specification oxygen flow will result if the flow control knob is set between flow rates.

6. Properly position your nasal cannula and adjust it for comfort.

NOTE: Ensure the cannula is fully inserted and secure. During inhalation, you should hear or feel oxygen flow to the prongs of the nasal cannula. The proper placement and positioning of the prongs of the nasal cannula in your nose is critical to the amount of oxygen delivered to the respiratory system of the end user.

7. You should be receiving oxygen now. Check to make sure you feel oxygen flow into your nose and that there are bubbles in the humidifier bottle (if used).

8. Turn the flow control knob to the off (0) position when the reservoir is not in use.

9. Under certain environmental conditions with continuous use, the HELiOS reservoir may develop an excessive amount of ice on the coils visible under the shroud. You should defrost the unit between uses to minimize this ice buildup.

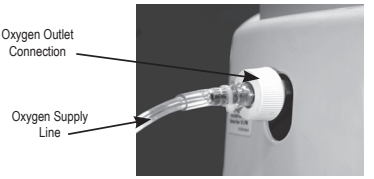
To de-frost the unit:

- Fill a portable unit so that you can continue to receive oxygen while the HELiOS reservoir defrosts
- Set the knob on the external flow control valve to the off (0) position and allow the unit to warm to room temperature, as indicated by the melting of all ice from under the shroud.
- Check the moisture container frequently during defrosting and empty as required.
- The container should be emptied whenever the water reaches the (1/1) line visible on the outside of the container. If the water is not emptied, moisture may spill onto your floor.
- To empty the moisture container, pull out on the container and pour the water into a sink for disposal.

Emptying the Moisture Container

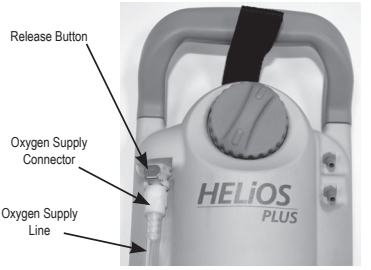
Operating Instructions – Using the HELiOS Supply Line

1. Thread the oxygen supply line nut onto the DISS connection of your HELiOS reservoir. Make sure to tighten the nut until no hissing sound is heard.



Attaching the oxygen supply line to the reservoir

2. Connect the opposite end of the oxygen supply line to an H300 Plus or H850 Marathon by pushing the supply line into the connector on the left-hand side of the unit.



Attaching the oxygen supply line to the H300 or H850 portable

3. Breathe from your portable as normal, following the operating instructions provided with the H300 or H850 unit. Use only in the demand mode only for the H850.

NOTE: For H300's and H850's that have the CPC connector installed, Retrofit Kit P/N 20748595 is available.

Maintenance

Clean the fill connectors on both the stationary and portable units with a clean, dry, lint-free cloth between each fill to prevent freezing and possible equipment failure.

There are no user-serviceable parts in the Helios.

Your service provider is responsible for any maintenance that my be required per the technical manual of this device. Call your service provider for any maintenance requirements.

The expected service life is a minimum of five years.

User Troubleshooting

The following information is intended to help you troubleshoot and solve simple operational problems that you may experience when using your HELIOS Reservoir.

Issue	Solution
The Reservoir makes a hissing sound.	• Hissing can occur to maintain the correct operating pressure within the Reservoir. It is most likely to hiss after filling or when the position of the Reservoir is changed. Hissing can last for 30-60 minutes after filling. Furthermore, improper filling or lower than normal operating pressure in the Reservoir will contribute to the unit not being able to fill portables and improper flows
The Reservoir flow stops during use.	• Ensure that the cannula is firmly attached to the Oxygen Outlet. • Ensure that the cannula is not kinked. • Ensure that there is oxygen in the Reservoir.
The Portable does not fill.	• Verify that there is oxygen in the Reservoir. • Ensure that the Portable and Reservoir fill connectors are fully engaged throughout the filling process.
The Portable vent valve does not close properly at the end of the filling process.	• If the vent valve fails to close and the hissing sound and oxygen vapor cloud continue, carefully remove the Portable by depressing the release button on the Reservoir. Venting from the bottom of the Portable will stop in a few minutes. Allow the unit to warm until you can close the vent valve. The Portable may require as long as 60 minutes to restore adequate pressure for accurate oxygen flow. If needed, use an alternate source of oxygen such as a flow control valve attached to the Reservoir.
The Portable does not disengage easily from the Reservoir after filling.	• The Portable and Reservoir fill connectors may have become frozen. • DO NOT USE FORCE OR USE WATER. Allow a few minutes for the frozen parts to warm, then disengage the Portable when the ice has melted. To prevent the units from freezing together, always wipe the male fill connector on the Reservoir and the female fill connector on the Portable with a clean, dry cloth before filling.
Liquid is spraying from the top of the reservoir.	• Contact Oxygen Provider • Open doors and windows. • Leave the area immediately.
Frost and ice buildup and or condensation.	• Some frost and condensation is normal on the warming coils • Condensate collector is full; empty the tray. • Ensure the Flow Control Knob is closed if not in use.

Cleaning Standard

WARNING: CLEAN ONLY AFTER THE UNIT IS EMPTY.

- Clean using a solution of mild dish washing detergent and water.
- Apply cleaning solution directly to a lint-free cloth. Approved cleaners include HydroPure and HydroKlean. Do not spray cleaners directly on the HELiOS Reservoir.
- Wipe the outside surface with the lint-free cloth until the outside surface is clean.

Caution: Do not use high temperature and high pressure washing equipment to clean these units.

- Do not get cleaner on any internal components or valves.
- Allow the unit to dry thoroughly before using.

Note: Note to health care provider – for reprocessing procedures, see applicable service manual.

Disposal

Always return HELiOS Reservoir, including all components, to your homecare provider for proper disposal. You can also contact your local city or town offices for instructions on proper disposal of the battery.

WEEE and RoHS

This symbol is to remind the equipment owners to return it to a recycling facility at the end of its life, per Waste Electrical and Electronic Equipment (WEEE) Directive.
Our products will comply with the restriction of Hazardous Substances (RoHS) directive. They will not contain more than trace amounts of lead or other hazardous material content.

Transport and Storage

The device should be stored in the upright position, and be well ventilated. Do not allow the device to lie on its side. Humidity up to 95% noncondensing. Temperatures range from -40°F to 158°F (-40°C to 70°C).

Operating temperature ranges from 14°F to 104°F (10°C to 40°C). Relative humidity range from 30% to 75% noncondensing.

Note: The atmospheric pressure range is 700 hPa to 1060 hPa (elevation of 10,000 Ft. to -1,000 Ft.).

Accessories

	15 in (38.1 cm) Roller Base for HELiOS Reservoirs, available for all models. NOTE: Only use roller base on flat surfaces.
	0-10 LPM External Flow Control Valve Allows you to breath continuously from it between 0-10 LPM. If prescribed, your health care provider will provide it.
	50 ft (15.24 m) HELiOS Oxygen Supply Line Used to connect an H300 or H850 portable unit to your reservoir to allow the portable to be used as a conserving device. Note: When using the HELIOS oxygen supply line with the H850, the portable must be in demand mode.

Note: To Equipment Provider: The following oxygen administration accessories are recommended for use with the HELiOS:

- Nasal Cannula: CAIRE Part Number 6-778057-00
- Firebreak: CAIRE Part Number 21126636

A firebreak is recommended for use with any cannula.

- CAIRE offers a firebreak intended to be used in conjunction with the oxygen reservoir. The firebreak is a thermal fuse to stop the flow of gas in the event that the downstream cannula or oxygen tubing is ignited and burns to the firebreak. It is placed in-line with the nasal cannula or oxygen tubing between the patient and the oxygen outlet of the HELiOS. For proper use of the firebreak, always refer to the manufacturer's instructions (included with each firebreak kit).
- Additional recommended accessories information is available online at www.caireinc.com.

Safety

WARNING: PORTABLE RF COMMUNICATIONS EQUIPMENT (INCLUDING PERIPHERALS SUCH AS ANTENNA CABLES AND EXTERNAL ANTENNAS) SHOULD BE USED NO CLOSER THAN 30 CM (12 INCHES) TO ANY PART OF THE LIBERATOR, INCLUDING CABLES SPECIFIED BY THE MANUFACTURER. OTHERWISE, DEGRADATION OF THE PERFORMANCE OF THIS EQUIPMENT COULD RESULT.

WARNING: USE OF ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED OR PROVIDED BY THE MANUFACTURER OF THIS EQUIPMENT COULD RESULT IN INCREASED ELECTROMAGNETIC EMISSIONS OR DECREASED ELECTROMAGNETIC IMMUNITY OF THIS EQUIPMENT AND RESULT IN IMPROPER OPERATION.

WARNING: USE OF THIS EQUIPMENT ADJACENT TO OR STACKED WITH OTHER EQUIPMENT SHOULD BE AVOIDED BECAUSE IT COULD RESULT IN IMPROPER OPERATION. IF SUCH USE IS NECESSARY, THIS EQUIPMENT AND THE OTHER EQUIPMENT SHOULD BE OBSERVED TO VERIFY THAT THEY ARE OPERATING NORMALLY.

Caution: Medical Electrical Equipment needs special precautions regarding Electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.

Caution: Portable and mobile radio frequency (RF) communications equipment can affect Medical Electrical Equipment.

Table 1

Guidance and Manufacturer's declaration—electromagnetic emissions

The HELiOS Reservoir is intended for use in the electromagnetic environment specified below. The customer or the user of the HELiOS Reservoir should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The HELiOS uses RF energy only for 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 HELiOS 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2*

Recommended separation distances between portable and mobile RF communications equipment and the HELiOS Reservoir

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz and 800 MHz	800 MHz to 2,5 GHz
	d=1.2√P	d=1.2 √P	d=2.3 √P
0,01	0.12 m	0.12 m	0.23 m
0,1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to 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.

* This table is included as a standard requirement for equipment which has been tested to specific test levels and over specific frequency ranges and been found compliant with regulations.

Table 3

Guidance and manufacturers declaration—electromagnetic immunity

The HELiOS Reservoir is intended for use in the electromagnetic environment specified below. The customer or the user of the HELiOS Reservoir should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+- 8kV Contact +- 2 kV, +-4 kV, +- 8 kV, +- 15 kV air	+- 8kV Contact +- 2 kV, +-4 kV, +- 8 kV, +- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.**
Electrical fast transient/burst IEC 610004-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable DC powered device Not applicable No data input/output lines	Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable DC powered device	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Not Applicable DC powered device	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Note: UT is the a.c. mains voltage prior to application of the test level.

** This statement indicates that the required testing was performed in a controlled environment and the HELiOS Reservoir are found to be compliant with regulations.

Table 4

Guidance and Manufacturer's Declaration—Immunity ME Equipment and ME Systems

Guidance and Manufacturer's Declaration—Immunity			
The HELiOS Reservoir is intended for use in the electromagnetic environment specified below. The customer or user of the HELiOS Reservoir should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 6 Vrms (In ISM Bands) 150 kHz to 80 MHz	Not applicable Battery powered device, No SIP/SOP	Portable and mobile RF communications equipment should be used no closer to any part of the HELiOS Reservoir, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ $d = 2,3 \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (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:
Radiated RF IEC 61000-4-3	80 MHz to 2.7 GHz	10 V/m 80 MHz—2,7 GHz 80 % AM at 1 kHz	

Test frequency (MHz)	Band[a)] (MHz)	Service[a)]	Modulation[b)]	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380–390	TETRA 400	Pulse modulation[b)] 18 Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM[C)] ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation[b)] 217 Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b)] 18 Hz	2	0.3	28
870						
930						
1720	1700–1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b)] 217 Hz	2	0.3	28
1845						
1970						
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b)] 217 Hz	2	0.3	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the HELiOS Reservoir may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50% duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Notes

Notes

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