BREAS | iLink by Breas

Instructions for Use: English

Ref: 007950 & 008448

Contents

Please read all the instructions in this Help Guide before using iLink 

- Warnings and Cautions ..... Page 3
- Symbols ..... Page 4
- Manufacturer Information ..... Page 5
- Customer Support ..... Page 5

- iLink by Breas:
  - Declaration ..... Page 6
  - Prerequisites, Labels and Replacement Accessories ..... Page 8
  - Connecting the iLink ..... Page 9
  - Frequently Asked Questions ..... Page 10
  - Cleaning & Storage Advice ..... Page 11
  - Technical Specifications ..... Page 12
  - Electromagnetic Immunity ..... Page 13
  - Electromagnetic Emissions ..... Page 14
  - Separation Distances ..... Page 15
  - Antenna Requirements ..... Page 16

Warnings and Cautions

Warnings:

- The iLink must be placed outside the patient environment (i.e. at least 1.5 meters from the patient and other patients).
- Do not place the iLink in direct sunlight or cover the iLink.
- Do not open the iLink or use the iLink if the casing is broken or damaged. In the event of a broken iLink please contact Customer Support.

- 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 iLink, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 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.
- 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.

Cautions:

- U.S. Federal law restricts this device to sale by or on the order of a physician. **Rx Only**

Notes:

- The iLink is dependant on an adequate cellular connection to be able to transmit data. The ability to review the latest data in EveryWare will be dependant on iLink's cellular connectivity, connection to a Breas Ventilator or Device and if both are powered on.

Symbols

Icons and Symbols used in this manual:

- In this manual, icons are used to highlight specific information. The meaning of each icon is explained in the table below:

Symbol	Meaning	Description
	Warning	Highlight potential mis-use of the iLink
	Caution	Risk of equipment damage, loss of data, extra work, or unexpected results
	Reference	Reference to other manuals with additional information on a specific topic
	Note	Information that may be valuable but is not of critical importance
	Follow Instructions for Use	Refer to this Instructions for Use/Help Guide
	Consult Instructions for Use	The User must consult this Instructions for Use / Help Guide
	Manufacturer	
	Serial Number	
	Reference Number	
	Date of Manufacture	
Rx Only		U.S. Federal law restricts this device to sale by or on the order of a physician.
	IEC protection Class II: Double insulated equipment	
	Polarity of DC Power Connector	
	Read User Manual for information about recycling and disposal	
	Do not use if package is damaged	
	Power Button	
	CE	Meets all requirements for CE marking according to applicable European health, safety and environmental protection legislation
	UKCA	Meets all requirements for UKCA marking according to applicable United Kingdom health, safety and environmental protection legislation

Manufacturer & Customer Support Information

Legal Manufacturer: Breas Medical AB

- Postal Address: Breas Medical AB, Företagsvägen 1, SE-435 33 Mölnlycke Sweden.
- Email Address: breas@breas.com
- Phone: +46 (0) 31 868800
- Fax: +46 (0) 31 868810

U.K Responsible Person: Breas Medical Ltd.

- Postal Address: Breas Medical Ltd., Unit A2, The Bridge Business Centre, Timothy's Bridge Road, Stratford upon Avon, CV37 9HW, U.K.
- Email Address: orders@nippyventilator.com
- Phone: +44 (0)1789 293460
- Fax: +44 (0) 1789 262470

Adverse Effects:

If a serious incident has occurred in relation to the iLink, please report it to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Customer Support & Manufacturer - Global:

- Address: Breas Medical AB, Företagsvägen 1, 435 33 Mölnlycke, Sweden.
- Email Address: breas@breas.com

iLink by Breas Declaration Introduction

- iLink by Breas provides cellular connection between a compatible Breas ventilator or device and EveryWare. The iLink sends therapy and device data recorded in the device to EveryWare, wirelessly and automatically, to assist the remote display of patient data. The iLink can receive remote setting changes and send confirmation messages to EveryWare.

- During periods of electromagnetic interference that are within limits specified by the EMC testing standards, the following allowances are acceptable:
  - iLink transmission to the web application can be interrupted or fail during the test
  - iLink can restart itself
  - iLink can stop functioning
  - Manual power cycle to reset and restart iLink.

- The following conditions are not allowed:
  - Mismatch between treatment data records in the web application and treatment data in ventilator.
  - No effect on the operation of the ventilator or device.

iLink by Breas Declaration Introduction contd.

For US:

- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
    - This device may not cause harmful interference.
    - This device must accept any interference received, Including interference that may cause undesired operation.
    - "Harmful interference" is defined in 47 CFR Section 21 by the FCC as follows: interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with [ITU] Radio Regulations.

Environment of Use:

- The iLink is intended to be used in homes, institutions and hospitals as an accessory to a ventilator system It is not intended for use in public space. iLink is not intended to be used together with portable applications such as wheelchairs, gurneys or personal family vehicles. It is not intended for use during emergency transports.

Intended Use (US only):.

- Intended for use as an accessory to EveryWare. EveryWare is indicated to support clinicians by managing data of patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. EveryWare provides remote patient data collection & viewing and is intended to be used by healthcare representatives in conjunction with compatible non-life support therapy devices to adjust prescription and/or performance settings. EveryWare is intended to be used in hospital, institutional, provider, and home care settings.

For Canada:

- This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s).
- Operation is subject to the following two conditions:
    - This device may not cause interference.
    - This device must accept any interference, including interference that may cause undesired operation of the device.

For UK:

- Hereby, Breas Medical AB declares that the radio equipment type included in this device is in compliance with the Radio Equipment Regulations 2017 (as amended).

For EU:

- Hereby, Breas Medical AB declares that the radio equipment type included in this device is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available via www.breas.com/declarations.

Prerequisites, Labels and Replacement Accessories

iLink by Breas:

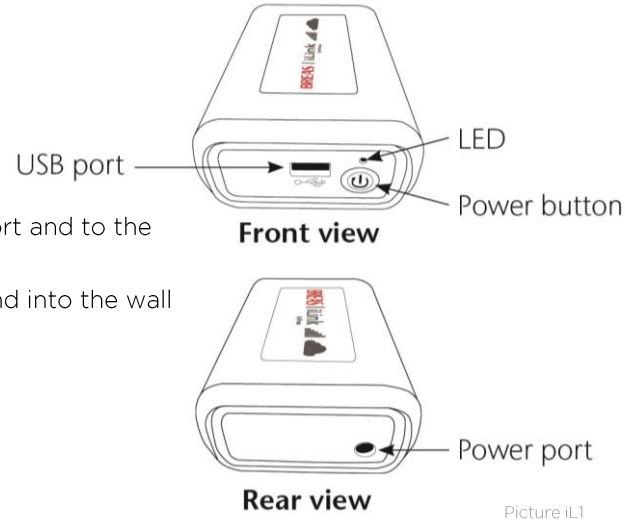
- The iLink communicates with EveryWare over a cellular https/SSL connection, every 15 minutes.
- The iLink Firmware will be kept up-to-date from within EveryWare, no user interaction is required.
- The iLink connects to a Breas ventilator or device via the USB cable and requires a separate power source, connected via the power adapter supplied.
- The iLink requires 4G/LTE cellular coverage.

iLink by Breas can be identified using the following labels:

Breas Recommended Replacement Accessories:

Part Number	Description
007966	5V Wall Mount Adapter Power Supply (US)
008401	5V Wall Mount Adapter Power Supply (UK)
008414	5V Wall Mount Adapter Power Supply (EU)
004886	USB A to B Cable
008436	USB cable for Vivo 45/LS and NIPPY 4/4+

Connecting the iLink



Picture iL1

Connecting iLink to a Breas ventilator or device:

1. Connect the iLink to the Breas ventilator or device by plugging the USB cable into its USB port and to the front of the iLink (Picture iL1).
2. Plug the power adapter supplied with the iLink into the Power port on the rear of the iLink and into the wall receptacle, ensuring switch is on.
3. Press the Power button on the iLink. Make sure the ventilator or device is also powered on.

The iLink software performs a self-test upon start-up and follows the LED sequence detailed below:

Sequence Stage	Description	Action
Powering Up	LED - Steady Red Bright.	Please wait . . .
Software Takes Over	LED - Flashes Red and Green.	Please wait . . .
Self-Test Results:		
Successful	LED - Steady Green Bright, dimming after 30 seconds.	iLink is working as expected.
Failed #1	LED - Solid Red.	Wait 10 minutes, if no change 'Power cycle' the iLink by disconnecting power to iLink, wait 30 sec. and reconnect.
Failed #2	LED - Blinking Red (In order of priority):	
	Temperature Sensor Issue: 1 Flash followed by 2 sec. pause.	Contact Customer Support.
	Modem Connection Issue: 3 Flashes (at 0.25 sec. intervals) followed by 2 sec. pause.	Try moving iLink to find a stronger signal.
	Device Connection Issue: 2 Flashes (at 0.25 sec. intervals) followed by 2 sec. pause.	Check the Breas device and iLink are connected using the USB cable and are both powered on.

Post Failed #1/#2 Self-Tests After blinking for the specific sequences described above for 30 sec, the Red LED will be in steady dim state (Green LED will be off).

Frequently Asked Questions (FAQ's)

iLink by Breas Frequently Asked Questions (FAQ's):

1. Are there any prerequisites for data to be transmitted by the iLink into EveryWare?
    - 1. A patient record needs to be created in EveryWare; 2. Have a compatible ventilator or device (inc. Firmware) assigned. 3. The iLink is dependent on an adequate cellular connection to be able to transmit data; 4. iLink connected to the ventilator/device using the supplied USB cable; and 5. both are powered on.

2. How many Breas ventilator or devices can be connected to a single iLink?
    - Unlimited. Users can connect as many as they like, but only one at time. If there is more than one device that needs to be connected/data transmitted, Users should wait at least 15mins per device to allow sufficient time to transmit the data before switching. Please ensure all ventilators or devices are assigned to the PATIENT record.

3. Can the iLink be used to transmit data from a non-compatible device? How do you protect the data from hacking?
    - No, only Breas compatible ventilators or devices can transmit data using the iLink. The iLink uses a secure cellular end-to-end connectivity with multiple layers of authentication, encryption and access control. The cellular modem is 'locked' which means even if the iLink was disassembled, the modem/SIM could not be used on another iLink or for any other purpose. Please note there is no Wi-Fi or Bluetooth connectivity.

4. How frequently does the iLink transmit data to EveryWare? Can I see the data real-time? How often is data being sent?
    - The iLink communicates with EveryWare every 15 minutes and sends any data available to EveryWare.

5. What happens to the data in the iLink, if the iLink does not have connection to EveryWare?
    - The iLink shall send data to EveryWare from the ventilator to which it is currently connected. Any buffered data from a ventilator(s) that is not connected to iLink shall not be sent until the corresponding ventilator is reconnected. Data from each ventilator shall be stored in different files with ventilator model and serial number in the filename.

Cleaning & Storage

iLink Instructions for Cleaning:

- Remove power from the iLink by disconnecting the power cable.
- Always be careful when cleaning to ensure that you do not damage the iLink.
- Fluid must not be allowed to enter the iLink.
- Never apply any liquids directly on the iLink by spraying, splashing, or pouring.
- Do not use an excessive amount of liquid when cleaning the iLink.
- Clean the outside of the iLink using a lint-free cloth with a mild soap solution, and/or ethanol 70% for surface disinfection.
- Do not autoclave the iLink and do not to place the iLink in direct sunlight or cover the iLink.

iLink Service and Repair:

- iLink does not require calibration or servicing.
- Any repair of the iLink must only be carried out by Breas service personnel.
- Do not open the iLink or use the iLink if the casing is broken or damaged. In the event of a broken iLink please contact Customer Support.

Change of Patients:

- iLink can be switched/moved between devices and between patients. Please follow the Instructions for Cleaning or Service and Repair advice above.

iLink Disposal:

- The iLink, any accessories and all replaced parts must be disposed of and recycled in accordance with the local environmental regulations regarding the disposal of used equipment and waste.
- Contact your service provider for information regarding the disposal procedure.

Technical Specifications

iLink by Breas

Dimensions & Weight	45 (H) x 81 (W) x 118 (D) mm 182g
Wireless Technology	4GLTE
Compatible Software Versions or newer.	EveryWare by Breas 1.5

For a full list of devices compatible with iLink, please refer to the EveryWare by Breas IFU.

Vivo 65 (US)	1.05
Vivo 65 (ROW)	5.01
Vivo 55	4.02
Vivo 50	2.16
Vivo 45 LS (US)	5.0.4
Vivo 45 LS (ROW)	3.1.4
NIPPY 4+	4.1.4
Vivo 45	1.1.4
NIPPY 4	2.1.4

Warranty	12 months. The iLink does not contain any serviceable parts.

iLink Environmental Conditions for Storage and Operation:

Storage/Transport Temperate	Min -25°C to Max 70°C
Operating Temperature	5°C to 40°C “for indoor use only”
Storage Humidity	10% to 90% non-condensing
Operating Humidity	20% to 90% non-condensing

Power Supply

Dimensions	36.8 (H) x 43.5 (W) x 74.0 (D) mm
Voltage	AC 90-264 V
Voltage Output	5 V
Current – Output (Max)	6 A
Cable Length	1.2 m
Form	Class II
Efficiency	Certified to IEC 62368-1 Standards and compliant with DoE Level VI and CoC Tier 2
Power	30 W
No Load Power Consumption	74 mW (Max)
Operating Temperature	-20°C to 50°C

Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity:

The iLink by Breas is intended for use in the electromagnetic environment specified below. The user of the iLink should assure that it is used in such an environment.

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± -2, 4, 8 & 15kV air	The relative humidity should be at least 5 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial, hospital and residential environment.
Surge IEC 61000-4-5	± 1kV to line	Mains power quality should be that of a typical commercial, hospital and residential environment.
Power Frequency (50/60Hz) Magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital and residential environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT, 0.5 cycle (multiple phase analysis); 0% UT, 1 cycle; 70% UT, 25/30 cycles (50/60 Hz); 0% UT, 250/300 cycles (50/60 Hz)	iLink might restart during voltage dips, short interruptions, and voltage variations on power supply input lines. The transmitted data integrity will be maintained.
Conducted RF (IEC 61000-4-6)	10 Vrms150 kHz to 80 MHz	d=0.35*√P m at 150 kHz to 80 MHz
Radiated FR (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz	d= 0.6*√P m at 80 MHz to 800 MHz d= 1.2*√P m at 800 MHz to 2.7 GHz

Notes:

- UT is the mains voltage prior to application of the test level. At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- a) Field 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 assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ventilator.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.
- iLink has been tested with a passing result for IMMUNITY to proximity fields from RF wireless communications equipment as per section 8.10 of IEC60601-1-2.
- Equation description:
- 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 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 this symbol:

Electromagnetic Emissions

iLink by Breas Guidance and Manufacturer's Declaration – Electromagnetic Emissions:

The iLink by Breas is intended for use in the electromagnetic environment specified below. The user of the iLink should assure that it is used in such an environment.

Emissions Test	Compliance Level	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The iLink 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 iLink 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 Emission IEC 61000-3-3	Complies	

Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the iLink:

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

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz to 80 MHz d= 0.35*√P m	80 MHz to 800 MHz d= 0.6*√P m	800 MHz to 2.5 GHz d= 1.2*√P m
0.01	0.035	0.06	0.12
0.1	0.11	0.19	0.36
1	0.35	0.6	1.2
10	1.1	1.9	3.6
100	3.5	6.0	12.0

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.

Rated maximum current in conductor (A)	Separation distance (m)
	50-60 Hz d=I/2πH= /188
1	0.05
10	0.5
100	0.16

For conductors rated at a maximum current not listed above, the recommended separation distance d in meters (m) can be estimated using the equation d=I/2πH, where I is the maximum current rating of the conductor in amperes (A) according to the transmitter manufacturer; H is the ventilator immunity compliance level to electromagnetic fields in the 50-60 Hz frequency span (30 A/m).

Notes:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Antenna Requirements

Cellular Transmission and Reception Bands:

	Band	Uplink (MHz)	Downlink (MHz)
Frequency Range	B1	1920 – 1980	2110 – 2170
	B2, PCS1900	1850 – 1910	1930 – 1990
	B3, DCS1800	1710 – 1785	1805 – 1880
	B4	1710 – 1755	2110 – 2155
	B5, GSM850	824 – 849	869 – 894
	B8, EGSM900	880 – 915	925 – 960
	B12	699 – 716	729 – 746
	B13	777 – 787	746 – 756
	B18	815 – 830	860 – 875
	B19	830 – 845	875 – 890
	B20	832 – 862	791 – 821
	B26	814 – 849	859 – 894
	B28	703 – 748	758 – 803
	B39	1880 – 1920	1880 - 1920

iLink by Breas RF Specifications:

Parameter	Value
4G LTE Technology	4G Cat M1, 4G Cat NB1, 2G
4G LTE TX Output Power	23dBm ± 2dB

Note

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