BIO-MED DEVICES

AIR/OXYGEN BLENDER

INSTRUCTION MANUAL

CATALOG #2120
REV 111422

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TABLE OF CONTENTS

ADDENDUM 1- Low Flow Selector Knob A1
ADDENDUM 2- Permanently Mounted Flowmeters A1
ADDENDUM 3- Dial Flowmeters A2
1. WARNINGS, CAUTIONS AND NOTES 1
2. EXPLANATION OF SYMBOLS 3
3. SPECIFICATIONS 5
4. INTRODUCTION AND OPERATION / INTENDED USE 6
5. SETTING UP THE BLENDER 7
6. TESTING THE BLENDER 8
7. USING THE BLENDER 8
8. TROUBLE SHOOTING GUIDE 8
9. CLEANING INSTRUCTIONS 9
10. BLENDER WARRANTY 9
11. SERVICE RECOMMENDATIONS 9
12. TRAINING RECOMMENDATIONS 10
13. DEVICE LIFETIME & END-OF-LIFE DISPOSAL 10
14. MATERIALS CONTENT 11
APPENDIX A (EU AGENT & UKRP) 12
APPENDIX B (MR INFORMATION) 13
APPENDIX C (UDI NUMBERS) 14

ADDENDUM 1- Low Flow Selector Knob

A low flow selector knob has been installed on some of the Bio-Med Devices Blenders (standard on units mounted on the Crossvent ventilators) in lieu of the right side output port. This enables the user to maintain accurate concentrations when using the bottom or left outputs for all flows within the specification of the blender with a simple turn of the knob.

A label attached to the side of the blender indicates how to position the knob for accurate concentrations at settings less than or greater than the flow rate indicated. The knob must be pushed in prior to turning.

ADDENDUM 2- Permanently Mounted Flowmeters

Several blenders, including the NEO_2 BLEND series, are offered with flowmeters mounted on the right side of the blender. In most cases, this flowmeter is mounted to a uniquely designed rotating switch that is used in the same manner as the knob described in Addendum 1. Any time these blenders are used in a flow range requiring the bleed to be active (see the Flow Table in Section 4), rotating this flowmeter as described below will activate the bleed as well as the flowmeter. Even if the flowmeter is not to be used, positioning it vertically so the bleed is active allows the blender to be used with its lower flows.

<u>The flow rate for these flowmeters should be set using the center of the ball.</u>

RIGHT SIDE FLOWMETER & LOW FLOWS

The right side flowmeter and the blender bleed are inactive when the flowmeter is angled towards the front of the blender. To activate it and initiate the required bleed for lower flows, push the flowmeter in towards the side of the blender and then rotate it clockwise (towards the back) to its vertical position. The internal bleed will now be active and the flow rate may be set using the knob on the flowmeter. As long as the flowmeter is in this position, any output port can be used for low flows even if the flowmeter itself is not being used. To return the flowmeter and bleed to its off (inactive) state, return it to its angled position by pushing it in and rotating it counterclockwise (towards the front).

LEFT SIDE FLOWMETER

 **CAUTION:** The flowmeter on the left side is stationary. Do not try to turn it.

If the flowmeter on the left side is to be used for flows requiring a bleed for accuracy (see the Flow Table in Section 4), be sure the knob (refer to Addendum 1) or right-side flowmeter (see above) is set properly.

ADDENDUM 3- Dial Flowmeters

Flowmeters offered by Bio-Med Devices that are set by rotating a dial on top of the flowmeter are not pressure compensating. Not pressure compensating means that in order for the flowmeter to accurately deliver the flow rate indicated by the dial, the supply pressure to the flowmeter input must at all times be the same pressure the flowmeter is rated for. If the flowmeter is rated for a 50 PSI supply pressure, then 50 PSI is required at the input in order for the set flow rates to be accurate.

In practice, these flowmeters are often connected to Air/Oxygen blenders and by doing so, the blender then becomes the supply source to the flowmeters.

WARNING: Before use on a patient, the oxygen concentration of the delivered gas should be checked at the setting intended for use. A separate, calibrated oxygen monitor (complying with ISO 80601-2-55) must be used whenever the blender is used on a patient.

It is important to understand that although there may be 50 PSI at the input to the blender, this does not mean there is always 50 PSI at the output of the blender (input to the flowmeters). As flow increases, there is an inherent reduction in pressure at the blender's output due to the restrictive nature, albeit slight, of the blender. Therefore, there is less than 50 PSI at the input to the flowmeters in this situation and flow accuracy suffers. As the input pressure to the flowmeter decreases, so does the flow rate relative to its setting.

Another variable to note with Air/Oxygen blenders is the concentration setting. As the concentration setting is varied, so varies the restrictive nature of the blender, further affecting the blender's output pressure. Think in terms of hot and cold water faucets. When you have just the hot or just the cold faucet turned on, the water pressure is less than when you have both faucets turned on. The blender acts in a similar fashion. More pressure is available when you are mixing air and oxygen than when you are just using one or the other.

Still another variable is the pressure downstream from the flowmeter. Since flow is created by one pressure being greater than another, it stands to reason that the less difference there is between the pressures, the less flow there will be. This downstream pressure may be very low, but needs to be mentioned.

So what is stated above are some of the variables that need to be considered when flowmeters that are not pressure compensating are used with blenders. Any additional device, other than the flowmeter, that delivers flow from the blender, be it a ventilator or other device, must also be taken into account. The flow this additional device is delivering exacerbates the situation so that device should be turned off when using the flowmeters.

1. WARNINGS, CAUTIONS AND NOTES

 WARNINGS

Never leave a ventilator patient unattended, or without remote monitoring.

If the pressure of the oxygen or air gas source increases or decreases resulting in a 20 PSI* (138 kPa) difference (*30 PSI [207 kPa] in the case of overseas devices and those manufactured for Draeger / Hill Rom / Air-Shields), the alarm will sound. This will affect the blender's output flow and oxygen concentration.

The blender alarm will sound if the air or oxygen gas source fails. This indicates to the user that the oxygen concentration or flow may not be accurate. A physician must determine the correct FIO2 setting.

The blender must not be exposed to extremely high temperatures, as in the case of steam autoclaving (which could reach 145° F / 63° C).

The alarm should not be obstructed, removed or tampered with in any way.

The blender is designed to operate from a 50 psig (345 kPa) source of air and oxygen.

Before use on a patient, the oxygen concentration of the delivered gas should be checked at the setting intended for use. A separate, calibrated oxygen monitor (complying with ISO 80601-2-55) must be used whenever the blender is used on a patient.

The bleed port on the bottom of the blender must not be covered at any time.

Some special order blenders may not have a bleed when using the right side outlet. When this is the case, the flow specifications for "flow without bleed" apply to the auxiliary right side outlet.

The factory-installed Air and Oxygen gas supply fittings, which contain essential check valves and filters, must not be substituted with any other parts not approved by Bio-Med Devices. Doing so may cause gas supply contamination due to back-flow.

This blender is not suitable for use with Oxygen 93.

Bleed oxygen flow can cause ignitions.

Do not attempt to service or perform maintenance while the blender is in use.

Only qualified medical personnel should operate the Blender.

CAUTIONS

Moisture or dirt can affect the operation of the blender; a clean dry gas source must be used at all times. The air must meet “USP grade” compressed air standard (formerly ANSI Z86.1-1973 grade F) and at 75 PSI (517 kPa) water vapor content cannot exceed a dew point of 5° F (2.8° C) below the lowest ambient temperature to which the blender and accessories are exposed. The oxygen should be “medical oxygen” per FDA terminology, that is, at least 99.0% pure. Both gases must contain < 37.5 milligrams of water per cubic meter of gas ($^{mg}/_{Nm^3}$) or < 50 ppm H_2O.

A water trap assembly and filter must be used to avoid malfunction should water accidentally get into the gas supply sources.

Do not use in an MRI room unless the blender has been built by Bio-Med Devices to be used for such an environment. This will be indicated by “MRI” on the blender front plate, and an MR-conditional label on the case. Note that the BMD MR-version Air / Oxygen Blenders are not CE-marked.

The flowmeter on the left side of the NEO_2 BLEND is stationary. Do not try to turn it.

If the blender does not pass the performance test, do not place the unit into service; call your dealer or service representative.

The blender should be checked by a qualified technician at the intervals specified in Section 11.

All Bio-Med Devices blenders are tested for backflow at the factory. However, some level of backflow (10 ml./hr.) is acceptable per the ISO standard 11195. It is recommended that when not in use, either the blender supply gases should be detached from the blender (or turned off by installing on/off valves) or the blender bleed function should be left on, to prevent any chance of cross contamination.

NOTES: The NEO_2 BLEND with two flowmeters conforms to the model #2003 configuration with flow limited by the flowmeters. Refer to Addendum 2 in the beginning of this manual.

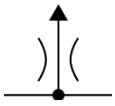
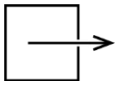
This blender has been degreased for oxygen service prior to delivery.

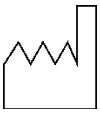
The upper flow limit is the total flow that the blender will pass, not the limit per port.

This device has no latex content.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

2. EXPLANATION OF SYMBOLS

Symbol	Definition / Explanation	BS EN ISO 15223-1 Standard Ref
	Warning: Consult accompanying documents	NA
	Caution: Consult accompanying documents	5.4.4
	MR Conditional- This device has been demonstrated to pose no known hazards in a specified MRI environment and with specified conditions of use.	NA-ASTM F2503-05
	MR Unsafe- This device is known to pose hazards in all MRI environments.	NA-ASTM F2503-05
	Follow Instructions for Use (symbol color is signal blue per ISO 3684)	NA-ref ISO 7010-M002
	Refer to manual for proper method of operation	5.4.3
	Alarm	NA- ISO 7000 ref # 5013
	Warning: Condensed water in air supply can cause malfunction of this device	NA-BMD
	Warning: Do not obstruct alarm or bleed holes in the bottom of this device	NA-BMD
	Gas bleed	NA
	Gas inlet	NA
	Gas outlet	NA

	Product should be kept dry	5.3.4
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.	NA-per FDA guidance
	Date of Manufacture	5.1.3
	Manufacturer	5.1.1
SN	Serial Number	5.1.7
REF	Catalog Number	5.1.6
	Authorized Representative in the European Community	5.1.2
	The CE mark displayed on this product signifies that this device is in compliance with the European Medical Devices Regulation (2017/745). As a prerequisite for the CE mark, Bio-Med Devices operates under an ISO 13485 compliant quality system (covering the design and manufacture of medical devices). The four-digit code underlying the CE mark (2797) pertains to Bio-Med's Notified Body, the British Standards Institute, whose function is to investigate and attest to the validity of CE-mark claims. Note that Bio-Med Devices' CE mark is not affixed to BMD MR-version Blenders. Also, Bio-Med Devices' CE mark does not apply to any mounted flowmeter, which is separately CE marked by the flowmeter manufacturer.	
	This symbol indicates that this device is in compliance with UK medical device legislation. The four-digit code underlying the UKCA mark (0086) pertains to Bio-Med's Notified Body, the British Standards Institute (England)	
	Country of Manufacture	
	Medical Device	
	Unique Device Identifier	
	Contains Hazardous Substances	

3. SPECIFICATIONS

Bio-Med Devices' line of blenders delivers accurate FIO_2 mixtures from one to up to three outlet ports, allowing it to power three items at once. Several flow ranges are available. They can be used with ventilators, nasal cannulas, mask CPAP and resuscitation bags. The 0-50 LPM Blender is a perfect compromise between the High Flow and Low Flow blenders as it requires less of a bleed for accuracies below 6 LPM than the High Flow while allowing greater maximum flow than the Low Flow Blender. The Low Flow version of the blender provides flows from 3 to 30 LPM with no gas bleed. Bio-Med Devices also offers MR-conditional versions that are made entirely of non-magnetic materials.

 **CAUTION:** Do not use in an MRI room unless the blender has been built by Bio-Med Devices to be used for such an environment. This will be indicated by “MRI” on the blender front plate, and an MR-Conditional label on the case.

Device-Specific Standards: Complies with ISO 11195.

Oxygen % Range: 21 to 100%

Oxygen % Accuracy: ±3% of full scale

Supply Pressure: Both supplies within range of 30-75 PSI (207-517 kPa) and Air & oxygen must be within 10 PSI (69 kPa) of each other.* Do not use on a patient or with a ventilator outside of this range.

> *Blender performance with supply pressures below range (0-30 PSI / 0-207 kPa) cannot be predicted. Due to low output pressure, it will not be able to adequately drive a ventilator. Not for patient use.
> Blender performance with supply pressures above range (75-112.5 PSI / 517-775 kPa) with supplies balanced, available output flows, and oxygen percentages will remain consistent with specification. Output pressures will be proportionally higher and may damage the ventilator. Not for patient use.

Maximum Flow: ≥120 LPM (≥50 LPM, 0-50 Flow blender; ≥30 LPM, Low Flow blender) @ 60% setting & 50 PSI (345 kPa) inlet pressures.

Standard Flow Ranges: Refer to table in Section 4.

Custom Configuration Flow Ranges: Refer to addendums and table in Section 4.

Pressure Drop: <6 PSI (42 kPa) at 50 PSI (345 kPa) inlet pressure and 40 LPM flow (10 LPM, Low Flow blender).

Low Supply Alarm: as described in Section 4.

Alarm/Bypass Reset: when inlet gas pressure differential is ≥6 PSI (42 kPa).

Alarm Intensity: 80 dB at 1 foot.

Input fittings: Oxygen female DISS, Air male DISS (NIST available)

Output Fitting(s): Male DISS, oxygen type.

Dimensions: Height 3 1/2" (8.9 cm)
Width 2 1/4" (5.7 cm)
Depth 2 7/8" (7.3 cm)

Weight: 2.35 lbs (1.07 kg)

No electronics incorporated.

Reverse Gas Flow: From either gas inlet to the other, complies with clause 9 of ISO 11195.

Operating Temperature: 41° to 104° F (5° to 40° C)

Ambient Humidity: 5 to 90% non-condensing

4. A. INTENDED USE / INDICATIONS FOR USE

The BMD blenders are precision air / oxygen blenders, intended for neonatal through adult human patients, in most medical environments from transport through intensive care (though not for homecare). They do not contact the patient, they are not invasive. The BMD blenders are durable medical equipment, which are in effect “reusable”. The BMD blender is not shipped sterile.

4. B. INTENDED USERS

The Air / Oxygen Blender is a medical device intended for use by qualified medical personnel, e.g., respiratory therapists and respiratory nurses.

4. C. INTRODUCTION AND OPERATION

This precision proportioning device mixes medical grade air and oxygen to any output concentration from 21% to 100% oxygen, for delivery to a variety of respiratory care devices. The blender uses source air and oxygen at a pressure of 50 PSI (345 kPa) connected to two D.I.S.S. fittings on the bottom of the blender. Each fitting has a built-in 48 micron particulate filter. The gas source then passes through a duckbill check valve which prevents reverse gas flows from either source.

The blender uses a double stage balancing system with the gas entering into the first stage to equalize the operating pressure of the gas sources before entering the proportioning stage.

The gases then flow into the proportioning stage where they are mixed to the percentage dialed in on the front panel knob. This stage has a double-ended valve with valve seats on either end. Each one of these valve seats controls the passage of the air or oxygen to the outlet of the blender.

Many different configurations of blenders and output ports are available. The model number can be found on the back of the blender. Use the front of the blender to identify which row to use in the table below to determine its flow range. The blender will be Low Flow, 0-50 LPM, High Flow or High/Low Flow. The flow limitations listed below apply, regardless of what is attached to the port. If the bleed is active, the "flows with bleed" applies to all output ports. Conversely, if the bleed is inactive, the "flows without bleed" applies to all ports.

> *NOTE: The upper flow limit is the total flow that the blender will pass, not the limit per port. As an example, if 30 LPM is passing through any one port on a Low Flow blender, then no other port should be used as 30 LPM is the upper flow limit for this blender.*

The bleed referred to in the table and elsewhere in this manual is activated in one of three ways depending on what is on the right side of the blender. If there is a DISS fitting, attaching a device to this fitting will turn on the bleed[1]. If there is a knob, setting it to the "<" position will turn on the bleed (refer to Addendum 1). If there is a flowmeter on a switch mounted here, rotating it to its vertical position will turn on the bleed (refer to Addendum 2). If none of these options are available on the right side, then the bleed cannot be turned on and off. The bleed will either always or never be present. The latter is the case for the High Flow, which has no bleed available.

[1] **WARNING:** ***Some special order blenders may not have a bleed when using the right DISS outlet. When this is the case, the flow specifications for without bleed apply.***

FLOW TABLE

Model	Flow Range without Bleed	Flow Range with Bleed
Low Flow	3-30 lpm	0-30 lpm (3 lpm Bleed)
Mid Flow (0-50 LPM)	6-50 lpm	0-50 lpm (6 lpm Bleed)
High Flow	15-120 lpm (No Bleed)	N/A
High/Low Flow	15-120 lpm (No Bleed)	2-108 lpm (10-12 Bleed)

> *NOTE: The NEO_2 BLEND conforms to the Low Flow configuration with flow limited by the flowmeters. Refer to Addendum 2 in the beginning of this manual.*

The blender has an audible alarm built in to detect if either of the gas sources changes by more than 20 PSI* (138 kPa) from the other. This will warn the user that they are running out of one of the gas sources or that there is a severe pressure drop in one source. If both gas sources drop or increase together such that a 20 PSI* (138 kPa) difference cannot be detected, then no alarm will sound. If the blender is connected but not being used and a 20 PSI* (138 kPa) difference in gas sources develops, the blender

will not alarm.
*(30 PSI [207 kPa] in the case of overseas devices and those manufactured for Draeger / Hill Rom / Air-Shields)

The blender alarm/bypass function will provide > 90 LPM (the full 30 LPM, Low Flow Blender) upon the loss of air or oxygen, if the remaining gas is at 50 PSI (345 kPa).

5. SETTING UP THE BLENDER

The Bio-Med Devices Blender can be either pole-, wall-, or rail-mounted for easy use for any desired application. The inlet fittings are located on the bottom of the blender and conform to Diameter Index Safety System (D.I.S.S.) so that air and oxygen connections cannot be reversed. Connect an air high pressure hose to the air fitting and an oxygen high pressure hose to the oxygen fitting on the bottom of the blender. Bio-Med Devices recommends an air inlet water trap be used between the air hose and inlet fitting to prevent moisture from entering the blender.

The primary outlet (refer to Addendum 1) on the bottom of the standard high flow blender is appropriate for high flow situations, as with most ventilators requiring flows up to 120 LPM. Flows of less than 15 LPM (6 LPM, 0-50 LPM blender; 3 LPM, Low Flow blender) require the auxiliary right side outlet (knob or switching flowmeter). If both outlets are used simultaneously, neither one will deliver its maximum flow.

6. TESTING THE BLENDER

The following checks should be performed before first placing the blender into service.

> *Note: If the blender does not pass these checks, do not place the unit into service; call Bio-Med Devices Service Department at (203) 458-0202.*

First, connect the 50 PSI (345 kPa) air and oxygen sources to the appropriate fittings and set the blender to 60% (the alarm should not activate). Check to see that the oxygen concentration is actually 60% by using a calibrated oxygen monitor. Disconnect the oxygen source from the blender and listen for the audible alarm. Once it alarms, reconnect the oxygen to stop the alarm and verify the oxygen concentration again. Next, disconnect the air source from the blender and listen for the audible alarm. Once it alarms, reconnect the air and verify the oxygen concentration again.

7. USING THE BLENDER

Connect the gas outlet of the blender either directly or via a high pressure hose to the ventilator or other equipment with which it is being used. Set the control on the front panel to the desired oxygen concentration. Turn on the 50 PSI (345 kPa) air and oxygen sources and set the controls on the ventilator or equipment being used. Use a calibrated oxygen analyzer to check the accuracy of the patient gas. When changing oxygen concentration, wait sixty seconds (equilibration time) before checking it against the analyzer.
To use the standard high flow blender for low flow applications, connect a flowmeter to the secondary outlet (refer to Addendums 1 & 2 at the beginning of this manual), and set the concentration with the knob on the front panel. Turn on the source gases, set the flowmeter, and check the output with a calibrated oxygen monitor.

8. TROUBLE SHOOTING GUIDE

PROBLEM	CAUSE OF PROBLEM	TO SOLVE PROBLEM
OXYGEN ANALYZER DOESN'T AGREE WITH SETTING OF BLENDER	ANALYZER OUT OF CALIBRATION	CALIBRATE OXYGEN ANALYZER
	BLENDER OUT OF CALIBRATION	CALL BIO-MED SERVICE DEPARTMENT
	DIRTY GAS SUPPLY	CALL BIO-MED SERVICE DEPARTMENT
	BLEED ON BOTTOM OF BLENDER IS RESTRICTED	CALL BIO-MED SERVICE DEPARTMENT
	AIR IS FLOWING INTO PIECE OF EQUIPMENT BEING USED AND DILUTING CONCENTRATION	CORRECT SITUATION BY STOPPING THE FLOW OF AIR
BLENDER ALARMING	AIR AND OXYGEN SOURCE PRESSURES HAVE GREATER THAN 20 PSI* (138 kPa) DIFFERENTIAL	BRING THE SOURCE PRESSURES WITHIN THE 20 PSI* (138 kPa) RANGE
	ALARM SYSTEM IS OUT OF CALIBRATION	CALL BIO-MED SERVICE DEPARTMENT
	DIRTY GAS IS CONTAMINATING ALARM SYSTEM	CALL BIO-MED SERVICE DEPARTMENT
THE ONLY TIME THE BLENDER IS ACCURATE IS WHEN THE SOURCE PRESSURES ARE EXACTLY THE SAME	PRESSURE BALANCE CHAMBER NOT WORKING PROPERLY	CALL BIO-MED SERVICE DEPARTMENT

*(30 PSI [207 kPa] in the case of overseas devices and those manufactured for Draeger / Hill Rom / Air-Shields)

9. CLEANING INSTRUCTIONS

Bio-Med Devices' line of blenders should be cleaned & disinfected by wiping the outside surfaces with alcohol (70% IPA) applied to a tissue or cloth. These blenders should never be sprayed with or immersed in any other liquid. Be sure not to allow ingress of any appreciable quantity of alcohol into any alarm or vent holes. Never insert anything into the holes in the alarm cover.

10. BLENDER WARRANTY

The Bio-Med Devices, Inc. warranty lasts for one year from date of purchase. This warranty covers parts and labor. Shipping costs are covered up to six months from date of purchase. This warranty is limited to defects in parts and workmanship; Bio-Med Devices will not be held responsible for misuse or abuse of the product.

All service must be done by Bio-Med Devices or an authorized service representative of

Bio-Med Devices. Bio-Med Devices will not be held responsible for unauthorized service work on any blender.

11. SERVICE RECOMMENDATIONS

Periodic preventive maintenance should be performed to ensure continued proper operation of the blender. The frequency of preventative maintenance is determined by many factors, some of which are:

Frequency & length of use
Quality of the compressed gas source(s)
Environmental conditions

Recommended Maintenance Schedule

Interval	Recommended Procedures
Prior to each use	Performance test
Every year between PM's	Calibration certification
Every 2 years	Major overhaul, cleaning and calibration **Recommend return to factory for this service**

12. TRAINING RECOMMENDATIONS

Upon receipt of the BMD blender, the qualified medical professional should at a minimum read this manual in its entirety, and follow their own facility's training guidelines for new equipment.

13. DEVICE LIFETIME & END-OF-LIFE DISPOSAL

The declared device lifetime of this durable medical equipment is 10 years, if proper preventive maintenance is sustained, as per the Service Recommendations listed in this manual (and barring abusive usage conditions). In factory PM, all of the components subject to normal wear are replaced. If the device ceases to function in specification, it should be returned to the factory for evaluation. Significant adverse usage events (e.g., unreasonable impact) might render the device beyond justifiable repair, for safety or financial reasons. Cease to reuse this device if out-of-spec operation is detected, or if physical signs of serious damage are noted (e.g., a skewed control knob, or fluid ingress).

To decommission the BMD Blender, the user may send it back to Bio-Med Devices for proper disposal and recycling of all applicable components. If this is not practical, the user may disassemble the device and recycle components using local recycling resources. It is recommended to separate out the brass, aluminum, and other metals for recycling. Elastomers should be discarded. There are no internal batteries or electronics. Please consider these potential hazards before attempting disassembly of the BMD Blender:

-Do not attempt dis-assembly with gas sources attached.
-Beware sharp corners of metal parts, which could cut one's hands.

This device and its packaging contain no hazardous materials. No special precautions need to be taken when disposing of the device and/or its packaging.

14. MATERIALS CONTENT

Individual internal components of this device contain the following IARC group 1 material of note, with content % per sub-part (not of the entire device) greater than 0.1% by weight:
Lead (only alloyed with copper, and always <4% by weight content of each individual copper alloy sub-part)

No special precautions are necessary on the part of the user (or patient). This includes use for potentially vulnerable populations such as children and pregnant or breast-feeding women, to whom accrue no known residual risks of the presence of these copper alloys in respiratory equipment. Such copper alloys have been a standard construction material in respiratory devices for decades, and have a specific exemption under the RoHS directive.

APPENDIX A

EC REP

Authorized Representative in the European Community:

Bio-Med Devices' Official Agent in Europe is:

Medicare Uitgeest BV
Westerwerf 10
1911JA Uitgeest
The Netherlands
NL

Telephone: +31 251 316358

UKRP

Bio-Med Devices' UK Responsible Person is:

Inspiration Healthcare Ltd.
2 Satellite Business Village, Fleming Way
Crawley, West Sussex, RH10 9NE England

Telephone: +44 (0) 330 175 0000

APPENDIX B

BMD Air/Oxygen Blender MR Information

Non-clinical testing has demonstrated that the BMD MR-version Air / Oxygen Blenders (only the blenders built specifically for MR usage, with an "M" suffix on the model #, and an "MRI" screened on the front plate) are MR Conditional. They can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla
- Spatial gradient field of 472-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning
- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this device.
- Additional requirements:

  The Blender must be used with the BMD MR-conditional stand, and the stand's wheels that have integral wheel locks must be locked.

  Do not place the Blender & stand closer than one foot away from the MR bore (do not place the Blender inside the MR bore).

If using supply gas cylinders and regulators, use only MR-conditional aluminum gas cylinders and regulators (observe manufacturer's published MR-conditional requirements).

Note that the BMD MR-version Air / Oxygen Blenders are not CE-marked.

APPENDIX C

UDI NUMBERS

2000K	813841020072
2000KM	813841020089
2001	813841020034
2001B	813841021062
2001F	813841020096
2001FB	813841021079
2001FEU	813841020102
2001FEUB	813841021253
2001K	813841020119
2001KB	813841021086
2001M	813841020126
2001MB	813841021093
2001N	813841020966
2001T	813841020485
2002	813841020041
2002F60A	813841020508
2002F70	813841020133
2002F70A	813841020515
2002F70B	813841021109
2002F70D	813841020140
2002F70X	813841020461
2002FP70	813841020157
2002K	813841020164
2002K2	813841020171
2002L	813841022212
2002M	813841020188
2003	813841020058
2003AJ1	813841020522
2003AJ2	813841020539
2003AJ3	813841020546
2003AS	813841021048
2003AS1	813841021055
2003B	813841021116
2003C	813841020553
2003D	813841020560
2003DA	813841020577
2003EF15B	813841021123
2003EF1B	813841021130
2003EFB	813841021147
2003F	813841020195
2003FF	813841020201
2003FF1	813841020218
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