mediTECH
MEDICAL GAS EQUIPMENT

Operating Manual for microVENT

microVENT World - microVENT CPR - microVENT Classic - microVENT European
microVENT UtilityVenT - microVENT Responder

READ THESE INSTRUCTIONS BEFORE USING THE EQUIPMENT

BNOS Meditech Ltd. is an ISO 13485:2016 certified company

MicroVENT are supplied in conformity under a quality system to meet Annex II of the Medical Devices Directive 93/42/EEC as amended 2007/47/EEC and The Medical Devices Regulations UK MDR 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).

MicroVENT are classified as Class IIa Medical Devices.

The above conformity routes have been inspected by the Notified Body Ref: CE 2797 being BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and for UKCA by UK Approved Body UKCA 0086 being BSI, Kitemark Court, Davy Avenue, Milton Keynes, MK5 8PP

Other Standards

microVENT also comply with the following standards:

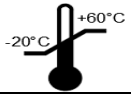
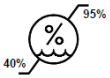
BS EN ISO 13485 :2016 +A11 :2021
EN ISO 10651-5 :2021
BS EN ISO 5356-1 :2015
BS EN ISO 5359 :2014 + A1 :2017
BS 5682:2015 (where BS standard connector specified by customer).
BS EN ISO 15223-1 :2021
BS EN 62366-1 :2015+A1 :2020
BS EN ISO 15001 :2011
BS EN ISO 14971 :2019/A11 :2021
BS EN ISO10524-1:2019/A1:2023

It is also certified that the equipment listed above fully complies with all the required mandatory standards and the performance, specifications, standards, and sources agreed and contracted for this order.

This manual is intended to provide operating instructions on the use of the microVENT® and should be studied carefully by all persons required to operate the equipment

CONTENTS

CHAPTER ONE: SYMBOLS

	Indicates a potentially hazardous situation which could result in injury to the user or others, if not avoided.
	Read these instructions before using the equipment
	Do not use any form of grease or oil
	Unique Device Identifier
	Do not use this device near any source of ignition No Smoking
	Product part number
	Serial Number
	Manufactured by
	Storage and operating temperatures.
	Date of manufacture and country of manufacturer.
	Distributor (If applicable)
	Next Maintenance or Service Due date
Vti	Inspiratory Tidal Volume
	Humidity conditions
	Authorised Representative details
	Medical Device

2. CHAPTER TWO: THE MICROVENT

2.1 INTRODUCTION

2.1.1 The microVENT World, European, CPR and Classic models are oxygen powered, automatic time cycled microVENT with MANUAL TRIGGERING for use in conjunction with respiratory arrest, respiratory difficulties and external cardiac massage designed to deliver oxygen ventilation to patients by way of a face mask or airway device attached to the microVENT. The device is designed for use by trained individuals/clinicians who are familiar with the device.

2.1.2 The microVENT Responder is an oxygen powered, manually operated microVENT. The "Responder" has no automatic function.

2.1.3 The microVENT UtilityVenT is an oxygen powered automatic time cycled microVENT. Unlike other microVENT it has no manual trigger.

2.1.4 The oxygen used by the Microvent has two functions. The latent energy of the compressed oxygen gas is used to power the microVENT. This means that the microVENT requires no other power source. It requires no batteries or mains electricity. The oxygen itself is then used at low pressures to ventilate the patient's lungs and thereby support life.

2.1.5 The microVENT is available as a handset unit without accessories or case. This can be attached to suitable oxygen specific outlet, such as in a hospital or ambulance, or a medical oxygen cylinder regulator. The purchaser is responsible for the provision of accessories needed to operate the handset unit such as a suitable oxygen source and resuscitation facemasks.

2.1.6 microVENT is also available from the manufacturer as a resuscitation kit. The microVENT Resuscitator Kit includes the accessories needed for normal use. (Oxygen cylinder not included but available as a separate item.) A complete kit can be purchased by "building" the contents as shown in the sales brochures. Contact the sales department for more details.

2.2 INTERNATIONAL CUSTOMERS (outside UK)

2.2.1 All microVENT can be supplied with alternative supply fittings and colour coding to meet the requirements of the country of use. Meditech regulators can also be supplied in international configurations to fit alternative national cylinder fittings and with output fittings meeting national requirements.

2.3 SAFETY PRECAUTIONS

2.3.1 This manual is intended to provide operating instructions on the use of the microVENT® r and should be studied carefully by all persons required to operate the equipment

WARNING: Federal law restricts this device to sale by or on the order of a physician.

WARNING:

Oxygen supports combustion. While the unit is in use, do not smoke or use a naked flame either during resuscitation, when providing oxygen therapy or when changing the cylinder.

Never use oil, grease, or solvents on any part of the cylinder, regulator, or resuscitator.

WARNING: **The Microvent must only be used by persons who have received adequate training because incorrect operation of the resuscitator can be hazardous. The Microvent should not be used on unattended patients, a competent user should be present when the device is used. Users should be trained in alternative methods of ventilation e.g., Mouth to mouth, BVM**

CAUTION: "Hands on" training sessions should be undertaken on a regular basis to familiarise operatives with the equipment and its functions.

WARNING: DEADSPACE - Users/Clinicians are able to determined their own style of face mask or airway device. However, the user will need to ensure that the dead space of any combination used meets the requirements of dead space statement below:

The dead space of the Microvent is no more than 6ml applicable to all models.

The total dead space will vary depending on face masks or airways used with the device.

Note: The dead space of any combination of facemask or airway device attached to the microVENT must not exceed 100ml or more when the device is used to deliver more than 300ml (Tidal Volume). When the device is used to deliver 300ml (Tidal Volume) or less the dead space of combination of facemask or airway device the dead space should not exceed 30% of minimum delivered volume.

2.3.2 At intervals in this manual WARNING and / or CAUTION boxes are used. Please ensure that these are read and understood.

2.3.3 This microvent is intended for first responders / paramedics / clinicians / trained users to a breathing emergency only and patients must be transferred to a transport / emergency ventilator conforming to ISO10651-3 as soon as such equipment becomes available. For information this resuscitator does conform to technical requirements of ISO10651-3.

SPECIFICATIONS

	microVENT Classic, Airmix, Adult / Child	microVENT Classic, Adult/Child	microVENT World, Airmix, Adult/Child	microVENT World, Adult/Child	microVENT CPR
Part Number-Advanced model (UK specification)	670-0060-00	670-0010-00	670-0531-00	670-0506-00	N/A
Part Number-Standard model (UK specification)	670-0061-00	670-0009-00	670-0539-00	670-0511-00	670-0483-00
Patient population range	Adult Child above 20 kg	Adult Child above 20 kg	Adult Child above 10 kg	Adult Child above 10 kg	Adult Child above10 kg
Automatic operation	Time cycled. Gas powered. (Patient assist synchronisation fitted on Advanced models)	Time cycled. Gas powered. (Patient assist synchronisation fitted on Advanced models)	Time cycled. Gas powered. (Patient assist synchronisation fitted on Advanced models)	Time cycled. Gas powered. (Patient assist synchronisation fitted on Advanced models)	Time cycled. Gas powered
Automatic flow rate (L/min)	43.2 to 21.6	43.2 to 21.6	36 to 11.25	36 to 11.25	36 to 9
Automatic tidal volume (L)	1.2 to 0.3	1.2 to 0.3	1.0 to 0.15	1.0 to 0.15 standard. 0.6 to 0.15 (670-0728-00)	0.6 to 0.15
Automatic oxygen concentration V/V	100% or 50%(nominal)	100%	100% or 50%(nominal)	100%	100%
Automatic I:E ratio	1:2	1:2	1:2	1:2	1:5
Automatic frequency (per minute)	12 to 24	12 to 24	10 to 25	10 to 25 10 to 20 (670-0728-00)	10
Manual flow rate (L/min)	40	40	40	40	40

	microVENT European, Adult/Child	microVENT European, Adult only	microVENT UtilityVenT, European, Adult only	microVENT Responder
Part Number- Advanced model (UK specification)	670-0215-00	670-0261-00	670-0339-00	670-0312-00
Part Number- Standard model (UK specification)	670-0213-00	670-0259-00	670-0583-00	
Patient population range	Adult Child over 14 kg	Adult	Adult	Adult Child over 10 kg
Automatic operation	Time cycled. Gas powered. (Patient assist synchronisation fitted on Advanced models)	Time cycled. Gas powered. (Patient assist synchronisation fitted on Advanced models)	Time cycled. Gas powered. (Patient assist synchronisation fitted on Advanced models)	Gas powered. Manual operation. No automatic operation.
Automatic flow rate (L/min)	21.5 to 15.5	21.5	21.5	No automatic operation
Automatic tidal volume (L)	0.6 to 0.2	0.6	0.6	No automatic operation
Automatic oxygen concentration V/V	100%	100%	100%	No automatic operation
Automatic I:E ratio	1:2	1:2	1:2	No automatic operation
Automatic frequency (per minute)	12 to 25	12	12	No automatic operation
Manual flow rate (L/min)	40	40	No manual operation	40 or 20 (user selectable)

	microVENT Classic, Airmix, Adult / Child	microVENT Classic, Adult/Child	microVENT World, Airmix, Adult/Child	microVENT World, Adult/Child	microVENT CPR
Pressure relief valve with audible warning limits maximum attainable delivery pressure (kPa)	4.5 (6.0 on request)	4.5 (6.0 on request)	4.5 (6.0 on request)	4.5 (6.0 on request)	4.5 (6.0 on request)
Expiratory resistance (kPa)	<0.5	<0.5	<0.5	<0.5	<0.5
Patient assist trigger pressure on advanced models (kPa)	<-0.5	<-0.5	<-0.5	<-0.5	Not applicable on "Standard" model
Inspiratory resistance without anti-air-entrainment diaphragm (kPa)	<0.5	<0.5	<0.5	<0.5	<0.5
Resuscitator weight-excluding supply hose (g)	262 (advanced) 250 (standard)	214 (advanced) 202 (standard)	262 (advanced) 250 (standard)	214 (advanced) 202 (standard)	210
Maximum resuscitator dimensions-excluding supply hose (mm)	120 x 55 x 100	120 x 55 x 100	120 x 55 x 100	120 x 55 x 100	120 x 55 x 100
Approximate duration when operating on automatic from 340L "D" size cylinder at 10 L minute volume (minute)	32, Airmix 60	32	32	32	N/A
Approximate duration when operating on automatic from 400L size cylinder at maximum minute volume (minute)	27, Airmix 54	27	38, Airmix 76	38	60
Approximate duration when operating on manual from 400L size cylinder with two 600mL breaths given every 24 seconds (minute)	125	125	125	125	125

	microVENT European, Adult/Child	microVENT European, Adult only	microVENT UtilityVenT, European, Adult only	microVENT Responder
Pressure relief valve with audible warning limits maximum attainable delivery pressure (kPa)	4.5 (6.0 on request)	4.5 (6.0 on request)	4.5 (6.0 on request)	4.5 (6.0 on request)
Expiratory resistance (kPa)	<0.5	<0.5	<0.5	<0.5
Patient assist trigger pressure on advanced models (kPa)	<-0.5	<-0.5	<-0.5	Not applicable
Inspiratory resistance without anti-air-entrainment diaphragm (kPa)	<0.5	<0.5	<0.5	<0.5
Resuscitator weight-excluding supply hose (g)	214 (advanced) 202 (standard)	214 (advanced) 202 (standard)	214 (advanced) 202 (standard)	200
Maximum resuscitator dimensions-excluding supply hose (mm)	120 x 55 x 100	120 x 55 x 100	120 x 55 x 100	120 x 55 x 100
Approximate duration when operating on automatic from 340L "D" size cylinder at 10 L minute volume (minute)	N/A	N/A	N/A	N/A
Approximate duration when operating on automatic from 400L size cylinder at maximum minute volume (minute)	50	50	50	N/A
Approximate duration when operating on manual from 400L size cylinder with two 600mL breaths given every 24 seconds (minute)	125	125	N/A	125

2.4.1 Operating environmental limits: -18 to +50 degrees Celsius, at 0 to 95 % non-condensing humidity.
2.4.2 Storage environmental limits: -40 to +60 degrees Celsius, at 0 to 95 % non-condensing humidity.
2.4.3 The microVENT is an automatic time cycled resuscitator. It is also a manually controlled gas powered device and when manually controlled the tidal volume and frequency are controlled directly by the operator. (Note: The microVENT UtilityVenT is an automatic only device, the microVENT Responder is a gas powered manual operated device – see specification pages and sales brochures for more details.)
2.4.4 The microVENT has a maximum attainable pressure of 45 cm water (4.5 kPa) unless otherwise specified by customer request. This is controlled by the pressure relief cap (The pressure relief setting is marked on the pressure relief cap).
2.4.5 Drive gas consumption to operate microVENT – Negligible.
2.4.6 Inspiratory resistance without Anti-Air-Entrainment diaphragm <0.5 cm H_2O (0.05 kPa).

WARNING: Fitting the Anti-Air-Entrainment diaphragm prevents spontaneous inhalation of atmospheric air through the Microvent. In the event of failure of the oxygen supply this could result in the patient being unable to breathe through the Microvent.

2.4.7 End-expiratory pressure in normal use is atmospheric pressure.
2.4.8 The microVENT is pressure limited by the pressure relief cap which incorporates a calibrated spring-loaded seal underneath the pressure relief cap. When patient airway pressure exceeds 4.5kPa the relief cap diaphragm/seal will lift and will relieve flow and subsequently ensure that patient airway pressure does not exceed the stated value.
2.4.9 Tolerances according to ISO 10651-5 The accuracy of specified ventilation parameters and all other performance related parameters are within the tolerance of +/-10% of the stated nominal value.
2.4.10 The **delivered volume** or **minute volume** and oxygen concentrations are not affected by pressure at the **patient connection** unless the patient airway pressure exceeds 45cm H2O (4.5kPa) at which point the pressure relief valve within the pressure relief cap will operate.

2.4 HOW TO READ AND UNDERSTAND THE MICROVENT SERIAL NO.

SN

2.5.1 Serial number can be found on the underside of the microVENT, next to the manual trigger.

Example M V R 0 1 2 1 5 5 5 5 5

The first letters refer to the type of microVENT. The next four numbers refer to the month and year of manufacture, in the example January (01) 2021 (21). The last five numbers refer to the production number of the unit. When communicating about your microVENT please quote the serial number in full.

3 CHAPTER THREE: GAS SUPPLY

3.1 GAS SUPPLY CONNECTIONS

3.1.1 The microVENT is designed to operate on medical oxygen from either a cylinder or pipeline. In the UK the connection fittings are of the shrouded BS 5682: 2015 quick connect type unless otherwise specified by the customer and allowed under the applicable relevant international standard. Other types of connections are supplied as the standard fittings in non-UK countries.

3.1.2 The microVENT can also be supplied ready to operate on medical air, in this event a medical air connection will be used.

3.1.3 The supply pressure should be within the range of 2.8 – 6 bar and should not exceed 10 bar. Medical gas supplies should where applicable meet the requirements of ISO10651-5 (however other standards now define medical gas supplies including pressure regulators). Pressure regulators meeting the requirements of ISO10524-1:2019 are considered to have superseded the pressure requirements of ISO10561-5 and are ideal for use with the Microvent.

3.2 CONNECTING TO A CYLINDER

3.2.1 Follow the instructions provided by the cylinder supplier and regulator manufacturer.

WARNING

Oxygen supports combustion. While the unit is in use, do not smoke or use a naked flame either during resuscitation, when providing oxygen therapy or when changing the cylinder.

Never use oil, grease, or solvents on any part of the cylinder, regulator or microVENT.

CAUTION

When connected to a portable supply such as a small cylinder and regulator always turn off the oxygen at the cylinder valve when the microVENT is not in use. This is to prevent the cylinder becoming empty due to leakage.

CAUTION

The microVENT is dependent upon the oxygen supply to enable it to function. Always ensure adequate supplies of oxygen are available. Monitor the use of the cylinder by observing the contents gauge.

4 CHAPTER FOUR: OPERATING PROCEDURE

4.1 MANUAL VENTILATION AND CARDIAC MASSAGE (CPR)

4.1.1 The application of oxygen is recommended as soon as it is available in both basic life support and advanced life support.[1,2]

4.1.2 The Resuscitation Guidelines 2000 and 2005 highlighted the advantages of resuscitating with lower volumes and flow rates. These help to limit airway pressures reducing the chances of gastric insufflation, vomiting and subsequent aspiration and pneumonia.[1,2,3]

4.1.3 With 100% oxygen resuscitation we help ensure oxygenation at these smaller tidal volumes.

4.1.4 The microVENT is fitted with a Manual Trigger to help the user to resuscitate the patient following the appropriate basic life support resuscitation guidelines.

4.1.5 By using the Manual Trigger the operation of the device can be easily timed with the chest compressions following the latest recommendations to ventilate during CPR at a ratio of two ventilations to 30 compressions [4]. Squeezing the trigger initiates flow of 100% oxygen from the device. Releasing the trigger allows the patient to exhale. The microVENT is designed to enable the user to hold the resuscitation mask and control the airway with a two-handed grip, operating the trigger with one finger (Fig:4). The use of the two-handed grip enables the user to control the airway and give a good seal to the face mask. This grip is considered easier to perform than the one-handed grip needed when operating a bag-valve-mask.

4.1.6 All microVENTs feature a pressure relief valve that prevents dangerous airway pressures being achieved. An audible warning sounds when the relief valve is operating. Users should use the test method described 5.3.18 (within warning section). The principle of the alarm detection is that the pressure relief valve will relieve pressure within the device and therefore the patient mask / airway device / patient airway and also simultaneously sound the alarm when the delivered pressure by the means described above exceeds 45cm H2O / 4.5kPA. the pressure relief valve and alarm function will continue to operate, and the alarm will be audible until the pressure drops below 45cm H2O / 4.5kPa.

4.1.7 Advanced models of the Microvent are fitted with a Patient Assist Valve. The Valve is connected via a port to the patient connection (patient valve) and will trigger an inspiratory phase of one breath (at the same BPM and Vti at which the device is currently set) if the patient assist valve detects a negative pressure at the patient connection of -2.5cm H2O/ (-0.25kPa) during the exhalation phase of automatic mode of cycling. The inspiration phase will follow i.e., as per normal automatic cycling. The patient assist valve only operates during automatic resuscitation and is disabled in the manual mode. If the patient assist valve continues to detect the required negative pressure to trigger its operation after one cycle has been delivered it will continue to deliver breaths. This ventilation mode is sometimes known as SIPPV (Synchronised Intermittent Positive Pressure Ventilation).

WARNING

At all times during resuscitation the rise and fall of the patient's chest should be monitored to ensure adequate ventilation.

CAUTION

Users are recommended to consult the ILCOR / AHA / ERC / UK or their national resuscitation guidelines regarding the latest recommendations for CPR.

References:
1 American Heart Association in collaboration with the International Liaison Committee on Resuscitation (ILCOR). Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care. An international consensus on science. Circulation 2000;102(Suppl.I): I-1 –I-384.

2 American Heart Association in collaboration with the International Liaison Committee on Resuscitation (ILCOR). Guidelines 2000 for cardiopulmonary resuscitation and emergency cardiovascular care — An international consensus on science. Resuscitation 2000; 46:1–447.
3 European Resuscitation Council Guidelines 2000 for Adult Basic Life Support
A statement from the Basic Life Support and Automated External Defibrillation Working Group 1 and approved by the Executive Committee of the European Resuscitation Council. Resuscitation 48 (2001) 199–205
4 *Circulation* 2005;112;12-18; originally published online Nov 28, 2005.

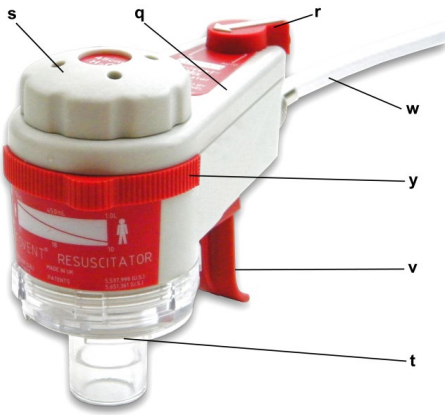
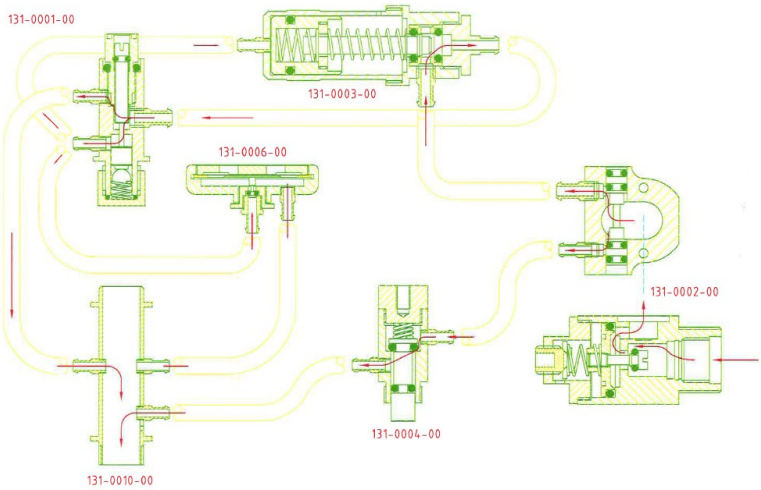


Figure 1: The microVENT World (Adult / Child model illustrated)

Key to components in figure 1:
q = microVENT body
r = Manual / automatic selector
s = Pressure limiting (and audible warning) valve
t = Patient valve assembly
v = Manual trigger
w = Oxygen supply hose
y = Tidal volume and frequency selector (on Professional - Adult/Child - models not used on Industrial - Adult Only - models)

Figure 2: The Microvent Pneumatic Circuit

131-0001-00 = Microvent time/flow sub assembly
131-0003-00 = Control valve sub assembly
131-0006-00 = Patient assist assembly
131-0002-00 = Regulator sub-Assembly
131-0004-00 = Microvent manual trigger sub assembly
131-0010-00 = Relief sub assembly



4.1.7 Having established that the patient is not breathing, position the patient as for mouth-to-mouth resuscitation. The airway can be opened by head tilt, chin lift or jaw thrust. The head tilt method is illustrated in figure 3.

Figure 3: Opening the airway

4.1.8 Clear the patient's mouth of any foreign materials and check to see if the patient has commenced spontaneous breathing.

4.1.9 Attach the microVENT to an active regulated gas supply:

- Connect the oxygen input fitting on the microVENT supply hose to the oxygen regulator attached to the cylinder in accordance with the regulator manufacturers instructions, turn on the Oxygen Cylinder valve slowly.
- Or connect the oxygen input fitting on the microVENT supply hose to an oxygen wall outlet in the hospital or ambulance.

4.1.10 On the microVENT select the manual setting (Fig:1, r). Use the appropriate size of Face Mask and attach to the Patient Valve (t).

4.1.11 If no respiratory effort is observed position yourself above the patient's head and apply the Face Mask over the patient's nose and mouth and use both hands to obtain a good seal and support the jaw (Fig:4).

4.1.12 Squeeze the Manual Trigger (Fig:1, v) towards the Face Mask and observe the rise of the patient's chest. The operation of the Manual Trigger does not require a violent pull. A gentle squeeze of the trigger will supply oxygen and inflate the lungs.

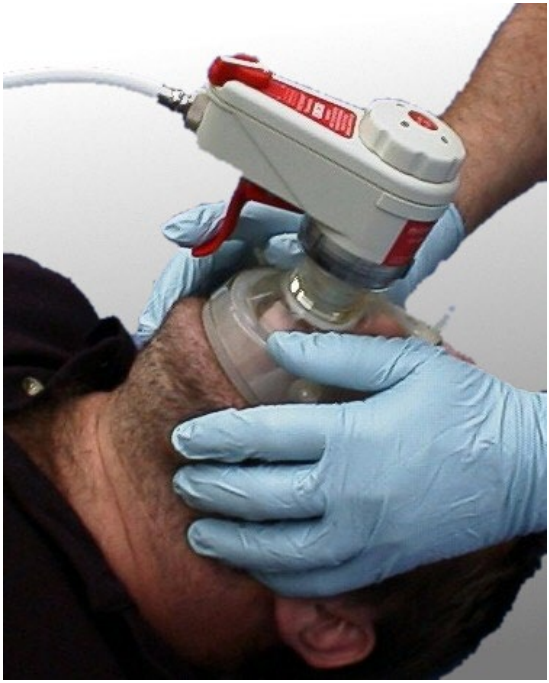
4.1.13 Excessive pressure on the Manual Trigger will not result in more oxygen being supplied to the patient and may damage the device.

4.1.14 Once sufficient patient chest rise has been observed, release the manual trigger so the resuscitator is no longer inflating the patient’s lungs. This allows the patient to passively exhale back through the mask and out through the patient valve. It is normal to allow 2 to 3 seconds exhalation (expiratory) time, so the patient has completely exhaled. (It is not necessary to remove the facemask or Microvent from the patient’s face for the patient to exhale.)

4.1.15 If the patient's chest does not rise or gas escapes around the mask or the Pressure Relief Valve (Fig:1, s) operates, with an audible tone, reposition the patient's head and adjust your hand position to obtain an effective seal and an open airway.

4.1.16 Over inflation will be indicated by excessive chest rise and eventually by the operation of an audible tone of the Pressure Relief Valve. Under inflation will be indicated by too shallow a rise in the patient's chest.

Figure 4: Operating the microVENT using the manual trigger.



The microVENT and face mask can be held in position by both hands while maintaining the patient's airway and operating the manual trigger.

4.2 AUTOMATIC VENTILATION

4.2.1 If the patient is suffering from respiratory arrest or respirator insufficiency
If in the event of cardiac arrest, resuscitation restarts the patient's heart.
If the patient is intubated (or the airway is protected by Combitube or LMA)
If circumstances dictate that manual ventilation with the microVENT is not possible or
If the patient is to be transported
Then automatic ventilation may be commenced.

4.2.2 If the patient makes an inspiratory effort during automatic ventilation, Advanced microVENTs have a respiratory assist sensor which, when the Anti-Air–Inhalation Diaphragm is fitted to the patient valve, enables the patient to trigger the microVENT inflations in time with their inspiratory effort. The Advanced microVENT applies the prescribed tidal volume when triggered, a mode of ventilation sometimes known as SIPPV (Synchronised Intermittent Positive Pressure Ventilation). If the patient stops breathing spontaneously the microVENT recommences automatic ventilation after the set expiratory time. The respiratory assist sensor is a factory fitted option, known as "Advanced". Models without the respiratory assist sensor are known as "Standard".

4.2.3 On Adult and Child microVENT the tidal volume and frequency of ventilation are controlled by the slider control on the front of the microVENT. (See figure 1 (y)). The volume is selected by the user so as to ensure visible and adequate chest rise of the patient. The patient should be carefully observed so as to ensure correct ventilation.

4.2.4 On Adult only microVENT the tidal volume and frequency are preset and there is no slider control.

4.2.5 Select the automatic setting (Fig 1, r). Use the appropriate size of Face Mask and attach to the Patient Valve (t). (Or connect to ET tube via an adapter)

4.2.6 If no respiratory effort is observed position yourself above the patient's head and apply the Face Mask over the patient's nose and mouth and use both hands to obtain a good seal and support the jaw (Fig:4).

4.2.7 Increase the tidal volume setting of the microVENT (Fig:1, y) until sufficient chest rise is observed with each breath. The microVENT has a I:E ratio of 1:2, this means twice as long is allowed for expiration as inspiration (The microVENT CPR has an I:E ratio of 1:5). The patient valve allows the patient to exhale to atmosphere. (It is not necessary to remove the facemask or microVENT from the patient's face for the patient to exhale.)

4.2.8 If the patient's chest does not rise or gas escapes around the facemask or the Pressure Relief Valve (Fig:1, s) operates, with an audible tone, reposition the patient's head and adjust your hand position on the mask and jaw to obtain an effective seal and an open airway.

4.2.9 Over inflation will be indicated by excessive chest rise and eventually by the operation of an audible tone of the Pressure Relief Valve. Under inflation will be indicated by too shallow a rise in the patient's chest.

WARNING

At all times during resuscitation the rise and fall of the patient's chest should be monitored to ensure adequate ventilation.

4.3 AIRMIX (AIR ENTRAINMENT OPTION)

Introduction:

4.3.1 Airmix air entrainment is a factory-installed option available on the microVENT. Airmix increases the duration of a portable oxygen supply by mixing the oxygen with ambient air. The usage of oxygen at adult settings is approximately halved, so a supply lasts over twice as long as it would if used at 100% oxygen. The concentration of oxygen (FiO_2) available to the patient is reduced to approximately 50%.

4.3.2 Airmix can currently only be used when the microVENT is used in its automatic mode. The selector switch should always be returned to the 100% position (indicating 100% oxygen) when the resuscitator is being used in manual mode.

CAUTION:

The Airmix selector switch has two positions, these are selected by sliding the control from one extreme of its travel to the other. Failure to position the control at the 100% position or the 50% position may result in lower delivered volume (Vti) of the Microvent.

Using Airmix:

4.3.3 With the microVENT in automatic mode slide the Airmix control (Fig:5, z) to the 50% position (Airmix on). Ensure the Airmix control is at the full extent of its travel.

4.3.4 The Airmix will now entrain ambient air and blend this with the oxygen delivered to the patient. The tidal volume and frequency of the resuscitator will be maintained on adult settings. On child settings an increase in tidal volume may be experienced due to the nature of entrainment valve.

WARNING: On child settings an increase in tidal volume may be experienced when switching to Airmix due to the nature of entrainment valve.

WARNING: Where exact volumes and oxygen concentrations need to be known users are advised to use additional monitoring equipment.

4.3.5 Through patient observation ensure that the patient is still being correctly ventilated and oxygenated.

4.3.6 When the Airmix function is no longer needed then return the Airmix control (Fig:5, z) to the 100% position (Airmix off).

WARNING

The microVENT Airmix when set at 50% entrains gases from the atmosphere when operating and should not be used in contaminated environments including use in hazardous or explosive atmospheres. On Airmix models set the Airmix control to the 100% position (Airmix off) if used in a contaminated environment.

Figure 5: microVENT World with Airmix

Key to item in Fig 5:
z - Airmix selector switch

Figure 6: Component assembly

The microVENT Component Assembly Inc. Part No.

q	microVENT body
s1	Pressure limiting (and audible warning) valve-131-0005-45
s2	Sounding board 131-0183-00
t1	Patient valve diaphragm (duckbill) 673-0011-00
t2	Patient valve body 673-0010-00
t3	Anti-air-inhalation diaphragm 033-1011-00

For spare part numbers also see appendix 2 or contact sales@meditech.uk.com

4.4 USE IN TOXIC ATMOSPHERES

4.4.1 During ventilation in atmospheres containing smoke, water or toxic gas, the Anti-Air-Inhalation Diaphragm (Fig:6, t3) should be fitted to the Patient Valve. This Diaphragm helps ensure that the patient can receive only pure oxygen during ventilation. Anti-Air-Inhalation is achieved by fitting a simple removable diaphragm onto the Patient Valve.

WARNING

The microVENT Airmix when set at 50% entrains gases from the atmosphere when operating and should not be used in contaminated environments. On Airmix models set the Airmix control to the 100% position (Airmix off).

4.5 USE IN CLEAN ATMOSPHERES

4.5.1 When the Anti-Air-Inhalation-Diaphragm (Fig:6, t3) is fitted and the microVENT is being used on a patient, if the oxygen supply runs out the patient will not be able to breath ambient air spontaneously through the Microvent.

WARNING

The patient cannot breathe ambient air when the Anti-Air-Inhalation Diaphragm is fitted, continued use of the anti-air-inhalation diaphragm on an advanced model Microvent will allow the patient to inhale 100% oxygen if an inspiratory effort is made by the patient. The anti-air-inhalation diaphragm is not recommended for use on a standard model microVENT. The standard model microVENT is not principally designed for use in a toxic environment however if a standard model microVENT is used in a toxic environment for reasons of emergency and has the anti-air-inhalation diaphragm fitted it is essential that the diaphragm is removed as soon as possible when the patient is moved to a safe non-toxic environment. If an anti-air-inhalation diaphragm is used with a standard model microVENT, which is not recommended by the manufacturer risks associated with use of the device will increase.

4.6 ACTION TO BE TAKEN IF PATIENT VOMITS DURING RESUSCITATION

4.6.1 Your microVENT or Resuscitation Kit should be supplied with facemasks with a clear or translucent uncoloured body so that face colour can be observed and any contamination of the mask and or the clear patient valve can be seen.

4.6.2 Should the patient vomit into the Face Mask during resuscitation the following steps should be followed to clear the obstruction from the resuscitator:

4.6.3 Remove the Face Mask from the patient's face.

4.6.4 Clear any contaminant from patient's airway by the method taught in your first aid or resuscitation training either using a Suction Device, positioning, or using a finger sweep.

4.6.5 Remove the Face Mask from the Patient Valve (Fig:6, t2]

4.6.6 Unscrew Patient Valve (t2) from microVENT Body (q) being careful to ensure the Duckbill Diaphragm (t1) is not mislaid and shake out any contaminant from the Patient Valve, Face Mask and Duckbill Diaphragm.

4.6.7 Operate the Manual Trigger to blow out any contaminant.

4.6.8 Unscrew Pressure limiting valve (Fig:6, s1), remove the Sounding board (s2) (which is a push fit), shake out any contaminant, push the Sounding board back into place and screw the Pressure limiting valve back into place.

4.6.9 Re-assemble Patient Valve Diaphragm, Patient Valve Body, and Face Mask,

4.6.10 Operate Manual Trigger to ensure correct function.

4.6.11 Repeat Operating Instructions (from step 4.1 [manual] or 4.2[automatic]).

4.6.12 Do not clean with solvent based agents, Meditech recommend soap / mild detergent solution and water.

4.6.13 For disinfection see section 5.3.

4.7 ADDITIONAL CONSIDERATIONS

4.7.1 Low Cylinder Contents. A situation may arise where the Oxygen in the cylinder may reach a very low level with or without the operator being aware of the fact. The pressure therefore becomes too low to operate the microVENT. The pressure this occurs at is dependent on the individual pressure regulator characteristics but should not occur above 8 Bar (112.p.s.i.) indicated cylinder pressure when using a quality regulator.
Customers can request a hose in line low pressure alarm feature on some MicroVENT models.
If this is supplied, an audible alarm will be heard when the pressure is low.

4.7.2 Cylinder Replacement Pressure. The cylinder replacement pressure is normally indicated on the regulator pressure gauge. Many gauges indicate the red refill region beginning at 30 Bar (435 p.s.i.) pressure. It is strongly recommended that once the pressure reaches this section the cylinder is switched for a fully charged cylinder.

4.7.3 Immersion in liquids. It is recommended that the microVENT is not immersed in any liquids at any time. However accidental immersion may occur. If this event does happen wipe clean the microVENT of any detritus picked up from the fluid with a suitable lint free cloth and then allow the microVENT to drain of any liquids. Once all liquids appear to have drained from the body of the microVENT perform functional tests as per section four of this manual.

5 CHAPTER FIVE: SERVICING

CAUTION

The microVENT® is designed to provide respiratory support in an emergency situation. Failure to follow the maintenance and inspection routines properly could result in incorrect operation of the Microvent.

5.1 ROUTINE MAINTENANCE

5.1.1 To ensure proper operation of the device, regular inspection and checking of the device for correct function should be undertaken by a responsible member of staff on at least a monthly basis. This check is to ensure that all Components and Accessories are present, the Oxygen Cylinder is full and that the microVENT is in working order.

5.1.2 The following recommendations for servicing frequency are:

5.1.3 Monthly checks as per the checklist below.

5.1.4 Specification checks and preventive maintenance at 12 months.

5.1.5 In accordance with the Medical Device Alert MDA/2003/007, the Medical Oxygen Supply Hose is required to be replaced on a 5-yearly basis. If there is any doubt in ascertaining the age of the oxygen supply hose, please contact B.N.O.S. Meditech Ltd with the oxygen supply hose batch number as indicated on the hose.

5.1.6 Automatic units (microVENT Classic and Responder) should also be checked and run on a weekly basis

5.1.7 Details of Service Contracts available can be obtained from BNOS Meditech Ltd.

5.2 CHECKLIST – in full at least every month and after each use.

Check C, D & E before each use.

	Check	Action
A	Inspect carrying case for signs of wear, damage, or impact.	Repair or replace as necessary.
B	Open case and check contents for missing items. (Use a check list)	Repair or replace as necessary.
C	Check oxygen cylinder contents by opening the cylinder valve and reading the contents gauge.	Replace with a full cylinder if necessary.
D	Operate the resuscitator in all modes (automatic and manual) to check function. With the patient port open and the trigger operated a flow should be felt from the patient port.	In the case of any problems withdraw the microVENT from use and make alternative arrangements to cover the risk. Contact your service agent.
E	Test the function of the Pressure Relief Valve by occluding the patient port and operating the manual trigger. The pressure relief and audible warning should operate.	In the case of any problems withdraw the microVENT from use and make alternative arrangements to cover the risk. Contact your service agent.
F	Turn off the oxygen cylinder at the oxygen cylinder valve. Return all contents to the carrying case checking that all items are present Return the microVENT to its designated storage position.	Keep a written record of all checks and maintenance.

These checks do not take long and as well as ensuring your equipment is always ready for immediate use, they give the operators a chance to handle the microVENT and to familiarise themselves with it. The operation of the instrument during checks uses very little gas, however, always be sure to have a spare cylinder available to replace a depleted unit.

5.3 CLEANING THE microVENT AND ACCESSORIES

CAUTION: Do not use solvent-based cleaning agents to clean the microVENT and accessories. Alcohol may damage the plastics used in the construction. Pre-clean all parts with warm soapy water; it is recommended that a general-purpose detergent be used.

5.3.1 Routine cleaning of the equipment should be undertaken to maintain the equipment in a clean condition. The device should be cleaned before its first use (when new) and after each subsequent use and between patients following the instructions in this section of the Instructions for Use.

5.3.2 The microVENT body should not normally be immersed in liquid.

5.3.3 Pre-clean all parts with warm water with a mild detergent solution. It is recommended that a general-purpose detergent is used.

5.3.4 Rinse thoroughly with clean water.

5.3.5 Note: Surface wipe the actual microVENT body (Fig:6, q). The Patient valve body (Fig:6, t2), 'Duck Bill' Patient valve diaphragm (t1) and Anti-air-inhalation gasket (t3) can be submerged in soapy water and in disinfecting and sterilising solutions (check material compatibility).

5.3.6 To disinfect-

5.3.7 For disinfection purposes a chlorine dioxide-based product (e.g., the Tristel Wipes and solution system) should be used, at a nominal concentration of 0.02% wt/vol. The concentration refers to chlorine dioxide in water. Follow the manufacturers directions for safe use.

5.3.8 Alternatively, hypochlorite bleach solution can be used, though this is thought less effective against certain infection risk such as spores.

a. Ordinary Use: 1,000ppm hypochlorite solution e.g. (Sani-chlorTM)
b. When blood/bodily fluids are present: 10,000ppm hypochlorite solution should be used.

5.3.9 When using disinfecting and sterilising products always follow the manufacturers directions for safe use.

5.3.10 The parts should be rinsed thoroughly with warm water, dried thoroughly, and stored dry.

5.3.11 Wipe the microVENT body (q) using disposable absorbent paper.

5.3.12 Note: The Patient valve body (t2), 'Duck Bill' Patient valve diaphragm (t1) and Anti-air-inhalation gasket (t3) and the reusable silicone resuscitation face masks can be submerged in the disinfecting / sterilising solution.

5.3.13 Face mask for resuscitation (not oxygen therapy), can also be cleaned using detergent solution and disinfected or sterilised by wiping or immersion in the sterilising products.

5.3.14 When cleaning components of the resuscitator ensure that all traces of cleaning solution are removed and that the surfaces are dried. It is not expected that residues of cleaning materials will cause a malfunction, however, as a precaution on items such as the diaphragm, special care should be taken to remove all traces of cleaning agents. Allow to dry before refitting to the microVENT.

5.3.15 After refitting, test the microVENT functions before returning to storage.

5.3.16 Single use components.

5.3.17 As standard certain components are supplied with the kits intended for single patient use. Do not attempt to clean and sterilise any components that are designated as single use as immersion of these items into a sterilising solution can cause degeneration of the materials. Single use components should be disposed off after use and replacements fitted. Single use components include Airways. Therapy Masks, Suction catheters (and suction collection jars marked as ‘single use’, “single patient use” or “disposable”.

5.3.18 To make cleaning and disinfection easier disposable resuscitation facemasks and filters are available which are also intended for single patient use.

CAUTION
Do not attempt to clean and sterilise any components that are designated as single use. Dispose of these components after use.

WARNING
A functional test should be carried out after cleaning and reassembly: after reassembling the microVENT operate where applicable the device in automatic mode and occlude the patient valve outlet. The pressure relief device within the pressure relief cap should operate audibly. This will ensure that the device is functioning correctly. Carry out the same test in the manual mode by operating the manual trigger with the patient valve outlet occluded, again the pressure relief valve should operate audibly.

5.3.19 By following the above steps, you will ensure that your microVENT stays in proper condition and will always be ready for use when you need it.

5.4 PRODUCT LIFE SPAN

5.4.1 The microVENT has been designed for the demands of the pre-hospital emergency medical market to give the user many years of reliable service. The microVENT is manufactured from the finest quality materials with individual components subject to strict quality control tests to ensure high standards under ISO 13485. The microVENT is designed to have a Product Life Span of 15 years, excluding abuse to the device. When the product reaches the end of its usable life, please ensure that it is suitably disinfected/cleaned and disposed of in the normal way taking into account any local requirements for recycling of materials. Devices which are properly identified as having been disinfected/cleaned can be returned to the manufacturer, prior notice must be given, for correct method of disposal. Incineration of the device is not recommended.

5.4.2 In accordance with the Medical Device Alert MDA/2003/007, the Medical Oxygen Supply Hose is required to be replaced on a 5-yearly basis. If there is any doubt in ascertaining the age of the oxygen supply hose, please contact B.N.O.S. Meditech Ltd with the oxygen supply hose batch number as indicated on the hose.

5.4.3 We reserve the right to change design without prior notice

IMPORTANT NOTICE
Manufacturers Warranty is for a period of 1 year and includes parts and labour. It does not include transport costs. The responsibility and cost of returning and collecting the unit from the manufacturer or their authorised representative is the owners.
Any disassembly of the Microvent or regulator beyond that detailed in this manual will invalidate the warranty and the manufacturers disclaim any liability for products that have undergone unauthorised repair.

Appendix 1: MATERIALS SPECIFICATION

Part	Material
Housing	ABS/polycarbonate (Bayblend T45)
Labels	Polycarbonate
Patient valve body	Polycarbonate
Patient valve diaphragm	Silicone Rubber
Anti-air-inhalation diaphragm	Silicone Rubber
Manual trigger	Nylon – glass reinforced
Trigger retaining pins	Stainless steel
Internal Components	Brass CZ121, Some electroless nickel plated
	Aluminium 2011T3
	Arcap AP 1D
	Delrin (Tecaform AD)
	Spring stainless steel
Tubing	Polyurethane
Filter	Sintered Bronze
'O' Rings	EPDM, Nitrile Rubber or Silicone Rubber
Miscellaneous minor components	Polypropylene, Neoprene, Polyethylene, Nylon 6, PVC, Polyester reinforced PVC, Carbon steel
Resuscitation Face Mask	Polycarbonate and Silicone or Polysulphone and Silicone or Silicone
Hose assembly	
Hose	PVC (Anti-static Inner)
BS 5682: 2015 Connectors	Brass CZ121, Electroless Nickel plated
Ferrules	Brass, Bright Nickel plated

microVENT SPARE PARTS

Appendix 2: SPARE PARTS (OPERATOR REPLACEABLE PARTS)

Part No.	Description	Illustration
	microVENT Spares	
131-0005-45	Pressure limiting valve (45cm water)	Fig:6, s1
131-0005-60	Pressure limiting valve (60cm water)	
131-0183-00	Sounding board	Fig:6, s2
673-0011-00	Patient valve diaphragm (Duckbill)	Fig:6, t1
673-0010-00	Patient valve body	Fig:6, t2
033-1011-00	Anti-air-inhalation gasket	Fig:6, t3
131-0017-00	2m White Oxygen Hose with Schrader Fitting (may require training and will require use of tools)	Fig: 1w
	User Operating Manual microVENT	
	Brief Operating Instructions “microVENT Responder”	
	Brief Operating Instructions “microVENT Classic” and “microVENT European”	

mediTECH
MEDICAL GAS EQUIPMENT

COMPANY CONTACT DETAILS
This device is designed and
manufactured by:

B.N.O.S. MEDITECH LTD
9 FIFTH AVENUE, BLUEBRIDGE IND EST
HALSTEAD, ESSEX, CO9 2SZ, ENGLAND
Tel : +44 (0)1787 479 475
Fax : +44 (0)1787 477 747
E-mail : sales@meditech.uk.com
Website: www.meditech.uk.com

EC REP

EU REPRESENTATIVE:
MEDICAL DEVICE MANAGEMENT LTD
BLOCK B, THE CRESCENT BUILDING
NORTHWOOD, SANTRY
DUBLIN 9, D09 C6X8
IRELAND
Tel: +353 (0) 1893 4143

CE
2797

UK CA
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