INFANT RESUSCITATION CABINET

INSTRUCTIONS FOR USE

CE0086

INDEX

Definitions and Symbols

Definitions

Note: The remark “Note” is used in the text to indicate procedures or conditions, which might otherwise be overlooked or incorrectly understood. A note may also be used to clarify apparently contradictory or confusing situations.

Caution: The remark “Caution” is used to draw attention to a procedure, which must be followed exactly in order to avoid potentially damaging the equipment.

Warning: The remark “Warning” is used in the text to draw attention to dangerous situations in connection with the operation, cleaning or maintenance of the equipment if there is a possibility of injury or danger of death to the operator or patient.

Symbols

This symbol is used throughout this document in conjunction with the advisory declarations detailed above. Its primary function is to draw the reader’s attention to the accompanying remark, which contains important information.

This symbol is used throughout this document. Its primary meaning is “Consult accompanying documentation” and refers to the individual manuals or documents for the items of equipment that are supplied with the Viamed Infant Resuscitation Cabinet.

These individual manuals are included as appendices to this manual.

INTRODUCTION

This document contains the instructions for the operation, cleaning and basic maintenance of the wall mounted Viamed Infant Resuscitation Cabinet.

Viamed is not liable for the proper functioning of any part of this system if it is not operated according to the instructions, if the maintenance recommendations in this manual are not followed, or if repairs are carried out using non-approved components.

Only qualified personnel should carry out servicing of this equipment. Maintenance documents can be obtained through your local distributor or direct from Viamed.

Servicing personnel must be aware of the potential clinical implications of incorrectly serviced equipment.

The personnel who work with this equipment should read this manual carefully and should fully understand all instructions contained therein. The manual should be kept so that it can be easily inspected; it is advisable to store it in an easily accessible place.

If any function or part of this manual is not clear, please contact Viamed or your distributor in order to obtain further information or clarification.

Overview

The Viamed Infant Resuscitation Cabinet contains a carefully selected group of products; each main item can be purchased as a single item for use individually.

Viamed have combined these devices into one product in an arrangement ideally suited to Maternity and Neonatal Intensive Care environments.

Devices forming component parts of the Resuscitation Cabinet:

- Cabinet with drop down door, integral bed and mattress
- Wall-mounted Ceratherm 600-3 radiant warmer
- Tom Thumb infant resuscitation unit
- Low suction controller
- Suction receiving jar
- Digital Apgar timer
- Storage bins
- Air/oxygen blender (optional)

The Tom Thumb infant resuscitation unit delivers medical oxygen; if blended gas mixes are required an optional air/oxygen blender and oxygen analyser are available.

All the components carry the correct and relevant CE marking.

CAUTION
Before operating the resuscitation cabinet system, please refer to the individual instruction manuals for the component devices, which are attached as appendices to this manual.

RESUSCITATION CABINET

Infant Resuscitation Cabinet Complete With Air / Oxygen Blender (Optional)

The cabinet has been designed to conceal the internal equipment when closed and provide easy access when open.

The cabinet body is finished with a hardwearing, anti-microbial coating.

The drop down platform has an integral bed, on which the mattress is placed. Additional bedding material may be placed on the mattress but care should be taken to ensure that this does not become trapped in the space between the platform and the cabinet when raising the platform.

Excessive weight should not be applied to the drop down platform. The maximum loading, including the pressure applied by the operator(s), should not exceed 25 Kg in total.

Whilst in use, the patient should be under close observation at all times.

When closing the cabinet, ensure that there are no obstructions; the cabinet should close easily and without significant force. Once the door is in the upright position, turn the catches to secure it in the closed position.

CAUTION
The door should not present resistance or need to be held closed in order to secure the catches.
Securing the catches whilst forcing the door closed may cause damage to the catches: damage of this type is not covered by the warranty.

WALL MOUNTED RADIANT WARMER

Radiant Warmer with Double-Hinged Arm

The Ceratherm 600-3 radiant warmer is mounted on a double-hinged arm, allowing the unit to be stowed away when not in use and moved into position over the resuscitation bed when required.

The radiant warmer utilizes a ceramic heating element that has very good radiation properties and generates invisible infrared radiation of around 3 µm. This radiation spectrum is absorbed very effectively by the skin and causes no harm to the patient's eyes. Do not touch the heating element at any time as this poses the risk of burns. Additionally, touching the element, even when cold, can adversely affect the performance of the element.

The radiant warmer should only be moved using the side handles, which will remain cool to the touch, even when the device is in use.

The radiant warmer has four programmable heat output levels, which can be selected directly by pressing the buttons [heat level 1-4]. The default settings for the heat levels are 20, 50, 75 and 98%.

For normal use in a delivery room environment, levels 3 or 4 should be used, depending upon the ambient temperature and the requirements of the patient.

Providing the distance between the surface on which the patient lies and the lower edge of the radiant warmer is not less than 80cm, Level 4 will not cause harm to the patient, even with prolonged use.

The Ceratherm 600-3 is fitted with a modern LED lamp. This cutting-edge light source has a lower energy consumption and higher service life than other lights. The LED lamp offers 2 brightness levels to illuminate the patient area.

Using The Radiant Warmer

CAUTION
Before operating the radiant warmer, please refer to the complete instruction manual, attached as an appendix to this manual and observe all safety precautions contained therein.

Prior to introducing a patient to the Resuscitation Cabinet, the radiant warmer can be used to pre-warm the patient surface.

The only parts of the radiant warmer that the operator needs to touch in order to operate the device are the side handles on the head unit and the control panel. Using the side handles, manoeuvre the warmer into position over the bed on the drop down platform of the resuscitation cabinet.

Turn on the radiant warmer and set the required power setting as per the instructions contained in the radiant warmer instruction manual.

After use, allow the radiant warmer to cool before manoeuvring the head unit into its stowed position: sideways and as close to the wall as the mounting arm will allow.

Handle the warmer with care when repositioning; the ceramic heating element is fragile and could be damaged by shock or impact.

WARNING!
The radiant warmer gets hot whilst in use.
Do not obstruct the upper ventilation grille.
Use only the side handles, which remain cool, to reposition the unit.

Alarm Monitoring

If the unit has been set to a heat output above level 1 for 15 minutes, a reminder alarm is activated. The alarm signal is both acoustic (buzzer sounds in five short intervals) and visual (alarm LED flashes red).

If the alarm confirmation button is pressed within 8 seconds of the alarm beginning, the alarm is deactivated for the next 15 minutes and the heater head continues operation at the previous heat output. If no alarm confirmation is given within this 8-second period, heat output is reduced to 20% for safety reasons. The red alarm LED displays this status visually until the heater head is either switched off with the on/off button or the alarm is confirmed with the alarm confirmation button. The alarm is deactivated for the next 15 minutes and the heater head continues operation at the previous heat output.

NOTE
In order to comply with the requirements of EN 60601-2-21:2010, the radiant warmer is required to activate an alarm every 15 minutes when operating in manual mode. It is not possible for the operator to disable this alarm, however, the alarm monitoring function is no longer active when the device has already reverted to its safety-power level.

LOW SUCTION CONTROLLER

The Viamed Infant Resuscitation Cabinet is supplied with one of two low suction controllers, designed specifically for medical use: Oxylitre S714 or Therapy Equipment Diamond Series.

Oxylitre S714 Low Suction Controller

Therapy Equipment Diamond Low Suction Controller

Vacuum Source Connector

The suction controller is supplied with a 3m vacuum hose assembly, which terminates in a British Standard (BS5682) probe. The device is intended for connection to a wall vacuum outlet.

Inlet Connection and Filter

The inlet connection forms an integral part of a detachable filter cartridge designed to prevent the ingress of fluids into the controller and the pipeline system. The filter should be replaced annually or if it becomes discoloured or wetted for any reason. Please see individual instructions for the model of suction controller in use in the appendices of this manual.

Vacuum Gauge

The controller is fitted with an easy to read, dual scale colour coded gauge.

Model	Suction level
Oxylitre S714 Low Suction Controller	0 to -200 mmHg (0 to –25kPa)
Therapy Equipment Diamond Low Suction Controller	0 to -150 mmHg (0 to –20kPa)

Setting Suction Levels: Therapy Equipment

CAUTION
Before operating the Therapy Equipment Diamond low suction controller, please refer to the complete instruction manual, attached as an appendix to this manual and observe all safety precautions contained therein.

To increase the level of suction, rotate the control knob on the top of the suction controller in a clockwise direction.

To decrease the level of suction, rotate the control knob on the top of the suction controller in an anti-clockwise direction.

The Therapy Equipment Diamond low suction controller has a separate ON/OFF control in the form of a 'flag' lever on the right hand side of the device.

To activate suction, move the lever to the vertically downward position, the word 'ON' is displayed on the flag. To turn the suction off, move the lever to the vertically upright position, the word 'OFF' is displayed on the flag.

WARNING
The suction level on the Therapy Equipment Diamond low suction controller will remain set at the level last used.
The suction level must be set before each use to a level determined by guidelines within the customer's own organisation.

Setting Suction Levels: Oxylitre

CAUTION
Before operating the Oxylitre low suction controller, please refer to the complete instruction manual, attached as an appendix to this manual and observe all safety precautions contained therein.

To increase the level of suction, rotate the control knob on the top of the suction controller in an anti-clockwise direction.

To decrease the level of suction, rotate the control knob on the top of the suction controller in a clockwise direction.

The Oxlitre S714 low suction controller does not have a separate ON/OFF control: to turn the suction off, decrease the suction level to the minimum setting.

WARNING
The suction level must be set before each use to a level determined by guidelines within the customer's own organisation.

SUCTION RECEIVING EQUIPMENT

The Viamed Infant Resuscitation Cabinet is supplied with the VacSax Advance suction receiving system as standard, comprising of a reusable suction receiving canister and a disposable liner.

VacSax Advance Suction Receiving System

Viamed do not supply suction catheters, however, the system is designed for use with standard 10mm suction tubing compatible with a wide range of commonly used suction catheters.

Whichever receiving system is used, ensure that the suction tubing and catheter is replaced after each use.

CAUTION
Before operating the VacSax Advance suction receiving system, please refer to the complete instruction manual, attached as an appendix to this manual and observe all safety precautions contained therein.

The VacSax Advance suction receiving liner is single patient use and should be disposed of as per the instructions contained in the device's individual user manual contained in the appendices of this manual.

The VacSax advance suction receiving canister and the tapered vacuum port connector are reusable and can be cleaned in accordance with the guidelines in the MAC Manual "Part 2; Cleaning (manual) - non-immersion"; see instructions later in this document.

As the VacSax Advance suction receiving liner contains an integral filter, it is not necessary to replace the tapered vacuum port connector and the suction tubing that connects it to the suction controller unless the tubing becomes discoloured or wetted, otherwise, these items should be replaced annually.

APGAR TIMER

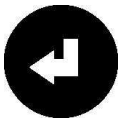
The digital Apgar timer is a battery-powered digital timer with preset audible timing indications at 1, 5 and 10-minute intervals.

The timer has a large, clear LCD display and is operated using the keys on the front of the instrument.

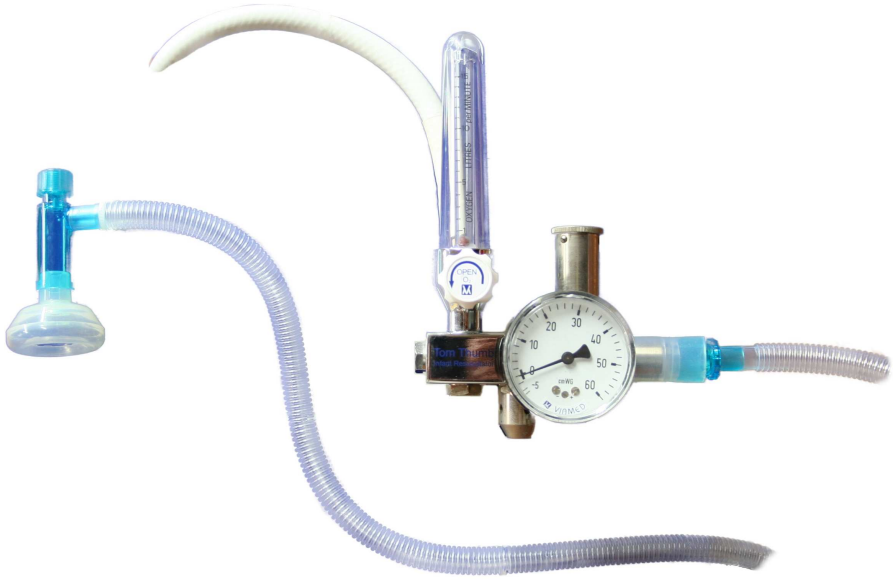
Viamed Digital Apgar Timer

CAUTION
Before operating the Viamed Digital Apgar Timer, please refer to the complete instruction manual, attached as an appendix to this manual and observe all safety precautions contained therein.

The Functions of the Keys

Key	Function
 **START**	• Starts counting from 00:00. • Returns to *Counting Mode* whilst in *Freeze Mode.*
 **FREEZE/ UNFREEZE**	• Enters and exits *Freeze Mode.* Display 'freezes' whilst the actual elapsed time continues counting, but is not displayed. Exiting *Freeze Mode* returns to *Counting Mode*, resuming from the ongoing total elapsed time.
 **RESET**	• Resets counter, returning timer to *Standby Mode.*

TOM THUMB INFANT RESUSCITATOR



Viamed Tom Thumb Infant Resuscitator

The Tom Thumb Infant Resuscitator is supplied in one of two variants: the TT490-15, which has a 3m oxygen hose terminated with a BS probe, or the TT480, which is designed to be connected to an existing flowmeter or air/oxygen blender via low-pressure tubing.

The Tom Thumb allows the delivery of resuscitation gases at controlled flow and pressure. A flowmeter is used to control the flow rate of gas and the adjustable pressure relief valve is used to set the maximum pressure delivered to the patient during resuscitation.

The Tom Thumb incorporates a secondary, non-adjustable precision blow-off valve for added safety.

CAUTION
Before operating the Tom Thumb Infant Resuscitator, please refer to the complete instruction manual, attached as an appendix to this manual and observe all safety precautions contained therein.

For ease of access and referral, a compact, laminated copy of the Tom Thumb instruction manual is attached to the outside of the resuscitation cabinet. Additional copies can be requested from Viamed if required.

WARNING
Do not operate the Tom Thumb TT490-15 at flows greater than 15 Litres/min.
Do not operate the Tom Thumb TT480 at flows greater than 15 Litres/min.

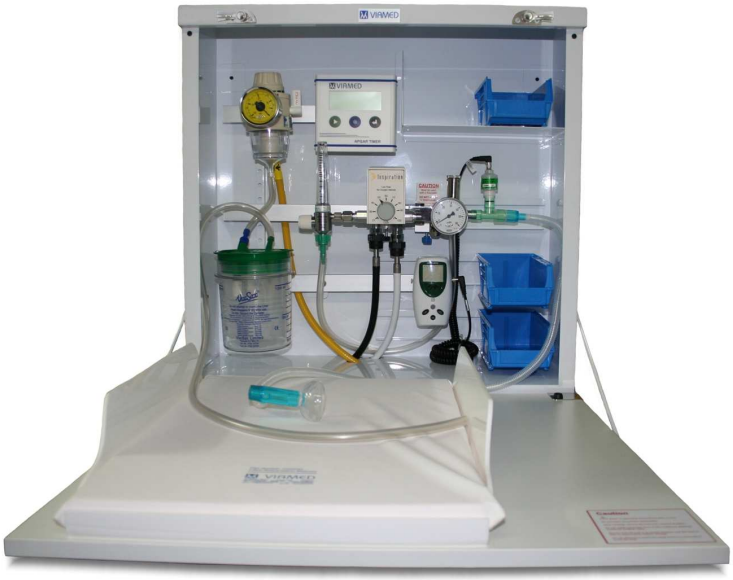
LOW FLOW AIR/OXYGEN BLENDER

The Viamed Infant Resuscitation Cabinet may be used with a Bio-Med Devices model 2003 low flow air/oxygen blender, providing a model TT480 Tom Thumb is installed. The TT480 has a tapered inlet to connect via low-pressure tubing to the output flowmeter of an air/oxygen blender.

The Bio-Med Devices model 2003 air/oxygen blender is a precision proportioning device for mixing medical grade air and oxygen to any concentration from 21% to 100% oxygen at a flow-rate up to 30 L/min and delivering it to a variety of respiratory care devices.

Bio-Med Devices model 2003 Low Flow Air/Oxygen Blender

CAUTION
Before operating the Bio-Med Devices low flow air/oxygen blender, please refer to the complete instruction manual, attached as an appendix to this manual and observe all safety precautions contained therein.



Infant Resuscitation Cabinet with a Low Flow Air/Oxygen Blender and Oxygen Analyser Installed

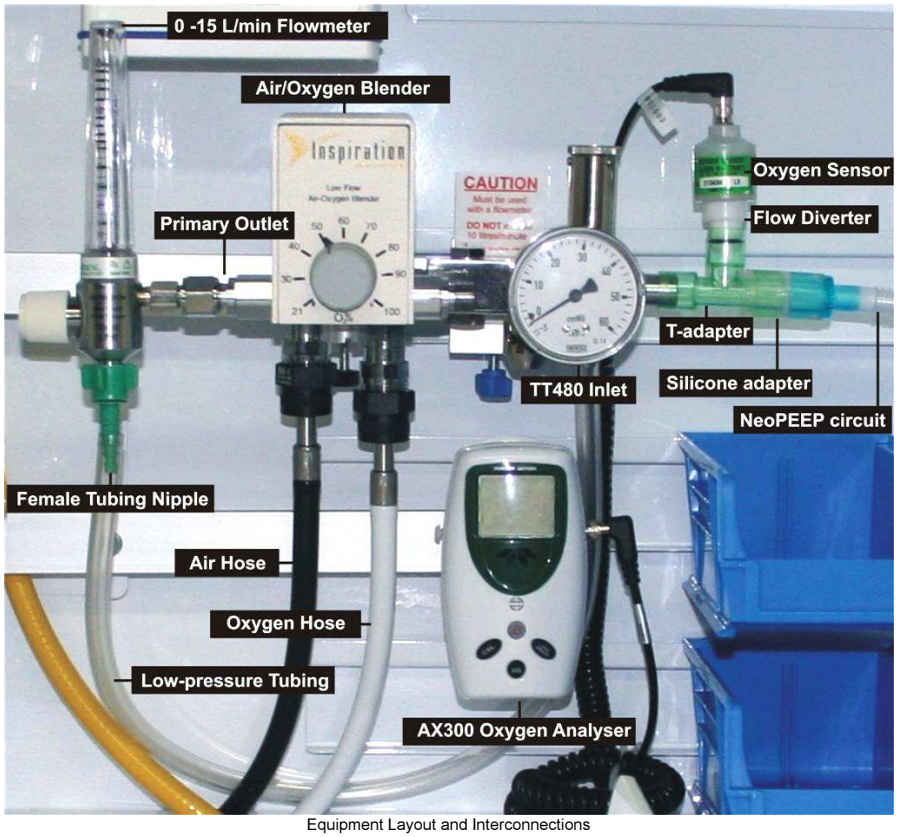
Viamed can also supply the Bio-Med Devices low flow air/oxygen blender as an upgrade option for existing resuscitation cabinet systems. If a Tom Thumb model TT490-15 is installed, which has an integral oxygen hose, this will require modification to a model TT480 Tom Thumb with a low-pressure tapered inlet.

Note: for cabinets supplied prior to 2009, the medirail sections may need to be replaced with longer lengths in order to accommodate an air/oxygen blender within the cabinet: please contact Viamed for further details.

Equipment Layout and Interconnections

The equipment should be connected as shown in the image below.

Note: an oxygen anaylser can be incorporated into the cabinet system if local guidelines deem it necessary, however, one would only be supplied if specified by the customer.



Equipment Layout and Interconnections

Pre-use Checks

Before use, check that a high-pressure air hose is connected to the air fitting and a high-pressure oxygen hose is connected to the oxygen fitting on the bottom of the blender.

Check that the air and oxygen hoses are connected to a supply of air and oxygen via fixed wall outlets.

CAUTION
It is recommended that the infant resuscitation cabinet system operate from a medical gas pipeline system.
If the cabinet has been configured to operate from gas cylinders, ensure that the air and oxygen hoses are connected to the cylinders and that the cylinders are delivering the correct pressure as determined by the engineer(s) who configured the system. If in doubt, consult an engineer.

Ensure that a 0 – 15 L/min flowmeter is connected to the primary outlet of the blender, which on the Bio-Med Devices model 2003 is the outlet on the left of the device when looking from the front.

Ensure that a flowmeter female tubing nipple is connected to the blender flowmeter, and that this is in turn connected using low-pressure tubing to the Tom Thumb infant resuscitator.

If an oxygen analyser is to be used, ensure that a paediatric T-adapter is connected to the outlet of the Tom Thumb.

Ensure that a NeoPEEP patient circuit is connected to the outlet of the Tom Thumb (or paediatric T-adapter if present) using a 15mm I.D. to 15mm I.D. silicone adapter.

Before using the blender to deliver gas to a patient, set the control on the front of the blender to the desired oxygen concentration. If required, a calibrated oxygen analyser can be used to check the accuracy of the patient gas.

Calibrating the Oxygen Analyser

Viamed supply the Teledyne AX300 oxygen analyser as an option, which can be mounted inside the resuscitation cabinet.

Note: for cabinets supplied prior to 2009, the middle and lower medirail sections may require replacing with longer lengths in order to accommodate a blender and oxygen analyser: contact Viamed for further details.

CAUTION
If using an oxygen analyser, please consult the Operator's Manual for that device prior to use.

The oxygen sensor is connected via a flow diverter into the paediatric T-adapter, the T-adapter is connected to the outlet of the Tom Thumb, and the patient circuit is connected to the T-adapter.

Oxygen Sensor Connected to T-Adapter via a Flow Diverter

Remove the oxygen sensor from the T-adapter by pulling it straight out of the port.

Unscrew the flow diverter to expose the sensor to air.

Calibrate the oxygen analyser as detailed in the operator's manual for that device.

Once the calibration has been performed and the analyser is displaying an air reading, reconnect the flow diverter and insert the sensor into the T-piece.

To check the accuracy of the patient gas delivered by the blender, set a flow by adjusting the flowmeter on the blender. Set the control on the front of the blender to the desired oxygen concentration and verify that the reading on the oxygen analyser corresponds to the concentration that has been set.

NOTE
The accuracy of the blender is ±3% of full scale
When changing oxygen concentration, wait sixty seconds for the gas mixture to stabilize before checking it against the analyser.

WARNING
Determining the flow rates, Peak Inflation Pressure (PIP), Positive End-Expiratory Pressure (PEEP) and oxygen concentration for resuscitation are clinical decisions: follow your own organization's protocols and, if in any doubt, consult your Key Trainer or a relevant qualified person.

CONSUMABLES AND PARTS LIST

Note: the Viamed resuscitation cabinet is available in different configurations, the parts list contains equipment from all variants; care must be taken when re-ordering replacement parts. If in doubt, please contact Viamed to determine the correct item.

For parts not listed, such as spare parts required to effect repairs, please contact Viamed.

Parts	
Part no.	**Description**
0310002	Complete resuscitation cabinet including all parts
0310302	Wall mounted radiant warmer – Ceratherm 600-3
0330120	Element for radiant warmer – 600W ceramic
0330124	LED light for Ceratherm 600-3 radiant warmer
0330105	Cabinet body
0332100	Resuscitation cabinet door catch
0320021	Resuscitation bed, 35cm (14”) wide
0320043	Mattress, 35cm (14”) wide
0310035	Low suction controller (Oxylitre S714)
0330040	Suction hose assembly, 3m (Oxylitre)
0310050	Low suction controller (Therapy Equipment Diamond Series 7725-3)
0330033	Suction hose assembly, 3m (Therapy Equipment)
3833-132	VacSax reusable suction canister
3833-007	VacSax tapered suction connectors, pack of 10
9910-340	VacSax disposable liners, box of 25
0320010	Universal rail clamp with ‘V’ for mounting VacSax suction jar
0310100	Apgar Timer (note: mounting bracket sold separately)
0320200	Mounting bracket with rail clamp for mounting Apgar timer
0310020	Size 3 storage box
0310030	Tom Thumb resuscitation unit, type TT480 without flowmeter
0310034	Tom Thumb resuscitation unit, type TT490-15-3M with flowmeter
0330218	Oxygen hose assembly for Tom Thumb TT490-15-3M, 3m
0310200	Low-flow air/oxygen blender including flowmeter, hoses and mounting bracket
0310201	Low-flow air/oxygen blender (blender only)
0320210	Flowmeter, 0 – 15 L/min for use with air/oxygen blender
0320214	Rail mount bracket for use with air/oxygen blender
0320216	NIST hose with MKIV oxygen probe, 3m, for use with air/oxygen blender
0320217	NIST hose with MKIV air probe, 3m, for use with air/oxygen blender
0330213	O-ring, thick. Each Tom Thumb uses 1, replaced during service
0330214	O-ring, thin. Each Tom Thumb uses 6, replaced during service
0120103	Paediatric T-adapter, 15mm I.D. to 15mm O.D. with 15mm I.D. port Note: only required if connecting an oxygen analyser into the patient circuit

Consumables required for routine daily operation	
Part no.	**Description**
3210011	NeoPEEP circuit with variable PEEP, single patient use (without mask) The NeoPEEP circuit can be used with size 0, 0.5 or size 1 masks
3210070	Single use silicone face mask, size 0
3210067	Single use silicone face mask, size 0.5
3210071	Single use silicone face mask, size 1
9910-340S	VacSax disposable liner, single unit Can be purchased singly or in boxes of 25
9910-340	VacSax disposable liners, box of 25
0120140	Silicone adapter for connecting NeoPEEP circuit to Tom Thumb Note: only required if the previous adapter has been disposed of. As an alternative, disposable adapters can be used.
0120141	Disposable adapter for connecting NeoPEEP circuit to Tom Thumb

Consumables required periodically and during service	
0310104	Filter for Oxylitre S714 low suction controller, single unit 1 filter required per system. Can be purchased singly or in boxes of 30
0310105	Filters for Oxylitre S714 low suction controller, box of 30
0310111	Filter for Therapy Equipment 7725 low suction controller, single unit 1 filter required per system. Can be purchased singly or in boxes of 10
0310112	Filters for Therapy Equipment 7725 low suction controller, box of 10
0330035	Suction clear tubing, 1m Approximately 50cm of tubing is required per system
0330213	O-ring, thick. Each Tom Thumb requires 1, which is replaced during service
0330214	O-ring, thin. Each Tom Thumb requires 6, which are replaced during service
0330040	Vacuum hose assembly, 3m (Oxylitre) Hose should be replaced at least every 4 years, regardless of the condition of the hose
0330033	Vacuum hose assembly, 3m (Therapy Equipment) Hose should be replaced at least every 4 years, regardless of the condition of the hose
0332000	Annual service kit for model 2003 blender 1 service kit required per blender
0332001	Overhaul kit for model 2003 blender Overhaul recommended every 4 years. Overhaul kit includes an annual service kit

Operator and Service Manuals	
Part no.	**Description**
0391045	Resuscitation cabinet operator's manual
0391050	Resuscitation cabinet installation manual
0390007	Tom Thumb TT490-15 instructions for use
0390006	Tom Thumb TT480 instructions for use
0390022	TT480 service manual
0390023	TT490-15 service manual
0390021	Tom Thumb valves service manual (common to all Tom Thumb variants)
2122	Bio-Med Devices Air Oxygen blender operator's manual
0392000	Digital Apgar Timer operator's manual
0391021	Ceratherm 600-3 operator's manual
0391022	Ceratherm 600-3 service manual
0391023	Ceratherm 600-3 supporting documents on CD

SERVICING

It is recommended that the resuscitation cabinets, its internal components and the radiant warmer be serviced annually. Service contracts are available; please contact Viamed for further information.

Service training courses are available from Viamed and service training courses for the air/oxygen blender are available from Inspiration Healthcare; please contact Viamed for further information.

Service the individual items of equipment using their respective Service or Operator's manuals, copies of which are available from Viamed.

For versions of the Tom Thumb that have an integral flowmeter and hose, Viamed recommends that the hose is inspected for wear or damage every 3 months and replaced every 4 years regardless of condition of the hose.

If the Viamed Infant Resuscitation Cabinet has been supplied with a Therapy Equipment low suction controller, the manufacturer recommends that the vacuum hose be replaced at least every 4 years, regardless of the condition of the hose.

If the Viamed Infant Resuscitation Cabinet has been supplied with an Oxylitre low suction controller, the manufacturer recommends that the vacuum hose be replaced at least every 4 years, regardless of the condition of the hose.

If the Viamed Infant Resuscitation Cabinet has been supplied with an air/oxygen blender, the manufacturer recommends that the air and oxygen hoses be replaced at least every 4 years, regardless of the condition of the hose. Additionally, the air/oxygen blender should be subject to a complete overhaul every 4 years, please contact Viamed or Inspiration Healthcare for further details on how to achieve this.

The following table details the parts that will be required for service, along with the frequency with which they should be replaced. Which parts are required will depend upon the specific configuration of the resuscitation cabinet in question.

Routinely replaced parts		
Part no.	**Description**	**Replacement frequency in years**
0330213	O-ring, thick. Each Tom Thumb uses 1, replaced during service	1
0330214	O-ring, thin. Each Tom Thumb uses 6, replaced during service	1
3833-007	VacSax tapered suction connectors, pack of 10	1
0310104	Filter for Oxylitre low suction controller, single unit	1
0310109	Filter for Therapy Equipment low suction controller, single unit	1
0330035	Suction clear tubing, 1m (approx 50cm per system)	1
0330218	Oxygen hose assembly for Tom Thumb, 3m (note: only for TT490-15)	4
0330040	Suction hose assembly, 3m (Oxylitre)	4
0330033	Suction hose assembly, 3m (Therapy Equipment)	4
0320216	NIST hose with MKIV oxygen probe, 3m, for air/oxygen blender if installed	4
0320217	NIST hose with MKIV air probe, 3m, for air/oxygen blender if installed	4
0332000	Annual service kit for model 2003 blender	1
0332001	Overhaul kit for model 2003 blender – includes annual service kit	4

Document ref:	0391055
Version:	1.4

Viamed Infant Resuscitation Cabinet Service Sheet

Hospital / Organisation:	
Location (department, room number):	
Engineer (print):	
Service Date:	

Action	Notes	OK
Cabinet Body – Serial number:		
Check for overall signs of damage Comments:		☐
Check door catches for functionality and signs of damage Comments:		☐
Check integrity of welds on the door hinges Comments:		☐
Check hinges for damage or deformation Comments:		☐
Check the restraining bars for damage or deformation Comments:		☐
Check the cabinet is securely fixed to wall Comments:		☐
Check medirails and tighten any loose rails Comments:		☐
Check grommets on the hose inlets are in place and intact Comments:		☐
Check the bumper stops that prevent door banging during closing (note: not all cabinets require these) Comments:		☐
Check 'caution' sticker is in place on the platform Comments:		☐
Check bed for damage i.e. cracks, chips Comments:		☐
Check all the bed mounting screws are in place Comments:		☐
Check mattress for damage i.e. tears, split seams Comments:		☐
Tom Thumb – Serial Number:		
Follow service procedure as detailed in the Tom Thumb service manual Comments:		☐
Check oxygen hose, if present, for wear, and replace if necessary (at least every 4 years) Hose replaced? Yes ☐ No ☐ Date of last hose replacement: Comments:		☐

Action Notes	OK
Low Suction Controller – Serial number:	
Follow service procedure as detailed in suction controller operator's or service manual Comments:	☐
Change filter assembly Comments:	☐
Check vacuum hose for wear, and replace if necessary (at least every 4 years) Hose replaced? Yes ☐ No ☐ Date of last hose replacement: Comments:	☐
Check rail clamp is securely attached to suction controller Comments:	☐
Replace suction tubing between suction controller and receiving liner Comments:	☐
Replace tapered connector on suction tubing Comments:	☐
Check receiving canister for damage, replace if necessary Comments:	☐
Radiant Warmer – Serial number: Note: if the unit is hard wired, a PAT test may not be applicable: consult your organisation's regulations. Is unit hard-wired? Yes ☐ No ☐ PAT test performed? Yes ☐ No ☐ Pass ☐ Fail ☐ Comments:	
Follow service procedure as detailed in radiant warmer service manual Comments:	☐
APGAR Timer – Serial number:	
Change batteries Comments:	☐
Follow service procedure as detailed in Apgar timer operator's manual Comments:	☐
Air/Oxygen blender (if present) – Serial number:	
Follow service procedure as detailed in radiant warmer service manual Comments:	☐
General	
Check storage bins present Comments:	☐
Tidy any trailing hoses, using tie-wraps if necessary Comments:	☐
Clean the cabinet with suitable cleaning wipes (Viamed recommends TECcare Control) Comments:	☐
Additional notes or comments:	

	Version:	1.1

Digital Apgar Timer Service Sheet

Hospital / Organisation:	
Location (department, room no.):	
Engineer (print):	
Service Date:	

Action	Further action required	OK
Serial number:		
Batteries replaced Comments:	☐	☐
Check for overall signs of damage Comments:	☐	☐
Check START button enters *Counting Mode* Comments:	☐	☐
Check FREEZE button enters *Freeze Mode* Comments:	☐	☐
Check FREEZE button resumes *Counting Mode* Comments:	☐	☐
Re-enter *Freeze Mode*, check START button resumes *Counting Mode* Comments:	☐	☐
Check RESET button enters *Stand-by Mode* Comments:	☐	☐
Start a stopwatch whilst simultaneously pressing START (note: there may be a slight pause before the timer begins counting, ensure they are running in synchronisation before proceeding)		
Check single beep audible indication at 1 minute Comments:	☐	☐
Check two beeps audible indication at 5 minutes Comments:	☐	☐
Check three beeps audible indication at 10 minutes Comments:	☐	☐
Check count is synchronized with the stopwatch at 10 minutes, ± 1 sec Comments:	☐	☐
Check mounting clamp and bracket are securely fastened Comments:	☐	☐
Clean unit as detailed in the Operator's Manual Comments:	☐	☐
Additional notes or comments:		

CLEANING

Cleaning guidelines in this manual complement those given in the Medical Devices Agency document “Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory Committee to Department of Health Medical Devices Agency”. This document is more commonly known as the ‘MAC Manual’, and is referred to as such in this document for convenience.

With reference to the MAC Manual, “Introduction to Part 1 - Table 1: Classification of infection risk associated with the decontamination of medical devices”; many of the items of equipment comprising the Viamed Wall-Mounted Resuscitation Cabinet system are classified as low risk, due to being “In contact with healthy skin, or not in contact with the patient”.

The recommended decontamination method for low risk items is to clean in accordance with the guidelines in the MAC Manual “Part 2; Cleaning (manual) - non-immersion”.

Clean as per MAC Manual “Part 2; Cleaning (manual) – non-immersion”

- Radiant warmer
- Cabinet body
- Mounting rails
- Storage bins
- Integral bed
- Mattress
- Tom Thumb infant resuscitator
- Low suction controller
- VacSax suction receiving canister (can also be steam sterilized if required)
- Apgar timer

Cleaning Guidelines

The items listed above are low risk and not intended to be disinfected or sterilized, but where an alcohol wipe is used, this may have a disinfecting effect. After manual cleaning, an alcohol wipe containing 70% ethanol can be used over all external surfaces, observe safety precautions detailed later in this document.

It is recommended that a neutral detergent solution be used in accordance with the manufacturer’s guidelines. For maximum efficacy, Viamed recommends the use of TECcare Control: a high-level broad-spectrum disinfectant cleaner with prolonged antimicrobial protective effect.

Sodium hypochlorite solutions are not recommended due to their potential corrosive effect on some metals.

The equipment within the cabinet system is mounted on standard mounting rails. To remove the equipment, loosen the rail clamps by rotating the securing bolts until the equipment can be lifted free of the rail.

It is recommended that the bed be cleaned in-situ. Should it be necessary, the bed can be removed by removing the 6 screws holding it in place. Care should be taken when re-attaching the bed not to over-tighten the screws.

NOTE: the following instructions detail the method of manual cleaning (non-immersion) as directed by the MAC Manual. Should these instructions contradict guidelines in place within the customer's own organization, or those of the manufacturer of the cleaning detergent, please contact your Sterile Services Department or other responsible body within your organization for advice.

Equipment Required

- A warm water/detergent solution at correct dilution.
- A clean, disposable, absorbent, non-shedding cloth for application of detergent solution.
- A clean, disposable, absorbent, non-shedding cloth or mechanic drying facility (e.g. drying cabinet or industrial hot air dryer).
- An appropriate chemical neutraliser, first aid kit and eyewash bottle, in case of splashing with detergent.

Procedure

- If the item is electrical, ensure that it is disconnected from the mains supply before commencing the cleaning procedure.
- Wearing protective clothing, immerse the cleaning cloth in the detergent solution and wring thoroughly.
- Commencing with the upper surface of the item, wipe thoroughly ensuring that detergent solution does not enter electrical components.
- Periodically rinse the cloth in clean water and repeat the above steps.
- Surfaces should be carefully hand-dried using a cloth or industrial hot air dryer or placed into a drying cabinet.

Note: Non-immersion, manual cleaning is not a disinfection process, but where an alcohol wipe is used to dry surfaces, this may have a disinfecting effect.

- Safely dispose of cleaning materials and alcohol wipes, if used.

Monitoring and Control

Owing to the lack of control methods available to the user to test the efficiency of non-immersion cleaning, the user should be aware of the factors that may alter the efficiency of the method:

- staff training
- physical application
- nature of soil
- accessibility of cleaner to item/part of equipment
- detergent concentration

Safety Precautions

- Always wear protective waterproof clothing, robust gloves and eye protection if splashing is likely to occur.
- After removing protective clothing on completion of task, thoroughly wash and dry hands.
- Avoid splashing.
- Precautions should be taken when using alcohol, as it is flammable.
- The 'pooling' of alcohol on equipment should be avoided and alcohol evaporation ensured, if necessary by forced air drying. Care should also be taken to ensure that alcohol does not enter the item e.g. via ventilation slots.

Items that can be Steam Sterilized at 121º C as per HTM 2010, Part 3

- VacSax suction receiving canister
- VacSax suction taper

Items Intended for Single Patient Use Only

- Breathing circuit
- Suction tubing
- VacSax suction receiving liners
- Suction catheters

WARNING
Do not attempt to reprocess items intended for single patient use.

WARRANTY

Viamed guarantees all parts of the Viamed wall mounted Infant Resuscitation Cabinet System for a period of 12 months from the date of purchase.

Some components of this system, for example low suction controllers, may be covered by a manufacturer's warranty in addition to the standard warranty: please contact Viamed for further details.

The best materials and workmanship have been employed throughout every stage of manufacture and every part is thoroughly tested before dispatch.

This warranty covers defects in materials and manufacture but excludes damage caused by accident, misuse or neglect.

Should a component develop a defect within the warranty period, it will be repaired or replaced at Viamed's discretion.

In the event of warranty claims or queries regarding this product when purchased outside the UK, please contact your local distributor.

COMPANY DETAILS

All products are CE marked to the requirements of MDD 93/42 EEC and are supplied in accordance with our quality system accreditations:
BS EN ISO 9001:2008 and ISO 13485:2003.

Contact details:

Viamed Ltd.
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT
United Kingdom

Tel: +44 (0)1535 634542
Fax: +44 (0)1535 635582

Email: info@viamed.co.uk
Web: www.viamed.co.uk

NUFER·MEDICAL

CERATHERM 600-3

Radiant Heater

Instruction Manual

FOR THE OPERATORS AND THOSE RESPONSIBLE FOR THE CARE AND MAINTENANCE OF THIS UNIT:

- Read through this **instruction manual** thoroughly before using the unit.
- Keep this **instruction manual** in a place where it can be referred to whenever needed.

CE 0123

Contents

1. Introduction

1.1 General

This instruction manual describes the intended use, operation, specifications, care and maintenance of the CERATHERM 600-3 radiant heater.

Read through this instruction manual carefully and familiarise yourself with the content before operating the CERATHERM 600-3. To ensure that the unit is used safely, follow the operating guidelines and explanations that are given in this instruction manual. The CERATHERM 600-3 must only be operated by persons who have been properly trained and instructed, under the supervision of a skilled medical specialist who is familiar with the currently known risks and benefits of using a radiant heater.

NUFER MEDICAL is in no way responsible for errors or accidents that are the result of non-compliance with the instructions on operation, care, maintenance and any other content given in this instruction manual. The same applies for repair work performed on the unit if such work is performed by unauthorised persons or if unapproved original components are used.

The CERATHERM 600-3 must only be used for its intended purpose as per chapter 1.2 of this instruction manual.

Keep this instruction manual in a place where it can be referred to whenever needed. In the event of technical problems or malfunctions, please inform your local NUFER MEDICAL sales partner immediately. If you do not understand the content of this instruction manual, contact your local NUFER MEDICAL sales partner for more information.

1.2 Purpose

The CERATHERM 600-3 radiant heater is designed to preheat examination and baby changing tables and to maintain the body temperature of new-borns, children and adults.

1.3 Electromagnetic Emissions and Electromagnetic Compatibility

The CERATHERM 600-3 radiant heater meets all the requirements of the EN 60601-1-2 industrial standard.
Accordingly, the unit's electromagnetic emissions are very low and cannot impair the functioning of electronic equipment located in the immediate vicinity.
Ensure that any electronic equipment that is used in the vicinity of the CERATHERM 600-3 radiant heater also meets the requirements of EN 60601-1-2. Equipment with electromagnetic emissions that are too high can impair the radiant heater's ability to function safely.

Do not use any wireless communication devices within 5 metres of the radiant heater. The mains power supply to which the CERATHERM 600-3 radiant heater is connected must meet the legal and technical requirements for a hospital or clinic mains power supply in terms of dielectric strength, frequency stability and pulse spikes etc. Ensure that the radiant heater is not exposed to electrostatic discharge.

1.4 Scope of Delivery

The CERATHERM 600-3 radiant heater is supplied with a mains cable, instruction manual and declaration of conformity. Approved accessories are described in chapter 16.

1.5 Maintenance Procedure

No particular maintenance is required for the CERATHERM 600-3 radiant heater, except for the annual safety check described in chapter 20 of the CERATHERM 600-3 service manual. The unit does not have any special wear parts.

1.6 Support

Maintenance for the CERATHERM 600-3 radiant heater must only be performed by persons who have been authorised by NUFER MEDICAL or the local trained sales partner. If repair work is required, the unit must be returned to the NUFER MEDICAL sales partner located in your country, along with a completed 'Repair Request Form' (see chapter 17). Further information is available from the customer service department of:

NUFER MEDICAL AG

Morgenstrasse 148
CH-3018 Bern / Switzerland

Tel. +41 (0)31 958 66 66
Fax +41 (0)31 951 46 73

info@nufer-medical.ch
www.nufer-medical.ch

2. Definitions and Symbols

2.1 Definitions

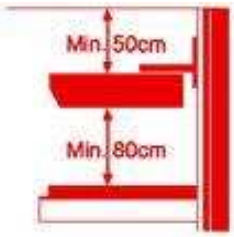
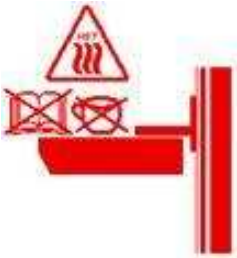
Please take time to familiarise yourself with the definitions given below before you use the radiant heater. The following expressions are used in this instruction manual:

Expression	Symbol	Description
Warning:		This expression is used in the text to draw your attention to hazardous conditions in connection to the operation, cleaning or maintenance of the unit if there is a risk of injury or death for the operator or the patient.
Caution:		This expression is used in the text to draw your attention to a process that must be followed exactly to avoid injury to the user or patient, or damage to the unit.
Note:	Text with border	This expression is used in the text to draw your attention to processes or conditions that you could otherwise overlook or misunderstand.

2.2 Symbols

Please take time to familiarise yourself with the symbols given below before you use the radiant heater. This lists includes all the symbols that are displayed on the unit to aid operation or as a warning or note:

Symbol	Explanation
	Ensure that the instruction manual is observed.

	Dangerous voltage.
	**Warning sign:** Refer to the relevant section of the instruction manual for further information.
	**Warning sign:** Hot surfaces **-> Risk of burns.**
	**Warning sign:** Ensure that there is a clearance of at least **80 cm** between the reclining surface and the bottom edge of the heater head. There must be a clearance of at least **50 cm** between the ceiling/false ceiling and the top edge of the heater head **-> Risk of fire and risk of burns.**
	**Warning sign:** Do not reach into the heater head **-> Risk of burns.**
	**Warning sign:** Do not place any objects on the protective grille **-> Risk of fire.**

	**Operation:** Switches unit on and off (observe chap. 8) **Display:** The unit's operating mode (observe chap. 8)
	**Operation:** Alarm confirmation (observe chap. 8) **Display:** Alarm (observe chap. 8 and safety guidelines in chap. 2)
	**Operation:** Preset heat level 1 (20% output) **Display:** Heat level 1 active
	**Operation:** Preset heat level 2 (50% output) **Display:** Heat level 2 active
	**Operation:** Preset heat level 3 (75% output) **Display:** Heat level 3 active
	**Operation:** Preset heat level 4 (98% output) **Display:** Heat level 4 active
	**Display:** Heating active (observe chap. 8.3)
	**Operation:** Lighting 20% on/off (observe chap. 9) **Display:** None
	**Operation:** Lighting 100% on/off (observe chap. 9) **Display:** None
	**Operation:** Master switch (supply voltage on/off, see chap. 7) **Display:** Mains supply on
	Potential equalisation connection. If the unit is used in a room that corresponds to **Category 3 or 4** under Swiss Low-Voltage Installation Standard NIN / 7.10, this connection must be connected to the room's potential equalisation connection.

CE 0123	The unit meets the requirements of EU Directive 93/42/EEC/Annex II. Monitoring is provided by TÜV SÜD Product Service GmbH, 80339 München.
	The unit must be disposed of in accordance with EU Directive 2002/96/EC. Get in touch with your allocated NUFER MEDICAL sales partner.

3. Safety guidelines

Please ensure that the following safety guidelines are observed. The guidelines must be observed during the installation and use of the radiant heater:

	The radiant heater must only be connected to a power socket with a **protective earth connection**. Connection values of the power socket: 230 V AC +/−10%, 50–60 Hz, 6 A.
	The unit is fitted with a **ceramic heater** that is sensitive to knocks and blows. **Ensure that the unit is not exposed to any strong knocks or blows**.
	Ensure that **the wall mount is fastened** into solid masonry and that suitable wall-plug screws are used. Lightweight walls must be appropriately reinforced in the wall-mount area. **The client's specialist personnel are responsible for the secure fastening of the radiant heater.** **-> Risk to user and patient safety.**
	Parts must neither be removed from or attached to the radiant heater and no other modifications must be made **-> Risk to user and patient safety.**
	Ensure that there is **a clearance of at least 80 cm** between the reclining surface and the bottom edge of the heater head; there must be a clearance of at least **50 cm** between the ceiling/false ceiling and the top edge of the heater head **-> Risk of fire, risk to user and patient safety.**

	The radiant heater may increase patient water loss unnoticeably. It is vital that the patient is constantly monitored by the care staff **-> Risk to patient safety.**
	Changing the underlay (using dark cloths, heating pads etc.) can result in higher temperatures on the reclining surface and affect the patient's body temperature **-> Risk to patient safety.**
	Do not touch the patient and the radiant heater simultaneously. Possible potential differences between the unit and the care surface may **place patient safety at risk**.
	The radiant heater always functions as a manual radiant heater. No patient information is transmitted to the unit during use. The care personnel are therefore responsible for the patient's condition at all times.
	Ensure that **no liquids** enter the unit. If liquids do enter the inside of the unit, **shut the unit down immediately** and have it checked by an authorised person and repaired as required. A safety check must be performed before the unit can be used again.
	The radiant heater is fitted with an LED bulb to light up the care surface / the patient's body. Ensure that neither user nor patient look directly into the bulb.
	External conditions can affect the radiant heater's performance. Do **not** operate the unit at temperatures **below +5°C or over +30°C**. The relative humidity should not exceed 90%. Ensure that no condensation forms on the unit.
	External conditions (such as temperature and drafts) and other equipment in the vicinity (e.g. phototherapy equipment) can affect the patient's body temperature.

	Ensure that the radiant heater is positioned above the centre of the care surface. Do not operate the radiant heater **at a right angle to the care surface.**
	The radiant heater must only be used in a horizontal position with heat radiating downwards **-> Risk of fire, risk to user and patient safety.**
	The radiant heater must not be used in **environments that are at risk of fire or explosion**, i.e. in the immediate vicinity of anaesthetic gases or other highly flammable gases, liquids or materials **-> Risk of fire or risk of explosion.**
	The openings in the housing on the top side of the heater head must be kept clear at all times to guarantee sufficient **air circulation**. Do not lay any cloths, objects or flammable substances on the topside of the heater head **-> Risk of fire.**
	Never touch the protective grille on the top of the unit or the reflector and heater on the underside of the unit when the heater head is in use. **-> Risk of burns, risk to user safety.**
	The radiant heater must only be **operated** by persons who have been properly **trained and instructed**, under the supervision of a **skilled medical specialist** who is familiar with the currently known risks and benefits of using a radiant heater **-> Risk to user and patient safety.**
	The patient must **never be left unattended** beneath the radiant heater while it is switched on **-> Risk to patient safety.**
	It is vital that care staff independently monitor the patient's temperature **-> Risk to patient safety.**

	When the housing of the heater head is removed, there is a **risk of electric shock**. The unit's mains cable must always be disconnected before the housing of the heater head is opened.
	When the heater head has been on for 15 minutes, an acoustic and visual **alarm is activated**. The alarm can be delayed for a further 15 minutes by pressing the  button.
	When the radiant heater is being used above infant incubators or heating beds, it must be ensured that there is **sufficient clearance** between the bottom edge of the heater head and any heat-sensitive materials such as Plexiglas or acrylic glass. Ensure that there is **at least 80 cm** clearance at all times. Set the **heat output no higher than level 3** (75%).
	The radiant heater must only be operated with **original accessories** that NUFER MEDICAL has expressly approved for use with the CERATHERM 600-3. Observe the relevant information in chapter 16.
	In the event of a technical alarm  **shut the unit down immediately** and have it checked by an authorised person and repaired as required. A safety check must be performed before the unit can be used again.
	Before any cleaning or disinfection is performed, **ensure that the unit is shut down and disconnected from the mains supply**. Observe the relevant information in chapter 12.
	Repair and maintenance work must only be performed on the radiant heater by authorised personnel. Only components that NUFER MEDICAL has expressly approved for use with the CERATHERM 600-3 may be used.
	After the unit is **decommissioned**, it must be **disposed of correctly** in accordance with EU Directive 2002/96/EC. Get in touch with your allocated NUFER MEDICAL sales partner.

4. General Description

The built-in ceramic heater has very good radiation properties and generates invisible infrared radiation of around 3 µm. This radiation spectrum is absorbed very effectively by the skin and causes no harm to the patient's eyes.

5. Assembly

5.1 Minimum Clearance

After you have removed the packaging, compare the unit data on the specification plate with the electrical connection data. Electricity is supplied via a 220–240 V AC 50/60 Hz mains socket with a connection value of 6 A.
Ensure that the wall- and ceiling mount (fixed or mobile) is fastened into solid masonry (brickwork, sand-lime brick or concrete) and that suitable wall-plug screws are used.

Mount the heater head:

- with a clearance of at least 80 cm and no more than 100 cm between the reclining surface and the bottom edge of the heater head.
- with a clearance of at least 50 cm between the ceiling/false ceiling and the top edge of the heater head.

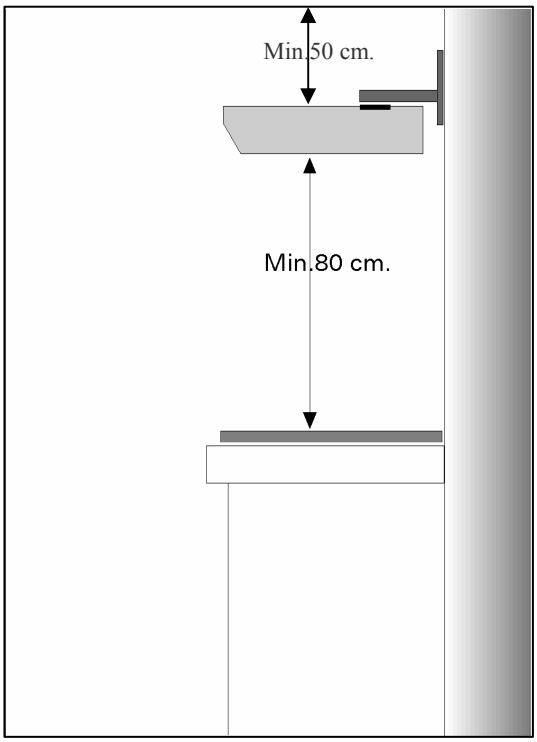


Figure 1

Ensure that there is always a clearance of at least 80 cm between the reclining surface and the bottom edge of the heater head.

Ensure that there is always a clearance of at least 50 cm between the ceiling/false ceiling and the top edge of the heater head.

The thickness of the underlay must also be taken into account.

Neglecting to do so may result in burns or fire.

6. Product description

The CERATHERM 600-3 radiant heater has four programmable heat output levels, which can be selected directly by pressing the buttons [heat level 1-4].

The default settings for the heat levels are 20, 50, 75 and 98%. All levels can be adjusted by a specialist upon request (within certain limits, e.g. safety level no larger than 20%).

All heat outputs above the safety level are monitored with a 15-minute reminder alarm. This alarm is intended as an aid for the user only; it does not relieve the user of a duty to supervise the patient.

An indicator lamp is built in to monitor actual heat output.

The patient is lit by a modern high-power LED lamp, which has the following advantages over a halogen lamp:

- More natural colour temperature (4000°K)
- No UV- or IR-radiation component
- Longer service life
- Lower energy consumption

-> Observe the relevant information in chapter 15 (Lighting)!

The light can be set to one of two brightness levels (default setting: 20% and 100%). These values can be set by a specialist in 10% increments.

The lighting switches on and off gradually, i.e. with a smooth transition, so it has a less disruptive impact on the patient.

In standby mode, the lighting has an automatic shut-off function. If the lighting is switched on and no lighting button has been pressed for 20 minutes, the lighting switches off automatically. This function can be disabled as required.

The installed software version can be displayed as necessary.

The setting of the relevant parameters is described in chapters 18 and 19 of the CERATHERM 600-3 service manual.

6.1 Description of Parts

Underside:

Figure 2

No.	Designation	Function
12	Reflector	Radiates heat
13	Hand grip	Adjusts the radiant heater
14	LED light	Lights the patient **-> Observe the relevant information in chapter 15!**
15	Ceramic heating element	Generates heat

Table 1

Topside:

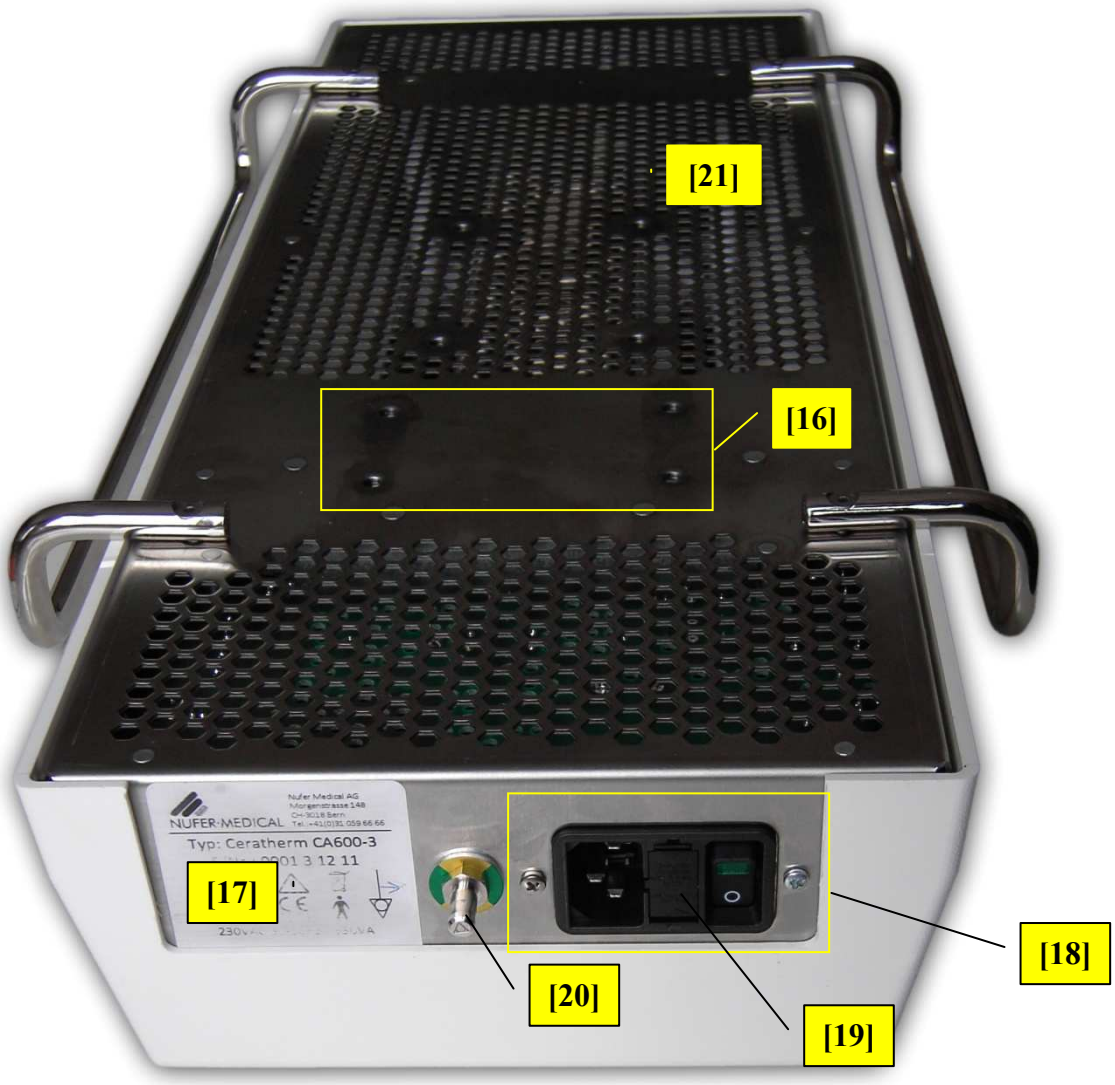


Figure 3

No.	Designation	Function
16	Heater head mount	Fastens the heater head to the ceiling/wall and trolley
17	Specification plate	Displays serial number, mains connection, fuse data and various symbols
18	Unit socket	Connects to 220–240 V / 50 Hz power supply
19	Fuses	Main fuses 2 × 3.15 AT
20	Potential equalisation connection	Connects to room's potential connection (room categories 3 and 4)
21	Protective grille	Functions as heat guard and provides ventilation

Table 2

7. Operation

Operation of the CERATHERM 600-3 radiant heater has been kept deliberately straightforward. Use of the unit is largely self-explanatory.

7.1 Master switch

The unit's ON/OFF switch is located on the rear side. This is normally switched on at all times. The heater head itself is switched on/off with ON/OFF button [7] on the front side. If this button is used to switch off the unit, it switches to energy-saving standby mode.

Note	**If the unit is switched off at the mains switch while it is not in standby mode (i.e. while heat level 1–4 is active), the mains failure alarm sounds. The unit cannot differentiate between mains failure and being switched off in such a case. Pressing alarm confirmation button [6] during a mains failure alarm silences the buzzer. The alarm LED will continue to flash until the supply voltage returns or the energy storage unit is empty (min. 15 min).**

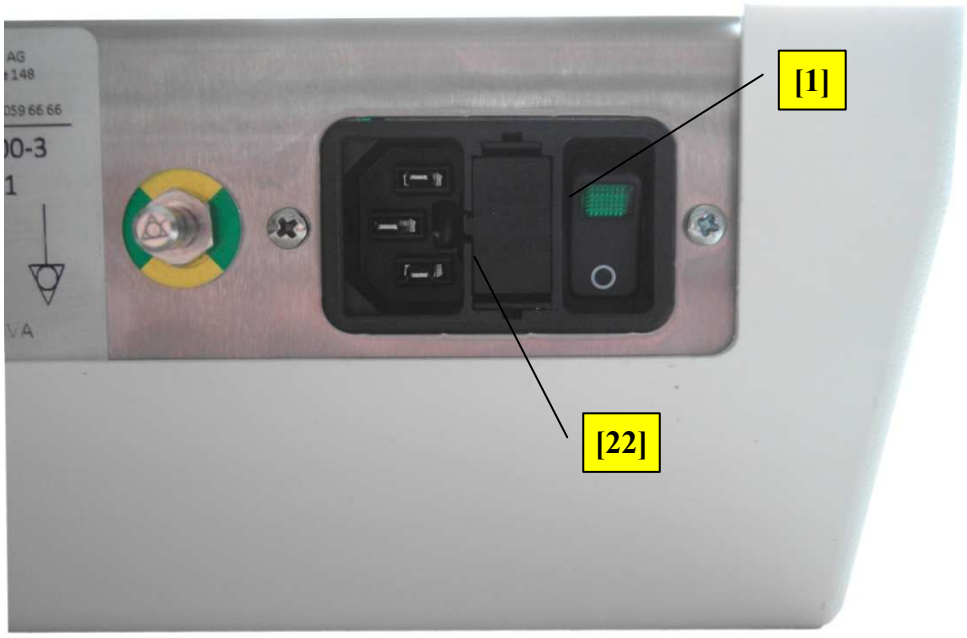


Figure 4

No.	Designation	Function
1	Master switch	Disconnects the radiant heater from the mains supply
22	Fuse holder	Contains two 3.15 AT microfuses (20 × 5 mm)

Table 3

7.2 Control Elements on the Front

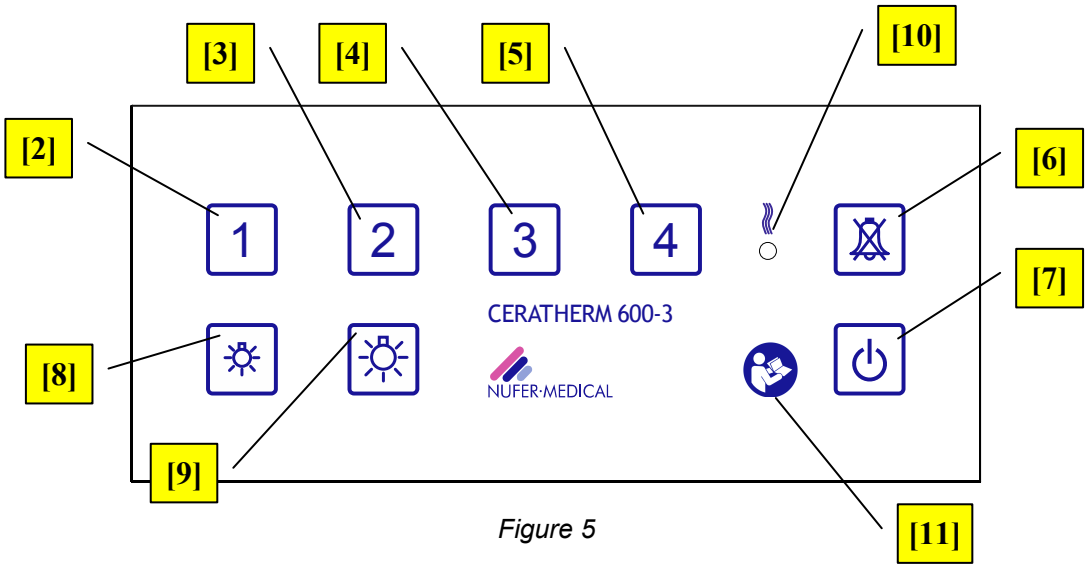


Figure 5

No.	Designation	Function
2	Illuminated button: Heat level 1	Sets heat level 1 with 20%[1]
3	Illuminated button: Heat level 2	Sets heat level 2 with 50%
4	Illuminated button: Heat level 3	Sets heat level 3 with 75%
5	Illuminated button: Heat level 4	Sets heat level 4 with 98%[2]
6	Illuminated button: Alarm confirmation	Resets an alarm
7	Illuminated button: ON/OFF	On: Level 1 is activated / Off: Heater head on standby
8	Button: LED 20%	Switches LED lighting on and off, at 20%
9	Button: LED 100%	Switches LED lighting on and off, at 100%
10	LED: Heat output indicator	Displays the heat output via differing blink rates
11	Warning: Read manual.	Read through the manual before commissioning.

Table 4

Button illumination:

- Buttons 2–7 are illuminated.
- Buttons 8 and 9 are not illuminated.

Note	**When the buttons are referred to in the text below, the number will be given in square brackets [ ].**

[1] Given output corresponds to default settings.
[2] Cannot be any higher than 98% because of the internal hardware monitoring circuit.

8. Commissioning

When the radiant heater is switched on via the mains switch on the rear side, the unit is initially in standby mode.

1. If you require additional light, switch on the LED lamp with a low [8] or high [9] brightness level.

2. Switch on the heater head by pressing on/off button [7]. The heat output is automatically set to heat level 1 (20%) to keep the reclining surface warm. (The reclining surface is pre-warmed after roughly 5–10 minutes.)

3. If greater output is desired as per table 4, select one of the heat levels 2–4 directly [3,4,5]. The yellow heat output indicator LED [10] displays whether the radiant heater is providing the desired output.

4. If heat level 2, 3 or 4 is selected, a reminder alarm will sound after 15 minutes. If this alarm is not confirmed with alarm button [6] within 8 seconds, output is reduced to the safety level (20%) for safety reasons. If the alarm is confirmed within 8 seconds, the heater will operate for a further 15 minutes, at the previous heat output.

5. The heater head can be switched to standby mode by pressing the green on/off button [7].

6. Once the controls have been set to standby mode via on/off button [7] on the front, the unit can be fully shut down by pressing mains switch [1] on the rear side.

8.1 Adjusting the Heat Output

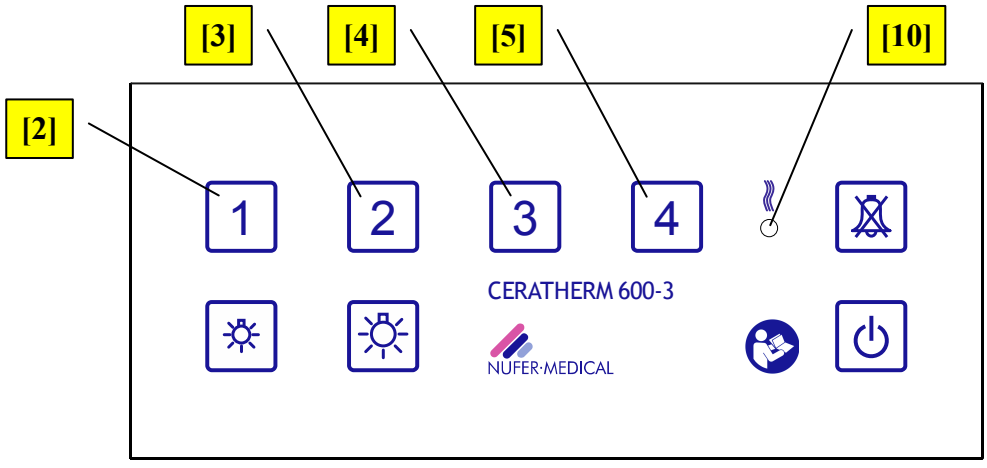


Figure 6

The four-level controls allow heat output to be perfectly adjusted to suit particular requirements. The following standard values are set by default:

Level 1 = 20% Level 2 = 50 % Level 3 = 75 % Level 4 = 98 %

Note	**The safety level (level 1) can be set no higher than 20%.** **For technical reasons, level 4 cannot be set above 98%.**

The heat output of the individual levels 1–4 can be customised for particular applications by **authorised maintenance staff**, for example:

Level 1 = max. 20% Level 2 = 40% Level 3 = 60% Level 4 = 80%

8.2 Practical Examples of Output Level Settings

1 Level 1: e.g. for pre-heating the reclining surface or keeping it warm, and for continuous operation

2 Phase 2: e.g. for normal operation for a baby changing or examination table

3 Phase 3: e.g. for additional heat during resuscitation, in the delivery room or operating theatre

4 Phase 4: e.g. for increased heating requirements in the operating theatre, for anaesthesia or in the recovery room

8.3 Checking the Set Output

The set output is displayed via heat output indicator LED [10]. The LED signals the activation of the heating element. If the LED is flashing, the heater is active. If the LED is dark, the heat element is switched off. One heat period corresponds to roughly 2 seconds. If a 50% output has been selected, for example, the LED lights up for roughly 1 second and is out for roughly 1 second. The LED lights up longer as output increases.

8.4 Alarm Monitoring

If the unit has been set to a heat output above level 1 for 15 minutes, a reminder alarm is activated. The alarm signal is both acoustic (buzzer sounds in five short intervals) and visual (alarm LED flashes red).
If alarm confirmation button [6] is pressed within 8 seconds of the alarm beginning, the alarm is deactivated for the next 15 minutes and the heater head continues operation at the previous heat output. If no alarm confirmation is given within this 8-second period, heat output is reduced to 20% for safety reasons. The red alarm LED displays this status visually until the heater head is either switched off with on/off button [7] or the alarm is confirmed with

alarm confirmation button [6]. The alarm is deactivated for the next 15 minutes and the heater head continues operation at the previous heat output.

	**The patient must never be left unattended on the reclining surface.** **The supportive alarm monitoring function is not activated at safety level.**

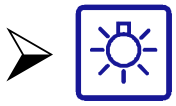
9. LED Lighting

The CERATHERM 600-3 is fitted with a modern LED lamp. This cutting-edge light source has a lower energy consumption and higher service life than other lights. -> Observe the relevant information in chapter 15!

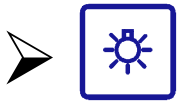
9.1 Operation

The CERATHERM 600-3's LED lighting has two brightness levels, which can be switched on and off as follows:

If the LED lighting is switched off:



- Press once: LED switches to bright level (default: 100%).
- Press once: LED switches off again.



- Press once: LED switches to low-light level (default: 20%).
- Press once: LED switches off again.

When the lighting is switched on, the brightness can be switched from 20% to 100% or vice versa by pressing the relevant lamp button. The light can be switched off by pressing the previously selected button again.

9.2 Changing the Brightness Values

The brightness values can be set by a specialist in 10% increments from 10–100%.

10. Troubleshooting

The CERATHERM 600-3 controls are able to detect and report the following malfunctions:

1. Supply voltage interruption (mains failure)
2. Circuit breaker interruption (triac)
3. Circuit breaker short-circuit (triac)
4. Safety switch interruption (relay)
5. Safety switch short-circuit (relay)
6. Reduced voltage from 12 V supply voltage
7. Overtemperature in unit

If a mains failure occurs during operation (i.e. at heat level 1–4), an acoustic alarm is given. The alarm LED also flashes at brief intervals. The alarm continues for roughly 15 minutes. The buzzer can be silenced during the alarm by pressing alarm confirmation button [6]. The alarm LED will continue to flash until the supply voltage returns or the energy storage unit is empty (min. 15 min).

If power supply returns, the heater head restarts as follows:

Duration of mains failure less than 15 minutes:

Heater head is activated automatically and continues heating at the previous heat level.

Duration of mains failure longer than 15–20 min.:

The heater head is in standby mode. The unit must be switched on again and the desired heat level must be selected!

The alarm signal can only be given for the full 15 minutes if the heater head was switched on roughly 3–5 minutes before the mains failure, to allow the energy storage unit the charge fully.

In event of errors 2–7, the illuminated heat-level buttons 1–4 [2,3,4,5] are used to display the error code:

Error code	1	2	3	4
Error	Triac error. Short-circuit or safety relay not closed.	Triac error. Interruption.	Overtemperature. Temperature inside heater heat above 50 °C.	Reduced voltage from 12 V supply.
Solution	Switch off radiant heater. Contact customer service (see chapter 1.6).	Switch off radiant heater. Contact customer service (see chapter 1.6).	Switch off heater. Check whether any ventilation openings are blocked. Allow heater head to cool down. Switch heater back on. If the error occurs again, contact customer service (see chapter 1.6).	Switch off radiant heater. Contact customer service (see chapter 1.6).

Table 5

11. Testing the Control Elements

When the controls are switched on, all relevant components (illuminated buttons, buzzer) are briefly switched on to check whether they are functioning correctly.

12. Cleaning/Disinfection

12.1 General information

	The radiant heater must be kept clean and dry. We recommend regular cleaning to preserve the unit's full functionality. Use a cloth that has been moistened with lukewarm water. Alcoholic cleaning agents must be diluted. Do not use any abrasive cleaning agents.
	Before cleaning, ensure that the radiant heater has cooled down and disconnect it from the mains power supply (by disconnecting the mains cable).
	Ensure that no liquid enters the unit or the unit socket.
	If any liquid or powder is spilled, disconnect the radiant heater from the power supply immediately by disconnecting the mains cable. Clean and dry the unit carefully.
	If liquid has **entered the unit**, discontinue operation of the unit. Contact customer service (see chapter 1.6).
	The radiant heater must not be autoclaved or immersed in liquid. The radiant heater must only be disinfected by wiping over surfaces. Only alcoholic disinfectants may be used.

13. Warranty

13.1 Warranty Period

The warranty period for CERATHERM 600-3 is given in the documents enclosed with the unit. Different warranty periods may apply for different countries. The warranty covers the repair of the unit and the replacement of defective parts in the event of manufacturing or material faults.

13.2 Warranty Restrictions

The warranty **becomes void** in the event of modifications or repairs being performed by unauthorised persons and/or non-observance of the inspection/maintenance intervals.
The warranty does **not** include the rectification of malfunctions that have been caused by unintended use, inappropriate handling, penetration of liquids, dirt or normal wear and tear.

NUFER MEDICAL only considers itself responsible for the factors affecting the unit's safety, reliability and performance if the following conditions are met simultaneously:

a) Assembly, enhancements, reconfiguration, modifications or repairs have been performed by authorised persons as per chapter 1.6.
b) The electrical installation of the room in which the unit is operated meets the legal and technical requirements for a hospital or clinic mains power supply.
c) The unit is used in accordance with this instruction manual.

Caution! The radiant heater must only be used with accessories and replacement parts that have been deemed safe to use in a NUFER MEDICAL check (see chapter 16 and 21 in the service manual).

The information given in this instruction manual corresponds to current conditions. Subject to changes that serve technical progress without notice.

14. Disposing of the Unit

The unit must be disposed of in accordance with EU Directive 2002/96/EC. Get in touch with your allocated NUFER MEDICAL sales partner.

15. Specifications*

Model	CERATHERM
Type	600-3
Article number	521A-60020-3
Conformity	CE mark (Directive 93/42/EEC, Annex II)
Notified Body	TÜV SÜD Product Service (CE 0123)
IP protection class	IP20
Contamination level class	2
Electrical protection rating	I (with protective earth connection)
Medicinal product class	IIb (Directive 93/42/EEC, Annex IX, Rule 9)
Applied industrial standards:	-EN 60601-1:2007 -EN 60601-2-21:2010 -EN 60601-1-2:2006
Mains connection voltage	230 V +/−10%, 50–60 Hz
Power consumption, standby	0.03 VA
Power consumption, max.	630 VA
Fuses	2 × 3.15 AT microfuses, 5 x 20mm (in the unit socket) 1 x 800mAT microfuse, 5 x 20mm (internal on the powerboard)
External conditions during *transport*	-Temperature: −10 to +50 °C -Relative air humidity: 20 to 90% (no condensation)
External conditions during *storage*	-Temperature: -10 to +50 °C -Relative air humidity: 20 to 90% (no condensation)
External conditions during *operation*	-Temperature: +5 to +30 °C -Relative air humidity: 20 to 90% (no condensation)
Heating element	Ceramic, 600 W, wavelength 2-10µm (IR-B/C)
Lighting	LED, 1 x 3W / 700mA / 4.5V, colour temperature 4000°K, without built-in power source
Alarms	-Acoustic and visual after 15 minutes, with automatic heat output reduction to 20% of max. output. -Mains failure -Technical malfunction (with error code)
Operating position	Horizontal, heat radiating vertically downwards
Assembly options	As per with accessories, chapter 16
Transport	In original packaging
Safety checks	Every 12 months as per service manual specifications, chapter 20
Disposal	In accordance with Directive 2002/96/EC. Get in touch with your allocated sales partner.
Dimensions	270 × 105 × 540 mm (W × H × L)
Weight	4.3 kg (without accessories)

Material, housing	ABS (temperature-resistant plastic)
Material, chassis	CNS (stainless steel)
Material, reflector	CNS (stainless steel)

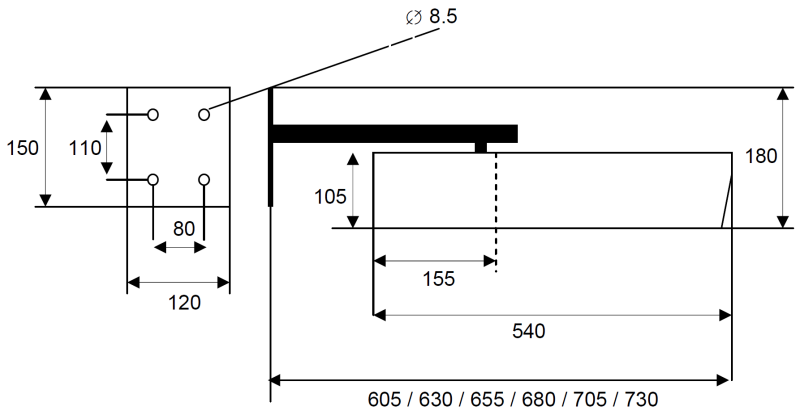
*NUFER MEDICAL reserves the right to make changes to the unit that may affect these specifications, at any time and without notice.

16. Accessories

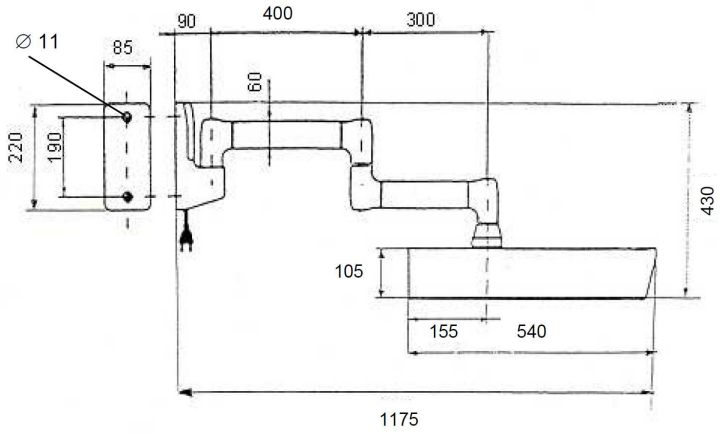
Regarding the accessories approved for the CERATHERM 600-3 radiant heater:

	With regard to assembly and use, observe the assembly and operating instructions supplied with the accessories. NUFER MEDICAL is in no way responsible for errors or accidents that are the result of non-compliance with the instructions on assembly, operation, care, maintenance and any other content given in the instruction manual supplied with the accessories. The same applies for repair work performed on the accessories if such work is performed by unauthorised persons or if unapproved original components are used.

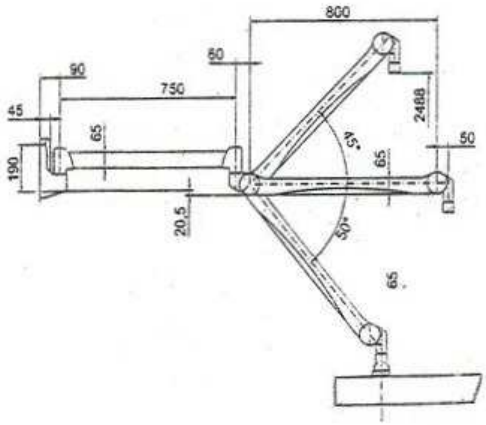
16.1 Wall mount, fixed, non-pivoting (optional)

	
Article number: 521A-60023-3	Non-pivotable. Distance from wall adjustable as per drawing.

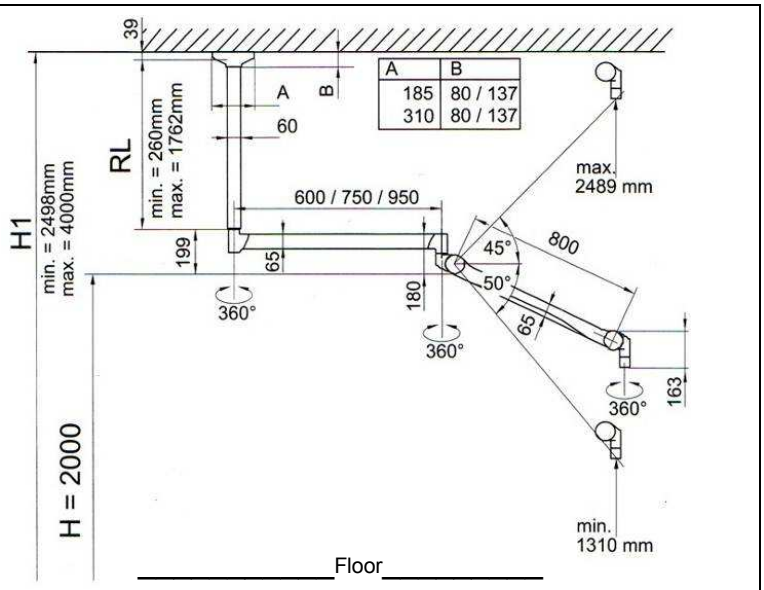
16.2 Wall mount with double-joint arm (optional)

	
Article number: 521A-60022-3	Pivotable, 360°. No height adjustment. Arm length as per drawing.

16.3 Wall mount with double-joint arm, long, with height adjustment (optional)

	
Article number: 521A-60025-3	Pivotable, 360°. With height adjustment. Arm length as per drawing.

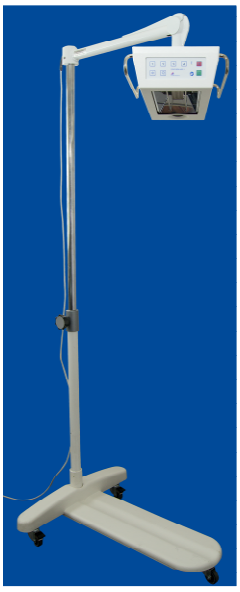
16.4 Ceiling mount with double-joint arm, long, with height adjustment (optional)

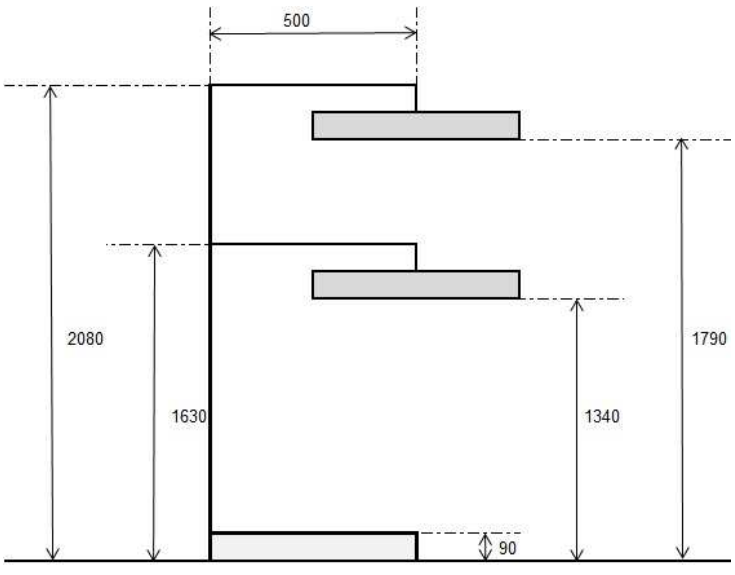


A	B
185	80 / 137
310	80 / 137

Article number: 521A-60024-3	Pivotable, 360°. With height adjustment. Arm length as per drawing. Ceiling tube length customer-specific.

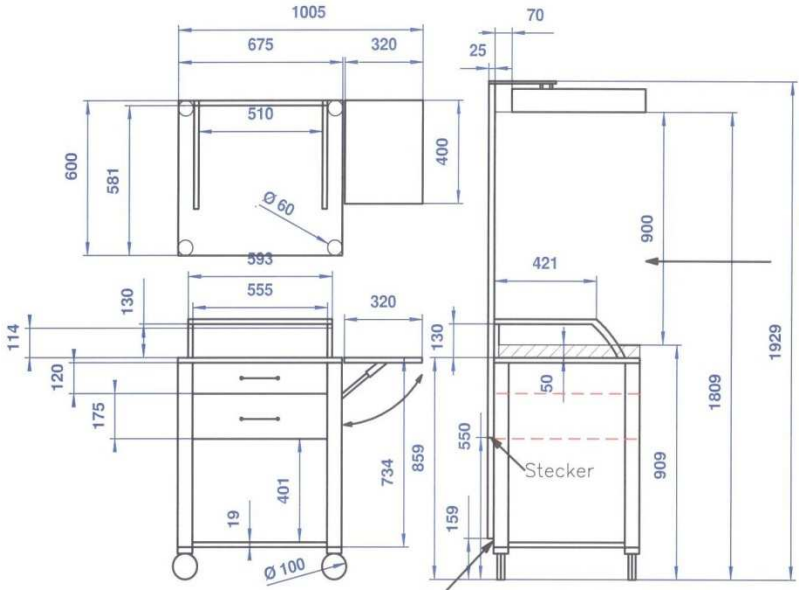
16.5 Mobile stand, with height adjustment (optional)





Article number: 521A-60035-3	With height adjustment. Triple-bar trolley base with two brakes. Dimensions as per drawing.

16.6 Baby changing table, mobile (optional)

	
Article number: 521A-60026-3	Mobile body. Heater head non-pivotable. No height adjustment. Dimensions as per drawing. Special measurements on request.

17. Repair Request Form

REPAIR REQUEST FORM

Address of national representative:

Customer name and address:

Name of contact: Tel. :

Invoice number:

Model: CERATHERM 600-3		Accessories:		
Serial number:				

Detailed description of failure or problem:

Anticipated work/repair:

Repair		
Warranty repair		
Delivery of replacement unit		
Other		Description:

Date: Signature:

Intended recipients	Users
Status	Valid

Date	07/01/2013
Doc. version	1.3
Software version	Version 1.0 or later
Authors	Varitronic AG/A.H., Nufer Medical AG/DU
File name	14.171.X_GA_Ceratherm_600_3_EN

NUFER MEDICAL AG

Morgenstrasse 148
CH-3018 Bern / Switzerland

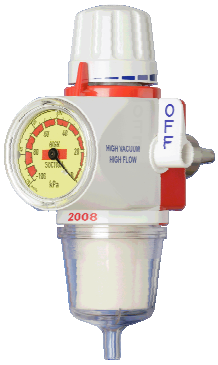
Tel. +41 (0)31 958 66 66
Fax +41 (0)31 951 46 73

info@nufer-medical.ch
www.nufer-medical.ch

CE 0123

Therapy Equipment Ltd
UNIT 1, CRANBOURNE AVENUE, CRANBOURNE INDUSTRIAL ESTATE
POTTERS BAR, HERTS, EN6 3JN TEL: 01707 652270 FAX: 01707 652622
Certificate Number MD 595894

DIAMOND RANGE SUCTION UNIT



High Diamond Suction Unit (Red Back)

Low Diamond Suction Unit (Orange Back)

Thoracic Diamond Suction Unit (Green Back)

INSPECTION

Remove the Diamond Suction Unit from the packaging and inspect for damage. If there is any damage, DO NOT USE, and contact Therapy Equipment Ltd.

FUNCTION/INTENDED USE

⚠ The Diamond Suction Unit should only be used by Hospital personnel authorised and trained in its use.

⚠ Read all instructions before using – DO NOT USE the Suction Unit if you do not understand the instructions given in these User Instructions.

The function of the Diamond Range Suction Unit is to provide a controllable Suction level from a Piped Vacuum supply.

There are three types available:

High Suction/High Flow	-	Vacuum 0 to –625mmHG
Low Suction/High Flow	-	Vacuum 0 to max –150mmHG (Relief Valve (full relief) set at –180mmHG)
Thoracic Suction	-	Vacuum 0 to max –60cmH2O (Relief Valve (full relief) set at –75cmH20)

The unit should be operated and stored in a dry clean environment within the temperature range of -10℃ to +40℃.

USER INSTRUCTIONS

1. Unpack the Controller from the packaging
2. Push the Controller Probe into the Yellow Vacuum Wall Outlet.
3. Push the ¼" Bore Plastic Suction Tubing over the coned end of Pipeline Protector Bowl at the bottom of the unit, ensuring that a good fit is achieved, and that the tubing cannot come loose. The Suction Tubing should be a maximum of 2 Metres between the Suction Controller and Receiver Jar.
4. Turn the unit on using by moving the On/Off Tap on the side of the unit 180° so that the ON is showing.
5. The level of vacuum required can then be adjusted by turning the Control Knob on the top of the unit. (Increase – clockwise; Decrease – anti-clockwise).
6. To pre-set the vacuum level before use, occlude the Suction Tubing between the Controller and the Receiver Jar. Turn the Control Knob until the required level of suction reads on the gauge at the front of the unit. The Suction Unit can now be switched off, and will apply the set vacuum level, the next time the unit is switched on.
7. The unit should be switched off by moving the On/Off Tap on the side of the unit back to the OFF position whenever not in use.

High/Low Suction controllers should not be used for continuous drainage.

The Pipeline Suction Unit should only be used by persons who have received adequate instructions in its use.

It is the responsibility of the end user to ensure that the correct unit and vacuum level is selected. Therapy Equipment accepts no responsibility for the selection of an incorrect unit or vacuum setting

DIAMOND PIPELINE PROTECTORS

The Pipeline Protector is a complete plastic bowl fitted to the bottom of the Diamond Range Suction Controller. The unit is supplied complete with a Hydrophobic Filter that automatically shuts down the Suction Controller when the filter comes into contact with fluid, thereby giving 100% protection against possible contamination of the Vacuum Pipeline. To assist end users in identifying Pipeline Protectors that have activated, the filter will turn pink.

The Pipeline Protector should be changed immediately if the filter turns pink or discoloured (the original colour is white). It is also recommended that the Pipeline Protector be changed routinely as follows:

High Usage Area i.e. Theatres, HDU etc.	-	Every 3 months
Low Usage Area i.e. Wards etc.	-	Annually

The Pipeline Protector is changed by turning the plastic bowl in an anti-clockwise direction until the bayonet mechanism releases. The entire plastic bowl complete with filter should be disposed of and replaced with new. The new Pipeline Protector should be fitted by lining up the 'lugs' on the Bowl with the mating sections of the underneath of the Suction Unit, and turning in a clockwise direction until the bowl is locked into place.

Spare Pipeline Protectors - Part No. 7900 (Pack of 10)

The function checks detailed under Preventative Maintenance should be carried out after any dismantling and reassembly of the unit, including Pipeline Protector changes.

CLEANING INSTRUCTIONS

Wipe over the outside of the unit and the gas supply hose with an alcohol or disinfecting wipe. If you suspect that the unit is contaminated, remove it from use and refer the device to the appropriate department.

TECHNICAL SPECIFICATION

The range of Pipeline Suction Equipment manufactured by Therapy Equipment Ltd fully conforms to ISO 10079-3:2009.

Inlet Connection	-	Direct British Standard Vacuum Probe		
Outlet Connection	-	6.4mm Male – Tapered		
Constitutional Materials	-	External Components	-	ABS
		Internal Metal Components	-	Stainless Steel
		On/Off Tap	-	Glass Filled Nylon
Flowrates	-	High Suction Unit – In Excess of 55LPM @ -80 kPa Low Suction Unit – In Excess of 20LPM @ -20 kPa Thoracic Suction Unit – In Excess of 20LPM @ -6 kPa		

WARNINGS

DO NOT autoclave, or immerse in liquid

DO NOT attempt to use if the collection canister is full, or if the Pipeline Protector is wet or discoloured

DO NOT use if the Suction Controller becomes internally contaminated.

ENSURE all connections are tight and leak free

TROUBLESHOOTING

PROBLEM	ANALYSIS	ACTION
Faulty Gauge	Suction Controller indicating wrong vacuum	• Return to the Hospital Department responsible for maintenance or Manufacturer
Relief Valve on Thoracic or Low Suction Malfunctions	Too high vacuum maybe applied to the patient	• Adjust the controller up to the full, and ensure that the relief valve is functional, before connecting to the patient.
Pipeline Protector malfunction or has been contaminated	Suction Controller will not function or if Pipeline Protector becomes contaminated will cease to function	• Ensure adequate safeguard against contamination of Controller • Ensure that the new Pipeline Protector is functional if contamination has occurred.
Breakage of On/Off Tap	If Tap is in Off Position the Controller will not function	• If Tap is in On Position the Controller can be turned off by means of the Control Knob • Visual Inspection to ensure that the Suction Controller is not damaged • If damaged return the unit to the Hospital Department responsible for maintenance or Manufacturer
Leaking On/Off Tap	When the unit is turned on the Suction will creep up to	• Preset the unit to -100mmHg, occlude the Pipeline Protector and

	maximum when occluded	ensure the suction maintains the correct level • If creeping return the unit to the Hospital Department responsible for maintenance or Manufacturer

RECEIVER JARS

A Suction Receiver Jar Assembly should always be used in conjunction with Suction Controllers. Whilst Therapy Equipment supplies its own Receiver Jar system, the Suction Controllers can be used with any manufacturer's Jar System, including Disposable Liner Systems. Standard Receiver Jars can be used with High and Low Suction Controllers, however more specialist Drainage systems are required for use with Thoracic Suction Controllers to maintain the very low levels of Suction being applied.

REPLACEMENT PARTS DETAILS

A Full range of spares are available (see Catalogue),

USE OF ANIMAL TISSUES/PHTHALATES

The standard Direct Diamond Suction unit has not been manufactured using any Animal Tissue or Phthalates. We should confirm however that Phthalates are used in the manufacture of the flexible High Pressure Hose, Suction Tubing and Disposable Liner (full details are available on request).

PREVENTATIVE MAINTENANCE/PRE-USE CHECKS

Whilst the Suction Controllers are supplied with a Lifetime Function Warranty (7 years), the unit should be included in an annual service inspection.

- The unit should be wiped with an Alcohol or Disinfecting Wipe to clean
- A check for leakage as follows:
  1. Turn Suction Controller on and adjust Control Knob to maximum
  2. Occlude Pipeline Protector/Filter Jar outlet and wait for full vacuum (in excess of –500mmHG) to register on gauge.
  3. Adjust Control Knob to minimum.
  4. The gauge should not drop showing the unit is leak tight (A drop over the complete scale on the Low Controller taking 15 seconds or more is acceptable)
- A check for function/flowrate as follows:
  1. Turn Suction Controller on and adjust vacuum to maximum
  2. Occlude Patient outlet on Receiver Jar and ensure that a vacuum of –400mmHG (High Suction) or –150mmHG (Low Suction) is registered within 4 seconds.
- The Pipeline Protector (Part No. 7900) should be regularly changed. The frequency of the change depends on hospital policy however we recommend every 3 months in a high usage area e.g. Theatre and annually in a low usage area e.g. Wards.

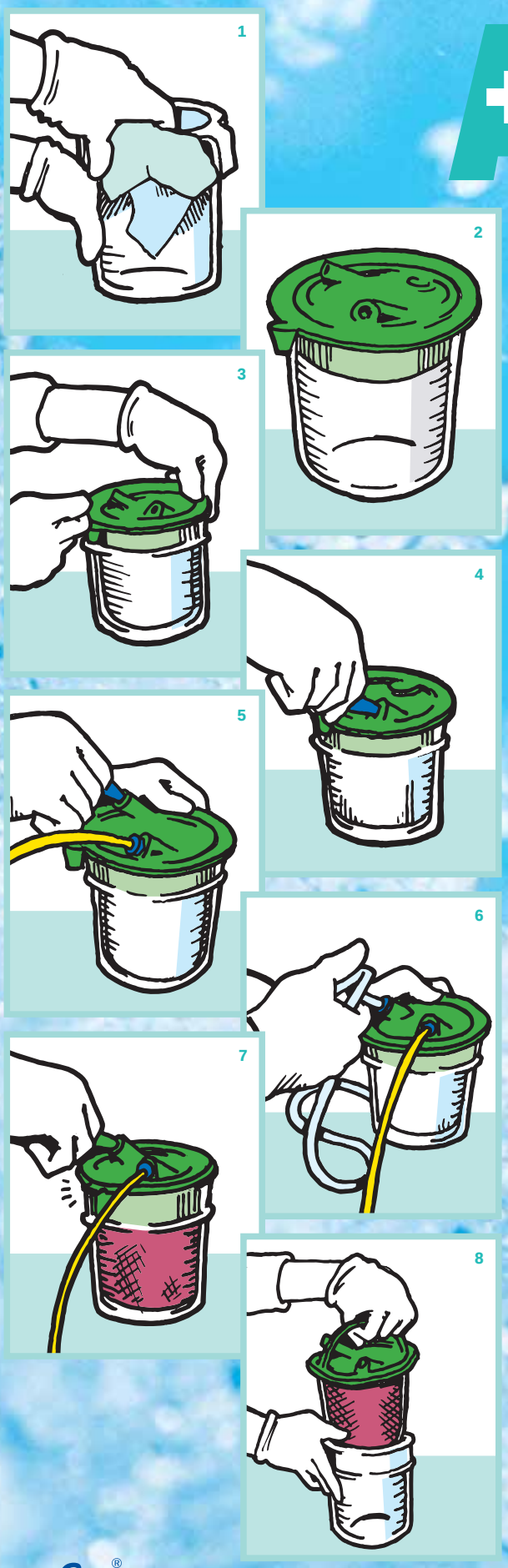
For Diamond Thoracic Suction Units only:

1. Turn the Thoracic Diamond Range Suction On/Off tap downwards so the ON is showing
2. Occlude the Pipeline Protector and turn the Control Knob clockwise to MAXIMUM and make sure the Vacuum level reaches in excess of -50cmH2O
3. While still occluded, turn the Control Knob to MINIMUM and make sure the Vacuum Gauge registers zero.

Regular strip down maintenance on the Suction Controller is not required.

CE 0086

Revision No.	0	1	2	3	4	5	6	7	8	9
Date	03/01/08	15/05/08	01/09/08	23/12/08	26/11/09	21/05/10	02/10/12	25/10/12	31/01/13	24/06/13
Issue	A	B	C	D	E	F	G	H	I	J



VacSax Advance

1 Litre Liners

VACSAX ADVANCE RANGE OF DISPOSABLE SUCTION LINERS
INSTRUCTIONS FOR USE FOR ADVANCE LINERS

Connection and use:
Read all instructions thoroughly before attempting to use this equipment, pay special attention to warnings and precautions - these are indicated thus ⚠

Before use check the product has not reached its use by date. This can be found printed on the liner and packaging label.

1. Ensure rigid canister is clean - wipe the inner rim surface with a damp cloth if necessary.
   Use the correct size canister for your liner!
2. Remove liner from carton.
3. Place liner into rigid canister and push firmly. Check patient port is facing forward for ease of connection.
4. Push the taper connector on the vacuum tubing from suction controller into the vacuum port with a twisting motion
5. Connect the patient tubing firmly to the patient port to ensure a good fit. Turn the Suction controller on to MAXIMUM and then set to desired level.

⚠ 6. **PRE-USE CHECK: Confirm that suction is present at the patient tube by manually occluding the patient tube end before proceeding.**

⚠ **If liner is set up prior to use and may not be used for some considerable time. Please ensure that the cap is kept in a clean condition in accordance with your hospital policy.**

AFTER USE:

ENSURE You wear gloves.

⚠ **IMPORTANT! Do not turn off vacuum source while disconnecting patient tubing. If system has been overfilled fluids may pass back down patient tubing!**

7. Remove patient tubing and fit stopper located on rim into port
8. Remove the vacuum connection and using the handles, lift the liner out of its canister

⚠ **Refer to disposal instructions**

These instructions should be used in conjunction with the instructions supplied with the product

Note: If a liner has been used it should be replaced within 24 hours to ensure maximum vacuum. Before use check the product has not reached its use by date. This can be found printed on the liner and packaging label.

ISO: 9001 REGISTERED
ISO: 13485 REGISTERED

Conforms to: 93/42EEC Medical devices directive

Single use

Important information

Latex Free

Packaging 100% Recycled 100% Recyclable

VacSax®
VacSax Limited, Western Wood Way,
Langage Science Park, Plymouth, PL7 5BG, UK.
T: +44 (0)1752 337000 F: +44 (0)1752 337600

www.vacsax.com

Operator's Manual

Digital Apgar Timer

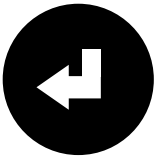
VIAMED

Description

The Viamed Apgar Timer is a battery powered digital timer with preset audible timing indications at 1, 5 and 10-minute intervals.

The timer has a large, clear LCD display and is operated using the keys on the front of the instrument.

The Function of the Keys

Key	Function
	• Starts counting from 00:00 • Returns to *Counting Mode* whilst in *Freeze Mode.*
	• Enters and exits *Freeze Mode*. Display 'freezes' whilst the actual elapsed time continues counting, but is not displayed. Exiting *Freeze Mode* returns to *Counting Mode*, resuming from the ongoing total elapsed time.
	• Resets counter, return to *Standby Mode.*

Standby Mode

The Apgar Timer does not have an ON/OFF switch. When not counting, the Apgar Timer enters *Standby Mode*.

In *Standby Mode* the display is blank with the exception of a flashing colon (:) to indicate that the timer is functioning correctly.

If the display is completely blank with no flashing colon, the timer may require battery replacement. Replace batteries on an annual basis.

Counting Mode

To enter *Counting Mode*, press the START button. 

When the Apgar Timer begins counting, the display counts upwards from 00:00 in 1-second intervals up to a maximum of 1 hour (59:59 on display), it will then enter *Standby Mode* automatically.

Whilst counting, the timer will indicate the Apgar scoring intervals with audible beeps:

1 minute:	1 beep
5 minutes:	2 beeps
10 minutes:	3 beeps

Freeze Mode

It is possible to freeze the display whilst the actual time continues to count in the background; this is to allow for recording the time from the start of the counting cycle of a particular event.

To enter *Freeze Mode*, press the FREEZE button. 

Whilst the display is frozen, the colon (:) continues to flash.

Freeze Mode can be exited and *Counting Mode* resumed by pressing the START or FREEZE button.

Upon unfreezing, the Apgar timer will continue counting, resuming from the ongoing total elapsed time.

Should an Apgar scoring interval be reached whilst the Apgar timer is in *Freeze Mode*, the timer will beep as it would in *Counting Mode* to indicate that interval, but will remain in *Freeze Mode* until exited by the user.

Reset Function

The *Reset Function* allows the timer to be reset and placed back into *Standby Mode*.

Press the RESET button to reset the timer. 

Specification

Dimensions (excluding bracket)	142 mm (W) x 130 mm (H) x 40 mm (D)
Weight	551g
Display	4 digit LCD display. Digit height: 25 mm.
Power requirements	4 x AA/LR6/MN1500 1.5 V Alkaline Batteries
Controls	Start, Freeze/Unfreeze, Reset
Audio indications	1, 5, 10 minutes

Battery Replacement

For optimal performance, batteries should be replaced on an annual basis.

If the Apgar timer is to be removed from service or stored, the batteries must be removed.

The LCD flashing between the messages "Lo" and "Batt" indicates a low battery condition, when this message appears, the batteries should be replaced at the earliest opportunity.

To replace the batteries, remove the mounting bracket from the rear of the timer using a 3/16th inch Allen Key, then using a narrow blade screwdriver release the battery cover. Remove the existing batteries and insert new ones (4 x AA/LR6/MN1500 1.5V Alkaline), observing the correct polarity.

Depleted batteries should be disposed of as per local regulations.

Routine Maintenance

It is recommended that the Apgar timer be checked at least annually to ensure correct performance.

Perform service checks as detailed on the Service Sheet overleaf. There are no user serviceable parts inside: if the device does not meet the specification please return it to Viamed for repair.

	Document Ref: Version:	1.1

Digital Apgar Timer Service Sheet

Hospital/Organisation:	
Location (department, room no.):	
Engineer (print):	
Service Date:	

Action	Further action required	OK
Serial Number:		
Batteries replaced Comments:	☐	☐
Check for overall signs of damage Comments:	☐	☐
Check START button enters *Counting Mode* Comments:	☐	☐
Check FREEZE button enters *Freeze Mode* Comments:	☐	☐
Check FREEZE button resumes *Counting Mode* Comments:	☐	☐
Re-enter Freeze Mode, check START button resumes *Counting Mode* Comments:	☐	☐
Check RESET button enters *Stand-by Mode* Comments:	☐	☐
Start a stopwatch whilst simultaneously pressing START		
Check single beep audible indication at 1 minute Comments:	☐	☐
Check two beeps audible indication at 5 minutes Comments	☐	☐
Check three beeps audible indication at 10 minutes Comments:	☐	☐
Check count is synchronized with the stopwatch at 10 minutes, ± 1 sec Comments:	☐	☐
Check mounting clamp and bracket are securely fastened Comments:	☐	☐
Clean unit as detailed in the Operator's Manual Comments:	☐	☐

Additional notes or comments:

Optional Accessories

Part Number	Description
0320200	Medirail Mounting Bracket
0121199	Swivel Mount
0121200	Universal Mounting Clamp

Cleaning and Decontamination

For routine cleaning, the Apgar timer can be cleaned with isopropyl alcohol, or with a mild detergent solution in accordance with the detergent manufacturer's recommendations.

For decontamination, clean in accordance with the guidelines in the MAC Manual "Part 2; Cleaning (manual) - non-immersion".

Warranty

Viamed warranty ensures that goods are free from defects of manufacture for a period of one year from the date of shipment from Viamed.

Liability shall be limited solely to the replacement and repair of the goods and shall not include shipping costs or other incidental costs.

The warranty does not cover damage caused by misuse, neglect, accidental damage, or by repairs other than those performed by Viamed or an authorized service centre.

CE

VIAMED

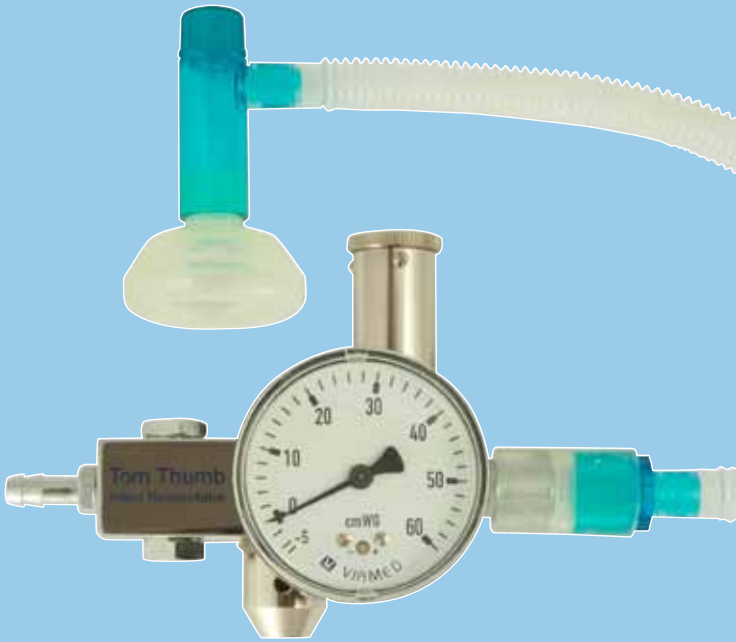
BS EN ISO 9001:2008
ISO 13485:2003

FS 28344 MD 78787

Viamed Limited · 15 Station Road · Cross Hills
Keighley · West Yorkshire · BD20 7DT · United Kingdom
Tel: +44 (0)1535 634 542 Fax: +44 (0)1535 635 582
Email: info@viamed.co.uk Website: www.viamed.co.uk

Tom Thumb
Infant T-Piece Resuscitator
Model: TT480 Series

Instructions for Use



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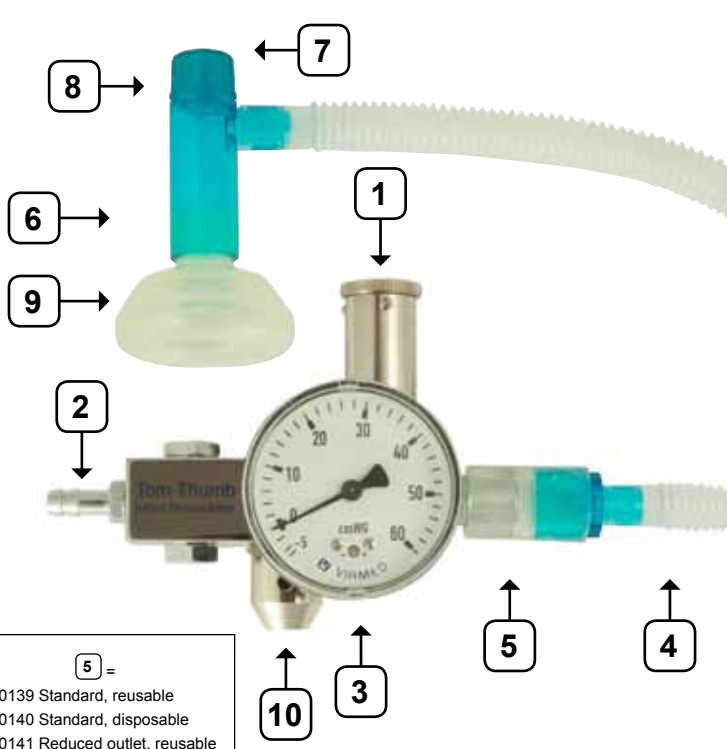
Pre-use Set Up

- Adjust the external flowmeter(s) to minimum and the adjustable pressure valve control [1] to minimum (fully counter clockwise).
- Connect the inlet [2] to the external flowmeter(s) of the oxygen or blended oxygen/air supply.
- Check that the pressure gauge [3] reads zero (inside the black band). If not, then the Tom Thumb requires servicing.
- Connect the NeoPEEP patient circuit [4] to the Tom Thumb outlet using the adapter [5].
  Do not apply to the patient at this stage.
- **Set the flowmeter to the required flow rate, up to the maximum of 15 l/min.**
- Occlude the patient opening of the 'T-Piece' [6] and the PEEP* valve outlet [7] to create an air tight seal.
- Turn the adjustable pressure valve control [1] until the required PIP* is set, as shown by the pressure gauge [3].
- Uncover the PEEP valve outlet [7]. Adjust the PEEP setting by adjusting the PEEP control cap [8] on the NeoPEEP patient circuit - until the reading on the pressure gauge [3] indicates that the correct PEEP has been achieved.
- Connect the 'T-piece' [6] to a suitable resuscitation mask [9] or to the patient's E.T. tube.
- The Tom Thumb is now ready for use.

* Note:
PIP = Peak Inspiratory Pressure
PEEP = Positive End Expiratory Pressure

- ⚠ For use by qualified trained personnel only.
- ⚠ Maximum gas inlet flowrate of 15 l/min.
- ⚠ Use flow rates within the range of the flowmeter.
- ⚠ Adjust outlet pressure after altering the flow rate.
- ⚠ Do not attempt to adjust the safety valve [10].
- ⚠ 1cm WG = 1cm H_2O = 0.981mb
- ⚠ Gauge ± 1.6% FSD



[5] =
0120139 Standard, reusable
0120140 Standard, disposable
0120141 Reduced outlet, reusable

The Tom Thumb Infant T-Piece resuscitator is easy to use, compact and robust infant resuscitator, has been designed to enable safe, controlled and fatigue-free resuscitation.

Guidelines for Use During Resuscitation

1. Follow the pre-use set up procedure and set the required flow rate and outlet pressures; as defined by the hospital's protocol for resuscitation. Ensure pressures are checked prior to adminstering gas to the patient.
2. Apply the mask to the patient and cover the 'T-Piece' PEEP valve outlet to inflate the patient's lungs at the set flow rate and pressure.
3. Uncover the 'T-Piece' PEEP valve outlet and allow the patient's lungs to deflate.
4. Repeat steps 2 & 3 as necessary during the resuscitation of the patient (follow the hospital's protocol for resuscitation).

Cleaning and Care

Clean using a clean cloth dampened with cleaning solution approved by the hospital. The Tom Thumb is not intended to be sterilized. Do not autoclave. Do not allow moisture or foreign matter to enter the safety valve [10] or the adjustable valve [1]. Damage will occur if the Tom Thumb is subjected to severe mechanical shock or if dropped.

Servicing

The Tom Thumb should be serviced every 12 months; or if the pressure gauge does not read zero (outside of the black band) with no flow, or if the unit's accuracy is in doubt.

Viamed recommends that the gas hoses should be checked every 3 months, and replaced every 4 years as a minimum.

Patient Circuit Parts

Single use Silicone Round Facemask

Part Number	Model Ref.	Size	Qty
3210073	200600D	0	Pack of 20
3210068	200550D	0.5	Pack of 20
3210074	200500D	1	Pack of 20

Single use NeoPEEP Neonatal Resuscitation Circuit

Part Number	Model Ref.	Length	Qty
3210013	800100/BLUE	1.0m	Pack of 20
3210014	800100/BLUE includes adapter 0120141	1.0m	Pack of 20
3210023	800150/BLUE	1.5m	Pack of 20

Reusable Circuit Adapters (single units)

Part Number	Model Ref.	Size	Usage
0120140	PF 1515	15mm I.D. - 15mm I.D.	Reusable
0120141	KC 2124	15mm I.D./22mm O.D. - 15mm I.D./22mm O.D.	Disposable
0120139	PF 1510	15mm I.D. - 10mm I.D.	Reusable

Warranty

Viamed warrants that the goods are free from defects of manufacture, for a period of one year from the date of shipment from Viamed.

Liability shall be limited solely to the replacement and repair of the goods and shall not include shipping costs or other incidental damages.

This warranty is null and void if any items are subjected to misuse, negligence, accident; or repairs - other than those performed by Viamed or an authorized service centre.

Storage & Operating Temperature -16°C - +60°C
No limits to atmospheric pressure.

The life time of the TT480 is greater than 10 years with regular servicing.

These instructions apply to the following Tom Thumb TT480 Series (without flowmeter).

Part Number	Description
0310030	With Medirail mounting
0310080	Reduced outlet and Medirail mounting
0310093	Rectangular mounting block
0310094	With pole mount

Disposal of Unit

The Tom Thumb infant resuscitator should be disposed of in accordance with local ordinances and regulations.

Alternatively, the Tom Thumb unit can be returned to Viamed, using the address below; if it accompanied by a decontamination certificate. You are responsible for the return packaging and carriage costs, but we will process the returned unit free of charge on your behalf.

Viamed Limited · 15 Station Road · Cross Hills
Keighley · West Yorkshire · BD20 7DT · United Kingdom
Tel: +44 (0)1535 634 542 Fax: +44 (0)1535 635 582
Email: info@viamed.co.uk Website: www.viamed.co.uk

Part Number: 0390006 Date: 09/15

AIR/OXYGEN BLENDER

INSTRUCTION MANUAL

CATALOG #2120
REV 060112

CE
0086

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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 7767 or ISO 21647) 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

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 7767 or ISO 21647) 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.

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

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.

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.

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.

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.

2. EXPLANATION OF SYMBOLS

MR Conditional

MR Unsafe

Caution: Consult accompanying documents

Refer to manual for proper method of operation

Warning: Condensed water in air supply can cause malfunction of this device

Warning: Do not obstruct alarm or bleed holes in the bottom of this device

Rx Only

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Date of Manufacture

Manufacturer

SN

Serial Number

REF Catalog Number

EC REP Authorized Representative in the European Community

CE 0086

The CE mark displayed on this product signifies that this device is in compliance with the European Medical Devices Directive (Council Directive 93/42/EEC). 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 (0086) 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.

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 : 1995.

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 3/4 lbs (1.25 kg).

No electronics incorporated.

Reverse Gas Flow: From either gas inlet to the other is zero (complies with clause 6 of ISO 11195).

4. INTRODUCTION AND OPERATION

The Bio-Med Air/Oxygen Blender is a precision proportioning device for mixing medical grade air and oxygen to any concentration from 21% to 100% oxygen and delivering it 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 only be cleaned by wiping the outside surfaces with alcohol 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**

APPENDIX A

Authorized Representative in the European Community:

Bio-Med Devices' Official Agent in Europe is:

Medical Market I.N.T. AB
Sehlstedtsgatan 6
115 28 Stockholm
Sweden

Telephone: +46-08-767 70 00
Fax: +46-08-731 90 09

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).