

INFANT RESUSCITATION CABINET

OPERATOR'S MANUAL





C€0086

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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



Attention: consult accompanying documents



Type B



Attention: hot surface



AC Power



Equipotential plug



Power ON



Power OFF

C€0123

Indicates this device in compliance with EU-Directive 93/42/EEC/Annex II.3. 0123 is the Notified Body Number. All radiators with this signification are with regard to the production supervised from TÜV Product Service.



Date of Manufacture

SPECIFICATIONS AND TECHNICAL DATA

Radiant Warmer

Power requirement: 220-240 V AC, 50/60 Hz, 630 W

Protection class: I

Degree of protection: B, IP20

Test provision: IEC 601-2 TUV / CE

Low Flow Air/Oxygen Blender (model IHC2003)

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.

Maximum Flow: ≥30 LPM (Low Flow blender) @ 60% setting & 50 psi (345 kPa) inlet pressures.

Pressure Drop: <6 psi (42 kPa) at 50 psi (345 kPa) inlet pressure and 10 LPM flow.

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

Alarm Intensity: 80 dB at 30 cm (1 ft)

Input fittings: Oxygen NIST, Air NIST

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

Dimensions: Height: 8.9 cm (3 1/2")

Width: 5.7 cm (2 1/4") Depth: 7.3 cm (2 7/8")

Weight: 1.25 Kg (2 3/4 lbs)

No electronics incorporated

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

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 product 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 600-2 radiant warmer
- Tom Thumb infant resuscitation unit
- Low suction controller
- Suction receiving jar
- Digital Appar timer
- Storage bins

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

All the components carry the correct and relevant CE marking.

WALL MOUNTED RADIANT WARMER



Radiant Warmer with Double-Hinged Arm

The radiant warmer is mounted on a double-hinged arm, allowing the unit to be folded flat to the wall when not in use.

Precautions

The radiant warmer must not be used in the immediate vicinity of explosive anaesthetic gases or mixtures.

The distance between the surface on which the patient lies, and the lower edge of the radiant warmer, must not be less than 80cm. If this instruction is not followed, prolonged exposure to the heat radiation may cause burns.

"Danger of burns": Contact with the protective guards, element and reflector should be

avoided.

"Danger of fire": The grille on the upper side of the radiant warmer must remain

unobstructed at all times.

Do not place any items on the grille.

Patients must not be left unattended whilst the radiant warmer is in use.

Do not operate the device if the casing has been removed or is damaged.

Servicing and maintenance should be restricted to qualified technical personnel.

Use of the radiant warmer should be restricted to trained medical personnel.

Use of a radiant warmer can increase fluid loss from a patient.

Handle the warmer with care; the ceramic heating element is fragile.

Do not touch the heating element at any time as this can adversely affect the performance of the element.

The heating element gets very hot when in use: take care if the warmer has recently been used or tested, and allow it to cool before storage. The side handles remain cool to touch.

Each Ceratherm 600-2 Infant Radiant Warmer is safety tested to Class 1, Type B and a test report is supplied. It is recommended that the equipment be retested for safety and function upon receipt, and at least annually thereafter.



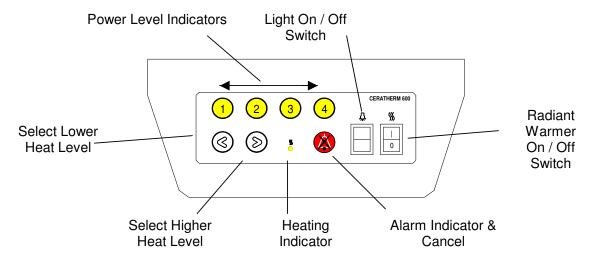
WARNING!

The radiant warmer gets hot whilst in use.

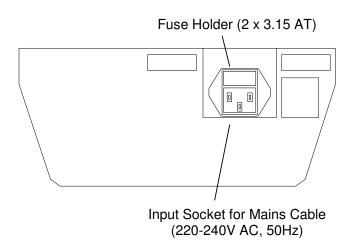
Do not obstruct the upper ventilation grille.

Use only the side handles, which remain cool, to reposition the unit.

Front



Rear



Adjusting the Heat Output

Switch radiant warmer On/Off switch to ON. This switch is the master power switch for the device; no electrical functions are active with this switch in the OFF position.

Using the forward and reverse buttons (< and >) set the desired heat output level. The current heat output setting is shown by an illuminated yellow indicator ①, ②, ③ or ④.

The heat output can be adjusted using the four heat output settings (1 - 4). The factory-set levels correspond to the following values, the values indicated correspond to a percentage of the maximum power output of the heating element:

Level 1	= 25%	1	2	3	
Level 2	= 50%	1	2	3	(A)
Level 3	= 75%	1	2	3	4
Level 4	= 99%	1	2	3	4

The various power levels can be used as follows:

Level ①: To keep the support surface warm for continuous operation.

Level ②: For normal operation on changing and examination areas.

Level ③: Additional warmth for resuscitation, the labour room or for the operating theatre.

Level @: For increased heat, in the operating theatre, during anaesthesia, or for adults.

Using the Halogen Lamp

The non-dazzling halogen lamp is used for illuminating the patient area.

To turn on the lamp, set the light On/Off switch to ON.

Note: the lamp can only be used when the radiant warmer On/Off switch is in the ON position.

If it is required, the halogen lamp can be used without the heating element, to do this adjust the heat output of the radiant warmer to zero. The heat output is set to zero when the reverse button (<) is repeatedly pressed until all yellow indicators (① -) are extinguished.

LED Heating Indicator

The Heating Indicator illuminates when the element is being heated, and is off when it is not. This 'duty-cycle' occurs over a period of a second, the percentage of time that the indicator is illuminated during that second represents the power level in terms of a percentage of the maximum output.

Alarm and Safety-Power Function

The radiant warmer incorporates a safety feature, which reduces the output power if the device is left unattended. An audible and visual alarm is triggered a period of 15 minutes after the last key-press; this is to inform the operator that the device is still active.

The safety alarm activates an audible alarm signal, which consists of a series of beeps over a 5 second period, and the red Alarm Indicator on the front panel begins to flash.

The alarm is cancelled by pressing the flashing Alarm Indicator, if this is done during the first 8 seconds after the onset of the alarm condition, the radiant warmer will continue to function at the current power setting, the Alarm Indicator stops flashing and the 15-minute timer begins again.

If, after 8 seconds from the onset of the alarm condition the alarm has not been cancelled, the heat output of the radiant warmer reduces to a pre-set value, which is 20% of the maximum power output of the device.

Note: when the radiant warmer enters the reduced safety-power setting, the yellow power level indicator remains illuminated at the previous power level; this is to inform the user of the power level that the device will return to when the alarm is cancelled.

When the alarm is cancelled, the radiant warmer reverts back to the previous power level, the Alarm Indicator stops flashing and the 15-minute timer begins again.



WARNING

The radiant warmer must not be left unattended whilst in use.

RESUSCITATION CABINET



Infant Resuscitation Cabinet in Standard Configuration

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

The drop down platform has an integral bed, on which the mattress is placed. Additional blanket 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 be no greater than 25 Kg.

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 catch 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 catch.

Securing the catch whilst forcing the door closed may cause damage to the catch: damage of this type is not covered by the warranty.

LOW SUCTION CONTROLLER

The Viamed Infant Resuscitation Cabinet is supplied with one of two low suction controllers, designed specifically for medical use: the Oxylitre S714 or the Therapy Equipment 4725-3M.



Therapy Equipment 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.

Patient Inlet Connection

The inlet connection forms an integral part of a detachable filter cartridge or Disposable Hydrophobic Filtration Unit. This filtration unit has been designed to prevent the ingress of fluids into the controller and the pipeline system.

Once the filter has been used for patient therapy, or if wetted for any reason, it must be replaced. If the filter membrane is wet, the chemical coating on it will prevent fluid passing through it and may restrict the flow of suction.

Vacuum Gauge

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

Model	Scale readings
Oxylitre S714	0 to 200 mmHg (0 to 25kpa)
Therapy Equipment 4725-3M	0 to 300 mmHg (0 to 40kpa)

Safety Valve

The suction controller is fitted with an internal safety valve system. This will protect the suction controller from being damaged if inadvertently connected to a positive pressure outlet.

Setting Suction Levels: Therapy Equipment

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 4725-3M 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 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

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 suction controller does not have a separate ON/OFF control: to turn the device 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 disposable suction receiving system as standard, or a reusable Therapy Equipment suction jar by request.



Vacsax 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.

Instructions for Use; Vacsax Advance System

Ensure rigid canister is clean: wipe inner rim with damp cloth if necessary. If the canister is contaminated it may be autoclaved at 121° C or cleaned with water-based disinfectants; see instructions later in this document.

Use the correct size canister for the liner.

Remove liner from carton.

Place liner into rigid canister and push down firmly. Ensure patient port is facing forwards for ease of connection.

Push the taper connector on the vacuum tubing from suction controller into the vacuum port with a twisting motion.

Connect the patient tubing firmly to the patient port to ensure a good fit.

Turn the low suction controller on and set to maximum, then set to the desired vacuum level.

Pre-use check: Confirm that suction is present at patient tube by manually occluding the patient tube end before proceeding.

After use: Ensure that you wear gloves when handling used liners.

Important: Do not turn off vacuum source whilst disconnecting the patient tubing, if the system has been overfilled fluids may pass back down the patient tubing.

- Remove patient tubing and fit the stopper located on the rim into the patient port.
- Disconnect the suction tubing from the vacuum port of the liner and switch off the vacuum at the suction controller.
- To remove the liner from the canister, use the handles on the side of the liner to lift the used liner carefully out of the canister.
- Dispose of liner in accordance with hospital policy.
- Dispose of vacuum tubing set if it becomes contaminated during use.

Note: the tapered vacuum port connector is 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.

Instructions for Use; Therapy Equipment System (Optional)

The Therapy Equipment suction jar is a reusable jar manufactured from polysulphone, it may be autoclaved at 121° C or cleaned with water-based disinfectants in accordance with the guidelines in the MAC Manual "Part 2; Cleaning (manual) - non-immersion"; see instructions later in this document. Additionally, it may be pre-washed using an automated disinfector operating at 90° C.

Connect the suction controller to the receiving jar using 10 mm diameter suction tubing, ensure that the tubing is connected firmly onto the connection marked 'vacuum'.

Connect the patient tubing to the receiving jar using 10 mm diameter suction tubing, ensure that the tubing is connected firmly onto the connection marked 'patient'.

Always use tubing that is a good fit over the connectors of the suction jar.

Always clean the jar thoroughly after use.

The jar cradle requires only external cleaning, which must be done in accordance with the guidelines in the MAC Manual "Part 2; Cleaning (manual) - non-immersion"; see instructions later in this document.

APGAR TIMER

Description

The digital Appar 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

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.

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.

Specifications

Dimensions (excluding bracket)	142 mm (W) x 130 mm (H) X 40 mm (D)
Weight	551 g
Display	4 digit LCD. Digit height: 25mm
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 in accompanying Service Sheet. There are no user serviceable parts inside: if unit does not meet the specification please return it to Viamed for repair.

Optional Accessories

Part	Description
Number	
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".

TOM THUMB INFANT RESUSCITATOR



Instructions for Use are attached to the Tom Thumb within the resuscitation cabinet. Please refer to these before using the Tom Thumb.

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 oxygen at controlled flow and pressure. A flowmeter is used to control the flow rate of oxygen, and the adjustable pressure relief valve is used to set the maximum pressure delivered.

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



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 10 Litres/min.

Pre-use Set-up TT490-15

The Tom Thumb is supplied with a laminated set of instructions that should be kept attached to the device for reference. Refer to these instruction cards, included later in this section, for an illustration of the device and the numbers detailed in the instructions below.

Adjust the flowmeter ${\tt ①}$ to minimum (fully clockwise) and the adjustable pressure valve control ${\tt ②}$ to minimum (fully counter clockwise).

Ensure that the flowmeter oxygen hose ③ is connected to the external oxygen supply.

Check that the pressure gauge @ reads zero. If not, the Tom Thumb requires servicing.

Connect the NeoPEEP patient circuit ⑤ to the Tom Thumb outlet using the connector ⑥ provided. Do not apply to the patient at this stage.

Set the flowmeter to the required flow rate, up to a maximum of 15 L/min.

Occlude the patient opening of the 'T-Piece' ② and the PEEP (Positive End Expiratory Pressure) valve outlet ® to create an airtight seal.

Turn the adjustable pressure valve control ② until the required PIP (Peak Inflation Pressure) is set, as shown by the pressure gauge ④.

Uncover the PEEP valve outlet ®. Adjust the PEEP setting by adjusting the PEEP control cap ® on the NeoPEEP patient circuit until the reading on the pressure gauge ④ indicates that the correct PEEP has been achieved.

Connect the 'T-Piece' To a suitable resuscitation mask on or to the patient's E.T. tube.

The Tom Thumb is now ready for use.

Pre-use Set-up TT480

Ensure that the Tom Thumb is connected via low-pressure tubing to a flowmeter, which is in turn connected to a supply of oxygen or mixed gas. If using an air/oxygen blender, refer to the relevant section in this manual to perform the necessary pre-use checks on the blender.

Follow the above pre-use set-up procedures as described for TT490-15.

Note: when setting the maximum pressure, the needle on the gauge of the Tom Thumb should be stable and oxygen will be heard hissing from the adjustable valve. If the needle is not stable and no hissing can be heard, it is likely that the mask is not entirely occluded; check the seal by repositioning the mask until a stable reading is achieved.



CAUTION

For use by qualified and trained personnel only.

Use flow rates within the range of the flowmeter.

Adjust outlet pressure after altering the flow rate, if the flow rate is subsequently altered, always re-set the pressure.

Do not attempt to adjust the safety valve.



WARNING

Flow rates, Peak Inflation Pressure (PIP), Positive End-Expiratory Pressure (PEEP) and oxygen concentrations for resuscitation are clinical decisions: if in any doubt consult your key trainer or a relevant qualified person.

The following pages contain the instruction cards for both variants of the Tom Thumb Infant Resuscitator.

A set of the appropriate instructions is provided with each instrument. Should additional copies be required, they can be created by copying and laminating the relevant instruction page or, alternatively, additional copies can be requested from Viamed.

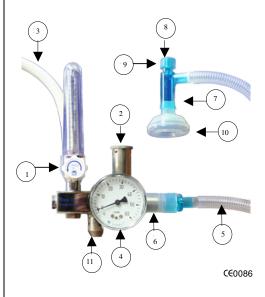
TT490-15 Instruction Card Template



PN 0390007 V3.1 01/09

Tom Thumb Infant Resuscitator Model: TT490-15

Instructions for Use



Pre-use Set Up

- Adjust the flowmeter ① to minimum (fully clockwise) and the adjustable pressure valve control ② to minimum (fully counter clockwise).
- Connect the flowmeter O₂ hose ③ to the external O₂ supply.
- Check that the pressure gauge @ reads zero. If not, the Tom Thumb requires servicing.
- Connect the NeoPEEP patient circuit [®] to the Tom Thumb outlet using the connector [®] provided. <u>Do not</u> apply to the patient at this stage.
- Set the flowmeter to the required flow rate, up to a maximum of 15 Lpm.
- Occlude the patient opening of the 'T-Piece' ② and the PEEP* valve outlet ® to create an air tight seal.
- Turn the adjustable pressure valve control ② until the required PIP* is set, as shown by the pressure gauge ④.
- Uncover the PEEP valve outlet ®. Adjust the PEEP setting by adjusting the PEEP control cap ® on the NeoPEEP patient circuit until the reading on the pressure gauge ® indicates that the correct PEEP has been achieved.
- Connect the 'T-Piece' ② to a suitable resuscitation mask ® 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

Guideline for Use during Resuscitation.

- 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 delivering to the patient.
- Apply the mask to the patient and cover the 'T-Piece' valve outlet to inflate the patients' lungs at the set flow rate and pressure.
- 3. Uncover the 'T-Piece' valve outlet and allow the patients lungs to deflate.
- 4. Repeat steps 2 & 3 as necessary during the resuscitation of the patient (follow the hospital's protocol for resuscitation).

Care, Cleaning, Location and Sterilisation.

Clean using a damp cloth. The Tom Thumb is not intended to be sterilised. Do not autoclave. Do not allow moisture or foreign matter to enter the safety valve or adjustable valve. Damage will occur if the Tom Thumb is subjected to severe mechanical shock or dropped.

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

The Oxygen Hoses should be checked every 3 months, and replaced ever 4 years as a minimum.

The rail bracket supplied with the Tom Thumb is designed to fit most medical rails.



Important.

For use by qualified and trained personnel only. 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 (11). Recommended O_2 inlet pressure of 4 bar.

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 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 authorised service centre.

Viamed Ltd.

15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT, United Kingdom Tel: +44 (0)1535 634542 Fax: +44 (0)1535 635582

info@viamed.co.uk www.viamed-online.com

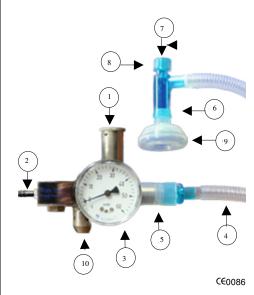
TT480 Instruction Card Template



PN 0390006 V3.1 01/09

Tom Thumb Infant Resuscitator Model: TT480

Instructions for Use



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. If not, the Tom Thumb requires servicing.
- Connect the NeoPEEP patient circuit [®] to the Tom Thumb outlet using the connector [®] provided. <u>Do not</u> apply to the patient at this stage.
- Set the flowmeter to the required flow rate, up to the maximum of 15 Lpm.
- Occlude the patient opening of the 'T-Piece' (and the PEEP* valve outlet (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 ①. Adjust the PEEP setting by adjusting the PEEP control cap ® 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' ® to a suitable resuscitation mask ® 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

Guidelines for Use During Resuscitation.

- 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 delivering to the patient.
- Apply the mask to the patient and cover the 'T-Piece' valve outlet to inflate the patient's lungs at the set flow rate and pressure.
- Uncover the 'T-Piece' valve outlet and allow the patient's lungs to deflate.
- Repeat steps 2 & 3 as necessary during the resuscitation of the patient (follow the hospital's protocol for resuscitation).

Care, Cleaning, Location and Sterilisation.

Clean using a damp cloth. The Tom Thumb is not intended to be sterilised. Do not autoclave. Do not allow moisture or foreign matter to enter the safety valve or adjustable valve. Damage will occur if the Tom Thumb is subjected to severe mechanical shock or dropped.

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

The Oxygen Hoses should be checked every 3 months, and replaced every 4 years as a minimum.

The rail bracket supplied with the Tom Thumb is designed to fit most medical rails.



Important.

For use by qualified and trained personnel only. 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 @. Recommended O_2 inlet pressure of 4 bar.

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 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 authorised service centre.

Viamed Ltd.

15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT, United Kingdom Tel: +44 (0)1535 634542 Fax: +44 (0)1535 635582 info@viamed.co.uk www.viamed-online.com

LOW FLOW AIR/OXYGEN BLENDER

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



CAUTION

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

Viamed supply the Bio-Med Devices model 2003 low flow air/oxygen blender as an option, which can be mounted inside the resuscitation cabinet.

Note: for cabinets supplied prior to 2009 the medirail sections may need to be replaced with longer lengths: contact Viamed for further details.



Bio-Med Devices model 2003 Low Flow 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.

The gas inlet fittings are located on the bottom of the blender and are designed such that the air and oxygen connections cannot be reversed.

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.

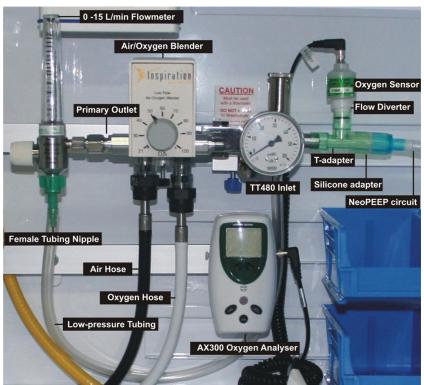
The blender alarm/bypass function will provide the full 30 L/min upon the loss of air or oxygen if the remaining gas is at 50 psi (345 kPa).



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

Equipment Layout and Interconnections

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



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.

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 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 and use a calibrated oxygen analyser 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 need to be replaced 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 (equilibration time) 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.

SERVICING

Service contracts are available; please contact Viamed for further information.

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

For versions of the Tom Thumb that have an integral flowmeter and hose, the manufacturer 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 5 years, regardless of the condition of the hose.

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.

Parts	
Part no.	Description
0310002	Complete resuscitation cabinet including all parts
0310025	Wall mounted radiant warmer
0330120	Element for radiant warmer – 600W ceramic
0330125	Halogen lamp for radiant warmer, 20W
0330105	Cabinet body with shelf and medirail
0330009	Resuscitation cabinet door catch
0320020	Resuscitation bed, 35cm (14") wide
0320043	Mattress, 35cm (14") wide
0310035	Low suction controller (Oxylitre S714)
0330040	Suction hose assembly, 3m (Oxylitre)
0310037	Low suction controller (Therapy Equipment 4725-3M)
0330033	Suction hose assembly, 3m (Therapy Equipment)
3833-132	VacSax reusable suction canister
3833-007	VacSax tapered suction connectors (pack/10)
9910-340	VacSax disposable liners (box/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, 3m
0310200	Low-flow air/oxygen blender including flowmeter, hoses and mounting bracket
0310201	Low-flow air/oxygen blender
0320210	Flowmeter, 0 – 15 L/min
0320214	Rail mount bracket for air/oxygen blender
0320216	NIST hose with MKIV oxygen probe, 3m
0320217	NIST hose with MKIV air probe, 3m

Consumab	es
Part no.	Description
0310104	Filter for Oxylitre low suction controller, single unit
0310105	Filters for Oxylitre low suction controller, box of 30
0310109	Filter for Therapy Equipment low suction controller, single unit
0310110	Filters for Therapy Equipment low suction controller, box of 10
0330035	Suction clear tubing, 1m
3210011	NeoPEEP circuit with variable PEEP, single patient use (without mask)
3210070	Single use silicone face mask, size 00
3210071	Single use silicone face mask, size 01
3210072	Single use silicone face mask, size 02
0120140	Silicone adapter for connecting NeoPEEP circuit to Tom Thumb
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
0332000	Annual service kit for model 2003 blender
0332001	Overhaul kit for model 2003 blender – includes annual service kit
	nd Service Manuals
Part no.	Description
0391045	Resuscitation cabinet operator's manual
0391050	Resuscitation cabinet installation manual
0390007	Tom Thumb TT490-15 operating instruction card
0390006	Tom Thumb TT480 operating instruction card
0390022	TT480 service manual
0390023	TT490-15 service manual
0390021	Tom Thumb valves service manual (common to all Tom Thumb variants)
2122	BioMed Devices Air Oxygen blender operator's manual

		Document ref: Version:	03910 1.1	55	
		version.	1.1		
Viamed Infant	Resuscitation Cabinet	Service Sheet			
Hospital / Organisation:					
Location (department, room number):					
Engineer (print):					
Service Date:					
Action		Further act	ion rec	uired	OK
				.	
Cabinet Body – Serial number:					
Check for overall signs of damage Comments:					
Check door catch – swivel catch on door Comments:					
Check door catch – retaining clasp on cal Comments:	pinet				
Check integrity of welds on the door hinge Comments:)S				
Check hinges for damage or deformation Comments:					
Check the restraining bars for damage or Comments:	deformation				
Check the cabinet is securely fixed to wal Comments:	I				
Check medirails and tighten any loose rai Comments:	ls				
Check grommets on the hose inlets are ir Comments:	place and intact				
Check the bumper stops that prevent doo Comments:	r banging during closing				
Check 'caution' sticker is in place on the place Comments:	olatform				
Check bed for damage i.e. cracks, chips Comments:					
Check all the bed mounting screws are in Comments:	place				
Check mattress for damage i.e. tears, spl Comments:	it seams				
Tom Thumb – Serial Number:					
Follow service procedure as detailed in the Comments:	e Tom Thumb service manua	I			
Check oxygen hose, if present, for wear,	and replace if necessary (at le	east every 4 years)			
Hose replaced? Yes □ No □ Date of last hose replacement: Comments:					

Action Further action required		uired	OK
Low Suction Controller – Serial number:			
Low Suction Controller — Senai number.			
Follow service procedure as detailed in suction controller operator's or Comments:	service manual		
Change filter assembly Comments:			
Check vacuum hose for wear, and replace if necessary (at least every	4 years)	П	П
Hose replaced? Yes □ No □ Date of last hose replacement: Comments:		_	
Check rail clamp is securely attached to suction controller Comments:			
Replace suction tubing Comments:			
Replace tapered connector 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 regulations.	t your organisation's		
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:			
General			
Check storage bins present			
Comments: Tidy any trailing hoses, using tie-wraps if necessary			
Comments: Check Operator's Manuals are in place			
Comments:			
Clean cabinet with isopropyl alcohol Comments:			
Additional notes or comments:			

		Version:	1.0
Digital	Apgar Timer Service Sheet		
Hospital / Organisation:			
Location (department, room no.):			
Engineer (print):			
Service Date:			
Action	Further action rec	quired	OK
Serial number:			
Batteries replaced Comments:			
Check for overall signs of damage Comments:			
Check START button enters Counting Mo	ode		
Check FREEZE button enters Freeze Mo Comments:	de		
Check FREEZE button resumes Counting	g Mode		
Re-enter <i>Freeze Mode</i> , check START but Comments:	tton resumes Counting Mode		
Check RESET button enters Stand-by Mo	ode		
Start a stopwatch whilst simultaneously p	ressing START		
Check single beep audible indication at 1 Comments:	minute		
Check two beeps audible indication at 5 minutes Comments:			
Check three beeps audible indication at 10 minutes Comments:			
Check count is synchronized with the stop Comments:	owatch at 10 minutes, +/- 1 sec		
Check mounting clamp and bracket are so Comments:	ecurely fastened		
Clean unit as detailed in the Operator's M	anual		

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.

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 locking nuts 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 reattaching 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 nonimmersion 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
- Therapy Equipment reusable suction receiving jar

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

All parts of the Viamed wall mounted infant resuscitation cabinet system are guaranteed for a period of 12 months from the date of purchase.

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 material 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 9001/2000 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