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27 November 2003

Dear Mr Hardaker,

Tom Thumb Resuscitator

My deep apologies for not replying earlier to your letter of Sept 30th. I can only offer two excuses - the first is that I have been away from home for much of the last five weeks, and the second is that I have a sufficiently strong belief in the still-untapped potential of this small and efficient piece of equipment to want to discuss this response with several colleagues before responding to you. You asked me primarily to comment on the draft instruction booklet so I will do that first. In your e-mail of the same date you also asked me to comment on the potential for a short training video or CD-ROM so I will mention this briefly too.

I hope you will not be taken aback by the large number of comments I have made, and that you will find the suggestions I have made constructive. They are based on much experience with a product that is almost identical to the one you currently have on the market, because early in-house prototypes of this device came into use in one of the two maternity units here in Newcastle almost twenty years ago now, and similar devices were soon being introduced into other local units.

TRAINING MANUAL

Introduction

Page 2, lines 3-5. I can understand why your company have included the phrase "exact values for pressure/flowrate of gas etc set on the Tom Thumb Resuscitation unit and cycles per minute etc used during resuscitation should be set down in a separate hospital protocol" since these are issues over which different clinicians may well have different views. However it greatly weakens the value of the whole leaflet if you do not offer any guidance at all on these issues. The UK Resuscitation Council has long issued guidance on such issues - guidance which is generally very similar to that provided by similar authorities in other countries, and I think it would be helpful to include this. You do not, as a company, have to say that you endorse these recommendations. It would be quite sufficient to say that is what the recommendations are (see comment below). An appendix might suffice.. I would go even further than this myself, because the main nationally-recognised neonatal course that the UK Resuscitation Council now runs - the Neonatal Life Support (NLS) course - quite specifically endorses the use of equipment of the type your company has on offer as having advantages over the "bag-and-mask" style of resuscitation that was previously the standard approach used round the world.

The merit of bagless mask resuscitation has already been widely recognised in Australia and New Zealand, where you will know that a New Zealand company already have a product similar to yours on the market. This is the NeoPuff, a product that works like yours, but which comes encased in a bulky plastic box, and which can not, in consequence, be rail mounted. Recent research in Melbourne has convinced many that accurate control of the pressure used to achieve initial aeration of the lung (easily achieved with the NeoPuff, but very difficult to achieve using bag-generated pressure) can do much to reduce the cascade of lung damage that many preterm babies currently suffer in the first few days of life. A large NIH funded trial using this equipment is about to open in the US, so there is every likelihood that, if this is successful, a similar approach will start to be used in the USA before long.

Care, cleaning, location and sterilisation

Page 2, lines 6-13. I don't think the average user is going to find this section very helpful as currently worded. You say "The Tom Thumb is not intended to be sterilised". Might it not be clearer to say that "it does not normally need to be sterilised"? There may, however, be situations where a unit may want to ensure all their equipment is safe after some serious epidemic of cross infection. While it is important to stress that the equipment is not autoclavable I rather suspect that it can, if necessary, be gas sterilised. If it can, it would be helpful to say so. The text also says nothing at present about the device's flexible tubing and face mask These items should, logically, be cleaned, resterilised, or replaced after use by hospital staff in the same way as other anaesthetic and resuscitation equipment. Some units may treat these things as disposable items, although repeated use only carries a very small risk as long as these items are always cleaned after use and then left dry.

The manual says "Do not allow moisture or foreign matter to enter the safety valve or adjustable valve" but it does not say what staff should do if they fear that it has. In fact the safety valve is deliberately positioned on the underside of the device to minimise this possibility. The manual goes on to say "Damage will occur if the Tom Thumb is subjected to severe mechanical shock or dropped" but, here again, it offers no advice as to what staff should do if the equipment is dropped - as it will inevitably be from time to time. In addition the phraseology "damage *will* occur"makes it sound as though the equipment is very fragile when I know for a fact that it is not.

I would have thought the logical approach would be to say that the device should be sent for servicing if it becomes wet or is dropped (which is what you, sensibly, say should be done at least once a year anyway). There is, however, nothing in text to say how the equipment should be serviced. Maybe this is outlined in a separate document. If it is, the existence of this document should be referred to. If it does not, then the current document should be extended to offer such advice. Any hospital capable of servicing its own anaesthetic equipment would have all the in-house skills needed to service the Tom Thumb, and it would enhance - rather than detract from - the sales potential of the device to say so.

Presumably the only routine servicing necessary is a check to ensure [1] that the safety valve does indeed vent the excess pressure when the set pressure is exceeded (a level not specified anywhere in the document), [2] that the pressure dial reads zero when the pressure is zero, and [3] that it does read 40 cm H_20 when the pressure is that high.

This section ends with a statement "The rail bracket (7) is designed to fit most medical [equipment] rails". I think the correct number here is 8 rather than 7 - although the clamp would be easier to see if readers were offered an end view as well as a side view of the device. If you are going to number this part, would it not also be appropriate to number the adjustable valve(3), the safety valve (9) and the dial (5) in this section of the Training leaflet (and explain that the numbers relate to the illustration on the next page) ? Finally I was left unclear as to whether a single universal claw makes it possible to clamp the device to most currently available forms of equipment rail, or whether a different claw would be needed depending on the type of rail in use. It may be that this matters little if you are only planning to sell the device in the UK. If you are interested in the option of a wider market, it may be appropriate to make it clear that different claws can easily be attached to match local need if required.

The final sentence of this section will be completely opaque to most users of the manual. I eventually realised that it referred to the option of having the dial placed on the end, rather than the side, of the main block. Since the existence of such a 'special' is not mentioned anywhere else in the text this will

leave most readers confused and perplexed. Might it not be better to have a brief final section saying that other optional configurations are possible (and illustrate at least one of these), and then reposition this final sentence here, rather than right at the beginning of the document ? However, I still remain unclear as to why you advise against mounting the device close to a wall or to the side of an incubator. I can only assume you are concerned about the risk of damage while the device is being placed on or taken off the rail. This whole section would be clearer if the reason for this advice was explained.

TT480

Illustration on page 3. It would be helpful to have the key to the illustration printed on the same page as the illustration itself. Two different elements of the device seem to have been labeled six, while there is no element numbered seven. The element numbered eight goes unexplained.

Text on page 3. I would have thought it would have been helpful to have specified in the text the pressure at which staff can expect the safety valve to operate. If it is possible, as a customised 'special', to have this set at a non-standard pressure on request, it would be helpful to have the pressure at which the safety valve is supposed to vent stamped on the side or bottom of the valve. Finally, instead of saying "Use flow rates of gas up to 15 litres/minute" it might have been clearer to say "Do not use gas flow rates of more than 15 litres per minute."

Pre-use checks (TT480)

Text on page 4.

Bullet point two. I found the instruction "adjust the external 0-15 litres/min flowmeter to minimum" a little confusing. Would it not be clearer to say "Make sure the flow is turned off"? The same bullet point goes on to say turn "the adjustable valve control (2) to minimum (fully counterclockwise)," but the illustration suggests that the control valve should be turned *clockwise* to make the device to vent at minimum pressure. Even more confusingly, in the illustration on the preceding page, the adjustable valve control is labeled (3), not (2).

Bullet point three. I would have thought it was clearer to have bullet point three before bullet point two and to have this read "Connect the inlet (4) of the Tom Thumb to a flowmeter designed to give a regulated gas flow of between 0 and 15 litres per minute.

Bullet point seven. The illustration suggests that the valve control should be turned *counter*clockwise to raise the device's outlet pressure, but the text says the opposite of this. I suspect the illustration is in error. Staff will soon learn by trial and error which way to turn the adjustable valve control, but I wonder if it would be helpful to have the top of the valve marked with an arrow (like the control knob on the flow meter in the illustration on page 6) to show the direction required in order to obtain increased pressure. The dial is labeled "cm WG". I wonder if it would help to say at least somewhere (possibly earlier) in the text that WG means water gauge - or pressure in centimeters of water.

Text on page 5.

The text refers to the fact that the T piece can be used with a fixed PEEP facility. It can also, more usefully, be used with a variable PEEP facility. If you want to maximise sales I think you should find a way of supplying both these products to those purchasing the Tom Thumb, or at least let people know where such products can be purchased. They are increasingly seen as important in the management of resuscitation in the preterm baby - and such babies are not nearly as forgiving of poor resuscitation at birth as babies born at term.

Pre-use checks (TT490 & TT490-15)
Text on page 6.
The illustration is clear, but it might help to have a key to the numbered parts printed on the same page as the illustration. There does not seem to be any explanation in the text as to what the difference between a TT490 and TT490-15 is. It might be helpful, if the training manual is to be used for sales purposes, to have a smaller lateral view of the same device showing how the device clamps onto any standard equipment rail.

Text on page 7.
There is confusion once more as to whether the adjustable valve control should be turned clockwise or counterclockwise to make the device delivers gas to the child at minimum pressure.

Text on page 8.
The same comments apply as for page 5.

Frequently asked questions
Text on page 9.
The text talks of a "standard" size T piece. While this statement suffices for sales within the UK (and also, probably, in Europe), I think it would be helpful to say that the T Piece has Standard International 15mm anaesthetic cone-connector fittings. This information is important if staff wish to employ the device with masks or PEEP devices purchasable from other companies. Personally, while I believe that the present standard Tom Thumb device is probably quite the best infant resuscitation device currently on the market, I would always want staff to have routine access to at least two different sized reusable face masks, and access (at least in the maternity unit) to a variable PEEP device. On the other hand I would personally ban the use of the cap that comes with the standard T piece connector (either by cutting it off prior to issue, or by using some other standard connector) ! Trying to give free-flowing oxygen to a spontaneously breathing child by leaving them near (or strapped to) a face mask is never an economical or reliable way of administering supplemental oxygen. Even small changes in position will alter the amount of oxygen the child receives in a unpredictable way. It is much more effective to deliver oxygen into a covered bassinet or from a simple nasal cannula.

UK RESUSCITATION COUNCIL RECOMMENDATIONS
I would not presume to state exactly what these are without first checking my facts with the Chair of the group responsible for the NLS course (Dr Sam Richmond, of Sunderland). In essence however it will be that, when a baby is being resuscitated for the first time at birth, the first task is to get air to enter the previously fluid-filled lung. To achieve this, the first 3-5 mask inflations should use a pressure of 30 cm H_2O and each inflation should last 2-3 seconds. Once air has entered the lung and the chest starts to move (a transition that is nearly always marked by a rise in the heart rate to something in excess of 100 bpm) most babies will start to breathe for themselves and further resuscitation is not usually needed. If further breathing support does seem appropriate, it is usually only necessary to use a pressure of 20 cm H_2O, and to apply this pressure for about one second 20-30 times a minute.

In the very preterm baby surfactant deficiency may make the lung harder to expand at birth. Excessive or abruptly applied pressure could, however, also damage the lung because these tissues still lack much of their normal elastic support. It could also cause expansion to become very uneven. For this reason resuscitation needs to be gentle and should not be rushed. Using an unnecessarily high gas flow can cause a very abrupt, and potentially damaging, rise is pressure. A relatively low gas flow should suffice if there is a reasonably good air seal between the face mask and the face.

In addition, it even more important to reduce the pressure used to support breathing in the preterm baby than it is in the term baby once the lung *has* opened up. Conversely, however, much more care may need to be taken to ensure that some air stays in the lung at the end of each breath. Blood will return to the left side of the heart without picking up any oxygen if this does not happen, and what surfactant there is will be used up even more quickly than usual. The best way to make sure that this does not occur is to keep the pressure applied from falling below 5 cm H_2O at the end of each breathe by attaching a variable (or fixed) Positive End Expiratory Pressure (PEEP) device to the T-piece port. A pulse oximeter may help to document the heart rate and also show how much oxygen is necessary. The early use of Constant Positive Airway Pressure (CPAP) using nasal prongs may help to prevent progressive de-aeration of the lung in babies who continue to require significant amounts of oxygen twenty minutes after birth.

Babies who stop breathing long enough to require resuscitation later in the neonatal period do not usually need to be resuscitated with a pressure as high as 30 cm H_2O if their lungs are relatively normal. Indeed, sustained ventilation with a pressure as high as this will eventually wash enough carbon dioxide out of the body to remove the body's main stimulus to breathing. While the resultant apnoea is not dangerous, it can cause diagnostic confusion. In the preterm baby there is even more reason to avoid an unnecessarily high pressure, because this risks causing traumatic interstitial lung emphysema and/or a pneumothorax. Excessive ventilation will also eventually wash enough carbon dioxide out of the blood to cause cerebral vasoconstriction, a response that could, if sustained, cause lasting brain damage.

It should not be difficult to get the Resuscitation Council to approve general guidance along these lines at some stage, and I feel quite strongly that it would make your proposed Training Manual much more useful if it could include an appendix at the end summarising this advice at least briefly.

TRAINING VIDEO

You mentioned in one e-mail to me that you might like to get a training video made. The Tom Thumb is so easy to use that I am not convinced that this is necessary, but a video would certainly prove useful if it incorporated some of the other advice from the UK Resuscitation Council course. I have a training video made twelve years ago by Newcastle Universities Audiovisual unit that I could bring over to show you at Keighley sometime if you so wish. It has been rendered out of date by recent developments, used an old Isolette resuscitation with a water column to limit (and display) pressure, and is longer than you would need, but does contain all the key teaching messages. A viewing might, at the very least, help you to decide what you did and did not want to see in any customised video about the Tom Thumb. I have no doubt we could manage to get something along these lines remade were it considered appropriate.

What is, of course, completely missing from your training manual is anything about the importance of positioning the head and jaw correctly if mask resuscitation is to be effective. At one level this is not your responsibility of course, and it would be presumptious for you to offer such advice in your own name. The acquisition of this skill is, however, central to effective resuscitation, and it is a belated a recognition of this that is driving clinicians to show greater interest in gentler and less invasive forms of neonatal resuscitation. If you do want to consider the production of an associated video I think this is an issue any video would certainly need to address.

More glaringly your manual as currently drafted says nothing about the fact that the Tom Thumb can be just as appropriately used with an endotracheal tube as with a face mask. In effect you are merely

exchanging a tolerably effective air seal round the face for a similar seal round the vocal cords, and bypassing any need to ensure that the jaw and tongue do not fall back and obstruct the free flow of air from the trachea to the mouth and nose. Because your T-piece port is designed for use with any standard 15 mm anaesthetic connector, it only takes a moment to replace the mask that comes with the device for an endotracheal tube. I am amazed there is no mention of this in the training manual This flexibility should certainly form an element of any training video.

Most of your sales to date have presumably been in the UK. However, there is no doubt that devices like yours are going to become much more widely used in the next few years as clinicians come to realise that pressure device controlled mask resuscitation has several important advantages over bag-and-mask resuscitation in any setting with access to a reliable supply of air or oxygen under pressure. That realisation is going to bring with it the potential to generate significant sales not only in places like North America (where the NeoPuff is already developing a toe hold) but also in many second and third world countries as well (as long as after-sales support can be guaranteed). If you would like me to come down to Keighley some time early next year to discuss some of these possibilities I would be pleased to do so. The scope for a training video takes on extra significance with this possible marketing option in mind

Yours sincerely,

Edmund Hey

cc Dr Sam Richmond,
Consultant Neonatologist,
Sunderland Royal Hospital,
Kayll Road,
Sunderland, SR4.

TOM THUMB RESUSCITATION UNIT (TT400 SERIES).

TRAINING INFORMATION.

CE

INDEX.

1. Introduction.

This training material is intended to be used only to train personnel in how the Tom Thumb Resuscition Unit functions and its intended use.

Exact values for pressure / flowrate of gas etc set on the Tom Thumb Resuscitation Unit and cycles per minute etc used during resuscitation should be laid down in a separate hospital protocol.

2. 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 on the gauge) with no flow or if accuracy is doubted.

The rail bracket ⑦ is designed to fit most medical rails. It is advised that the Tom Thumb is not mounted close to a wall or to the side of an incubator particularly if the gauge is fitted to the end of the body (specials only). Spacers are available if required.

3. 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 void if any items are subjected to misuse, negligence, accident, or repairs other than those performed by Viamed or an authorised service centre.

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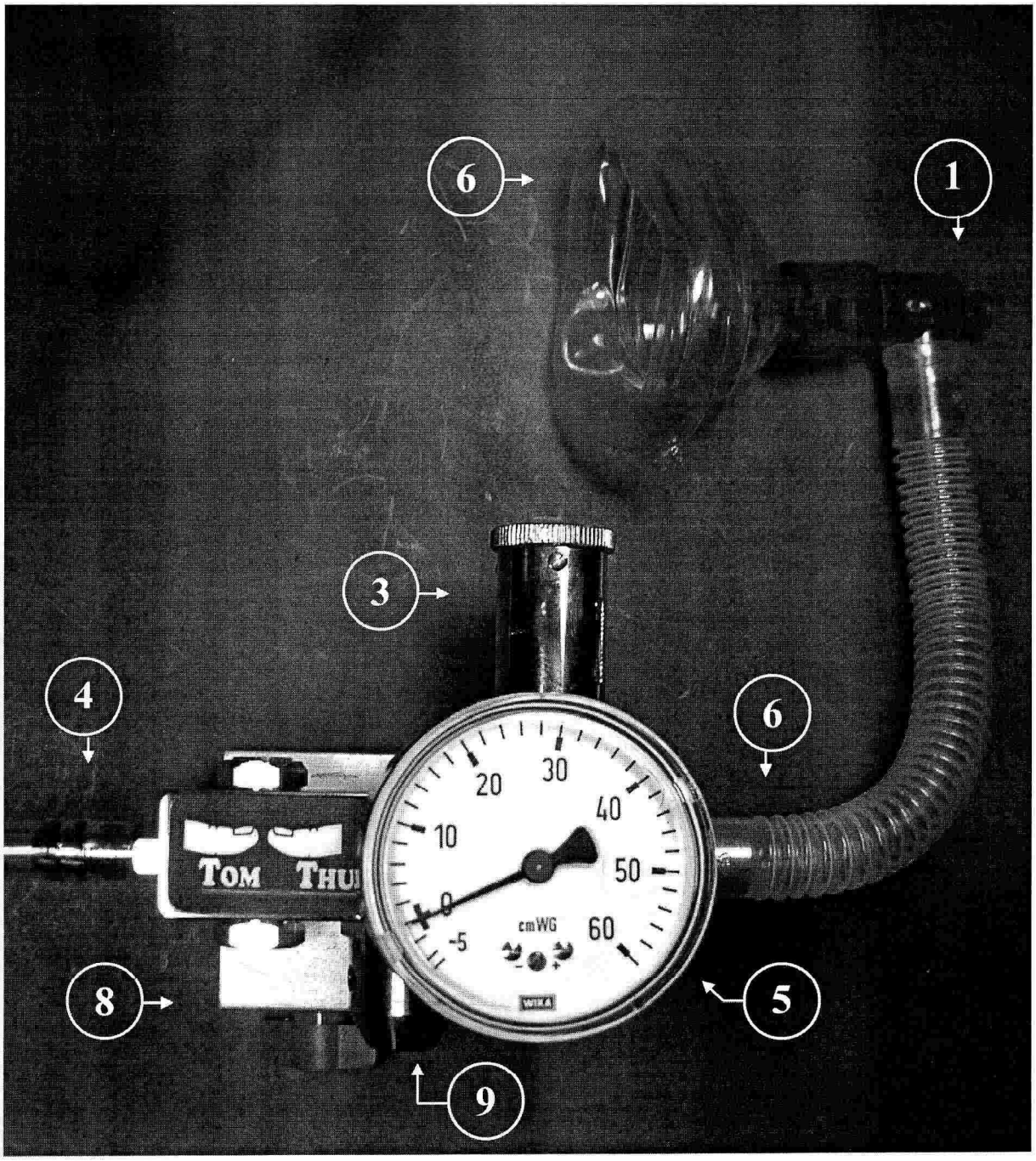
4. TT480.

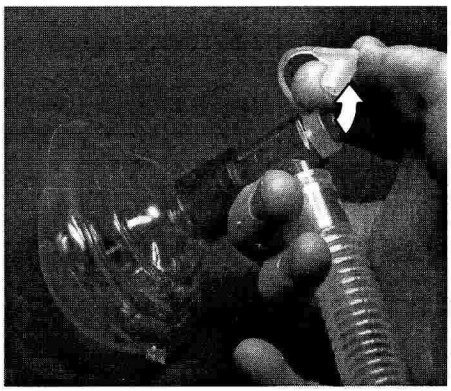


Important.

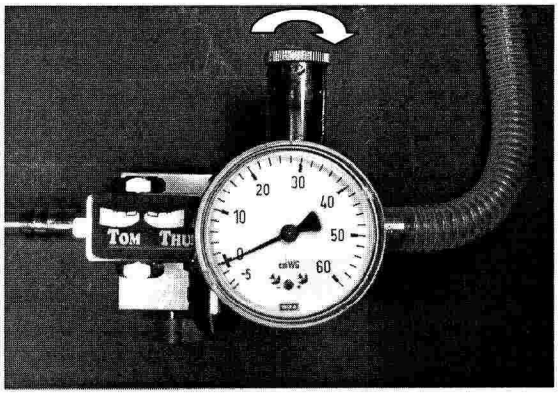
For use by qualified and trained personnel only.
Use flow rates of gas up to 15 litres / minute.
Adjust outlet pressure after altering the flow rate.
Do not attempt to adjust the safety valve ⑨.
O_2 inlet pressure from an external flowmeter.

1.1. Pre-use Checks (TT480).

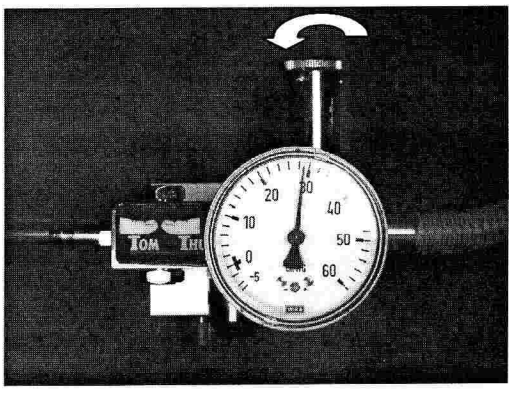
- Uncap the T piece port ①.



- Adjust the external 0-15 litres / min flowmeter to minimum and the adjustable valve control ② to minimum (fully counter clockwise).



- Connect the inlet ④ to the external flowmeter.
- Check that the pressure gauge ⑤ reads zero (within the black band on the gauge). If not, the Tom Thumb requires servicing.
- Connect the patient tubing ⑥ to the Tom Thumb outlet but do not apply the mask ⑦ to the patient.
- Set the external flowmeter to the required flow rate.
- Occlude the mask and the T piece port. Gradually turn the adjustable valve control clockwise until the required outlet pressure is shown on the pressure gauge (*).



- The Tom Thumb is now ready for use.

1.2. Guideline for Use during Resuscitation (TT480).

- Follow the pre-use checks and set the required flow rate and outlet pressure.
- Apply the mask to the patient and cover the T piece port to inflate the patients lungs at the set flow rate and pressure (*).
- Uncover the T piece port and allow the patients lungs to deflate (*).
- Repeat steps 2 & 3 as necessary during the resuscitation of the patient (follow the hospital protocol for resuscitation).

(*) Use the thumb to occlude the T piece port during pre-use checks and resuscitation. Disposable gloves or finger cots can be worn.

Use the T piece cap to occlude the T piece port on a longer term basis where free flowing facial oxygen can be given to an infant patient breathing normally.

Oxygen leaving the mask can be used to flow over the face of the patient; use the mask in the vicinity of the infants face to produce an oxygen enriched mixture to breathe (follow the hospital protocol for this technique).

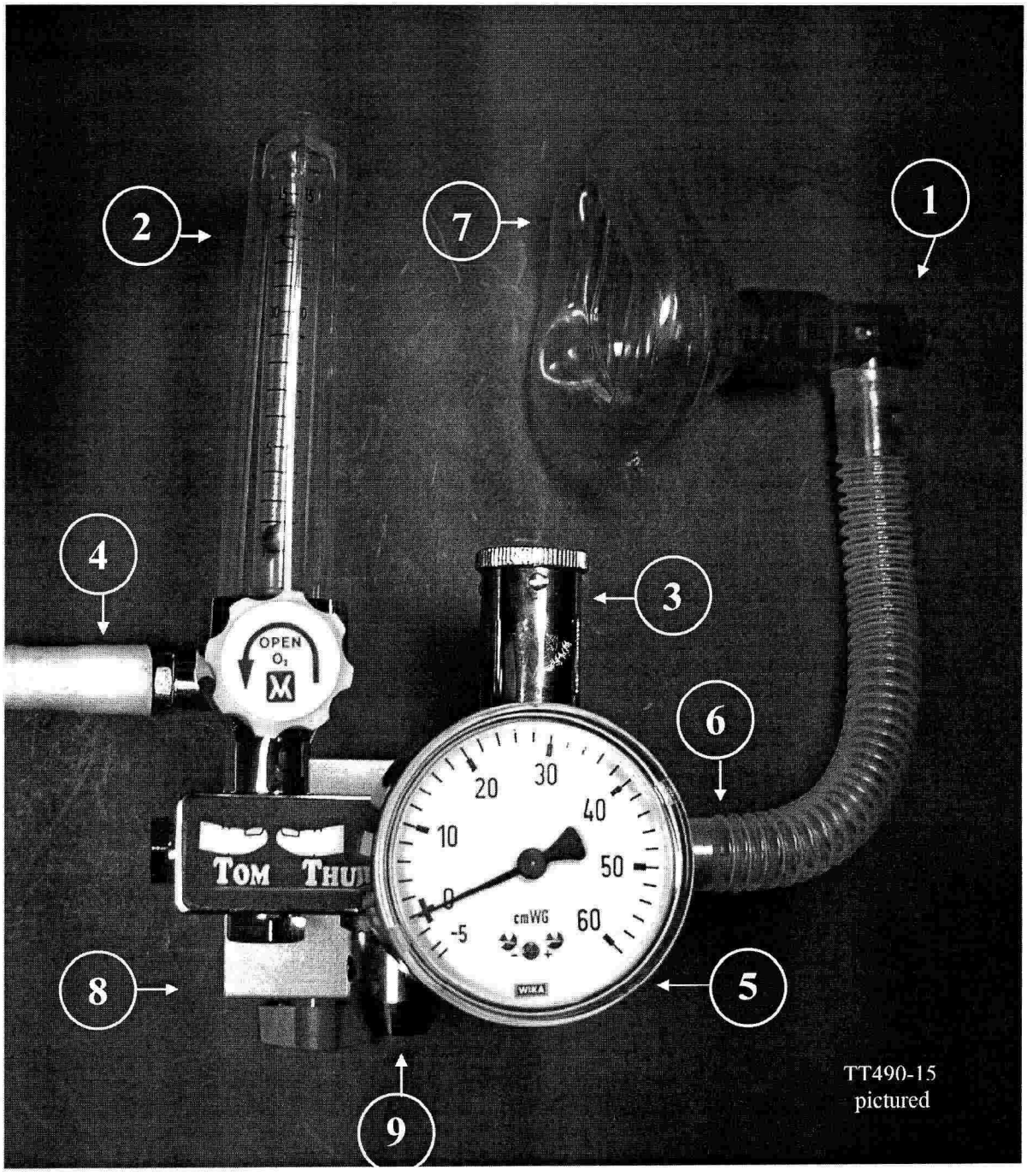
Important.

Do not apply the mask to the patient with the T piece port capped or permanently occluded under any circumstances.

NB. A T piece with a fixed PEEP facility can be used.

being not variable.
Where does it come from

5. TT490 and TT490-15.



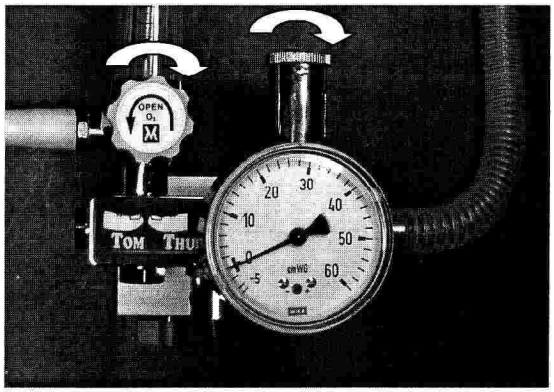
Important.

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 ⑨.
Recommended O_2 inlet pressure of 4 bar.

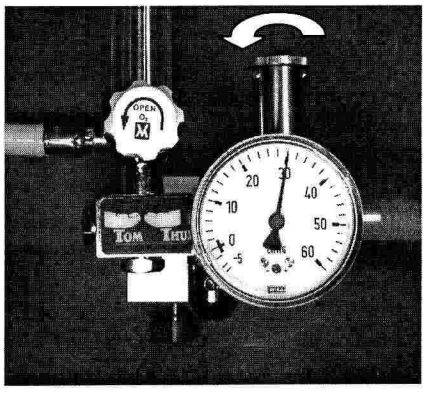
2.1. Pre-use Checks (TT490 & TT490-15).

- Uncap the T piece port ①.

- Adjust the flowmeter ② to minimum (fully clockwise) and the adjustable valve control ③ to minimum (fully counter clockwise).



- Connect the flowmeter inlet ④ to the O_2 supply.
- Check that the pressure gauge ⑤ reads zero (within the black band on the gauge). If not, the Tom Thumb requires servicing.
- Connect the patient tubing ⑥ to the Tom Thumb outlet but do not apply the mask ⑦ to the patient.
- Set the flowmeter to the required flow rate.
- Occlude the mask and the T piece port. Gradually turn the adjustable valve control clockwise until the required outlet pressure is shown on the pressure gauge (*).



- The Tom Thumb is now ready for use.

2.2. Guideline for Use during Resuscitation (TT490 & TT490-15).

- Follow the pre-use checks and set the required flow rate and outlet pressure.
- Apply the mask to the patient and cover the T piece port to inflate the patients lungs at the set flow rate and pressure (*).
- Uncover the T piece port and allow the patients lungs to deflate (*).
- Repeat steps 2 & 3 as necessary during the resuscitation of the patient (follow the hospital protocol for resuscitation).

(*) Use the thumb to occlude the T piece port during pre-use checks and resuscitation. Disposable gloves or finger cots can be worn.

Use the T piece cap to occlude the T piece port on a longer term basis where free flowing facial oxygen can be given to an infant patient breathing normally.

Oxygen leaving the mask can be used to flow over the face of the patient; use the mask in the vicinity of the infants face to produce an oxygen enriched mixture to breathe (follow the hospital protocol for this technique).

Important.

Do not apply the mask to the patient with the T piece port capped or permanently occluded under any circumstances.

NB. A T piece with a fixed PEEP facility can be used.

6. Frequently Asked Questions.

Q. Having carried out the pre-use checks and set flow rate and pressure required, in use the Tom Thumb delivers a greater pressure than that set?

A. Care should be taken that the T piece and mask are totally occluded when carrying out the pre-use checks. Any gas leaking from the mask or T piece will cause a higher pressure to be delivered in use when the seal around the mask and T piece are better. The mask should be firmly pushed against a solid smooth surface to completely occlude it during the pre-use checks. When the Tom Thumb is installed in resuscitation cabinet, do not use the mattress / bedding to attempt a seal at the mask as gas will escape causing an apparent over delivery of pressure than that set. When correctly occluded, a steady hiss of gas can be heard from the adjustable valve.

Q. In use, the Tom Thumb pressure gauge needle rises to the set pressure but the patients lungs are not inflating?

A. The Tom Thumb is delivering oxygen to the patient at the displayed pressure. If the lungs are not inflating, the patients airway may be blocked or the mask incorrectly positioned.

Q. In use, the Tom Thumb pressure gauge needle does not reach the set pressure and the adjustable valve cannot be heard releasing gas?

A. There is a leak in the circuit. This is most likely to be due to not achieving a good seal between the mask and the patient but may also to be due to not occluding the Tee piece port correctly. A physical leak such as a rupture within the circuit is unlikely to be the cause as this would have prevented the pre-use checks being completed successfully. If in any doubt, carry out the pre-use checks again.

Q. The tubing is longer than required. Can it be cut to size?

A. Yes. The tubing has regularly spaced 'bubbles' between corrugated sections and the tube can be cut at these points if necessary.

Q. The mask supplied is too big for some infants. Can we use different masks?

A. Yes. The T piece is a standard size and masks from other manufacturers can be connected in place of the standard mask.

Q. Can I give less than 100% oxygen?

A. Yes, a twin oxygen and air system is available.