CLINICAL EVALUATION REPORT

Compiled by

John Lamb

Tom Thumb Resuscitator

1. General details

Tom Thumb Resuscitator

Part Numbers: See DOCID 15747

Manufacturer:

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

2. Description of the device and its intended application.

Application: positive pressure ventilation

Tom thumb is a basic T-piece Resuscitator, DOCID14046 Section F1.

It is a Re-usable Non invasive short term device which uses a disposable T-Piece circuit to connect to the patient.

DOCID 7458. Diagram of basic pressure-limited T-piece resuscitator .

NHS Guide lines often refer to use **“T-piece resuscitator” or “resuscitaire (s)”** when referring to new born resuscitation guidelines. The terms T-Piece resuscitators and resuscitaries are referring to Tom Thumb type devices.

DOCID 17306 “Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review” From the Official Journal of the European Resuscitation Council Confirms the Tom thumb is a T-Piece resuscitator.

Tom thumb is manufactured out of Brass components See section M4 of the Technical file and incorporates no medical substances, tissues, or blood products Z13

Tom thumb does not involve Ionising Radiation Z12.

No Known carcinogenic substances are used in this product Z11 DOCID9455

Tom Thumb is not sterilized O1

Tom thumb does not contain software Section Y19 DOCID 7440

Tom thumb achieves its intended purpose of hand ventilating neonates by means of a Blow-Off valve to limit the pressure. DOCID 2435 Adjustable Valve.

3. Intended therapeutic and/or diagnostic indications and claims

Use of self-inflating bags for neonatal resuscitation. (Oddie S1, Wyllie J, Scally A.)

“**BACKGROUND**:

Lung inflation is the most important, and most difficult step in newborn resuscitation. A wide variety of devices are used to achieve lung inflation, but there are relatively few data to guide clinicians in their choice of device.

METHODS:

We tested the ability of instructors and trained candidates on a newborn life support course to deliver initial inflation breaths to a test lung, using a pressure limited blow-off valve, a 240-ml self-inflating bag and a 500-ml self-inflating bag in sequence.

RESULTS:

Use of a 240-ml self-inflating bag was associated with shorter initial inflations of 1.8 s mean (95% CI 1.60-1.99 s), compared with 2.42 s (2.24-2.61 s), 2.40 s (2.08-2.71 s) for 500-ml self-inflating bags and "Tom Thumb" T piece, respectively. Delivery of breaths within a target pressure range of 30+/-5 cm H2O was significantly better using a T piece than either self-inflating bag (proportion within target range 0.05 (95% CI 0-0.11), 0.17 (95% CI 0.12-0.23), 0.89 (95% CI 0.83-0.94) for 240-ml and 500-ml self-inflating bags and "Tom Thumb" T piece, respectively. Excessive pressure delivery with both sizes of self-inflating bag was frequent.

CONCLUSIONS:

These data do not support use of 240-ml or 500-ml self-inflating bags for resuscitation of newborn term infants. A variable pressure T piece blow-off system may be the easiest device to use for newborn resuscitation and the most reliable at delivering desired pressures for set times.”

DOCID11656

Conditions to be treated : Lung inflation’s, safety via adjustable blow-off value and secondary safety value.

4. Context of the evaluation and choice of clinical data types.

The Clinic Evaluation has been performed via, Clinical Experience data / documentation and Clinical literature search(s).

Sources of data/documentation used in clinical evaluation.

Review of Essential requirements Current DOCID 17310

Review Risk Assessment current DOCID 15751

Post-market Surveillance report:

Section 1 Stock Identification

Section 2 Supplier Review

Section 3 Sales Review

Section 4 Countries Review

Section 5 Returns / Services Review

Section 6 Design Changes Review

Section 7 IFU Review

Section 8 Labels Review

Section 9 Documentation updates Review

Section 10 Internal Issues Review

Section 11 Clinical Data / FDA Incidents Search

Current DOCID 15747

Benefits of Tom Thumb against residual risks report DOCID 16043

All returns / failure records since 2001 are computerized and reviewed annually.

See post market surveillance reports DOCID 15747.

There have been no recalls of Tom Thumb units.

All units have Q.A. Records and service records indicating the devices perform as intended.

Sales / Returns and service logs data See DOCID 15747

Tom thumb units have been on the Market since 1980's. There have been no signification design changes in 20-30 years..

Technology:

DOCID 2362: The principles of T-Piece resuscitators was first introduced to Viamedt in 1984 by a Dr E. Hays – Consultant paediatrician.

Further history of T-Piece resuscitators DOCID 14011 indicates this type of devices being used in 1983.

This device was predicated on the IMI device prescribed in DOCID 14011 but additions of safety valves were added.

Approximately at the same time Fisher and Paykel were involved in the design of the Neo-Puff device. Both devices doing the same job in the same way. The only difference being in the ascetics – the tom thumb was designed to be used in a variety of places where the neo-puff would not be appropriate, e.g. attached to incubators.

5. Summary of the clinical data and appraisal

As there have been no clinical trials carried out on behalf of Viamed, this report is based on literature search . Technical File “Tom Thumb “

Comparison of the T-piece resuscitator with other neonatal manual ventilation devices:

Colin Patrick Hawkes Anthony Ryan Eugene Michael Dempseya
Department of Neonatology, Cork University Maternity Hospital, Ireland
Department of Paediatrics and Child Health, University College Cork, Ireland t

Aim: To review the literature surrounding various aspects of T-piece resuscitator use, with particular emphasis on the evidence comparing the device
to other manual ventilation devices in neonatal resuscitation.
Data sources: The Medline, EMBASE, Cochrane databases were searched in April 2011.
Ongoing trials were identified using www.clinical trials.gov and www.controlled-trials.com
Additional studies from reference lists of eligible articles were considered.
All studies including T-piece resuscitator use were eligible for inclusion.
Results: Thirty studies were included. There were two randomised controlled trials in newborn infants comparing the devices, one of which addressed short and intermediate
term morbidity and mortality outcomes and found no difference between the T-piece resuscitator and self inflating bag. From manikin studies, advantages to the T-piece resuscitator include the delivery of inflating pressures closer to prede-termined target pressures with least variation,
the ability to provide prolonged inflation breaths and more consistent tidal volumes.
Disadvantages include a technically more difficult setup, more time required to adjust pressures during resuscitation, a larger mask leak and less ability to detect changes in
compliance.
Conclusions:
There is a need for appropriately designed randomised controlled trials in neonates to high-light the efficacy of one device over another. Until these are performed,
healthcare providers should be appropriately trained in the use of the device available in their departments, and be aware of its own limitations.
This paper discusses the various options for hand ventilation of Neonates. None of these devices should be used without training and hospital protocols being in place

Introduction

Between 5 and 10% of newborn infants require resuscitation at birth.1,2
Effective positive pressure ventilation can be vital to successful neonatal resuscitation.3
Current guidelines in neonatal resuscitation recommend three devices; the self inflating bag (SIB), flow-inflating bag (FIB) and T-piece resuscitator (TPR).4–6
The prevalence of TPR use varies throughout the world, and many surveys describing their use have been published. In 2004, they were used in 48%
of centres in Australia and New Zealand,7
and 30% of centres in an international survey involving 23 countries.8
More recent surveys identified that they are used in 31% of centres in Ireland,9 45% of resuscitation areas in Spain,10 80% of Austrian
Abbreviations: PIP, peak inspiratory pressure; PEEP, positive end expiratory pressure; TPR, T-piece resuscitator; NP, Neopuff; SIB, self inflating bag; FIB, flow inflating bag; NRP,
Significantly better using a T piece than either self-inflating bag (proportion within target range

0.05 (95% CI 0–0.11), 0.17 (95% CI 0.12–0.23), 0.89 (95% CI 0.83–0.94) for 240-ml and 500-ml self-inflating bags and “Tom Thumb” T
piece, respectively. Excessive pressure delivery with both sizes of self-inflating bag was frequent.
Conclusions:
These data do not support use of 240-ml or 500-ml self-inflating bags for resuscitation of newborn term infants. A variable pressure T piece blow-off system may be the easiest device to use for newborn resuscitation and the most reliable at delivering desired pressures for set times
Suggests the T occluder i.e Neopuff is best method
The NeoPuff and Tom Thumb are engineering wise identical and are interchangeable.

Children and Young Peoples Nursing at a galance
Alan Glasper, Jane Coad, Jim Richardson - 2014 - Medical
Effective resuscitation of the newborn baby requires good **organization** and ... T-piece circuit; Tom Thumb or T-piece device • Self-inflating bag (500 mL)
Stresses the importance protocols and good practice.…

Neonatal Emergencies - Page 78 - Google Books Result

Sabaratnam Arulkumaran Aris Papageorghiou

2011 - Medical

Introduction

Resuscitation of the newborn infant differs from that of any other age ... or preferably a pressure-limited 'Tom Thumb' or other ventilation device.

Neonatal support for stand alone Midwifery Led Units

2011 - Medical

Introduction

Resuscitation of the newborn infant differs from that of any other age …

or preferably a pressure-limited 'Tom Thumb' or other ventilation device.

Providing newborn resuscitation at the mother’s bedside: assessing the safety, usability and acceptability of a mobile trolley

Margaret R Thomas1, Charles W Yoxall1*, Andrew D Weeks2 and Lelia Duley3

6. Corresponding author: Charles W Yoxall Bill.Yoxall@lwh.nhs.uk
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For all author emails, please log on.

BMC Pediatrics 2014, 14:135 doi:10.1186/1471-2431-14-135
The electronic version of this article is the complete one and can be found online at:http://www.biomedcentral.com/1471-2431/14/135

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The LifeStart® trolley manufactured by Inditherm (October 2012).

The trolley was introduced into Liverpool Women's Hospital, a busy tertiary referral unit with approximately 8,000 births per year. The trolley had additional equipment attached, namely: suction equipment, a gas flow metre (Oxylitre Ltd. Manchester, UK), a gas blender (Inspiration Health Care Ltd. Leicestershire, UK) and a t-piece resuscitator (Tom Thumb infant resuscitator, Viamed Ltd.Yorkshire, UK). Our practise is to place all babies born before 30 weeks gestation into a plastic bag immediately after birth to assist in maintaining body temperature. For all babies born before 28 weeks a self heating gel mattress is used in addition to this. Although the trolley has a warming system incorporated into it, this had not been evaluated as the only method of providing thermal support during initial stabilisation of extremely preterm babies. We, therefore, continued to use the plastic bags and self heating gel mattresses in addition to the warming system provided by the trolley for babies born before 30 weeks and 28 weeks respectively. The trolley was used for any delivery at which an Advanced Neonatal Nurse Practitioner (ANNP) or paediatrician was required to attend, according to the hospital policy:

The Midwife's Labour and Birth Handbook - Google Books Result

Vicky Chapman 2013 - Medical

Device

A Tpiece device,e.g. Tom Thumb,may be more effective (Wyllieetal., ... and a common reason for failed initial resuscitation (see Tables 18.1and 18.2).

Mercury Medical

Guidelines for resuscitation

WORKSHEET for Evidence-Based Review of Science for Emergency Cardiac Care Worksheet author(s)

Date Submitted for review: Clinical question. In neonates(P) receiving positive pressure during resuscitation, is positive pressure ventilation by T-piece resuscitator (I) superior to bag ventilation (C) for improving outcome - specify (O)? Is this question addressing an intervention/therapy, prognosis or diagnosis? Intervention State if this is a proposed new topic or revision of existing worksheet: Subsidiary question from a previous worksheet Conflict of interest specific to this

question Do any of the authors listed above have conflict of interest disclosures relevant to this worksheet? No Search strategy (including electronic databases searched). The subject area was included in a previous worksheet for C2005. I included relevant articles from the earlier worksheet. To look for new data on the subject I searched all new material from Jan 2004 to September 2009. I searched the Cochrane database using the keywords resuscitation, newborn; mask ventilation, newborn; and T-piece, newborn and identified no reviews or registered trials. I searched Pub Medusing the following keywords and in all cases limited to articles with abstracts: Resuscitation and newborn 1534 hits. Positive pressure ventilation and newborn 480 hits T-piece 48 hits Mask ventilation 84 hits I searched Embase for the same time period with the following terms, limited to articles with abstracts Resuscitation and newborn 793 hits Positive pressure ventilation and newborn 112 hits T-piece 157 hits Mask ventilation 220 hits. • State inclusion and exclusion criteria All titles and abstracts were reviewed. Articles were selected as relevant if they described the use of both devices in some way that would permit comparison for initial resuscitation after birth in humans or in relevant animal models or bench models. Reference lists of selected articles were reviewed for further possible articles. Review articles and articles describing surveys of practice were not included. • Number of articles/sources meeting criteria for further review: 7, all were LOE

Innovation in immediate neonatal care: development of the Bedside Assessment, Stabilisation and Initial Cardiorespiratory Support (BASICS) trolley A D Weeks,1 P Watt,2 C W Yoxall,3 A Gallagher,4 A Burleigh,5 S Bewley,6 A M Heuchan,7 L Duley8

Providing newborn resuscitation at the mother's bedside: assessing the safety, usability and acceptability of a mobile trolley

Margaret R Thomas,1 Charles W Yoxall,1 Andrew D Weeks,2 and Lelia Duley3

The trolley was introduced into Liverpool Women's Hospital, a busy tertiary referral unit with approximately 8,000 births per year. The trolley had additional equipment attached, namely: suction equipment, a gas flow metre (Oxylitre Ltd. Manchester, UK), a gas blender (Inspiration Health Care Ltd. Leicestershire, UK) and a t-piece resuscitator (Tom Thumb infant resuscitator, Viamed Ltd. Yorkshire, UK).

www.rcjournal.com/contents/12.09/12.09.1638.pdf

by JW Salyer - 2009 - Cited by 6 - Related articles
about the performance of self-inflating-bag resuscitators in neonatal scenarios. ..... theTom Thumb brand, which is marketed in Europe and has a factory-preset …

Newborn baby died over hospital blunder

A baby died 20 minutes after birth when her lungs burst after being mistakenly flooded with **oxygen**, an inquest heard yesterday.

Kathryn Leigh needed help when she was delivered in a frail and floppy condition in an ***emergency caesarean*** *section. But, the 8lb 1oz infant was connected to an oxygen tube meant for adult patients instead of a 'Tom Thumb'* ***resuscitator*** *for children.*

Oxygen was pumped into her lungs at 60lb per square inch, about twice the pressure used for car tyres and 137 times that of the children's resuscitator.Neonatal consultant Bob Welch admitted a 'gross error' had taken place at the Royal Shrewsbury Hospital, but no one has admitted connecting the tube to the wrong mechanism.The inquest jury returned a verdict of misadventure, reducing Kathryn's parents Philip, 35, and Sonia, 30, to tears – because they believe the hospital has escaped with little punishment.The couple, from Telford, Shropshire, had hoped a ruling of unlawful killing could be considered, but this was not allowed.Dr Anirban Maitra, who was responsible for Kathryn's resuscitation, said that when the baby had been handed to him, she was very frail and 'floppy' while her chest was not moving. But he refused to answer several questions under a rule allowing him not to respond to any which could incriminate himself.

This is typical of the very few problems encountered with the Tom Thumb. Other problems include failure due to misuse damage due to mishandling(dropping) or failure due to lack of service (vary rare)

Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review

Colin Patrick Hawkes Anthony Ryan Eugene Michael Dempsey

The Management of Labour

By Arulkumaran

LMA IN NEONATE RESUS

Scancrit.com

Posted on April 16, 2012 by Thomas D

Dear Thomas,

Thank you that is very helpful. I was referring to use of a Neopuff or other PEEP apparatus such as the Tom Thumb. These will give much more reliable and consistent pressures than is possible with a BVM. Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review Colin Patrick Hawkes , C. Anthony Ryan and Eugene Michael Dempsey

6. Data analysis

Performance

Performance has been proved by clinical use supported by papers written by clinicians , senior medical staff and T-Piece resuscitators referenced in most NHS infant resuscitation guide lines.

Safety
Tom thumb units have been on the Market since 1980's. There have been no signification design changes in 20-30 years.
The only incident involving the Tom Thumb units was in 1994 27th April. See DOCID2227

All returns / failure records since 2001 are computerized and reviewed annually. See post market surveillance reports DOCID 15747.

There have been no recalls of Tom Thumb units.

There are no MHRA incident reports regards t-piece resuscitators, Legal action was taken against a hospital concerning miss-use of a tom thumb by-passing the T-piece resuscitator completely

All units have Q.A. Records and service records indicating the devices perform as intended.

Sales / Returns and service logs data See DOCID 15747

This product has always required hospital protocol and training before use. See example below
"All registered staff working in Maternity Services:"
All registered staff, working within maternity and neonatal services, who care for newborns in the hospital or community setting should be competent to perform basic newborn life support as required. Initial training on induction will be provided to all appropriate groups of staff and updated as per RCHT Maternity services training needs analysis.
Staff who are newborn life support providers (NLS) following Resuscitation Council UK assessment are deemed competent for the time that the qualification remains valid. Staff who are accredited Resuscitation Council Instructors will be deemed competent whilst their accreditation is valid." Royal Cornwall Newborn Guidelines

Product Literature and Instructions for Use
Product literature and Instructions for Use are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact on the use of the device.

Conclusions

In line with all the known published clinical guidelines for neonates on resusication,positive pressure ventilation is advised.
The Tom thumb device fulfills the requirements i.e. it delivers a breathable gas at a maximum pressure determined by hospital protocols and is fail safe in as much as it has a maximum pressure blow-off valve.
There are risks associated with any medical procedure that delivers a "high pressure to a neonate" these risks are ameliorated by protocols and the safety feature of the device.
The safety of the device can be demonstrated by the huge numbers of applications and only positive user feedback and complaints file.

According to Colin Patrik Hawkes et al "Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review"
" Nevertheless, TPR users should also be aware of certain limitations of the device. Resuscitation is a dynamic process where the resuscitator needs to adapt to the response or non-response of the

newborn. TPR users are not as good at detecting changes in compliance42 as users of the SIB and FIB. TPR users also need more time to change the inflating pressures during resuscitation, compared to users of the SIB or FIB.22 Mask leak is greater with the TPR than with other devices,19,24,40,44 and changes to gas flow rate have significant effects on PIP,54 PEEP50,54,57 and mask leak.57 This device is probably the most technically difficult of the 3 devices to prepare for use, as is shown by the seven-step TPR setup procedure described elsewhere.52 This has implications for Neonatal Resuscitation Program (NRP) instructors and the training of NRP providers. Operators who do not frequently use the device, and are not receiving regular training in its setup, forget how to prepare C.P. Hawkes et al. / Resuscitation 83 (2012) 797–802 801 the device for use.52 Instructors should be aware that increases in gas flow before, or during resuscitation can result in significant increases in pressures unless the operator adjusts the dials accordingly.53,54,56 This risk can be reduced by restricting gas flow, through the use of low flow flowmeters,56 or a flow restrictor.58 The alternatives to the TPR are not without risk, and excessive pressures21 and tidal volumes46 are also possible with the SIB and FIB. The TPR does appear to offer a number of advantages over the SIB and FIB, but at the expense of a more difficult setup and the potential to provide dangerous inflating pressures in inexperienced hands. Like the SIB and FIB, the operator uses heart rate, chest rise, oxygen saturation and, sometimes, disposable colorimeters68,69 to determine if adequate and safe inflation is taking place. Tidal volume may be a more useful guide, but no currently available manual ventilation device in common use provides this information to the user. Future innovation to the TPR to improve its safety profile and clinical use may include internal gas flow restriction, internal limitation of maximum pressures and feedback on tidal volume delivery. Randomised controlled trials involving infants addressing short- and long-term morbidity outcomes are now under way,65,66 and may provide important evidence regarding whether or not the TPR improves resuscitation outcomes and reduces morbidity in comparison to the self inflating bag,66 or if sustained lung inflation with the TPR is superior to SIB ventilation.65 Until evidence of clinical benefit is available, we recommend that healthcare providers are appropriately and regularly trained in the use of whatever device being used in their clinical practice, and are aware of the particular limitations of that device.”
NB numbers refer to references by author

Information on author

John S. Lamb
Educated at;-
Heaton Grammar school 1953-1958
Sunderland Polytechnic (now Sunderland university) HNC Applied Physics.
1962 – 1965 Radiotherapy(Medical Physics) Design development and repair of medical electronic equipment.
From 1965 and through the 1970’s medical equipment began to expand into specialist areas.
Many original products were developed and manufactured in this period requiring a general overall understanding of medical equipment, the medical environment and medical procedures.
Many current products and procedures were introduced tested and improved without formal clinical trails or standards . The time period between design and subsequent use could be measured in days.
It became import very early on to work closely with the then DHSS and to apply a high standard of manufacture and quality control. Many of these applications were incorporated in the medical requirements which eventually formed the current CE system.
The current Viamed manufactured products were designed , developed and manufactured in the early 1980’s so although original design information is still available no formal clinical trials were carried out.

On the publication of BS5750 Viamed achieved ISO in 1993 one of the first small ISO medical companies. This was no small achievement for a company of about 12 people.
From there we have consistently progressed to the current position.
Throughout the period of Viamed 1977- we have consistently returned extremely low numbers of both complaints and MHRA correspondence. Products are proved reliable by the low number of failures and continuous sales.

John S. Lamb
26/08/2016