CLINICAL EVALUATION REPORT

Compiled by

John Lamb,Derek Lamb

Tom Thumb Resuscitator

General details

Tom Thumb Resuscitator

Part Numbers: See DOCID 15747

Manufacturer:

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

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.

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.

Context of the evaluation and choice of clinical data types.

The subject of Clinical Investigation - the method of PPV (positive pressure ventilation) has been established since before CE Marking/Formal Clinical trials so there are no clinical trials of using PPV. We have found however some reports on comparing different types of PPV equipment.

We do have an Article written by Sam Oddie, Jonathan Wyllie, Andrew Scally, Comparing Self inflating bag PPV against our Tom Thumb unit - published May 2005, It also refers to the Neo Puff resusitator as an equivalent system (ID11656).

A more recent article "Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review" Colin Patrick Hawkes a,b, C. Anthony Ryana,b, Eugene Michael Dempseya,b (ID17306) - also compares T-Piece resusitators with manual ventilation. Again they are not Evaluating 'PPV' but which equipment should be used. So we do not have any Clinical Investigations/Literature reviews for PPV. We only have the safety of the device route Annex X 1.1d.

Sources of data/documentation used in clinical evaluation evidence.

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 2006/2007 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 1990's. There have been no design changes in 11 years.

Technology:

DOCID 2362: The principles of T-Piece resuscitators was first introduced to Viamed 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.

Demonstrating safety and performance via data records (Annex X 1.1d) .

Digital proof of sales 1994 although limited information available see DOCID17366

Original Source Database z:\main\databases/apr97 files/Uksales/uksales89.apr

Required program for opening lotus approach 1997 *.

Also see Incident 27 April 1994 DOCID 2227 refers to Viamed Pressure relief block i.e. the Tom Thumb.

1998 Onwards Proof of sales and Invoice numbers DOCID17367

Original Source Database z:\main\STATS/spsales/1999-2001/all_spsales.apr

Required program for opening lotus approach 1997 *.

Invoice records are difficult to locate pre 2000. Earliest proof of sale

Invoice 50607 to Drager Limited on 24th March 1999 DOCID17375

Proof sale prior to December 1998 DOCID17376 Sunderland Royal Hospital

Oldest traceable Service history from paper archives:

Tom Thumb Serial Number VMA9001 sold to Sunderland Royal Hospital:

Service 29/03/1999 by Stuart Van DOCID17368

Serviced 23/02/2000 by Stuart Van DOCID17373
Service/Repair 30/04/03 by James Brown DOCID17369

Service 01/09/2005 by Edward Sendrowski DOCID17372
Service 05/10/2006 by Edward Sendrowski DOCID17374
Service November 2007 by Derek Lamb DOCID17378
Service 13 November 2008 by Derek Lamb DOCID17379

New bar-code tracking ID429985 Generated 2010 to allow tracking in the current Intrastats system.

Service logs 2010 – 2016 by Phil Crossley DOCID17370
Service log 2016 final report by Phil Crossley DOCID17371

Sunderland Royal Infirmary have 48 Units. At least one of the units has been in service since 1998. all 48 Units have service records as per unit VMA9001.

As shown in the letter dated 7th December 1998 Sam Richmond states they have never had any problems with them DOCID17376. Tom Thumb unit VMA9001 has been functioning since 1998 – the first yearly service being March 1999, and as of 14 July 2016 is still performing to required specifications DOCID17368. There is no reason the unit will not perform to specifications for another 10-20 Years with regular servicing as per service manual DOCID15677.

All New Build Tom thumb units are 100% Tested and Q.a. Tested prior to dispatch records stored electronically since 2007.

complaints and vigilance data.

There have been no Vigilance reports on Tom Thumb units and no direct customer complaints. However the returns / service DOCID15747 shows broken gauges
A total of 3 in 2014. and 2 in 2015 shows this is not a design issue due to the limited number of damaged units.

Product Changes

See DOCID2994 / DOCID2219, The Tom Thumb is basically the same device today as originally introduced in 1994.

It has been 11 Years since the last design change, 4th April 2005 Permabond MH052 DOCID2994.

Conclusion

With 22 years on the market the device has proved itself to be fundamentally a safe device and as the example records from Sunderland royal the Tom Thumb has proved itself to be reliable with at least one device now 18 Years old and still performing to the required specifications.

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

NOTE
* Lotus Approach requires older Microsoft OS. Will it will function and open in the latest version windows 10. It crashs when attempting to Print. So the