Product Review

Tom Thumb Series

March 2000

Product review

Tom Thumb

Topic of investigation: **Pressure relief valves**

A thorough testing of a production TT490-15 (Tom Thumb with 0-15 Litres/min flow meter) was carried out to evaluate the safety valves.

Evaluation

The standard QA evaluation procedure was carried out to check for correct calibration. Using the stipulated flow rate of 10 L/min no problems were found. However if the flow meter setting was increased it was noticed that the pressure indicated on the manometer rose higher than the 45 cmH2O limit, as set on the fixed blow off valve. The 15 L/min flow meters have a purge facility which allows an unmeasured flow to be supplied.

Test results

TT490-15

Flow meter Reading	**Fixed blow off Valve setting**	**Variable blow off valve setting**	**Digital Manometer Reading**
5 L/min	50 cmH2O	Removed	47 cmH2O
10 L/min	50 cmH2O	Removed	50 cmH2O
15 L/min	50 cmH2O	Removed	52 cmH2O
*Above 15 L/min	50 cmH2O	Removed	100 cmH2O
5 L/min	Removed	Set to Maximum	40 cmH2O
10 L/min	Removed	Set to Maximum	44 cmH2O
15 L/min	Removed	Set to Maximum	48 cmH2O
*Above 15 L/min	Removed	Set to Maximum	100 cmH2O

* The flow was increased slowly until the manometer reached its maximum, further increase in flow was possible but this could damage the manometer.

Due to the above results it was decided to complete the same test on a standard TT490-5L Tom Thumb with 0-5 L/min flow meter.

TT490-5

Flowmeter Reading	**Fixed blow off Valve setting**	**Variable blow off valve setting**	**Digital Manometer Reading**
5 L/min	50 cmH2O	Removed	50 cmH2O
*Above 5 L/min	50 cmH2O	Removed	100 cmH2O
5 L/min	Removed	Set to Maximum	41 cmH2O
*Above 5 L/min	Removed	Set to Maximum	96 cmH2O
3 L/min	Removed	Set to limit of 20 cmH2O	20 cmH2O

5 L/min	Removed	Set to limit of 20 cmH2O	21 cmH2O
*Above 5	Removed	Set to limit of 20 cmH2O	71 cmH2O

* The flow rate was increased slowly until the maximum flow was reached.

Summary of results

If either Tom Thumb was used correctly with a flow setting of between 3 and 15 L/min the variable and fixed blow off vales worked in accordance with their respected specification. However one of the main purposes of the Tom Thumb is to prevent the user from administrating to high a pressure to the patient, particularly if user or mechanical problems occur. Both Tom Thumbs fail to give this reassurance.

Rectification trail

Mr Geoff Black (Telephone number 01279 723051) designed the Tom Thumb on behalf of Viamed/Therapy Equipment. He was consulted about the design and the specifications of the original devices. He stated that due to the small diameter of the blow off valves the flow has a direct and gross affect on the settings of the blow off valves.

All the dimensions for both blow off valves were tested during the design and found to work in the range of 3 to 8 L/min. The springs were tested and designed by trial and error rather than a mathematical formula for the tension and length. Thus as long as the original specification components are used the Tom Thumb will function correctly at a flow of around 5 L/min.

If higher flows are required a complete new set of springs need to be evaluated.

To explain why we experienced problems with the TT490-5 Therapy Equipment were consulted (Mr Stephen Munn Telephone number 01707 652270).
We are assuming at this ponit that the current TT490-5 is be the same design/specification as the original Tom Thumb, as per the CE file.

Therapy Equipment: New 5 L/min flow meters are supplied to customers with a hose or Schrader probe, these have a restrictor in the assembly as a mechanism to prevent the internal flow ball from hitting the jar top with great speed if the flow meter is connected with the settings at maximum flow. These restrictors inadvertently restrict the maximum flow achievable to be 8 L/min.

Viamed purchases the Oxygen hose and the flow meter as separate items from Therapy Equipment, then fit a 90 degree elbow between the hose and the flow meter. No restrictor is supplied or fitted, thus making it possible to achieve the high flow rates as experienced.

Solution options

A restrictor with a hole tolerance of 0.45/0.48 mm should be fitted to every Tom Thumb.

Apparently there are no records to state that a restictor has ever been fitted to the TT490 series of Tom Thumbs, this leads to the conclusion that all 482 Tom Thumbs which have been supplied need to be checked and if required fitted with the correct restrictor. All TT490-15's potentially need to be recalled and fitted with 5 L/min flow meters.

All TT480 Tom Thumbs (with out flow meters) should be fitted with a restrictor or labeled to state that only 5 L/min flow meters should be used.

If all Tom Thumbs are to be serviced it may be worth considering to standardise on the labels used on the variable blow off valves, i.e. arrows and wording. A label stating the blow off value of the fixed and variable valves.

April 2000

Following a discussion with Barbra Helps from Drager and her subsequent discussions with Neonatal practitioners we agreed that the issue of over pressure in Tom Thumb style devices was a well know fact. The user guides previously supplied by Viamed clearly states that the unit should be tested before use, this was considered good enough reason not to implement a product recall. Instead we decided to contact users to clarify the situation.

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Test Results With A Restrictor Fitted

TT490-5 Serial number VMA001 with a 0.45-0.48mm restrictor fitted

Flowmeter Reading	**Fixed blow off Valve setting**	**Variable blow off valve setting**	**Digital Manometer Reading**
3 L/min	50 cmH2O	Removed	46 cmH2O
5 L/min	50 cmH2O	Removed	50 cmH2O
*Above 5 L/min	50 cmH2O	Removed	51 cmH2O
3 L/min	Removed	Set to maximum	42 cmH2O
5 L/min	Removed	Set to maximum	43 cmH2O
*Above 5	Removed	Set to maximum	43 cmH2O

* The flow rate was increased slowly until the maximum flow was reached.

TT490-5 Serial number VMA002 with a 0.45-0.48mm restrictor fitted

Flowmeter Reading	**Fixed blow off Valve setting**	**Variable blow off valve setting**	**Digital Manometer Reading**
3 L/min	50 cmH2O	Removed	41 cmH2O
5 L/min	50 cmH2O	Removed	42 cmH2O
*Above 5 L/min	50 cmH2O	Removed	Over 60 cmH2O
3 L/min	Removed	Set to maximum	41 cmH2O
5 L/min	Removed	Set to maximum	42 cmH2O
*Above 5	Removed	Set to maximum	42 cmH2O

* The flow rate was increased slowly until the maximum flow was reached.
This restrictor failed to restrict the flow, upon investigation no obvious reason was found. Due to the accuracy required for the aperture size in the restrictor it is assumed that in this case the aperture was larger than the specified 0.45-0.48 mm.

A new restrictor was fitted to the same device and re-tested

TT490-5 Serial number VMA002 with a 0.45-0.48mm restricotor fitted

Flowmeter Reading	**Fixed blow off Valve setting**	**Variable blow off valve setting**	**Digital Manometer Reading**
3 L/min	50 cmH2O	Removed	45 cmH2O
5 L/min	50 cmH2O	Removed	46 cmH2O
*Above 5 L/min	50 cmH2O	Removed	48 cmH2O
3 L/min	Removed	Set to maximum	44 cmH2O
5 L/min	Removed	Set to maximum	44 cmH2O
*Above 5	Removed	Set to maximum	44 cmH2O

* The flow rate was increased slowly until the maximum flow was reached.

The same unit using a new restricor passes the specification test.

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It can be clearly seen that the restrictors work but thorough testing needs to be carried out on each device with a restrictor fitted.

Solution Carried out

All customers, see attached list who have purchased a Tom Thumb device was contacted by letter and supplied with a plastisied user guide with fitted chain.

FILE	HOSP/Company	FULL_NAME	TITLE	DEPARTMENT	SIGNED_BY	DATE C
220	Horton General Hospital	Dr R A F Bell	Consultant Paediatrician	Special Care Baby Unit	Peter Lamb	4/4/00
600	Pilgrim Hospital	Miss S Holmes	Sister in Charge	Special Care Baby Unit	Peter Lamb	4/4/00
600	Pilgrim Hospital	Ms Pat Appleby	Clinical Nurse Manager	Maternity Department	Peter Lamb	4/4/00
830	Fairfield General Hospital	Dr Prabu	Consultant Paediatrician	Special Care Baby Unit	Peter Lamb	4/4/00
1450	Buckland Hospital	Dr S Williamson	Consultant Paediatrician	Special Care Baby Unit	Peter Lamb	4/4/00
1520	Dryburn Hospital	Dr Thalayasingam	Consultant Paediatrician	Special Care Baby Unit	Peter Lamb	4/4/00
1635	Simpson Memorial Mat. Pavilion	Miss P Newmarch	Clinical Nurse Manager	Special Care Baby Unit	Peter Lamb	4/4/00
1760	Queen Elizabeth Hospital	Mrs Richardson	Clinical Nurse Manager	Special Care Baby Unit	Peter Lamb	4/4/00
1770	Medway Maritine Hospital	Dr Ducker	Neonatal Paediatrician	Neonatal Unit Level 4	Peter Lamb	4/4/00
2610	Lincoln County Hospital	Dr C Millns	Consultant Paediatrician	Neonatal Intensive Care Unit	Peter Lamb	4/4/00
3170	Queen Charlottes & Chelsea Hosp	Dr D Azzopardi	Senior Lecturer Neonatalology	Neonatal Intensive Care Unit	Peter Lamb	4/4/00
3310	St. Georges Hospital	Dr P Hamilton	Consultant Neonatologist	Neonatal Intensive Care Unit	Peter Lamb	4/4/00
3710	South Cleveland Hospital	Dr S Sinha	Consultant Paediatrician	Neonatal Intensive Care Unit	Peter Lamb	4/4/00
3800	Royal Victoria Infirmary	Dr D W A Milligan	Consultant Neonatologist	Special Care Baby Unit	Peter Lamb	4/4/00
3860	North Tyneside General Hospital	Dr W T Houlsby	Consultant Paediatrician	Special Care Baby Unit	Peter Lamb	4/4/00
3885	Mount Vernon Hospital	Mr L Sissons	Buyer	Supplies Department	Peter Lamb	4/4/00
3910	Nottingham City Hospital	Dr D A Curnock	Consultant Paediatrician	Neonatal Intensive Care Unit	Peter Lamb	4/4/00
4330	Birch Hill Hospital	Dr R Smith	Consultant Paediatrician	Special Care Baby Unit	Peter Lamb	4/4/00
4640	Royal Shrewsbury Hospital	Dr Welch	Consultant Paediatrician	Special Care Baby Unit	Peter Lamb	4/4/00
4670	Wexham Park Hospital	Mrs Kealoha	Senior Sister	Specicial Care Baby Unit	Peter Lamb	4/4/00
4760	Southport D G Hospital	Mr D Murray	Department Manager	Supplies Department	Peter Lamb	4/4/00
4900	North Tees General Hospital	Dr R C Dias	Consultant Paediatrician	Special Care Baby Unit	Peter Lamb	4/4/00
4910	City General Hospital	Mr N Reader	Equipment Liaison	Supplies Department	Peter Lamb	4/4/00
4920	North Staffs Maternity Hospital	Dr S A Spencer	Clinical Director	Neonatal Intensive Care Unit	Peter Lamb	4/4/00
4990	Sunderland Royal Infirmary	Dr S Richmond	Clinical Director	Special Care Baby Unit	Peter Lamb	4/4/00
5340	West Cumberland Hospital	Dr P Carter	Consultant Paediatrician	Special Care Baby Unit	Peter Lamb	4/4/00

Barbra Helps - Drager (file 9044) Date 13-March 2000
Miss P Newmarch- Simpson Mamorial (file 1635) date 25-5-00

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Customers who have requested the modification, I.E. a restrictor fitted will have their details logged on the 'Repairs file', this work will be carried out free of charge

At the time of compiling this report two customers have requested that the restrictors are fitted:
Grantham 2 units
Queen Elizabeth Hospital - Gateshead 2 units.

A new test procedure has been drafted to increase the accuracy and clarity of documentation which is completed during the final Quality Assurance for each device.

A decision also needs to be made on whether a 5 L/min or 15 L/min flow meter is fitted as standard. The restrictor will work on both flow meters although thorough testing needs to take place on the 15 L/min version.

The advantage of using the 15 L/min version is that flows greater than 5 L/min can be clearly seen on the scale where as on the 5 L/min version this is the maximum scale indication, anything above this is not indicated.

It must be stressed that all units need to be thoroughly tested for the maximum achieveable pressure when restrictors are fitted. This is due to the potential specification failure of the restictors.

Copy of letter supplied to all Tom Thumb users

In accordance with our BS EN ISO9001 EN 46001 quality system Viamed has recently re-appraised in all aspects the Tom Thumb resuscitation device.

The Tom Thumb has been designed to be a flow/pressure regulated device enabling the user to control and view the pressures being administered. However if the flow rate is increased, the pressure in the Tom Thumb will also increase. Due to the increase in volume of gas within the system the blow off values will change, thus allowing a potential greater PEEK pressure to the patient. A standard Tom Thumbs' blow off valves have been calibrated to allow a maximum pressure relief of 50 cmH2O at a flow rate of between 5-10 L/min, if for instance the flow rate is increased to above 15 L/min this pressure relief will increase beyond the 50 cmH2O. All flow meters used with the Tom Thumb have a purge facility allowing higher flows than indicated on the glass tube. In accordance with the Tom Thumb user manual the standard flow setting is 5 L/min.

Restrictors can be fitted to limit the maximum inlet flow but this would also restrict the user from administering high pressures when required by particular patients. If you would like a restrictor fitted please contact Viamed to arrange the required work.

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Our records indicate that your hospital has one or more of these devices on site and therefore we have enclosed the relevant number of user guides for the Tom Thumb series. We would like to reiterate the instructions, of testing the pressure before administration to the patient.

Please do not hesitate to contact me if you have any queries on this matter or any other matter.

Report compiled by :
Peter Lamb
13-March- 2000
Revised 24-5-2000

	TT460	TT470	TT480	TT490	TT495	TTSM	*Total*
	Qty sold	Qty sold	Qty sold	Qty sold	Qty sold	Qty sold	Qty sold
1450(1450)Buckland Hospital(SET)				1			1
1520(1520)Dryburn Hospital(NOR)				4			4
161(161)Wansbeck General Hospital(NOR)			7				7
1760(1760)Queen Elizabeth Hospital(NOR)				3			3
1770(1040)Medway Maritine Hospital(SET)				10			10
1770(1770)Medway Maritine Hospital(SET)				12			12
2610(2610)Lincoln County Hospital(TRE)			1	4			5
2990(2990)Kings College Hospital(SET)				4			4
3170(3170)Queen Charlottes & Chelsea Hosp(NWT)				1			1
3310(3310)St Georges Hospital(SWT)			12				12
3710(3710)South Cleveland Hospital(NOR)			18				18
3800(3800)Royal Victoria Infirmary(NOR)			33	2			35
3860(3860)North Tyneside General Hospital(NOR)			1	5			6
3885(3885)Mount Vernon Hospital(NWT)			8				8
3910(3910)Nottingham City Hospital(TRE)			14				14
4040(220)John Radcliffe Hospital(OXF)				1			1
4330(4330)Birch Hill Hospital(NWR)		7		7			14
464[illegible]640)Royal Shrewsbury Hospital(WM)				9			9
467[illegible]4670)Wexham Park Hospital(OXF)				2			2
4710(4710)South Tyneside District Hospital(NOR)			2				2
4760(4760)Southport D G Hospital(MER)			8				8
4900(4900)North Tees General Hospital(NOR)			5	9		1	15
4910(4910)City General Hospital(WM)				7			7
4920(4920)North Staffs Maternity Hospital(WM)				6			6
4990(4990)Sunderland Dist. Gen. Hospital(NOR)			18				18
5000(5000)Sunderland Eye Infirmary(NOR)			3				3
5122(5122)Jamaica Hospital League Of Friend()				1			1
5270(5270)Queen Elizabeth II Hospital(NWT)				0			0
5340(5340)West Cumberland Hospital(NOR)				1			1
600(600)Pilgrim Hospital(TRE)				2			2
8000(8000)DO NOT USE 8000(X)	10	3		3	10		26
830(830)Fairfield General Hospital(NWR)				3			3
9044(9044)DRAEGAR(X)	109			5	111		225
Total	119	10	130	102	121	1	483

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	TT46[illegible]	TT480	TT4[illegible]	TT90[illegible]	TT19[illegible]	TTSM	*Total*
	INV qty	INV qty	INV qty	INV qty	INV qty	INV qty	INV qty
1040 [illegible]ll Saints Hosp(See Medway Mart)			10				10
1450 [illegible] Hospital			1				1
1520 Dryburn Hospital			4				4
161 Wansbeck General Hospital		7					7
1760 Queen Elizabeth Hospital			3				3
1770 Medway Maritine Hospital			12				12
220 Horton General Hospital			1				1
2610 Lincoln County Hospital		1	4				5
3170 Queen Charlottes & Chelsea Hosp			1				1
3310 St. Georges Hospital		12					12
3710 South Cleveland Hospital		18					18
3800 Royal Victoria Infirmary		8	2				10
3860 North Tyneside General Hospital		1	5				6
3885 Mount Vernon Hospital		8					8
3910 Nottingham City Hospital		14					14
4330 Birch Hill Hospital			7				7
4640 Royal Shrewsbury Hospital			5				5
4670 Wexham Park Hospital			2				2
4760 Southport D G Hospital		8					8
4900 North Tees General Hospital		5	9			1	15
4910 City General Hospital			7				7
4920 North Staffs Maternity Hospital			6				6
4990 Sunderland Royal Hospital		18					18
5000 Sunderland Eye Infirmary		3					3
5122 Jamaica Hospital League Of Friend			1				1
5270 Queen Elizabeth II Hospital			0				0
5340 West Cumberland Hospital			1				1
600 Pilgrim Hospital			2				2
8000 Maryland Industrial Estate	10		3		10		23
830 Fairfield General Hospital			3				3
9044 Draegar	109		3	2	111		225
Total	119	103	92	2	121	1	438

1635 SIMPSON MEMORIAL

4120 PETERBOROUGH.

Smart
Funding Innovation

RS 28343 FS 28344

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BS EN ISO 9001 BS EN 46001
Registration No 12917565 in England

VIAMED

Tom Thumb Test Sheet

Equipment

Description	Tom Thumb.	Model	TT490-15
Date	23.7.99	S/N	VMA 9118.
Time Calib.	AM	Time Q.A.	AM

Before Starting Final Q.A. Ensure the Calibration Time is Greater than hour before Final Q.A.

Test Results

*Note TT490-15 is calibrated at 15 Lpm

Test Equipment				P/F
	Check All ports/connectors for leaks	✓	✓	P
	Pressure Guage Test	**Pressure 10CmH20**	**Pressure 50 CmH20**	
CE078	Readings	10	49	P
	Flowrate	Set to 5 Lpm		
CE079	O2 15Lpm	9.5		P
	Adjustable Valve @ 15 Lpm	**Minimum (<5 Cm H_2O)**	**Maximum (>43 & <47 Cm H_2O)**	
CE078		32	45	P
	Safety Valve @ 15 Lpm		**Maximum (>45 & < 50 Cm H_2O)**	
CE078			47.	P
Visual Checks				
Check	Gauge cannot be removed without tools.		✓	P
Check	Gauge appears Straight.		✓	P
	All Adjustable Settings are set to a minimum		✓	P
	Lables have been attached	CE Lable	✓	P
		S/N Lable	✓	P
		TomThumb Lable	✓	P

Signed : [signature]

RS 28343 RS 28344

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Registration No 12917565 in England

Dräger

FACSIMILE MESSAGE

To: Peter lamb

Fax No: 01535 635582
Pages: 2
Date: 14th March 2000.
CC:
From: The desk of Barbara-Anne Helps
Product Marketing Manager, Neonatal.

Subject: Instructions for use

Dear Peter, I have copied for you the Safety message from Draeger. This is situated at the front of the user manual.

Regards

Barbara-Anne Helps

Draeger Medical
The Willows
Mark Road
Hemel Hempstead
Herts HP2 7BW
Tel: 01442 213542
Fax: 01442 240327

For Your Safety and that of Your Patients

Strictly follow the Instructions for Use

Any use of the apparatus requires full understanding and strict observation of these instructions. The apparatus is only to be used for purposes specified here.

Maintenance

The apparatus must be inspected* and serviced* regularly by trained service personnel at six monthly intervals (and a record kept).
Repair* and general overhaul of the apparatus may only be carried out by trained service personnel.
We recommend that a service contract be obtained with DrägerService and that all repairs also be carried out by them. Only authentic Dräger spare parts may be used for maintenance*.
Observe chapter "Maintenance Intervals".

Not for use in areas of explosion hazard

This apparatus is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely to occur.

Safe connection with other electrical equipment

Electrical connections to equipment which is not listed in these Instructions for Use should only be made following consultations with the respective manufacturers or an expert.

Liability for proper function or damage

The liability for the proper function of the apparatus is irrevocably transferred to the owner or operator to the extent that the apparatus is serviced or repaired by personnel not employed or authorized by DrägerService or if the apparatus is used in a manner not conforming to its intended use.

Dräger Medizintechnik GmbH cannot be held responsible for damage caused by non-compliance with the recommendations given above. The warranty and liability provisions of the terms of sale and delivery of Dräger Medizintechnik GmbH are likewise not modified by the recommendations given above.

Dräger Medizintechnik GmbH

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*
Definitions:
Inspection = examination of actual condition
Service = measures to maintain specified condition
Repair = measures to restore specified condition
Maintenance = inspection, service, repair

Therapy Equipment Ltd

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POTTERS BAR, HERTS, EN6 3JN TEL: 01707 652270 FAX: 01707 652622

Cert. No. FM 37970

Fax Cover Sheet

DATE: March 9, 2000 **TIME:** 11:05

TO: Peter Lamb
Viamed

PHONE:
FAX:

RE: **FLOWMETER INLET**

Number of pages including cover sheet: 1

Message

Dear Peter,

I refer to our recent telephone conversation regarding the Flowmeter Inlet fitted to all Low Flow Flowmeters.

I would advise you that the Inlet hole is drilled to a diameter tolerance of 0.45/0.48mm.

Please feel free to give me a call if I can be of any further assistance.

Kind Regards,

Steve Munn