

# **Product Review 01**

**Tom Thumb Series**

**March 2000**

## 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 cmH<sub>2</sub>O 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 cmH <sub>2</sub> O	Removed	47 cmH <sub>2</sub> O
10 L/min	50 cmH <sub>2</sub> O	Removed	50 cmH <sub>2</sub> O
15 L/min	50 cmH <sub>2</sub> O	Removed	52 cmH <sub>2</sub> O
*Above 15 L/min	50 cmH <sub>2</sub> O	Removed	100 cmH <sub>2</sub> O
5 L/min	Removed	Set to Maximum	40 cmH <sub>2</sub> O
10 L/min	Removed	Set to Maximum	44 cmH <sub>2</sub> O
15 L/min	Removed	Set to Maximum	48 cmH <sub>2</sub> O
*Above 15 L/min	Removed	Set to Maximum	100 cmH <sub>2</sub> O

\* 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 cmH <sub>2</sub> O	Removed	50 cmH <sub>2</sub> O
*Above 5 L/min	50 cmH <sub>2</sub> O	Removed	100 cmH <sub>2</sub> O
5 L/min	Removed	Set to Maximum	41 cmH <sub>2</sub> O
*Above 5 L/min	Removed	Set to Maximum	96 cmH <sub>2</sub> O
3 L/min	Removed	Set to limit of 20 cmH <sub>2</sub> O	20 cmH <sub>2</sub> O
5 L/min	Removed	Set to limit of 20 cmH <sub>2</sub> O	21 cmH <sub>2</sub> O
*Above 5	Removed	Set to limit of 20 cmH <sub>2</sub> O	71 cmH <sub>2</sub> O

\* 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 valves worked in accordance with their respected specification. However one of the main purposes of the Tom Thumb is to prevent the user from administering 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 point that the current TT490-5 is to 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, and 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 restrictor 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.

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April 2000

Following a discussion with Barbara 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.

## 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 restrictor 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 restrictor passes the specification test.

**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, that have purchased a Tom Thumb device were contacted by letter and supplied with a plastisied user guide with fitted chain.

Barbara Helps - Drager (file 9044) Date 13-March 2000

Miss P Newmarch- Simpson Memorial (file 1635) date 25-5-00

FILE	HOSP/Company	FULL_NAME	TITLE
3000.6	PerkinElmer Instruments	Esther Boile	
9900	Medex Medical	Mr T Carmichael	
680	Royal Sussex County Hospital	Mr B Jolly	
390	Bedford Hospital	Ms S Picarno	
1	Steve Hudson	test name	Sales Manager
2710	Walton Hospital(closed)-2650	Mr S Graham	
2710	Walton Hospital(closed)-2650	Mr S Graham	
4490	Scarborough Hospital	Sister Collinson	
4560	Northern General Hospital	Mr J D Carter	
9680	(JNA Ltd.)	Mr A Holder	
396	Royal Victoria Hospital	Mr D Magill	
9166	Ulster Anaesthetics	Mr A McKee	
2360	Airedale General Hospital	Mr Wagstaff	Chief Technician

**NB: To view full list above, double click the box.**