

Product Review

SpO2 Probes

February 2002

Topic of investigation: Under reading of Ohmeda Pobes

A thorough testing of a production batch of P867RA Finger Probes was carried out to evaluate the under-read of Probe to Monitor, using the DL3000 Simulator.

Evaluation

The standard QA evaluation procedure was carried out to check for the correct calibration of the monitor. The “R” curve was checked in the software and found to be correct

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 Torn Thumb with 0-5 L/min flow meter.

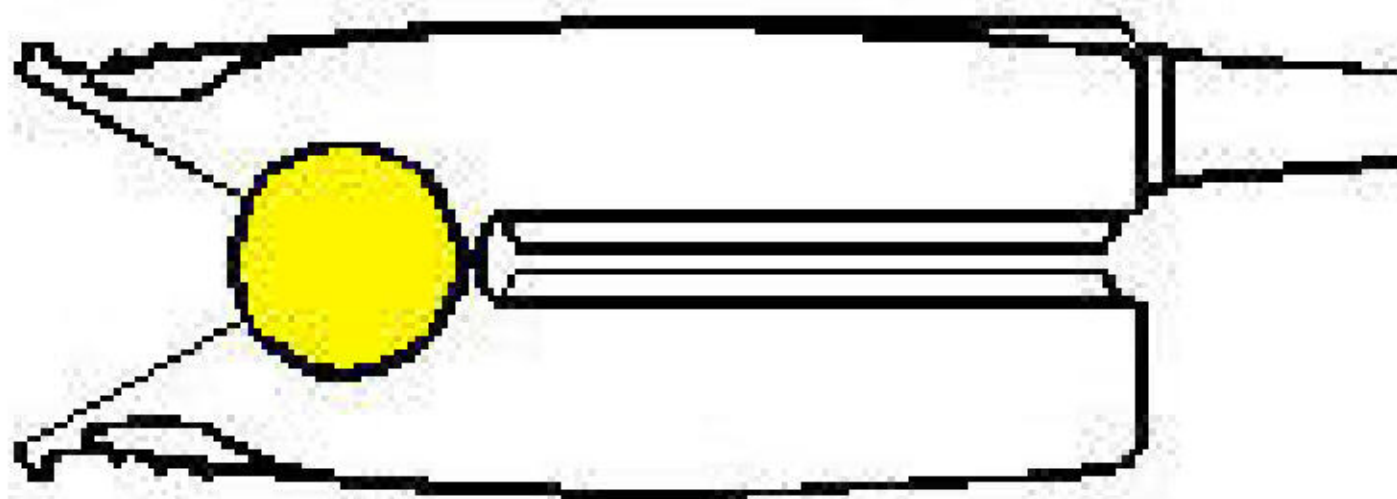
TT490-5

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

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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.

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