CUSTOMER COMPLAINT REPORT

		CCR No.	119
		Date:	19 FEB 04
Customer:	CITY GENERAL HOSPITAL	**P.O.**	
File No.:	4920	**Invoice:**	
Address:	STOKE-ON-TRENT, ST4 6QG		
Product:	TOM THUMB	**Despatched:**	
Serial No.(s):			
Manufacturer / Supplier	VIAMED		

Nature of Complaint:

TOM THUMB DID NOT FUNCTION CORRECTLY WHEN REQUIRED, IT FAILED TO DELIVER OXYGEN AT PRESSURE.

Result of Investigation:

THE UNIT WAS FOUND TO HAVE VARIOUS FAULTS, WHEN CHECKED -

THE ACCOMPANYING REPORTS DETAILS THESE FAULTS

Signed: [signature] **Date:** 18-03-04

Corrective Action:

External:

REPORT & EVIDENCE FORWARDED TO M.H.R.A ON 10/5/04.

Internal:

SERVICE REPORT COMPLETED (J.B.) UNIT NOW IN QUARANTINE AWAITING INSTRUCTIONS

Signed: [signature] **Date:** 27-5-04

MDA Informed?	**YES**	**NO**		**QC 12**

Subject : Tom Thumb incident - City General, Stoke-on-Trent
Date : Thu, 12 Feb 2004 12:19:00 +0000
Linked to : Peter Henry
From : Steve Hardaker <steve.hardaker@viamed.co.uk>
To : SNIXON (Steve Nixon) <GoldMine User>
Cc : JSLAMB (John Lamb) <GoldMine User>; KEVIN (Kevin Rush) <GoldMine User>

Dear all,

Just to make everyone aware of the issue surrounding the Tom Thumb incident, the information I have is as follows:

Peter Henry, Clinical Technology, rang on Thursday 12th Feb 04 to say they had an incident involving a Tom Thumb. As with all incidents this was reported to the MDA who will be investigating.

The Hospital have withdrawn all 12 Tom Thumbs from service pending their own investigation into the incident, Peter suggested initial indications are that the Pressure Relief Valve had been adjusted to its minimum setting resulting in the device delivering oxygen with little or no pressure and therefore appearing defective. It is not clear if a patient was at risk but certainly no serious injury or fatallity arose.

To ensure the safe functioning of the 12 Tom Thumbs they have, and to assist in their investigation, he has requested service and calibration information as soon as possible.

It was aggreed that Kevin will update the servicing information into a format which can be supplied to the customer. Kevin will also look into the feasibility of 2 service kits: 1 with all the replacement parts for the service of 1 Tom Thumb, the other with the tools required to do the service. This will allow us to sell 1 service toolkit for each customer and 1 service parts kit for each Tom Thumb.

As I may not be in the office when the manual is finished I have written the covering letter and asked Kevin to send it to the customer with the manual as soon as possible.

Steve H.

University Hospital of North Staffordshire NHS

NHS Trust

Corporate Services Division
Department of Clinical Technology
City General Site
Newcastle Road
Stoke on Trent
Staffordshire
ST4 6QG

Tel: 01782 552562
Fax: 01782 552182

Our ref: FS/js/113679/113680/208/209/04

13th February 2004

F.A.O. Steve Hardaiter
Viamed Limited
15 Station Road
Crosshills
Keighley
W. Yorks
BD20 7DT

Dear Mr Hardaiter

Please find enclosed one Tom Thumb Ventilator, model TC 480/490, serial number G16, for investigation as requested by the Medicines and Healthcare Products Regulatory Agency. This unit was the subject of an adverse incident. The MHRA reference 2004/002/005/401/886/887 refers as does our incident report 113679/80 (208/209/04).

Thank you for your assistance in this matter and I look forward to receiving your report.

Yours faithfully

p.p. S. Slyhee

Frank Smith
Deputy Operations Manager

Enc

VIAMED

Viamed Limited · 15 Station Road · Cross Hills
Keighley · West Yorkshire · BD20 7DT · United Kingdom
Tel: +44 (0)1535 634542/636757 Fax: +44 (0)1535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk

INVESTIGATION INTO TOM THUMB UNIT G16.

THE FLOWMETER READS 1 LPM WHEN FULLY CLOSED.
THE FLOWMETER IS LOOSE AND CAN BE MOVED BY HAND.
THE PRESSURE GAUGE IS LOOSE AND CAN BE UNSCREWED BY HAND.
THE PRECISION VALVE IS OUT OF CALIBRATION AND REACHES 60 + cmWG.
WHEN THE FLOWMETER TAP IS PUSHED INWARDS THE PRESSURE DROPS INTERMITTENTLY.
THE FLOWMETER IS SLIGHTLY LEAKING AROUND THE BODY BLOCK CONNECTION WHEN TESTED WITH SNOOP FLUID.
THE FLOWMETER TAP FEELS LOOSE.
THE UNIT CANNOT REACH 50 cmWG WHEN FLOWMETER IS FULLY OPENED.

THE UNIT HAS NO APPARENT MAJOR DAMAGE BUT MAY HAVE BEEN DROPPED / SUBJECTED TO SHOCK ON THE FLOWMETER TAP.

WHEN TESTED THE UNIT FAILED IN 6 OUT OF 8 FEILDS.

Customer Complaint No. 119

MHRA Ref: 2004/002/005/401/886

The following report was conducted on the 18th March 2004

The report was conducted by: J. Brown – Technician

Serial Number G16

The Tom Thumb unit was returned from the customer on the 13th February 2004

Report

- The flowmeter reads "1Lpm" when fully closed.
- The flowmeter is loose, and can be rotated by hand.
- The pressure gauge is loose, and can be rotated by hand.
- The precision valve is out of calibration and reaches 60+ cmWG.
- When the flowmeter tap is pushed inwards, the pressure drops intermittently.
- The flowmeter is slightly leaking around the body block connection when tested with "Snoop" fluid.
- The flowmeter tap is loose, allowing to easy a movement.
- The unit cannot reach 50 cmWG, when the flowmeter is fully opened.

When tested, against the requirements on the calibration sheet QC33d, the unit failed in 6 out of the 8 fields.

CONCLUSION

The unit has no apparent major damage, but may have been dropped / subjected to shock, on the flowmeter tap

It would appear from the above findings that the unit has not undergone any service / maintenance, and general neglect has resulted in the above findings being apparent.

Kevin J. Rush
18th March 2004

VIAMED Ltd.
15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT, UK.
Website : www.viamed.co.uk. Email : info@viamed.co.uk.
Tel : +44 (0)1535 634542. Fax : +44 (0)1535 635542.

TOM THUMB CALIBRATION / TEST & Q.A. SHEET.

Description.	Tom Thumb.
Model.	TT 490-15.
Serial No.	G16
Time & Date of Calibration / Test.	18.03.04
Time & Date of QA.	

Do not start QA check within 1 hour of the calibration / test. Labelling is to be attached after calibration / test. Record the manometer reading in millibars below, ensuring the TT490-15 meets the limits specified.

Test Equipment	Test	Specification	Reading		P/F
			Cal	Q.A.	
Snoop liquid.	Check all ports / connections for leaks.	No bubbling.		N	F
CE 078.	Adjustable Valve : @ 15 Lpm	Minimum : ⩽ 8 cmH_2O.		3.7	P
CE 078.	Adjustable Valve : @ 15 Lpm.	Maximum : ⩾ 43 & ⩽ 47 cmH_2O.		45.2	P
CE 078.	Precision Valve : @ 15 Lpm.	Maximum : +3.0 cmH_2O over the adjustable valve setting.		60+	F
CE 078.	Pressure Gauge Test.	Pressure : @ 50 cmH_2O.		MAX 46.3	F
Visual check.	Gauge cannot be removed without tools.			N	F
Visual check.	Gauge appears straight.			N	F
Visual check.	All adjustable settings are set to a minimum.				
Visual check.	Labels are attached.	CE label.		X	F
		Viamed Flowmeter label.		✓	
		Serial No. label.		✓	
		Tom Thumb label		✓	

Calibration :

Signed : .....

Q.A check :

Signed : .....

TOM THUMB CALIBRATION / SERVICE SHEET.

ADDITIONS TO REPORT – INTERNAL INSPECTION

INSIDE BODY BLOCK IS FREE OF ANY MATTER.
ALL PORTS CLEAN AND FREE OF MATTER.
O-RINGS LOOK WORN BUT ARE INTACT INCLUDING THE ONES SITUATED INSIDE THE FLOWMETER TAP.
ADJUSTABLE VALVE MECHANISM IS VERY STIFF AND REQUIRES RE-GREASEING.
VALVE SEAT REQUIRES RE-GREASING
THREAD SEAL TAPE NEEDS REPLACING ON BLOW OFF VALVE, RIGHT ANGLE ADAPTOR AND OF HOSE.

UNIT WORKS BUT IS IN NEED OF A FULL SERVICE.

Fig 2

Fig 3

Fig 1

Fig 4

TT490 – Serial Number G16 – Complaint Number CCR 119

Pictorial Evidence

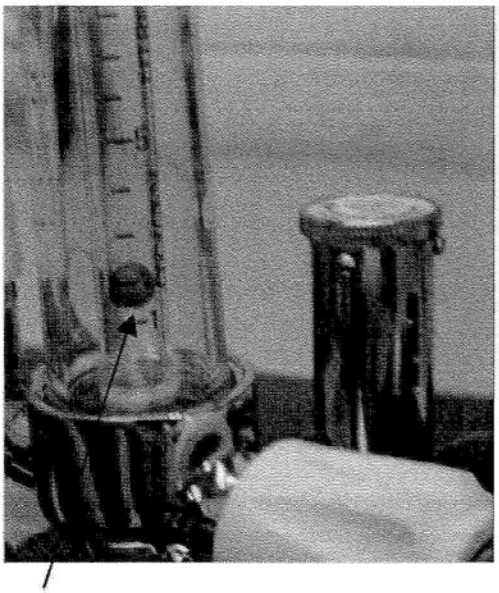


Figure 1

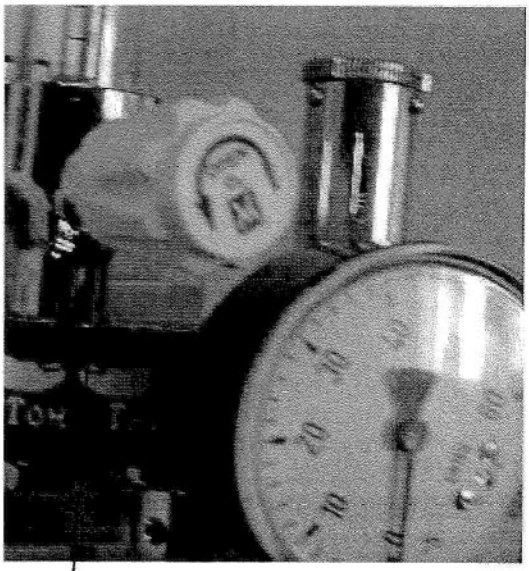


Figure 2

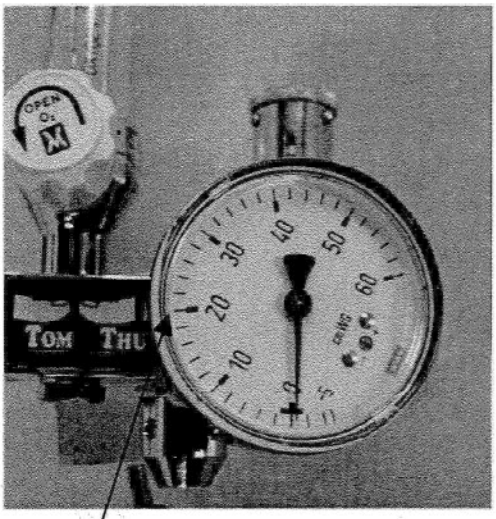


Figure 3

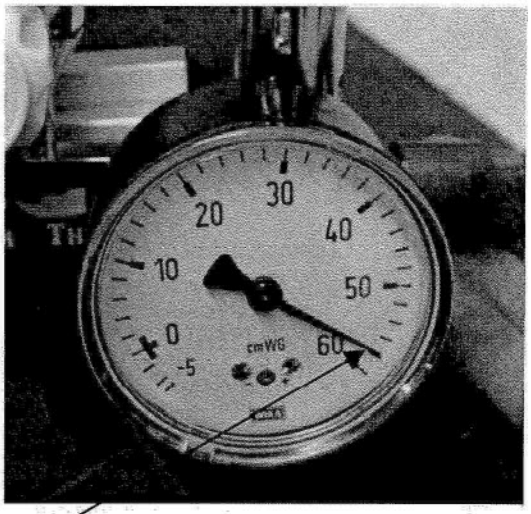


Figure 4

Mr R. Saunders
Unit Manager, Adverse Incident Centre
MHRA
Hannibal house
Elephant & Castle
London
SE1 6TQ

Re: MHRA Ref – 2004/002/005/401/886
Customer Complaint No. 119

Dear Mr Saunders,

The following report is the conclusions of Viamed in response to the original complaint as above.

The initial complaint was raised by Mr Peter Henry (12th Feb 2004), Clinical Technology, City General, Stoke-on-Trent. Telephone Number 01782 715444

The following report was conducted on the 18th March 2004

The report was conducted by: J. Brown – Technician

Serial Number G16 -

The Tom Thumb unit was returned from the customer on the 13th February 2004

Technical Report:

- The flowmeter reads "1 Lpm" when fully closed. (Fig 1)
- The flowmeter is loose, and can be rotated by hand. (Fig 2)
- The pressure gauge is loose, and can be rotated by hand. (Fig 3)
- The precision valve is out of calibration and reaches 60+ cmWG. (Fig 4)
- When the flowmeter tap is pushed inwards, the pressure drops intermittently.
- The flowmeter is slightly leaking around the body block connection when tested with "Snoop" fluid.
- The flowmeter tap is loose, allowing to easy a movement.
- The unit cannot reach 50 cmWG, when the flowmeter is fully opened.

When tested, against the requirements on the calibration sheet QC33d, the unit failed in 6 out of the 8 fields.

Service Report:

Upon internal inspection, during servicing, the following were noted:

- Inside the body block was free of any foreign matter.
- All the ports were clean and free of any foreign matter.
- The "O" – rings were worn but otherwise intact, including the "O" – rings situated inside the flowmeter tap.
- The adjustable valve mechanism was found to be very stiff and requires re-greasing.
- The blow-off valve, right angle adapter and the Oxygen hose require replacement PTFE tape.

The unit was found to be functioning but requires a full service, including parts, to bring it back into specification.

CONCLUSION

The unit has no apparent major damage, but may have been dropped / subjected to shock, on the flowmeter tap

It is assumed, from the above findings, that the unit may not have undergone any major service / maintenance, e.g. "O-ring" changes, since the flowmeter was replaced with one of 15 Lpm, approximately 4 years ago, and has possibly resulted in the above findings.

Kevin J. Rush
Regulatory Control
22nd March 2004

Approved

J.S. Lamb
Managing Director

P.S.
Sorry for the delay, the report had to have the final approval by J.S. Lamb

MHRA
Safeguarding public health

Medicines and Healthcare products Regulatory Agency

Hannibal House
Elephant and Castle, London SE1 6TQ

General enquiries
Telephone 020 7972 8000 Fax 020 7972 8108
E-mail devices@mhra.gsi.gov.uk
www.mhra.gov.uk

Direct line

Direct Fax

E-mail

16/02/2004

Mr J Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
BD20 7DT

MHRA Ref 2004/002/005/401/886
MHRA ADVERSE INCIDENT CENTRE (Direct Tel / Fax: 020 7972 8080 / 8109)

Dear Mr J Lamb

We have recently received the attached report from NORTH STAFFORDSHIRE HOSPITAL (DEPT OF CLINICAL TECHNOLOGY) (their ref:113679 (208/04)) concerning the following device:

Device ANAESTHETIC MACHINES & MONITORS
Item VENTILATOR
Model Tom thumb ventilator
Batch Number
Serial Number

Please could you investigate this matter and tell us of your findings and any action you propose taking, liaising with the reporter as necessary. We are content for them to release any samples or devices which may help your investigation. When requesting any samples, please could you show the reporter a copy of this letter. Our intention is to relay your response to the reporter. If you have any concerns about us doing so, please inform us as to what those concerns are, and we will consider them before deciding whether or not to share your response with the reporter.

Unless you have already done so in earlier correspondence with MHRA, could you please provide the following information for our ongoing risk analysis. Please provide answers as they become available: we realise that in some instances it will not be possible to provide accurate answers until the investigation is complete.

- is the device involved in this incident CE-marked under any of the medical devices Regulations?
- is the report relevant to any other CE-marked devices that you manufacture?
- have you received any similar reports involving this model in the UK / Europe / worldwide?
- how many of these devices have you sold in the last year in the UK / Europe / worldwide?
- (where applicable) has the analysis of the manufacturing records for this batch indicated any abnormalities?

If the investigation of the incident reveals problems that might lead to, or might have led to death, serious deterioration of health or a product recall, this will activate the vigilance procedures in the Medical Devices Directives. Other enforcement measures may also be necessary, depending on the nature and seriousness of the problem.

Yours sincerely

Mr R Saunders
Unit Manager, Adverse Incident Centre

Medicines and Healthcare products Regulatory Agency was created on 1 April 2003 from the merger of the Medical Devices Agency and the Medicines Control Agency.

tel 19/03/04 delay Explains

Head Office
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7273 0000 Fax 020 7273 0353
E-mail info@mhra.gsi.gov.uk

2004/c02/e05/401/886

MDA ADVERSE INCIDENT REPORT FORM

Origin of report	
If you are a member of the public please tick box: ☐ Member of the public If NOT please complete the details below:	
* Reporting Organisation (give details)	University Hospital of North Staffordshire
* Address	Department of Clinical Technology, City General Site, Newcastle Road, Stoke-on-Trent, Staffordshire, ST4 6QG
* Reporter's Name	Frank Smith
Position/Occupation	Deputy Operations Manager
Telephone Number	01782 552562
E-Mail	jane.stephens@uhns.nhs.uk This address will be used to send you a copy of the completed form.
Laboratory (If relevant)	
Prosthetic & Technician Service Co (If relevant)	
Local Reference Number	113679 (208/04)
Consultant in Charge (if known)	
This report confirms a	○ Telephone report ● Fax report ○ Neither

Type of "Injury" (tick one only)												
○ Fatality		○ Serious		○ Revision		○ Distress		○ Minor		● None		

Type of device (tick one only) ***Please note this will then take you to the relevant report form***

- ○ Joint prostheses excluding hip & knee (for hip & knee please see "H
- ○ Lasers & accessories
- ○ Magnetic resonance equipment & accessories
- ○ Mobile x-ray systems
- ○ Monitors & electrodes
- ○ Non-active implants
- ○ Ophthalmic equipment
- ○ Orthotics
- ○ Patient hoists
- ○ Patient monitoring equipment
- ○ Physiotherapy equipment
- ○ Prostheses - external limb
- ○ Resuscitators
- ○ Staples & staple guns
- ○ Stretchers
- ○ Surgical instruments
- ○ Surgical power tools
- ○ Sutures
- ○ Temporary pacing leads
- ○ Thermometers
- ○ Ultrasound equipment
- ○ Urinary catheters
- ● Ventilators
- ○ Walking sticks / frames
- ○ Wheeled Mobility & accessories including powered & non-powered v
- ○ Wound drains
- ○ X-ray equipment; systems & accessories
- ○ Intravenous catheters & cannulae
- ○ Other

- ○ Active implantable devices (general)
- ○ Administration & giving sets
- ○ Anaesthetic machines & monitors
- ○ Anaesthetic & breathing masks
- ○ Autoclaves
- ○ Bath aids
- ○ Beds & mattresses
- ○ Blood pressure measurement
- ○ Breast implants
- ○ Cardiovascular implants & devices
- ○ Commodes
- ○ Contact lenses & care products
- ○ CT systems
- ○ Dental materials & appliances
- ○ Dialysis equipment
- ○ Diathermy equipment & accessories
- ○ Dressings
- ○ Endoscopes & accessories
- ○ Endotracheal tubes & airways
- ○ Enteral feeding systems
- ○ External defibrillators
- ○ External Pacemakers
- ○ Feeding tubes
- ○ Gloves
- ○ Guidewires
- ○ Hip & Knee implants
- ○ Hypodermic syringes & needles
- ○ Implant materials
- ○ Implantable pacemakers/defibrillators & leads
- ○ In Vitro Diagnostic Medical Devices
- ○ Infant incubators
- ○ Infusion pumps; syringe drivers
- ○ Insulin syringes

GENERAL MEDICAL DEVICES

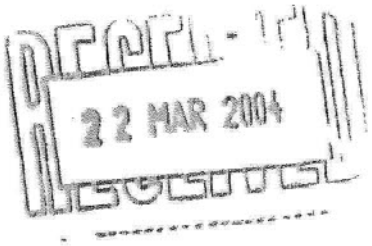
Details of device	
* Product	Tom Thumb Ventilator
Model	
Catalogue No	
Serial No	
* Manufacturer	NK
Manufacturer phone number	
Supplier	
Batch no.	
Date of manufacture	
Expiry date	
Quantity defective	1
Location of device now	
Is there a CE-Mark ?	○ Yes ○ No
If Yes, was the manufacturer or supplier contacted ?	○ Yes ○ No

Injury details
None

Nature of defect / details of incident	
Please see fax	
Contact name for further details	Frank Smith
Telephone number	01782 552562

Action taken by staff / manufacturer / supplier	
Please see fax	
I confirm that any necessary decontamination has been completed. PLEASE NOTE IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST.	
Method of decontamination	

MHRA
Safeguarding public health



Medicines and Healthcare products Regulatory Agency

Hannibal House
Elephant and Castle, London SE1 6TQ

General enquiries
Telephone 020 7972 8000 Fax 020 7972 8108
E-mail devices@mhra.gsi.gov.uk
www.mhra.gov.uk

Direct line

Direct Fax

E-mail

18/03/2004

Mr J Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
BD20 7DT

MHRA ADVERSE INCIDENT CENTRE (Direct Tel / Fax: 020 7972 8080 / 8109)

Dear Mr Lamb

Re: MHRA Ref 2004/002/005/401/886
Your Ref

We recently sent you a letter requesting that you investigate an incident reported by NORTH STAFFORDSHIRE HOSPITAL (DEPT OF CLINICAL TECHNOLOGY) (their ref:113679 (208/04)) and involving the following device:

Device ANAESTHETIC MACHINES & MONITORS
Item VENTILATOR
Model Tom thumb ventilator
Batch

According to our records, no final response has been received to date.

It is very important, for a number of reasons, that you reply as soon as possible so that we can complete our actions concerning this matter.

If you have already replied within the last few days please ignore this letter. If you have replied earlier than this, would you please send a copy of your letter to us at the address above.

Yours sincerely

pp

Mr R Saunders
Unit Manager, Adverse Incident Centre

PLEASE QUOTE OUR REFERENCE IN ANY REPLY

Copy for information :Frank Smith,NORTH STAFFORDSHIRE HOSPITAL (DEPT OF CLINICAL TECHNOLOGY)

Medicines and Healthcare products Regulatory Agency (MHRA):
Medicines and Healthcare products Regulatory Agency was created on 1 April 2003 from the merger of the Medical Devices Agency and the Medicines Control Agency.

Head Office
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7273 0000 Fax 020 7273 0353
E-mail info@mhra.gsi.gov.uk

29/03/2004

Mr R. Saunders
Unit Manager, Adverse Incident Centre
MHRA
Hannibal house
Elephant & Castle
London
SE1 6TQ

Re: MHRA Ref – 2004/002/005/401/886

Dear Mr Saunders,

In response to your letter dated 18/03/2004 with regard to the above reference, we have recently investigated the device in question and John Lamb has spoken to Mr Smith at the North Staffordshire Hospital regarding the outcome.

A complete report is currently being compiled and a copy will be forwarded to you on its completion.

Yours Sincerely

Kevin J. Rush
Systems Administrator

Mr R. Saunders
Unit Manager, Adverse Incident Centre
MHRA
Hannibal house
Elephant & Castle
London
SE1 6TQ

Re: MHRA Ref – 2004/002/005/401/886
Customer Complaint No. 119

Dear Mr Saunders,

The following report is the conclusions of Viamed in response to the original complaint as above.

The initial complaint was raised by Mr Peter Henry (12th Feb 2004), Clinical Technology, City General, Stoke-on-Trent. Telephone Number 01782 715444

The following report was conducted on the 18th March 2004

The report was conducted by: J. Brown – Technician

Serial Number G16 -

The Tom Thumb unit was returned from the customer on the 13th February 2004

Technical Report:

- The flowmeter reads "1 Lpm" when fully closed. (Fig 1)
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- The flowmeter tap is loose, allowing to easy a movement.
- The unit cannot reach 50 cmWG, when the flowmeter is fully opened.

When tested, against the requirements on the calibration sheet QC33d, the unit failed in 6 out of the 8 fields.

Service Report:

Upon internal inspection, during servicing, the following were noted:

- Inside the body block was free of any foreign matter.
- All the ports were clean and free of any foreign matter.
- The "O" – rings were worn but otherwise intact, including the "O" – rings situated inside the flowmeter tap.
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- The blow-off valve, right angle adapter and the Oxygen hose require replacement PTFE tape.

The unit was found to be functioning but requires a full service, including parts, to bring it back into specification.

CONCLUSION

The unit has no apparent major damage, but may have been dropped / subjected to shock, on the flowmeter tap

It is assumed, from the above findings, that the unit may not have undergone any major service / maintenance, e.g. "O-ring" changes, since the flowmeter was replaced with one of 15 Lpm, approximately 4 years ago, and has possibly resulted in the above findings.

Kevin J. Rush
Regulatory Control
22nd March 2004

Approved

J.S. Lamb
Managing Director

P.S.
Sorry for the delay, the report had to have the final approval by J.S. Lamb

cc JLAMB

MHRA

Safeguarding public health

Medicines and Healthcare products Regulatory Agency

Hannibal House
Elephant and Castle, London SE1 6TQ

General enquiries
Telephone 020 7972 8000 Fax 020 7972 8108
E-mail devices@mhra.gsi.gov.uk
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Direct line

Direct Fax

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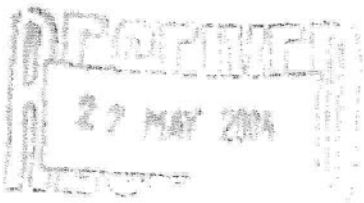
21/05/2004



Mr J Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
BD20 7DT

Your Ref 113679 (208/04) 119
MHRA Ref 2004/002/005/401/886

MHRA ADVERSE INCIDENT CENTRE (Direct tel / Fax: 020 7972 8080 / 8109)

Dear Mr J Lamb,

Thank you for your report in connection with the following device:

Device : ANAESTHETIC MACHINES & MONITORS
Item : VENTILATOR
Model :Tom thumb ventilator
Batch :
Serial Number :

So far as we are concerned, the file on this report is now closed. However, we shall continue to monitor the situation and would welcome details of any additional or similar incidents.

Many thanks for your help in bringing this matter to a conclusion.

Yours sincerely

pp

Mr R Saunders
Unit Manager, Adverse Incident Centre

PLEASE QUOTE OUR REFERENCE IN ANY REPLY

Medicines and Healthcare products Regulatory Agency (MHRA)
Medicines and Healthcare products Regulatory Agency was created on 1 April 2003 from the merger of the Medical Devices Agency and the Medicines Control Agency.

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