



Steve Hardaker <viamed.steve.hardaker@gmail.com>

Re: Incident in 2002

1 message

Steve Hardaker <steve.hardaker@viamed.co.uk>
Reply-To: steve.hardaker@viamed.co.uk
To: Janet Rennie <jmr@janetrennie.com>

23 May 2018 at 15:11

Dear Dr Rennie,

Thank you kindly for your response. Please find attached my summary of events for review.

Your name does appear in the report as a participant in the investigation at the time, however, this is an internal company document that will not be released externally and your name will not be attached to it other than in that context.

Under our ISO Quality Management system, we are required to document any adverse incidents that involve our products. Our external auditors (British Standards Institute) can request to see all of the documentation that we hold regarding our products and this information is handled confidentially. Our reporting methods are more robust now than they were 16 years ago and this is very much a housekeeping exercise in summarising the facts whilst we are still able to contact people who can substantiate them.

No further action will come of this, I just wanted to give you the opportunity to add any comments to my summary before it gets finalised in the event that I may have missed something. I was hoping that some detailed information might still exist, such as a copy of the original assessment that you made, but confirmation that it is no longer available is equally valued.

Thank you for your time and I look forward to hearing from you.

Regards,

Steve

Steve Hardaker
Technical Support Manager
Viamed Ltd.

Website: www.viamed.co.uk
email: steve.hardaker@viamed.co.uk
Tel: +44 (0)1535 634542
Fax: +44 (0)1535 635582

Sign up to our mailing list, go to www.viamed.co.uk/sign-up
Twitter: twitter.com/ViamedLtd
Facebook: facebook.com/ViamedLtdUK

Company registered in England, No. 1291765.
E-mail Disclaimer

The information in this email is confidential and may be legally privileged.

It is intended solely for the addressee. Access to this email by anyone else is unauthorized.

If you are not the intended recipient, any disclosure, copying, distribution or any action taken or omitted to be taken in reliance on it, is prohibited and may be unlawful.

If you feel you have received this email in error or would like to be removed from our mailing list, please reply with delete in the subject line or call +44 (0)1535 634542

On 23 May 2018 at 11:58, Janet Rennie <jmr@janetrennie.com> wrote:

Dear Mr Hardaker

Thanks for the e mail. I am happy to review your summary as long as my name does not get attached to it in any shape or form.

This incident was a long time ago and the papers have been destroyed, but my recollection matches with yours.

Kind regards

Janet Rennie

Dr Janet M Rennie MA MD DCH FRCP FRCPCH FRCOG

Consultant in Neonatal Medicine

Elizabeth Garrett Anderson Obstetric Wing

University College Hospital

2 North [250 Euston Rd](#)

[London NW1](#) 2PQ

Tel (mobile) 07787 503169

Tel (Hospital PA) 0207344 78094

e mail: jmr@janetrennie.com

e mail: janet.rennie@nhs.net

This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>



Incident at Royal Shrewsbury in August 2000 - 20180328.pdf
30K



Steve Hardaker <viamed.steve.hardaker@gmail.com>

Re: Incident in 2002

1 message

Steve Hardaker <steve.hardaker@viamed.co.uk>

23 May 2018 at 18:01

Reply-To: steve.hardaker@viamed.co.uk

To: Janet Rennie <jmr@janetrennie.com>

Dear Janet,

Thank you for your comments.

I deliberated whether to include the quotation from Dr Mohajer as I also found the comment to be inaccurate and misleading. The statement doesn't explicitly state that the correct resuscitation device should have been used and also implies that oxygen is delivered direct from the cylinder. I was also not comfortable with the use of the terminology "the correct amount of oxygen" as opposed to delivering oxygen at the correct PIP and flow rate.

I will remove that last quoted paragraph as it serves no purpose.

Thank you very much for your help; this is all that I need to close this off.

Regards,
Steve

Steve Hardaker
Technical Support Manager
Viamed Ltd.

Website: www.viamed.co.uk

email: steve.hardaker@viamed.co.uk

Tel: +44 (0)1535 634542

Fax: +44 (0)1535 635582

Sign up to our mailing list, go to www.viamed.co.uk/sign-up

Twitter: twitter.com/ViamedLtd

Facebook: facebook.com/ViamedLtdUK

Company registered in England, No. 1291765.

E-mail Disclaimer

The information in this email is confidential and may be legally privileged.

It is intended solely for the addressee. Access to this email by anyone else is unauthorized.

If you are not the intended recipient, any disclosure, copying, distribution or any action taken or omitted to be taken in reliance on it, is prohibited and may be unlawful.

If you feel you have received this email in error or would like to be removed from our mailing list, please reply with delete in the subject line or call +44 (0)1535 634542

On 23 May 2018 at 16:52, Janet Rennie <jmr@janetrennie.com> wrote:

Thanks – I am happy with this which is factual account.

If the Tom Thumb device had been in the circuit as was intended, the pressure of oxygen from the wall supply would have been limited and the baby would not have died – of extensive air leaks. The circuit was bypassed. I seem to remember we had some photographs taken by Dr Bob Welch when he arrived on the scene. I no longer have anything relating to this case.

The RCPCH resuscitation booklet did specifically warn of the dangers of not resuscitating babies with oxygen which had not been passed through a pressure limiting device. Sadly this is not the only case I've advised on where this has happened.

Dr Mohajer is an obstetrician, not a neonatologist. She is not right – oxygen should never be given direct from a cylinder either. It would be best if this quote was removed because it is not accurate.

Kind regards

Janet

From: Main Account [mailto:viamedinbox@gmail.com] **On Behalf Of** Steve Hardaker
Sent: 23 May 2018 15:11
To: Janet Rennie
Subject: Re: Incident in 2002

Dear Dr Rennie,

Thank you kindly for your response. Please find attached my summary of events for review.

Your name does appear in the report as a participant in the investigation at the time, however, this is an internal company document that will not be released externally and your name will not be attached to it other than in that context.

Under our ISO Quality Management system, we are required to document any adverse incidents that involve our products. Our external auditors (British Standards Institute) can request to see all of the documentation that we hold regarding our products and this information is handled confidentially. Our reporting methods are more robust now than they were 16 years ago and this is very much a housekeeping exercise in summarising the facts whilst we are still able to contact people who can substantiate them.

No further action will come of this, I just wanted to give you the opportunity to add any comments to my summary before it gets finalised in the event that I may have missed something. I was hoping that some detailed information might still exist, such as a copy of the original assessment that you made, but confirmation that it is no longer available is equally valued.

Thank you for your time and I look forward to hearing from you.

Regards,

Steve

Steve Hardaker
Technical Support Manager
Viamed Ltd.

Website: www.viamed.co.uk
email: steve.hardaker@viamed.co.uk
Tel: +44 (0)1535 634542
Fax: +44 (0)1535 635582

Sign up to our mailing list, go to www.viamed.co.uk/sign-up

Twitter: twitter.com/ViamedLtd

Facebook: facebook.com/ViamedLtdUK

Company registered in England, No. 1291765.

E-mail Disclaimer

The information in this email is confidential and may be legally privileged.
It is intended solely for the addressee. Access to this email by anyone else is unauthorized.
If you are not the intended recipient, any disclosure, copying, distribution or any action taken or omitted to be taken in reliance on it, is prohibited and may be unlawful.

If you feel you have received this email in error or would like to be removed from our mailing list, please reply with delete in the subject line or call +44 (0)1535 634542

On 23 May 2018 at 11:58, Janet Rennie <jmr@janetrennie.com> wrote:

Dear Mr Hardaker

Thanks for the e mail. I am happy to review your summary as long as my name does not get attached to it in any shape or form.

This incident was a long time ago and the papers have been destroyed, but my recollection matches with yours.

Kind regards

Janet Rennie

Dr Janet M Rennie MA MD DCH FRCP FRCPCH FRCOG

Consultant in Neonatal Medicine

Elizabeth Garrett Anderson Obstetric Wing

University College Hospital

2 North [250 Euston Rd](#)

[London NW1](#) 2PQ

Tel (mobile) 07787 503169

Tel (Hospital PA) 0207344 78094

e mail: jmr@janetrennie.com

e mail: janet.rennie@nhs.net

This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>

This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>

This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>



Steve Hardaker <viamed.steve.hardaker@gmail.com>

RE: Incident in 2002

1 message

Janet Rennie <jmr@janetrennie.com>

23 May 2018 at 16:52

To: "steve.hardaker@viamed.co.uk" <steve.hardaker@viamed.co.uk>

Thanks – I am happy with this which is factual account.

If the Tom Thumb device had been in the circuit as was intended, the pressure of oxygen from the wall supply would have been limited and the baby would not have died – of extensive air leaks. The circuit was bypassed. I seem to remember we had some photographs taken by Dr Bob Welch when he arrived on the scene. I no longer have anything relating to this case.

The RCPCH resuscitation booklet did specifically warn of the dangers of not resuscitating babies with oxygen which had not been passed through a pressure limiting device. Sadly this is not the only case I've advised on where this has happened.

Dr Mohajer is an obstetrician, not a neonatologist. She is not right – oxygen should never be given direct from a cylinder either. It would be best if this quote was removed because it is not accurate.

Kind regards

Janet

From: Main Account [mailto:viamedinbox@gmail.com] **On Behalf Of** Steve Hardaker

Sent: 23 May 2018 15:11

To: Janet Rennie

Subject: Re: Incident in 2002

Dear Dr Rennie,

Thank you kindly for your response. Please find attached my summary of events for review.

Your name does appear in the report as a participant in the investigation at the time, however, this is an internal company document that will not be released externally and your name will not be attached to it other than in that context.

Under our ISO Quality Management system, we are required to document any adverse incidents that involve our products. Our external auditors (British Standards Institute) can request to see all of the documentation that we hold regarding our products and this information is handled confidentially. Our reporting methods are more robust now

than they were 16 years ago and this is very much a housekeeping exercise in summarising the facts whilst we are still able to contact people who can substantiate them.

No further action will come of this, I just wanted to give you the opportunity to add any comments to my summary before it gets finalised in the event that I may have missed something. I was hoping that some detailed information might still exist, such as a copy of the original assessment that you made, but confirmation that it is no longer available is equally valued.

Thank you for your time and I look forward to hearing from you.

Regards,

Steve

Steve Hardaker
Technical Support Manager
Viamed Ltd.

Website: www.viamed.co.uk
email: steve.hardaker@viamed.co.uk
Tel: +44 (0)1535 634542
Fax: +44 (0)1535 635582

Sign up to our mailing list, go to www.viamed.co.uk/sign-up

Twitter: twitter.com/ViamedLtd

Facebook: facebook.com/ViamedLtdUK

Company registered in England, No. 1291765.

E-mail Disclaimer

The information in this email is confidential and may be legally privileged.

It is intended solely for the addressee. Access to this email by anyone else is unauthorized.

If you are not the intended recipient, any disclosure, copying, distribution or any action taken or omitted to be taken in reliance on it, is prohibited and may be unlawful.

If you feel you have received this email in error or would like to be removed from our mailing list, please reply with delete in the subject line or call +44 (0)1535 634542

On 23 May 2018 at 11:58, Janet Rennie <jmr@janetrennie.com> wrote:

Dear Mr Hardaker

Thanks for the e mail. I am happy to review your summary as long as my name does not get attached to it in any shape or form.

This incident was a long time ago and the papers have been destroyed, but my recollection matches with yours.

Kind regards

Janet Rennie

Dr Janet M Rennie MA MD DCH FRCP FRCPCH FRCOG

Consultant in Neonatal Medicine

Elizabeth Garrett Anderson Obstetric Wing

University College Hospital

2 North [250 Euston Rd](#)

[London NW1 2PQ](#)

Tel (mobile) 07787 503169

Tel (Hospital PA) 0207344 78094

e mail: jmr@janetrennie.com

e mail: janet.rennie@nhs.net

This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>

This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>

This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>



Steve Hardaker <viamed.steve.hardaker@gmail.com>

Incident in 2002

1 message

Janet Rennie <jmr@janetrennie.com>

23 May 2018 at 11:58

To: "steve.hardaker@viamed.co.uk" <steve.hardaker@viamed.co.uk>

Dear Mr Hardaker

Thanks for the e mail. I am happy to review your summary as long as my name does not get attached to it in any shape or form.

This incident was a long time ago and the papers have been destroyed, but my recollection matches with yours.

Kind regards

Janet Rennie

Dr Janet M Rennie MA MD DCH FRCP FRCPCH FRCOG

Consultant in Neonatal Medicine

Elizabeth Garrett Anderson Obstetric Wing

University College Hospital

2 North [250 Euston Rd](#)

[London NW1 2PQ](#)

Tel (mobile) 07787 503169

Tel (Hospital PA) 0207344 78094

e mail: jmr@janetrennie.com

e mail: janet.rennie@nhs.net

This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>



Steve Hardaker <viamed.steve.hardaker@gmail.com>

Incident investigation from 2002

1 message

Steve Hardaker <steve.hardaker@viamed.co.uk>

22 May 2018 at 17:24

Reply-To: steve.hardaker@viamed.co.uk

To: janet.rennie@nhs.net

Dear Dr Rennie,

I apologise for the unsolicited contact after such a long period of time but I am currently reviewing the technical files for the Viamed Tom Thumb infant resuscitator in accordance with the requirements of the latest ISO standards and I am hoping that you can offer some vital information from many years ago.

You will recall, I'm sure, the distressing incident that occurred in August 2000 at Royal Shrewsbury Hospital involving the fatality of a newborn during a failed resuscitation attempt.

At that time, I sent you a Tom Thumb TT480 infant resuscitator at the request of a DS Andrews of West Mercia CID for you to assess in your expert capacity.

We understand that the Tom Thumb was exonerated from direct involvement in the fatality as it had been bypassed from the system and a higher pressure oxygen source had been used in its place, however, I have been unable to locate a report or formal communication that substantiates this in writing; I only have text summaries of phone calls and newspaper reports retrieved after the inquest.

My question is whether you would be so kind as to review my summary of the incident as viewed from Viamed's perspective (condensed to a single side of A4) and offer any comments or clarification that you see fit.

I do not wish to send this if you are unwilling or professionally able to respond but, if you would like to comment, with your permission I would like to forward the summary.

I should stress that there is no legal connotation to this request; this is a technical exercise to update our product files to show the results of any and all investigations in which the Tom Thumb was involved, and the more information that we have, the better.

Please could I ask that you kindly acknowledge receipt of my email, even if your response to my request is negative. Thank you in advance and I look forward to hearing from you.

Regards,

Steve Hardaker
Technical Support Manager
Viamed Ltd.

Website: www.viamed.co.uk

email: steve.hardaker@viamed.co.uk

Tel: +44 (0)1535 634542

Fax: +44 (0)1535 635582

Sign up to our mailing list, go to www.viamed.co.uk/sign-up

Twitter: twitter.com/ViamedLtd

Facebook: facebook.com/ViamedLtdUK

Company registered in England, No. 1291765.

E-mail Disclaimer

The information in this email is confidential and may be legally privileged.

It is intended solely for the addressee. Access to this email by anyone else is unauthorized.

If you are not the intended recipient, any disclosure, copying, distribution or any action taken or omitted to be taken in reliance on it, is prohibited and may be unlawful.

If you feel you have received this email in error or would like to be removed from our mailing list, please reply with delete in the subject line or call +44

