Medicines and Healthcare Products Regulatory Agency

Dr Andrew Harris
Coroner for Inner South District Greater London
Southwark Coroner's Court
1 Tennis Street
Southwark
London SE1 1YD

Dr Ian Hudson
151 Buckingham Palace Road
Victoria
London SW1W 9SZ
United Kingdom

Telephone
+44 (0)20 3080 6100
Email
[redacted]
mhra.gov.uk

Your ref: 2648-11
My ref: 13445

14 April 2014

Dear Dr Harris

Regulation 28 Report: William Arthur Brockett-Deakins (deceased)

Thank you for your Regulation 28 report of 26 February which we received on 3 March 2014. Here is my reply to your Matters of Concern (3):

This incident occurred in 2007 and it was not reported to MHRA by Guy's and St Thomas' NHS Trust or any other organisation.

As the make and model of the cardiotocograph (CTG) device was not specified in your report, we asked your Officer, [redacted] on 11/3/2014 if this detail was known. [redacted] informed us on 28/3/2014 that the CTG model in use was a M1353A. This was a popular model of CTG machine and was placed on the market by Philips Healthcare and sold in the UK between 1992 and 2006.

We contacted Philips Healthcare to establish if they were made aware of this incident at the time and if so, whether they had inspected the device to confirm it was working correctly. Philips Healthcare found no notification of this incident in their records thus they did not inspect the device.

One of our predecessor Agencies, The Medical Devices Agency (MDA), published and disseminated a Safety Notice to relevant healthcare professionals in August 2002, warning of the risks associated with the interpretation of CTG traces. This Safety Notice, **MDA SN2002(23)**, was extant in 2007 and a copy is appended to this letter.

This Safety Notice was an update to earlier advice as adverse incident reports received by the MDA in 2002 indicated that CTGs were still being incorrectly relied upon to monitor foetal heart rate. Five reports were received in 2002 where CTGs had produced an apparently normal trace during labour but the baby was delivered stillborn. In all these cases the baby had been dead for a number of hours. Two cases showed values of twice the maternal heart rate (MHR x 2) and three cases showed values of one and half times the maternal heart rate (MHR x 1.5), although there has been some dispute as to the source of these signals. It is however well known that CTGs can display twice the maternal heart rate (MHR x 2) and half the foetal heart rate (FHR ÷2).

However, MHR multiplied by one and a half is a confusing artefact that can be difficult to recognise. It appears that when there is no foetal heart beat the CTG may respond to a weak signal derived from a combination of the maternal aorta, iliac and uterine arteries.

Our advice on CTG use was revised in 2010 to become MDA 2010/054, and is our current advice.

The reference to the MHR x 1.5 artefact was removed from MDA 2010/054 as there had been no further reports received since SN2002(23) was published.

Modern CTG units now incorporate maternal ECG or pulse oximetry functions and many have prompts to double-check if readings of MHR x 2 occur. It is possible that some older units remain in clinical use but there is insufficient evidence provided by users and manufacturers for MHRA to advise that they should be removed from use.

In June 2013, MHRA published a special maternity edition of 'One Liners', which again highlighted the issues of interpreting CTG readings.

For information, the National Institute for Health and Care Excellence (NICE) guidance on intrapartum care was also updated in 2007, (CG55, - section 1.12)

http://publications.nice.org.uk/intrapartum-care-cg55/guidance#16-normal-labour-first-stage

I hope this information gives you the assurance that we have appropriate safety advice available to those using CTG medical devices.

Yours sincerely,

Dr Ian Hudson
Chief Executive

MDA SN2002(23)
August 2002

MEDICAL DEVICES AGENCY

SAFETY

NOTICE

Cardiotocograph (CTG) monitoring of fetus during labour — update

MANUFACTURER / SUPPLIER
Various

PROBLEM
A number of stillbirths have occurred in the presence of CTG traces interpreted as being normal. This caused distress for the mothers and clinical staff involved.

For the attention of:

NHS Trusts (England)	— Chief Executives
National Care Standards Commission	— Headquarters
Primary Care Trusts (England)	— Chief Executives

ACTION
Users should be aware that in the presence of a dead fetus the CTG may still display a tracing apparently from the fetus and within the normal heart rate range. In order to minimise this possibility users should take the following actions:-

Before Use
Establish the presence of a fetal heartbeat by auscultation, before starting CTG monitoring, by using a Pinard stethoscope [and before re-connection after a break in monitoring].

- If there are any indications of a problem (mother reports no fetal movements, difficulty with auscultation), ultrasound imaging should be used to establish the condition of the fetus.
- Users must read the manufacturer's instructions and use the monitor in accordance with those instructions.

During Use
Record maternal pulse rate regularly and check that it is different from the fetal heart rate (**FHR**).

- Compare the recorded maternal pulse rate with the CTG display and chart.
- Compare the actual maternal pulse with the sound from the loudspeaker.
- If the maternal pulse is synchronised with the sound from the loudspeaker, the CTG is monitoring maternal heart rate (**MHR**).
- Be aware that the CTG may be displaying a "doubled" **MHR** (80 x 2 = 160 bpm), or "half" **FHR** (150÷2 = 75 bpm).
- Fetal scalp electrodes are considered to be more reliable than ultrasonic transducers, although there is still a need to confirm that **FHR** is being correctly displayed.
- Categorise **FHR** trace as a whole, with reference to individual features and the clinical picture. (For further information see 'Clinical Practice Algorithm' within NICE Clinical Guideline).
- If there are any problems establishing or confirming a fetal heartbeat then treat CTG displays with caution.
- If in doubt, consult clinical colleagues.

SAFETY

NOTICE

DISTRIBUTION REQUIRED

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution by:

TRUSTS to:

- Liaison Officers (for onward distribution)
- Consultant Obstetricians
- Directors of Midwifery
- Midwifery Managers and Supervisors
- Medical and Midwifery staff
- Community Midwives
- Clinical Risk Managers
- Biomedical Engineering staff

NATIONAL CARE STANDARDS COMMISSION to:

- Headquarters (for onward distribution)
- Hospitals in the Independent Sector

PRIMARY CARE TRUSTS to:

- Liaison Officers (for onward distribution)
- Community Midwives
- General Practitioners

BACKGROUND

Further to the publication of Safety Notice MDA SN 9813 in March 1998 and the CTG Poster earlier this year (see Appendix) additional reports indicate that there is still a problem with the use of cardiotocographs.

Cardiotocographs monitor the fetal heart rate in relation to maternal contractions. They assist in the management of labour, but should not be relied upon to diagnose the condition of the fetus.

Five reports have been received this year where CTG machines have produced an apparently normal trace during labour and the baby was delivered stillborn. In all these cases the baby had been dead for a number of hours. Two cases showed values of MHR x 2 and three showed values of MHR x 1.5, although there is some dispute as to the source of these signals.

It is known that CTGs can display double the maternal heart rate (MHR x 2) and half the fetal heart rate (FHR ÷2). However, MHR multiplied by one and a half is a confusing artefact that is difficult to recognise.

CTGs use a low power ultrasound Doppler signal to detect movement within the mother's abdomen. The fetal heartbeat is a weak signal in a noisy environment. Signal processing techniques are used to extract a periodic/repetitive signal. In the majority of cases the FHR is correctly displayed and accelerations and decelerations are faithfully reproduced.

However, it would appear that when there is no fetal heart beat the CTG may respond to a weak signal derived from a combination of the maternal aorta, iliac and uterine arteries. The resulting trace shows reactivity and variability due to maternal heart rate changes and muscle contractions. This condition only occurs in a small number of stillbirths but causes distress for all those involved.

FURTHER GUIDANCE

National Institute for Clinical Excellence – The Use of Electronic Fetal Monitoring, Clinical Guideline: NICE May 2001. Web: www.nice.org.uk

Royal College of Obstetricians and Gynaecologists – The Use of Electronic Fetal Monitoring: RCOG May 2001. Web: www.rcog.org.uk

Medical Devices Agency – Cardiotocograph (CTG) monitoring of foetus during labour, Safety Notice: MDA SN 9813 March 1998.

Medical Devices Agency – Poster Cardiotocographs CTGs April 2002: A4 size copies can be downloaded from our website at www.medical-devices.gov.uk and A3 size posters are available by request. Please email Caroline.Ainsworth@doh.gsi.gov.uk or telephone 020 7972 8127.

SAFETY

NOTICE

ENQUIRIES

Enquires to the MDA should quote reference number **20020523.005-3** and be addressed to:

Technical aspects
Mr G R Smith or Mr R A Glover
Medical Devices Agency
Hannibal House
Elephant and Castle
London SE1 6TQ

Tel: 020 7972 8198 or 020 7972 8245 respectively
Fax: 020 7972 8106

Email: Geoff.Smith@doh.gsi.gov.uk
Richard.Glover@doh.gsi.gov.uk

Clinical aspects:
Dr S Ludgate
Medical Devices Agency
Hannibal House
Elephant & Castle
London SE1 6TQ

Tel: 020 7972 8123
Fax: 020 7972 8111

Email: Susanne.Ludgate@doh.gsi.gov.uk

HOW TO REPORT ADVERSE INCIDENTS

Incidents relating to medical devices must be reported to the Medical Devices Agency as soon as possible.

Further information about: reporting incidents; on-line incident reporting facilities (introduced during September 2001); and downloadable report forms is available from MDA's website (http://www.medical-devices.gov.uk).

Alternatively, further information and printed incident report forms are available from:
MDA Adverse Incident Centre
Medical Devices Agency, Hannibal House, Elephant & Castle, London SE1 6TQ
Telephone 020 7972 8080 or Fax 020 7972 8109
or e-mail: mb-mda-aic@doh.gsi.gov.uk
(An answerphone service operates outside normal office hours)

From January 2000, MDA Safety Warnings have been available in full text on the MDA Internet site: http://www.medical-devices.gov.uk/

MDA is an Executive Agency of the Department of Health

APPENDIX

Cardiotocographs CTGs

Cardiotocographs (CTGs) monitor the fetal heart rate in relation to maternal contractions. Some CTGs have the potential for confusing fetal and maternal heart rates and this may lead to fetal problems going unnoticed.

Before Use

Establish the presence of a fetal heartbeat by auscultation before starting CTG monitoring by using either a Pinard stethoscope or hand held Doppler ultrasound device.

- If there are any indications of a problem (mother reports no fetal movement, difficulty with auscultation), ultrasound scanning should be used to establish the health of the fetus.
- Users must read the manufacturer's instructions and use the monitor in accordance with those instructions.

Further Guidance

National Institute for Clinical Excellence – *Clinical Guideline: Electronic Fetal Monitoring*, Clinical Guideline: NICE May 2001. Website: www.nice.org.uk

Medical Devices Agency – *Cardiotocograph (CTG) monitoring of foetus during labour*, Safety Notice: MDA SN 9813 March 1998.

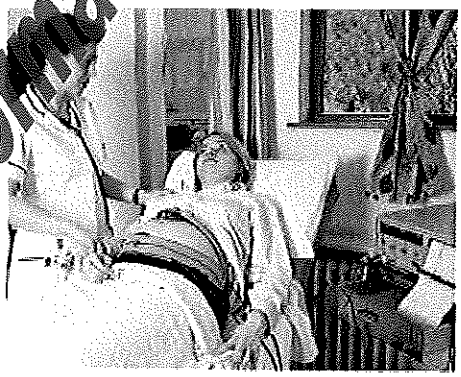
Published by the Medical Devices Agency – an executive agency of the Department of Health
For technical or safety related information on any medical device, see our website: www.medical-devices.gov.uk

MDA MEDICAL DEVICES AGENCY

Safeguarding Public Health

During Use

Record maternal pulse rate regularly and check that it is different from the fetal heart rate (FHR).



- Compare the recorded maternal pulse rate with the CTG display and chart.
- Compare the actual maternal pulse with the sound from the loudspeaker.
- If the maternal pulse is synchronised with the sound from the loudspeaker, the CTG is monitoring maternal heart rate (**MHR**).
- Be aware that the CTG may be displaying a 'doubled' **MHR** (80 x 2 = 160 bpm), or 'half' **FHR** (150÷2 = 75 bpm).
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- If there are any problems establishing or confirming a fetal heartbeat then treat CTG displays with caution.
- If in doubt, consult clinical colleagues.