

FIELD SAFETY NOTICE ALERT

Team3 Fetal Monitor

Product affected by this notice :

Product Name(s):	TEAM3A & TEAM3I
Affected Serial Numbers:	All
Order / Ident Codes (DI):	See appendix 1 for all variants
Product First Sold:	October 2016

GMDN:	37796
EMDN:	Z12080101
SRN:	SE-MF-00000696
Basic UDI-DI:	5060693520389WY
510k/Clearance Number:	K200975/D410520
HC License number:	104905 (Antepartum) & 104907 (Intrapartum)
ARTG Identifier:	116216

Resolution in summary:	Upgrade Fetal Monitor with revised software (v19.4.1)
No pages:	15 inclusive of the declaration form

FSN01-23 Rev 2

Date of 1st issue: 3rd April 2023

Revised: 25th April 2023

HUNTLEIGH

A MEMBER OF THE ARJO FAMILY

To whom it may concern;

We are contacting you to provide information regarding an update to the recently launched Field Safety Corrective Action.

It has come to our attention that while the upgrade to version 19.4 software has been successful in the vast majority of cases, we have identified an issue when upgrading some units. The issue occurs when a large amount of data has been retained in the TEAM3 Patient database, resulting in the unit resetting when the database is searched.

As a solution to this issue and to compensate for the large amount of data being retained, a minor software update (Patch) has been developed. As a result of this development, the upgrade process will need to be completed using the revised Software (version 19.4.1).

Please be aware that retaining a large amount of Patient records on the TEAM3 will decrease the systems optimum performance and slow down the Patient input command response rate.

It is recommended that the Team3 uses an archiving system as this will facilitate the management of Patient files without compromising the performance of the Team3.

The revised software - 19.4.1 is available through the same channels as the previous version and is described in full as follows;

Description of problem;

Huntleigh Healthcare Ltd has become aware of a software vulnerability, which manifests itself with the fetal monitor's touch screen freezing. This freeze disables the functions that are being displayed. Whilst the occurrence of this vulnerability is extremely rare and audio remains present throughout the screen freeze, user intervention is required to restart the fetal monitor.

Risk based approach;

Through discussions with the UK competent authority (MHRA) it has been agreed to remove the necessity for user intervention by automatically restarting the fetal monitor when the device detects any power loss and/or interference. The automatic restart will reinstate all functions/features and settings. The restart will appear as a normal ON/OFF action and will take approximately 20 seconds from start to finish with the action noted on the CTG trace as well as a transient note on the touch screen.

Please note that Dawes Redman CTG analysis will reset to the beginning of the analysis after the system automatically restarts.

Actions to be taken by the User and/or Distributor;

It is important that the Patient database is managed with content of database kept to a minimum. A software upgrade – V19.4.1 - must be installed on the TEAM3 Fetal Monitors listed in Appendix 1. This upgrade will be available to download from the Huntleigh Healthcare website (<https://www.huntleigh-diagnostics.com/Team3Upgrade19.4.1>) together with clear instructions on how to install the software on the fetal monitor.

Appendix 2 also details instructions regarding the software download and installation.

Note: If you experience problems in down loading the software from the website, a prepared memory stick can be made available and delivered upon request.

Huntleigh Healthcare Limited
35 Portmanmoor Road
Cardiff CF24 5HN
United Kingdom

Phone: +44 (0)29 2048 5885
Fax: +44 (0)29 2049 2520
Email: sales@huntleigh-diagnostics.co.uk
www.huntleigh-diagnostics.com

VAT Reg: GB 382 474 630
Registered No: 942245 England & Wales.
Registered Office: ArjoHuntleigh House,
Houghton Hall Business Park, Houghton Regis,
Bedfordshire, LU5 5XF

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Once the upgrade is complete on all devices within your facility, please return the completed Declaration (refer to Appendix 3) to: FSN01-23HHL@Arjo.com.

Transmission of Field Safety Notice;

Please ensure that this notice is circulated to all appropriate personnel.

Patient safety and customer satisfaction are of paramount importance to Huntleigh Healthcare Ltd and we regret the obvious inconvenience that this notice will cause.

Contact

Please do not hesitate to contact the following personnel should you have any further questions or require any assistance:

QRE Director	Email: steve.monks@arjo.com	Tel: +44 (0) 2920485885 Ext: 7107
Complaints Specialist	Email: michael.James@arjo.com	Tel: +44 (0) 2920485885 Ext: 7016
Service Manager (Gary Newton)	Email: TeamUpgrade-HHL.UKCAR@arjo.com	Tel: +44 (0) 2920485885 Ext: 7112
Product Management	Email: David.dobbs@arjo.com	Tel: +44 (0) 2920485885

Sincerely,



Mike Thompson
Managing Director



Steve Monks
QRE Director

Document Introduction/Revision History

Rev.	Date	Description of Introduction/revision	Compiled By
1	03/04/2023	Introduction of FSN.	S. Monks
2	25/04/2023	Informed user of the need to repeat upgrade using v19.4.1. Noted the importance of managing the Patient database. Also clarified the preferred capacity of Memory stick (4GB to 8GB)	S. Monks

Appendix 1

List of Products Affected by Field Safety Notice

Item	Description	Device Identifier
OBIX IM2	TEAM3 INTRAPARTUM/PRINTER+NIBP+SPO2+EMHR-TWINS	05051968041234
OBIX IM3	TEAM3 INTRAPARTUM/PRINTER+NIBP+SPO2+EMHR-TRIPLETS	05051968040985
TEAM3A	ANTEPARTUM/PRINTER	05051968032485
TEAM3A 3	ANTEPARTUM/PRINTER-TRIPLETS	05051968035196
TEAM3A B	ANTEPARTUM/PRINTER+BATTERY	05051968032492
TEAM3A E	ANTEPARTUM/ECTG	05051968032508
TEAM3A N	ANTEPARTUM/PRINTER+NIBP	05051968032522
TEAM3A S	ANTEPARTUM/PRINTER+SPO2	05051968032560
TEAM3A B3	ANTEPARTUM/PRT+BATTERY-TRIPLETS	05051968035202
TEAM3A E3	ANTEPARTUM/ECTG-TRIPLETS	05051968035219
TEAM3A EB	ANTEPARTUM/ECTG+BAT	05051968032515
TEAM3A ENS	TEAM3 ANTEPARTUM +NIBP + SPO2,NO PRINTER	05051968039842
TEAM3A N3	ANTEPARTUM/PRT+NIBP-TRIPLETS	05051968035233
TEAM3A NB	ANTEPARTUM/PRINTER+NIBP+BAT	05051968032539
TEAM3A NS	ANTEPARTUM/PRINTER+NIBP+SPO2	05051968032546
TEAM3A S3	ANTEPARTUM/PRINTER+SPO2-TRIPLETS	05051968035271
TEAM3A SB	ANTEPARTUM/PRINTER+SPO2+BAT	05051968032577
TEAM3A EB3	ANTEPARTUM/ECTG+BAT-TRIPLETS	05051968035226
TEAM3A NB3	ANTEPARTUM/PRT+NIBP+BAT-TRIPLETS	05051968035240
TEAM3A NS3	ANTEPARTUM/PRT+NIBP+SPO2-TRIPLETS	05051968035257
TEAM3A NSB	ANTEPARTUM/PRINTER+NIBP+SPO2+BAT	05051968032553
TEAM3A SB3	ANTEPARTUM/PRT+SPO2+BAT-TRIPLETS	05051968035288
TEAM3A ENSB	TEAM3 ANTEPARTUM +NIBP + SPO2 + BATTERY,NO PRINTER	05051968039859
TEAM3A NSB3	ANTEPARTUM/PRT+NIBP+SPO2+BAT-TRIP	05051968035264
TEAM3G1	ANTEPARTUM/PRINTER/BASIC/SINGL	05051968033192
TEAM3G1-ECTG	ANTEPARTUM/ECTG/BASIC/SINGL	05051968033208
TEAM3G2	TEAM 3A BASIC	05051968033093
TEAM3G2-ECTG	TEAM 3A ECG BASIC	05051968033109
TEAM3I	INTRAPARTUM/PRINTER	05051968032584
TEAM3I 3	INTRAPARTUM/PRINTER-TRIPLETS	05051968035295
TEAM3I B	INTRAPARTUM/PRINTER+BATTERY	05051968032591
TEAM3I N	INTRAPARTUM/PRINTER+NIBP	05051968032997
TEAM3I S	INTRAPARTUM/PRINTER+SPO2	05051968033017
TEAM3I B3	INTRAPARTUM/PRINTER+BAT-TRIPLETS	05051968035301
TEAM3I N3	INTRAPARTUM/PRINTER+NIBP-TRIPLETS	05051968035318
TEAM3I NB	INTRAPARTUM/PRINTER+NIBP+BATTERY	05051968033000
TEAM3I NS	INTRAPARTUM/PRINTER+NIBP+SPO2	05051968033031
TEAM3I S3	INTRAPARTUM/PRINTER+SPO2-TRIPLETS	05051968035356

Item	Description	Device Identifier
TEAM3I SB	INTRAPARTUM/PRINTER+SPO2+BATTERY	05051968033024
TEAM3I NB3	INTRAPARTUM/PRT+NIBP+BAT-TRIPLETS	05051968035325
TEAM3I NS3	INTRAPARTUM/PRT+NIBP+SPO2-TRIPLET	05051968035332
TEAM3I NSB	INTRAPARTUM/PRINTER+NIBP+SPO2+BATTERY	05051968032980
TEAM3I SB3	INTRAPARTUM/PRT+SPO2+BAT-TRIPLETS	05051968035363
TEAM3I NSB3	INTRAPARTUM/PRT+NIBP+SOP2+BAT-TRI	05051968035349
TEAM3A ENM	ANTE/ECTG+NIBP+SPO2NEL	05051968041920
TEAM3A NM	ANTE/PRINT+NIBP+SPO2NEL	05051968041937
TEAM3A NM3	ANTE/PRINT+SPO2NEL-TRIP	05051968041944
TEAM3A NMB	ANTE/PRINT+NIBP+SPO2NEL+BAT	05051968041951
TEAM3A NMB3	ANTE/PRINT+NIBP+SPO2NEL+BAT-TRIP	05051968041968
TEAM3A M	ANTE/PRINT+SPO2NEL	05051968041975
TEAM3A MB	ANTE/PRINT+SPO2NEL+BAT	05051968041982
TEAM3I NM	INTRA/PRINT+NIBP+SPO2NEL	05051968041999
TEAM3I NM3	SP-777232 ANALOGUE SCREEN PCB	05051968042002
TEAM3I NMB	INTRA/PRINT+NIBP+SPO2NEL+BAT	05051968042019
TEAM3I NMB3	INTRA/PRINT+NIBP+SPO2NEL+BAT-TRIP	05051968042026
TEAM3I M	INTRA/PRINT+SPO2NEL	05051968042033
TEAM3I MB	INTRA/PRINT+SPO2NEL+BAT	05051968042040
TEAM3I ENSB	TEAM3 INTRAPARTUM/ECTG+NIBP+SPO2+BAT	05051968042064
OBIX AM2N	ANTEPARTUM - TWINS	05051968042071
OBIX IM2 D	INTRAPRTM/NIBP+SPO2+EMHR+DVI-TWIN	05051968042972
TEAM3A-USA ENM	ANTE/ECTG+NIBP+SPO2NEL	05051968042989
TEAM3A-USA NM	ANTE/PRINT+NIBP+SPO2NEL	05051968042996
TEAM3A-USA NM3	ANTE/PRINT+NIBP+SPO2NEL-TRIP	05051968043009
TEAM3A-USA NMB	ANTE/PRINT+NIBP+SPO2NEL+BAT	05051968043016
TEAM3A-USA NMB3	ANTE/PRINT+NIBP+SPO2NEL+BAT-TRIP	05051968043023
TEAM3A-USA M	ANTE/PRINT+SPO2NEL	05051968043030
TEAM3A-USA MB	ANTE/PRINT+SPO2NEL+BAT	05051968043047
TEAM3I-USA NM	INTRA/PRINT+NIBP+SPO2NEL	05051968043054
TEAM3I-USA NM3	INTRA/PRINT+NIBP+SPO2NEL-TRIP	05051968043061
TEAM3I-USA NMB	INTRA/PRINT+NIBP+SPO2NEL+BAT	05051968043078
TEAM3I-USA NMB3	INTRA/PRINT+NIBP+SPO2NEL+BAT-TRIP	05051968043085
TEAM3I-USA M	INTRA/PRINT+SPO2NEL	05051968043092
TEAM3I-USA MB	INTRA/PRINT+SPO2NEL+BAT	05051968043108
OBIX IM2 B	INTRA/NIBP+SPO2+EMHR+BATT-TWIN	05051968043412
TEAM3I E	TEAM3 INTRAPARTUM/ECTG	05051968044013
TEAM3A-USA EN	ANTE/ECTG+NIBP USA	05051968044020
TEAM3A-USA ENB	ANTE/ECTG+NIBP+BAT USA	05051968044037
TEAM3A-USA	ANTEPARTUM/PRINTER USA	05051968044242
TEAM3A-B-USA	ANTEPARTUM/PRINTER+BATTERY USA	05051968044259
TEAM3A-E-USA	ANTEPARTUM/ECTG USA	05051968044266

Item	Description	Device Identifier
TEAM3A-EB-USA	ANTEPARTUM/ECTG+BATTERY USA	05051968044273
TEAM3A-EN-USA	ANTEPARTUM/ECTG+NIBP USA	05051968044280
TEAM3A-ENB-USA	ANTEPARTUM/ECTG+NIBP+BATTERY USA	05051968044297
TEAM3A-N-USA	ANTEPARTUM/PRINTER+NIBP USA	05051968044303
TEAM3A-NB-USA	ANTEPARTUM/PRINTER+NIBP+BATTERY USA	05051968044310

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Team3 V19.4.1 Upgrade Installation Monitoring Purpose and Scope

This document describes the whole process of obtaining and installing the upgrade-monitoring tool, creating an upgrade USB stick, upgrading one or more Team3 devices and uploading the log files to the Huntleigh server.

Obtain and Install the Team3 V19.4.1 Upgrade Package

Download the Team3 Upgrade Installation Monitoring Tool

Using a PC running Microsoft Windows 10 or 11 connected to the internet, open a web browser and navigate to the following website address:

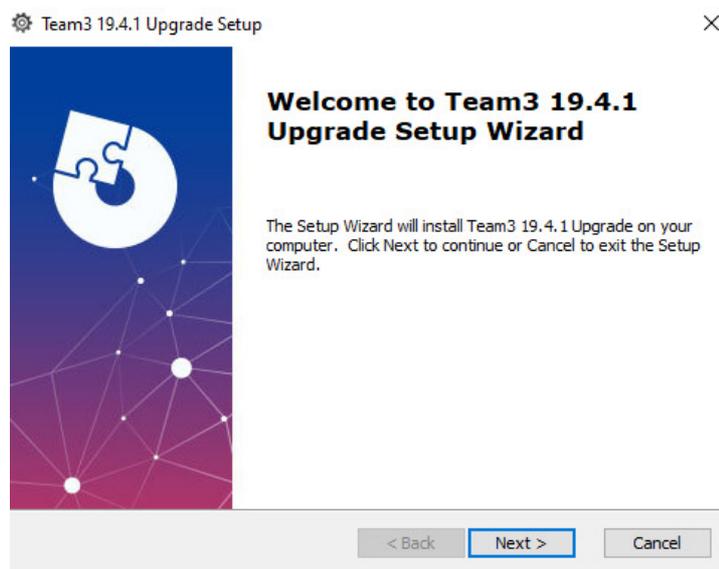
<https://www.huntleigh-diagnostics.com/Team3Upgrade19.4.1>

in addition, follow the instructions to download the software.

N.B. It is likely that several security warnings will be displayed before the download will be allowed – please accept all warnings to proceed with the download.

Install the Team3 Upgrade Installation Monitoring Tool

Once downloaded, run the executable 'Team3 19.4.1 Upgrade.exe' to install the software on the PC. Right click on the executable, select 'Run as administrator', and enter administrator credentials. The Setup Wizard will be displayed:



Follow the steps of the Setup Wizard to complete the installation.

Create the Team3 Upgrade USB Stick

Select appropriate USB media

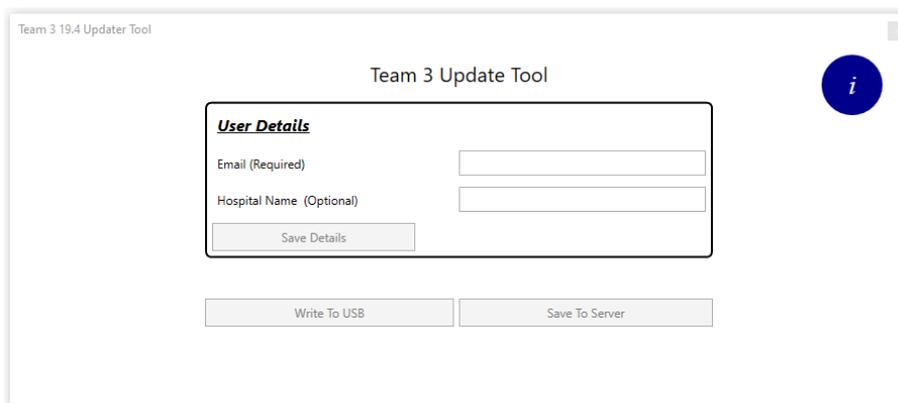
It is important to use a good quality USB memory stick for performing the upgrade operation. We recommend a using named brand such as SanDisk, Transcend or Kingston. The chosen device must be between 4GB to 8GB, and be able to physically fit into a USB socket on the rear of the Team3.

Write Upgrade files to USB

Insert the USB stick into an available port on the PC. It is recommended but not compulsory that all other USB memory devices are removed while performing the operation. Run the software in administration mode by:

- Clicking on the Windows Start Menu, scroll down and expand the Huntleigh folder icon
- Right click on the 'Team3UpdateTool' and expand 'More' options
- Select 'Run as administrator' and enter the administrator credentials

The following main screen will be displayed. Note that on first run, all of the control buttons are greyed out and unavailable. This will be the case until a valid email address is entered in the appropriate field.

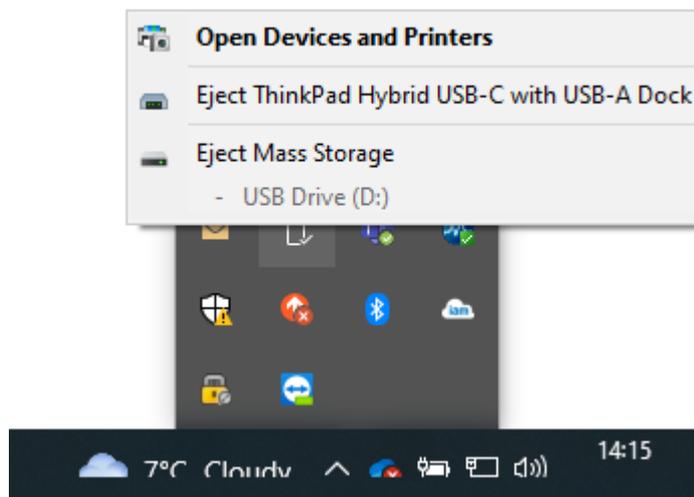


- Enter a valid email address – the 'Save Details' button becomes available
- Optionally enter hospital details and click on 'Save Details' button
- Click on 'Write To USB' button which is now available

The 'Configure USB Device' dialog will be displayed providing a drop down list of all the USB devices of the appropriate size connected to the PC.

Select the correct device from the list and click the 'Configure USB Device' button. A warning will indicate that the contents will be erased - click 'Yes' to confirm the operation. The device will be formatted to FAT32 after which the upgrade files will be written to it. On successful completion, a notification will be sent to the Huntleigh server indicating that an upgrade USB stick has been created, provided a connection can be made. The whole process will take about a minute.

Close the dialog box and exit the application.



Eject the USB device (this is important) and remove it from the PC. It is now ready to be used to upgrade Team3 units.

Upgrade Team3 Units

Please note all local and global settings will be reset to factory default. Determine and follow the correct procedure to perform the upgrade as detailed below:

Upgrade Process Identification

Units Pre 19.1

- Insert the USB containing the upgrade software.
- Power on the unit.
- Follow the onscreen instructions.
- Go to “Upgrade verification” to confirm completion.

Units 19.1 and greater

Units with serial numbers at issue status 6, (21) 777##6#####, use process 1.

Units with serial numbers at issue status 7, (21) 777##7#####, use process 2.

Some units were supplied prior to the issue status change, to identify the upgrade process for these units:

Power up the Team 3 and observe:

Units Requiring Process 1 Upgrade Method.

- The screen will go black after the initial splash screen is displayed.

Units Requiring Process 2 Upgrade Method

- The splash screen will remain displayed and the progress bar at the bottom of the screen will be displayed.

Upgrade Process 1

- Plug Team3 into mains supply
- Insert the USB containing the upgrade software.
- Power on the unit.
- When the screen goes black, count 5 seconds.
- Press the power button for 5 seconds then release.
- If the button is held for longer than 5 seconds, the unit will power down after 10 seconds.
- Follow on screen instructions.

Upgrade Process 2

- Insert the USB containing the upgrade software.
- Power on the unit.
- Count 5 seconds when the splash screen first appears
- Press the power button for 5 seconds then release.
- If the button is held for longer than 5 seconds, the unit will power down after 10 seconds.
- Follow on screen instructions

On successful completion, there will be a message to remove the USB stick, and after doing so, the Team3 unit will power down. The unit has now been upgraded.

Repeat the above process for all Team3 units to be upgraded using the same USB stick.

Upgrade Verification

Power on the unit.

Touch 

Secure Settings

Touch

Enter passcode(default 12345)

Version Information

Touch

Check the settings for the upgraded monitor are equal to the settings arrowed below.

Version Information	
Component	Version
System Version	19.4.1
Language Version	16
Serial Number	<NO SERIAL NUMBER SET!>
Session	3459c430-580b-4141-97fb-2339b5b063ef
IP Address	127.0.0.1
Physical Address	00:E0:4B:60:A2:4F
Total On Time	2h 33m 10s [Started 3/27/2023 11:04:31 AM]
UIP	5.308.8480.27742 built 3/21/2023 3:24:44 PM
Main Board	4
Peripheral Driver	0.0.6.1
PP: Printer	0.0.5.45 N
CP: Ultrasound	0.0.01.0017
CP: FECG	0.0.00.0003
CP: MECCG	0.0.00.0003
CP: ClinicalCPLD	2.5
CP: ClinicalDsp	0.0.05.0263
CP: CommsProcessor	X
CP: ClinicalHardware	Antepartum; Dsp 2; Anlg 4

Upload Log Files to Huntleigh Server

Return to the PC with the Upgrade Monitoring Tool installed and insert the USB stick into an available USB socket. Run the 'Team3UpdateTool' application again in administration mode as detailed in 3.2 above. On this and subsequent runs, the Email and hospital details saved previously will be filled in automatically and the control buttons will be available.

Click on the 'Send To Server' button to display the Send To Server dialog box.

Select the upgrade USB stick from the drop down list and click the 'Send To Server' button.

A list of the Team3 Units upgraded using the stick is displayed in the scrollable message box. If a server connection could not be made, please try again later.



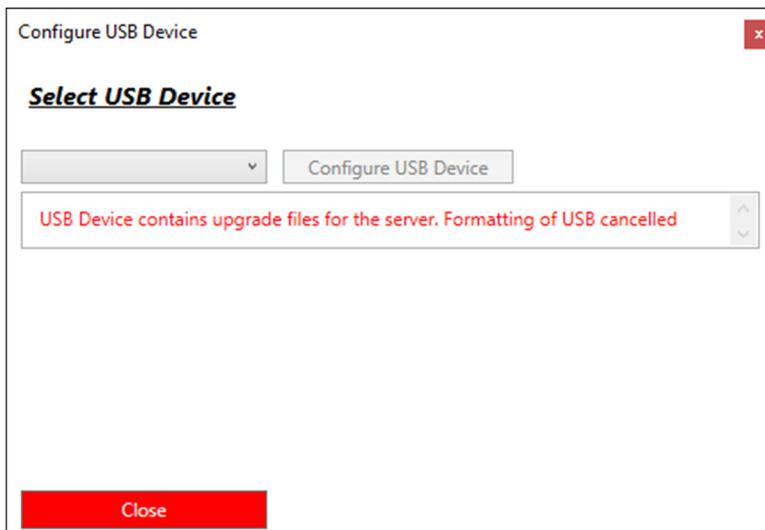
Close the dialog box and exit the application.

Troubleshooting

If there is no suitable USB memory stick inserted when trying to write the upgrade files, the following message is displayed:



If the USB memory stick contains log files created during an upgrade operation, the following message is displayed when trying to write the upgrade files:



In this case, close the dialog box and replace the USB stick to before trying again.

If the Team3 does not begin a software upgrade when following the correctly identified procedure for the model, ensure that the USB upgrade stick is fully inserted into one of the USB ports (not the Ethernet port) and retry.

If it is still not detected, it may be faulty or not compatible, in which case replace the USB stick with an alternative brand or one of the brands recommended in section 3.1.

Appendix 3

Declaration Form

FSN01-23

To be returned to;

Email: FSN01-23HHL@Arjo.com

Name:	
Position/Job Title:	
Facility Name / Address:	
Email:	
Tel:	

I declare that:

V19.4 Software has been installed onto Team Fetal Monitor for the following Serial Number(s);

Serial Number	(21)777
	Continuation sheet attached

Name (PRINT): _____

Signature: _____

Date: _____

