Urgent Field Safety Notice
Mosos CTG
Possibility of data misinterpretation in Mosos CTG

For Attention of: Midwife
Obstetrician
Biomedical engineer
IT specialist

Urgent Field Safety Notice (FSN)
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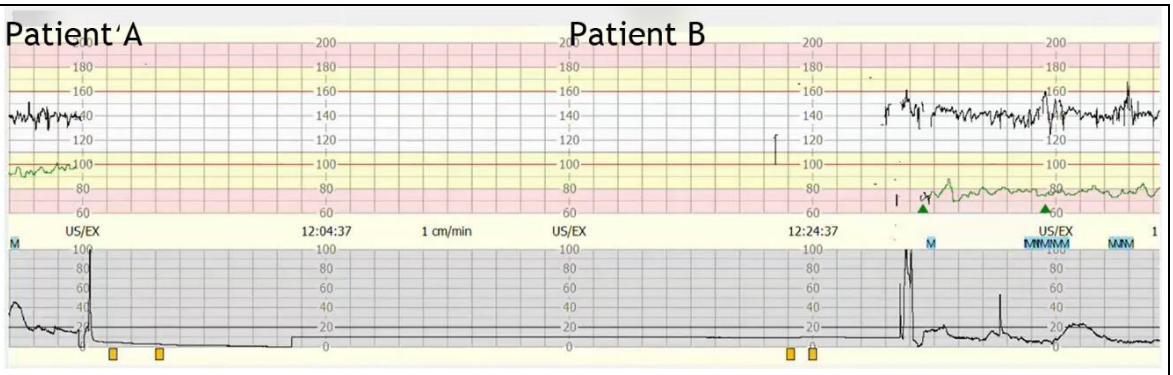
1. Information on Affected Devices	
1.	1. Device Type(s)
	Medical device software for obstetrics
1.	2. Commercial name(s)
	Mosos CTG
1.	3. Primary clinical purpose of device(s)
	Obstetric information system for the recording, (central) monitoring, and archiving of CTG signals.
1.	4. Device Model/Catalogue/part number(s)
	HCTS has software version instead
1.	5. Software version
	Mosos <CTG> 12.04.xx; 12.13.13; 12.13.22; 12.14.09; 12.14.15; 12.14.18; 12.15.05; 12.15.07; 12.15.08: 12.15.09: 12.15.10; 12.15.11; 12.15.12; 12.15.13; 12.15.14; 12.15.15; 12.15.16; 12.15.17.

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	In Mosos CTG, a CTG trace from a previous patient may remain visible while viewing the current patient's data, if the connection between Mosos and the CardioTocograph is not closed in between patients. Although the name displayed on the Central Monitoring screen of Mosos CTG corresponds to the current patient, the trace shown may include data from the previous patient, potentially leading to confusion or misinterpretation. This is due to the technical solution imbedded in Mosos CTG (the live view of Console and Central Monitoring modules). This solution stores data (like fetal and maternal heart rate) in a circular fashion for efficiency and real time performance. NOTE: The patients records and history are correct and will only show the CTG trace that belongs to the patient. For the live view to visibly contain CTG data for more than one patient the following conditions have to be met: • The connection between Mosos CTG and physical CTG device remains active between two patients. • The time interval between two consecutive patients is relatively low, therefore two CTGs may appear as one and the short interruption could be interpreted for example as a toilet break of the same patient.

	
2.	2. Hazard giving rise to the FSCA
	In Mosos CTG, CTG traces of two patients may be visible in one view, while only the name of the current patient is displayed and there is no clear interruption between two CTGs. Due to this, healthcare providers may be exposed to misleading visual data, which could lead to incorrect and/or delayed clinical decision making. Such situations may lead to the following: 1. Necessary interventions not carried out with adverse outcome, such as fetal distress 2. Unnecessary interventions carried out, such as a not needed C-Section

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** Until Mosos CTG software is upgraded to eliminate the issue permanently, the following action/s should be taken by the users: **1. Manual Disconnection Between Patients:** The user shall make sure that connection between Mosos CTG and physical CTG device is inactive/disabled after a patient's monitoring session ends. For example by turning off the CTG device or unplugging all connected transducer cables from the CTG device. **2. When reviewing historical CTG traces, always use the Mosos CTG Console instead of Central Monitoring.** Ensure that you connect and disconnect the patient properly in Mosos. To review a previous CTG trace, use the [Review/Print CTGs] option in the Mosos Console. This feature displays only the CTG data associated with the selected patient.	
3.	2. By when should the action be completed?	It is suggested to implement these actions as soon as possible and continue to use them in practice until permanent software solution is implemented and installed.
3.	3. Is customer Reply Required?	Yes

	(see Annex I "Customer Response Form", to be filled in by customer and returned to address provided in the Customer Response Form)	
3.	**4. Action Being Taken by the Manufacturer** 1. Nexus Astraia B.V. (formerly ICT HCTS B.V.) is currently developing a permanent software solution to resolve this issue in the next Mosos CTG release. Customers will be informed as soon as the update is available. 2. As an interim risk mitigation measure, the Instructions for Use (IFU) / user manual for the affected software versions will be updated to include a warning related to this issue. This update aims to inform users of the identified risk and provide guidance on safe usage until the software solution is available and customers can be upgraded.	

	4. General Information	
4.	1. FSN Type	New
4.	2. Manufacturer information **(For contact details refer to Annex I of this FSN)**	
	a. Company Name	**Nexus Astraia B.V. (formerly ICT Healthcare Technology Solutions B.V.)**
	b. Address	[redacted]
	c. Website address	
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	4. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices are available. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Annex I - Customer Response Form

Please complete the information below and return the completed form to **support-hcts@ict.eu**

Hospital / Facility Name:	
Customer Id. Number (if applicable)	
Customer Address / City / Postal Code / Country	
Contact Name / Phone / Email address	
Title or Function	
Department/Unit	
Signature / Date	

Please fill in information below as applicable:

☐ The information and required actions have been communicated to all relevant users within our organization.

☐ I have followed the instructions provided to me in this FSN and will implement one or more actions outlined in section 3.1.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Contact Information:

Once completed, please return this form to: <*support-hcts@ict.eu*>

For questions concerning the issue, you can contact Nexus Astraia B.V. (formerly ICT Healthcare Technology Solutions B.V.) Support Department at support-hcts@ict.eu and/or your local Account Manager or Clinical Application Specialist.