

Urgent FIELD SAFETY NOTICE

Device: **Sarns™ Modular Perfusion System 8000**

Reference: FSN1208 2012-12

Action: **Advisory**

Attention: Chief of Perfusion, Director of Operating Room Services, Director of Biomedical Services, Risk Management

CONSOLIDATED CORRECTION NOTIFICATION

This recall notification is a correction that consolidates information regarding multiple issues for Sarns™ Modular Perfusion System 8000 to facilitate communication and reduce user inconvenience due to administrative load.

This package consolidates information regarding the following issues for Sarns™ Modular Perfusion System 8000:

Issue reference	Subject
AA-2012-003-C:	Ultrasonic Air Sensor
AA-2012-016-C:	Malfunctions of Power Distribution and Battery Backup Systems
AA-2012-017-C:	Malfunctions of the Arterial and Cardioplegia Monitors

REASON FOR CORRECTION

These consolidated recall notifications are the result of retrospective review and remediation activities associated with the 2011 consent decree between Terumo CVS and the U.S. Food and Drug Administration (FDA). These activities include a review of past compliance-related decisions dating from 2004 regarding products manufactured at Terumo CVS Ann Arbor, Michigan, USA.

DETAILS ON AFFECTED DEVICES:

Reference	Description	Serial Number Range
16405	Base for Sarns System 8000, base 4 pump, 220V/240V safety monitor included	1001-1466
16406	Base for Sarns System 8000, base 5 pump, 220V/240V safety monitor included	1001-1004, 1007-1055, 1057-1310, 1648, 1649, 1657, 1822, 1823

Note: Terumo CVS is using the serial number for the base of the Sarns System 8000 to define the affected population for this field safety notice.



Please note that we are not recommending that you stop using your Sarns system 8000.



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Reference: **AA-2012-003-C: Ultrasonic Air Sensor**
Action: **Advisory**

Description of the problem:

Terumo Cardiovascular Systems (Terumo CVS) has received multiple reports of false alarms generated by the air bubble detection system used with the Sarns™ Modular Perfusion System 8000.

Terumo CVS has concluded that it is necessary to amend the device Operator's Manual to:

- Alert all users of the potential for a malfunction of the air bubble detection system
- Reinforce the mitigation procedures in the event of a malfunction

It is highly unlikely that a user will experience this malfunction of the air bubble detection system based on the number of reports received over the last four years and the number of installed Sarns™ Modular Perfusion System 8000 machines in the affected population. However, users should always be prepared to respond to an air alarm, real or false. Therefore, users should know the configuration of the safety systems on their machines and the systems' response to an air alarm.

There have been no reports of patient injury as a result of this failure.

Potential hazard:

If an air bubble detection system malfunction occurs during set-up, the user can address the issue prior to initiating cardiopulmonary bypass; there is no patient risk.

If an air bubble detection system malfunction occurs during cardiopulmonary bypass, patient risk is dependent on the pumping system model, the type of pump, and the configuration of its safety systems. With certain configurations, an air alarm will stop the pump, possibly resulting in temporary interruption of arterial blood flow, air entrainment in the system, or the need to continue the case with a disabled air sensor.

- **Interruption in arterial blood flow** can result in a range of clinical consequences, the severity of which would be determined by several variables, including the duration of the pump stop, the patient's baseline physiologic status and the patient's temperature. The effects of the interruption would range from a temporary, well tolerated reduction in blood pressure to cellular death resulting in neurologic dysfunction, cardiac dysfunction due to inadequate myocardial protection, end organ dysfunction, or death in the case of an extended period of no flow.
- **Air entrainment in the system** could result in undetected air entering the patient's circulation, an embolic event that could result in stroke, neurologic or end organ dysfunction, cardiac dysfunction or death.

In any event, a pump stop requires intervention by the user and can create distraction.

Corrective Action:

Terumo CVS is creating an addendum to the Operator's Manual for the Sarns System 8000 ([See attached Addendum LC-7480en \(826206_A\)](#)). Terumo CVS advises users to place the addendum where it can be easily referenced in the Operator's Manual – immediately preceding page 3-1.

The addendum:

- Alerts all users of the potential for a malfunction of the air bubble detection system
- Reinforces the mitigation procedures in the event of a malfunction

Reference: **AA-2012-016-C: Malfunctions of Power Distribution and Battery Backup Systems**
Action: **Advisory**

Description of the problem:

Terumo Cardiovascular Systems (Terumo CVS) has received multiple reports since 2007 of various malfunctions of the power distribution and battery back-up systems for the Sarns™ Modular Perfusion System 8000.

Very few of the reports occurred during cardiopulmonary bypass; the majority of the malfunctions were detected during set-up or routine preventive maintenance.

The malfunctions can be broadly categorized as follows:

- Loss of wall (AC) power
- Battery back-up malfunction
- Battery status indicator malfunction

Terumo CVS' initial investigation has determined that:

- Although the majority of the malfunctions were detected during set-up or were reported during routine preventive maintenance, they could have occurred during clinical use.
- There are multiple root causes for the malfunctions; investigation is ongoing.
- The Operator's Manual for the Sarns system 8000 does not provide sufficient instruction on:
 - How to respond to a blinking red indicator light
 - How to ensure the function of the battery back-up prior to each case

As a result, Terumo CVS is informing users of the Sarns system 8000 of the risks associated with these malfunctions, reminding users to review the instructions in the Operator's Manual, and providing an addendum to the Operator's Manual with additional instruction.

There are no known reports of patient injury as a result of these issues.

Potential hazard:

General Hazard Information

In most cases, the malfunctions are easy to detect, and the majority have been detected during set-up or routine preventive maintenance – not during cardiopulmonary bypass.

If the malfunctions were to occur during cardiopulmonary bypass, the risk to the patient ranges from negligible to severe, and is dependent on:

- The patient's condition
- The user's experience and competency
- The user's knowledge of the instructions in the Operator's Manual, specifically the battery operations

The complete loss of system power would result in loss of all patient functions, including arterial blood flow and myocardial protection. Depending on the competence and experience of the clinical team and the availability of backup equipment, a prolonged lack of support could result in death or serious injury.

Detailed Hazard Information

Description of Reports	How to Detect a Failure	What to Do in Event of Failure
<p><u>Loss of wall (AC) power</u> Reports of these malfunctions have been few, and include:</p> <ul style="list-style-type: none"> - AC power not operating - Various power cord malfunctions - Pump power loss or reset - System circuit breaker trips - Hospital circuit breaker trips - Loss of power to auxiliary outlet 	<p>These malfunctions are easily detectable:</p> <ul style="list-style-type: none"> - The system loses function, or - The system switches to battery power 	<p>Follow the instructions in the Operator's Manual for the Sarns system 8000: <i>Perfusing the Patient: If Emergency Occurs</i>, page 7.3</p>
<p><u>Battery backup malfunction</u> Reports of these malfunctions have been rare, and include:</p> <ul style="list-style-type: none"> - System not switching to battery - Battery not holding a charge - No audible alarm when battery backup was initiated - Red flashing indicator light 	<p>These malfunctions are likely to be detected in advance if the user follows the instruction in the Operator's Manual to check battery status at the beginning of the case and to follow battery maintenance procedures.</p> <p>NOTE: The Operator's Manual does not provide sufficient instruction on how to respond to a red flashing indicator light, or how to ensure battery back-up function prior to each case.</p>	<p>Follow the instructions in the Operator's Manual for the Sarns system 8000: <i>Learning about your Modular System; System Base and Power</i>, pages 1.20 – 1.21</p> <p>Also, review the attached addendum. Place the addendum before page 1.13</p>
<p><u>Battery status indicator malfunction</u> Reports of these malfunctions have been rare, and include:</p> <ul style="list-style-type: none"> - The battery indicator is on when the system is operating on wall power - The battery charge indicator is not lit or dimly lit - No audible alarm when the system is on battery power 	<p>These malfunctions are likely to be detected in advance if the user follows the instruction in the Operator's Manual to check battery status at the beginning of the case and to follow battery maintenance procedures.</p>	<p>Follow the instructions in the Operator's Manual for the Sarns system 8000: <i>Learning about your Modular System; System Base and Power</i>, pages 1.20 – 1.21</p>

Corrective Action:

Terumo CVS is taking the following actions:

- Issuing this notification as a Safety Advisory to alert all Sarns 8000 system users of the possibility of malfunction and remind them to review the appropriate sections of the Operator's Manual.
- Providing an addendum to the Operator's Manual to clarify instruction for responding to a blinking red battery status indicator and ensuring the function of the battery back-up prior to each case ([See attached Addendum LC-7481en \(827365_A\)](#)).

Reference: **AA-2012-017-C: Malfunctions of the Arterial and Cardioplegia Monitors**
Action: **Advisory**

Description of the problem:

Terumo Cardiovascular Systems (Terumo CVS) has received multiple reports since 2007 of various malfunctions of the arterial and cardioplegia monitors for the Sarns™ Modular Perfusion System 8000.

The malfunctions can be broadly categorized as follows:

- Monitor power malfunctions
- Inability to measure pressure
- Inaccurate pressure readings and/or false pressure alarms

Terumo CVS' initial investigation has determined that:

- There are multiple root causes for the malfunctions; investigation is ongoing.
- While the Operator's Manual for the Sarns system 8000 provides instruction on how to respond to the malfunctions, Terumo CVS believes the instruction can be clarified for responding to false alarms.

As a result, Terumo CVS is informing users of the Sarns system 8000 of the risks associated with these malfunctions, reminding users to review the instructions in the Operator's Manual, and providing an Addendum to clarify the instruction for responding to a false alarm.

There are no known reports of patient injury as a result of these issues.

Potential hazard:

General Hazard Information

If the malfunction of the arterial or cardioplegia monitor occurs prior to initiating cardiopulmonary bypass, it could inconvenience the user or delay the case; the risk to the patient is dependent on the patient's status.

If the failure occurs during cardiopulmonary bypass, the risk to the patient ranges from negligible to severe and is dependent on:

- The patient's condition
- The user's experience and competency
- The user's knowledge of the instructions in the Operator's Manual

In the most severe cases, loss of the ability to monitor **arterial system pressure** can result in acute pressure increase in the arterial circuit, with the following potential consequences:

- Tubing disconnection that leads to:
 - Major blood loss, with the risk of hypotension, hypovolemia, hypoperfusion, and transfusion
 - Macro air introduction in the circuit, with the risk of air embolism to the brain or other organs
 - Risk of infection
- Damage to the vasculature at the arterial cannulation site

In the most severe cases, loss of the ability to monitor **cardioplegia system pressure** can result in acute pressure increase in the cardioplegia circuit, with the following potential consequences:

- Tubing disconnection that leads to minor blood loss, but which could require a transfusion
- Damage to the coronary vasculature

Detailed Hazard Information

Description of Reports	How to Detect a Failure	What to Do in Event of Failure
<p><u>Monitor Power Malfunctions</u> Reports of these malfunctions have been few, and include:</p> <ul style="list-style-type: none"> - Monitor fails to power on - Monitor shuts off during use - Monitor resets or reboots 	<p>The malfunctions are easily detectable:</p> <ul style="list-style-type: none"> - The screen on the monitor goes blank - Information is no longer displayed 	<p>Follow the instructions in the Operator's Manual for Sarns system 8000: <i>Monitoring Temperature, Pressure, Time and Volume</i>, pages 4.1- 4.10</p>
<p><u>Inability to Measure Pressure</u> Reports of these malfunctions have been few, and include:</p> <ul style="list-style-type: none"> - Monitor does not provide a pressure reading - User cannot calibrate pressure 	<p>The malfunctions are easily detectable:</p> <ul style="list-style-type: none"> - 'CAL' remains displayed - Display is blank - '---' or '999' is displayed 	<p>Follow the instructions in the Operator's Manual for Sarns system 8000: <i>Monitoring Temperature, Pressure, Time and Volume</i>, pages 4.1- 4.10</p>
<p><u>Inaccurate and/or False Pressure Alarms</u> Reports of these malfunctions have been rare, and include:</p> <ul style="list-style-type: none"> - Monitor provides inaccurate pressure readings and/or triggers false alarms 	<p>This malfunction can be difficult to detect:</p> <ul style="list-style-type: none"> - The user may be unable to resolve a high pressure alarm - The user may notice a displayed pressure reading is significantly different than what might be clinically expected <p>In some cases, such a malfunction can result in a pump stop based on a false positive alarm.</p>	<p>Follow the instructions in the Operator's Manual for Sarns system 8000: <i>Monitoring Temperature, Pressure, Time and Volume</i>, pages 4.1- 4.10</p> <p>In addition, please review the attached addendum and place it in the Operator's manual, just before page 4.1</p>

Corrective Action:

Terumo CVS is taking the following actions:

- Issuing this notification as a Safety Advisory to alert all Sarns 8000 system users of the possibility of malfunction and remind them to review the appropriate sections of the Operator's Manual.
- Providing an addendum to the Operator's Manual to clarify instruction on how to respond to a false alarm (See attached [Addendum LC-7482en \(827364_A\)](#)).

Customer instructions

- 1) Review this consolidated Field Safety Notice, and assure that all users are aware of this notice.
- 2) Please place the enclosed addenda in your Operator's Manual as instructed per issue.
- 3) Confirm receipt of this notice, by filling and faxing the enclosed Customer Reply Form to the fax number indicated.
- 4) In any event, call your local Terumo CVS Technical Service as soon as possible

Europe: Technical Support - Medical Electronics - Call Free Number from:

AT	0800-293711	BE	0800-94410	DK	808-80701
FI	0800-115226	IE	1800-553224	CH	0800-563694
FR	0800-908793	IT	800-785891	GB	0800-9179659
DE	0800-1808183	NL	0800-0222810	NO	800-12270
GR	00800-3212721	ES	900-963251	SE	020-791373

Other countries call +32 16 381204 at international rates.

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We confirm that this *consolidated Field Safety Notice* has also been notified to your national Competent Authorities.
We encourage you to contact us or your local Terumo representative with any questions or concerns:

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