

## **Urgent Field Safety Notice** **Medtronic Bio-Console 560** Service Update

<b>Bio-Console 560 Extracorporeal Blood Pumping Console</b>		<b>Serial Numbers</b>
Model Numbers	560BC, 560BCS, 560BC1, 560BCS1, R560BCS1	Refer to Table 1

March 2021

Medtronic Reference: FA962

Dear Risk Manager or Healthcare Professional,

Medtronic is initiating an Urgent Field Safety Notice for specific Medtronic Bio-Console 560 Extracorporeal Blood Pumping Console (Bio-Console 560) devices at your facility.

Medtronic has received reports of an issue with a single electrical component within the system controller module of a limited quantity of Bio-Console 560 devices. This subset may exhibit electrical failure causing the device to stop pumping. The models and serial numbers in the scope of this Urgent Field Safety Notice are listed in Table 1, below. Medtronic will perform a correction by replacing the system controller module in your affected Bio-Console 560 devices.

No reports of patient injury or adverse events related to this issue have been received. As long as users follow the Bio-Console 560 Operator and Reference Manual, no additional patient risk is anticipated as a result of this electrical component failure.

To date, Medtronic has received nine (9) device performance field reports related to this component issue. In two (2) of the nine (9) reports, the Bio-Console 560 electrical failure occurred during a clinical procedure, which required the users to utilize the Emergency Handcrank according to the Bio-Console 560 Operator and Reference Manual. In the other seven (7) of the nine (9) reports, the electrical failure occurred during the initial start-up of the Bio-Console 560 prior to clinical use, which required the users to use a back-up Bio-Console 560 according to the Bio-Console 560 Operator and Reference Manual. When the electrical failure occurs, it may be accompanied by a burning smell and/or a small amount of smoke. The failing component is manufactured with fire retardant material, so there is no risk of fire when the component failure occurs. We are not able to predict if, or when, one of the identified Bio-Console 560 devices may malfunction.

The affected components were distributed and used in service repairs between APR-2019 and FEB-2021. Medtronic has since resolved this component issue, and as of 12-FEB-2021, all newly distributed Bio-Console 560 devices are no longer susceptible to this malfunction. Only Bio-Console 560 devices serial numbers listed in Table 1 are in the scope of this advisory. This issue does not affect any other Medtronic product or equipment.

The attached Table 1 itemizes the serial numbers of the Bio-Console 560 devices distributed to your location.

**Medtronic requests that you take the following actions:**

- Review Table 1 for affected devices in your facility.
- Use unaffected Bio-Console 560 devices, if available, until the correction has been completed for your affected Bio-Console 560 devices.
- Contact your local Medtronic Field Service Representative to schedule the service event to your affected Bio-Console 560. Please reference Technical Service Update (TSU) "MOD0204" when scheduling.

# Medtronic

The Competent Authority of your country has been notified of this action. Please share this notification with others in your organization as appropriate.

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. If you have questions regarding this material, please contact your Medtronic Field Representative at <XXXX>.

Sincerely,

Local / BU Manager

**Table 1: Bio-Console 560 Affected Serial Numbers List**

<b>Bio-Console 560 Console Affected Model Numbers and Serial Numbers</b>
<b>Models: 560BC, 560BCS, 560BC1, 560BCS1, R560BCS1</b>
560B100212, 560B100257, 560B100482, 560B100783, 560B101368, 560B101504, 560B101838, 560B101895, 560B102745, 560B102746, 560B102747, 560B102930, 560B102931, 560B102932, 560B102933, 560B102934