

CardioMEMS™ Corrective Action FAQ

As you have learned, Abbott is proactively conducting a corrective action for the CardioMEMS™ HF System Patient and Hospital Electronics Systems. The following information is intended to provide a quick reference for hospital clinicians and administrators implementing the required action or interacting with patients on this issue.

- **This issue does not impact the implanted sensor and has no reported or expected impact to patient safety.**
- It is safe to continue using affected electronics systems until a replacement is received.
- We are working to replace all affected electronics systems as quickly as possible.
- If you have any questions not addressed by this document or the official notification, please contact our Technical Support team at 1-844-MYCMEMS (692-6367).

WHAT IS THE ISSUE?

Abbott is advising its customers that a small number of CardioMEMS™ Patient Electronics Systems (Model CM1100) and Hospital Electronics Systems (Model CM3000) may deliver a system error message, known as Error 5. While this message is supposed to appear if the electronics encounters extreme high or low temperatures or sudden temperature changes, these units may deliver a false Error 5 message due to an incorrectly configured component within the device electronics.

WHAT DO I NEED TO DO?

1. For Hospital Electronics Systems and Patient Electronics Systems not yet issued to a patient, complete the *Acknowledgement & Consent Form* indicating which units are in your possession and return the form to CMEMS-NOTICES@abbott.com.
2. If you have an implant procedure scheduled in the next 3 weeks and all Patient Electronics Systems on your shelf are affected, contact 1-844-MY-CMEMS (692-6367) so that we can expedite your exchange.
3. You do not need to contact patients who have been issued an affected Patient Electronics System. We will be working with the Clinics who manage patients after implantation to arrange for notification and replacement of their units.

IS ERROR 5 A PATIENT SAFETY ISSUE? IS THE IMPLANTED SENSOR AFFECTED?

There has been no patient harm reported or expected to occur in association with this issue. Continued use of CardioMEMS™ Electronics Systems is considered safe. The implant is not affected by this issue.

HOW MANY DEVICES ARE IMPACTED?

Based on complaint information received to date, an estimated 0.10% of interrogations performed with patient systems, and 1.3% of interrogations performed with hospital units affected by this issue will result in an Error 5 message.

WE IMPLANT THE DEVICE AT OUR FACILITY BUT DO NOT FOLLOW PATIENTS. WILL YOU BE CONTACTING CLINICS WHO SEE THESE PATIENTS REGULARLY?

Abbott will be contacting patient management clinics as well as implanting hospitals to ensure that all those affected are notified of the situation.

HOSPITAL ELECTRONICS SYSTEM QUESTIONS:

WHAT IS THE PROCESS TO REPLACE OUR HOSPITAL ELECTRONICS SYSTEM?

In order to replace your affected Hospital Electronics System, we must receive your signed and completed Acknowledgement & Contact Form. Once this form is received, Abbott will contact the Primary Point of Contact you choose to arrange for return and replacement of the units listed on the form. Only units with serial numbers listed on this form will be replaced.

HOW QUICKLY WILL SOMEONE CONTACT ME AFTER I COMPLETE THE FORM? HOW LONG DOES IT TAKE TO GET A NEW HOSPITAL SYSTEM?

You will be contacted within a couple of weeks to arrange for your replacement system. The time estimated for system replacement will be dependent on how many requests are received, but our goal is to replace all units as soon as possible after receiving the Acknowledgement form.

WE HAVE A CARDIOMEMS IMPLANTATION SCHEDULED AND MY HOSPITAL ELECTRONICS SYSTEM IS AFFECTED. SHOULD I POSTPONE MY CARDIOMEMS CASE?

It is safe to use an affected Hospital System, and systems may undergo troubleshooting if Error 5 occurs, although the troubleshooting process may take 60 – 90 minutes. In order to expedite replacement of your Hospital Electronics System, complete and return your Acknowledgement and Contact form and call 1-844-MYCMEMS (692-6367). If you have an additional Hospital System it may be helpful to have that system available as backup.

IF AN ERROR 5 OCCURS BEFORE MY UNIT IS REPLACED, WHAT SHOULD I DO?

If you encounter an Error 5 message during a CardioMEMS implant procedure, immediately contact our Technical Support team at 1-844-MYCMEMS (692-6367) to troubleshoot the problem and reset your system. The troubleshooting process may take 60 – 90 minutes. If a backup Hospital System is available this may be the most efficient resolution.

WE HAVE HAD THE ERROR 5 FIXED ON OUR HOSPITAL SYSTEM BEFORE. DO WE NEED TO RETURN IT?

It is safe to use your Hospital Electronics System if your system has been reset after an Error 5 message. It is unlikely that the Error 5 message will happen again on your system, but Abbott will replace the system. If you would like to have your unit replaced immediately, complete the Acknowledgement and Contact Form and return to Abbott as instructed.

WHY IS THIS AN URGENT RECALL IF YOU'RE NOT GIVING ME A NEW UNIT RIGHT AWAY?

Abbott takes quality issues very seriously and wants to resolve the situation as quickly as possible. The U.S. Food and Drug Administration (FDA) utilizes standard language for all events like this one, and Abbott is committed to strict compliance with FDA guidance documents. Because this issue does not put patients at risk, we are managing the replacements as described earlier in this document.

PATIENT ELECTRONICS SYSTEM QUESTIONS:

OUR PATIENTS HAVE CALLED IN AND CUSTOMER SERVICE HELPED FIX THIS ERROR BEFORE. DO THEY NEED TO RETURN THEIR SYSTEMS?

It is safe to use the Patient Electronics System if it has been reset after an Error 5 message. It is unlikely that the Error 5 message will happen again on that unit, but Abbott will replace the system if this occurs. If they would like to have their system replaced immediately, patients should complete the Acknowledgement and Contact Form and return to Abbott as instructed.

A PATIENT HAS ALREADY RECEIVED A REPLACEMENT SYSTEM AFTER HAVING THE ERROR 5 MESSAGE; DO THEY NEED TO RETURN THEIR SYSTEM?

If the serial number on the back of the Patient Electronics System matches the serial number in your letter, it is possible for an inappropriate Error 5 to occur on that system.

IF AN ERROR 5 OCCURS BEFORE MY PATIENT'S SYSTEM IS REPLACED, WHAT SHOULD THEY DO?

If an Error 5 occurs on your patient's System, instruct them to contact Abbott at 1-844-MYCMEMS (692-6367) (U.S.) for troubleshooting assistance. Clinicians and patients outside the United States should contact their local Abbott Representative, who will facilitate troubleshooting assistance. Our Technical Support Team will ensure that they receive the necessary documents to replace their electronics system.