



CardioMEMS™ Corrective Action FAQ

Abbott is conducting a voluntary recall for a select number of CardioMEMS™ Patient Electronics Systems, in order to replace an improperly configured component. The following information is intended to provide a quick reference for patients who have a Patient Electronics System that contains the faulty component.

- **This issue does not impact your implanted sensor and has no reported or expected impact to your safety.**
- It is safe to continue using your Patient Electronics System until you have received a replacement System.
- 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 notifying patients that a small number of CardioMEMS™ Patient Electronics Systems (Model CM1100) 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 IS THE RISK ASSOCIATED WITH THE ISSUE?

It is safe to continue using your CardioMEMS™ Electronics System. The implanted sensor is not affected by this issue. If the Error 5 message appears on a Patient Electronics System, the system will not be able to take pulmonary arterial (PA) pressure measurement readings until it has undergone troubleshooting by our technical team or is replaced. No injury or harm to patients has been reported or is expected to occur because of this issue.

WHAT DO I NEED TO DO?

1. Confirm that the Serial Number on the back of your Patient Electronics System matches the Serial Number in your official notification letter, then complete the *Acknowledgement & Consent Form* and return it to CMEMS-NOTICES@abbott.com. Once we receive your form, Abbott will contact you to arrange for return and replacement of your Patient Electronics System.
2. Do not return your Electronics System to your Hospital or Clinic; replacement of your System can only be conducted by Abbott.

DO I NEED TO NOTIFY MY DOCTOR IF I GET AN ERROR 5 AND CANNOT TAKE READINGS?

Abbott has already notified your physician. You are not required to notify your physician if you are unable to take your daily pressure reading, but you may do so if you choose. We ask that if you are unable to take a reading due to Error 5 you contact 1-844-MYCMEMS right away so that we can arrange for a replacement system.

WHAT IS THE PROCESS TO REPLACE MY PATIENT ELECTRONICS SYSTEM?

To replace your Patient Electronics System, we must receive your signed and completed *Acknowledgement & Contact Form*. Once this form is received Abbott will contact you to arrange for return and replacement of the units listed on the form. Abbott will provide the necessary shipping and postage for System returns. Only Systems with serial numbers listed on this form will be replaced.

HOW QUICKLY WILL SOMEONE CONTACT ME AFTER I SEND IN THE FORM? HOW LONG DOES IT TAKE TO GET A NEW 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.

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

If you encounter an Error 5 message, contact our Technical Support team at 1-844-MYCMEMS (692-6367) to troubleshoot the problem and reset your system.

ERROR 5 HAS BEEN FIXED ON MY SYTEM BEFORE. DO I NEED TO RETURN IT?

It is safe to use your Patient 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 System replaced immediately, complete the *Acknowledgement and Contact Form* and return to Abbott as instructed.

I HAVE ALREADY RECEIVED A REPLACEMENT SYSTEM AFTER HAVING THE ERROR 5 MESSAGE; DO I NEED TO RETURN MY SYSTEM?

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

WHY IS THIS CALLED AN URGENT RECALL IF YOU'RE NOT GIVING ME A NEW SYSTEM 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.

IT'S VERY DIFFICULT FOR ME TO GET TO THE POST OFFICE. CAN SOMEONE PICK UP MY SYSTEM FROM MY HOME?

Abbott will arrange for FedEx to come to your home to retrieve the unit, so it is not necessary for you to leave home in order to exchange your unit. Abbott will contact you once your new unit has been shipped to you to schedule the pickup of your returned system by FedEx.

WILL REPLACING MY UNIT COST ME ANYTHING?

No. Abbott will provide you with instructions, packing material and a shipping label for System return, so you will not need to pay for shipping or your replacement System. **Do not ship your System until you receive instructions from Abbott, as this may delay your replacement.**

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.

MY LETTER SAID A REAL ERROR 5 IS POSSIBLE. WHAT CONDITIONS OR TEMPERATURES CAN CAUSE A REAL ERROR 5 MESSAGE?

The Electronics must register a temperature above 158°F (70°C) or below -13°F (-25°C) for a real Error 5 message to occur. An Error 5 may also occur if the electronics is exposed to a very rapid temperature change. A real Error 5 message is very rare.