Interference between CT and Electronic Medical Devices

This website provides information about a rare and preventable type of interference between Computed Tomography (/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct) (CT) and electronic medical devices. This information updates and replaces our 2008 preliminary public health notification.

CT is a valuable type of diagnostic imaging. Most patients undergo CT scans without any adverse consequences. However, the FDA has received a small number of reports of adverse events that we believe to be associated with CT imaging of some implantable and wearable electronic devices (eg. insulin pumps, cardiac implantable electronic devices and neurostimulators).

Our current understanding is that when a CT scanner **directly** irradiates the circuitry of certain implantable or wearable electronic medical devices (i.e. when the device is visible in the resulting CT image), it can cause sufficient electronic interference to affect the function and operation of the medical device.

The probability that this interference can cause clinically significant adverse events is extremely low. Furthermore, the probability of x-ray electronic interference is lower (/radiation-emitting-products/electromagnetic-compatibilityemc/effects-x-ray-irradiation-ct-imaging-pacemakers-and-implantable-cardioverter-defibrillators-icd) when the radiation dose and the radiation dose rate are reduced.

Interference is completely avoided when the medical device is outside of the primary x-ray beam of the CT scanner.

The electronic medical devices for which we have received reports of adverse effects and have updated our recommendations are:

- Insulin pumps
- Cardiac implantable electronic devices (pacemakers and implantable cardioverter defibrillators)
- Neurostimulators

Patients: Physicians recommend CT scans for medical reasons. **The probability of an adverse event is extremely low.**

Healthcare providers: The presence of the devices mentioned above should NOT preclude the performance of an appropriate, medically indicated CT scan. The probability of an adverse event being caused by exposing these devices to CT irradiation

is extremely low, and it is greatly outweighed by the clinical benefit of a medically indicated CT examination.

CT continues to be the preferred tomographic imaging technology for patients with implantable or wearable medical devices. CT is safer for patients with devices of unknown magnetic resonance imaging (MRI) (/mri-magnetic-resonance-imaging) safety status. You should be aware that an MR Conditional device is only safe within the MR environment that matches its conditions of safe use. Any device with an unknown MRI safety status should be assumed to be MR Unsafe.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with the product. We encourage health care providers and patients who suspect a problem with a medical imaging device to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting Program (/medwatch-fda-safety-information-and-adverse-event-reporting-program).

- Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements (/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.
- Medical device manufacturers, distributors, importers, and device user facilities (which include many health care facilities) must comply with the Medical Device Reporting (MDR) Regulations of 21 CFR Part 803 (/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).

You can avoid adverse events by following our recommendations specific for each type of device:

Insulin Pumps | **Cardiac Implantable Electronic Devices** | **Neurostimulators**

Insulin Pumps

Background information

The FDA has received a small number of reports of adverse events during CT imaging of insulin pumps (including continuous glucose monitoring or sensor augmented systems). The adverse events noted in these reports included:

- Low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia)
- loss of consciousness

- ketoacidosis, a serious condition that can lead to diabetic coma or death
- seizures
- dizziness
- fainting
- injuries related to falls
- heart failure
- hypertension
- one death

Although the adverse effects listed above were reported to occur during CT scanning, there is no evidence of direct causation from the CT irradiation. The number of adverse event reports we received is very small compared to the number of patients with insulin pumps who were scanned without adverse effects. Although there is literature (/radiation-emitting-products/electromagnetic-compatibilityemc/effects-x-ray-irradiation-ct-imaging-pacemakers-and-implantable-cardioverter-defibrillators-icd) to document the rare effects on implantable cardioverter defibrillators (ICDs) and pacemakers, there is no equivalent evaluation of insulin pumps.

Recommendations for Patients

Physicians recommend CT scans for medical reasons. The probability of an adverse event is extremely low. You can help reduce the risk by doing the following:

Before the CT scan

- Tell the referring physician who ordered the CT scan that you have an insulin pump. This will help them plan imaging that minimizes the risks of adverse effects.
- Bring your remote insulin pump controller with you to the imaging facility if your pump is controlled by a remote device. Make sure that you bring your glucose meter and back-up insulin and insulin syringe that you use in case of pump problems.
- Contact the physician managing your diabetes to make a plan for the day of your scan.
    - Determine if it's feasible to attach the insulin pump to an alternative location so that it will be outside the direct path of the CT x-ray beam.
    - If the insulin pump is located inside the area to be CT scanned and cannot be safely moved (i.e. when the insulin pump is adhered to your skin or when the insulin delivery cannula is not long enough), work with your physician to determine if your insulin pump can be safely turned off and for how long. Turning a pump off will reduce the likelihood of the CT scan adversely affecting the pump. Before you turn off your insulin pump for the duration of

the CT scan check your blood glucose level to ensure that it is within the expected range. Follow your physician's recommendations for what to do prior to turning off the pump.

During the CT scan

- Follow the plan you developed with your physician.
- If the insulin pump is tethered to a cannula and can be safely moved outside the direct x-ray beam (without disconnecting it), work with the radiologic technologist to reposition the insulin pump so it will not be exposed directly to the x-ray beam during the CT scan.
- If the insulin pump cannot be moved but your physician has determined that it can be turned off:
    - Follow your physician's instructions for turning off the pump.
    - Communicate with the radiologic technologist to minimize the time the insulin pump is off; let the technologist know the maximum time that your physician has recommended the pump can be turned off.
    - Remember to turn your insulin pump back on after the scan. Follow your physician's instructions for restarting insulin after pump interruption.
- If the insulin pump cannot be turned off safely, let the radiologic technologist know so they can plan imaging that will minimize the risk of adverse effects on the function of the insulin pump.
- If your physician has made other recommendations, such as the use of insulin by injection, follow those instructions.
- Tell the radiologic technologist if you experience symptoms such as lightheadedness, fainting, or if you hear alarm or alert sounds from the pump during or immediately after the CT scan.
- Contact your physician as soon as possible if you had seizures or loss of consciousness during or after the procedure or if you heard alarm or alert sounds from the pump.

After the CT scan

- **Confirm your insulin pump is working correctly.** Ensure that it is turned on and it has the correct basal rates, correct time and date, etc. Look for any alarm or alerts or error codes.
- Check your blood glucose level to ensure it is within the recommended range. Follow your physician's recommendations for what to do after restarting the pump.

Recommendations for Physician ordering CT scan

The presence of an insulin pump should NOT preclude the performance of an appropriate, medically indicated CT scan. The probability of an adverse event being caused by exposing these devices to CT irradiation is extremely low, and it is greatly outweighed by the clinical benefit of a medically indicated CT examination. CT continues to be the preferred tomographic imaging technology for patients with implantable or wearable medical devices. CT is safer for patients with devices of unknown magnetic resonance imaging (MRI) (/mri-magnetic-resonance-imaging) safety status. You should be aware that an MR Conditional device is only safe with the MR environment that matches its conditions of safe use. Any device with an unknown MRI safety status should be assumed to be MR Unsafe.

- If the CT scan will cover the area over the insulin pump discuss with the patient whether the insulin pump can be safely moved, attached at a different location, turned off and for how long, or if alternative diabetes management is required.
- Communicate this information to the imaging facility that will be performing the CT scan to help them plan imaging that will minimize the risk of adverse effects on the function of the insulin pump.

Recommendations for Radiologist and Radiologic Technologist

The presence of an insulin pump should NOT preclude the performance of an appropriate, medically indicated CT scan. The probability of an adverse event being caused by exposing these devices to CT irradiation is extremely low and it is greatly outweighed by the clinical benefit of a medically indicated CT examination. CT continues to be the preferred tomographic imaging technology for patients with implantable or wearable medical devices. CT is safer for patients with devices of unknown magnetic resonance imaging (MRI) (/mri-magnetic-resonance-imaging) safety status. You should be aware that an MR Conditional device is only safe with the MR environment that matches its conditions of safe use. Any device with an unknown MRI safety status should be assumed to be MR Unsafe.

CT imaging facilities can use the following recommendations to develop protocols for planned and for urgently needed CT scans.

- If the insulin pump is tethered to a cannula and can be safely moved during the CT scan, work with the patient to move the insulin pump so it will not be directly exposed to the primary x-ray beam and will remain outside of direct CT x-ray beams throughout the exam. Note that only the electronics of the insulin pump can be affected by x-ray radiation.
- If the insulin pump cannot be safely moved:
    - Ask the patient if it can be safely turned off during the CT scan and for how long.

    - Set a timer and remind the patient to turn their insulin pump back on after the scan and to check it for proper function.

- If you cannot determine that an insulin pump can be safely moved or turned off, use the following recommendations to reduce risk of potential adverse interactions between the CT x-ray radiation and the insulin pump:
    - Use CT radiographs (i.e. scouts or localizer views) while setting up the CT scan to identify the pump location relative to the programmed scan range. Note: CT radiograph scans have not been associated with x-ray interference with electronic medical devices.
        - If possible, avoid including the insulin pump inside the scanning range. It is important, however, to ensure that CT images of the prescribed anatomy are taken so that the necessary diagnostic information is obtained. Confirm the required anatomic range with the supervising radiologist.
        - For CT procedures where the medical device is located within the programmed scan range and cannot be safely moved or turned off, minimize direct x-ray exposure to the electronics of the infusion pump by using:
            1. the lowest dose consistent with the needed level of diagnostic image quality and
            2. a lower dose delivery rate. This can be accomplished by using a longer rotation time or lower pitch value, if appropriate for the ordered CT exam.
        - **Imaging exams that would involve scanning directly over the electronics of the device for more than several seconds require additional care and should not be performed unless the device can be safely relocated or turned off. Examples of these scans are CT perfusion exams or interventional procedures such as CT fluoroscopy. If moving or turning the insulin pump off is not possible and the scan is urgently needed, careful monitoring of the device during and after the procedure is required.**
- Be mindful that interference is possible and be ready to terminate the scan if the patient experiences adverse symptoms. Although adverse symptoms are rare they can include alarm sounds from the pump, lightheadedness, fainting, seizures and loss of consciousness.

Recommendations for Physician managing the patient's diabetes and insulin pump use

The presence of an insulin pump should NOT preclude the performance of an appropriate, medically indicated CT scan. The probability of an adverse event being caused by exposing these devices to CT irradiation is extremely low and it is greatly outweighed by the clinical benefit of a medically indicated CT examination. CT continues to be the preferred tomographic imaging technology for patients with implantable or wearable medical devices. CT is safer for patients with devices of unknown magnetic resonance imaging (MRI) (/mri-magnetic-resonance-imaging) safety status. You should be aware that an MR Conditional device is only safe within the MR environment that matches its conditions of safe use. Any device with an unknown MRI safety status should be assumed to be MR Unsafe.

- If your patient is scheduled for a CT exam, work with them to determine a location to attach the insulin pump so that it will be outside the direct path of the CT x-ray beam.
- If the insulin pump cannot be moved or attached to a location outside the direct path of the CT x-ray beam, determine whether it can be safely turned off and for how long. Communicate this information to the imaging center that will be performing the exam so that staff can work with the patient to minimize the probability of an adverse effect related to the insulin pump.