

US FreeStyle Libre Systems and Radiologic Procedures

The FreeStyle Libre 2, FreeStyle Libre 2 Plus, FreeStyle Libre 3, and FreeStyle Libre 3 Plus sensors have been cleared by the FDA to be worn during radiologic studies including X-ray imaging, computed tomography (CT), and magnetic resonance imaging (MRI).¹ In 2022 Abbott Diabetes Care conducted a study² to evaluate the effects of CT, X-ray, and MRI procedures on FreeStyle Libre sensors. After rigorous 3rd party testing, it was determined that FreeStyle Libre systems sensors do not need to be removed and can safely be used after imaging procedures including X-ray, CT and MRI (see MRI conditions below). While the study results apply to all FreeStyle Libre systems sensors including FreeStyle Libre Pro and FreeStyle Libre 14 day, the recent FDA clearance is specific to the FreeStyle Libre 2 sensor, FreeStyle Libre 2 Plus sensor, FreeStyle Libre 3 sensor, and FreeStyle Libre 3 Plus sensor.

The FDA has determined that X-ray caution and limitation and CT contraindications may be removed from the labeling. There is no waiting period after a CT-scan or X-ray to be able to safely use the FreeStyle Libre system sensor.

MRI Safety Information³:

Depending on the type of procedure and scan required, there is potential for the accuracy and functionality to be compromised, so it is best to wait 1 hour following MRI exposure to ensure the FreeStyle Libre systems sensor is operating normally. After 1 hour, the accuracy and functionality of the device is not compromised. You can safely have a 1.5T or 3T MRI exam while wearing your Sensor, under the conditions listed in the chart below. Injury may result if the conditions are not followed. Leave your phone and Reader outside of the exam room.

Parameter	Condition
Device Name	Libre 3 or Libre 3 Plus Sensor Libre 2 or Libre 2 Plus Sensor
Static Magnetic Field Strength (B0)	1.5T and 3T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	40 T/m (4,000 G/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
RF Conditions	Maximum Whole-body SAR: 2 W/kg
Scan Duration	1.5T scanners: Up to 1 hour of continuous scanning without cooling period.
	3T scanners: Up to 12 minutes of scanning between the pelvis and the sternum with a cooling period of 2 minutes between scans. Up to 1 hour of continuous scanning without cooling period when scanning elsewhere.
Scan Regions	All landmark locations are acceptable within

	the region-specific scan durations described above.
Image Artifact	The presence of a Libre 3 or Libre 3 Plus Sensor may produce an image artifact of 5.8 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.
Device Functionality	Device readings may be inaccurate during active MRI scanning but device functionality fully returns to normal operation by 1 hour following MRI exposure.

The contraindication related to diathermy therapy remains unchanged. The sensor should be removed. The exposure to diathermy may damage the sensor, which could impact proper device function and cause inaccurate readings. Please see the other Indications and Important Safety Information in the respective User’s Manuals.

Fluoroscopy, a type of X-ray, will have no impact on the sensor performance.

There are no contraindications, warnings and limitations regarding use with ultrasound procedures.

The FreeStyle Libre Systems have not been studied with PET scan procedures; therefore, Abbott is unable to attest to the accuracy or performance of the Systems under such use case conditions. While the radiation levels from tracers used in a PET scan are generally quite minimal, the sensor readings could be impacted by the glucose tracer, generating a signal, since 2-deoxyglucose is a substrate for glucose oxidase, the enzyme utilized by the FreeStyle Libre Systems sensors.

References

1. FDA 510(k); accessed June 2024 from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233537>
2. Matievich, William, Namvar Kiaie, and Timothy C. Dunn. "Safety and Functional Integrity of CGM Sensors When Used During Radiologic Procedures Under High Exposure Conditions." *Journal of Diabetes Science and Technology* (2022). <https://doi.org/10.1177/19322968221106206>
3. Data on File. Abbott Diabetes Care.

Important Safety Information

FreeStyle Libre 14 day system: Failure to use FreeStyle Libre 14 day system as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or FreeStyleLibre.us for safety info.

FreeStyle Libre 2 and FreeStyle Libre 3 systems: Failure to use FreeStyle Libre 2 or FreeStyle Libre 3 systems as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If glucose alarms and readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or FreeStyleLibre.us for safety info.