

Section 7.9 US Federal Communications Commission (FCC) Notice

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference; and
2. This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.



Caution:

Exposure to Radio Frequency Radiation. The equipment contains a transmitter with FCC ID: R68MTCHDRCT. The antennas used for this transmitter must be installed to provide a separation distance of at least 20 cm (0 feet 7.87 in) from all persons and must not be co-located or operated in conjunction with any other antenna or transmitter. End-users must follow the instructions from this document for transmitter operating conditions to satisfy Radio Frequency exposure compliance.

Section 7.10 Protocols and Standards

This wireless functionality references and uses the following industry protocols and standards:

- 802.11b and 802.11g are wireless networking standards developed by the Institute of Electrical and Electronics Engineers (IEEE). 802.11b/g apply to wireless LANs and work in the 2.4 GHz band and operate at a maximum raw data rate of 11Mbps for 802.11b and 54 Mbps for 802.11g. 802.11g devices are backwards compatible with 802.11b devices. Refer to ISO/ IEC 8802-11:2005 standards for local and metropolitan area networks for more information.

- 802.11i (WiFi Protected Access2) is a security standard for wireless networks. Refer to IEEE 802.11i for more information. Your device will be configured to 802.11i-PSK with AES-CCMP encryption or equivalent.
- TCP/IP (Transmission Control Protocol/Internet Protocol) is a standard data transport protocol used for the Internet and other similar networks. Refer to RFC 1122 for more information.

Section 7.11 Electronic Records

The AmiCORE instrument can be configured to export data to be used to create an electronic record. In this context, an “electronic record” is data stored for official quality or regulatory purposes. To create an electronic record, the operator enters all information related to the donor and procedure, as required by the center’s SOPs.

When a procedure is completed, the data is automatically transmitted to the data management system for reporting.



Note: Compliance with USFDA’s 21 CFR Part 11 for Electronic Records is only achievable when integrated at a system-wide level. The data from the AmiCORE instrument on its own is not fully 21 CFR Part 11 compliant.



Note: Consult with your center’s RA/QA Representative for details on your center’s specific adaptation of manufacturing and electronic records.



Note: Required information according to your center’s SOPs must be entered to qualify as an electronic record.