

Axonics R20 Neurostimulator



Implant Manual

Rechargeable | Model 5101

Rx only

English

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WIRELESS COMMUNICATION

Model: 5101

FCC ID: 2AEEGS

IC: 20225-S

FCC Compliance

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 transmitter is authorised by rule under the Medical Device Radio Communication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation.

This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radio Communication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

IC Compliance

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of this device.

FCC and IC Compliance

This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Note: Changes and modifications to the Neurostimulator are not authorised by Axonics and could void FCC and IC certification and negate the user's authority to use the product.

Quality of Wireless Service

This device operates in the 402-405 MHz frequency and the maximum effective radiated power of the Neurostimulator communication is below the limit of 25 µW ERP/EIRP as specified in EU: EN ETSI 301-839 and USA: FCC 47 CFR Part 95; Subpart I. The Remote Control, Clinician Programmer or Charger must be within 1 meter from the implant for successful communication.

Wireless Security

The Neurostimulator can only communicate with a single Remote Control that is paired to it using the Clinician Programmer. Any Axonics Clinician Programmer or Charger can communicate with a Neurostimulator. Additional mechanisms exist to ensure the integrity of radio data.

CUSTOMER SERVICE

For questions regarding the Axonics SNM System, call our **Customer Support Center** toll-free at **+1-877-929-6642**.

Additional information and product manuals can be found at our website: www.axonics.com

Adverse Event Reporting

In case of any serious incident related to the product, please report to Axonics (+1-877-929-6642) as well as the competent authority of your state, which can be found here: <https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human>.



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