

§ 95.2565

specify a channeling scheme for MedRadio systems.

(a) MedRadio transmitters associated with medical implant devices, which incorporate a frequency monitoring system as set forth in § 95.2559(a), may transmit on any frequency in the 401–406 MHz band.

(b) MedRadio transmitters associated with medical implant devices, which do not incorporate a frequency monitoring system as set forth in § 95.2559(a), may transmit on any frequency in the 401–402 MHz or 405–406 MHz bands, or on the frequency 403.65 MHz in the 402–405 MHz band.

(c) MedRadio transmitters associated with medical body-worn devices, regardless of whether a frequency monitoring system as set forth in § 95.2559(a) is employed, may transmit on any frequency in the 401–402 MHz or 405–406 MHz bands.

(d) MedRadio transmitters that are used externally to evaluate the efficacy of a more permanent medical implant device, regardless of whether a frequency monitoring system as set forth in § 95.2559(a) is employed, may operate on any frequency in the 402–405 MHz band, provided that:

(1) Such external body-worn operation is limited solely to evaluating with a patient the efficacy of a fully implanted permanent medical device that is intended to replace the temporary body-worn device;

(2) RF transmissions from the external device must cease following the patient evaluation period, which may not exceed 30 days, except where a health care practitioner determines that additional time is necessary due to unforeseen circumstances;

(3) The maximum output power of the temporary body-worn device must not exceed 200 nW EIRP; and

(4) The temporary body-worn device must comply fully with all other MedRadio rules applicable to medical implant device operation in the 402–405 MHz band.

(e) Only MedRadio transmitters that are part of a Medical Micropower Network (MMN) may operate in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands. Each MedRadio transmitter that is part of an MMN must be capable of operating in each of the fol-

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lowing bands: 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz. All MedRadio transmitters that are part of a single MMN must operate in the same band.

(f) Only MedRadio transmitters that are part of a Medical Body Area Network (MBAN) may operate in the 2360–2400 MHz band.

§ 95.2565 MedRadio frequency accuracy.

Each MedRadio transmitter type must be designed to maintain a frequency stability of ± 100 ppm of the operating frequency over the applicable temperature range set forth in this section. Frequency stability testing shall be performed over the appropriate temperature range.

(a) 25 °C to 45 °C in the case of medical implant transmitters; and

(b) 0 °C to 55 °C in the case of MedRadio programmer/control transmitters and medical body-worn transmitters.

§ 95.2567 MedRadio radiated power limits.

Each MedRadio transmitter type must be designed such that the MedRadio equivalent isotropically radiated power (M-EIRP) does not exceed the limits in this section. Compliance with these limits must be determined as set forth in § 95.2569.

(a) *Transmitters subject to frequency monitoring—401–406 MHz.* For MedRadio transmitters that are not excepted under § 95.2559(b) from the frequency monitoring requirements of § 95.2559(a):

(1) The M-EIRP within any 300 kHz bandwidth within the 402–405 MHz band must not exceed 25 microwatts.

(2) The M-EIRP within any 100 kHz bandwidth within the 401–402 MHz or 405–406 MHz bands must not exceed 25 microwatts.

(b) *Transmitters excepted from frequency monitoring—401–402 MHz and 405–406 MHz.* For MedRadio transmitters that are excepted under § 95.2559(b)(2) or (3) from the frequency monitoring requirements of § 95.2559(a):

(1) The M-EIRP of any transmitter operating in the 401–401.85 MHz or 405–406 MHz bands must not exceed 250 nanowatts in any 100 kHz bandwidth.