ICS 11.040.40
CCS C35

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1874-2023

Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices

有源植入式医疗器械 电磁兼容 植入式心脏起搏器、植入式心律转复除颤器和心脏再同步器械的电磁兼容试验方案

Issued on: March 14, 2023 **Implemented on: May 1, 2024**

Issued by: National Medical Products Administration

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Foreword

This document is drafted in accordance with the provisions of GB/T 1:1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents": This document is equivalent to ISO 14117:2019 "Electromagnetic Compatibility of Active Implantable Medical Devices Implantable Cardiac Pacemakers, Implantable Electromagnetic Compatibility Test Rules for Cardioverter-Defibrillators and Cardiac Resynchronization Devices: Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents: This document is proposed by the State Drug Administration: This document is under the jurisdiction of the Active Implant Subcommittee (SAC/TC110/SC4) of the National Standardization Technical Committee on Surgical Implants and Orthopedic Devices: This document was drafted by: Shanghai Institute of Medical Device Inspection, Medtronic (Shanghai) Management Co:, Ltd:, Biotronic (Beijing) Medical Devices Machinery Co:, Ltd:, Chuangling Cardiac Rhythm Management Medical Devices (Shanghai) Co:, Ltd:, and Lepu Medical Electronic Instrument Co:, Ltd: The main drafters of this document: Wang Weiming, Li Qifei, Liu Jiawei, Zhang Botian, Qu Zehao, Qiu Fengwei, Jinhua:

The number and number of electromagnetic (EM) emitters that patients implanted with active implantable cardiovascular devices were exposed to during their daily activities during the last 20 years Types have risen sharply: This trend is expected to continue: Due to the potentially life-sustaining nature of these devices, patients, industry and regulators The relationship between such transmitters and active implantable cardiovascular devices [pacemakers and implantable cardioverter-defibrillators (ICDs)] has been interaction between: The risks posed by this interaction include device inhibition or delivery of inappropriate therapy which, in the worst case, could lead to Serious injury or death of the patient: In recent years, other active implantable cardiovascular devices have emerged, not only pacemakers and ICDs, but also through Devices that optimize ventricular

synchronization to improve cardiac output: Compared with pacemakers and ICD devices, although such devices can provide additional therapy, most of the EMC Requirements are similar, so in most cases the concepts that apply to pacemakers also apply to CRT-P devices, and for CRT-P Devices are tested in a manner similar to that for pacemakers: Similarly, concepts applicable to ICD devices are also The body applies to CRT-D devices, therefore, the method of testing CRT-D devices is similar to the method of testing ICD devices: Through standard test methods, the manufacturer can evaluate the electromagnetic compatibility performance of the product and prove that it can be used in the uncontrolled electromagnetic environment that the patient may encounter: environment, its products have an appropriate level of electromagnetic compatibility: It is important to make the manufacturers of emitters of electromagnetic fields and any other devices (intentional or not) aware that such devices may interfere with Normal operation of active implantable cardiovascular devices: It is important to understand that even if the device complies with the requirements of this document and the emitter complies with relevant human exposure safety standards and relevant regulatory emissions Requirements [eg: Federal Communications Commission (FCC) regulations], such interactions may also occur: Compliance with biosafety guidelines does not necessarily guarantee electromagnetic compatibility with active implantable cardiovascular devices: In some cases, for For such devices, the reasonably achievable electromagnetic immunity performance is lower than the limit value of such biological safety requirements: Please refer to Appendix M for the principle of applying ICNIRP1998 levels: The principles applicable to transmitters above 10 MHz can be found in Appendix M: The potential for a transmitter device to interfere with an active implantable cardiovascular device is complex and depends on the following factors:

---The frequency content of the transmitter,

---signal power,

---Patient proximity,

---coupling coefficient, and

--- Exposure duration: Transmitters with a fundamental carrier frequency not greater than 1 kHz have the potential to be sensed directly by cardiac pacemakers or ICDs: In addition, the heart A pacemaker or ICD can also sense a high-frequency carrier with a baseband modulation frequency below 500 Hz, at a sufficiently close range, and at a sufficiently high power: Additional details on this issue can be found in Appendix M: This document clarifies the electromagnetic compatibility of cardiac pacemakers and ICDs (not greater than 3000MHz), divided into several sub-terms:

a) 0Hz<=f< 385MHz In the lower frequency bands (< 385MHz), there are many electromagnetic transmitters (eg: broadcast radio and television) and many new or existing New applications of technology may increase the probability of interaction between the

transmitter and the patient's pacemaker and ICD: Examples are as follows:

---Electronic Article Surveillance (EAS) system;

---Access control system (radio frequency identification or RFID);

--- New wireless services in UHF and VHF bands;

---Maglev track system;

--- Radio frequency (RF) medical operations (such as high frequency surgery and ablation therapy);

---metal detector;

1 Scope

YY/T 1874 is the electromagnetic compatibility test protocol for the three implanted cardiac rhythm devices: pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices. These are the implants where interference is not a nuisance but a hazard, since a device that misreads an external field can withhold a pace or deliver a shock that was never needed. The document sets out how such a device is exposed to electromagnetic fields under test, at what levels and frequencies, and how its response is judged, covering the everyday sources a patient meets as well as the clinical environments they pass through. At more than fifty thousand words it is one of the longest documents in the series. For a cardiac rhythm manufacturer seeking Chinese registration, this is the protocol the EMC evidence has to follow.

This document specifies procedures for the evaluation of one or more of the bradycardia, tachycardia, and cardiac Electromagnetic compatibility (EMC) test methods for active implantable cardiovascular devices for resynchronization and other treatments: NOTE: This document is designed for pulse generators used with endocardial leads or epicardial leads: For those who do not use endocardial or epicardial electrocardiography Pulse generators using polar lead technology, adjusted at the discretion of the manufacturer using these technologies: This document specifies performance limits for such devices when interacting with EM transmitters that may operate in the following two EM spectral ranges:

---0Hz<=f< 385MHz;

---385MHz<=f<=3000MHz: This document also specifies the requirements for the protection of such devices from EM fields in medical environments, defines the required accompanying documents, and provides information about EM transmitter manufacturers and expected immunity levels: This document applies to transvenous lead systems that can provide one or more of bradycardia, tachycardia, and cardiac resynchronization, etc: Therapeutic Active Implantable Cardiovascular Devices:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references, Only the version corresponding to the date applies to this document; for undated references, the latest version (including all amendments) applies to this document:

ISO 14708-1:2014 Surgical implants Active implantable medical devices Part 1: General requirements for safety, marking and information provided by the manufacturer

GB 16174:1-2015 Surgical implants Active implantable medical devices Part 1: General requirements for safety, marking and information provided by the manufacturer (ISO 4708-1:2000, IDT)

ISO 14708-2:2019 Surgical implants Active implantable medical devices Part 2: Cardiac pacemakers

GB 16174:2-2015 Surgical Implants Active Implantable Medical Devices Part 2: Cardiac Pacemakers (ISO 14708-2:2005, IDT)

ISO 14708-6:2019 Surgical implants Active implantable medical devices Part 6: Active devices for the treatment of tachyarrhythmias

YY 0989:6-2016 Active implantable medical devices for surgical implants Part 6: Active implantable medical devices for the treatment of tachyarrhythmias (including implantable defibrillators) specific requirements (ISO 14708-6:2010, IDT)