Project
21613-15

CCC del Uruguay S.A.
Cardiac Implantable Optimizer Smart Mini

Test Report
Exposure
Medical Device Radio Communications Service

Prepared for:

CCC del Uruguay S.A
General Paz 1363
Montevideo, Uruguay 11400

By

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8 Apr 2021

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Revision History

Revision Number	Description	Date
Final		8 Apr 2021

Errata:

None.

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Certificate of Compliance

FCC MRA Designation Number: US5270
NVLAP Accreditation Number: 200062-0

Applicant	Device & Test Identification	
CCC del Uruguay S.A. Gral Paz 1363 Montevideo, Uruguay 11400 Certificate Date: 8 Apr 2021	Model(s): Laboratory Project ID:	Cardiac Implantable Optimizer Smart Mini 21613-15 (22421)

The EUT(s) listed above were tested utilizing the following documents and found to be in compliance with the required criteria.

FCC Part 95			
Subpart I Medical Device Radio Communications Service			
Test	**Class/Limits Met**	**Test Level**	**Test Date**
Permissible Exposure Evaluation 95.2585	Complies	1.1307(b) and 2.1093 exposure limit satisfied	26 Jun 2020

This report has been reviewed and accepted by the Applicant. The undersigned is responsible for ensuring that this device will continue to comply with the rules listed above.

_____
Representative of Applicant

1.0 Introduction

1.1 Scope

This report describes the extent to which the equipment under test (EUT) conformed to the exposure limits of the USA.

1.2 EUT Description

This device is a wireless controlled implantable pulse generator for medical applications.

Table 1.2.1: Equipment Under Test

Manufacturer	Model	Description
CCC del Uruguay S.A.	Cardiac Implantable Optimizer Smart Mini	Medical Radio Transceiver

2.0 Permissible Exposure Evaluation 95.2585

2.1 Procedure

The human exposure is determined using the transmit power as weighed per the operational transmission time required.

2.2 Limits

Requirement	Limits
Radiofrequency radiation exposure requirements specified in §§ 1.1307(b) and 2.1093.	≤1.0 mW* SAR exclusion per FCC KDB 447498.
47 CFR § 1.1307 (b)(2)(iv) Equipment authorized for use in the Medical Device Radiocommunication Service (MedRadio) as a medical implant device or body-worn transmitter (as defined in subpart I of part 95 of this chapter) is subject to routine environmental evaluation for RF exposure prior to equipment authorization, as specified in §§ 2.1093 and 95.2585 of this chapter by finite difference time domain (FDTD) computational modeling or laboratory measurement techniques. […] 47 CFR § 2.1093 (c)(1) Portable devices […] the Medical Device Radiocommunication Service (MedRadio), and […] are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use.	
*FCC 447498 D01 General RF Exposure Guidance v06: Paragraph 4.2.4. *Transmitters implanted in the body of a user When the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is ≤ 1.0 mW, SAR test exclusion may be applied. The maximum available output power requirement and worst case operating conditions must be supported by power measurement results, based on device design and implementation requirements, and fully justified in a SAR analysis report according to KDB Publication 865664 D02, in lieu of SAR measurement or numerical simulation.*	

2.3 Results

The EUT satisfied the requirement.

Highest recorded field strength of the EUT 402-405 MHz radio is 55.7 dBuV/m at 10 meters as measured without phantom human torso simulator. This is conservative worst-case figure as the time-based averaging is not applied.

This calculates to EIRP of 0.0012 mW which is below the 1.0 mW limit as cited in the FCC 447498 KDB, paragraph 4.2.4, as the exclusion threshold.

Further, even if the full allowed power of 74.7 dBuV/m at 10 meters were radiated by the EUT, the EIRP would calculate to less than 0.1 mW.

Regarding the inductive link radio at 13.56 MHz; this is generated by the programmer wand used by the physician. The operation of the inductive link is relatively brief to read the security encryption key. Subsequently, the programming wand is removed from the patient and the Medical Radio remains active during the examination.

It is concluded that the RF exposure is below the exclusion threshold of 1.0 mW and the SAR exclusion applies.

End of Report