

Generation of Test Signals acc. ISO 14708 for Testing of Cardiac Pacemakers Application Note

Products:

R&S [®] SMA100A	R&S [®] SML
R&S [®] SMF100A	R&S [®] SMT
	R&S [®] SMIQ

This application note describes how to generate test signals with Rohde & Schwarz signal generators of the R&S[®] SMx family (R&S[®]SMA100A, R&S[®]SMF100A, R&S[®]SML, R&S[®]SMT, and R&S[®]SMIQ) to perform interference testing on implantable medical devices using a small application software.

Table of Contents

1	Overview	4
2	Hardware and Software Requirements	5
3	Test Setup	6
4	Running the Test Scenario	8
	4.1 Test Scenario TC 27.2 TS1	10
	4.2 Test Scenario TC 27.2 TS2	11
	4.3 Test Scenario TC 27.3 TS	12
	4.4 Test Scenario TC 27.4 TS	14
5	Literature	16
6	Ordering Information	16

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1 Overview

The medical advances in technology have allowed many patients to live a longer lifespan, for example by the use of active implantable medical devices like cardiac pacemakers for patients with problems of irregular heart beats, or patients that suffer from heart attacks frequently.

The technological world has improved our lives with many electronic devices that might cause interference and malfunction of devices that are susceptible to such interferences. Therefore, various tests need to be conducted on active implantable medical devices to check their susceptibility to electrical influences due to external electromagnetic fields.

This application software will generate test signals according to the ISO 14708-2:2005 [1] standard, Chapter 27.2 – 27.4, using Rohde & Schwarz signal generators R&S[®]SMA100A or R&S[®]SMF100A. The software is also compatible with Rohde & Schwarz signal generators R&S[®]SML, R&S[®]SMT, and R&S[®]SMIQ, which are no longer available for orders.

Other Rohde & Schwarz signal generators such as R&S[®]SMB100A, R&S[®]SMC100A, R&S[®]SMBV100A, R&S[®]SMJ100A, and R&S[®]SMU200A, can be used with the limitation of the LF Generator signal level being clipped on test scenario TC 27.3 TS.

2 Hardware and Software Requirements

PC hardware requirements

CPU	: Pentium 1 GHz or better
RAM	: 1 GB or more
Monitor	: SVGA colour monitor
Data Connection Interface	: GPIB or LAN port

PC software requirements

Microsoft 32-bit operating system (Windows 2000/XP)
Visa Library 4.0 or higher

Instrument basic requirements

LF Generator

Frequency Range	from 16.6 Hz to 167 kHz
Amplitude Range	from 0 V to 7 V (U_{p-p})

AM Modulator

Carrier Frequency	500 kHz
Modulating Frequency	130 Hz
Amplitude	2 V (U_{p-p})
Modulating Index	95%

3 Test Setup

The test setup for the cardiac pacemaker (implantable pulse generator) according to ISO 14708-2:2005 is shown in Figure 1.

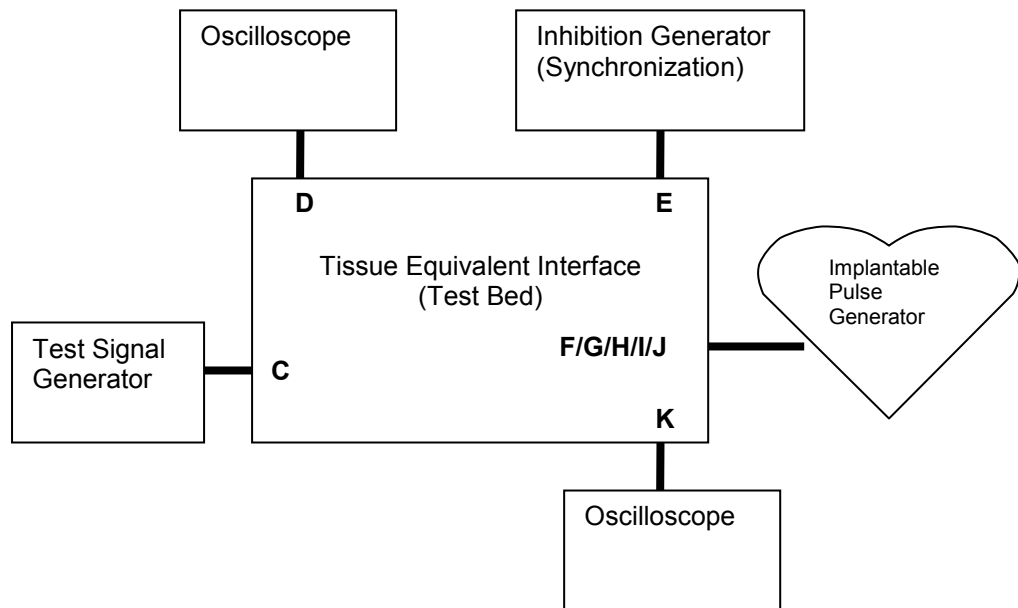


Figure 1: Hardware connection overview setup.

The implantable pulse generator is connected to the tissue equivalent interface for testing. The inhibition generator is used in test scenario TC 27.4 TS and it provides a synchronization signal for the implantable pulse generator, allowing the pulse signal from the implantable pulse generator to occur synchronously with the inhibition generator signals (see ISO 14708-2:2005 [1] standard, Chapter 6.1.2). The test signal generator provides the interference to the implantable pulse generator and the results are captured on two different oscilloscopes.

The application software simulates the test signal generator using a R&S[®] SMx signal generator.

The instrument connection is set up as follows:

1. Connect a laptop/PC GPIB or LAN port with the signal generator GPIB or LAN port.
2. Connect the LF signal output port of the signal generator to port C of the test bed for the following tests:
 - TC 27.2 TS1
 - TC 27.3 TS
 - TC 27.4 TS
3. Connect the RF signal output port of the signal generator to port C of the test bed for the following test:
 - TC 27.2 TS2

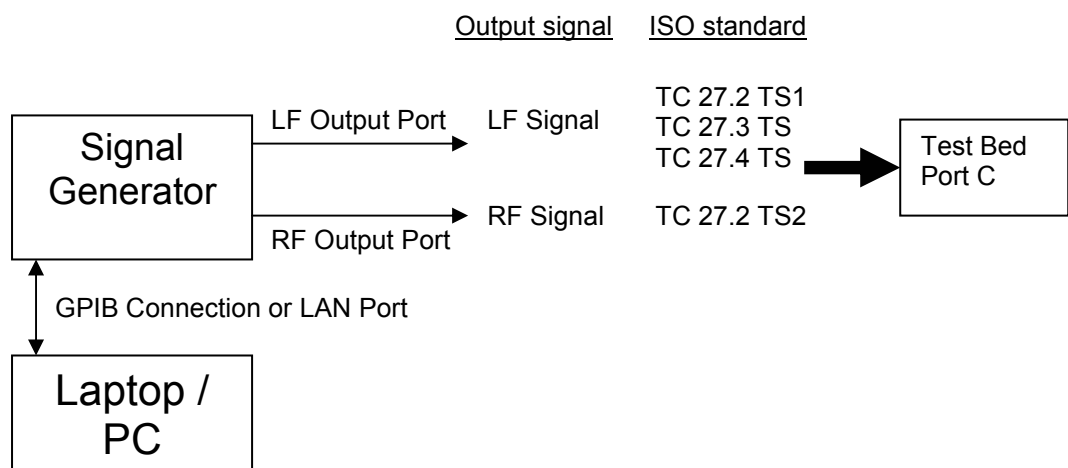


Figure 2: Hardware connection test signal generator setup.

4 Running the Test Scenario

Copy and unzip the files into the laptop/PC and launch *ImplantRadiation.exe*.

The *Implant Radiation* software user interface will appear as shown in Figure 3.

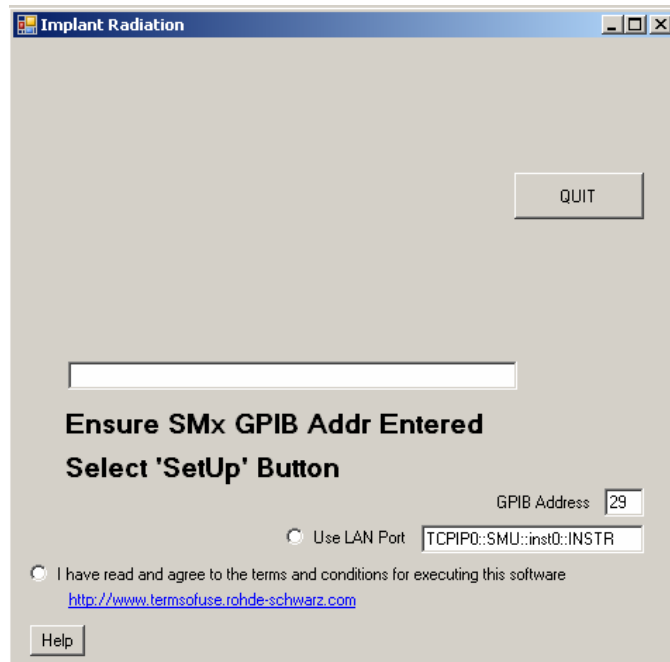


Figure 3: *Implant Radiation* software user interface

Before starting any tests, click on the radio button below to acknowledge that the terms and conditions for executing this software are agreed upon. A *Setup* button will appear after the acknowledgement.

If a GPIB port is used for controlling the signal generator, ensure that the GPIB address of the signal generator is set correctly for this particular test software, and click on the *Setup* button.

If a LAN port is used for controlling the signal generator, click on the radio button *Use LAN Port* and input the address of the LAN port in the text box below the radio button. The format should be:

TCPIP0::ipaddr::instr0::INSTR

where *ipaddr* can be either the address of the LAN port or the hostname of the signal generator.

The program will initialize the signal generator, and a message box will show the name and serial number of the signal generator that is currently used for testing. An *Initialisation Complete* text will appear and the buttons to select for the various test scenarios will appear as shown in Figure 4.

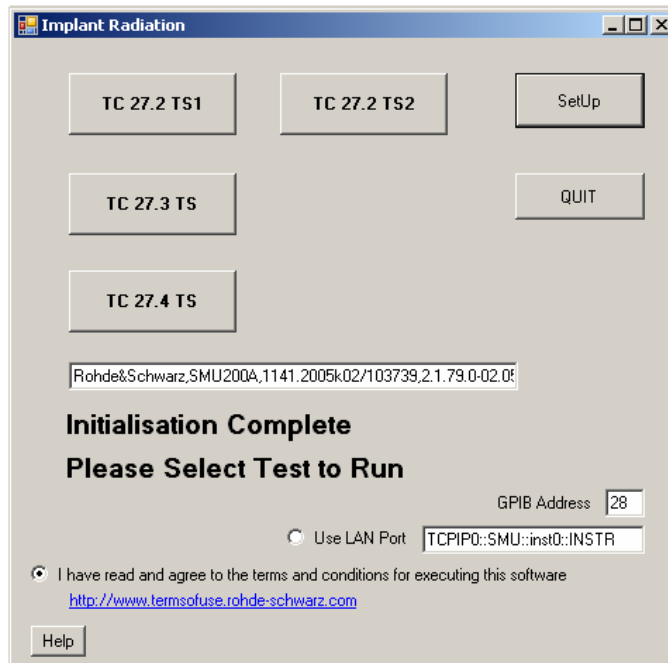


Figure 4: Initialisation complete.

4.1 Test Scenario TC 27.2 TS1

Select *TC 27.2 TS1* in order to start the test scenario. Make sure that the LF Output port is used to send the signal to the DUT. The text *TC 27.2 Test Signal 1 Active Loop* will appear to indicate that the test signal is being generated by the signal generator. The test signal will be a continuous active loop signal. In order to stop the test signal, the *SetUp* button needs to be pushed.

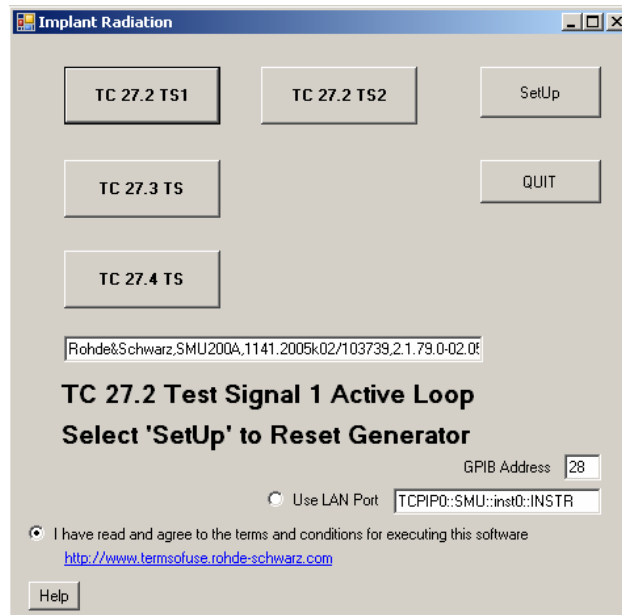


Figure 5: Running TC 27.2 TS1 scenario.

The test signal for TC 27.2 TS1 will be generated as:

- Sinusoidal signal of 1 V (peak-to-peak).
- Frequency swept from 16.6 Hz to 20 kHz at rate of one decade per minute.
- Continuous looping sweep in frequency.

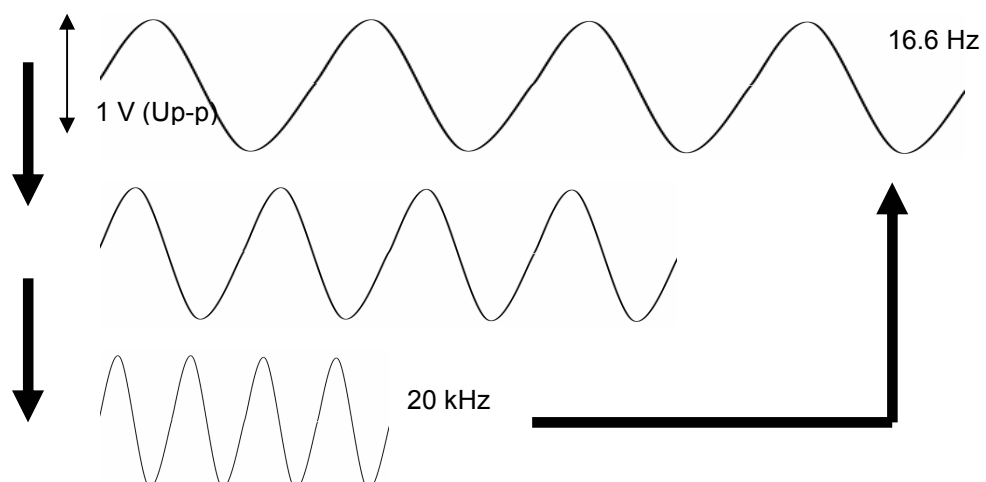


Figure 6: Flow diagram of TC 27.2 TS1 test signal.

4.2 Test Scenario TC 27.2 TS2

Select *TC 27.2 TS2* in order to start the test scenario. Make sure that the RF Output port is used to send the signal to the DUT. The text *TC 27.2 Test Signal 2 Active Loop* will appear to indicate that the test signal is being generated by the signal generator. The test signal will be a continuous active loop signal. In order to stop the test signal, the *SetUp* button needs to be pushed.

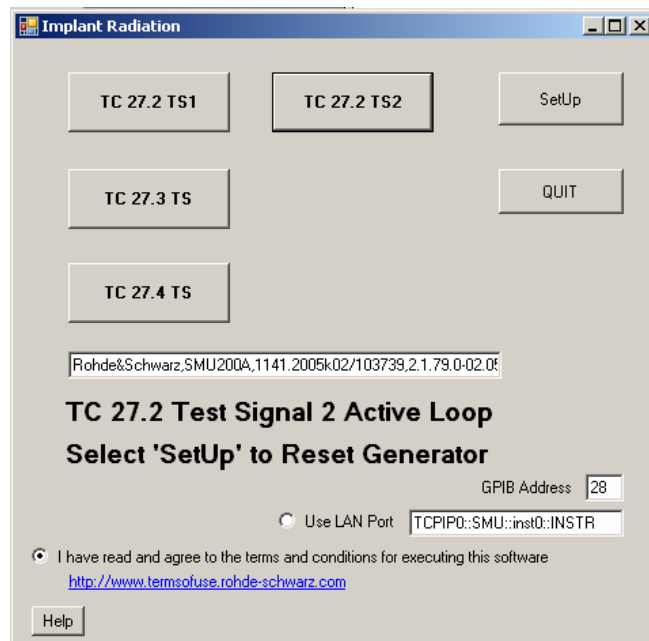


Figure 7: Running TC 27.2 TS2 scenario.

The test signal for TC 27.2 TS2 will be generated as:

- Sinusoidal carrier signal of frequency at 500 kHz.
- Continuous amplitude modulation at 130 Hz.
- Maximum peak-to-peak voltage of modulated signal at 2 V.
- Modulation index of 95 %.

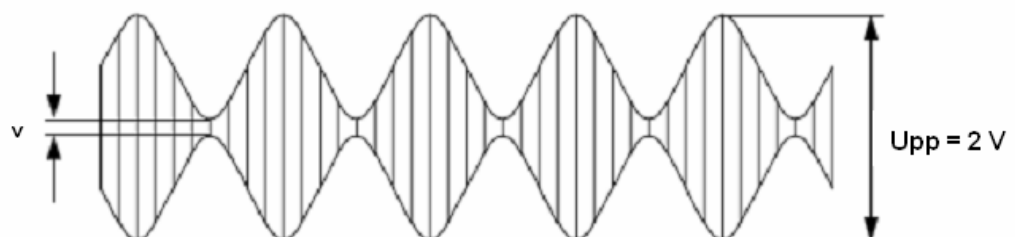


Figure 8: TC 27.2 TS2 test signal.

4.3 Test Scenario TC 27.3 TS

Select *TC 27.3 TS* in order to start the test scenario. Make sure that the LF Output port is used to send the signal to the DUT. The text *TC 27.3 Test Signal Running* will appear to indicate that the test signal is being generated by the signal generator. The test signal is not a continuous active loop signal. In order to stop the test signal before it completes, the *SetUp* button needs to be pushed. Alternatively the *QUIT* button can be pushed to terminate the program.

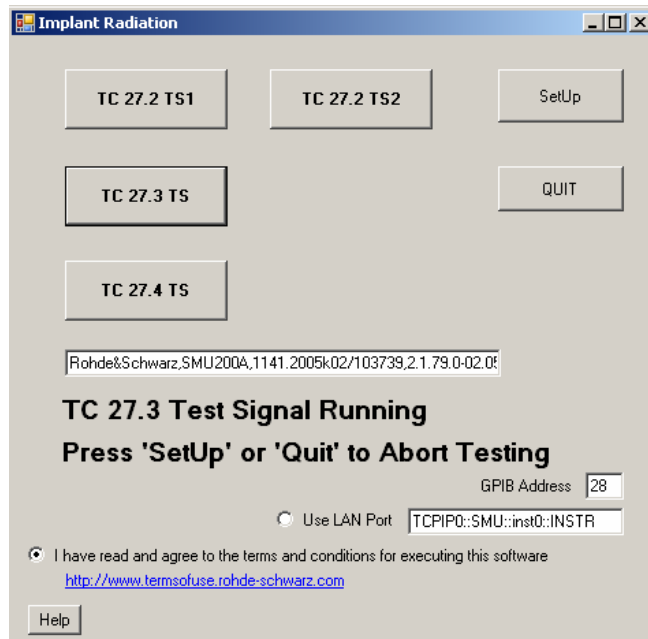


Figure 9: Running TC 27.3 TS scenario.

The test signal for TC 27.3 TS will be generated as:

- Frequency swept over 16.6 Hz to 140 kHz at rate of one decade per minute.
- Sinusoidal signal of 1 V (peak-to-peak) from 16.6 Hz to 20 kHz.
- Dwell time at 5 s.
- Amplitude increase by factor of m , with $m = (\text{current frequency}/20 \text{ kHz})$ from 20 kHz to 140 kHz.

Table 1 shows the maximum LF output level for the signal generators that can be used for test scenario TC 27.3 TS. Signal generators that cannot generate a LF output level up to 7 V (Up-p) will have the signal clipped at the maximum LF output level that it can generate.

Signal Generator	Maximum LF Output Level V (Up-p)
SMA100A	8.0
SMF100A	12.0
SML	8.0
SMT	8.0
SMIQ	8.0

Table 1: Signal generator maximum LF output level.

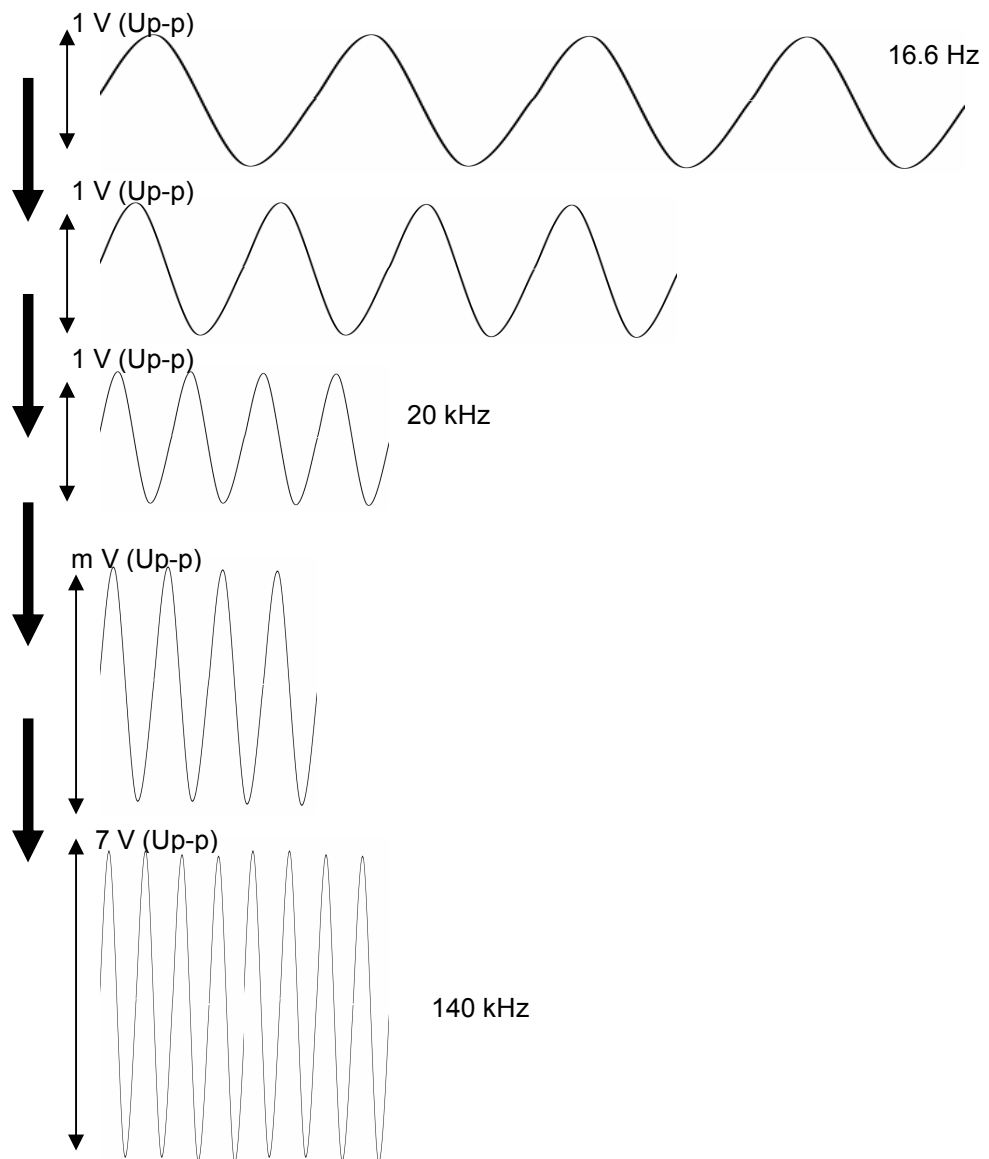


Figure 10: Flow diagram of TC 27.3 TS test signal

4.4 Test Scenario TC 27.4 TS

Select *TC 27.4 TS* in order to start the test scenario. Make sure that the LF Output port is used to send the signal to the DUT. The text *TC 27.4 Test Signal Running* will appear to indicate that the test signal is being generated by the signal generator. The test signal is not a continuous active loop signal. In order to stop the test signal before it completes, the *SetUp* button needs to be pushed. Alternatively the *QUIT* button can be pushed to terminate the program.

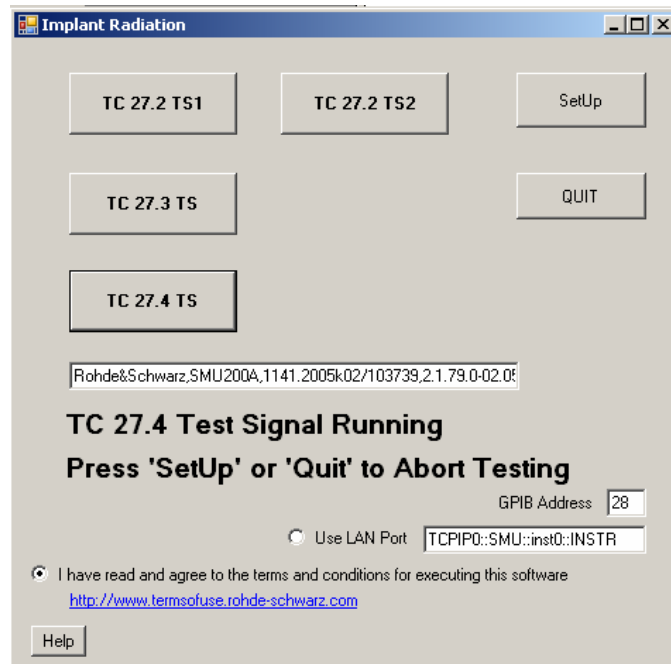


Figure 11: Running TC 27.4 TS scenario.

The test signal for TC 27.4 TS will be generated as:

- Frequency swept over 16.6 Hz to 167 kHz at four distinct and well spaced frequencies per decade
Frequencies : 16.6 Hz, 41.5 Hz, 83 Hz, 124.5 Hz,
: 167 Hz, 417.5 Hz, 835 Hz, 1.2525 kHz,
: 1.67 kHz, 4.175 kHz, 8.35 kHz, 12.525 kHz,
: 16.7 kHz, 41.75 kHz, 83.5 kHz, 125.25 kHz,
: 167 kHz
- Continuous looping sweep in frequency.
- Sinusoidal signal of amplitude gradually increasing from 0 V to 1 V (peak-to-peak) with 800 ms interval at 0.1 V spacing per increment.

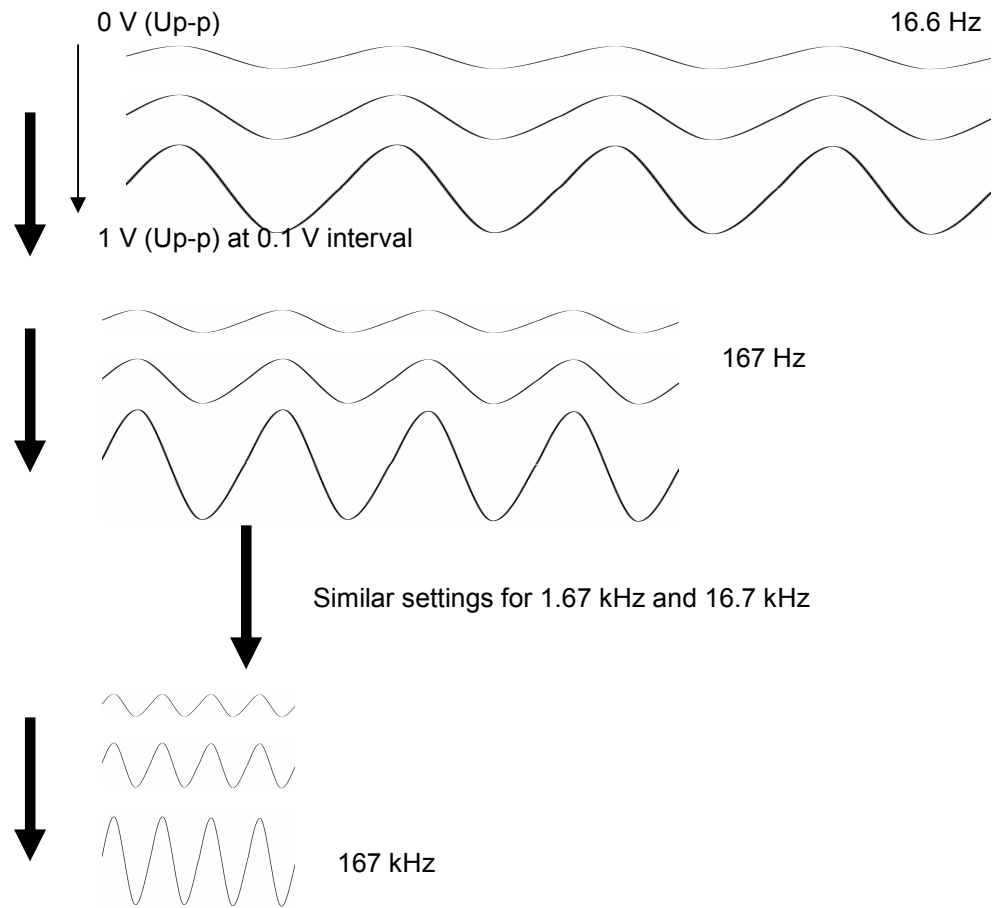


Figure 12: Flow diagram of TC 27.4 TS test signal

5 Literature

[1] International Organization for Standardization (ISO); ISO 14708-2:2005
Implants for surgery -- Active implantable medical devices -- Part 2: Cardiac
pacemakers

6 Ordering Information

R&S [®] SMA100A	Signal generator base unit	1400.0000.02
R&S [®] SMB100A	Signal generator base unit	1406.6000.02
R&S [®] SMBV100A	Signal generator base unit	1407.6004.02
R&S [®] SMC100A	Signal generator base unit	1411.4002.02
R&S [®] SMF100A	Signal generator base unit	1167.0000.02
R&S [®] SMJ100A	Vector signal generator base unit	1403.4507.02
R&S [®] SMU200A	Vector signal generator base unit	1141.2005.02

About Rohde & Schwarz

Rohde & Schwarz is an independent group of companies specializing in electronics. It is a leading supplier of solutions in the fields of test and measurement, broadcasting, radiomonitoring and radiolocation, as well as secure communications. Established 75 years ago, Rohde & Schwarz has a global presence and a dedicated service network in over 70 countries. Company headquarters are in Munich, Germany.

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