SP02EN

HE Instruments LLC

SPECIFIC PROCEDURE FOR CALIBRATION OF ECG SIMULATOR, TECHPATIENT CARDIO V4 rev. 2

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SECTION I
IDENTIFICATION AND DESCRIPTION

1 - Instrument identification

This document provides instructions for the calibration of an ECG simulator, TechPatient CARDIO Version 4. The manufacturer's manual was used as the prime data source in compiling these instructions. The equipment being calibrated will be referred to as the DUT (device under test) throughout this document.

2 – Calibration report

The calibration report or calibration certificate must include the following information about the DUT and the performed procedures:

a. Manufacturer Name and Model Name.
b. Model Version including Software Variations.
c. Serial Number.
d. Calibration conditions.
e. Standards used for calibration: manufacturer, model number, serial number, calibration status.
f. Calibration procedure.
g. Test results: parameter setup, expected value, measured value, measurement uncertainty.
h. Declaration of conformity.
i. Declaration of traceability.

3 – Calibration description

DUT parameters and performance specifications which pertain to this calibration are listed in Table 1.

Table 1 – Product specifications

Pulse Amplitude (Common: aVL)	Lead II Range	0.5 mV, 1 mV, 2 mV, 4 mV
	Lead I, Lead III Range	0.25 mV, 0.5 mV, 1 mV, 2 mV
	V1 to V6 Range	0.5 mV, 1 mV, 2 mV, 4 mV
	Calibrated Accuracy	± (0.5% + 20 µV)
Pulse Interval	Pulse Rate Range	20 PPM to 300 PPM in 1 PPM steps*
	Calibrated Accuracy	± 0.1 %
Pulse Width	Design Parameter	40 ms
Rise Time	Design Parameter	1.3 ms

Pulse amplitude is determined for each output combination at 4 mV. For Lead II combination, pulse amplitude is determined at 0.5 mV, 1 mV, 2 mV and 4 mV.

For the purpose of calibration, pulse amplitude will be determined by direct measurement of DC voltage. This procedure is performed to enable a higher accuracy measurement, possible through the use of a DC voltmeter, and is based on the fact that amplitude is defined at the medium point in the pulse width. This first order system has a settling time, relative to the defined amplitude accuracy, of 5 ms. A DC voltage measurement is considered to be equivalent to a pulse amplitude measurement 20ms after the rising edge of the pulse.

Pulse interval is determined at 60 PPM, 80 PPM and 100 PPM.

For the purpose of calibration, pulse interval will be determined by direct measurement of Pulse Interval on the High Signal Output. This procedure is performed to enable a higher accuracy measurement by reducing uncertainties associated with external noise contaminating the input of the internal comparator of the measurement instrument. Every output signal of device is derived from the same timebase and is equivalent to each other.

SECTION II
EQUIPMENT REQUIREMENTS

1 - Equipment required

Table 2 identifies the specific equipment to be used in this calibration procedure.

Table 2 – Equipment required

Equipment type	Measured parameter	Measurement range (Min.)	Measurement accuracy (Max.)
Multimeter / DC Voltmeter	DC voltage	-10mV to 10mV	± 7 µV
Frequency counter / Pulse Interval meter	Pulse interval	100ms to 1000 ms	± 0.03 %

2 – Accessories required

Table 3 identifies the accessories required for performing this calibration procedure.

Table 3 – Accessories required

Accessory	Description
9V Standard PP3 Battery	Condition: Brand New
Test leads	4mm Banana L: 0.5m Max.
Test probe	X1 attenuation

SECTION III
CALIBRATION PROCESS

1 - Preliminary instructions

Power up the test equipment 90 minutes prior to calibration to reach the specified accuracy, unless otherwise indicated by their respective operator's manual.

Install battery and power up the DUT for 15 minutes prior to calibration and ensure the Suspend setting is removed to prevent it from turning off. Set the Noise Sources to None to prevent them from interfering with calibration. Set the Common Lead to aVL.

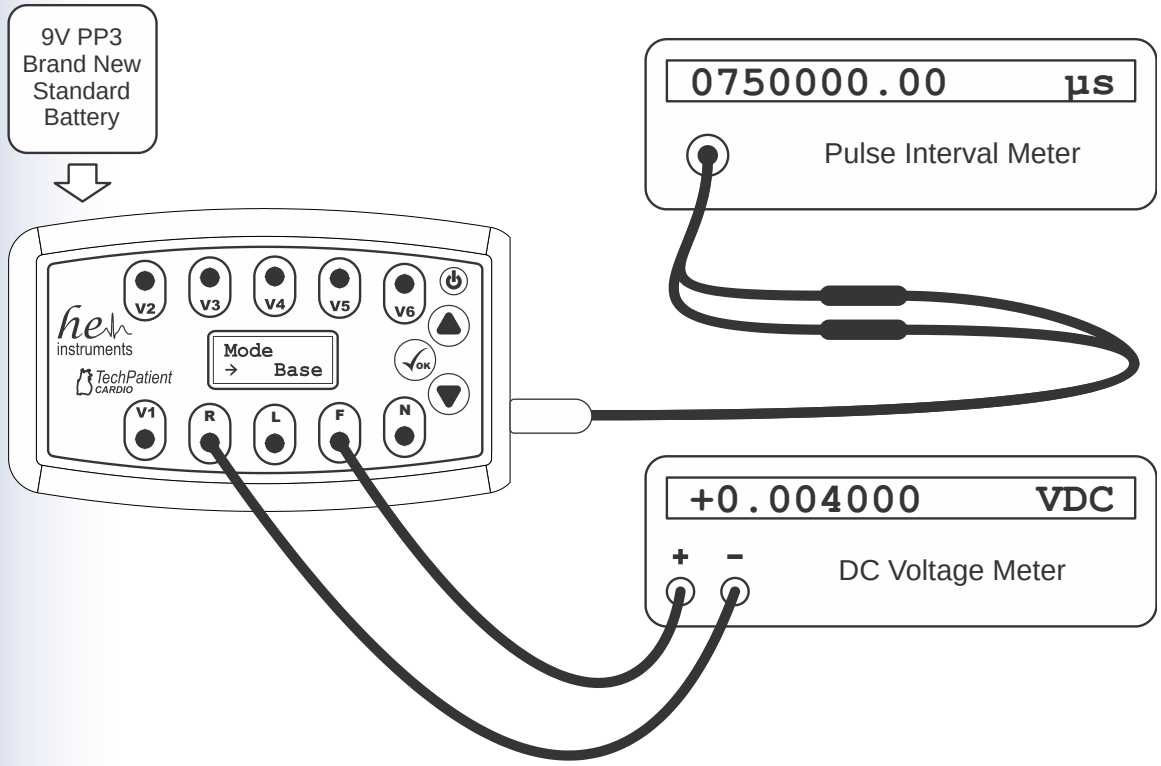
2 – Equipment setup

Measurement equipment must be connected to the DUT according to Figure 1. The DC Voltage meter must be setup to the smallest range capable of measuring 4 mV. The Pulse Interval meter must be setup to the smallest range capable of measuring 1 second.

Measurement equipment must be properly grounded to meet the manufacturer's specified accuracy.

The calibration procedure should be performed in a protected environment without significant ambient temperature or relative humidity drifts.

Figure 1 – Equipment Setup



3 – Calibration Procedure

3.1 – Ambient Conditions

3.1.1 - Determine ambient temperature and relative humidity.

3.1.2 - Ambient temperature and relative humidity should be determined again after completing calibration to ensure no significant changes occurred (± 5 ºC / ± 9 ºF) .

3.2 – Pulse Amplitude Calibration

3.2.1 - Set Mode to Baseline and % DC to 0%.

3.2.2 - Determine DC voltage for Lead I by measuring voltage between the L terminal (+) and the R terminal (-).

3.2.3 - Determine DC voltage for Lead II by measuring voltage between the F terminal (+) and the R terminal (-).

3.2.4 - Determine DC voltage for Lead III by measuring voltage between the F terminal (+) and the L terminal (-).

3.2.5 - Determine DC voltage for Precordial Leads by measuring voltage between each V# terminal (+) and the N terminal (-).

3.2.6 - Each determination should be repeated 5 times to account for random uncertainties (Type A).

3.2.7 - Set % DC to 12.5% and determine DC voltage for Lead II by measuring voltage between the F terminal (+) and the R terminal (-).

3.2.8 - Set % DC to 25% and determine DC voltage for Lead II by measuring voltage between the F terminal (+) and the R terminal (-).

3.2.9 - Set % DC to 50% and determine DC voltage for Lead II by measuring voltage between the F terminal (+) and the R terminal (-).

3.2.10 - Set % DC to 100%.

3.2.11 - Determine DC voltage for Lead I by measuring voltage between the L terminal (+) and the R terminal (-).

3.2.12 - Determine DC voltage for Lead II by measuring voltage between the F terminal (+) and the R terminal (-).

3.2.13 - Determine DC voltage for Lead III by measuring voltage between the F terminal (+) and the L terminal (-).

3.1.14 - Determine DC voltage for Precordial Leads by measuring voltage between each V# terminal (+) and the N terminal (-).

3.3 – Pulse Interval Calibration

3.3.1 - Set Mode to Pulse, Amplitude to 4 mV, Amplitude Deviation to 0% and PPM Deviation to 0%.

3.3.2 - Set PPM to 100 PPM

3.3.3 - Adjust the input attenuation and trigger level of your measurement instrument until a consistent value near 600 ms appears on its screen. The measured interval should be similar from one pulse to the other.

3.3. 4 - Set PPM to 60 PPM and determine Pulse Interval.

3.3.5 - Set PPM to 80 PPM and determine Pulse Interval.

3.3.6 - Set PPM to 100 PPM and determine Pulse Interval.

3.3.7 - Each determination should be repeated 5 times to account for random uncertainties (Type A).

3.3.8 – Overflow situations if any should be properly addressed.

4 – Final procedure

Each measured value specified on the calibration certificate should be formed by the mean of the five determinations and the combined uncertainty accounting for random process (Type A) and measurement instrument specified uncertainty (Type B). The expansion factor, if any, should be clearly specified.