

PROTOCOL FOR SAFETY & FUNCTIONALITY TEST

tCOM+

The Sentec Digital Monitoring System (SDMS) is designed to comply with the standards IEC 60601-1, ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1. For safety reasons, it is recommended that the SDMS undergoes a Safety & Functionality Test according to the tCOM+ Service Manual (HBQ-197) once a year (but the latest every two years). Please fill in this form (one form per monitor).

Record the serial number and the software-specific information of the tested items. You will find this information in the menu "System Information".

THE SDMS SAFETY AND FUNCTIONALITY TEST CONSISTS OF SEVERAL TESTS OF THE FOLLOWING EQUIPMENT:

- Sentec V-Sign™ Sensor 2 or OxiVenT™ Sensor (« Sentec TC Sensor »)
- tCOM+ Monitor
- tCOM+ Docking Station
- AC Power Adapter
- Sensor Adapter Cable

This document must be retained at least until the next safety and functionality test is performed.

TEST SUMMARY

Product Identification			
tCOM+ SN:		SW version system:	
Sensor SN:		SW version:	
Test tools			
Multimeter:			
Safety analyser:			
Sentec TC Sensor	Not passed <input type="checkbox"/>	Passed* <input type="checkbox"/>	
tCOM+ Patient Monitor	Not passed <input type="checkbox"/>	Passed* <input type="checkbox"/>	
tCOM+ Docking Station	Not passed <input type="checkbox"/>	Passed* <input type="checkbox"/>	
AC Power Adapter	Not passed <input type="checkbox"/>	Passed* <input type="checkbox"/>	
Sensor Adapter Cable	Not passed <input type="checkbox"/>	Passed* <input type="checkbox"/>	
Safety & Functionality test:	Not passed <input type="checkbox"/>	Passed* <input type="checkbox"/>	
Date of the next safety-related test:			
Organization:		Location:	
Service technician (name):			
Signature:		Place, date (YYYY-MM-DD):	

* It is mandatory that all test items pass the test. Otherwise, contact your local Sentec representative.

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Completely fill in the tables below. Confirm that the tests have been performed successfully. If required, note test results. Confirm successfully passed tests with a check mark.

Sentec TC Sensor				
Test	Results			Passed
Visual inspection				<input type="checkbox"/>
Labeling				<input type="checkbox"/>
Sensor temperature display/surveillance				<input type="checkbox"/>
Cleaning/inspecting without membrane				<input type="checkbox"/>
Sensitivity test (PCO ₂ and/or PO ₂)				<input type="checkbox"/>
Function test: PCO ₂	Value:	<input type="text"/>	mmHg / kPa	<input type="checkbox"/>
Function test: PO ₂ (OxiVenT™ Sensor only)	Value:	<input type="text"/>	mmHg / kPa	<input type="checkbox"/>
Function test: SpO ₂ + PR	Value:	<input type="text"/>	%	<input type="checkbox"/>
	Reference:	<input type="text"/>	%	<input type="checkbox"/>

tCOM+ Monitor				
Test	Results			Passed
Visual inspection				<input type="checkbox"/>
Labeling				<input type="checkbox"/>
Electrical safety check (IEC 62353)				<input type="checkbox"/>
POST (Power on self-test)				<input type="checkbox"/>
Buzzer/speaker (POST)				<input type="checkbox"/>
Power button				<input type="checkbox"/>
Clock settings				<input type="checkbox"/>
Display				<input type="checkbox"/>
Analog output**				<input type="checkbox"/>
Serial data port (RS-232) **				<input type="checkbox"/>
Rechargeable lithium battery capacity	Required runtime:	<input type="text"/>	h	<input type="checkbox"/>
		<input type="text"/>	min	
Alarm by display				<input type="checkbox"/>
Alarm by speaker				<input type="checkbox"/>
Alarm by LED Bar				<input type="checkbox"/>

** Test only required if interface is used.

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tCOM+ Docking Station			
Test	Results		Passed
Visual inspection			<input type="checkbox"/>
Gas indicator			<input type="checkbox"/>
Docking Station Gasket replaced (recommended)			

Sensor Adapter Cable			
Visual inspection			<input type="checkbox"/>

Calibration Gas Bottle			
Calibration Gas bottle expiry date	Date (YYYY-MM-DD):		<input type="checkbox"/>