

Chapter 3: Maintenance and Checkout

This chapter includes preventive maintenance procedures as well as checkout procedures required after Mini Telemetry installation, repair, or maintenance. These procedures must be performed by authorized service personnel.

3.1 Procedure Schedules

The following table lists all maintenance and checkout procedures, specifies when and how often each procedure should be performed, and provides the average time that it takes to perform each procedure.

For good care and maintenance of the Mini Telemetry, perform preventive maintenance procedures at specific time intervals. The checkout procedures shall be performed after any installation, repair, maintenance, or part replacement.

Table 3-1 Checkout Procedure Schedule

Checkout Procedure Name	Average Time	Checkout to be performed		
		after first Installation	as Preventive Maintenance	after Repair or Part Replacement
3.4.1 Visual Inspection	5 minutes	YES	Annually	YES
3.4.2 General Cleaning	5 minutes	As needed	As needed	As needed
3.4.3 Functional Checks	10 minutes ¹	YES	Annually	YES
3.4.4 Electrical Safety Tests	10 minutes	NO ²	Annually	YES
3.4.5 Battery Maintenance	4 hours (recharge)	Required upon long storage at specific intervals.		

¹ Average time excludes the time required to do distribution antenna network check which is a variable time depending on the facility construction, layout and the size of coverage area.

² Electrical safety test is not required after the first installation of the product. Each product unit is tested in the factory prior to shipment to the customer.



CAUTION:

Table 3-1 shows the minimum frequencies required for maintenance. Always follow hospital and local regulations for required frequencies.



WARNING:

Do not service the Mini Telemetry while it is in clinical use.

3.2 Environmental Requirements

The unit shall be installed, serviced, and operated within the following environmental conditions:

Temperature:	10 - 40° C
Relative humidity:	5% - 95% (non-condensing)
Pressure:	700-1060 mbar (525-795 mmHg)

3.3 Tool Requirements

The following table lists the service tools required to perform the preventive maintenance and checkout procedures:

Table 3-2 Checkout Procedures Tool Requirements

Checkout Procedure Name	Service Tools Needed	Quantity Needed
3.4.1 Visual Inspection	None	Not applicable
3.4.2 General Cleaning	Soft cloth, cleaning solution,	As needed
3.4.3 Functional Checks	Fetal Simulator or US/ECG/TOCO Transducers*	1
3.4.4 Electrical Safety Tests	Electrical safety analyzer	1
3.4.5 Battery Maintenance	T10 Torx screw driver	1

* Additional tools required to perform distribution antenna network check. See Appendix E for details.

3.4 Maintenance and Checkout Procedures

3.4.1 Visual Inspection

1. Disconnect the transmitter power adapter and the receiver power cord from the wall outlet.
2. Examine the power cord and power adaptor for any signs of damage. Replace the power adaptor and power cord if damage is evident.
3. Check that the power cord retainer on the rear panel of receiver unit is in place.
4. Check that the power cord retainer securely retains the cord in the receiver AC inlet.
5. Examine both the transmitter and receiver units for any damaged (cracked or broken) or missing parts, such as the plastic enclosure, input connectors, display, antenna, carrying strap or receiver panels. If any part is damaged or missing, replace it.

- Examine both the transmitter and receiver units for any missing labels. Make sure the labels are attached in the proper locations. For a list of labels, refer to section 7.2 For the proper location of each label, refer to Figure 7-8.

3.4.2 General Cleaning



CAUTION:

Unplug the fetal or maternal/fetal monitor and the receiver from the AC power source and detach all accessories. Do not immerse accessories in any liquid. Do not use abrasive cloth or cleaners on the monitor, the receiver, the transmitter, or any accessories.

- Wipe any fluids from the surface of each unit or the carrying strap.
- Dampen a soft cloth with the recommended cleaning solution (See table 3-3 and 3-4) and gently clean the surfaces.
- Wipe with a cotton cloth dipped in water to remove any traces of cleaning agent.
- Dry with a soft, dry cloth.

The following table lists approved cleaning solutions for the units surfaces:

Table 3-3 Cleaning Solutions for Unit Surfaces

Generic Formulation	Maximum concentration level
Hydrogen peroxide	6 %
Sodium hypochlorite	100 parts per million (ppm)
CaviCide®	100 % spray (Don't spray directly on the equipment. Apply to the cloth).

Table 3-4 Cleaning Solutions for Carrying Strap

Generic Formulation	Maximum concentration level
Hydrogen peroxide	6 %
Sodium hypochlorite	100 parts per million (ppm)
CaviWipes™	Not Applicable

3.4.3 Functional Checks


Install and set up the Mini Telemetry system with a Coro 170/250/250cx monitor as instructed in "Installation" and then turn on the monitor, Mini Telemetry receiver and transmitter to do the following checks.

3.4.3.1 Indicator Checks


- Check the Signal Indicator on the receiver front panel and confirm that it is illuminated in continuous green. If the indicator is flashing, refer to chapter 5 for troubleshooting.

2. Check the low battery indicator on the receiver front panel and confirm that it is off. If the indicator is illuminated in red, refer to chapter 5 for troubleshooting.
3. Check the power indicator on the receiver front panel and confirm that the indicator illuminates in green when the receiver unit is turned on.

3.4.3.2 Ultrasound Input Check

1. Connect a Coro 5700 ultrasound transducer or a fetal simulator connector to the Mini Telemetry transmitter.
2. Confirm that:
 - The corresponding connector status indicator on the transmitter unit is filled and a short beep is generated.
 - The corresponding FHR on the monitor displays "---" or the value set by the simulator.
 - The corresponding FHR mode is US.
 - A telemetry symbol () is printed on the strip chart paper (As for Coro 250/250cx, a telemetry symbol is displayed on the screen too).
 - The recorder prints the message "US" on the center margin of the strip chart paper after approximately 20 seconds.
3. Place the transducer front on the palm of your hand and gently push the back side of transducer in a rhythmic manner to simulate heartbeat. Confirm that FHR heartbeat indicator(heart symbol) and FHR value are displayed on the monitor. Also confirm that the transmitter speaker is generating audio tones in response to simulated heartbeat. Press on the volume button of the transmitter and confirm that the tones volume change in response to button presses.
4. Plug the headset into the headset connector and repeat step 3. Confirm that you hear the generated audio tones from both headset speakers. Press on the volume button of the transmitter unit and confirm that the tones volume change in response to button presses.

3.4.3.3 ECG Input Check

1. Connect the fetal simulator ECG connector to the Mini Telemetry transmitter.
2. Confirm that the corresponding connector status indicator on the transmitter display is filled and a short beep is generated.
3. Confirm that a telemetry symbol is printed on the strip chart paper (As for Coro 250/250cx, a telemetry symbol is displayed on the screen too).
4. Confirm that the corresponding FHR value on the monitor reads the value set by the simulator.
5. Confirm that the corresponding FHR indicator  flashes
6. Confirm that the ECG beep is generated by the monitor.

3.4.3.4 UA Input Check

1. Place the receiver's UA Mode Selector switch in the TOCO position.
2. Connect a TOCO transducer or a fetal simulator connector to the Mini Telemetry transmitter:
 - If the monitor has a UA display: the display reads an arbitrary pressure value.
 - If the monitor does not have a UA display: turn on the strip chart recorder and check that TOCO prints on the paper's mode annotation line.
3. Press the monitor's UA Reference button to set the UA value to 10 relative units. Verify the following on the monitor:
 - If the monitor has a UA display: the display reads 10 relative units.
 - If the monitor does not have a UA display: turn on the strip chart recorder and check that the UA REF message and TOCO mode annotation both print on the paper.
4. Apply gentle pressure to the tocotransducer pressure sensing button and verify that the monitor (display or uterine activity trace) responds to the pressure input. Increasing force should produce an increasing value and vice versa.
5. Place the receiver's UA Mode Selector switch in the IUP position. Verify the following on the monitor:
 - If the monitor has a mode indicator, the "IUP" mode should be indicated.
 - If the monitor does not have a mode indicator, turn on the strip chart recorder and check that the "IUP" mode annotation prints on the paper.

NOTE: Place the UA Mode Selector switch back in the TOCO position unless you plan to monitor with an IUFC.

3.4.3.5 Mark Key Check

1. Connect at least one transducer to the transmitter unit and then press the Mark key on the transmitter. Verify that an appropriate mark is printed on the paper and **T** appears on the transmitter display.

3.4.3.6 Distributed Antenna Network Check

If Mini Telemetry is supposed to operate with a distributed antenna system, designed and installed for Mini Telemetry in the facility, perform antenna system installation checkout tests (See section E.2 in Appendix E) to make sure that the antenna system provides proper wireless coverage.

3.4.4 Electrical Safety Tests

Electrical safety tests may be performed under normal ambient conditions of temperature, humidity, and pressure.

Use an approved electrical safety analyzer and follow the operating instructions supplied by the manufacturer of the electrical safety analyzer to perform the checks on the Mini Telemetry unit only, with no other equipment attached. For reliable leakage current checks, Ground Resistance Check shall be performed first.

3.4.4.1 Power Outlet Test

Before starting the tests, the power outlet from which the monitoring device will get electrical power must be checked. This test checks the condition of the power outlet to ensure correct results from leakage tests.

For international power outlets, refer to the internal standards agencies of that particular country. Use a digital multimeter to ensure the power outlet is wired properly.

If other than normal polarity and ground is indicated, corrective action must be taken before proceeding. The results of the following tests will be meaningless unless a properly wired power outlet is used.

3.4.4.2 Ground Resistance Check

Perform this check on the Mini Telemetry receiver unit only, with no other equipment attached.

1. Attach the Mini Telemetry receiver's power cord to the safety analyzer.
2. Verify that the safety analyzer's main AC power cord is plugged in a working outlet.
3. Select the safety analyzer's setting to measure ground resistance.
4. Measure the resistance between the ground pin on the line cord plug and the equipotential lug of the Mini Telemetry receiver enclosure. The ground resistances must be less than 0.1 Ω .

3.4.4.3 Earth Leakage and Enclosure Leakage Current Checks

Perform these checks on the Mini Telemetry transmitter and receiver units, with no other equipment attached.

When checking the transmitter, the transmitter power adaptor shall be plugged into the safety analyzer for leakage current measurements.

1. In normal conditions and in all possible operating modes, the earth leakage current shall be less than 300 μ A and enclosure leakage current shall be less than 100 μ A.
2. If required by local ordinances, in single fault condition and in all possible operating modes, the earth leakage current shall be less than 1000 μ A and enclosure leakage current shall be less than 300 μ A.

3.4.4.4 Patient-to-Ground and Patient-to-Line Leakage Current Checks for US

Perform these checks on the transmitter unit. The transmitter power adaptor shall be plugged into the safety analyzer for leakage current measurements.

1. Connect an ultrasound transducer to the Mini Telemetry transmitter's US input.
2. Configure a safety analyzer to perform a patient leakage test.

3. Turn on Mini Telemetry transmitter using the transmitter's **ON** button.
4. In normal conditions and all possible operating modes, verify that:
 - The Patient-to-Ground leakage current is less than 100 μ A
 - The Patient-to-Line leakage current is less than 5000 μ A
5. If required by local ordinances, in single-fault conditions and all possible operating modes, verify that:
 - The Patient-to-Ground leakage current is less than 500 μ A

3.4.4.5 Patient-to-Ground and Patient-to-Line Leakage Current Checks for TOCO

Perform these checks on the transmitter unit. The transmitter power adaptor shall be plugged into the safety analyzer for leakage current measurements.

1. Connect an TOCO transducer to the Mini Telemetry transmitter's TOCO input.
2. Configure a safety analyzer to perform a patient leakage test.
3. Turn On the Mini Telemetry transmitter using the transmitter's ON button.
4. In normal conditions and all possible operating modes, verify that:
 - The Patient-to-Ground leakage current is less than 10 μ A
 - The Patient-to-Line leakage current is less than 50 μ A
5. If required by local ordinances, in single-fault conditions and all possible operating modes, verify that:
 - The Patient-to-Ground leakage current is less than 50 μ A

3.4.4.6 Patient-to-Ground and Patient-to-Line Leakage Current Checks for IUP

Perform these checks on the transmitter unit. The transmitter power adaptor shall be plugged into the safety analyzer for leakage current measurements.

1. Connect an IUP transducer to the Mini Telemetry transmitter's IUP input.
2. Configure a safety analyzer to perform a patient leakage test.
3. Turn On the Mini Telemetry transmitter using the transmitter's ON button.
4. In normal conditions and all possible operating modes, verify that:
 - The Patient-to-Ground leakage current is less than 10 μ A
 - The Patient-to-Line leakage current is less than 50 μ A
5. If required by local ordinances, in single-fault conditions and all possible operating modes, verify that:
 - The Patient-to-Ground leakage current is less than 50 μ A

3.4.4.7 Patient-to-Ground and Patient-to-Line Leakage Current Checks for ECG

Perform these checks on the transmitter unit. The transmitter power adaptor shall be plugged into the safety analyzer for leakage current measurements.

1. Connect an ECG cable to the Mini Telemetry transmitter's ECG input.
2. Configure a safety analyzer to perform a patient leakage test.
3. Turn On the Mini Telemetry transmitter using the transmitter's ON button.
4. In normal conditions and all possible operating modes, verify that:
 - The Patient-to-Ground leakage current is less than 10 μ A
 - The Patient-to-Line leakage current is less than 50 μ A
5. If required by local ordinances, in single-fault conditions and all possible operating modes, verify that:
 - The Patient-to-Ground leakage current is less than 50 μ A

3.4.5 Battery Maintenance



WARNING:

To avoid the risk of injury, observe the following battery safety precautions:

- Do not heat the battery or discard them in fire.
 - Do not use damaged battery.
 - Do not disassemble or alter the battery.
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The battery will self-discharge over time. If storage of Mini Telemetry is necessary for an extended period of time (more than 3 months), the battery shall be disconnected and then monthly re-connected and recharged to avoid reduction in battery capacity.