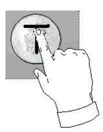
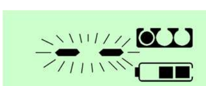
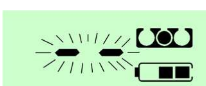
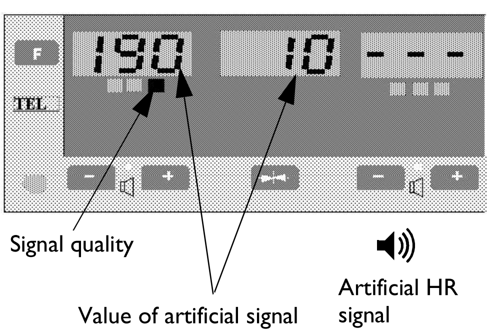
Performance Assurance Tests

Self Test

The system performs a basic-level self test when you switch it on. You hear a beep, and all the display elements are shown for about one second, and then the display reverts to normal display mode.

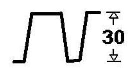
Parameter Test

This tests the entire signal path from the individual transducers connected via radio frequency, through the base station, to the fetal monitor with artificially generated test signals. We recommend you perform this test once a day, and whenever you doubt the reliability of the measurements. The parameter test does not test the transducers themselves, there is a separate test for this (see “Testing Transducers” on page 67).

	Base station display	In this example, one US transducer and one Toco transducer are docked. No other transducers are active. Initial displays appear as shown. The battery indicator is lit on the base station. The bed label is visible on both displays. The transducer display shows which slot is occupied.
	Ultrasound transducer display (slot 1)	
	Toco transducer display (slot 2)	
  		To start the test, with no transducers or alarms active: 1 Press and hold down T. The test mode remains active for as long as you keep T pressed. Battery charging stops, and the transducers behave like normal, active transducers. However, to differentiate between test mode and normal operation of a registered transducer, the two-digit numeric display in the LCD window shows the two segment bars (--) blinking. If you remove a transducer while the parameter test is still in progress, the transducer shuts down.
		2 Each transducer transmits an artificial signal, via the programmed RF channel, to its registered slot on the base station. After decoding and processing, the artificial signals are fed via the analog connection to the telemetry interface input of the fetal monitor. The signals coming from the base station are then processed and displayed by the fetal monitor.

3	Check the values displayed by the fetal monitor to get an overview of the condition of the entire system. The following table specifies the signals that are generated during the test. As the mode of the ECG transducers is unknown to the base station (as it is configured outside of the base station), an ECG transducer is always mapped to the MECG mode. This avoids potential mode errors.
4	To stop the test, release the T key.

Expected signals generated during the system test:

	US		DECG* (Place in Slot 1)	TOCO (Place in Slot 2)	ECG Transducer is in Slot 2	MECG* (Place in Slot3)
Test Outputs	**Slot 1**	**Slot 3**				
Value on fetal monitor LED display, Recorder, OBMS-IF	190 bpm	170 bpm	200 bpm Note: Ensure there is no US transducer in slot 3 (Error 9 will appear)	 Signal with 30 units amplitude range and 20s period duration	An IUP reading appears on the fetal monitor. IUP measurements are not currently supported. Disregard any measurement you get.	120 bpm
Fetal monitor speaker	Artificial HR signal			N/A	N/A	“click”
Test tolerance**	+/- 2.5 bpm		+/- 2.5 bpm	+/- 10% period duration	N/A	+/- 2.5 bpm

*Test ECG transducers **without** the adapter cables attached.

**Signal is variable. Jitter should normally be within +/- 2.5 bpm. However, this could possibly be higher due to external factors, such as interference or the environment. On slot 1, the jitter can be higher than on slot 3.

Testing Alarms

Details of how to test alarms is given in the *Instructions for Use*.

Safety Tests

This section defines the test and inspection procedures applicable to the Avalon CTS Cordless Fetal Transducer System. Use the tables in the following section to determine what test and inspection results must be reported after an installation, upgrade, or repair has been carried out.

- Test Blocks in Table 1 tells you when to carry out the safety tests.
- Test and Inspection Matrix in Table 2 tells you how to carry out the safety tests.

WARNING Safety test requirements are set acccording to international standards, such as IEC/EN 60601-1 and IEC 60601-1-1, their national deviations, such as UL2601-1, CAN/CSA-C22.2 No. 601.1-M90 and No 601.1-S1-94, and specific local requirements.

The safety tests detailed in this chapter are derived from international standards but may not be sufficient to meet local requirements.

CAUTION The correct and accurate functioning of the equipment is ensured by the successful completion of the safety tests, performance test, and the system test.

Safety Test Procedures

The test procedures outlined in this section are to be used only for verifying the safe installation or service of the product in its place of use. The safety tests described here refer specifically to installation, setup, repair and upgrade activities, and not to the aspects of safety that have already been tested during final acceptance at the factory.

Use safety testers complying with IEC 60601-1 internationally, or any local regulations applicable to the country of the installation. For safety test procedures see the operation instructions of the safety tester used, and follow any local regulations.

If you use the Metron safety tester, the Metron Report should print results as detailed in this chapter, along with other data.

For information and ordering guides for Metron products contact:
Metron AS, Vegamot 8, N-7048 Trondheim, Norway
www: http://www.metron-biomed.com

When to Perform Safety Tests

This table tells you when to perform specific safety tests. See page 47 for test details.

Table 1: M2720A: When to perform safety test blocks

Service Event	Test Block(s) Required - Complete These tests
Installation The product is customer installed. For installation instructions refer to the *Instructions for Use* for your monitor.	Perform Visual, Power On, Performance and Safety test blocks (see Table 2).
Preventive Maintenance Preventive maintenance is the responsibility of the customer (see page 51).	Perform Visual test block (see Table 2).
Repair This Service Guide contains repair instructions for the Avalon CTS.	Perform Visual, Power On and Performance test blocks (see Table 2), and whenever power supply or fuses are removed/ replaced, perform Safety test block.
Upgrade For upgrade information refer to “Upgrades”, on on page 69.	Perform Visual, Power On, Performance test blocks (see Table 2).
Combining or Exchanging System Components	Perform the System Test (see Table 2 and “System Test” on page 50).
All other service events	Perform Visual, Power On and Performance test blocks (see Table 2).

How to Carry Out the Test Blocks

Key to Table 2 P = Pass, F = Fail, X = test result value to be recorded.

Table 2: M2720A: Test and Inspection Matrix

Test Block	Test or Inspection to be Performed	Expected Test Results	What to Record on Service Record (Philips Personnel only)
Visual	Inspect the unit, transducers and cables for any damage. Are they free of damage?	If Yes, Visual test is passed.	V:P or V:F
Power On	Power on the unit. Does the self-test complete successfully?	If Yes, Power On test is passed.	PO:P or PO:F
Performance	Perform the parameter test with all parameters as described on page 44. Do these tests complete without errors?	If Yes, Performance Test is passed.	P:P or P:F
Safety (1)	Perform Safety Test: Protective Earth.	With mains cable: Maximum impedance = X1 (<= 100 mOhms)	S(1):P/X1 or S(1):F/X1
Safety (2)	Perform Safety Test: Enclosure Leakage Current - Normal Condition.	With mains cable: Maximum leakage current = X2 (<= 100µA)	S(2):P/X2or S(2):F/X2
Safety (3)	Perform Safety Test: Enclosure Leakage Current - Single Fault Condition - Open Supply.	With mains cable: Maximum leakage current = X3 (<= 500µA) (Note: maximum leakage current in the US: 300µA)	S(3):P/X3or S(3):F/X3
Safety (4)	Perform Safety Test: Enclosure Leakage Current - Single Fault Condition - Open Earth.	With mains cable: Maximum leakage current = X4 (<= 500µA) (Note: maximum leakage current in the US: 300µA)	S(4):P/X4or S(4):F/X4
System	Perform the system test according to IEC 60601-1-1, if applicable, after combining equipment to form a system.	See Safety Test (2) and Safety Test (3)	See Safety Test (2) and Safety Test (3)

Description of Applicable Safety Tests

Abbreviations

AP: Applied Parts	IUT: Instrument Under Test
GND: Ground	PE: Protective Earth

S(1): Protective Earth Test

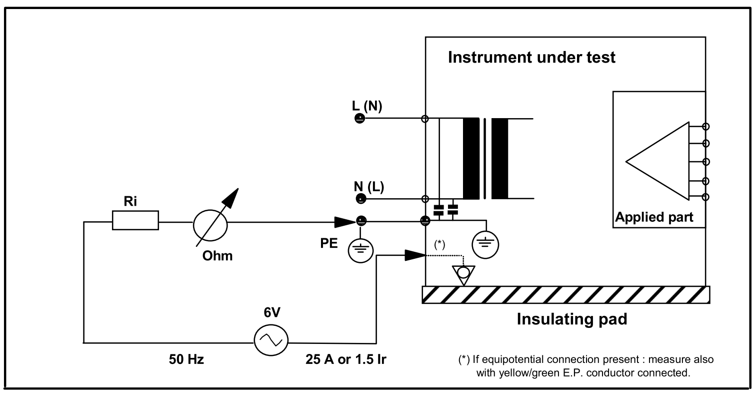
Test to perform:

The protective earth test measures impedance of Protective Earth (PE) terminal to all exposed metal parts of Instrument under Test (IUT), which are connected to the Protective Earth (PE) for safety reasons. Normally it includes the wiring in the mains cable (max. 200 mOhm).

A test current of 25 Amps is applied for five to ten seconds. It is recommended to flex the main cable during the test to identify potential bad contact or damage to the earth wire.

Safety Test according to IEC 60601-1 (Clause 18).

Report the highest value.



S(2): Enclosure Leakage Current Test - Normal Condition (NC)

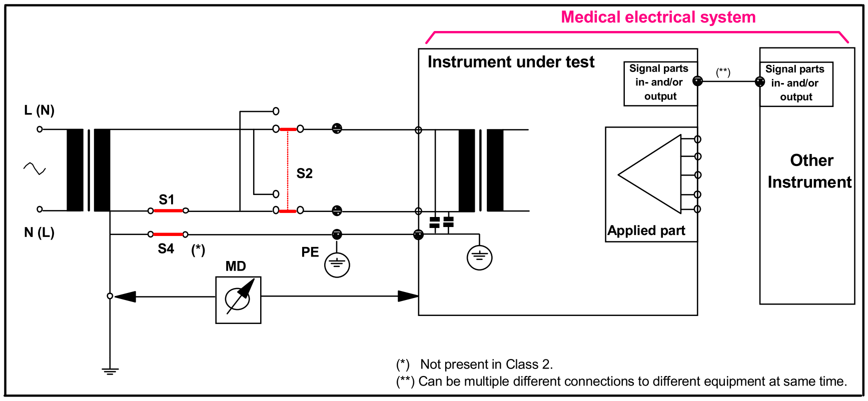
Test to perform:

The enclosure leakage current: normal condition is applicable to Class 1 and 2 equipment, type B, BF, and CF Applied Parts. The test measures leakage current of exposed metal parts of the Instrument Under Test; it tests normal and reversed polarity.

For Type BF and CF Applied Parts the test measures AP/GND.

Safety Test according to IEC 60601-1 (Clause 19.4g).

Report the highest value.



S(3): Enclosure Leakage Current Test - Single Fault Condition (SFC) Open Supply

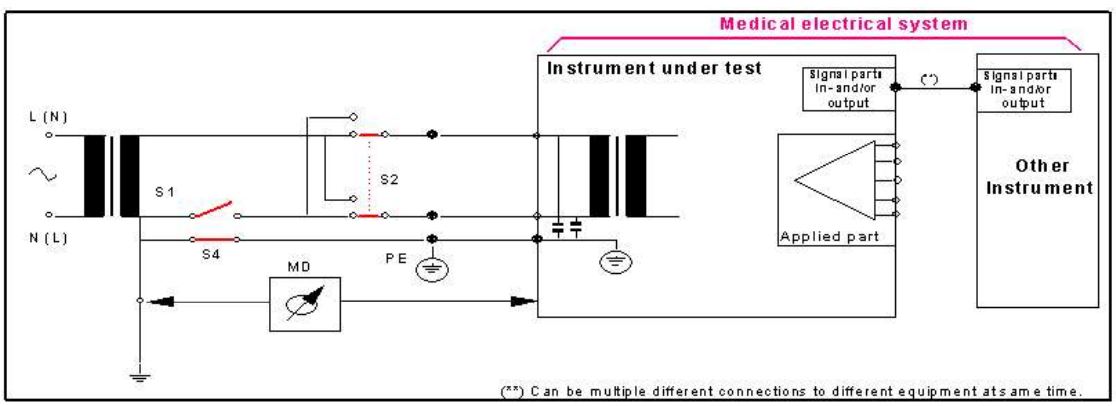
Test to perform:

The enclosure leakage current: single fault condition open supply is applicable to Class 1 and 2 equipment, type B, BF, and CF Applied Parts. The test measures leakage current of exposed metal parts of Instrument Under Test with one supply lead interrupted; it tests normal and reversed polarity.

For type BF and CF Applied Parts measures AP/GND.

Safety Test according IEC 60601-1 (Clause 19.4g).

Report the highest value.



S(4): Enclosure Leakage Current - SFC Open Earth (Ground)

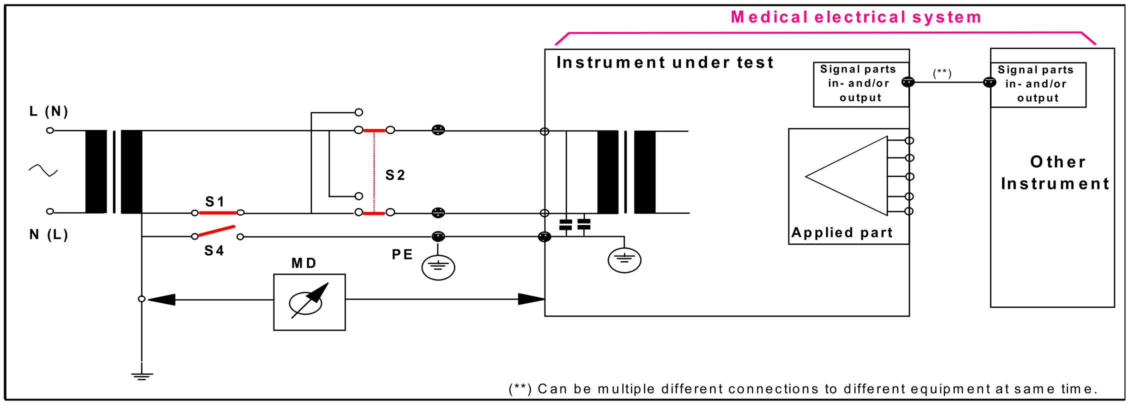
Test to perform:

The enclosure leakage current: single fault condition open earth (ground) is applicable to Class 1 equipment, type B, BF and CF Applied Parts. The test measures leakage current of exposed metal parts of Instrument Under Test with Protective Earth open-circuit; it tests normal and reversed polarity.

For type BF and CF Applied Parts the test measures AP/GND.

Safety Test according IEC 60601-1 (Clause 19.4g).

Report the highest value.



Instrument Safety Test

You must perform the instrument safety test every time you exchange, repair, upgrade or in any other way work on the power supply or the power inlet. You must test the system as a stand-alone system, and as a system in conjunction with the fetal monitor.

The instrument safety test is made up of four separate tests :

- Protective Earth Test
- Enclosure Leakage Current - Normal Condition
- Enclosure Leakage Current - Single Fault Condition
- Patient Leakage Current - Single Fault Condition

System Test

After mounting and setting up a system, perform system safety tests.

What is a Medical Electrical System?

A medical electrical system is a combination of at least one medical electrical device and other electrical equipment, interconnected by functional connection or use of a multiple portable socket-outlet.

General Requirements for a System

After installation or subsequent modification, a system must comply with the requirements of the system standard IEC/EN 60601-1-1. Compliance is checked by inspection, testing or analysis, as specified in the IEC 60601-1-1 or in this book.

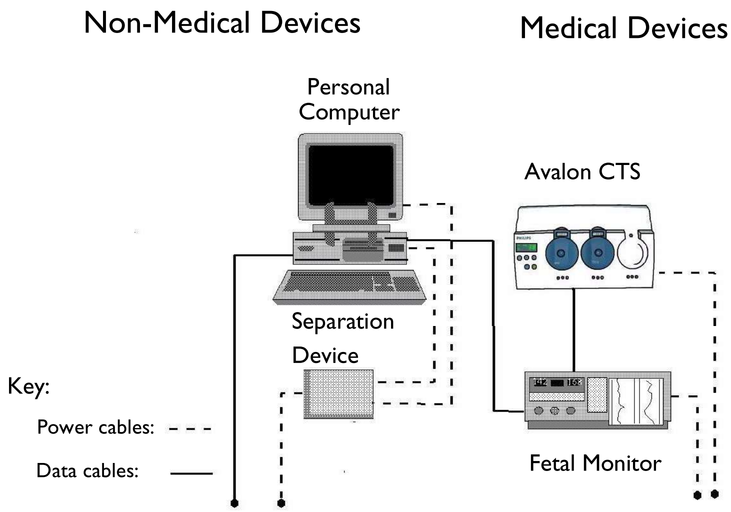
Medical electrical equipment must comply with the requirements of the general standard IEC/EN 60601-1, its relevant particular standards and specific national deviations. Non-medical electrical equipment shall comply with IEC and ISO safety standards that are relevant to that equipment.

Relevant standards for some non-medical electrical equipment may have limits for enclosure leakage currents higher than required by the standard IEC 60601-1-1. These higher limits are acceptable only outside the patient environment. It is essential to reduce enclosure leakage currents when non-medical electrical equipment is to be used within the patient environment.

WARNING Do not connect any devices that are not supported as part of a system.

System Example

This illustration shows a system where both the medical electrical equipment and the non-medical electrical equipment is situated at the patient's bedside.



WARNING Any non-medical device placed and operated in the patient's vicinity (within a distance of 1.5m from the patient's bed) must be powered via an approved separation device (for example, an isolation transformer).

If the personal computer (or any other non-medical electrical device) is situated outside the medically used room, you must take measures to reduce leakage currents, such as providing an additional protective earth, a non-conducting enclosure, or a separation device.

We highly recommend using a separation device whenever you connect non-medical electrical equipment.

Regular Preventive Maintenance

The care and cleaning requirements that apply to the Avalon CTS and the monitoring accessories are described in the *Instructions for Use*. This section details the periodic maintenance recommended for the base station, transducers and accessories.

Mechanical Inspection

All rear panel connections must be tight. Check all exterior housings for cracks and damage. Check the condition of all external cables, especially for splits or cracks and signs of twisting. If serious damage is evident, the cable should be replaced immediately. Check that all mountings are correctly installed and secure. Refer to the instructions that accompany the relevant mounting solution. Check that the protective earth cable is properly and securely connected.

Visual Check

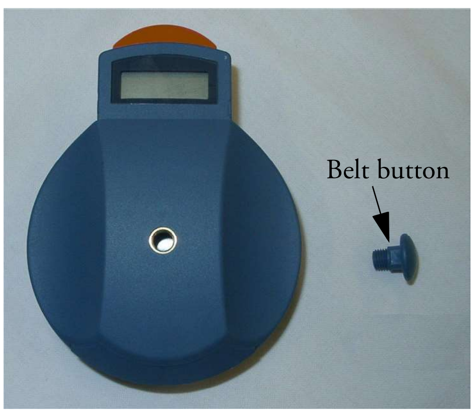
Ensure there are no cracks in the transducer housing. Make sure the battery drawer fits properly into the transducer housing, and that the sealing lip is in good condition. Inspect the LCD window, and if there is water or condensation behind the window, replace the transducer. On the ECG transducer, ensure that the adapter cable socket is not damaged.

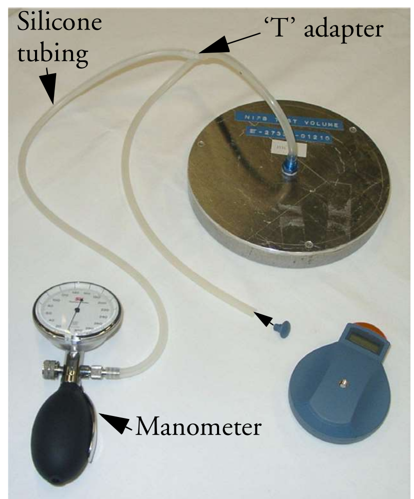
Toco Ventilation/Belt Button

The Toco transducer requires air exchange for drift-free operation (see also the section "Underwater Monitoring" in the *Instructions for Use)*. This is done by a ventilation membrane incorporated in the belt button. The effectiveness of the ventilation membrane should be checked at least once a year to ensure that free air exchange takes place. If the membrane is congested, the belt button must be exchanged (see the instruction sheet, "Removing and Replacing the Transducer Belt Button" that accompanies the belt button replacement kit, or see page 91 in this manual).

Testing the Ventilation Membrane

If you want to test the ventilation membrane in the belt button, you need the following:





- Manometer.
- Test volume chamber.
- Three lengths of silicone tubing with a 'T' adapter.

1 Remove the belt button from the transducer using the special tool (see the instruction sheet "Removing and Replacing the Transducer Battery/Belt Button").

2 Connect the manometer to the volume chamber using two lengths of the silicone tubing and 'T' adapter as shown. Connect one end of the remaining length of silicone tubing to the 'T' adapter, and the other to the threaded end of the belt button.

3 Apply pressure with the manometer (for example, 250 to 260 mmHg).

4 Release the manometer valve. The pressure should fall rapidly, to indicate that the membrane is functioning correctly.

5 If the pressure does not fall rapidly, then the ventilation membrane is congested. Replace the belt button (see page 91, or the instruction sheet, “Removing and Replacing the Belt Button”, that accompanies the belt button replacement kit (part number M2720-64001) containing:
- three replacement buttons.
- a special tool to remove the button.
- the instruction sheet.

Battery Check

If you suspect that battery performance is below normal expectations, and especially if the operating time consistently falls below 16 hours, charge the batteries.. Batteries that have a reduced capacity can still be used, even though they will have a shortened operating time, but a replacement should be considered as soon as possible.

When battery performance is suspect, even after a normal charge cycle, run the battery check. The Battery Check is a diagnostic procedure for determining the operating time of a fully charged battery. In normal operation, the battery will rarely approach a state of full discharge, typically only a small proportion of the total capacity will be used.

Even a battery with suspect performance will still have a relatively high capacity when it is freshly charged. **As a result, the test takes approximately eight hours. For the duration of the test, the Avalon CTS cannot be used.** To limit this down time, the test automatically stops if the batteries have reached the minimum operating time.

Removing a transducer from the base station during a battery check will start the transducer shut down process.

To run the battery check, all transducers must be inactive and at least one transducer must be docked in the base station. In the following example describes a battery check with two docked transducers, Transducer 1 and Transducer 2, in slots 1 and 2 respectively. Transducer 2 has a battery exhibiting reduced performance.

Starting the Battery Check

Step	Action	Display looks like...
1	Press the two arrow keys simultaneously. The bed label blinks, the two-digit display goes blank.	
2	Press twice to enter the ‘A’ settings. ‘A’ flashes in the display.	
3	Press C. ‘A1’ appears, and the ‘1’ blinks.	
4	Press twice to increment ‘A’ setting to 3.	
5	Press C. Base station display shows two segment bars for the duration of the check.	

Stopping the Battery Test

You can cancel the battery check at any stage by pressing C for more than one second, or by switching the base station to stand-by.

Stages of the Battery Check

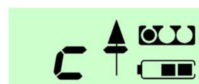
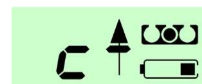
The battery check has four stages:

1 Battery charge cycle

2 Fast battery discharge

3 Battery capacity display

These stages are indicated by special patterns in the transducer LCD window.

<table>
<tr><th>Stage</th><th>Description</th><th>Transducer 1 display</th><th>Transducer 2 display</th></tr>
<tr><td rowspan="2">1</td><td rowspan="2">Battery charge cycle
• The battery symbols of slots 1 and 2 blink, indicating that battery charging is in progress.
• Transducers
– remain unprogrammed
– shut down if removed</td><td></td><td></td></tr>
<tr><td colspan="2">The right-hand horizontal segment bars of the two-digit numeric display wander up and down (from bottom up). This indicates that battery charging is in progress.</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">Fast battery discharge
• The battery is rapidly discharged.</td><td></td><td></td></tr>
<tr><td colspan="2">The right-hand horizontal segment bars of the two-digit numeric display wander up and down (from top down). This indicates that fast battery discharge is in progress.</td></tr>
<tr><td rowspan="2">3</td><td rowspan="2">Battery capacity display
• Transducer display shows the estimated operating time when:
– the discharge time is over
or
– the battery is empty
• In this example, the battery of Transducer 2 should be changed, as the estimated operating time is below the minimum 16 hours.</td><td></td><td></td></tr>
<tr><td colspan="2">The estimated operating time of the battery (in hours) alternates with the symbol ‘H’.</td></tr>
</table>

After the battery check has finished, the estimated operating time remains displayed until you press C for more than one second, or switch the base station to stand-by.

Reading Battery Check Data Using the Service Support Tool

The results of the last battery test performed are stored in the base station's EEPROM. There is no time stamp. This data can be read using the Service Support Tool, and this can be useful, for example, if the results of the battery check were not noted. Refer to the *Service Support Tool Help* for details.

Battery Exchange

If the battery requires replacement, use the battery kit (M2720-64001). This contains:

- a replacement battery already fitted into a replacement battery drawer
- a special tool for removing the battery drawer
- an instruction sheet

For details of how to replace the battery, see the Instruction Sheet "Removing and Replacing the Transducer Battery" that accompanies the battery replacement kit, or refer to page 75 in this guide.