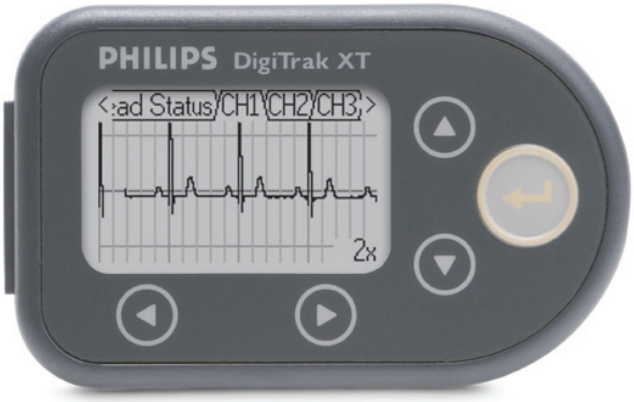

DigiTrak XT Recorder

Instructions for Use

PHILIPS

Notices

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Edition 1
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Applicable to Model 860322

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- Assembly operations, extensions, readjustments, modifications and repairs are carried out by Philips authorized personnel only.
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Limitations of Warranty

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- Improper or inadequate maintenance by buyer.
- Buyer-supplied software or interfacing.
- Unauthorized modification or misuse.
- Operation outside of the environmental specifications for the product.
- Improper site preparation.
- Improper maintenance.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables, and battery. This warranty does not apply to any product that Philips Medical Systems determines has been modified or damaged by the customer.

Service Agreements

Periodic inspections and maintenance service are recommended to ensure effective operation. Call your Philips Sales and Service Office for details regarding a Customer Support Services Agreement for your specific requirements.

Global Medical Device Nomenclature (GMDN)

The 5-digit GMDN code adjacent to the symbol is defined in the EN ISO 15225.

GMDN 38276

Unpacking and Storage

The equipment is packed in its own reusable shipping container. When unpacking the equipment, inspect the carton for physical damage. Any damage should be reported immediately to the shipping company. Open the shipping container and compare the contents to the packing list. There is only one packing list per shipment. If there are several parcels, the shipping list is normally attached to the largest container. If the packing list does not agree with the items received, contact a Philips Response Center. The shipping container should be saved to permit reshipment.

Medical Device Directive

DigiTrak XT, model 860322 complies with the requirements of the Medical Device Directive 93/42/EEC and carries the CE 0123 mark accordingly.

Authorized EU-representative:

Philips Medizin Systeme
Böblingen GmbH
Hewlett Packard Str. 2
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Germany

Safety and Warning Information

Chapter 1. Using the DigiTrak XT Recorder

Chapter 2. Service and Specifications

Appendix A.

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Safety and Warning Information

The DigiTrak XT Holter Monitor is a battery operated solid state recorder, designed for up to 168 hours (7 days) continuous recording of ambulatory electrocardiograph (AECG) data. It has the ability to detect and record pacemaker pulses according to the appropriate criteria for AAMI pacer detection.

The DigiTrak XT is an AAMI Type I device and part of a conventional AECG monitoring system where an ECG is recorded in Multi Media Card (MMC) memory within the recorder. After the recording is complete, the DigiTrak XT recorder is connected via the docking station to a USB port on the Holter computer. Follow the instructions provided with the Holter application to download and analyze the recorded ECG data.

Indications for Use

The DigiTrak XT Holter recorder is intended for patients requiring ambulatory (Holter) monitoring.

CAUTION The DigiTrak XT recorder is not intended for use on infants weighing under 10 kilograms (22 pounds), as required by IEC 60601-2-47:2001.

Such monitoring is most frequently used for the indications below:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
- Evaluation of patients for ST segment changes
- Evaluation of a patient's response after resuming occupational or recreational activities (for example, after myocardial infarction or cardiac surgery)
- Clinical and epidemiological research studies
- Evaluation of patients with pacemakers
- Reporting of time and frequency domain heart rate variability
- Reporting of QT interval

Equipment Symbols

Symbol	Meaning
	Attention: Consult accompanying documents
 0123	Symbol on label indicates Philips meets the applicable requirements of the European directive 93/42/EEC
	Type B equipment contains adequate protection against electrical shock, particularly regarding the allowable leakage current and the reliability of protective earth connection (when present)
	Dispose of in accordance with the requirements of your country.
2000 	Date of manufacture
	China ROHS
SN	Serial number
REF	Not shown - catalogue number is DigiTrak XT
GMDN 38276	The 5-digit Global Medical Device Nomenclature (GMDN) code adjacent to the symbol is defined in the EN ISO 15225.

Precautions

- Patient leads must be removed from electrodes before defibrillation.
- When using Pacer Detect, be aware that false positive and false negative pacer detects may occur.
  - False positives — may result from poor electrode hookup or high noise conditions.
  - False negatives — may occur with bipolar pacers due to a weak pacer pulse signal at the patient's skin surface.
- The presence of pacemaker signals in the ECG trace should not be considered true representations of the actual pacemaker stimulus amplitude when viewing the ECG data.
- Observe local laws for disposal of alkaline and lithium batteries.
- Do not leave the battery in the recorder when it is not in use. Damage from corrosion could result.
- Use of rechargable batteries is not recommended.
- For the best recording results, the patient should be instructed to avoid close proximity to heavy electrical equipment or other sources of electromagnetic interference such as electric blankets, heating pads, etc.
- The DigiTrak XT recorder should not be immersed in water. The patient should be instructed not to wear the recorder in the shower or bath.
- The DigiTrak XT recorder supports an Early Out feature that allows a trained individual to stop a recording before the selected recording time has elapsed. Failure to follow this procedure may result in the loss of all recorded ECG data.
- This product consists of devices that may contain mercury, which must be recycled or disposed of in accordance with local, state, or federal laws. Within this system, the backlight lamps in the monitor display contain mercury.

Electrode Application

- It is recommended that trained medical personnel handle the application of electrodes.
- Use only electrodes designed for longer term Holter monitoring.
- Proper preparation of the patient's skin is absolutely essential for obtaining a quality ECG recording. Refer to your electrode provider or this guide for instructions on skin preparation techniques.
- Apply electrodes as shown in the diagrams of the Monitor Hookup Kits, the Electrode Placement diagrams in this guide, or as instructed by a physician.

Materials Used

The DigiTrak XT recorder, belt clip, and patient cable do not contain any latex material.

Security Recommendations

To further strengthen the security and confidentiality of your patient records and system in general, we recommend that you implement additional security measures, including:

- Remind your patients that the recorder contains confidential patient data and they should safeguard the recorder while it is in their possession.
- Store the recorders in a secure location when not in use.
- Delete patient data from the recorder after it has been downloaded to Holter. (See "Deleting Patient Information" on page 1-19 for instructions.)

Conventions

This book uses the following text conventions:

WARNING **Warning statements describe conditions or actions that can result in personal injury or loss of life.**

CAUTION Caution statements describe conditions or actions that can result in damage to the equipment or loss of data. Caution statements alert the user that the clinician has the responsibility of determining significance of results due to actions and varying factors present with each case.

NOTE Notes contain additional information on using this product.

1

Using the DigiTrak XT Recorder

The DigiTrak XT Holter Monitor is a battery operated solid state recorder, designed for up to 168 hour (7 day) continuous recording of ambulatory electrocardiograph (AECG) data. It has the ability to detect and record pacemaker pulses according to the appropriate criteria for AAMI pacer detection.

Features include:

- Multi-day recording, up to 168 hours (7 days)
- Easy navigation of user menus
- Streamlined form factor and light weight for patient comfort
- Workflow enhancements, featuring the ability to preprogram user demographics information, on-screen lead status and gain adjustment
- Reliability improvements, featuring a reinforced patient cable connector and power-on self tests to check for battery life
- Supportability enhancements, featuring easy removal and replacement procedures
- Security enhancements, featuring soft encryption of data. Encryption is the conversion of data into a form that cannot be understood by unauthorized people. Decrypting is the process of converting encrypted data back into its original form so that it can be understood.

This chapter provides the following information:

System Requirements

Your Holter software must be at Version 2.9 or later in order to perform multi day scans greater than 48 hours. See the *Philips Holter Installation and Configuration Guide* or the *Philips Holter Instructions for Use* for a complete list of system requirements.

Using the DigiTrak XT with Legacy Software

You must install the DigiTrak XT Compatibility software to use the DigiTrak XT with Holter releases 2.7, 2.8, and 2.8.1. See the *DigiTrak XT Compatibility Software Installation Instructions* that came with the DigiTrak XT CD for more information.

Accessing Documentation Updates at InCenter

Updates to the documentation are provided periodically. To access the latest documentation, visit the Philips InCenter website, at https://incenter.medical.philips.com/default.aspx.

If you do not yet have an InCenter user ID, register by clicking the link "Click here for access to software updates and documentation for cardiology products" on the right side of the page. A user ID and password will be sent to the email address you provide, enabling access to documentation updates, as well as free software updates, when available.

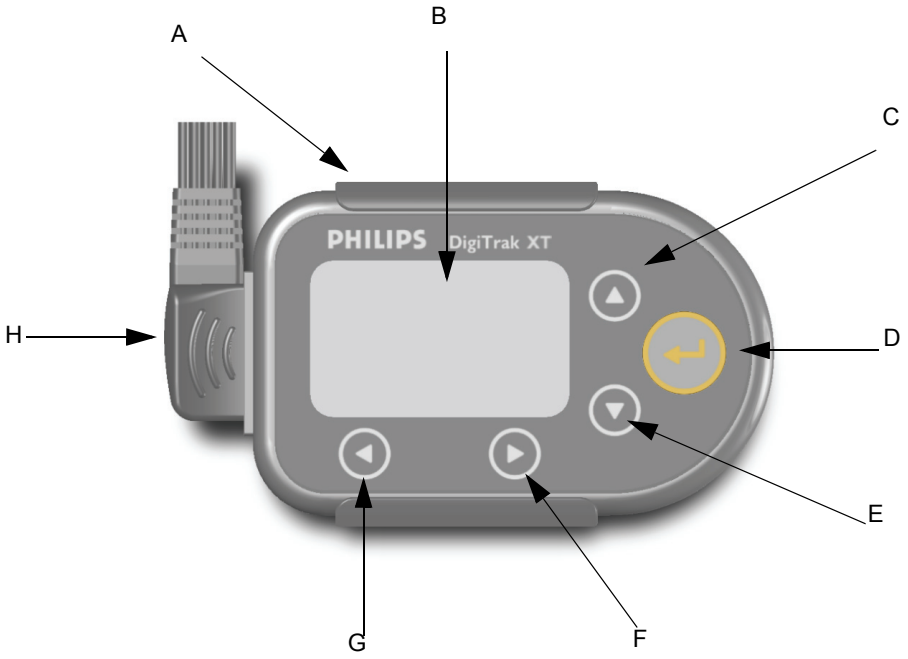
Accessing Documentation at the Philips Website

Documentation for many Philips medical products can be downloaded from the Philips website, at www.medical.philips.com/goto/productdocumentation.

Getting Acquainted with the DigiTrak XT

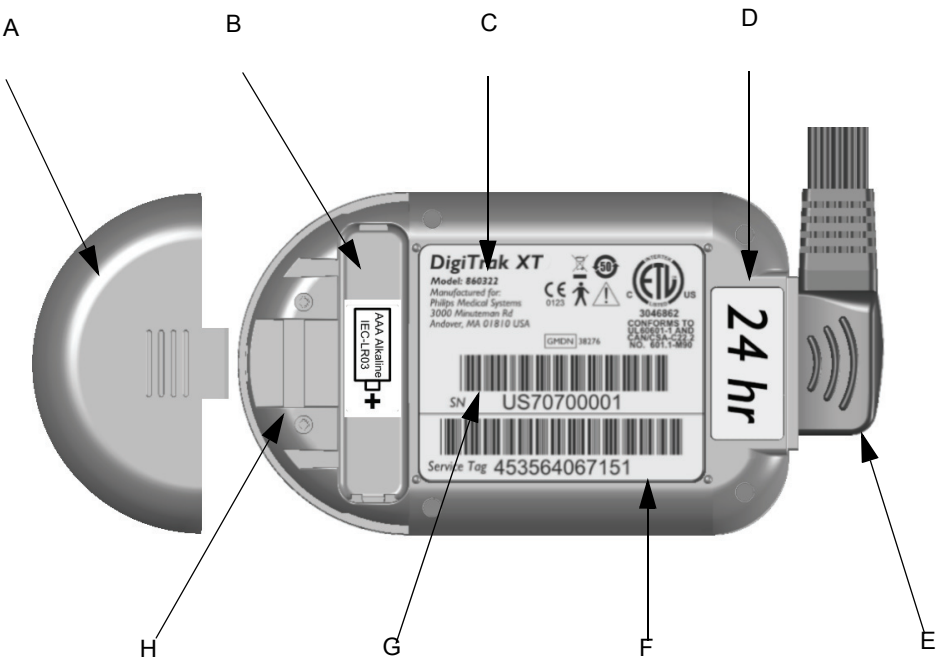
The DigiTrak XT's buttons and connections are carefully organized to facilitate ease of use.

Front View



Reference Letter	Description
A	Belt clip
B	Recorder screen
C	Up arrow
D	Enter, Event button
E	Down arrow
F	Right arrow
G	Left arrow
H	Patient cable

Back View



Reference Letter	Description
A	Battery door
B	Battery compartment
C	Model number
D	Recorder configuration label
E	Patient cable
F	Service tag
G	Serial number
H	Recorder tether slot

About Recorder Functions

The following table describes the recorder screens and menus.

Table 1-1 DigiTrak XT recorder functions

Screen	Description
Lead Status	Displays the connection status of each lead.
CH1, CH2, CH3	Displays the signal trace in real time with pacer pulse marks, if selected. There is one screen for each ECG channel. ■ The gain setting is the same for all channels and is displayed in the lower right corner of the screen. ■ If Pacer Detector is on, the pacer pulse marks are displayed below the trace to indicate each pacer pulse detection and you can adjust the threshold for pacemaker spike detection.
Settings	Determines the following recorder settings: ■ Record Time – 24, 48, 72, 96, 168 hr ■ Pacer Detector – ON or OFF. (The default for pacer detect is OFF. It must be turned ON for each procedure in which it will be used or saved as part of the default settings.) ■ Language – English, Spanish, German, French, Italian, Portuguese, Swedish, Dutch ■ Contrast – 20- 95% ■ Sample Rate – 175 s/s ■ Resolution – 10 bit ■ Save as Default – Yes or No. The default for saving settings is No. Yes saves the current configuration (including date and time settings) as the default.
Date/Time	Set the following date and time options: ■ Month, Day, Year ■ Date Format – MM/DD/YYYY, YYYY/MM/DD, DD/MM/YYYY, YYYY/DD/MM ■ Hour and Minute ■ Auto DST – ON or OFF. Daylight savings time uses the United States convention. ■ Time Format – 12 or 24 hr

Table 1-1 DigiTrak XT recorder functions *(continued)*

Screen	Description
About	Displays the following information about the recorder: ■ Product name ■ Serial number ■ Firmware version information
Start	After configuring or reviewing all the settings, select the start screen and press *Enter*. This will start the recording. During recording, the recorder displays the current time and time remaining to record.

Navigating the Recorder Display

Use the following buttons to navigate the DigiTrak XT screens:

Button	Description
	Left arrow. Moves from one tab to the next and changes values within a field.
	Right arrow. Moves from one tab to the next and changes values within a field.
	Down arrow. Moves from one field to the next.
	Up arrow. Moves from one field to the next.
	Enter. Used to change settings and to save the current settings. Event marker. Used by the patient to record events.

If scroll arrows appear on the display, it indicates additional fields that are located off the screen. Use the up and down arrow keys to access these additional fields.

Using the Belt Clip

To insert the recorder into the belt clip

1. Slide the belt clip over the battery end of the recorder until it snaps into place.
2. Rotate the belt clip until it locks into the desired position.

To remove the recorder from the belt clip

- Slide the battery end of the recorder out of the belt clip.

Getting Started

The following sections describe how to set up the recorder for use.

NOTE If the recorder is turned off for any reason, for example, to shut it down early, you must remove the battery. To restart the recorder, insert the battery and press *Enter*. When the recorder is powered on, default settings are in effect; any custom settings are lost. In addition, the previous ECG recording is erased.

Setting the Recorder Date and Time (First Time Use only)

To set the recorder date and time

NOTE Use an alkaline battery for recordings up to 96 hours. Use a lithium battery for recordings over 96 hours.

1. Make sure a fresh AAA battery is in the recorder.

NOTE The recorder enters sleep mode after 20 seconds of no activity. If this happens, simply press *Enter* to turn the recorder on.

2. Use the arrow buttons to display the Date/Time tab.
3. Press *Enter*.
4. Use the up and down arrows to select the parameter to change (hour, minute, date, and so on), and use the left and right arrows to change the setting of the parameter.
5. Press *Enter* to accept the changes.
6. To start a recording, display the Start tab and then press *Enter* to begin recording.
7. If you do not want to start a recording, remove the battery to shut down the recorder.

Step One — Connecting the Recorder to the Dual Dock

You connect the recorder to the docking station to enter patient information and to download data collected in the DigiTrak XT recorder to the Holter application. The data is transferred to and from the Holter system via a USB docking station. The docking station is connected to the PC through a USB port; you place the recorder in the docking station to transfer the data. The dual dock refers to the docking station that accommodates both the DigiTrak XT and DigiTrak Plus recorders.

Ensure the dual dock is connected to the Holter computer before proceeding.

To connect the dual dock to the Holter computer

▶ Plug the USB connector from the dual dock into an available USB port on the computer.

To connect the recorder to the dual dock

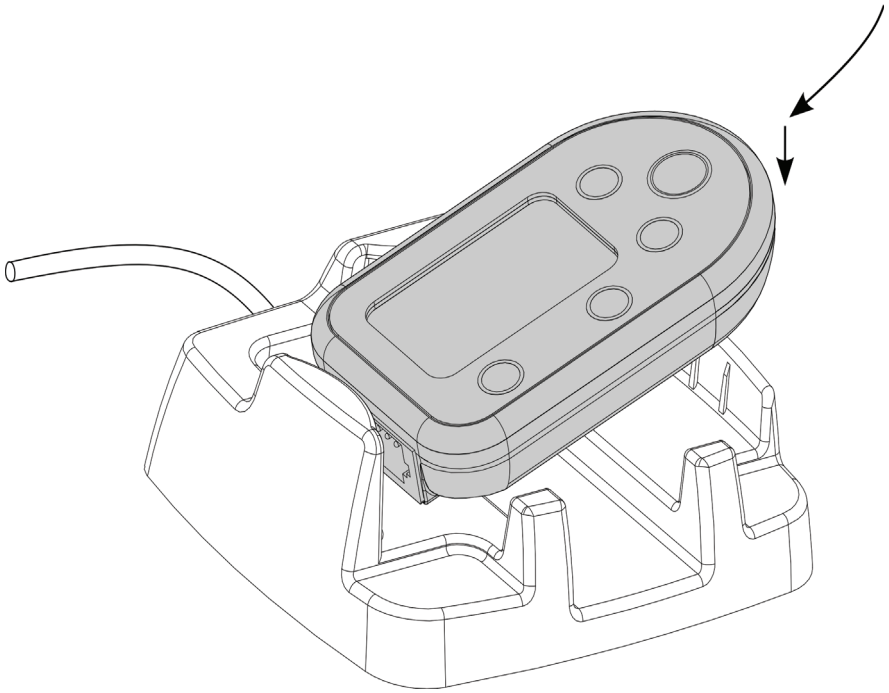
1 Remove the battery from the recorder.

2 Remove the belt clip or pouch from the recorder, if attached.

CAUTION Do not insert the recorder at a high angle or with the pins facing out. Inserting the recorder from a high angle will result in bent pins.

3 Gently slide the left side of the recorder straight into the dual dock station (at the angle shown) with the pins facing the side (under the flap). The recorder snaps into place.

4 Gently press down on the right side of the recorder to lock it into the dual dock station. There should be light resistance.



CAUTION Do not force the recorder into the dual dock. If it does not easily snap into place, remove the recorder and try installing it again.

USB connected appears on the recorder display when the recorder is properly connected and the Preloading message appears in the bottom right of the Holter application window (if there is data on the recorder). The dual dock is now operational and you are ready to enter or download data.

Step Two — Entering the Patient's Name (Optional)

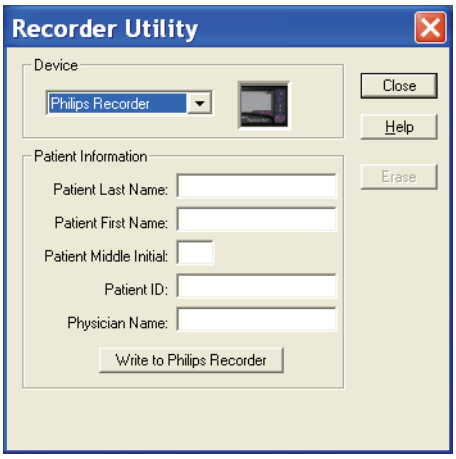
To enter patient information

1 With the dual dock connected to the PC, insert the recorder into the dual dock.

2 Launch the Holter program.

3 Click **Tools > Recorder Utility**.

The Recorder Utility screen appears.



4 Select Philips Recorders as the type.

5 Enter the patient information (last name, first name, ID, and so on).

6 Click **Write to Philips Recorders**.

After several seconds the data is written to the recorder.

NOTE All patient information is displayed on the recorder if you entered it using the Holter 2.9 software. Although previous versions of software store the patient information and display it on the report, only the patient name is displayed on the recorder screen.

7 Remove the recorder from the dual dock.

Step Three — Preparing the Patient

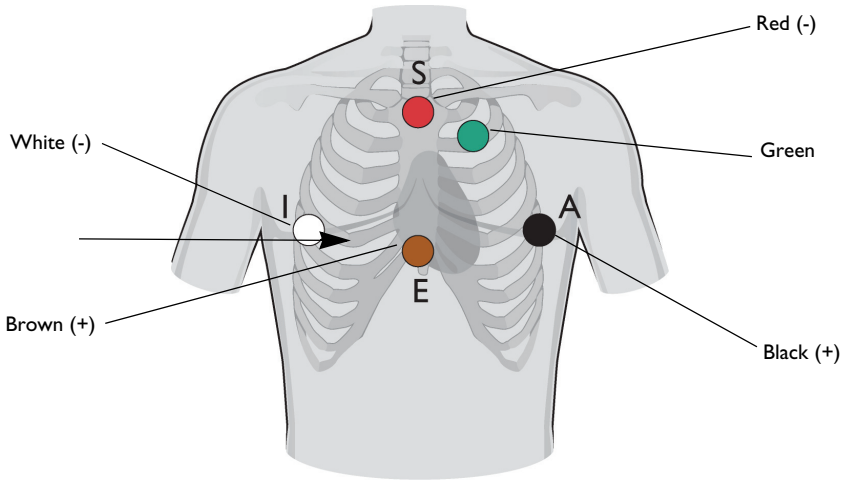
Before You Begin

- Insert a fresh AAA battery with each patient. Be sure to observe the correct battery polarity.
- Instruct the patient not to tamper with the recorder, remove the battery, or disconnect the patient cable.

To prepare the patient

1. Prepare the patient's skin prior to applying the electrodes. Skin is a poor conductor of electricity, so skin preparation is important in achieving good electrode-to-skin contact.
   - If necessary, clip hair at the electrode sites (or shave sites, if needed).
   - Clean and abrade the skin at the electrode site. Wash skin thoroughly with soap and water.
   - Dry the electrode sites briskly to increase capillary blood flow in the tissues and to remove oil and skin cells.
2. Attach the leads to the electrodes before placing them on the patient.
3. Apply the electrodes by peeling them, one at a time, from the protective backing and sticking them firmly to the patient's skin. (Refer to Figure 1-1 for proper electrode placement.) Press around the entire edge of each electrode to ensure they are secure. Make sure the lead wires do not pull on the electrodes.

Figure 1-1 Electrode Placement



CAUTION Lead colors for EASI Holter hookups are different from those used for EASI telemetry hookups. Lead placements are the same.

Electrode	Placement
E (Brown)	Level of 5th intercostal space, midsternum
A (Black)	Same level as **E** and **I**, left mid-axillary line
S (Red)	Top of sternum (manubrium)
I (White)	Same level as **E** and **A**, right mid-axillary line
Ground (Green)	Center of sternum or any convenient location

Raw Channel	Description
Channel 1	**E** (+) to **S** (-) Similar to MC V1, anterior view of the heart
Channel 2	**A** (+) to **S** (-) Similar to MC V6, a lateral view of the heart -- useful for ST measurements
Channel 3	**A** (+) to **I** (-) CC6, similar to the inferior lead aVF – approximation suitable for ST measurements

Step Four — Checking the Lead Status and ECG Signal Quality

To check the lead status

1. Make sure a fresh AAA battery is in the recorder.

   The recorder turns on as soon as you put in a battery. The recorder performs a self-test and the splash screen appears for a couple of seconds, with the message Press any key to start displayed at the bottom of the screen. If the cable is not connected, the message No Cable appears at the bottom of the screen and you cannot proceed.

2. Insert the patient cable (lead set) into the recorder connector. Press firmly to be sure it is seated properly.

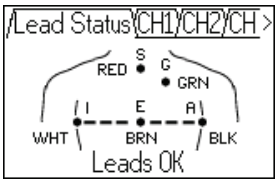
3. Press any button to enter the menus.

   If you entered patient information, it is displayed. Otherwise, the Leads Status tab appears.

NOTE All patient information is displayed on the recorder if you entered it using the Holter 2.9 software. Although previous versions of software store the patient information and display it on the report, only the patient name is displayed on the recorder screen.

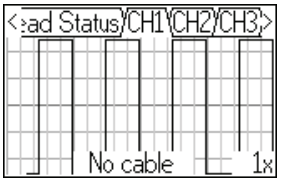
4. Use the arrow buttons to select the Lead Status tab.

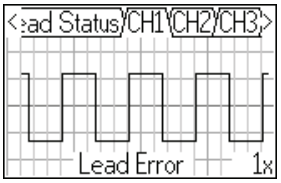
5. Check the diagram for loose connections.
   - ⊡ indicates a lead has a good patient connection
   - ◘ (flashing) indicates a lead does not have a good patient connection
   - Leads OK or Leads Error message displayed



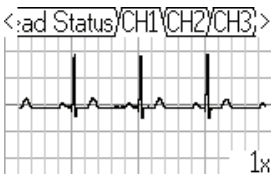
6. Use the arrow buttons to select the CH1, CH2, and CH3 tabs and check the ECG signal quality.

7 Observe the screen for cable and lead errors as follows.





8 When all the leads are properly connected, the ECG waveform appears.



9 Use the arrow buttons to change the gains settings of the display, as shown in the following table.

NOTE The recording for all resolutions is always made at the 1X gain setting.

Table 1-2 Gain Settings

Gain on screen	Millivolt range
0.5X	± 5 peak-to-peak
1X	± 2.5 peak-to-peak
2X	± 1.25 peak-to-peak

10 Proceed to Settings and select Pacer Detector, if applicable.

11 Use the arrow buttons to select the Start tab and press *Enter* to start the recording.

NOTE If you do not start the recording, the DigiTrak XT automatically starts recording after 30 minutes, provided there are no lead errors.

During a Recording

During a recording, the DigiTrak XT displays the date, current time, and the time remaining for the recording as well as any lead or cable error, if present.

Step Five — Removing and Shutting Down the Recorder

To retrieve the recorder

1. When the patient returns, remove the recorder from the patient.

   The recorder automatically shuts down after the record time you set has expired. To shut down the recorder before the specified time expires, see "Stopping a Recording (Early Out)" on page 1-19.

2. Remove the patient cable.

   If you pre-loaded the patient information, the patient name appears on the recorder screen until you download the data.

Step Six — Downloading Data from the Recorder

To download data from the recorder into the Holter system

1. Launch the Holter application.
2. Connect the recorder to the Holter system as described on page 1-9. Be sure to remove the battery from the recorder.

   The text Preloading appears in the lower right-hand corner of the PC screen.

CAUTION **Do not** disconnect the recorder whenever the *Preloading* message is flashing. To cancel the Preloading sequence, double-click the Preloading message and select Abort.

If you accidentally unplug the recorder during a preload sequence, restart the PC to clear the DigiTrak XT device. ***If the recorder is unplugged prematurely, the ECG is corrupted.***

3. Leave the recorder connected until downloading of the data is complete.

   You can perform an analysis while downloading data.
4. When downloading of the data is complete, detach the recorder from the dual dock, then scan and save the ECG.
5. Repeat steps 1-3 for subsequent new patients.
6. Refer to the *Philips Holter Instructions for Use* for information on performing a scan.

Changing Recorder Settings

You can change various recorder settings (specified in Table 1-1) and save them (along with the date and time settings) as the default through the Settings tab.

To change recorder settings

1. Select the Settings tab.
2. Change the settings, as necessary.
3. Select **OK** and press *Enter* to save the settings.

Saving Default Settings

To save the settings as the recorder default settings

1. Change the settings, as necessary. Change the date and time settings as necessary (located on the Date/Time tab).
2. Select Save as default (located on the Settings tab) and press *Enter* to save the settings.

Pacemaker Detection

Pacemaker detection for the DigiTrak XT recorder is automatically defaulted to OFF. You must turn it On for each procedure in which it is used or save the setting as part of the default settings.

Pacemaker Threshold

The DigiTrak XT recorder allows the user to adjust the threshold for pacemaker spike detection. The purpose of this feature is to raise or lower the threshold of the recorder detection in order to eliminate spikes from a rate-modulated pacemaker or lower the threshold to allow for better detection of bipolar pacemakers.

NOTE Adjusting the threshold on the DigiTrak XT recorder does NOT affect any threshold settings on the patient's pacemaker. The adjusting of the threshold settings are confined totally to the function of the recorder.

You do not have to adjust the pacemaker recording threshold for all recordings.

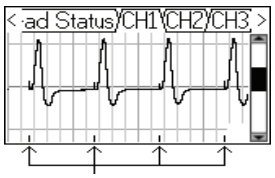
Adjusting Pacemaker Thresholds

To adjust a pacemaker threshold

1. Select the Settings tab.
2. Ensure that the Pacer Detector setting is ON.
3. While viewing the ECG waveform, press *Enter* to display the pacemaker threshold indicator on the right side of the screen.

   The top position of the bar indicates maximum sensitivity. The indicator defaults to one below the maximum sensitivity.

NOTE The Enter button toggles between the pacemaker threshold indicator and the gain setting.



4 Check to see if there are pacer pulses in the pacer detection channel on the bottom of the screen.

5 If there are many pacer pulses in the pacer detection channel and less or none in the ECG channel, reduce the sensitivity of the pacemaker threshold indicator.

6 If there are no pacer pulses in the pacer detection channel and there are pacer pulses in the ECG channel, increase the sensitivity of the pacemaker threshold indicator.

7 Use the arrow buttons to select the Start tab and press *Enter* to start the recording when you are satisfied that the correct pacer pulses are being detected.

Registering an Event (Patient Event Marker)

The DigiTrak XT allows an easy way for the patient to record events. Once an event has been marked, the patient must wait one minute to register another event.

To register an event

▶ Press *Enter* each time to mark an event.

The marked event time stamp appears on the recorder screen. After 20 seconds have elapsed, the time stamp is cleared from the recorder screen.

Stopping a Recording (Early Out)

The recorder supports an Early Out feature that allows a trained individual to stop a recording before the selected recording time has elapsed.

To stop a recording in progress

1. Hold the left arrow and *Enter* buttons simultaneously.

   A menu is displayed with the choices Stop Recording or Exit Menu.

2. Select **Stop Recording** and press *Enter*.

   The messages, Shutting down please wait. Recording complete appear, the recording stops and the recorder shuts down.

3. If you do not want to shut down the recorder, select **Exit Menu**.

   The recorder status screen appears and the recording continues.

Deleting Patient Information

Patient information (including ECG data) is erased from the recorder the next time you turn on the recorder. Once you press a key to enter the recorder's menus, the message Initializing Card briefly appears on the screen. When this occurs, the MMC card is erased and any previous patient and ECG information is deleted from the recorder.

If you are storing the recorder after downloading data, you can use the following procedure to erase the patient data.

To delete patient information

1. Remove the battery from the recorder.
2. Insert a battery into the recorder.

   The recorder turns on as soon as you put in a battery. The recorder performs a self-test and the splash screen appears for a couple of seconds, with the message Press any key to start displayed at the bottom of the screen. If the cable is not connected, the message No Cable appears at the bottom of the screen and you cannot proceed.

3. Insert the patient cable (lead set) into the recorder connector. Be sure it is seated properly.
4. Press *Enter*.

   The message Initializing Card briefly appears on the screen. When this occurs, the MMC card is erased and any previous patient and ECG information is deleted from the recorder.

2

Service and Specifications

This chapter provides information about servicing your recorder, device specifications, and available parts and accessories.

Service & Maintenance

Cleaning

To clean the recorder

1. Remove the battery from the recorder.
2. Dampen a soft cloth with a mild detergent and water mixture.
3. Clean the recorder, lead wires, and belt clip.
4. Remove any adhesives from the patient lead wires with an adhesive tape remover solution or swab with mild detergent.

CAUTION Do not use alcohol or acetone to clean the lead wires as this can cause the wires to stiffen and the insulating plastic to crack. Do not immerse the recorder in water.

Troubleshooting

If you are having problems with the recorder, refer to the table below first. If your issue is not addressed, call the Response Center.

Table 2-1 Troubleshooting

Symptom	Solution
No display or Recorder does not power on	■ Ensure that any previous ECG recording has been downloaded to the Holter application. ■ Ensure battery is inserted with correct polarity. ■ Install a new 1.5V AAA battery. ■ Ensure patient cable (lead set) is connected and press *Enter*.
Low battery	■ Install a new battery. ■ Inspect battery compartment, clean contacts if necessary.
Self Test Error 52. Stuck Key. Reboot. message	■ Can be caused by pressing a key when inserting the battery. Try reinserting the battery, making sure you are not pressing any of the recorder keys. If the message persists, call for service
Battery does not last 24 or 48 hours	■ Ensure a new alkaline battery is being used. Do not use rechargeable batteries.
Battery does not last 96 or 168 hours.	■ Ensure a new lithium battery is being used. Do not use rechargeable batteries.
Recorder does not run as long as expected	■ Check the Record time in the Settings screen. ■ Ensure a fresh alkaline battery is being used for 24 or 48 hour recordings. ■ Ensure a fresh lithium battery is being used for 96 or 168 hour recordings.
No Cable	■ Ensure patient cable (lead set) is connected to the recorder. The recorder will not pass the splash screen unless a cable is connected. ■ Check that the recorder pins are not broken or bent. Check that the cable connector is not damaged.

Table 2-1 Troubleshooting *(continued)*

Symptom	Solution
Noise artifacts on ECG signal	■ Ensure you have prepared the patient's skin according to the instructions on page 1-12. ■ Ensure the electrodes are properly applied to the patient. ■ Ensure the leads are making proper contact with the electrodes. ■ Ensure patient cable (lead set) is making contact with the electrodes. ■ Replace the lead set.
No Lead Connected message	■ Ensure you have prepared the patient's skin according to the instructions on page 1-12. ■ Ensure the electrodes are properly applied to the patient. ■ Ensure the leads are making proper contact with the electrodes. ■ Ensure patient cable (lead set) is connected. ■ Replace the lead set.
Leads Error	■ Ensure you have prepared the patient's skin according to the instructions on page 1-12. ■ Ensure the electrodes are properly applied to the patient. ■ Ensure the leads are making proper contact with the electrodes. ■ Ensure patient cable (lead set) is connected. ■ Replace the lead set.
Defective Card message	■ Remove and reinsert battery. Note that when you restart the recorder, all patient and ECG information is erased from the memory card and cannot be recovered. ■ If message still appears, call for service.
Existing ECG in recorder. The patient's name is displayed on the recorder screen. The recorder does not power on.	■ Download the ECG data to the Holter application.
Self test failure	■ Write down the error code. ■ Restart the recorder. ■ Call for service.

Table 2-1 Troubleshooting *(continued)*

Symptom	Solution
No splash screen when recorder is placed in dual dock	■ Ensure that the DigiTrak XT cable or dual dock cable is firmly connected to a USB port on the PC. ■ Ensure that the PC is powered on. ■ Replace the DigiTrak XT cable or dual dock. ■ Remove battery from the recorder before placing it in the dual dock.

Calling for Service

For telephone assistance, call the Response Center nearest to you or visit the website at www.medical.philips.com/main/services/response_center

Be prepared to provide the following information:

- Model number
- Serial number
- Service tag number

Call customer support before returning a recorder to make shipping arrangements.

North America Response Centers

Country	Telephone Number
Canada	(800) 323 2280
Mexico	01 800 710 8128
Puerto Rico	1 787 754 6811
United States	(800) 722 9377

South America Response Centers

Country	Telephone Number
Argentina	54 11 4546 7698
Brazil	0800 701 7789
Chile	0800 22 3003
Columbia	01 8000 11 10 10
Peru	51 1 620 6440

Europe Response Centers

Country	Telephone Number
Austria	43 1 60101 820
Belgium	32 2 525 7102 (French) 32 2 525 7103 (Flemish)
Czech Republic MCR Response Center (located in The Netherlands)	31 40 2781619
Denmark	45 80 30 30 35
Finland	358 615 80 400
France	0 810 835 624
Germany	0180 5 47 5000
Greece MCR Response Center (located in The Netherlands)	31 40 2781619
Hungary MCR Response Center (located in The Netherlands)	31 40 2781619
Italy	0800 232100
Netherlands	31 40 27 211 27
Norway	47 800 84 080
Poland MCR Response Center (located in The Netherlands)	31 40 2781619
Rumania MCR Response Center (located in The Netherlands)	31 40 2781619
Russia MCR Response Center (located in The Netherlands)	31 40 2781619
Slovak Republic MCR Response Center (located in The Netherlands)	31 40 2781619
Spain	34 90 230 4050

Europe Response Centers *(continued)*

Country	Telephone Number
Sweden	46 200 81 00 10
Switzerland	0800 80 3000 (German) 0800 80 3001 (French)
United Kingdom	44 0870 532 9741 Fax: 44 01737 23 0550

Asia Response Centers

Country	Telephone Number
Australia	1800 251 400
China	800 810 0038
Hong Kong	852 2876 7578
India	1600 112 444
Indonesia	62 21 7910040, ext 8610
Japan	81 0120 095 205
Korea	82 02 3445 9010
Malaysia	1800 886 188
New Zealand	0800 251 400
Philippines	63 2 8162617 ext. 875
Singapore	1800 Philips
Taiwan	0800 005 616
Thailand	02 614 3569

Africa and Middle East

Country	Telephone Number
All countries MCR Response Center (located in The Netherlands)	31 40 2781619

Supplies & Parts

Approved supplies and parts for the DigiTrak XT are listed in the following tables.

To order supplies:

- In the USA, call 1-800-227-7843.
- Outside the USA, contact your local Philips Medical Systems Sales Office, your authorized Philips Medical Systems Dealer or Distributor, or visit our website at http://shop.medical.philips.com

Description	Philips P/N
Solid Gel ECG Electrode, 5/pouch	M4612A
Adult Plastic Tape ECG electrode, disposable	13942E
DigiTrak XT pouch	989803153451

NOTE For better protection of the recorder, we strongly recommend using the DTXT pouch (part # 989803153451). The pouch provides extra protection and cushioning.

The following part can be ordered by contacting the Response Center.

Description	Philips P/N
Battery door	453564067201

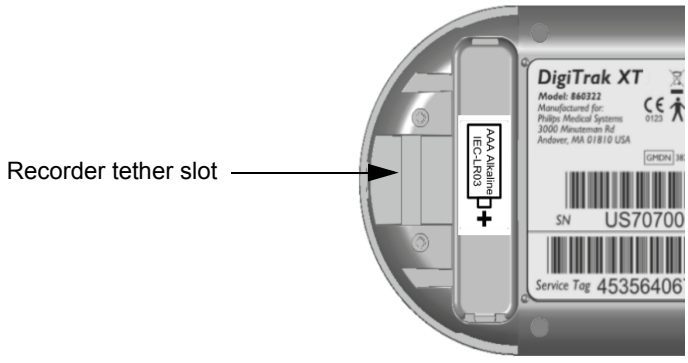
The following parts can be ordered by contacting your local Philips Medical Systems Sales Office or your authorized Philips Medical Systems Dealer or Distributor.

Description	Philips P/N
USB Dual Dock	989803157511
Patient diaries (200)	M4701A
24-inch patient cable (lead set)	989803157481
36-inch patient cable (lead set)	989803157491
54-inch patient cable (lead set)	989803157501
DigiTrak XT hookup kit (1 patient diary, 1 alkaline AAA battery, 1 alkaline AA battery, 5 electrodes)	M3730-62600
Patient electrodes (300)	M4706A
Belt clip	989803158191
Belt clip (10-pack)	989803158210

Replacing the Battery Door

To replace a broken battery door

1. Cut the rubber tether on the battery door.
2. Remove any tether pieces from the recorder.
3. Insert the tether of the new battery door through the recorder tether slot. Make sure the small hook at the end of the tether pops out from underneath the recorder tether slot.



4. With the battery door fully closed, slide the door to release the locking mechanism.
5. Lift the battery door at it's widest point.

   When installed correctly, the battery door automatically pivots about the tether. The battery door will hang off the end of the recorder.

Specifications

Functional	
Channels	3
Recorded amplitude resolution	10 bits
Recording	Full disclosure
Download interface	USB
Sample rate	175/sec maximum
Frequency response	0.05Hz to 60Hz, @-3dB
Signal verification	LCD display
Event switch	Press *Enter*
Pacemaker Detection	Programmable on/off
Memory	
Capacity/Recording time	256 MB up to 96 hours 512 MB up to 168 hours (7 days)
Recording type	MMC
Physical	
Dimensions	91.44 x 55.88 x 19.05mm (3.60 x 2.20 x 0.75inches)
Weight with battery	70 g. (2.5 oz.)
Enclosure	Molded plastic (UL 94V-2)
Operating position	Any orientation
Electrical	
Gain setting	0.5X, 1X, 2X
Connector	11 pin
Patient cable	5 lead
Environmental	
Operating temperature	0°C to +45°C/32°F to 113°F
Non-operating temperature	-10°C to +70°C/14°F to 158°F
Operating humidity	10% to 95% (non-condensing)
Non-operating humidity	5% to 95% (non-condensing)

Battery	
Type	(1) AAA Alkaline IEC-LR3 for recordings up to 96 hours (1) AAA Lithium for recordings longer than 96 hours
Life	168 hours (7 days)
Warranty	
	24 months from shipment

A

Electromagnetic Compatibility (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the DigiTrak XT recorder.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the DigiTrak XT recorder according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The DigiTrak XT complies with the requirements of standard EN 60601-1, as follows:

- The equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- IPX3 ordinary equipment (enclosed equipment with protection against spraying water). The recorder will withstand exposure to liquids, such as rain, or splashing water. The recorder will not survive full immersion or liquid spray under pressure. The patient should be instructed not to wear the recorder in the shower or bath.
- Internally powered equipment
- Mode of operation - continuous operation.

The DigiTrak XT recorder should not be used adjacent to, or stacked on top of other equipment. If the DigiTrak XT recorder must be used adjacent to or stacked on top of other equipment, verify that the recorder operates in an acceptable manner in the configuration in which it will be used.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. For more information on troubleshooting, see “Troubleshooting” on page 2-2.

The list of cables with which Philips claims compliance with emissions and immunity requirements of IEC 60601-1-2 are listed on page 2-7.

Only use Philips Medical Systems replacement parts with the DigiTrak XT recorder. The use of non-approved replacement parts may result in increased Radiated Emissions or decreased Electromagnetic Immunity of the DigiTrak XT recorder.

Table A-1. Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
The DigiTrak XT recorder is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the DigiTrak XT recorder should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment: guidance**
RF Emissions CISPR 11	Group 1	The DigiTrak XT recorder uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Table A-2. Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The DigiTrak XT recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the DigiTrak XT recorder should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply line +/- 1 kV for input/ output lines	N/A	The DigiTrak XT does not have AC or DC power lines.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	N/A	The DigiTrak XT does not have AC or DC power lines.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	N/A	The DigiTrak XT does not have AC or DC power lines.
Power frequency (50./60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the AC mains voltage prior to application of the test level.

Table A-3. Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The DigiTrak XT recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the DigiTrak XT recorder should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the DigiTrak XT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance D = 1.2vP D = 1.2vP 80 MHz to 800 MHz D = 2.3vP 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *D* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from surfaces, objects, and people.

Additional notes are on following page.

ADDITIONAL NOTES

A Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DigiTrak XT recorder is used exceeds the applicable RF compliance level above, the DigiTrak XT recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DigiTrak XT recorder.

B Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Table A-4. Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the DigiTrak XT recorder: for equipment and systems that are not life-supporting

The DigiTrak XT recorder is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DigiTrak XT recorder can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DigiTrak XT recorder as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter (m)**		
	150 KHz to 80 MHz D = 1.2vP	80 MHz to 800 MHz D = 1.2vP	800 MHz to 2.5 GHz 2.3vP
0.01	.12	.12	.23
0.1	.38	.38	.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12.0	12.0	23.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance *D* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

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