

January 27, 2020

Subject: UPDATE: Philips 860322 DigiTrak XT Holter Recorder –
Warranty Extension and On-Site Repair Consideration

Dear Valued U.S. Customer:

This letter is an update to our recent communications, which had informed you of Philips' progress in correcting an issue with the Philips 860322 DigiTrak XT Holter Recorder, in which the recorder would display an "Error: 602" message and thus be unavailable for use for a new patient study.

Steps to Clear Error 602

As of Monday, January 13, Philips distributed to customers a Customer Information Letter with detailed and validated repair instructions for resolving the above-indicated issue. The repair does not require specialized tools and can be performed in fewer than 15 minutes per recorder.

Customers have the option of repairing their recorders themselves or sending them to Philips' bench repair. To support requests for bench repair, Philips has expanded its capacity to perform those repairs. Instructions for the Bench Repair Program are attached. If you plan to use this program, please contact our Customer Care Solution Center at (800) 722-9377 (select Option #1) to obtain proper return-to-bench authorization documentation and no-charge shipping labels.

Warranty Extension and On-Site Repair Consideration

Philips is implementing the following two programs for the benefit of customers who own affected DigiTrak XT Holter Recorders that did experience the "Error: 602" message and therefore required repair:

- Warranty Extension Program
- On-Site Repair Consideration Program

Warranty Extension Program. For such repaired units ("*Repaired Units*"), Philips is providing an extended, post-repair warranty. Specifically, each Repaired Unit will receive either

- (1) a new warranty extended through January 31, 2021, or
- (2) an extension of the unit's existing warranty for an additional six months, whichever time period is longer.

The detailed terms of the warranty are described in the attached Warranty Extension Program document. This warranty program is available to eligible U.S. customers who provide Philips with the required Repair Completion Form by April 30, 2020.

On-Site Repair Consideration Program. Separate and in addition to the Warranty Extension Program, eligible U.S. customers who perform their own on-site repair of recorders, and provide Philips with the required repair completion documentation, will receive \$15 per recorder as consideration for repair expenses incurred. Eligible customers can request this payment by providing Philips with the required Repair Completion Form by April 30, 2020.



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Repair Completion Form

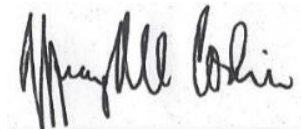
Eligible customers can request a customized Repair Completion Form (RCF) by sending an email to holter_1@philips.com (holter underscore 1). Please provide the following information in your request:

- Subject line: "RCF:" followed by your facility name
- Email content:
 - Contact name, title, phone number
 - Facility name and address
 - Serial number for one DigiTrak XT recorder repaired

You will receive the customized RCF via return email for confirmation, additional required information, and signature. Instructions will be provided for return of the RCF to Philips.

Again, Philips sincerely apologizes for the inconvenience this situation has caused. If you have questions regarding this issue or the repair of your recorders, please contact the Customer Care Solution Center at (800) 722-9377, Option #1.

Sincerely,



Jeffrey M. Corliss
Philips Healthcare
Product Management
General and Specialty Care – Diagnostic Cardiology Solutions

Attachments: Philips 860322 DigiTrak XT Holter Recorder Error 602 Bench Repair Program (United States)
Philips 860322 DigiTrak XT Holter Recorder Warranty Extension Program (United States)



UPDATE: Philips 860322 DigiTrak XT Holter Recorder – Warranty Extension and On-Site Repair Consideration
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Attachment

Philips 860322 DigiTrak XT Holter Recorder Error 602 Bench Repair Program (United States)

These instructions and forms apply only to Philips 860322 DigiTrak (“DTXT”) Holter Recorders that exhibit “Error 602.” **Do not use this form for other recorder repairs.**

CUSTOMER RESPONSIBILITY

Philips Healthcare requires a completed, pre-authorized DigiTrak XT Holter Recorder RMA Form and the Error 602 DTXT recorders to be shipped to the Philips Holter Repair Center. The Error 602 DTXT recorders listed on the RMA Form will be shipped and repaired free of charge.

INSTRUCTIONS

1. Use the DigiTrak XT Holter Recorder RMA Form (available from the Customer Care Solutions Center). It can be edited as a document or printed and filled out by hand. Each RMA Form can accept up to 25 recorders. For additional recorders, please print additional forms as needed.
2. For each Error 602 DTXT:
 - a. Select the recorder type, 24-hour, 48-hour, 4-day, or 7-day.
 - b. Enter the serial number.
Note that invalid serial numbers will cause delay in the repair.
3. Contact the Philips Customer Care Solutions Center. The CCSC can be reached at 1-800-722-9377, Option #1.
 - a. Enter the case number.
Note that an invalid case number will cause delay in the repair.
 - b. The CCSC will also supply a pre-paid shipping label to the Philips Holter Repair Center.
4. Enter all customer information to ensure the repaired units are returned to the proper location after repair.
5. Sign the RMA Form to acknowledge acceptance of the Terms and Conditions (below).
6. Keep a copy of the completed RMA Form for your records.
7. Package the serialized Error 602 DTXT recorders with NO CABLE, NO BATTERIES, and NO DOCKING STATION. The serialized recorders (up to 25 per box) must match the RMA Form.
Note that the DTXT recorders must be clean and free of any biological hazards, in accordance with the Transport Regulations. DTXT units that do not appear to meet such requirements will not be serviced and will be returned.
8. Include a signed copy of the RMA Form in the package.
9. Apply the pre-paid shipping label to the package and send to:
Philips Holter Repair Center, 1285 Corporate Center Drive, Suite 150, Eagan, MN 55121 Attention: DTXT Repair

TERMS AND CONDITIONS

1. The customer is responsible for ensuring the DTXT is clean and free of any biological hazards, in accordance with the Transport Regulations. *DTXT units that do not appear to meet such requirements will not be serviced and will be returned.*
2. Philips will provide a pre-paid shipping label and will provide return shipping.
3. The customer is responsible for ensuring that the device is properly packaged and shipped to the Philips Holter Repair Center. Philips Healthcare is not responsible for any lost or damaged shipments made to our facilities. Any device with suspected shipment damage will be subject to our Damaged Shipment Process. Philips will provide a pre-paid shipping label to the Philips Holter Repair Center, but will not accept COD (charge on delivery) shipments.
4. The DigiTrak XT Holter Recorder RMA Form is for US end user customers only.
5. Philips reserves the right to amend or change these terms and conditions at any time.



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Philips 860322 DigiTrak XT Holter Recorder Warranty Extension Program (United States)

The Warranty Extension described in this letter and in the document below is only for United States owners of eligible, affected Philips 860322 DigiTrak XT Holter Recorders. Any similar such program that may be offered in jurisdictions other than the United States will be offered on terms and conditions specific to that program and that program's jurisdiction.

Warranty Extension Program (United States)	
Eligible Units	All Philips 860322 DigiTrak XT Holter Recorders (" Recorders "): <ul style="list-style-type: none"> that experienced the Error 602 message* and therefore require repair and for which the repair completion documentation required by Philips is received by Philips on or prior to April 30, 2020.
Warranty Terms	The terms and conditions (<i>including all exclusions and restrictions</i>) of the new, extended warranty (<i>except for its time period</i>) are the same as the original, Philips manufacturer's warranty given on the Recorder at the time of its original purchase.
Extended Warranty Period	<ul style="list-style-type: none"> For Eligible Units whose original, purchase warranty expired or will expire on or before July 31, 2020: The new warranty shall: <ul style="list-style-type: none"> Commence upon the "Repair Date," and Expire at 11:59:59 E.T., January 31, 2021. For Eligible Units whose original, purchase warranty will expire after July 31, 2020: The extended warranty shall: <ul style="list-style-type: none"> Commence immediately upon expiration of such original purchase warranty, and Expire at 11:59:59 E.T. of the 180th day thereafter
What is the "Repair Date"?	<ul style="list-style-type: none"> If customer repairs the Recorder: the date Philips receives from customer of the Recorder's repair documentation, including identification of the owner's institution/facility name, date of Recorder repair, service tag number, and serial number. If Philips repairs the Recorder: the date upon which Philips returns the repaired Recorder to customer.
What repair completion documentation must I provide?	The new or extended warranty will not become effective unless and until Philips receives, by April 30, 2020, the required documentation showing completion of the repair. (For repairs performed by Philips, the customer will not need to send such documentation; Philips will retain its own records effective from the date Philips returns the repaired unit to Customer.)

* If Philips receives a recorder for repair that does not exhibit the Error 602 message, but instead requires repair for some other reason, Philips will notify the customer. Any such recorder will not be eligible for this new or extended warranty program. Nonetheless, normal repair options for the customer shall apply, or the customer can choose to have the recorder returned without repair.

