

Customer Information Letter
Medical Device Correction
860306 Philips PageWriter TC30 Cardiograph
Blank I/O Module

Dear Customer,

Philips has detected a problem with your 860306, PageWriter TC30 Cardiographs, that, if it were to occur, could potentially affect the performance of the device.

This Customer Information Letter is intended to inform you about:

- what the problem is and under what circumstances it can occur.
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem.

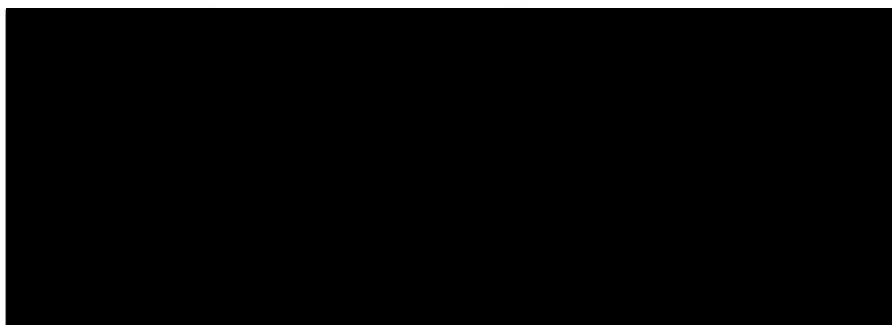
Philips has issued a correction to a manufacturing assembly problem for the 860306 Philips TC30 Cardiograph. Three additional non-functional ground springs on the Blank I/O module could become loose potentially leading to an internal short that could cause the cardiograph to stop working. As of today, we have not received any reports of these additional non-functional ground springs affecting the performance of the device.

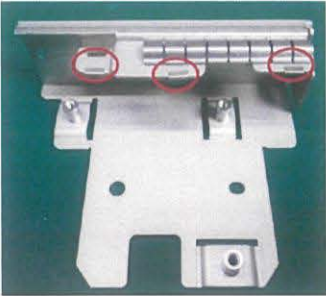
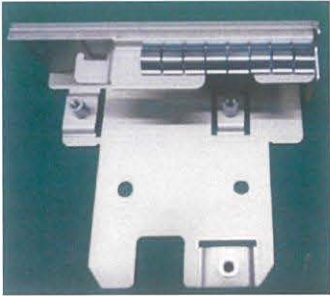

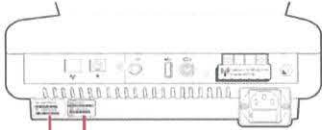


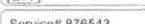

Please refer to the following pages, which provide information on how to identify affected devices and instructions for actions to be taken. Follow the "Action to be taken by Customer/User" section of the notice.

This notice has been reported to the appropriate Regulatory Agency.

Your satisfaction with Philips' products and with our response to this issue is very important to us. Please contact your local Philips representative <Philips representative contact details to be completed by the KM / country> with questions or concerns about this correction.

Sincerely,



<p>AFFECTED PRODUCTS</p>	<p>The affected products are the 860306, Philips PageWriter TC30 cardiographs, with serial numbers: CN11731422 and CN11731453.</p>
<p>PROBLEM DESCRIPTION</p>	<p>A manufacturing assembly problem has been detected on the 860306 Philips TC30 Cardiograph, where three additional non-functional ground springs on the Blank I/O module could become loose potentially leading to an internal short that could cause the cardiograph to stop working.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>Incorrect Assembly</p>  </div> <div style="text-align: center;"> <p>Correct Assembly</p>  </div> </div>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>You can determine whether your device is affected by identifying the Product number (REF) and serial number on the back of the 860306, Philips TC30 Cardiograph.</p> <div style="text-align: center;">  </div> <div style="text-align: center; margin-top: 20px;">  <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;"> <p>REF 876543  SN US80900000  OPT</p> <p>Service# 876543  SN US80900000 </p> </div> </div>
<p>ADVICE ON ACTIONS BY CUSTOMER / USER</p>	<p>Upon receipt of this notification, promptly locate your affected device.</p>

ADVICE ON ACTIONS BY CUSTOMER / USER	Upon receipt of this notification, promptly locate your affected device.
ACTIONS PLANNED BY PHILIPS	Philips has issued a correction, free of charge. You will be contacted by a Philips representative to schedule an appointment to perform the removal of the additional non-functional ground springs from your Philips TC30 Cardiograph.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>