

Important Safety Information

Incorrect Printout of screening results may occur with 17 key Echo-Screen Plus devices.

Voluntary Field Update

November 03, 2011

Dear Customer,

The purpose of this letter is to inform you of a firmware bug recently discovered and contained in 17-key Echo-Screen Plus devices that may lead to incorrect printout of screening results in rare instances. If the Navigation Arrows (up and/or down) buttons are pressed prior to pressing the OK button in the printout menu to begin printing, there may be a mismatch of patient and test results on the printed label.

Natus has immediately taken steps to develop a software solution to correct this problem. The new firmware will be available on November 11, 2011. Please contact your local distribution partner for firmware update of your device(s).

Identification of medical devices in question

The print error identified involves the following Echo-Screen products:

- **All** Natus branded 17-key Echo-Screen Plus devices with language code N1 or N2,
- **All** FZ (Fischer-Zoth) branded 17-key Echo-Screen Plus devices with language code F1, F3 or E1

(Please note: 5 key Echo-Screen devices are **not** affected by this firmware issue.)

Description of failure and cause

According to the Echo-Screen instructions for use, the following steps are to be performed for a printout of the results via your label printer, as shown in the examples on the following page:

Step 1: Select "Print Results" from the Main Menu.



Confirm with OK to review the "Patient List".

```

.....MENU.....
Measure
View results
Print results
Transfer/Delete
Quick test
Options
.....OK.....OFF
    
```

Step 2: Select the patient whose results you want to print.



Confirm with OK to proceed to the "Patient Data" menu.

```

.....PATIENT LIST.....
Miller
Smith
Brown
Peters
Ford
Taylor
MENU.....OK.....BACK
    
```

Step 3: Press OK to activate "Print Results".



Resulting printout:

```

.....PATIENT DATA.....
Print menu

1234
Brown
Jack
01.01.2000    IN-Pat.
MENU.....OK.....BACK
    
```

```

echo-screen TDA +
1234
Brown
Jack
01.01.2000    IN-Pat.
-----
TEDAE Results
17.10 18:07    R: REFER
                L: -
Comment:
    
```

Attention,

If the Navigation Arrow buttons are pressed after having performed Step 2 and before pressing OK (Step 3), **An incorrect printout of results may occur!**

The results of another patient, as shown on the example to the right may incorrectly be attached to the selected patient name and printed. In this example, The Patient selected is named Brown, but the RESULTS label shows results from another patient.

Printout of incorrect results:

```

echo-screen TDA +
1234
Brown
Jack
01.01.2000    IN-Pat.
-----
TEDAE Results
17.10 18:06    R: PASS
                L: -
Comment:
    
```

Please note:

The screening data stored on the Echo-Screen is correctly associated with the proper patient. If the data is transferred from the device to a data management system (such as EchoLink), there is no problem. It will attach the correct screening result to the correct patient

This issue **only** occurs when labels are printed and the navigation arrows are pressed while that screen is displayed. Only the data printed on the label is affected.

Measures to be taken by user:

Until the new firmware is released and installed on your Echo-Screen, the users at your facility should be made aware of this issue and cautioned to avoid pressing the arrow keys when printing. We recommend that they also perform an extra check of the printed label against the result displayed on the screen to ensure that they match.

Disclosure of this safety information:

Please inform all of your Echo-Screen users/operators or further relevant individuals in your organization of this important safety information. If you have sold or otherwise transferred your Echo-Screen to a third party, please provide the name and contact information for this third party to Natus.

Natus Europe sincerely apologizes for any inconvenience. Please understand that this notification is part of our commitment to providing only the highest quality products to our customers and their patients.

Thank you in advance for your understanding and cooperation.

Respectfully,

Natus Europe GmbH



Service Hearing
Natus Europe GmbH



Quality Manager
Natus Europe GmbH