
To whom it may concern

Your ref.:

Our ref.: VB/QA

Date: 2007-Nov 29

Re. : Advisory Notice regarding 8814 Transducer

Dear Customer,

B-K Medical has identified a problem with some of our 8814 transducers.

The problem is a glued joint between the two parts of the housing. This joint may not have been properly processed in our manufacturing and it has been observed to open after a period of use.

We cannot exclude that your 8814 transducer could have this potential defect. This could affect the electrical safety and the sterilization of the transducer.

B-K Medical therefore recommends **not** using the transducer until it has been inspected by a B-K Medical representative.

If you have an urgent need for the transducer in the period between now and the inspection, you may use the following workaround:

1. Make sure, that no groove has appeared between the black part and the light green part of the housing
2. Use a sterile cover

B-K Medical will make every effort to find a solution for repair or exchange of transducers. Our field representative has been asked to assist the best possible.

We apologize for the inconvenience this may cause you, but we hope for your understanding and cooperation to avoid any risk to patients.

Sincerely
B-K Medical