Dear Customer,

This is a survey of Bluepoint MEDICAL, Germany, as part of Post Market Surveillance activities.

If you are a distributor, please send this survey to your customers and supply us with their feedback.

Thank you for taking time to fill out this survey! Your independent assessment and much appreciated comments support us during our continuous improvement of our devices to your benefit.

This survey is for the product family: Medical Breathalyzer

Product names: _____

1. Product Functions

☐ Excellent	Product fulfills the expected functions; no issues occurred during use of the product
☐ Good	Product fulfills the expected functions; no issues occurred within the first 2 years of use
☐ Fair	Product fulfills the expected functions; issues occurred within the first 2 years of use (less than 3%)
☐ Poor	Product does not fulfill the expected functions; issues occurred within the first 2years of use (less than 30%)
☐ Very poor	Product does not fulfill the expected functions; issues occurred within the first 2years of use (less than 50%)
List issues and comments:	

2. Label and Instructions for Use (IFU)

☐ Excellent	All product questions are answered by the IFU and label within short search time.
☐ Good	All product questions are answered by the IFU and label within moderate searchtime.
☐ Fair	Basic product questions are answered by the IFU and label.
☐ Poor	Difficult to understand IFU and label available.
☐ Very poor	No IFU is available, labels are not readable.
List issues and comments:	

3. Product Packaging

☐ Excellent	No damage to packaging or product during delivery. Packaging is easy to removeand to dispose.
☐ Good	No damage to packaging or product during delivery.
☐ Fair	Minor damage to packaging during delivery, but no damage to product.
☐ Poor	Moderate damages to product and package during delivery.
☐ Very poor	Major damages to product and package during delivery.
List issues and comments:	

4. Did any serious or non-serious incidents or any undesirable side-effects occur?

☐ **No** ☐ **Yes**, undesirable side-effects, non-serious or serious incidents occurred

Please list incidents or undesirable side-effects:

5. Did you have any issues using the product?

☐ **No** ☐ **Yes**, the product was not always easy to use/ operate

Please describe the issues in connection with the use/ operation of the product:

Name of Company Date Name, Position Signature

Thank you for your time to fill out this survey!

Please send the filled out survey form back either by:

e-mail: info@bluepoint-medical.com ; ***fax:*** +49-38823-5488-29

mail: bluepoint medical GmbH & Co KG, An der Trave 15, 23923 Selmsdorf, Germany

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This section is to be filled out by Bluepoint medical ONLY:

Assessment of the returned record

☐ The information is incomplete.
☐ The product related Feedback is very bad.
☐ Question 4 about incidents has been answered with “yes”.

Actions to be taken

☐ The information will be stored in the folder \\QMS/57_PMS.

☐ The customer needs to be contacted *immediately*, because:_____

☐ The customer needs to be contacted, because:_____

☐ Information will be sent to relevant PLVs.

☐ Information will be sent to relevant PLVs with comment to contact the customer.

☐ other:_____

Date (YYYY-MM-DD) Signature (QM Representative)

Space for additional comments:
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