

	Quality Management System	Revision 0
External Document	Bluepoint MEDICAL PMS-Customer Survey	Page 1 of 3

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: SpO₂ Sensors

Product names: _____

1. Product Functions

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

2. Label and Instructions for Use (IFU)

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

	Quality Management System	Revision 0
External Document	Bluepoint MEDICAL PMS-Customer Survey	Page 3 of 3

~~~~~  
*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: