Vital Signs Monitoring System IFU Addendum - IQ Messenger

REF 1200

FastFocus

Contents

1   General information

1.1   About the system(s)

This addendum to the instructions for use (IFU) is written and compiled in accordance with the European Medical Device Regulation (EU) 2017/745 and harmonized standards. This addendum provides additional information and updates on the operation of the FastFocus Vital Signs Monitoring System (hereinafter referred to as "FastFocus System" or "FastFocus Device") when integrated with "IQ Messenger medical SmartApp" (hereinafter referred to as "IQ Messenger"). The addendum helps you with the operation and the maintenance of the system and its modules in a safe and responsible manner.

Always read the *FastFocus' Instructions for Use 1200-051* (hereinafter referred to as *main IFU*) and all precautions and specifications before reading this addendum. This addendum can only be read in conjunction with the *Main IFU* and *IQ Messenger Medical IFU (rev. 13.1.0 and above)*.

*This IFU can be found on the IQ Messenger website.

Adhere strictly to the *main IFU,* and the accompanying *addendum* and *IQ Messenger Medical IFU* when carrying out operating procedures, following the specified sequence. Keep these documents close to the device. Failure to comply with these documents may cause measuring abnormality, equipment damage and human injury.

Online versions of related FastFocus documents can be found on FastFocus website:
https://fastfocus.nl/documentatie/

1.2   Intended Purpose of the FastFocus system in case of IQ Messenger integration

1.2.1   Intended Purpose of the device

If the FastFocus System is integrated with IQ Messenger, the intended purpose of the FastFocus' Vital Signs Monitoring System remains unchanged.

For a complete description of the intended purpose statement of the FastFocus System refer to the *main IFU section 1.2.*

A description of the intended purpose statement of IQ Messenger can be found in the *IQ Messenger Medical IFU.*

1.2.2   Intended Environment

The following is a repetition of the description of the Intended Environment, including cases where the IQ Messenger integration is involved:

The FastFocus' Vital Signs Monitoring System is intended for the use in professional healthcare facility environments. The most likely locations for patients to be monitored are general medical/surgical wards, general hospital, and alternate care environments.

⚠️ **Warning!**
The FastFocus' Vital Signs Monitoring System is not intended for use for continuous surveillance of vital physiological processes in anaesthesia, intensive care, or emergency care, and to monitor vital physiological parameters where the nature of variations is such that it could result in immediate danger to the patient. The device is not intended as a stand-alone diagnostic monitor, but the data may be applicable for use in diagnosis.

1.3 Contact

1.3.1 FastFocus
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1.4 Warning, caution and note

Warning!
A "warning" tells you that there is a risk of personal injury or death.

Caution!
A "caution" tells you that:
- there is a risk of damage to the system, and/or
- there is a risk of damage to other equipment.

Note!
A "note" gives more information.

1.5 Disclaimer
The manufacturer reserves all rights. No part of this document may be reproduced or published, electronically, mechanically, in print, photographic print, on microfilm or by any other means whatsoever, without the explicit consent of FastFocus B.V.

The content of this document has been compiled with the greatest possible care and this information can be regarded as reliable. Nevertheless, the manufacturer reserves the right to make alterations and improvements to the system. These may not yet have been described in the instructions. The manufacturer cannot be held liable for the outcome of the patients' treatment.

This document contains proprietary information that may not be disclosed to third parties. This document may not be used without the explicit written consent of the manufacturer.

These instructions are intended for personnel authorized to work with and/or service the medical device described in this manual.

Warning!

- Although the FastFocus system is compatible with IQ-Messenger Smart App and validated by both parties, FastFocus cannot be held responsible for the arrival and correct display of notifications in IQ-Messenger.
- The device is not intended for use for continuous surveillance of vital physiological processes in anaesthesia, intensive care, or emergency care, and to monitor vital physiological parameters where the nature of variations is such that it could result in immediate danger to the patient.

Note!

- The FastFocus messages to IQ-Messenger App are notifications, not alarms.

2   Safety precautions

First read the warnings, cautions, and notes in the FastFocus *main IFU chapter 2*. Additional warnings, and notes regarding FastFocus integration with IQ Messenger are given below:

2.1   Warnings

Warning!
- Always configure the label to the patient's correct bed number.
- The label must be linked to a different bed number if a patient is moved to a different bed number.
- Ensure that the IQ Messenger connection status (dot in upper right corner of the FastFocus user interface) shows green. If it shows "orange" the connection needs to be re-established.
- IQ Messenger notifications are not a substitute for regular patient health checks.
- IQ Messenger notifications may be received earlier or later than the FastFocus dashboard updates.
- Modification of this equipment (i.e., FastFocus System and/or IQ Messenger) is not permitted.
- Do not modify this equipment (i.e., FastFocus System and/or IQ Messenger) without the manufacturer's authorization.
- If this equipment is modified, appropriate inspection and testing must be performed to ensure continued safe use of the equipment.
- Connect only items that have been specified as part of the FastFocus System or that have been specified as being compatible with the FastFocus System i.e., IQ Messenger.

2.2   Notes

Note!
- To protect personal information (according to GDPR), it is recommended not to use the patient's name. If the system (i.e. FastFocus System or IQ Messenger) is left unattended and unlocked, unauthorized people could access privacy sensitive data.

3 Description

3.1 Vital Signs Monitoring System

The main IFU Chapter 3 Description contains a description of the FastFocus System and its elements.
A description of the IQ Messenger can be found in *Instructions For Use IQ Messenger Medical (rev. rev. 13.1.0 and above).*

3.2 IQ-Messenger Medical

The FastFocus system is compatible with the following IQ Messenger application and cannot be used with other SmartApps than:
IQ Smart App Medical
Version 13.1.0 and above

Reference documentation on FastFocus – IQ Messenger integration:
IQ Messenger API_v1.0
RestAPI_v2.0

3.3 System boundaries of FastFocus system and IQ Messenger

Figure 1 provides a schematic overview of the FastFocus and IQ Messenger system boundaries. FastFocus Notifications can be send to the customer's IQ Messenger REST API, whereafter the IQ Messenger service could forward the notification to the IQ Messenger medical SmartApp.
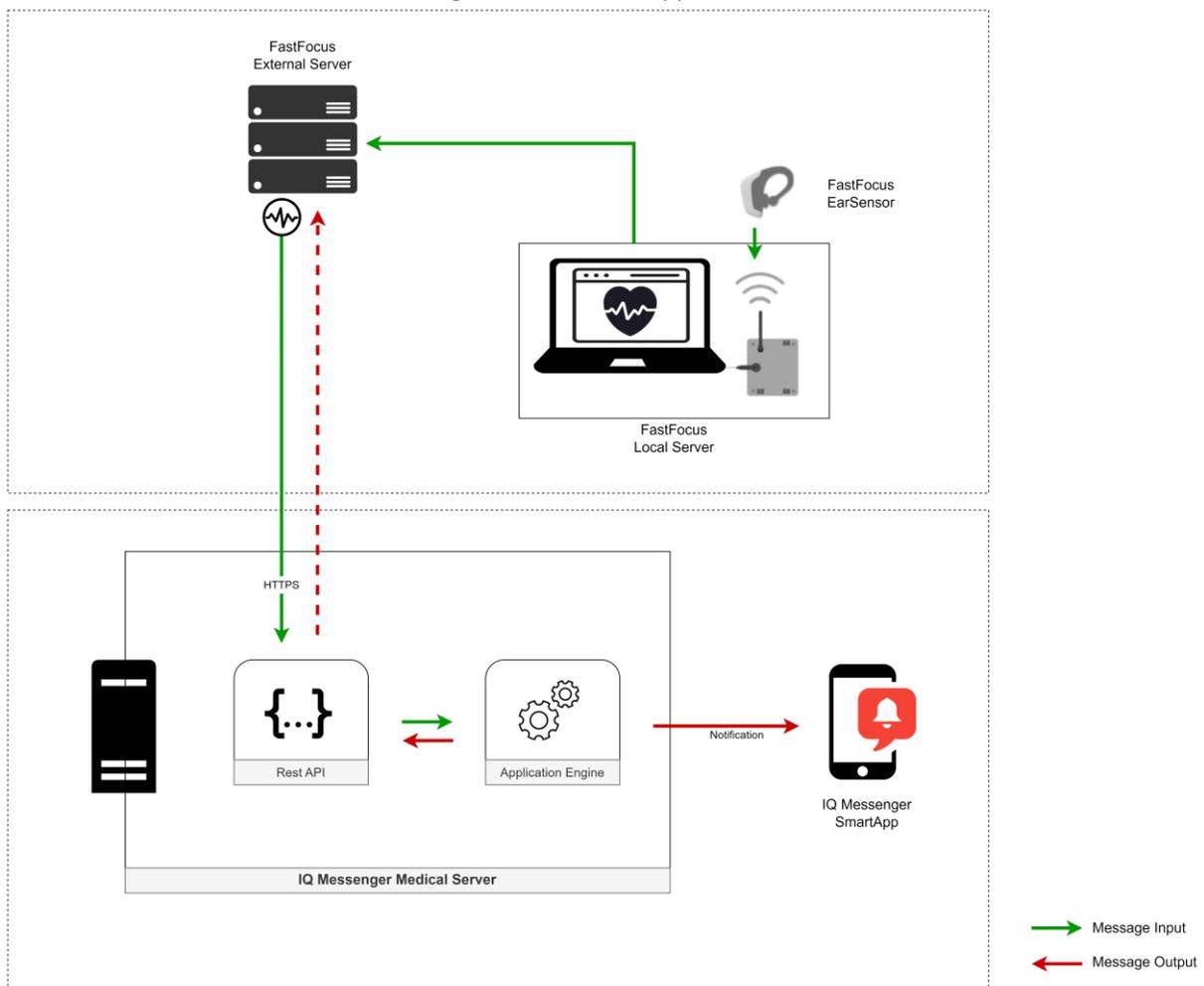
Figure 1: Systematic display of FastFocus and IQ Messenger system boundaries.

4 Explanation of FastFocus' notifications in IQ Messenger

4.1 Type of notifications

The FastFocus device is able send notifications to the IQ Messenger with the following vital sign information and technical information:

Type of vital sign and technical notifications	Priority level	Explanation
Vital Signs notifications:		
Multi sign notification (default)	High	Notification on multiple vital signs; combination of 2 or more vital signs notifications.
Multi sign notification (high)	High	Notification on multiple vital signs; combination of 2 or more vital signs notifications.
Multi sign notification (medium)	Medium	Notification on multiple vital signs; combination of 2 or more vital signs notifications.
Multi sign notification (low)	Low	Notification on multiple vital signs; combination of 2 or more vital signs notifications.
SpO2 notification	High	Notification on single parameter oxygen saturation.
RR notification	High	Notification on single parameter respiratory rate.
PR notification	High	Notification on single parameter pulse rate.
Posture notification	Low	Notification on posture and/or motion intensity.
Technical notifications:		
Battery Low	Low	Notification stating the battery level is low.
Battery Empty	High	Notification stating the battery level is empty.
Wrong Sensor Placement	Low	Notification stating the EarSensor needs repositioning.
No Tissue Found	Low	Notification stating the EarSensor did not detect human tissue.
Sensor No Communication	Low	Notification stating there has been no communication between the EarSensor and the Server. E.g. out of range.
System Anomaly Detected	High	Notification stating there is a technical issue detected.

Tabel 1: List of vital signs and technical notifications FastFocus is able to send to IQ Messenger.

4.2 Examples of FastFocus' notifications in IQ Messenger

4.2.1 Examples of a FastFocus vital signs notification

An example of a vital signs notification in IQ Messenger is shown in Figure 2, in this case a multi-sign notification.
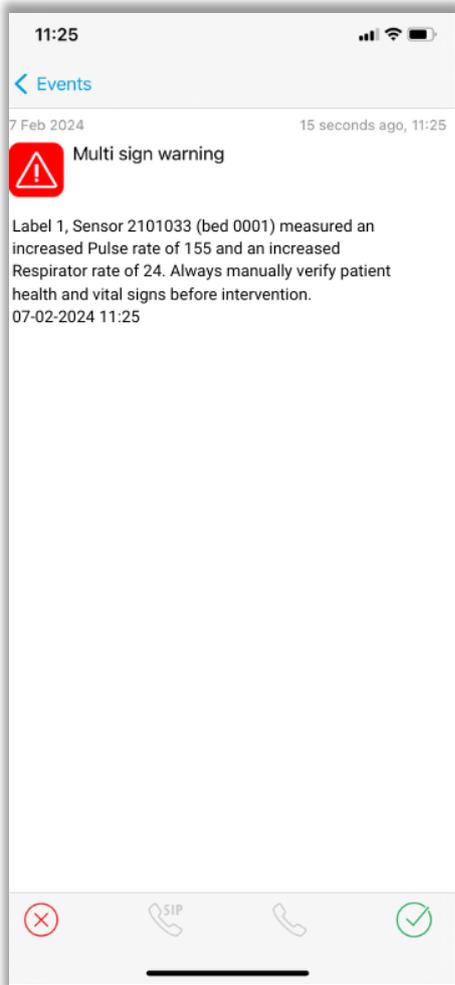
Figure 2: Example of a FastFocus' Multi Sign Notification in IQ Messenger.

An explanation of the text components of the Multi Sign notification in Figure 2 is given in Table 2.

Text components	Explanation
Multi Sign Warning	Type of the notification (refer to *table 1* in this addendum)
Label 1	Label name the healtcare professional gave to identify the patient in FastFocus user interface.
Sensor 2101033	Serial number of the EarSensor. In the FastFocus user interface named as 'device'.
(bed 0001)	Location identification. In FastFocus user interface named as 'bed'.
measured an increased Pulse rate of 155 and an increased Respiratory Rate of 24.	Automatic message containing measured values.
Always manually verify patient health and vital signs before intervention.	Automatic accompanying message.
07-02-2024 11:25	Date and time. Moment when notification is sent to IQ Messenger (timestamp).

Table 2: Explanation of the Multi Sign notification in IQ Messenger (Figure 2).

Another example of a vital signs notification, in this example a vital signs notification is shown in Figure 3.
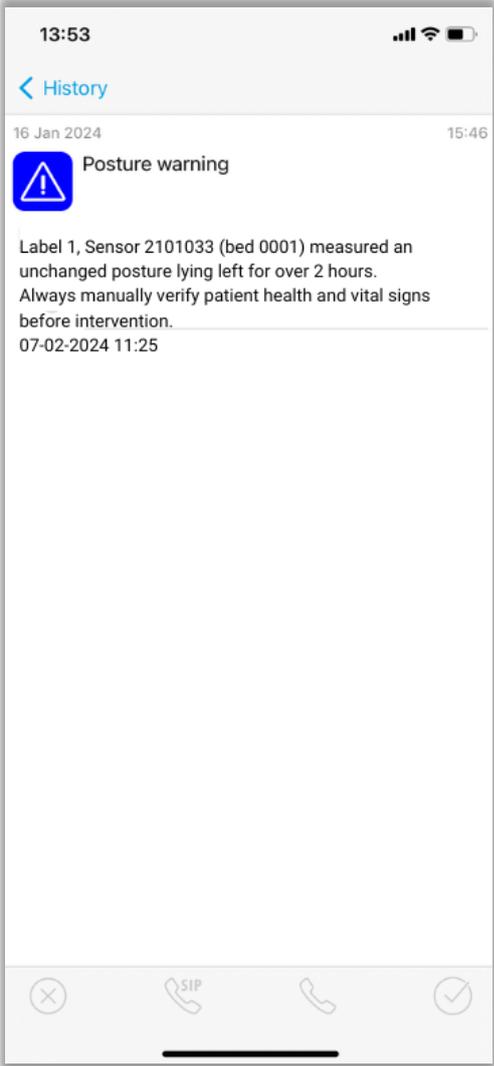
Figure 3: Example of a posture notification in IQ Messenger.

An explanation of the text components of the posture notification is given in Table 3.

Text components	Explanation
Posture Warning	Type of the notification (refer to *Table 1* in this addendum)
Label 1	Label name the healtcare professional gave to identify the patient in FastFocus user interface.
Sensor 2101033	Serial number of the EarSensor. In the FastFocus user interface named as 'device'.
(bed 0001)	Location identification. In FastFocus user interface named as 'bed'.
measured an unchanged posture lying left for over two hours.	Automatic message containing posture information.
Always manually verify patient health and vital signs before intervention.	Automatic accompanying message.
07-02-2024 11:25	Date and time. Moment when notification is sent to IQ Messenger (timestamp).

Table 3: Explanation of the example notification in Figure 3.

4.2.2 Example of technical notifications

An example of a technical notification, in this example a battery status notification, is shown in Figure 4.

Figure 4: Example of a FastFocus battery status notification in IQ Messenger.

An explanation of the text components of the battery status notification is given in Table 4.

Text components	Explanation
Battery empty	Type of the notification (refer to *Table 1* in this addendum)
Label 1	Label name the healtcare professional gave to identify the patient in FastFocus user interface.
Sensor 2101033	Serial number of the EarSensor. In the FastFocus user interface named as 'device'.
(bed 0001)	Location identification. In FastFocus user interface named as 'bed'.
Battery is empty	Automatic message containing technical notification.
Please change sensor	Automatic accompanying message.
07-02-2024 11:25	Date and time. Moment when notification is sent to IQ Messenger (timestamp).

Table 4: Explanation of the battery status notification in IQ Messenger (Figure 4).

5   Installation

First read the warnings, cautions, and notes in the *main IFU chapter 4 Installation*. Additional warnings regarding FastFocus integration with IQ Messenger are given below:

> **Caution!**
> - Installation and configuration of the server can only be performed by trained and authorized personnel following a work instruction.

5.1   First Installation and configuration of FastFocus' Vital Signs Monitoring System

Refer to the *main IFU chapter 4 Installation*, for the initial installation and configuration of the FastFocus' System. After installation, proceed with section 5.2 of this addendum.

5.2   Installation of FastFocus as a compatible device with IQ Messenger

Contact your IQ Messenger account manager for the latest installation instructions to install FastFocus as a compatible device with the IQ Messenger Medical service. Follow these instructions first. After completing these instructions continue with the section 5.3 of this FastFocus addendum.

5.3   Verification test of the FastFocus as a compatible device with IQ Messenger

A verification test must be performed by FastFocus before use. This is covered during FastFocus' own configuration procedure.

5.4   Installation verification

After installation, verify that the system is installed correctly and functioning properly by following the instructions in the main document *main IFU chapter 5 Verification* and chapter 6 of this addendum.

6   Verification

The instructions for verifying the correct functioning of the FastFocus system and its modules can be found in the *main IFU chapter 5*. Please read this carefully before proceeding with the instructions in the following sections of this addendum.

6.1   IQ Messenger integration

As part of the configuration procedure an employee of FastFocus will send a series of test notifications to IQ Messenger.

6.1.1   Additional functional test for IQ Messenger Integration

Required means
- Server
- IQ Messenger Application

Procedure
1. Turn on the installed Server using the laptop power button located on the top left (refer *main IFU section 6.2*).
2. Login to the Windows environment with your Windows credentials.
3. Login to the FastFocus Server software with your FastFocus credentials.
4. Check if the communication status between FastFocus and IQ Messenger is being displayed (refer to §7.1.1 of this addendum).
5. Create a label and link a bed to that label (refer to §7.1.1 of this addendum).
6. Verify if the label is coupled with bed number in the user interface by looking at the bed name in the dashboard.
7. Change the bed link with the label (refer to §7.1.3 of this addendum)
8. Verify if the label is coupled with the changed bed, by looking at the bed name in the dashboard table and see if it has been changed to the newly selected one.
9. Optionally, perform tests together with an employee of FastFocus during installation procedure to verify if messages are received and shown within the IQ Messenger App. (Note that this might require temporarily setting up a new event rule).
10. Delete the label (refer to §6.2.4 of the *main IFU*).
11. Logout from the Server software and shut down the laptop.

Criteria

If all the above steps could be performed successfully, the IQ Messenger integration passes the test. If one or more steps could not be performed successfully, contact FastFocus for assistance.

7   Operation

First, read chapter 6 of the *main IFU.* Chapter 7 of the addendum (this document) will either replace section(s), paragraph(s) and figure(s) of chapter 6 of the *main IFU* or will be additional due to the IQ Messenger integration.

7.1.1   § "6.2.1 Labels" in the main IFU will be replaced by this paragraph

In the user interface, you can create a label entity to link the EarSensor with the patient. Labels may include the bed number, patient number, or patient name, and are stored in the system database.

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i   **Note!**

- To protect personal information (according to GDPR), it is recommended not to use the patient's name. If the system is left unattended and unlocked, unauthorized people could access privacy sensitive data.

The Labels page displays all user created labels. When IQ Messenger is integrated with the FastFocus system, the Labels page contains one additional column (C) and one additional status indicator (N). See Figure 5.

Figure 5 – Labels Page view.

The following is shown in the columns:
- A.   The label names.
- B.   Location identification 'bed' within the healthcare institution.
- C.   The serial number of the EarSensor added to the label.
- D.   The status of the connection between the EarSensor and the Server.
- E.   Battery level.
- F.   Current posture/activity of the patient.
- G.   Current activity level.
- H.   Pulse rate of the patient; the time of the last measurement is shown right from it.
- I.   Respiratory rate of the patient; the time of the last measurement is shown right from it.
- J.   Blood oxygen level of the patient; the time of the last measurement is shown right from it.
- K.   Information messages.
- L.   Label Edit menu.

The dots above the columns indicate:
- M.   The status of the gateway connection; i.e. the connection between the gateway (also referred to as local server) and the external server.
- N.   The status of the connection between FastFocus system and IQ Messenger.

🟢   Active connection

🟠   Connection is inactive or delayed

In case of an orange status connection between FastFocus and IQ Messenger, refer to §8.1.1. of the chapter Trouble shouting in this addendum.

7.1.2 § "6.2.2 Adding a new label" in the main IFU will be replaced by this paragraph

- Press the plus (+) button icon to create a new Label entity:

- A new popup will appear where you can fill in the label name "Subject 1" and select a "bed" from the drop-down menu (refer to Figure 6):

Figure 6 – Add Label Window.

The newly added label will now be added to the overview. By pressing the three dots in the rightmost column of the label (●●●, column L in Figure 5 of this addendum), the label can be removed if it is no longer needed.

7.1.3 Changing a bed link

Read this paragraph after paragraph "6.2.4 Unlinking and Changing an EarSensor" of the *main IFU*.
When a patient is moved to another bed (location within the healthcare facility) the Label must be linked to this new 'bed'. This can be done by simply pressing the button [Change Bed] (refer to figure 7) located in the Edit menu, by clicking on the three dots in the rightmost column of the label (●●●, column L in Figure 5 of this addendum).
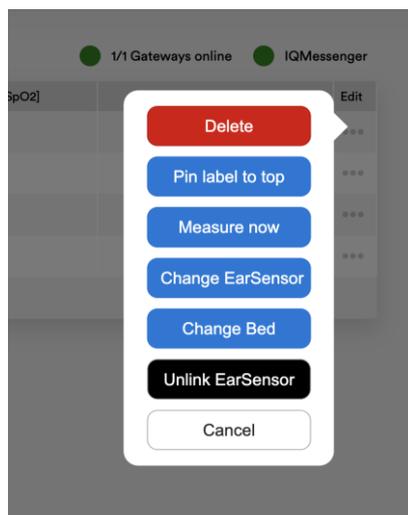
Figure 7 – Edit menu.

The new bed can be selected in the pop-up window (see Figure 8 of this addendum). Once a new bed has been selected, click on the OK button.
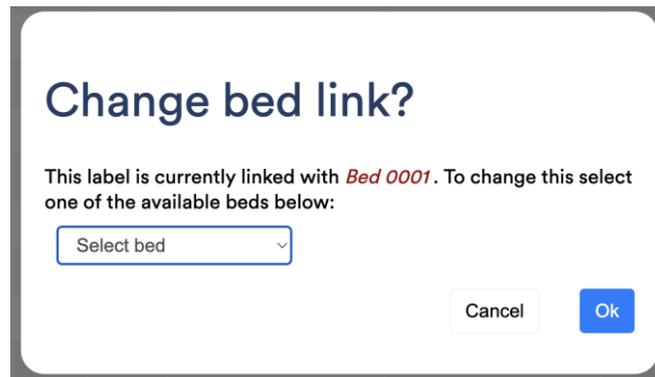
Figure 8 – Change bed link pop-up window.

7.1.4   Confidence level

Figure 9 below replaces Figure 28 of section "6.6 confidence levels" in the *main IFU*.

Figure 9 – Medium confidence levels on (amongst others) respiratory rate, the value "15" is shown grey instead of black.

7.1.5   § "6.8.1. Label Measurement Details" of the main IFU will be replaced by this paragraph

Once a Label entity has been created, a bed has been linked and an EarSensor has been linked, the measurement data is recorded and assigned to a label and bed number in the database. By clicking on the label name on the Label page (overview), the measurement details are displayed (refer to Figure 10 of this addendum).

On top of the screen, it is shown which Label is selected and which EarSensor and bed number is linked to it. The example in Figure 10 shows:
Sensor number: 2101065
Label: Ward D, room 12
Bed number: bed 012
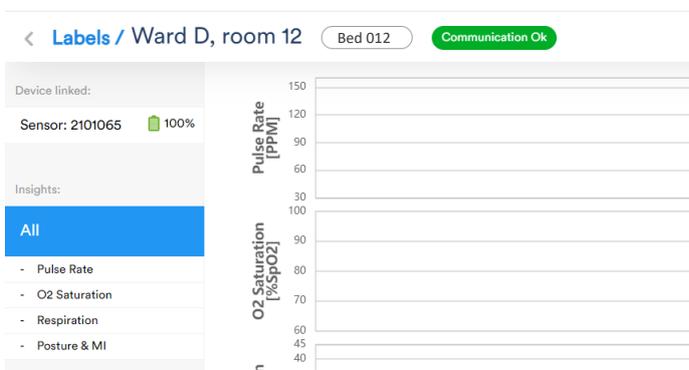
Figure 10 – Measurement details.

Different status indicators can be shown next to the label name. These are:

Communication Ok — The status "Communication Ok" is shown when the linked EarSensor is measuring correctly and the communication to the Server is ok.

No Communication — In case the EarSensor did not communicate with the Server for the last 3 minutes. E.g., out of range or empty battery.

Reposition EarSensor. ⓘ — The EarSensor should be repositioned. The EarSensor is not correctly placed on the ear. Correct measurements cannot be performed.

EarSensor not worn. ⓘ — The EarSensor is not worn. Place the EarSensor on the ear to resume measuring.

EarSensor in Docking Station — The EarSensor is placed in the Docking Station.

Next to the linked EarSensor the battery status is shown together with the battery percentage:

Battery empty. The device needs to be recharged and replaced.

Battery low. It is recommended to replace the EarSensor.

Battery level is ok.

8   Troubleshooting

Chapter 8 of the main IFU summarizes the most common problems you may encounter with the FastFocus Vital Signs Monitoring System. Additional issues related to a FastFocus integration with IQ Messenger can be found in this chapter of the addendum.

8.1   Messages

The Server displays important information about the status of the EarSensors linked to a Label e.g., communication and battery status.

8.1.1   No connection between FastFocus and IQ Messenger

As described in Chapter 7.1.1. of this addendum, the status of the connection between FastFocus and IQ-Messenger is displayed in the user interface in upper right corner above the table.

If the dot is colored orange, the connection is inactive or delayed, please contact FastFocus (see Figure 11). Contact details can be found in chapter 1.3. of this addendum.

Figure 11 – Connection status with IQ messenger is inactive or delayed.

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