Honeywell

Detailed Information on (Product) Failures or (Near) Events

Customer Data

Company*

Salutation

Titel

First name*

Last name*

Street/number*

ZIP*

City*

Phone number*

Product Data

Quantity*

Part number*

Description*

Serial/Lot number*

Invoice number*

Purchase date*

You have rated a (product) failure or a (near) event as safety-relevant.
Please describe the failure or the event in greater detail.

A. General Data

Date of complaint

When and how (kind of communication used) was the person informed that reported the complaint?

Name, function and address of reporting person:

First name

Last name

Function

Street/number

ZIP

City

Was there a formal notification to the competent authority? Yes ☐ No ☐

*mandatory field

B. Patient / User Data

If a patient or user was concerned by the reported event, we ask for the following anonymized data:

Age	Gender	Weight	Special physiological conditions

Participation in a clinical trial

More details

C. Details about the Event

Date of event, descriptions of circumstances

What kind of ambient conditions was the product/medical device being used in?

- [ ] in closed room
- [ ] in open room
- [ ] in an incubator
- [ ] Neon fluorescent tube or other strong light source in the immediate vicinity

If possible, please provide a picture of the area.

How was the EnviteC device or sensor involved in the event?

Country in which the event occurred

If possible, please attach relevant test results and anonymized patient data to this report.

Were other medical devices involved in the event? Yes [ ] No [ ]
If yes, please indicate the following details:

Type	Model	Serial number	More details

When measuring vital parameters: Which type of monitor was used? Please state the following details:

Type	Model	Software version	Serial / Lot number

Which failure message was indicated on the monitor?

If possible, please provide a picture of the monitor with the sensor used.

Has any adapter or extension cable been used? Yes ☐ No ☐
If yes, please state the following details, if available:

Type

More details

Who used/applied the medical device?

Job title | Position | Department

For SpO_2 sensors: How and how often was the sensor repositioned?

For SpO_2 sensors: Did the nurses use the sensor according to EnviteC user instructions? Yes ☐ No ☐

During measurement, were other vital parameters measured at the same time on the same monitor? Yes ☐ No ☐

If yes, which other parameters?

Please indicate the contact person at the final customer/end user with contact details:

First name | Last name | Phone number | E-Mail

Supplemental information

D. Details about the Medical Device

If not yet stated, please provide the following product details:

Product description | Min. or maximum shelf life | Serial/Lot number | Part number

Other descriptive details

The medical product is a: ☐ Disposable product ☐ Reusable product

☐ New product ☐ Reprocessed product

Is the medical device available for analyses? Yes ☐ No ☐

Has the product already been returned to EnviteC? Yes ☐ No ☐

Supplemental information

E. Miscellaneous

If available, please provide copies of communication from/to final customer, end user, operator and/or authorities.

Supplemental information

Please forward the completed document with any attachment to EnviteC-Service@honeywell.com

Your support is highly appreciated!