Medicines & Healthcare products Regulatory Agency

How to submit a Yellow Card report on a diabetes management related medical device

Whilst we appreciate as much detail as possible, **please note that most fields within this form are optional.** All reports are useful, even if you cannot provide all the information requested in the optional fields.

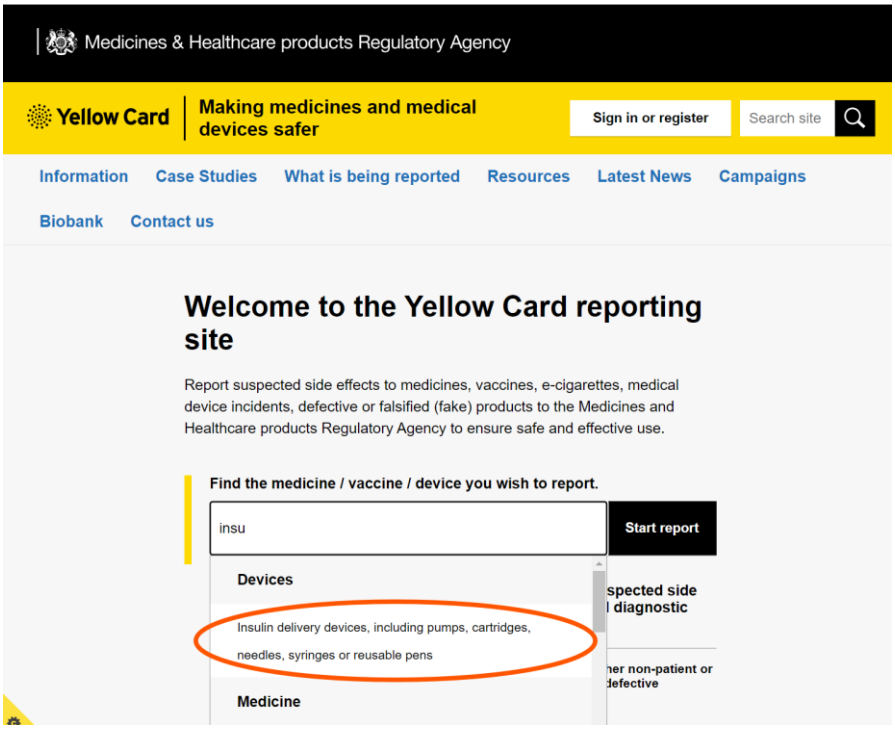
1. Go to www.mhra.gov.uk/yellowcard, or use the Yellow Card app available from the Apple App Store, or Google Play Store.

2. Select the relevant device type. Start typing either:

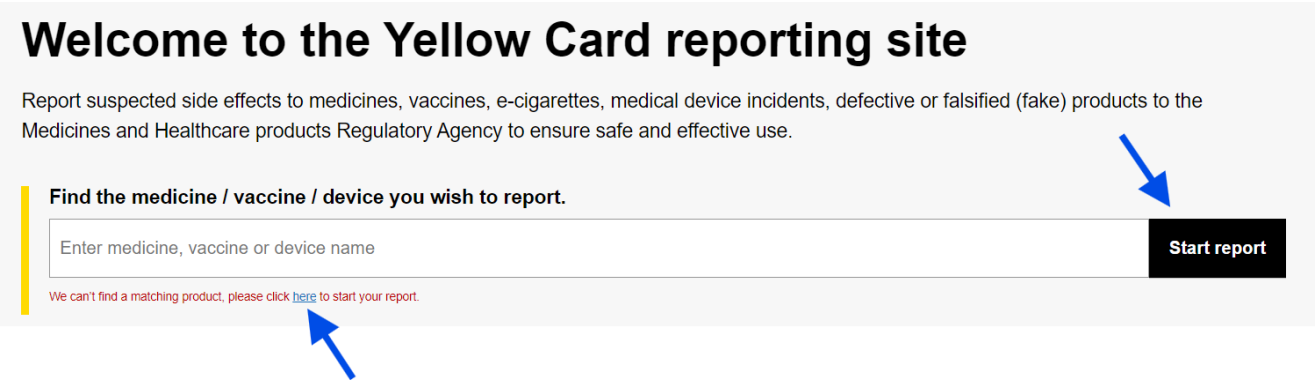
a) Insulin delivery devices, including pumps, cartridges, needles, syringes or reusable pens
or
b) Continuous glucose monitoring

then click on the correct entry as it appears in the list below, and press “Start report”.

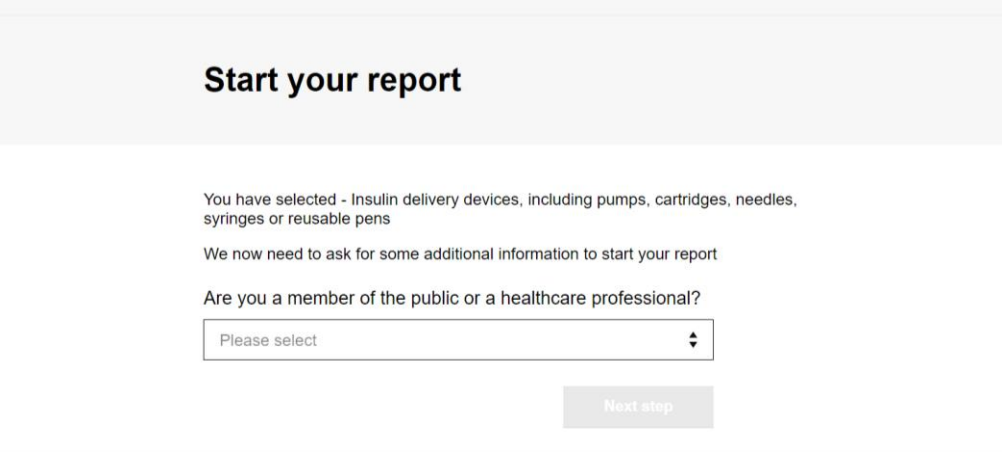
Do not enter the device brand name or manufacturer; you will be asked for this later.



If you are not sure which type of device is involved, leave the field blank, click “Start report” and then click “here” to take you to the form.



3. Confirm whether you are reporting as a member of the public or a healthcare professional. The questions you are asked will depend on your response.



4. Provide information about yourself. This includes details on how we can contact you.

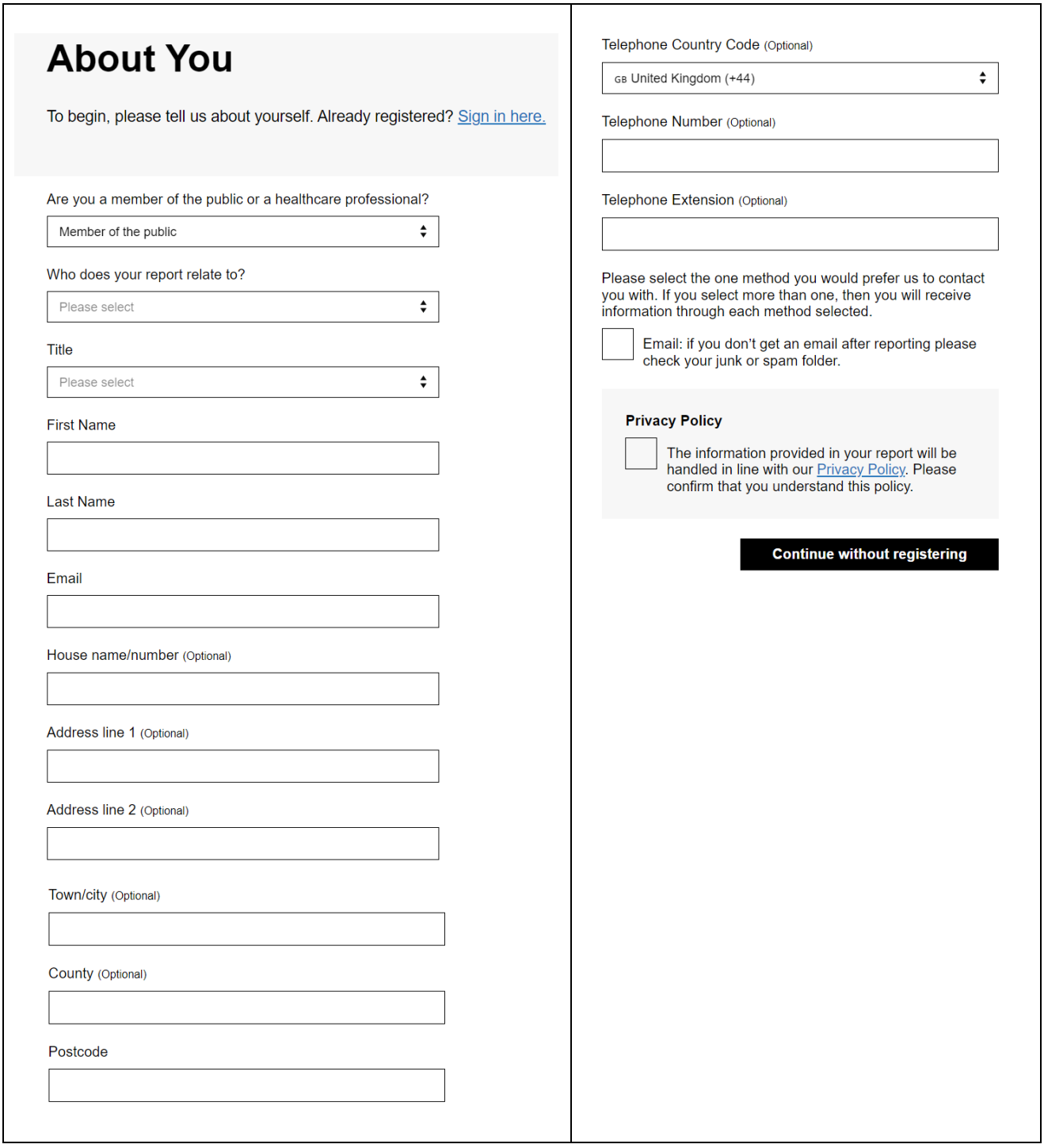
The following fields are mandatory – you will be unable to progress if any are left blank:

- who does your report relate to (you, your child or someone else)
- your title
- your first name
- your last name
- your email address
- your postcode
- confirmation that you have read the Privacy Policy

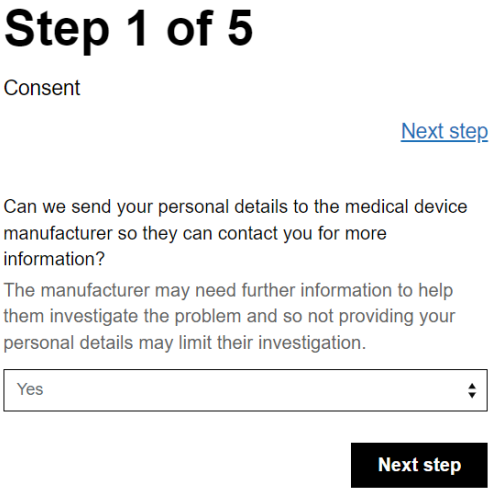
We ask for your name and contact details so that we can get in touch if we need more information to assess the Yellow Card report.

If you would prefer us to contact you via SMS rather than email, you must add your telephone number for the option to become live on the form.

If you do not want us to pass your contact details on to the manufacturer, you can confirm this on the next page in the form.



5. Confirm whether we have your consent to share your contact details with the device manufacturer.



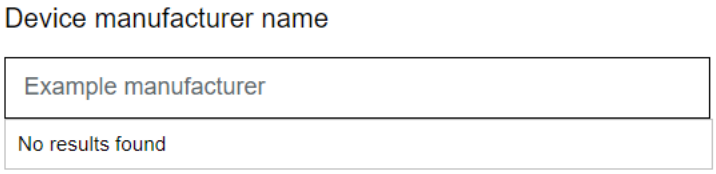
6. Provide details about the product you are concerned about.

The following 2 fields are mandatory; without this information we cannot process your report:

a) Device manufacturer name

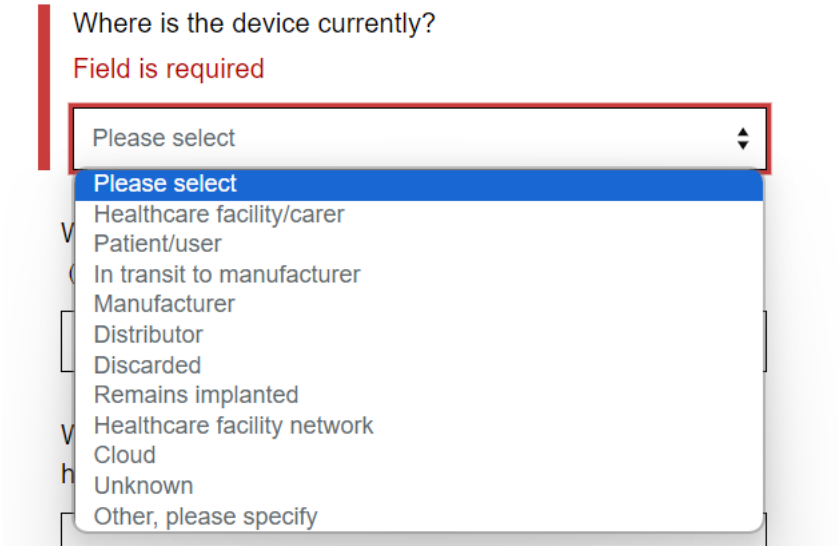
We need this so that we can pass on the details for the manufacturer to investigate. It is the responsibility of the manufacturer to investigate all reported issues. Without this information we cannot process your report.

Do not worry if typing in the manufacturer name brings up the message “no results found”, the information you have typed will be logged.



b) Where is the device currently?

We recommend that all devices involved in issues reported to us are retained as physical examination of the device can form key evidence in a root cause investigation. If you agree to your details being sent to the manufacturer, they will get in contact and request return of the device for investigation. Any guidance on how the device should be returned and how to get a replacement will be provided by the manufacturer.



Although the Yellow Card reporting system will take you through structured pages with only a small number of mandatory questions, we request that you provide as much relevant information as is readily available to reduce the need for follow-up. However, do not delay reporting just because some details are not known. The MHRA or the manufacturer will contact you if additional information is required.

Please provide:

- the device model and/or brand name

Without it, we will be unable to include your report in our signal identification processes.

If possible, please also provide the following information:

- Device serial/batch number
- Software version (if applicable)
- Date of manufacture (if known)

All other questions in this section are optional, but if you have the information, please provide it.

The complete form is shown below; the mandatory fields are highlighted in red and the recommended sections in blue.

Step 2 of 5

Medical Device Information

Previous step Next step

This section will collect information on the device. Please provide as much information as possible

Barcode number (Optional)

Device manufacturer name

Name of device model (Optional)

Brand Name (Optional)

Serial number(s) (Optional)

Lot/batch number(s) (Optional)

Software version (Optional)

Manufactured date, if available (Optional)

YYYY/MM/DD

Year Month Day

YYYY MM DD

Device expiry date (Optional)

YYYY/MM/DD

Year Month Day

YYYY MM DD

If you do not know the exact date for device use, please add estimate dates as known below.

Years (Optional)

Months (Optional)

Days (Optional)

Where is the device currently?

Please select

Who was using the device when the incident occurred? (Optional)

Please select

Where did you get the device? (e.g. online, shop, healthcare facility, please provide details) (Optional)

What marking is on the device? (Optional)

For example, UKCA / CE / CE UKNI

Please select

Previous step **Next step**

7. What went wrong with the device?

In this section, we need you to describe the issue you have identified and choose keywords that best describe the problem to help us group similar reports together. We also ask about the effect (if any) that the problem had on the user and those around them.

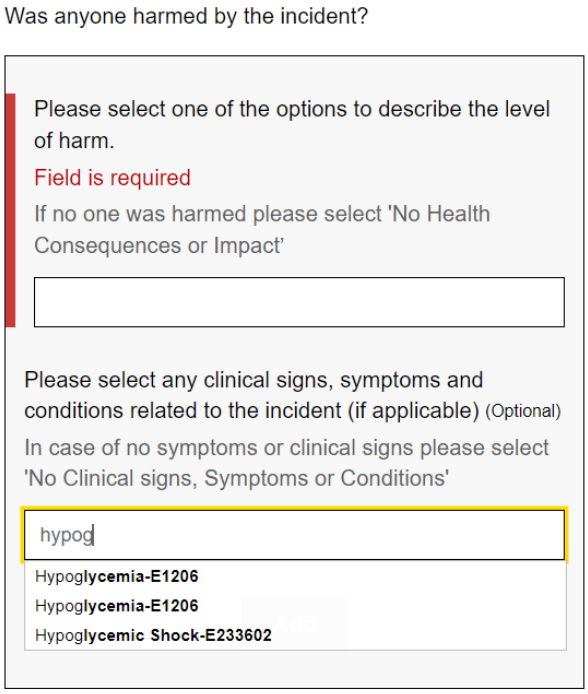
The following 4 fields are mandatory; without this information we cannot process your report:

a) Date incident from. If there was no event or incident, please use the date on which the problem was first identified

b) Date incident to (may be the same day)

c) Was anybody harmed as a result of the problem? Press “Add” to activate the following mandatory fields

Typing into the fields brings up suggested terms. Once complete, click “add". If there are multiple terms that apply, repeat until all information has been provided. This must be completed even if there was no harm experienced as a result of the problem.



i) The first box is for the general type of harm that occurred. Examples include no health consequences or impact, underdose, overdose, missed dose and hospitalisation.

ii) The second box is for the impact of the harm on the device user, i.e. clinical signs and symptoms. Examples include hypoglycaemia (low blood sugar), hyperglycaemia (high blood sugar), diabetic ketoacidosis, seizure, coma, and reaction.

We have provided a list of common terms associated with reports involving diabetes management equipment. The code numbers (e.g. E1206) are for our internal use only, please use the text to make your choice. If the same term appears twice, it doesn't matter which version you choose.

Note: The MHRA use the adverse event terminology coding system developed by the International Medical Device Regulators Forum. This means that you may see non-UK English spellings such as hypoglycemia within the list of terms to choose from.

d) Description of your concerns about the device, including faults with the device and any harm or near misses experienced. In this section, please include the following (if possible):

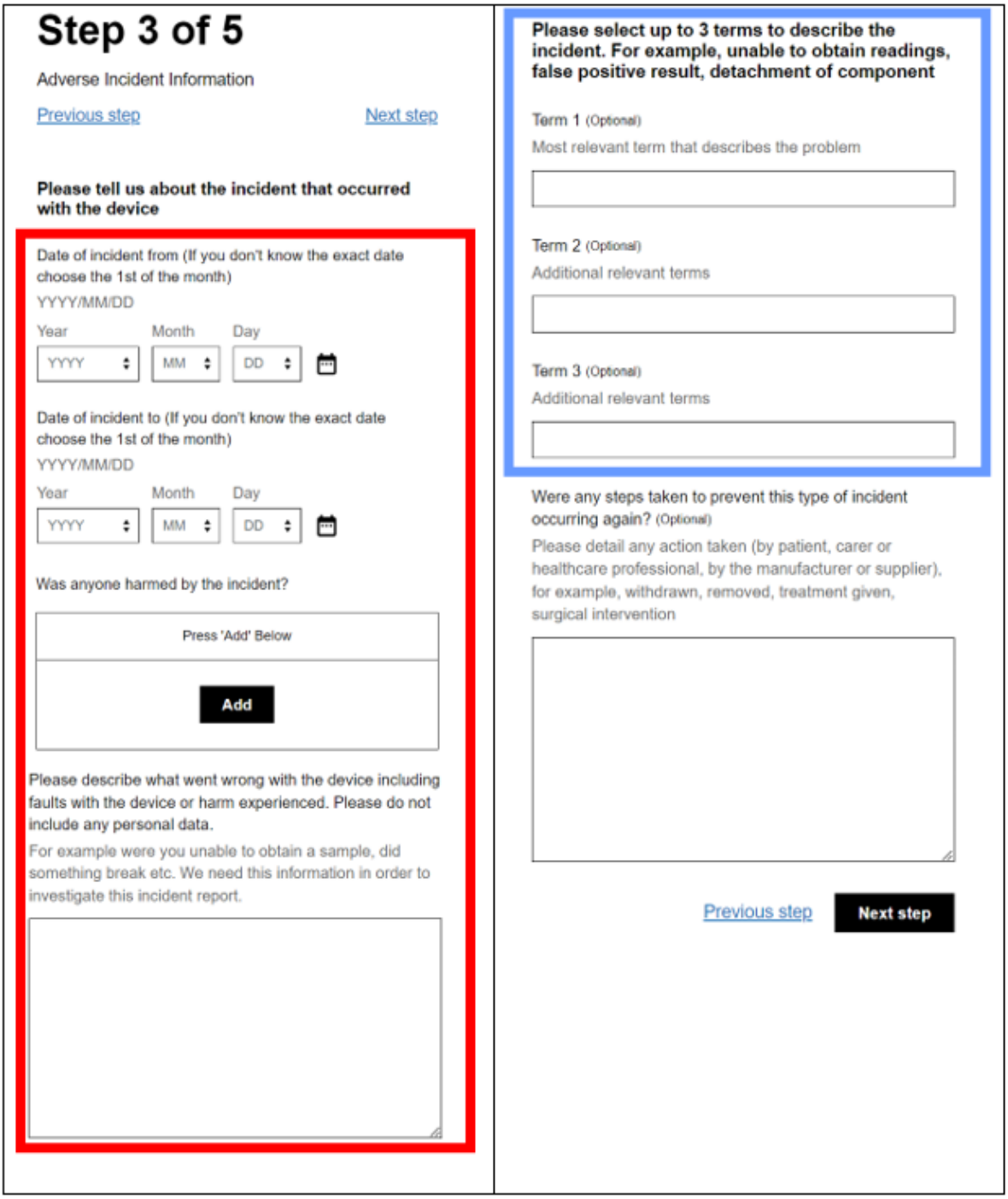
i. if the device needs to be calibrated, did you calibrate it and when was this last done?
ii. if you are using a smartphone as part of the system, what type is it (android or iPhone), and what version is running?
iii. a list of all products included in your diabetes management system (if known). Diabetes management systems are comprised of a number of different products, the majority of which will be classified as medical devices. If you are not sure whether the product you have concerns about is a medical device, submit a Yellow Card report and we will review.
iv. is there any additional information you can provide which suggests a possible cause for the problem you have identified?

If possible, please provide the following additional key information:

- keywords to describe the type of device problem

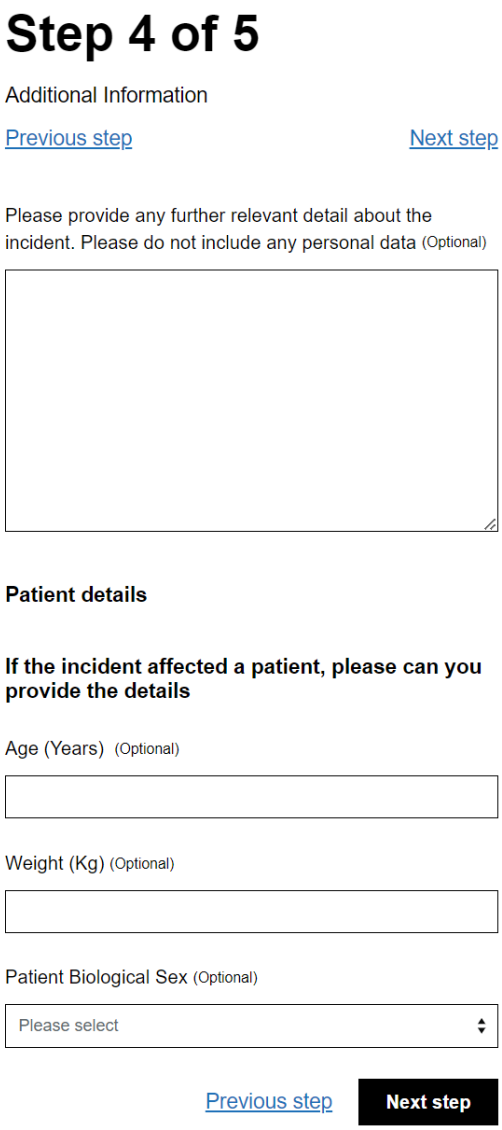
There are 3 fields to complete to give us a summary of the problem, and typing into the fields brings up suggested terms. Useful starting points for diabetes management devices include infusion, leak, reading, communication, battery and movement. We have provided a list of common terms associated with reports involving diabetes management equipment.

The complete form is shown below; the mandatory fields are highlighted in red and the recommended sections in blue.



8. Additional information

Any additional information you may have to share can be entered into these optional fields.



9. Attachments and submission

If you have any documents or photos to provide as supporting information, they can be attached here. Once your report is complete, press “Submit”.

Step 5 of 5

Attachments

Previous step

Please attach any additional documents you think may be relevant to the device or incident here. Please do not include any personal data on photos of packaging or failed devices. (Optional)

Press 'Add' Below
Add

Previous step **Submit**

Annex: Table of common terms

Listed below are common terms used in reports involving diabetes management equipment. Please note that this is not an exhaustive list and there may be a more suitable term for the particular concern you are reporting. The MHRA use the adverse event terminology coding system developed by the International Medical Device Regulators Forum. A full list of all available terms alongside further detail on the meaning of all terms can be found in the links provided at the top of each column.

Problem	**What went wrong with the device (A term)**	**What were the clinical signs and symptoms? (E term)**	**What was the overall impact on health? (F term)**
-	**-**	**E2403 - No Clinical Signs, Symptoms or Conditions** *No patient involvement or, no observable clinical symptoms or a change in symptoms is identified in the patient.*	**F26 - No Health Consequences or Impact** *No apparent harm occurred in relation to the adverse event.*
Not enough insulin given, blood sugar levels have gone too high	**A1407 - Insufficient Flow or Under Infusion** *Problem associated with an insufficient dose of therapeutic agents, e.g., drugs or fluids being delivered into a patient under positive pressure.* **A1409 - Obstruction of Flow** *Problem related to an obstruction or blockage within the device component (e.g. tube, opening, pipe) that results in restriction of flow (including blood clotting).* **A1408 - No Flow** *Problem arising from the device failing to*	**E1205 - Hyperglycemia** *Abnormally high level of glucose in the blood.* **E120501 - Elevated ketones/Diabetic Ketoacidosis** *Elevated ketones, including metabolic acidosis produced by accumulation of ketone bodies resulting from uncontrolled diabetes mellitus.* **E0109 - Convulsion/Seizure** *Sudden, involuntary skeletal muscular contractions of cerebral or brain stem origin.* **E0119 - Loss of consciousness** *A level of awareness that can be described as*	**F11 - Minor Injury/ Illness / Impairment** *A mild injury, illness or impairment which can be treated with minimal or no intervention, including monitoring only.* **F12 - Serious Injury/ Illness/ Impairment** *A severe injury, illness or impairment which requires hospitalization or medical intervention.* **F1205 - Temporary Impairment**

	deliver the specified liquid or gas.	*consistently not responsive to stimuli.* **E011901 - Coma** *A state of profound unconsciousness associated with markedly depressed cerebral activity.*	*Reversible deterioration of the state of health.* **F23 - Unexpected Medical Intervention** *Patient required an unforeseen medical intervention, excluding surgery, which was not on the original treatment plan.* **F1203 - Life Threatening Illness or Injury** *Patient suffered an illness or injury which if not treated would be fatal.*
Too much insulin given, blood sugar levels go too low	**A1402 - Excess Flow or Over-Infusion** *Problem associated with a delivery overdose of therapeutic agents, such as drugs or fluids being delivered into a device or a patient.*	**E1206 - Hypoglycemia** *Abnormally low level of glucose in the blood.* **E0109 - Convulsion/Seizure** *Sudden, involuntary skeletal muscular contractions of cerebral or brain stem origin.* **E0119 - Loss of consciousness** *A level of awareness that can be described as consistently not responsive to stimuli.* **E011901 - Coma** *A state of profound unconsciousness associated with markedly depressed cerebral activity.*	
Hardware problems	**A0504 - Leak/Splash** *Problem associated with the escape of a liquid (including blood and bodily fluids), gas or radiation from the vessel or container in which it is housed.* **A020101 - Dull, Blunt** *Problem associated with a device not being as sharp as intended or expected.*	For these problem types, the health impact and signs and symptoms will depend on the circumstances. Please use the link at the top of each column of this table to help you identify the best terms to use.	

	A040609 - Material Twisted/Bent *Problem associated with deformations that lead to twisting or bending of the device.* **A0404 - Crack** *Problem associated with an undesired partial separation and/or a visible opening along the length or width in the materials that are used in the device construction.* **A040101 - Fracture** *Problem associated with a partial or full-thickness crack in the device materials.*	**E2008 - Foreign Body In Patient** *An occurrence where any object including device or fragments is left unintentionally in the body.*	
Skin reaction to adhesive	**A01 - Patient Device Interaction Problem** *Problem related to the interaction between the patient and the device.*	**E1720 - Skin Inflammation/ Irritation** *An inflammatory process affecting the skin. Signs include red rash, itching, and blister formation. Representative examples are contact dermatitis, atopic dermatitis, and seborrheic dermatitis.* **E172003 - Contact Dermatitis** *An inflammatory skin condition caused by direct contact between the skin and either an irritating substance or an allergen.*	
Adhesive patch fell off (CGM	**A0512 - Unintended Movement**	For these problem types, the health impact	

sensor, infusion set patch, patch pump)	*Problem associated with an undesired movement of the device, which may be related to the device malfunction, misdiagnosis, or mistreatment.*	and signs and symptoms will depend on the circumstances. Please use the link at the top of each column of this table to help you identify the best terms to use.	
Inaccurate reading from CGM	**A0709 - Device Sensing Problem** *Problem associated with the device feature that are designed to respond to a physical stimulus (temperature, illumination, motion, cardiac rhythms) and that do not transmit a resulting signal for interpretation or measurement.*		
Communication failure between CGM sensor, transmitter or mobile phone or insulin pen	**A13 - Communication or Transmission Problem** *Problem associated with the device sending or receiving signals or data. This includes transmission among internal components of the device to which the device is intended to communicate.*		
Power issues	**A0708 - Power Problem** *Problem associated with the energy to operate the device.* **A0705 - Battery Problem** *Problem associated with the internal power of the device (e.g.*		

	battery, transformer, fuel cell or other power sources). **A0719 - Unexpected Shutdown** *Problem associated with the device unexpectedly powering down.*		
Display issues	**A0902 - Display or Visual Feedback Problem** *Problem with any deviation from the documented specifications of the device that relate to visual feedback. e.g. the display of information, images on a screen, or output from the device.*		
Software issues	**A11 - Computer Software Problem** *Problem associated with written programs, codes, and/or software system that affects device performance or communication with another device.*		
Unclear or missing documentation	**A21 - Labelling, Instructions for Use or Training Problem** *Problem associated with device markings/labelling, instructions for use, training and maintenance documentation or guidelines.*		