

Please fill in if the skin reaction is evident for longer than 30 minutes after removal of the medical device.

A

1. Name _____

2. Gender female male diverse

3. Age _____ years

4. System involved CGM: _____ (system name)
In use since: _____

Insulin pump: _____ (system name)
In use since: _____

5. Previous skin reaction(s) First skin reaction(s) ever recorded after using _____ (number) different systems.

_____ (system name(s))

several skin reactions have already occurred
 with increasing severity with changing severity

REPORT FORM

B

6. Skin appearances (efflorescences)

Erythema (redness)	
Papules	
Desquamation	
Crust formation	
Pustules/vesicles	
Weeping	
Pressure mark	
Hematoma	
Induration	
Injury	
Atrophy (can only be caused by implantable sensors)	

Localization
Please enter number(s) between 1–5 by using the diagram below

Additional information (optional)

7. Size of skin appearance _____ mm x _____ mm

8. Itching Please tick the severity of itching (0=no itching, 10=intense itching)

0 1 2 3 4 5 6 7 8 9 10

9. Temporal progression

System application	Start symptoms	System removal	Symptoms subsided
↓	↓	↓	↓
_____ Date	_____ Date	_____ Date	_____ Date

10. Severity of skin reaction mild moderate severe

C

11. Further actions (e. g. premature system removal, further therapy)

D

12. Suspected diagnosis Irritative contact dermatitis (ICD) Allergic contact dermatitis (ACD)
 Infection other _____

Date

Name

Signature

A

GENERAL INFORMATION

1.–3. Name, Gender, Age *Please enter patient name/subject ID (1), gender (2) and age (3).*

4. System involved *Please tick which system (CGM/IFGM or insulin pump) caused the skin reaction and enter the system's name. Additionally enter the first use of this system. (If necessary, previous system used can be documented as well.)*

5. Previous skin reaction(s) *Please enter if skin reactions due to CGM/IFGM systems or insulin pumps have occurred previously. Please enter how many systems were used until the first skin reaction appeared and enter the name(s) of the system(s). Please tick if several skin reactions already occurred and differ if the severity was steadily increasing or changing.*

B

FINDINGS

6. Skin appearances (efflorescences) *Localization: If one of the listed skin appearances exists, please enter number(s) between 1–5 by using the diagram to differentiate between (1) insertion site, (2) casing of the medical device (if available), (3) adhesive, (4) overtape and (5) outside the borders of the adhesive.*

Definitions of the listed skin appearances are:

Erythema	Redness of skin without skin level change.
Papules	Efflorescence, mostly spherical above the skin.
Desquamation	Increased accumulation of horn blades of the skin.
Crust formation	Dried secretion, exsudates or blood on skin surface or wounds.
Pustules	Vesicles in which the fluid has become infected by pathogens.
Vesicles	Small sacs filled with fluid (content either clear, serous or haemorrhagic).
Weeping	Secretion of fluid out of a wound or another efflorescence.
Pressure mark	Compressed tissue of mostly reddish/bluish colour with intact skin surface, not able to press away.
Hematoma	Skin discoloration due to blood leakage into tissue/deep and mostly bulging blood accumulation in the tissue.
Induration	Palpable superficial or deep, flat or knotty tissue consolidation.
Injury	Skin injury due to a catheter or sensor.
Athropy	Loss of skin substance. This can be evidenced by cigarette paper like pleating or by trough-shaped, smooth hollows and greater transparency of the skin. (Note: as a tissue related appearance atrophy can only be caused by implantable sensors).

7. Size of skin appearance *Please enter the size of the skin appearances in mm.*

8. Itching *Please ask your patient/subject whether itching is present and tick the severity of itching as classified by the patient/subject (0=no itching, 10=intense itching).*

9. Temporal progression *Please enter dates when: current system was applied, when first symptoms (also itching) started, the date when system was removed and when all symptoms subsided. Note: The dates do not have to differ (e.g. if symptoms are only recognized after adhesive removal).*

10. Severity of skin reaction *Please tick the severity of the skin reaction.*

Definitions of the severity categories (mild, moderate, severe) are:

mild	asymptomatic or mild symptoms; clinical or diagnostic observations only; no intervention indicated.
moderate	minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL*.
severe	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL**.

*Instrumental Activities of daily life (ADL) refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.**Self care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.

C

FURTHER ACTIONS

11. Further actions *In this free text space more details, e.g. regarding treatment, change to another system, use of a protective adhesive under the system as well as information about whether actions were effective.*

D

SUSPECTED DIAGNOSIS

12. Suspected diagnosis *In this section a suspected diagnosis can be made.*

Definitions for the listed suspected diagnoses are:

Irritative contact dermatitis (ICD)	Very common. Caused by irritation, e.g. from being covered (occlusion), sweating and heat accumulation under the device, tearing of the adhesive, etc. Symptoms: erythema with desquamation of varied extent, do not necessarily always occur (intermittent). Usually heals within a few days.
Allergic contact dermatitis (ACD)	Seldom (<5%). Symptoms: erythema, desquamation, papules and vesicles, crusts. Usually stronger and of longer duration than ICD, also often bacterial superinfection with weeping. Cause: Type 4 allergy due to one or more allergens (most acrylates, especially isobornylacrylate), after sensibilisation, life long immunological memory - thus, symptoms occur with repeated contact.
Infection	For example infection of the insertion site, or a super infection of a severe ICD, common at ACD. Fostered by scratching.