

Appendix 2 Registration form incidents involving medical technologies

To be completed **per day**, at the end of the shift.

Date:

Your respondent number:

Starting time of the shift today:

(rounded off to a quarter
e.g. 8.00, 10.15, 17.45, 20.30)

End time of the shift today:

(rounded off to a quarter
e.g. 8.00, 10.15, 17.45, 20.30)

How many patients have you seen today during the above shift?

Which of the medical technologies below did you work with during the above shift and how many patients did you use it with? (**multiple answers possible**)

Tick, technologies used with regard to:	Used with number of patients:
<input type="checkbox"/> Infusion therapy	
<input type="checkbox"/> Parenteral nutrition	
<input type="checkbox"/> Morphine pump	

OR

<input type="checkbox"/> I have not used any of these technologies today	→ You do not have to fill in anything else
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During your shift today, has there been an incident with one of the above medical technologies, where you were the user of the technology?

Tick	Description	
<input type="checkbox"/> No	→	You do not have to fill in anything else
<input type="checkbox"/> Yes, an adverse event	incident reaching the patient, whether or not causing harm to the patient	Continue with the questions on the backside
<input type="checkbox"/> Yes, a near miss	incident not reaching the patient, causing no harm to the patient (e.g. because it was discovered in time)	

Fill in the questions below **per adverse event or near miss**.

If more than one adverse event or near miss with the medical technologies occurred during today's shift and where you were the user, take a new registration form per adverse event/near miss and complete both the front and the other pages.

Medical technology with which the adverse event/near miss occurred and for which you further complete the following questions:

Tick, technology with regard to:
<input type="checkbox"/> Infusion therapy
<input type="checkbox"/> Parenteral nutrition
<input type="checkbox"/> Morphine pump

Time of the adverse event/near miss:

(rounded off to a quarter
e.g. 8.00, 10.15, 17.45, 20.30)

What is the main cause to which the adverse event/near miss is related (**one answer**):

Tick	Tick	Optional explanation
<input type="checkbox"/> Product device itself	<input type="checkbox"/> technical defect of the device <input type="checkbox"/> correct device not present or device component(s) missing <input type="checkbox"/> manual unclear, incomplete, not available or unsuitable for the home situation <input type="checkbox"/> device unsuitable for the home situation, because <input type="checkbox"/> incorrect medication preparation, administration or delivery <input type="checkbox"/> other, namely	
<input type="checkbox"/> Environment	<input type="checkbox"/> climate in the room (e.g. temperature, humidity, lightning, noise) <input type="checkbox"/> hygiene of the room <input type="checkbox"/> room too small <input type="checkbox"/> presence of children <input type="checkbox"/> presence of pets <input type="checkbox"/> power failure or interference with other electrical devices <input type="checkbox"/> incorrect use by patient and/or informal caregiver(s) <input type="checkbox"/> other, namely	
<input type="checkbox"/> Organization of care	<input type="checkbox"/> unclear tasks, responsibilities and/or authorizations <input type="checkbox"/> error or hand over error by a colleague or other healthcare professional <input type="checkbox"/> poor maintenance of the device, including cleaning <input type="checkbox"/> other, namely	
<input type="checkbox"/> Human factors: yourself as a user	<input type="checkbox"/> insufficient knowledge/skills regarding the use of the device <input type="checkbox"/> stress or fatigue <input type="checkbox"/> inattention or error <input type="checkbox"/> failure in situational awareness <input type="checkbox"/> incorrect calculation of medication <input type="checkbox"/> other, namely	

Consequences of the adverse event/near miss for the patient (**one answer**):

Tick Degree of harm	Description
<input type="checkbox"/> None	Patient outcome is not symptomatic, or no symptoms detected and no treatment is required.
<input type="checkbox"/> Mild harm	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (eg. extra observation, investigation, review or minor treatment) is required.
<input type="checkbox"/> Moderate harm	Patient outcome is symptomatic, requiring intervention (eg. additional operative procedure, additional therapeutic treatment), an increased length of care, or causing permanent or long-term harm or loss of function.
<input type="checkbox"/> Severe harm	Patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function.
<input type="checkbox"/> Death	On balance of probabilities, death was caused or brought forward in the short term by the incident.

Degrees of harm according to the World Health Organization's International Classification for Patient Safety[4]

Have you taken action(s) to discuss the adverse event/near miss?

	(multiple answers possible)	Optional explanation
<input type="checkbox"/> Yes, namely →	<input type="checkbox"/> discussed it with colleagues in the team <input type="checkbox"/> discussed it with the direct supervisor <input type="checkbox"/> discussed it with the patient and/or informal caregiver(s) <input type="checkbox"/> discussed it with the attending physician <input type="checkbox"/> made a formal report according to the protocol of the organization <input type="checkbox"/> other, namely	

OR

	(multiple answers possible)	
<input type="checkbox"/> No, because →	<input type="checkbox"/> lack of time <input type="checkbox"/> don't know which action(s) I should take or how <input type="checkbox"/> don't know whether the event is worth reporting or discussing <input type="checkbox"/> don't know the potential consequences with regard to liability <input type="checkbox"/> fear of sanctions or punishment against me <input type="checkbox"/> other, namely	

Were there any adverse events or near misses with other medical technologies than the three indicated during your shift today?