



Ypsomed			
<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 5px; background-color: #e6f2ff;"> RECEIVED By Ambadi Aditi Madhavan at 7:07 am, Jul 01, 2021 </div> <div> Complaint Form YpsoPump System </div> </div>			
		30.06.2021	
		Date of creation:	
Section 1	Reference No. or Study Number	36010622	Date of first contact (notification by caller): 29.06.2021 Date of event (when did the event happen): 28.06.2021
	Name of Reporting person (LCO)	MAFR1	Place of event (where did it happen): Switzerland
	Company:	Klicken Sie hier, um Text einzugeben.	
	Phone:	Klicken Sie hier, um Text einzugeben.	
	E-Mail:	Klicken Sie hier, um Text einzugeben.	
	Section 2		
Contacted by whom:			
<input type="checkbox"/> Patient <input checked="" type="checkbox"/> Medical Pers. <input type="checkbox"/> Other: Klicken Sie hier, um Text einzugeben.			
Section 3	Event	Communication to and with authorities to be handled solely by Ypsomed AG, Burgdorf (HQ). Notification of / by authorities <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, name of authority: Klicken Sie hier, um Text einzugeben. Authority Reference No.: Klicken Sie hier, um Text einzugeben.	
	Consequence of event: Explanation see Complaint handling AC/Distributors MS1 10091210 <input type="checkbox"/> Death <input checked="" type="checkbox"/> Hospitalization <input type="checkbox"/> Life-threatening <input type="checkbox"/> Medical significant (as reported by the reporting HCP) <input type="checkbox"/> Intervention by health care professional <input type="checkbox"/> Self-medication <input type="checkbox"/> Detected before first use <input type="checkbox"/> Help from third parties (not HCP) <input type="checkbox"/> Product Failure <input type="checkbox"/> Labelling <input type="checkbox"/> Legal situation <input type="checkbox"/> Notification by an authority		
	Description of event: Kaetoacidosis. At the hospital, it was found that the NovoRapid PumpCard was broken and that insulin had leaked.		
	Statement to your Complaint requested: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

Ypsomed	
Title: Complaint Form YpsoPump System	

Clarifying questions:

1. ***Age, of patient in years:**

<input type="checkbox"/> ≤ 3	<input checked="" type="checkbox"/> 4 - 12	<input type="checkbox"/> 13 - 18	<input type="checkbox"/> 19 - 34	<input type="checkbox"/> 35 - 64	<input type="checkbox"/> 65 - 79	<input type="checkbox"/> ≥ 80	<input type="checkbox"/> N/A / Unknown
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2. **YpsoPump user since:**

<input checked="" type="checkbox"/> 0 - 3 Months	<input type="checkbox"/> 4 - 6 Months	<input type="checkbox"/> 7 - 9 Months	<input type="checkbox"/> 10 - 12 Months
<input type="checkbox"/> > 1 Year	<input type="checkbox"/> > 2 Years	<input type="checkbox"/> > 3 Years	<input type="checkbox"/> N/A / Unknown

3. ***Diabetic since:**

<input type="checkbox"/> < 1 Year	<input type="checkbox"/> 1 - 5 Years	<input type="checkbox"/> 6 - 15 Years	<input type="checkbox"/> Longer than 15 Years	<input checked="" type="checkbox"/> N/A / Unknown
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4. ***BG level during event:**

Accurate value: >20.....	<input type="checkbox"/> MG/DL	<input checked="" type="checkbox"/> mmol/L	<input type="checkbox"/> N/A / Unknown
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5. ***Ketone value during event** (only necessary if BG value during event is higher than 250 MG/DL / 13.9 mmol/L):

Accurate value:	<input type="checkbox"/> MG/DL	<input type="checkbox"/> mmol/L	Measured from: <input type="checkbox"/> Doctor <input type="checkbox"/> Patient	<input checked="" type="checkbox"/> N/A / Unknown
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6. ***BG level after intervention:**

Accurate value:	<input type="checkbox"/> MG/DL	<input type="checkbox"/> mmol/L	<input checked="" type="checkbox"/> N/A / Unknown
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7. **When the adapter / tubing last was changed? Within:**

<input type="checkbox"/> 0-24h	<input type="checkbox"/> 25-48h	<input type="checkbox"/> 49-72h	<input type="checkbox"/> >72h	<input checked="" type="checkbox"/> N/A / Unknown
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8. **Brand / type of Insulin used:**

<input type="checkbox"/> Fiasp	<input type="checkbox"/> Lyumjev	<input type="checkbox"/> Humalog	<input type="checkbox"/> Apidra	<input type="checkbox"/> Sanofi Lispro
<input type="checkbox"/> NovoRapid	<input checked="" type="checkbox"/> NovoRapid (prefilled)	<input type="checkbox"/> Other:	<input type="checkbox"/> N/A / Unknown	

9. **Last cartridge change:**

<input type="checkbox"/> 0-24h	<input type="checkbox"/> 25-48h	<input type="checkbox"/> 49-72h	<input type="checkbox"/> >72h	<input checked="" type="checkbox"/> N/A / Unknown
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10. **Infusion Set Type at Pump Complaint:**

<input checked="" type="checkbox"/> Orbitmicro	<input type="checkbox"/> Orbitsoft	<input type="checkbox"/> InSet	Universal Cannula (tube length n/a)	<input type="checkbox"/> Micro	<input type="checkbox"/> Soft	<input type="checkbox"/> N/A / Unknown
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Needle length:

<input checked="" type="checkbox"/> 5.5mm	<input type="checkbox"/> 8.5mm	<input type="checkbox"/> 6mm	<input type="checkbox"/> 9mm	<input type="checkbox"/> N/A / Unknown
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Tube length:

<input type="checkbox"/> 110 cm	<input type="checkbox"/> 100 cm	<input type="checkbox"/> 80 cm	<input type="checkbox"/> 60 cm	<input checked="" type="checkbox"/> 45 / 46 cm	<input type="checkbox"/> N/A / Unknown
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11. **Other medical or external circumstances:** (Free text with mention of further medication, allergies, infectious diseases in the environment and external circumstances such as cold/heat, X-rays....)
 Klicken Sie hier, um Text einzugeben.

	Patient agrees to share data with NovoNordisk in case of cartridge / insulin issue: <input type="checkbox"/> yes <input checked="" type="checkbox"/> no Caller/patient is free to refuse to answer questions marked with * (due to data protection regulations)
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Title:		Complaint Form YpsoPump System			

Section 4	Complained Product:		Return expected? <input type="checkbox"/> Yes <input type="checkbox"/> No		Notes: Klicken Sie hier, um Text einzugeben.	
		Name of Product	Article No. REF	Quantity claimed	Manufacturer, if not Ypsomed AG	Batch No. LOT / Serial No.
	Main complained Product	Mylife YpsoPump	700009422	1	n/a	n/a
	Attached products	NovoRapid PumpCard	n/a	1	Novo Nordisk	unknown
	
	
	

Section 5	Forwarding to YPS HQ: All complaints have to be forwarded to complaints@ypsomed.com the same day the complaint was received (date of first contact), not later than within one business day.				
	Attachments <input type="checkbox"/> Yes number of pages <input checked="" type="checkbox"/> No				