CUSTOMER COMPLAINT FORM

Please complete one Form per Incident / Query. *Mandatory field

Section 1: Incident/Query/Feedback Record			
Insert Your Internal Complaint Number (If Applicable):		**Please mark box applicable:**	
		Delivery issue / Purchase Order issue	☐
Date and Time of Your Complaint reporting: *	19.11.2025	**Product Quality issue**	☒

Section 2: Customer and Distributor Details		
	Customer/Hospital Name	**Distributor Details (If Applicable)**
Distributor/Hospital Name: *	Connect Medizintechnik GmbH	
Contact Name: *	Martin Panusch	
Contact Email Address: *	martin.panusch@connect-medizintechnik.at	
Contact Telephone Number:		
Your Contact Name at SLE / Inspiration Healthcare Ltd (If known)		

Complete Section 3 for Patient related incident

Section 3: Regulatory Reporting				
Has the Incident Been Reported to a Competent Authority? *	Yes	☐	**If Yes, Who is the Body/Agency?**	
	No	☒	**Confirm Associated Reporting Reference Number?**	

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Complete section 4 for Product issue / Delivery issue

Section 4: Product Purchase / Delivery Details					
Purchase Order / Sales Order Number: *	#04219	**Quantity Ordered:**	85	**Quantity Affected:**	1
Product Description Name/Type: *	R-22MEDV	**Product Code: ***		Ref: 0110021	
Batch/Lot or Serial Number(s): *	V121884	**Total Usage Hours:**		0	

Section 5: Description of Fault / Incident / Feedback				
Date and Time of Incident: *	6.11.2025	**Who – Person(s) who Identified the Issue? ***		
When – When Did This Occur i.e. Goods In, Set/Start-Up, During Use, etc? *	was defective upon unpacking. The sensor always is at 0V, no matter the actual oxygen concentration	**Was the Device Being Used on a Patient? ***	Yes	☐
			No	☒
Software Version **(If applicable):**		**Patient Age/Weight (If Available):**		
What – Describe the sequence of events? **What happened and how did the Actual Problem / Incident occur? ***		**Did the Patient Suffer Any Harm? If Yes, Please Include Details:**		
		Was Medical/Surgical Intervention Required? If Yes, Please Provide Details: * **(This Includes Removing the Patient from the Device and Placing Them onto Another During Use.)**		
Were Any Actions Taken to Contain or Correct the Incident? *		**Mode of Operation at the Time of Incident:**		
		Were any additional modes enacted (e.g. VTV/ PS)		

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Section 5 (continued): Description of Fault / Incident / Feedback			
If used Non-invasively what interface (brand/type of generator or cannula) was used? **Was anything being delivered concomitantly with the ventilation? (e.g. Nitric oxide/ Nebuliser)**		**What circuit was in use at the time of the incident, brand / type / part no. (If available)**	

Section: Additional Information								
Photos or Video of Faulty Product Available?	Yes	☐	**Are Samples/Items Related to the Incident Available to Return?**	Yes	☒	**Are Log Files Available for Analysis?**	Yes	☐
	No	☐		No	☐		No	☐
Accessories / Other Devices Used Alongside the Product when the Issue Occurred: *						**Repeat Issue?**	Yes	☐
							No	☐

For ventilators, where log files available, please download log files. Instructions can be found from the related user manual.

Note. To assist the investigation, where log files are available, there is a MAXIMUM 14 CALENDAR DAY TIMEFRAME to download from the date of the reported incident.

Please contact a member of service or Post Market Complaint Handling team for any assistance either via telephone or email.

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