



Product: Heart-Lung-Machine (HLM) Tubing Sets

Clinic	
User name	
User role	
HMT Contact	
Product:	HLM Tubing Sets Extracorporeal circuit for heart-lung bypass operations
Variant/ Product number (PXXXX)	

A) Application-specific questions

- What qualification do the users have?
 - Cardio Technician / Perfusionist
 - Cardiac Surgeon
 - Other (please specify): _____
- Patient information (range or predominantly):
 - Age: from _____ to _____
 - Gender: m w d
- For which application area, were the products normally used in the clinic?
 - Cardiopulmonary bypass
 - Other (please specify): _____
- How long did the HLM Tubing sets typically pump? _____ Hour(s)

B) Questions regarding device set-up

- | | Y | N |
|--|--------------------------|--------------------------|
| 5. Was the packaging intact on delivery? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Was the information on the Instructions for use (IFU) and labels, easy to understand, user-friendly and do they provide clear and concise instructions? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Was the packing order of the components correct with regard to assembly on the HLM? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Were there any loose covers/caps discovered on opening the packaging? | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Has the set been assembled with the desired components? | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Are air bubbles easy to remove from circulation? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Please indicate on a scale of 1 to 4 how satisfied you are with the priming of the tubing sets and components. [•] | 1 | 2 3 4 |

[•] 1 = very satisfied, 2 = satisfied, 3 = dissatisfied, 4 = very dissatisfied



C) Questions regarding usability of devices

Y N

12. Did unexpected user-errors occur during the application?

If yes, please specify: _____

13. Have you experienced complications while using the product?

If yes, please specify: _____

14. On a scale from 1 to 4, how would you rate the usability of the products?*

1 2 3 4

15. How would you rate the safety of HLM sets on a scale of 1 to 4? *

1 2 3 4

16. Based on your experience with HLM tubing sets, please rate the compatibility of the tubing sets produced by HMT Medizintechnik as part of the cardiopulmonary circuit (scale of 1 to 4)?*

1 2 3 4

* 1 = very satisfied, 2 = satisfied, 3 = dissatisfied, 4 = very dissatisfied

D) General (Please indicate how satisfied you are on a scale of 1 to 4)*

17. Communication with HMT Medizintechnik GmbH

1 2 3 4

18. Execution of proposed changes

1 2 3 4

19. Information sharing with regard to changes made by HMT.

1 2 3 4

20. Overall product

1 2 3 4

* 1 = very satisfied, 2 = satisfied, 3 = dissatisfied, 4 = very dissatisfied

E) General Comments:

What do you particularly like about HLM tubing sets from HMT Medizintechnik GmbH?

What would you improve about this product?

Date

Signature: