Action Overview	Action Justification/Rationale	Action Specific to Fetal Perfusion Circuit
Define HF Requirements		
Solicit inputs from user focus groups to obtain preferences.	User groups offer insight in HF issues not apparent to designers	1. Interview pediatric cardiothoracic surgeons, perfusionists, clinical engineers, and nurses regarding HF preferences.
Observe users in each target environment.	How users interact with the environment on a daily basis will impact product design.	1. Observe pediatric cardiac surgery including CPB. 2. Observe perfusionists' use of pediatric CPB circuits.
Examine the company's (and its competitors') satisfaction and experiences with current devices.	Predicate devices can be rich sources of HF information that can be related to the design of this device.	1. Examine current pediatric CPB systems. 2. Review adverse events reports of CPB systems.
Perform a task analysis to identify specific task-related potential errors.	The possibility of task-related errors should be minimized through product design.	1. Observe and evaluate tasks of each participant during a "mock" fetal surgery (simulate surgical environment, circuit setup, and circuit use) . 2. During animal trials, conduct tasks analyses of physicians and perfusionists.
Ensure that human factors requirements are included in requirement specifications.	Human factors requirements impact product design and should be included in the product specifications.	1. Include human factors requirements in product design specifications.
Design Activities		
Conform to industry standards for user and device interfaces.	The company desires to be in compliance with industry standards.	1. Seek compliance with applicable international standard for blood pumps and perfusion circuits.
Use metaphors that are familiar to the user (such as a machine/device layout).	The user should not have to learn new terminology to use the device.	1. Research predicate devices and ensure continuity of terminology. 2. Integrate appropriate terminology into user manuals.
Introduce new technology where possible to simplify entry (voice activation, bar codes, touch screen, etc.) and presentation (graphics, audio, video, etc.).	New technology can simplify the product's user interface, thus reducing the chance of task-related errors.	1. Develop or utilize new technologies to simplify the user interface.
Implementation Activities		
Prepare user interface sketches for early review and input by user groups.	Early input by user groups will lead to the best possible UI and prevent costly design changes in the future.	1. Conduct focus groups on the device's user interface and integrate these findings into the product design. 2. Survey potential users regarding interface design and usability.
Test prototype hardware in the operational environment.	Prototype testing in the operational environment will bring to light major HF issues.	1. Incorporate human factors analysis into early clinical trials.
Refine the design based on concrete feedback from users.	Early design changes will produce result in a higher quality end product designed with HW in mind.	1. Incorporate finding of clinical trials' human factors analyses into final device design.
Verify that the final design meets specified human factors requirements.	Final design should meet the human factors requirements.	1. Evaluate final device design (in operation) to ensure that the human factors requirements specified in the PDS are met.

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Test Activities		
Ensure actual use scenarios are integrated into test procedures.	Final product must perform adequately in the actual operational environment.	1. Evaluate and validate human factors requirements during clinical trials.
Ensure that the full range of user expertise is integrated into test procedures.	Users of different expertise levels may use the device differently thus providing additional HF input.	1. During initial HF tests and clinical trials, observe users of various skill levels (e.g. first-year perfusionists and veteran perfusionists) to determine how skill level influences use of the device.
Ensure that user workload considerations are addressed in test procedures.	How the device is used may vary with the user's workload.	1. During initial HF tests and clinical trials, observe users with various work loads (e.g. beginning of shift vs. end of shift) to determine how work load influences use of the device.
Ensure that tests address system installation and configuration requirements.	Proper device configuration is just at important as proper device use.	1. Include circuit setup and configuration in HF analysis during initial tests and clinical trials.
User Documentation Activities		
Provide help and well-indexed supporting documentation.	Well written documentation will support proper device configuration and use.	1. Provide a comprehensive, well-written user manual with sections appropriate to different users (e.g. physician, perfusionist, and clinical engineer).
Use graphics where possible.	Graphics are easier to interpret than text in some cases.	1. Incorporate well labeled, descriptive graphics and diagrams into the user manual
Provide descriptive text and error messages.	Device error messages should be indexed for troubleshooting purposes.	1. Include a separate troubleshooting and error message section in the manual. 2. Consider incorporating error message interpretation into the device's user interface.
Provide examples scenarios of use.	To promote device use for indicated purposes.	1. Make clear the FDA approved uses of the device in the user's manual.
Solicit user/beta test feedback on user manual clarity and content.	Feedback will allow for revisions to be made to the manual before final production.	1. Distribute a beta version of the user's manual during early/clinical trials. 2. Gather feedback on the beta user's manual clarity and content. 3. Incorporate feedback into final version of the user's manual.

Note: The content in the column labeled "Action Overview" was taken from a July 2002 article in MDDI titled "Putting Human Factors Engineering Into Practice" by Christine Engelke and Daniel Olivier.