

Meeting Overview			
Meeting Title	T761 Eakin Healthcare Tech File SW review – SW coding changes		
Meeting Date	15 th June 2026	Meeting Location	MS Teams
Objective & Participants			
Objectives of the meeting	- Alarm changes - Language changes - SW versioning changes - Electrical Safety testing – Timeframe Dependency - Cybersecurity - Document Tracking - SW Workstream timeline delay		
Participants	Trinzo: Jacqui Fox David Didsbury Colm O'Rourke (absent)	Client: Rebecca Cuckoo Andrew Kane	

Meeting Minutes	
Alarm Code Change	<u>Audible Change</u> Andrew has completed the following 3 parameter changes in the SW code – No Issues noted: - Sound – Low, Medium, High - Screen Colour – Low (Cyan), Medium (Yellow), High (Red) - Flash – Low (solid), Medium (0.6Hz), High (2hz) Some uncertainty around the Alram Mute button LED. David noted in the current setup - the flash goes from flash to solid when muted. Andrew to review and investigate the mute button flash to ensure there is no issue between the existing and new setup Clinical review of code changes pushed out to next week, to include nursing and usability (Adil) <u>Code review</u> New alarm code should be completed by W/E 19th June - David is to review the code upon completion <u>Debug</u> David queried the debug menu's available commands. Andrew advised the audio debug does not appear on the display screen. Andrew and David to connect this week on the Debug test scripts to see what happens when the Debug is given particular commands. <u>SW Versioning</u> David reviewing the code to identify the presence of the 17 listed changes from Marturion within the code. Purpose to confirm where they are visible/implemented in the code – provide traceability. If changes cannot be clearly identified in the code then may need to retrospectively generate test data. <u>Document Change request</u> Andrew has raised the change request for the 3 changes below: 1) 1 Change request form to document all 3 changes Alarms 2) Languages 3) Retrospective v1.01 to v1.02 (comprising the 17 changes listed from Marturion

	(Andrew Barr) on 20 th May '26)
	Change Request for review internally this week – W/E 19 th June
Language Changes	Andrew has replicated 12 languages and upload – No issues with memory capacity. Some concerns around driver and font limitations for certain languages symbols, like Greek, Arabic and Vietnamese. David suggested the graphics display driver could be updated to include additional fonts.
Electrical Compliance testing	Andrew/Rebecca have confirmed all Electrical Compliance testing will be completed in house, no requirements for UL. Testing is planned for completion by 23rd July. David will use the test reports to complete his deliverables. Andrew is reviewing IEC60601-1 compliance documents and gap assessing against previous MDD documentation to captured testing gaps.
Cybersecurity	Rebecca and Andrew currently evaluating options for securing the USB port, including physical port locks and software controls to prevent unauthorized access or harmful software overwrites. Rebecca explained that the risk management file was being updated to reflect both hardware and software control measures, with a focus on preventing unwarranted interference with the device. David and Rebecca discussed scenarios where incorrect therapy settings could cause harm, especially for neonatal patients, and considered the effectiveness of alarms, physical limits, and the potential for password protection. Rebecca clarified that if residual risk remains high after implementing controls, a benefit-risk analysis would be conducted to justify not adding features like password protection, citing the need for rapid clinical intervention and the lack of field incidents. Rebecca purchased standards (81001-5-1 for cybersecurity and 27427 for respiratory equipment) for further assessment, she will share. Andrew and Colm to review their applicability.

Next steps		
Actions	Owner	Deadline
Andrew to review the mute button flash sequence V the existing setup	Andrew	19 th June '26
Clinical review of code changes for sounds, colour and flash	Rebecca	26 th June '26
Change request sign off	Andrew/Rebecca	22 nd June '26
Review the debug commands in the debug screen	Andrew/David	22 nd June '26
Andrew to review the graphics driver as possible solution for uploading language symbols	Andrew	22 nd June '26
Review IEC60601-1 standard compare to MDD documentation to outline what testing needs to be completed for electrical compliance testing	Andrew	26 th June '26
Complete Electrical compliance testing	Andrew	23 rd July '26
Trace SW to identify the change in the SW between v1.01 and v1.02 – Document	David	22 nd June '26

IF SW change cannot be seem generate retrospective test data	David/Andrew	30 th June '26
Update Rsk Mgmt file addressing USB port lock and GUI security controls – Review competitor controls	Rebecca	22 nd June '26
Share standards for review 81001-5-1 and 27427	Rebecca	16 th June '26
Review relevance of standards	Colm	22 nd June '26

