SOFTWARE REQUIREMENTS DOCUMENT

Prepared by:

Name	Position	Date	Signature
Guy Gurevitch	Director of Scientific and Clinical Affairs	27/7/2025	

Approvals:

Name	Position	Date	Signature
Ziv Kalfon	CTO		

Revision History

Rev#	BY	Date	ECO#	Description
01				

1 SCOPE AND BACKGROUND

1.1 This document defines the technical and functional requirements for the development and manufacture of a Magnetic Resonance (MR)-conditional EEG system to be used within the ELDA development framework. The system is intended for simultaneous EEG-fMRI recordings and must meet specifications for EEG signal integrity, MR safety, usability, and hygiene.

2 DOCUMENT CONVENTIONS

2.1 Mandatory requirements are indicated by "shall"

2.2 Comments may be shown in italics. Comments do not form part of the requirement but provide background or explanation of the requirement.

2.3 A unique number will identify each requirement. This number will be fixed and will not change as the document is revised to provide easy reference/traceability in other documentation

3 ABBREVIATIONS AND DEFINITIONS

3.1 Ancillary Process Specific Regulatory Requirements – Generic requirements defined for quality system processes. Such requirements are not product specific, and are therefore not considered design inputs for the product.

3.2 Design Validation – Process of formal testing to assure that the Finished Device meets its User Needs and Intended Use(s).

3.3 Design Verification – Process of formal testing and/or inspection to assure that each level of design output conforms to all associated specification(s).

3.4 Product Specific Regulatory Requirements – Requirements defined by the associated regulatory requirement(s) for a specific product which are included as design inputs for the product.

3.5 Requirement – Finished Device Level functional, physical/interface, packaging, labeling, and safety requirements, in addition to the standards/regulations/guidance, that the product must meet, which are used as the basis for device design.

3.6 CAP – Electrode placement system organized according to standard positions (e.g. 10-20, 10-10)

3.7 EEG – Electroencephalogram, a non-invasive method for measuring brain electrical potentials from the scalp.

3.8 ECG – Electrocardiogram, a non-invasive method for measuring electrical activity of the heart.

3.9 Electrodes – Metal conductors placed at specific locations, connected via wire to an amplifier and transducer, used for measuring bio-potentials.

3.10 ...

4 REFERENCED DOCUMENTS AND APPLICABLE STANDARDS

The references listed here should be considered when applying this requirements document. Referenced documents will be binding only if referred to by this document, and then, only to the extent to which they are referred to. Unless stated otherwise, the latest revision is applied.

4.1 Internal QAP

a. Table of standards ref GEN-QA-XXX

b. Design Control Procedures - QAP-RD-XXX

c. Risk Management Procedures - QAP-RG-XXX

d. Document control Procedures - QAP-QA-XXX

e. SW lifecycle procedure QAP-RG-XXX

4.2 External standards

	Standard	Scope	Required Deliverables
1	IEC 60601-1	General safety and essential performance of medical electrical equipment	Electrical safety test reports, design compliance file
2	IEC 60601-1-2	Electromagnetic compatibility (EMC)	EMC test reports, risk assessment
3	IEC 60601-2-26	Particular requirements for EEG equipment	Performance tests, waveform validation, impedance specs
4	IEC 62304	Software lifecycle processes for medical device software	Software plan, requirements, architecture, tests, traceability matrix, risk analysis
5	ISO 14971	Risk management for medical devices	Risk management file, hazard analysis, mitigation plans, residual risk assessment
6	ISO 13485	Quality management system for medical devices	QMS documentation, SOPs, audit records, training logs
7	IEC 62366	Usability engineering for medical devices	Usability engineering file, use scenarios, validation tests
8	ASTM F2503	Labeling for MRI safety (MR Safe/Conditional)	MRI safety testing report, labeling instructions
9	ISO 10993	Biological safety of materials in contact with patient	Biocompatibility test reports (Parts 5, 10, 12)
10	HL7 / FHIR	Data interoperability with hospital systems	Interface documentation, integration test reports
11	FDA Cybersecurity Guidance	Security and threat mitigation for connected devices	Threat model, security controls, update plan, logging & audit trail design
12	FDA Software Validation Guidance	General principles of software validation for medical devices	Validation plan, user needs traceability, test protocols and results, final validation report

13	MDCG	Cybersecurity requirements for medical devices under EU MDR	Cybersecurity design documentation, threat model, patching policy, incident response plan
14	AAMI TIR57:2023	Security risk management for medical devices	Security risk analysis, mitigation controls, integration with ISO 14971 risk file
15	BS/AAMI 34971:2023	Applying ISO 14971 to AI/ML systems in medical devices	ML-specific hazard analysis, model monitoring, data drift handling strategy
16	ASTM F2052-21	Standard test method for measurement of magnetically induced force	Test results, MR conditional instructions
17	ASTM F2119-24	Standard test method for evaluation of MR image artifacts	Test results, MR conditional instructions
18	ASTM F2182-19e2	Standard test method for measurement of radio frequency induced heating	Test results, MR conditional instructions
19	ASTM F2213-17	Standard test method for measurement of magnetically induced torque	Test results, MR conditional instructions
20	ISO/TS 10974 2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	

5 PRODUCT OVERVIEW

5.1 General Description

- The ELDA EEG System is a high-resolution, MR-conditional electroencephalography (EEG) system designed for simultaneous EEG-fMRI acquisition in clinical and research environments. It enables the acquisition, visualization, processing, annotation, and export of brain electrical signals with high temporal resolution and MRI compatibility.
- The system comprises the following components:
  - Hardware Unit (EEG Amplifier): A 64-channel, 24-bit resolution EEG amplifier capable of sampling at up to 5000 Hz per channel, designed for MR-conditional use.
  - Electrode Cap and Leads: Gel-based, MRI-compatible electrodes integrated into standard EEG cap layouts (e.g., 10-20, 10-10 system).
  - Control Interface Box: Connects the amplifier to the data acquisition computer via USB, with support for TTL triggers and impedance monitoring.
  - Software Suite (subject of this SRS)
- The system supports both manual and MRI-triggered recording modes, enforces impedance safety thresholds, and provides real-time signal visualization.

5.2 Intended Use

The ELDA EEG System is intended for the **recording, visualization, processing, and storage of electroencephalographic (EEG) signals** from the human scalp in clinical and research environments. It is specifically designed to support **simultaneous EEG acquisition during functional Magnetic Resonance Imaging (fMRI)** procedures.
The system allows qualified medical personnel, such as neurologists and EEG technicians, to:

- Acquire multichannel EEG data in real-time inside and outside the MRI scanner environment.
- Monitor electrode impedance and signal quality during setup and acquisition.
- Perform automated and manual signal preprocessing, including artifact detection and removal.
- Annotate EEG recordings and generate structured clinical reports.
- Export EEG data and annotations for integration with hospital systems or third-party analysis tools.

This device is intended for use on patients of all ages where EEG recordings are required, including in applications such as **epilepsy monitoring, sleep studies, cognitive research, and neuroimaging investigations**.

5.1 User characteristics

The system is to be used **by trained healthcare professionals** in clinical, hospital, or research settings. It is not intended for standalone diagnosis or for use in home environments.

6 SW MODULES

6.1 The software system shall be comprised of the following modules:

6.1.1 User Login

6.1.2 Patient Management

6.1.3 Patient Database

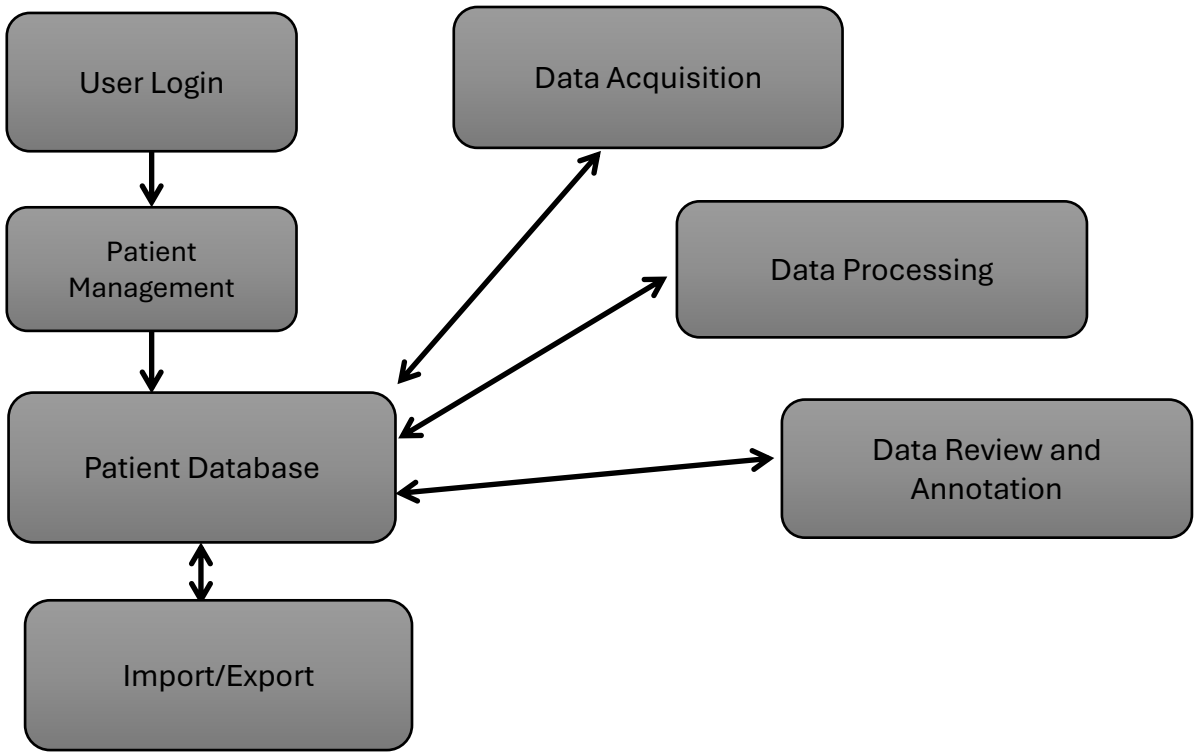
6.1.4 Data Acquisition

6.1.5 Data Processing

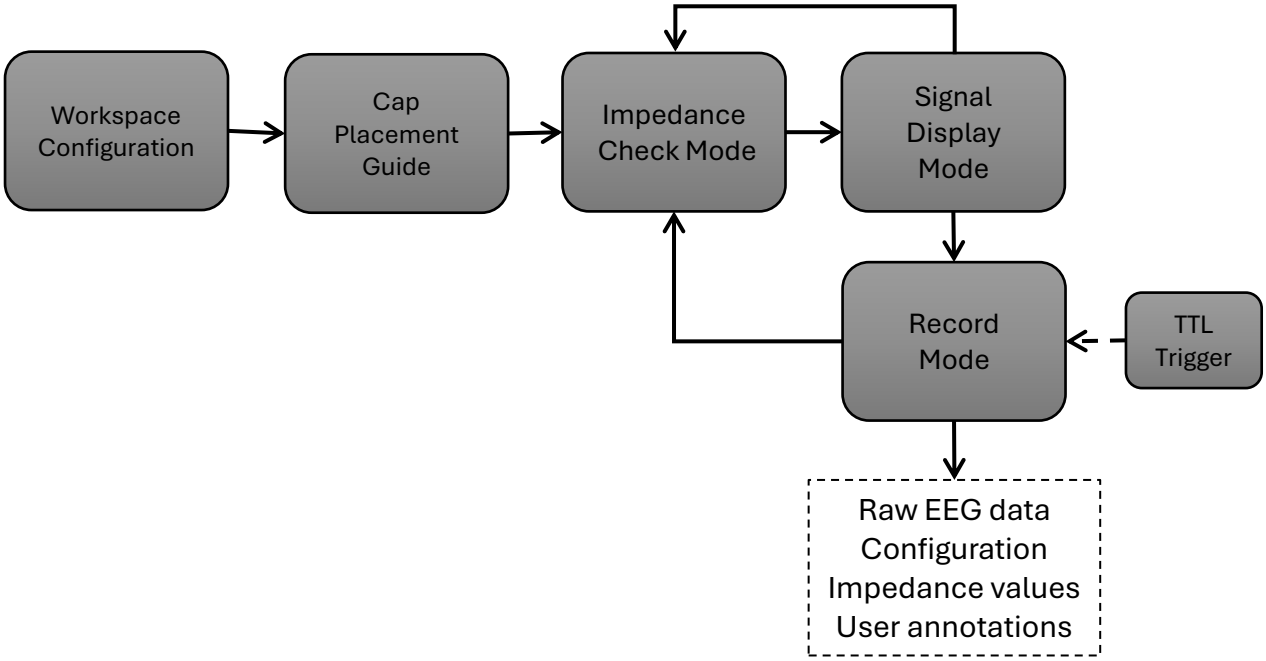
6.1.6 Data Review and Annotation

6.2 The software shall interact with the ELDA hardware via the USB interface box, control its configuration, and initiate data acquisition and file management.

6.3 Top level architecture



6.4 Data Acquisition Module Architecture



7 DETAILED REQUIREMENTS

The following tables summarize the detailed requirement for each software module

7.1 Operational Requirements

PRD	Requirement Description	Rationale / Comments
1	SW lang?	suggested Python has existing database for a lot of routines relevant to EEG
2	Technician mode access to HW ?	Reference to MKS SDK, study ad map the options for decision
3	HW\SW log	Which details\parameters should be logged?
4	HW\SW boot and self tests	
5	SW updates ?	

7.2 User Login

PRD	Requirement Description	Rationale / Comments

6	The system shall require secure user authentication through a login interface before operation begins.	
7	Each user shall be assigned with a profile and permissions (i.e. Technician, Physician, Admin)	
8	Auto-logout after inactivity	
9		

7.3 Patient Management

PRD	Requirement Description	Rationale / Comments
10	The system shall allow the creation of a new patient with a unique global ID	No duplicates across sites
11	The system shall allow loading of an existing patient from the patient database	
12	The system shall the user to manually edit patient information (i.e. Gender, Age, etc.)	

7.4 Patient Database

PRD	Requirement Description	Rationale / Comments
13	The system shall maintain all files related to a specific patient under the same database entry	
14	Each data file shall have a creation date and time and input source.	To help match EEG acquisition with external data and for differentiating acquired from processed data files
15	The system shall allow exporting patient EEG data in EDF+ format	For external processing or hospital documentation
16	The system shall allow exporting EEG annotations and snapshots in CSV and PNG formats	For review and merging with fMRI data
17	The system shall keep track of workflows initiated for each entry in the database (acquisition, processing, review)	
18	Entries that have been assigned all workflows shall prompt the user after 30 days for deletion of raw and processed data files	
19	Database encryption	Do we need\want? Export import implications?

20	How the metadata is linked for export? Is HL7/FHIR relevant?	

7.5 Data Acquisition

PRD	Requirement Description	Rationale / Comments
21	The system shall allow the creation of a new session and document the date and time	
22	The system shall allow the selection of a recording workspace from a predefined list or configure settings in admin mode (?)	Workspaces for out-of-scanner, MRI, custom settings – see appendix 9.1
23	The system shall perform a hardware connectivity check and document the unique hardware ID	Add hardware requirement
24	The system shall display the battery status on the screen	Add hardware requirement
25	The system shall guide the user through EEG cap placement and electrode connection steps	
26	Upon user confirmation, the system shall initiate an Impedance Check Mode	Through hardware communication
27	The system shall provide online visual feedback on the impedance values of each electrode (>100kOhm, 75-100, 50-75, 50-25, <25)	Preferred continuous color scale with tooltip of actual value
28	The system shall not allow moving forward unless all channels have impedance <50kOhm	High values can result in heating of the electrodes
29	Upon user confirmation the system shall display raw signals from all channels, with near real-time latency	
30	The system shall allow configuration of the display screen settings – channel count (1-all), scrolling between channel sets, pp amplitude (10uV, 20uV, 50uV, 100uV, 200uV, 500uV, 1mV), time scale (1s, 5s, 10s, 15s, 20s)	
31	The system shall perform signal quality tests for each channel and highlight bad quality channels in red	
32	The system shall allow the user to switch between impedance and display modes	For manual correction of electrode contact

33	The system shall record the last available impedance values for each channel and assign them to the next saved file	
34	In manual recording mode, the system shall allow the user to begin recording and start saving data batches.	
35	The system shall display the text 'Recording...' and a timer counting recording time	
36	In TTL Trigger mode, the system shall start saving data batches automatically when a trigger has been sent through the hardware	Preferred to also save the 5 seconds before the trigger
37	The system shall allow manual stopping of the recording and maintain all data saved until that time	In manual mode and in case of malfunction / emergency
38	In TTL Trigger mode, the system shall stop recording after a trigger was not acquired for more than 10 seconds	
39	The system shall allow up to 15 minutes of continuous recording	
40	Following each recording stop, or after 15 minutes, the system shall stop acquisition and perform an impedance test, saving the values for each electrode	To ensure proper connection for safety reasons
41	The system shall allow multiple recording segments in each session and save raw data in the patient's database entry with the relevant meta data (date/time, workspace settings, recording length, last impedance values)	
42	The system shall allow the user to add text comments to each recording file during acquisition or after recording has stopped	Notes on patient, issues etc.
43	Upon manual stopping of acquisition the system shall require the user to document the reason for stopping	

7.6 Data Processing

PRD	Requirement Description	Rationale / Comments
44	The system shall allow selecting patient entry from the database and initiate processing workflow	
45	The system shall run the automatic processing workflow on each raw data file	

46	The system shall allow the user to review the processed files and automatically selected inputs	
47	The system shall require confirmation on each processed data file, or manual input of parameters	
48	The system shall rerun the processing with manual inputs for selected files	
49	The system shall save user confirmed processed files in the patient database	

7.7 Data Review and Annotation

PRD	Requirement Description	Rationale / Comments
50	The system shall allow loading processed data from the patient database for review	
51	The system shall display processed data and allow the user to perform the following actions: - Scroll back/forward in 1 second jumps - Scroll back/forward 1 full time window - Change display montage (from list) - Change amplitude - Change timescale - Hide/display individual channels	
52	The system shall allow the user to add annotations on each data file by inputting: - Type of event (drop-down) - Start time - End time / length	
53	The system shall save the processed data file with annotations in the patient database	

7.8 Errors and warnings

PRD	Requirement Description	Rationale / Comments
54	Hardware disconnection during acquisition	Do we need audio beep..?
55	Battery warning during long sessions	
56	TTL triggers missed or malformed	
57	Low disk space for saving data	

7.9 UX\UI

PRD	Requirement Description	Rationale / Comments
58	Zoom/pan in signal view	

59	User-defined presets for visualization	
60	Keyboard shortcuts for annotation	
61	Do we need to produce "accessibility" layer?	