Artificial Intelligence in Software Testing of Medical Devices

Ensuring Compliance & Patient Safety under EU MDR

@ EUHA fair event, Nuremberg – 2025-10-22

BIMPRESS
Impressive Communication

MICROGENESIS

Artificial Intelligence in Software Testing of Medical Devices

Ensuring Compliance & Patient Safety under EU MDR

Robert | Business Partner

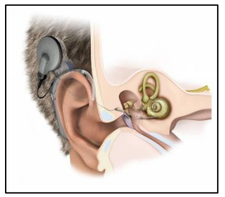
Hearing Tech

Hearing Aids (Class-1/2)

BTE - behind-the-ear
CIC - completely-in-canal

Hearing Implants (Class 3)

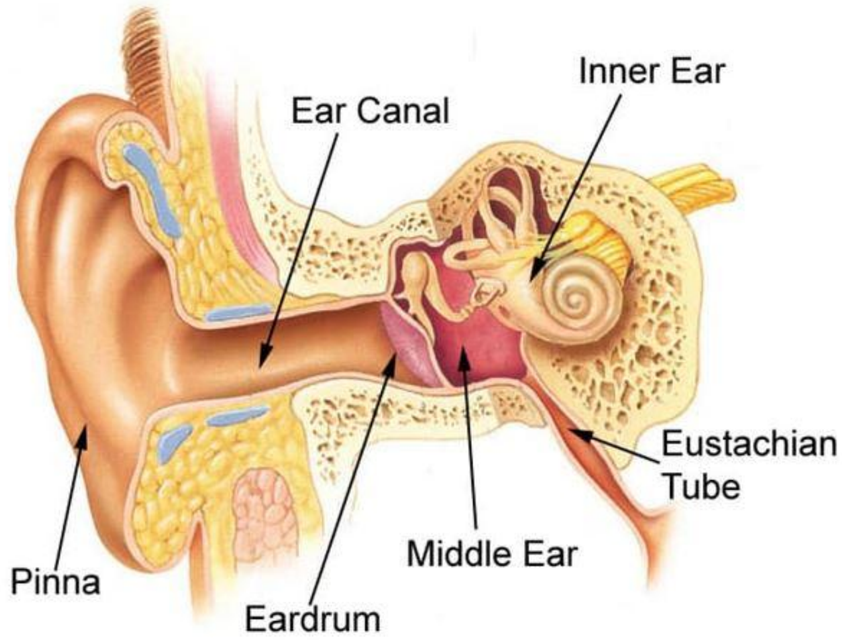
Cochlear
Bone Conduction
Middle Ear



20 Years of Experience in providing development and testing services to the Hearing Tech Industry

Ear the Organ of Hearing & Balance

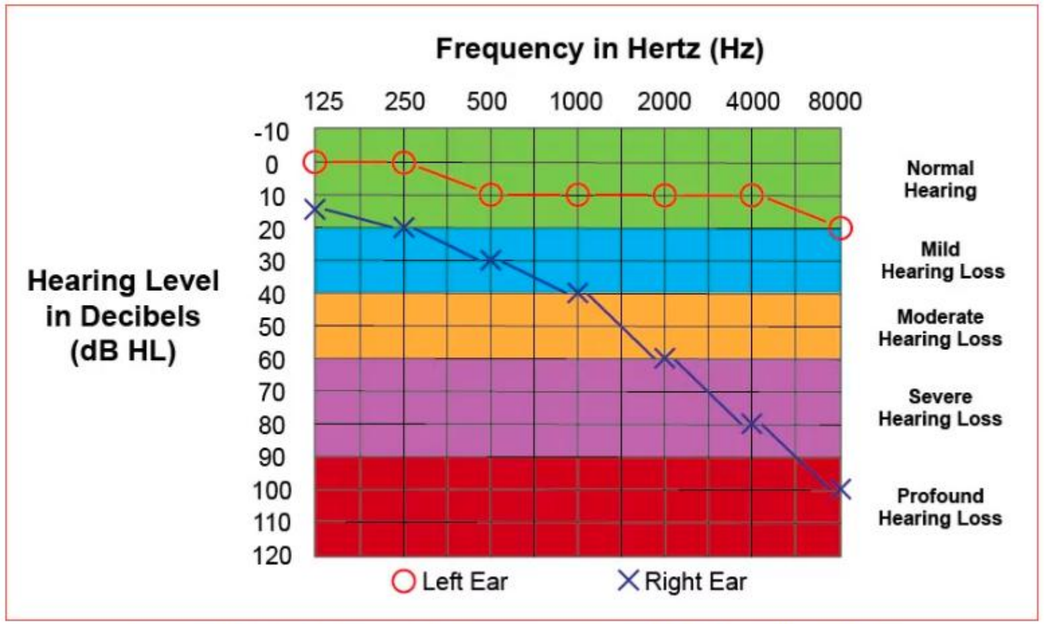
STEP	DESCRIPTION
1. Sound Entry	Sound waves enter through the auditory canal.
2. Vibration	Waves hit the eardrum and are converted into vibrations.
3. Amplification	Ossicles amplify vibrations and transmit them to the cochlea.
4. Signal Conversion	Hair cells in the cochlea convert vibrations into electrical signals.
5. Brain Processing	Signals travel via the auditory nerve to the brain for interpretation.



Audiograms

Visual representation of a person's hearing ability across different sound frequencies and volumes.

Axis	What It Represents
X-axis (Frequency)	Measured in Hertz (Hz), ranging from low pitches (250 Hz) to high pitches (8000 Hz).
Y-axis (Intensity)	Measured in decibels hearing level (dB HL), showing how loud a sound must be for the person to hear it. Lower on the graph = better hearing.



This sample audiogram shows a difference in hearing threshold for the right and left ears.

Types of Hearing Loss

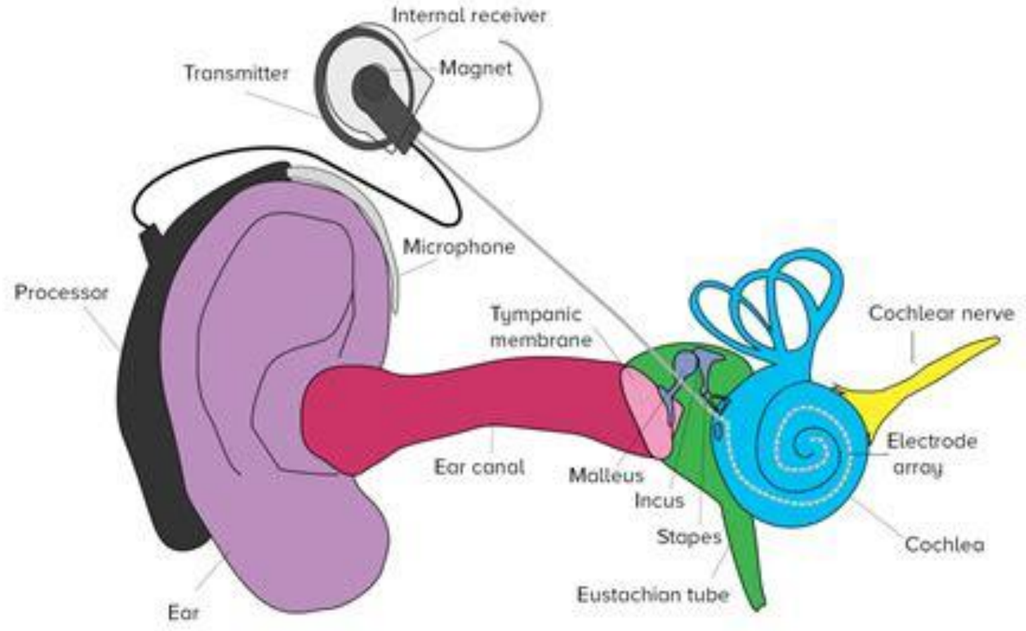
Hearing Loss	Description
Sensorineural	Damage to the cochlea or auditory nerve
Conductive	Common causes include ear infections, fluid buildup, earwax blockage, and structural abnormalities in the ear.
Age-Related (Presbycusis)	Presbycusis is the gradual decline in hearing affecting both ears, especially high-frequency sounds and speech clarity.
Noise-Induced	Prolonged exposure to loud sounds can cause temporary or permanent hearing loss, especially affecting high-frequency hearing.
Tinnitus	Hearing ringing or buzzing sounds without an external source, often linked to hearing loss or neurological issues.

Components of Hearing Aid

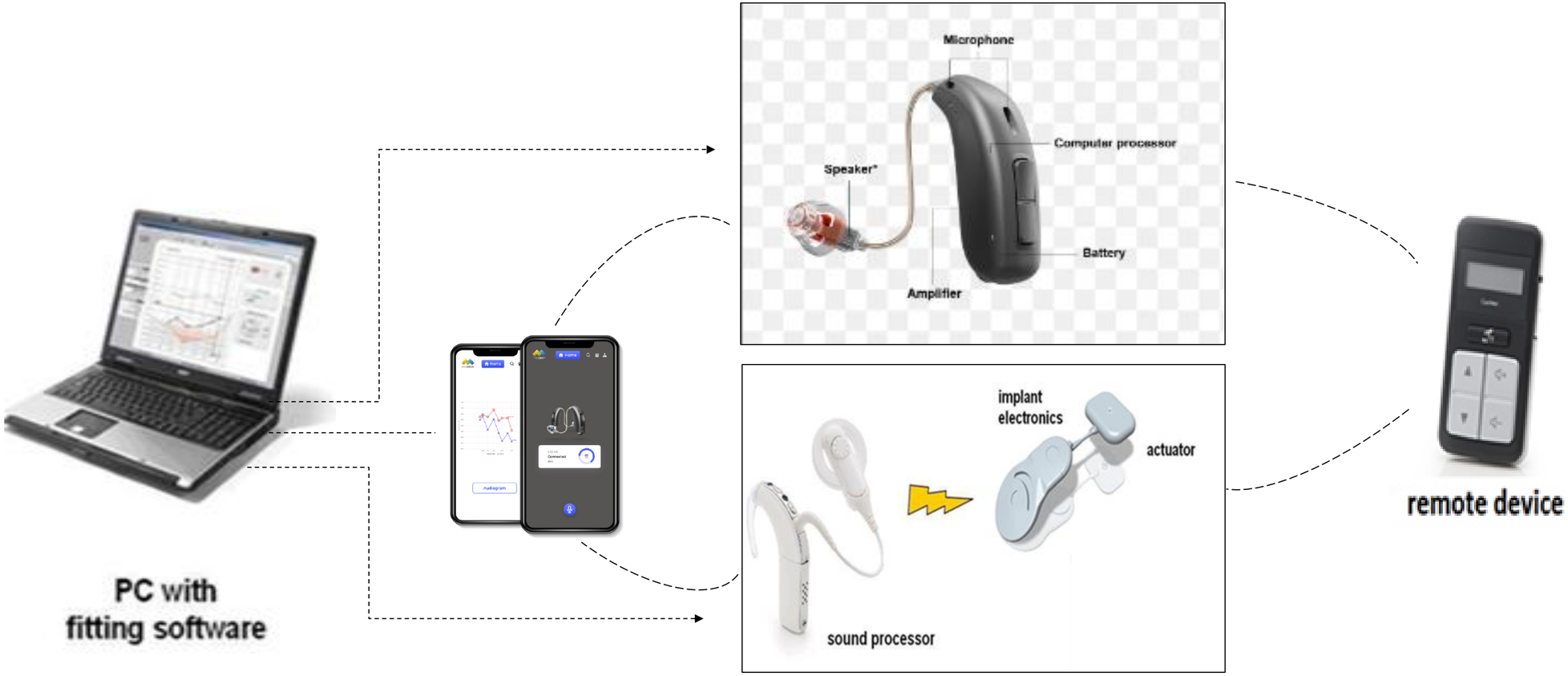
Component	Function
Microphone	Captures sound waves from the environment and converts them into electrical signals.
Amplifier	Boosts the electrical signals to make sounds louder and clearer.
Digital Signal Processor (DSP)	Filters and processes sound—enhancing speech, reducing noise, and customizing output based on user settings.
Receiver (Speaker)	Converts processed signals back into sound and delivers them into the ear canal.
Battery	Powers the entire device; modern versions often use rechargeable lithium-ion cells.
Telecoil (T-coil)	Enables connection to induction loop systems in public spaces for clearer sound.
Bluetooth/Wireless Chip	Allows streaming from phones, TVs, and other devices directly to the hearing aid.
Feedback Cancellation System	Prevents whistling or squealing sounds caused by sound leakage.
Directional Microphones	Focus on sounds coming from specific directions—especially useful in noisy environments.
Remote Control or App Interface	Lets users adjust volume, switch modes, or monitor battery life via smartphone or remote.

Components of Hearing Implant

- **Microphone**: Captures sound from the environment.
- **Speech Processor**: Converts sound into digital signals.
- **Transmitter Coil**: Sends signals across the skin to the internal receiver.
- **Receiver/Stimulator**: Converts signals into electrical impulses.
- **Electrode Array**: Delivers impulses directly to the auditory nerve inside the cochlea.



Hearing Tech Components



Communicating with Hearing Device

- **Wired Connection - USB or Proprietary Cable**
  The hearing aid is connected to a computer running the fitting software via a cable. Common in older models or during initial programming.

- **Wireless Connection – Bluetooth Low Energy (BLE)**
  Modern hearing aids use Bluetooth for direct pairing with fitting software. Allows real-time adjustments without physical cables.

- **Cloud Integration - Remote Programming**
  Audiologists can adjust settings remotely via cloud-based platforms.
  The hearing aid connects to the user's smartphone app, which communicates with the fitting software

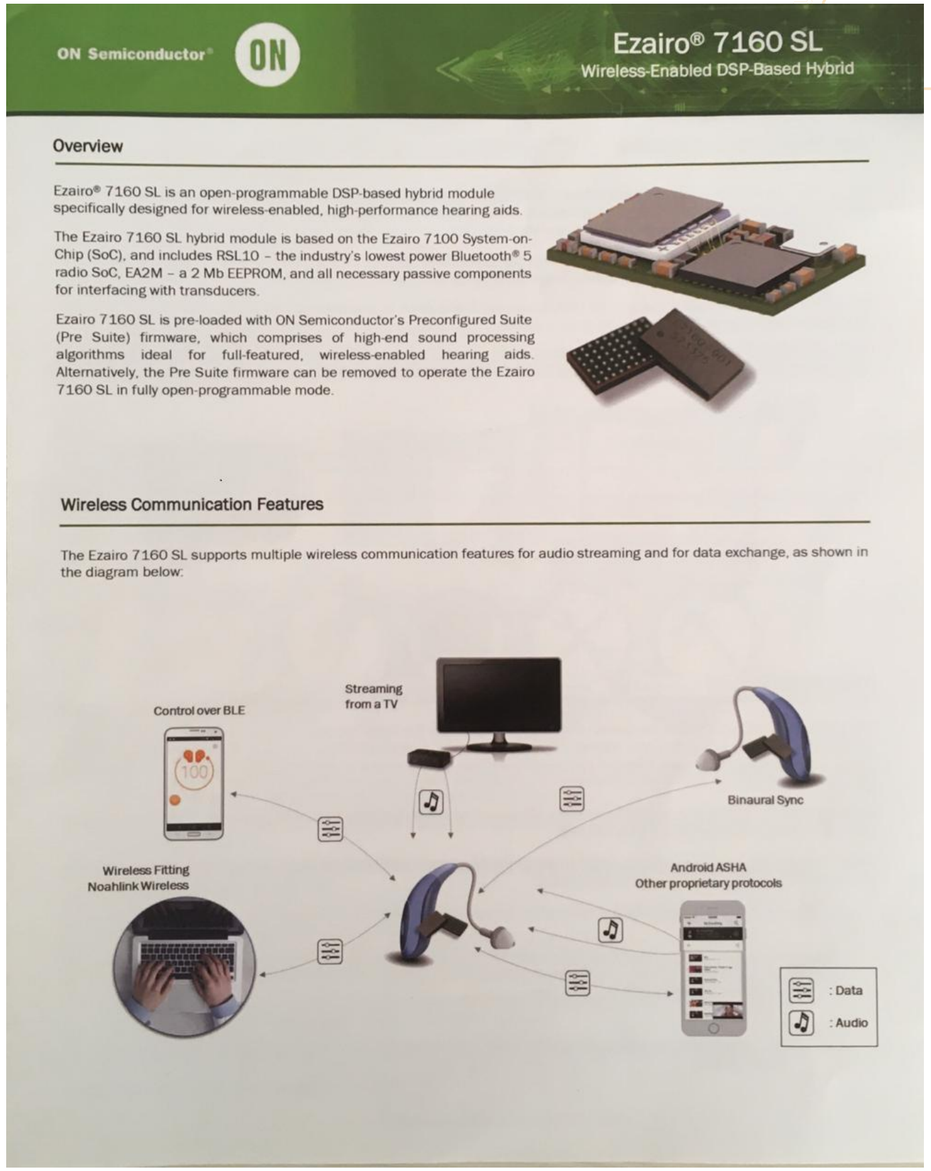
Digital Signal Processor (DSP) in Hearing Device

Specialized microchip that processes incoming audio signals in real time, using sophisticated algorithms to enhance clarity, reduce noise, and personalize the listening experience.

Function	Description
Sound Filtering	Separates speech from background noise, suppresses wind or sudden loud sounds.
Frequency Shaping	Amplifies specific frequency bands based on the user’s audiogram (hearing loss profile).
Dynamic Range Compression	Soft sounds are made audible, while loud sounds are kept comfortable.
Feedback Cancellation	Prevents the annoying whistling or squealing caused by sound leakage.
Directional Processing	Focuses on sounds coming from a specific direction (e.g., in front of the user).
Environment Adaptation	Automatically adjusts settings based on whether you're in a quiet room, a noisy café, or outdoors.

System on Chip (SoC) with DSP

- ❑ **DSP**
- ❑ **Memory**
- ❑ **I/O Interfaces**
- ❑ **Wireless Integration**
- ❑ **Software Development Kit (SDK)**:
  - C-based programming interface
  - Audio processing libraries
  - Debugging and simulation tools



ON Semiconductor

Ezairo® 7160 SL

Wireless-Enabled DSP-Based Hybrid

Overview

Ezairo® 7160 SL is an open-programmable DSP-based hybrid module specifically designed for wireless-enabled, high-performance hearing aids.

The Ezairo 7160 SL hybrid module is based on the Ezairo 7100 System-on-Chip (SoC), and includes RSL10 – the industry's lowest power Bluetooth® 5 radio SoC, EA2M – a 2 Mb EEPROM, and all necessary passive components for interfacing with transducers.

Ezairo 7160 SL is pre-loaded with ON Semiconductor's Preconfigured Suite (Pre Suite) firmware, which comprises of high-end sound processing algorithms ideal for full-featured, wireless-enabled hearing aids. Alternatively, the Pre Suite firmware can be removed to operate the Ezairo 7160 SL in fully open-programmable mode.

Wireless Communication Features

The Ezairo 7160 SL supports multiple wireless communication features for audio streaming and for data exchange, as shown in the diagram below:

Emerging Enhancements

- **AI & Machine Learning**: Adaptive sound environments, learning user preferences over time.
- **Edge Processing**: Real-time sound analysis without needing cloud connectivity.
- **Health Monitoring Sensors**: Some devices now track physical activity or even detect falls.

Fitting Software - Development

Provides tools for audiologists:

- ❑ Manage client data
- ❑ Perform hearing tests
- ❑ Audiogram Input & Analysis
- ❑ Program hearing aids
- ❑ Data Logging & Usage Insights

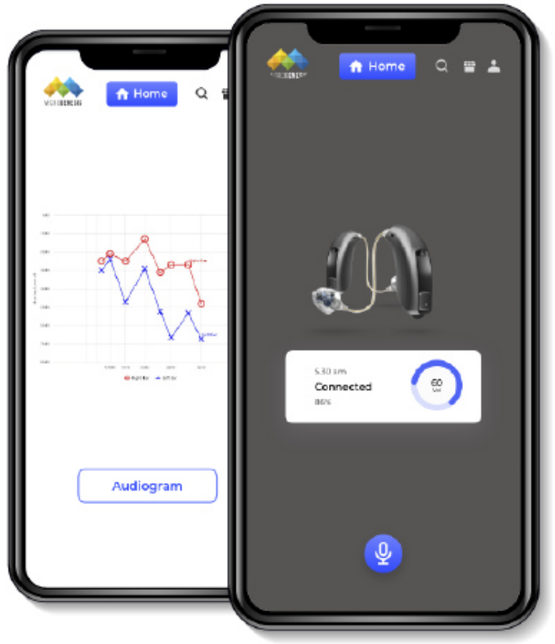
Horentek – Italy

Mobile App Development

- Manage hearing device
  - volume control
  - manage preset configuration
  - track battery status

- Features
  - Modern UX design for easy navigation
  - DLL’s built on Ezario platform
  - Supports both Android and iOS platform.

- Technology
  - Google Flutter & Dart



Hearing Tech Software

- **Software as a Medical Device (SaMD)**
  - **Definition:** Standalone software that performs medical functions without being part of a physical device.
    - **Fitting Software**
    - **Mobile App**
    - **Remote Control**

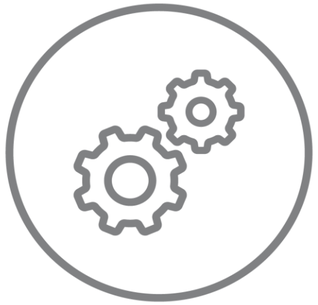
- **Software in a Medical Device (SiMD)**
  - **Definition:** Embedded software that is integral to the functioning of a physical medical device.
    - **Firmware in hearing device**

Expertise

Developing software solutions

Comprehensive and rigorous testing solutions

Future-ready frameworks to meet Regulatory Requirements



AI Augmented Test automation

Documentation

Regulatory Framework

Core Standards & Guidance

ISO 13485	**ISO 14971**	**IEC 62304**
Quality Management	Risk Management	Software Lifecycle
IEC 62366	**EU MDR Annex VIII**	**MDCG 2019-11**
Usability Engineering	Device Classification	Classification & Qualification

“Compliance isn’t optional — it's the foundation of patient safety in MedTech.”

Software Development Process

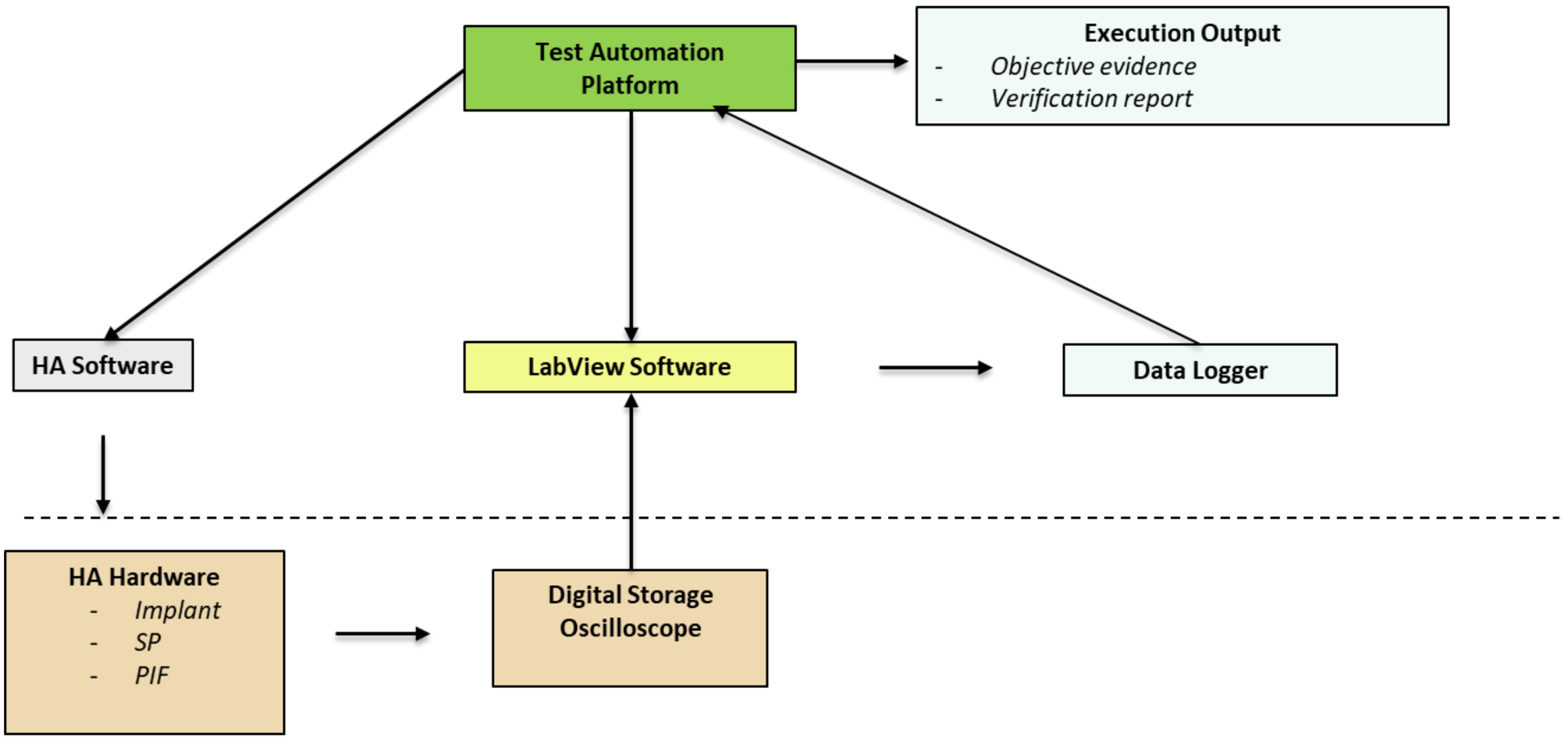
Requirements Capture

Architecture & Design

UX Creation

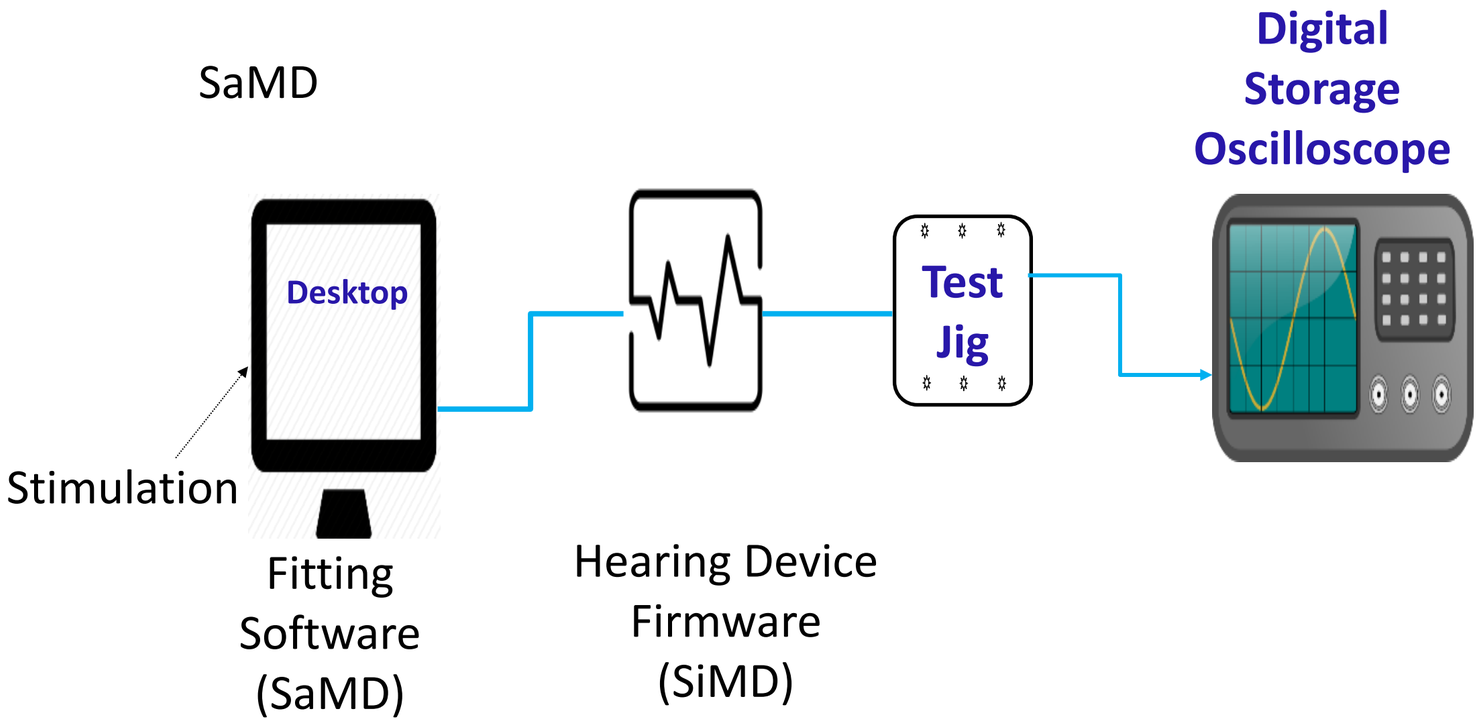
Code to Standards

Device Testing Framework



Cochlear™ *Belgium, Australia*

Hardware in Loop - Testing



Belgium, Australia

Testing Scope - RF LINK AND DATA LOGGING

- **RF Link**
  - Data and power transmission across RF Link (**external sound processor** and the **internal implant**).

- **Data Logging**
  - HA's low level raw data log files – device connection, FW, time taken for data usage etc
  - Wireless accessories volume, sensitivity, usage etc per day.

Testing Scope - BATTERY TESTING

- **Battery Life Estimation**
  - Using clinical software and measuring voltage and current

- **Power optimisation**
  - Impedance Measurement on Implant
  - Compliance Limit measurement on Implant
  - Different Skin Flap Thickness

- **Battery charger tests** –Specific to Implants

- **Audio streaming power optimisation**
  - Testing the power optimisation for wireless audio streaming accessories

Belgium, Australia

Testing Scope - FIRMWARE TESTING

- **Unit tests**: µC programming logic**,** check the loop function and code branches
- **System Test**: To allow for device interaction during execution, sound processing device operation modes, volume, sensitivity, LED indicator behaviour, pairing and use with wireless accessory
- **Remote Device System Test**: To verify the interfacing of processors with wireless accessory
- **Exploratory testing:** To test newly added features or functions based on requirements

Belgium, Australia

Customers

- Cochlear – Belgium, Australia
- Horentek – Italy
- Audiphone - Germany

Evolving Needs in Medical Device Testing

Why AI Matters Now ?

Exponential data growth in MedTech

Increasing complexity of SiMD & SaMD

Regulatory & safety demands intensifying

Faster innovation cycles required

To meet these new challenges without compromising on safety or compliance, we need a new approach — one that leverages AI to augment and evolve our testing frameworks.

How AI Enhances Testing

AI-driven Capabilities:

1. Automates & optimizes test case generation
2. Predicts potential errors before they occur
3. Identifies anomalies & security threats in real time
4. Expands test coverage, including edge cases
5. Simulates load & performance scenarios

The Future: Agentic AI

Emerging autonomous quality agents

Adaptive, self-directed validation of medical device software

Next step in safer, more efficient MedTech development

Development, Testing & Compliance Services

1. Fitting Software Modernization, Mobile App Development
2. Firmware & Embedded Systems Development
3. AI-driven software Verification & Validation
4. MDR compliance documentation & audit support
5. Risk & quality engineering frameworks
6. Lifecycle & post-market surveillance alignment

Dialog

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