Audixi 10 smart Audiometer

Our Company at a glance

What we do

Kiversal is a **medtech company** with the mission of **developing a new medical infrastructure** by using **smart medical devices** with high connectivity to achieve the **digital transformation** of processes

Company founded

headquarters

Feb 2016

Barcelona

Value Proposition

We want to become a benchmark in the medical sector by **connecting our diagnostic smart medical devices to the medical centres infrastructure and combining medical equipment, ICT and AI for the diagnosis of basic diseases** related to hearing loss

Audixi 10 | Description and configurations

DIGITAL AUDIOMETER, PRODUCTIVE AND CONNECTED

- Technology digital tablet. Easy to use. Fast learning.
- Remote and instant metrological calibration (fully operational)
- Customizable to specific customer needs
- Standalone (with Li-Po battery on '**+**' models)
- Connected to the Internet (and to the customer technology systems)
- Compatible to most printers on the market (network and USB)
- **Patented** calibration system assisted remotely
- **Plug & Play** transducer recognition system

CONFIGURATIONS (4 models)

- Audixi 10 A   Occupational medicine. **Air conduction** pure tone
- Audixi 10 B   Diagnostic. Air conduction + **bone conduction**
- Audixi 10 C   Advanced diagnostic. Air and bone conduction + **speech audiometry**
- Audixi 10 D   Clinic diagnostic. Air and bone conduction, speech audiometry + **over-threshold tests**

All models can optionally include High Frequency (HF) tests and Li-Po batteries (models +)

Models *Audixi 10 HF*:   AHF / BHF / CHF / DHF
Models *Audixi 10 +*:   A+ / B+ / C+ / D+ / AHF+ / BHF+ / CHF+ / DHF+

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Audixi 10

Innovation into audiometry

✓ **DIGITAL TRANSFORMATION**: Less time in the medical procedure to be performed applying ICT solutions (data **integration**: HIS/EMR)

✓ **INNOVATION**: Maintenance and calibration assisted remotely (**patented**), no downtime by using our **Plug&Play** recognition system for transducers

✓ **CLOUD connectivity (Machine Learning)**: automated speech audiometry testing with speech recognition on the cloud (KiCloud)

Digitize the audiometric sector

Remote maintenance and calibration

IoMT + Artificial Intelligence

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Audixi 10 features

Digital transformation
-Intuitive and easy-to-use interface.
-Compact, ergonomic and easy to use. Its technical capacity allows updates without changing product.
-Report generation with coloured audiogram in PDF, CSV and XML formats.
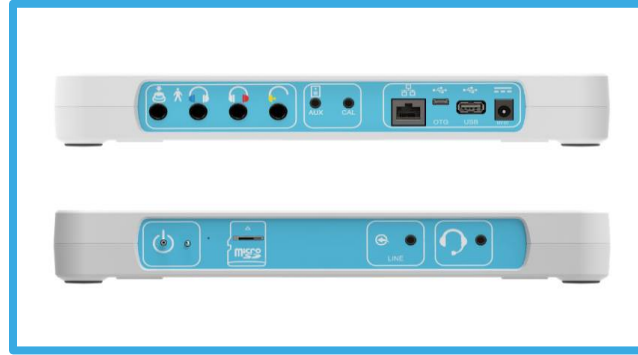
Productive and connected
-Direct data integration (HIS/EMR).
-File export to SFTP / SMB / GDT shared folder on your computer in PDF, CSV and XML formats.
-Reports emailed in PDF format.
-Remote management of the device (VNC client).
-Printing of reports on network (Ethernet, WiFi) and local (USB) printers.
-Agenda for the testing programming.
-Internal databases of patients and tests.

Innovation in calibration
-Safe, reliable and easy care.
-Its patented instant metrological calibration service makes your audiometer be fully operational, without unplanned stops or downtime.
-Different headphones (transducers) can be shared between several devices.
-Plug&Play transducer recognition system.

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Audixi 10 | Innovation into audiometry

WHY IS THE Audixi 10 A UNIQUE AND INNOVATIVE AUDIOMETER IN THE MARKET?

Competitive advantages:

- <u>**Digital technology**</u>. Ergonomic and easy to use. Rapid learning
- Automatic audiometry (from the most basic model). Configurable execution frequencies
- <u>**Portable and standalone**</u> (with rechargeable Li-Po battery: up to 6 hours of autonomy)
- **Connected to the Internet**. Prepared for remote monitoring and AI upcoming applications
- File export to shared folder in **SMB** protocol on your computer in PDF, CSV and XML formats.
- File export to shared folder in **SFTP** protocol: secure file transfer over the Internet
- File export to shared folder in **GDT** protocol: text files (German market)
- Direct data integration (HIS / EMR): REST and SOAP WebServices
- Report emailed in PDF format directly from the device
- Connectable to most printers on the market (local and / or network)
- Upgradable to higher models without changing physical device
- <u>**Remains fully operational**</u>. Without unplanned stops or downtime derived from maintenance and calibration
- Different headphones (transducers) can be shared between several devices
- Agenda for scheduling tests. Internal patient and tests databases (allows "multi-consultation")
- Reports with colour audiogram (PDF, CSV and XML formats)

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# Audixi 10 | Functions and Technical Specifications

FEATURES

- Two independent channels
- Manual pure tone audiometry with or without masking, narrowband or wideband
- Automatic pure tone audiometry (Hughson-Westlake) via air and bone conduction
- Speech audiometry: direct and/or recorded voice
- Over threshold tests: Sisi & Weber, UCL & MCL, ABLB & Stenger, MLB & Tone Decay (divided into 4 packages)
- Patient management and appointment calendar management
- Patients and tests database (up to 100,000 tests)
- Customizing the system: languages, date and time, local / remote calendar, diagnostics (3) levels (3), printers, network (DHCP or manual)
- Test report with colour audiogram (printing and e-mailed in PDF format, export to SFTP / SMB / GDT shared folder in PDF, CSV, XML formats, direct integration with REST and SOAP WebServices)
- Compatible with most printers on the market (Ethernet, WiFi and USB)

TECHNICAL SPECIFICATIONS

- Signals: continuous pure tone, pulsed tone, warble tone and external signal
- Synchronous and contralateral masking, narrowband or wideband
- Type 1, 2, 3 or 4 Pure Tone Audiometer depending on configuration (IEC 60645-1)
- Type A or B Speech Audiometer depending on configuration (IEC 60645-2)
- Attenuation stepping 1, 2 and 5 dB
- 10.1" colour multi-touch screen , screen resolution of 1024 x 600 pixels
- Power supply (100V...240V, 50/60Hz) and Li-Po battery (*optional*)
- Dimensions: 278 x 178 x 36 mm (L x W x H)
- Weight 1 kg (without battery)

Optional High frequency and Li-Po battery

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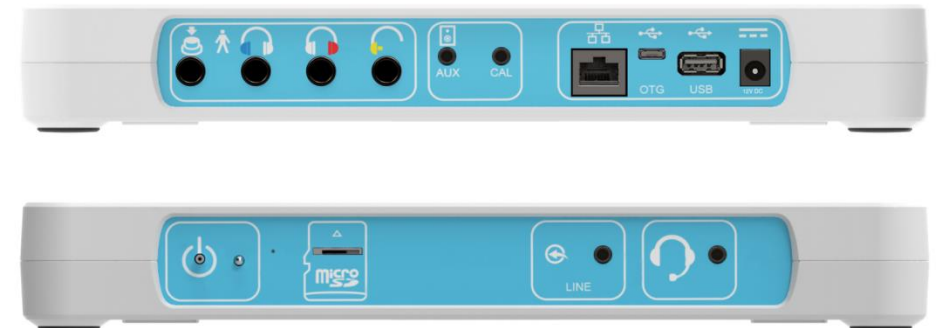
Audixi 10 | Levels & frequencies. Standards

LEVELS AND FREQUENCIES

➢ Via air conduction: Level (max.): -10 to 120 dB HL

Frequencies: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz

➢ Via bone: B71 Level (max.): -10 dB to 80 dB HL

Frequencies: 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 Hz

  B81 Level (max.): -10 dB to 90 dB HL

Frequencies: 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 , 8000 Hz

➢ High Frequency : Level (max.): -10 to 100 dB HL

Frequencies: 8, 9, 10, 11.2, 12.5, 14, 16 kHz

➢ Free field speakers: Level (max.): -10 to 100 dB SPL

Same frequencies as in high frequency and air conduction

STANDARDS AND REGULATIONS

✓ Medical Device 93/42 / EEC Class IIa

✓ ROHS2 2011/65 / EU

✓ EN 60645-1 / EN 60645-2 / EN 60645-4 / EN 60601-1 / EN 60601-1-2

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Audixi 10 | Reports and audiograms

DIAGNOSTIC SUITE:

Report with Colour audiogram (printing and e-mailed in Pdf format, export in Pdf, XML and CSV formats)

Index Calculation:
- ✓ ELI index (Early Loss Index)
- ✓ Index SAL (Speech Average Loss)
- ✓ Modified Klockhoff index

Calculation of diagnostics including Hearing loss degree:
- ➢ 1979 AMA/AAO (American Medical Association)
- ➢ BSA (British Society of Audiology)
- ➢ Fletcher Index

Connectivity & Data integration

All these features allow to **CONNECT** our device directly to the **SYSTEM**.

- ✓ SFTP/SMB (CIFS)/GDT Shared Folder connection

- ✓ ETHERNET CONNECTIVITY as standard

- ✓ Parseable messages in XML, CSV and PDF

SFTP/SMB (CIFS)/GDT
Shared Folder

PDF, CSV, XML files

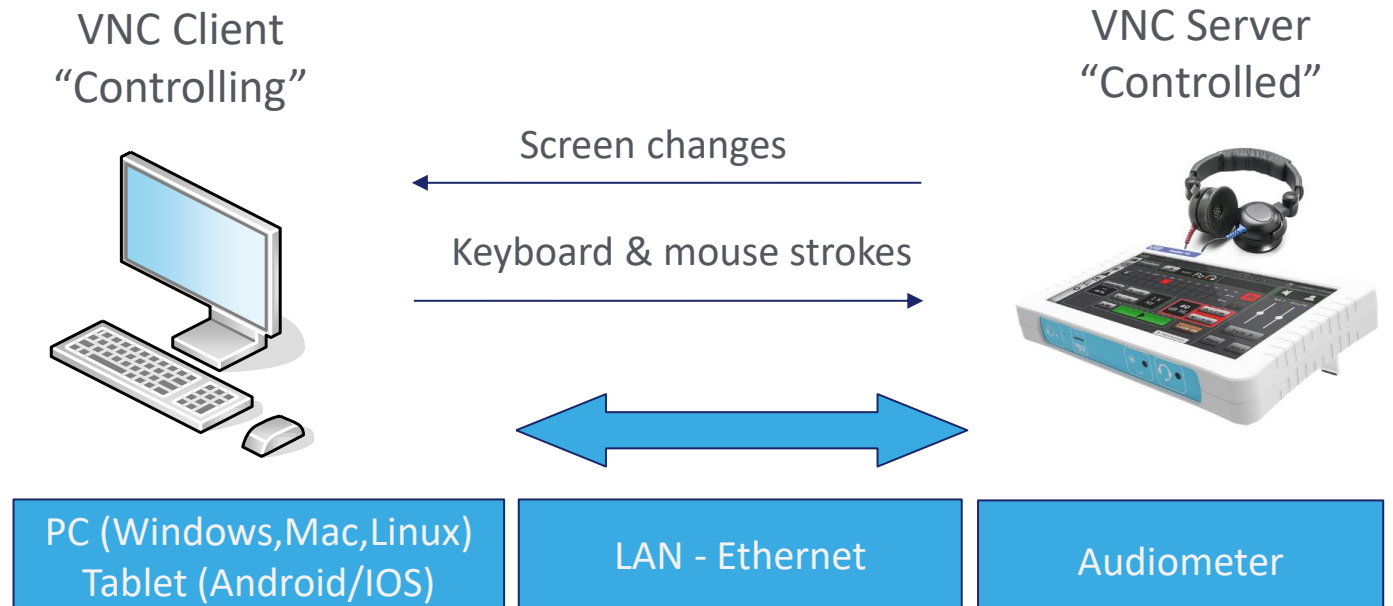| PC/Server (Windows,Mac,Linux) Tablet (Android/IOS)	LAN - Ethernet	Audiometer

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VNC Remote Control

These features allow to **CONTROL** our device **REMOTELY**.

- VNC is a graphical desktop-sharing system that uses the Remote Frame Buffer protocol (RFB) to remotely control another computer.

- It transmits the keyboard and mouse events from one computer to another, relaying the graphical-screen updates back in the other direction, over a network.

- Free VNC clients: TightVNC (Windows, Mac, Linux), Remmina (Linux)

VNC Client "Controlling"

Screen changes

Keyboard & mouse strokes

VNC Server "Controlled"

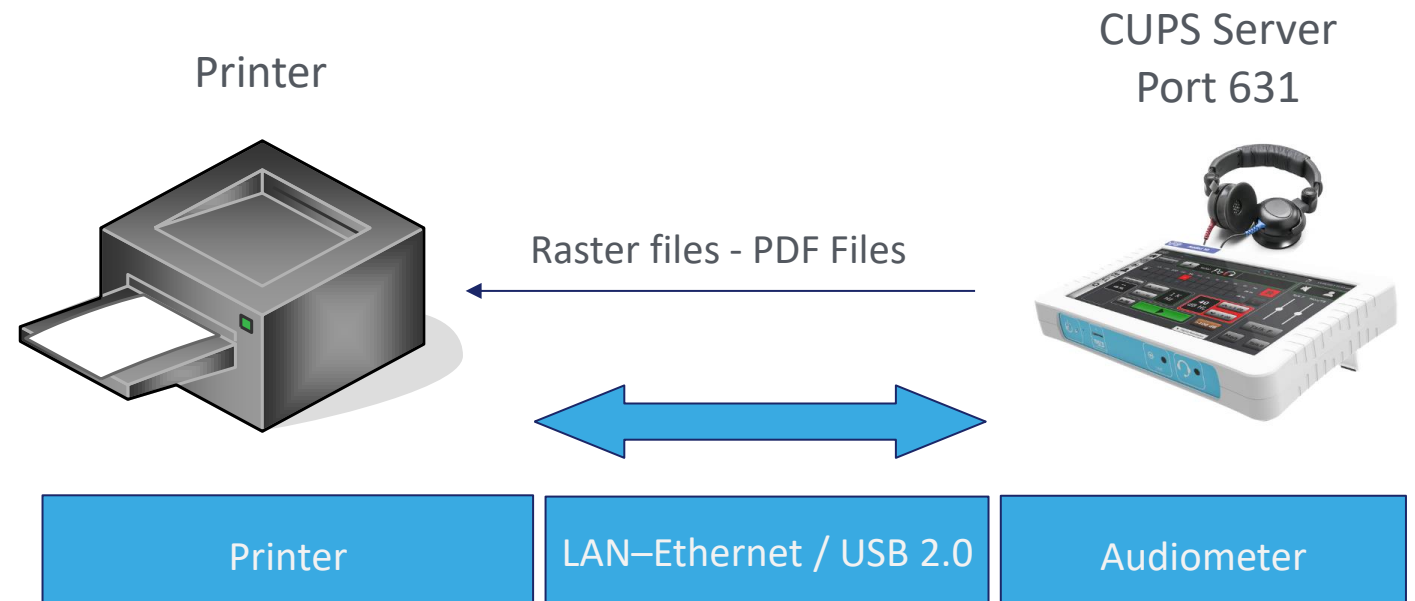| PC (Windows,Mac,Linux) Tablet (Android/IOS)	LAN - Ethernet	Audiometer

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Printer connectivity CUPS server

These features allow to **PRINT** reports in USB or network printers.

- The audiometer implements a CUPS server: CUPS is the standards-based, open source printing system developed by Apple Inc. for macOS® and other UNIX®-like operating systems. CUPS uses the Internet Printing Protocol (IPP) to support printing to local and network printers.

- Generic Drivers are installed:
  ESC – Dot Matrix
  PCL 3, 4, 5c, 6
  Postscript

- PPD Drivers can be downloaded from https://www.openprinting.org/printers or from manufacturers

Printer

CUPS Server
Port 631

Raster files - PDF Files

| Printer | LAN–Ethernet / USB 2.0 | Audiometer |

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Audixi 10 | Our range of smart-audiometers

No need to change our device. **Audixi 10** can be upgraded from **Occupational Medicine** to **Clinical Diagnosis** by adding the corresponding transducers and/or accessories and releasing Software licenses.

Occupational medicine (Models A to AHF+)
- Screening: pure tone audiometry (PTA) tests, via air conduction, with or without Masking and Automatic audiometry (Hughson-Westlake)

Diagnosis (Models B to BHF+)
- Plus via bone conduction: manual and automatic tests with or without masking

Advanced Diagnosis (Models C to CHF+)
- Plus Speech audiometry: SRT, WRS, UCL/MCL Sources: direct and/or recorded voice (CD, FLAC) and over-threshold tests UCL and MCL

Clinical Diagnosis (Models D to DHF+)
- Plus Over threshold tests: Sisi and Weber; ABLB and Stenger; MLB and Tone Decay

NEW OPTIONAL TESTS:
- **OPTIX Module** for Vision Control as a Software module for Audixi 10
- **Masking assessment**: Auto masking and Masking help
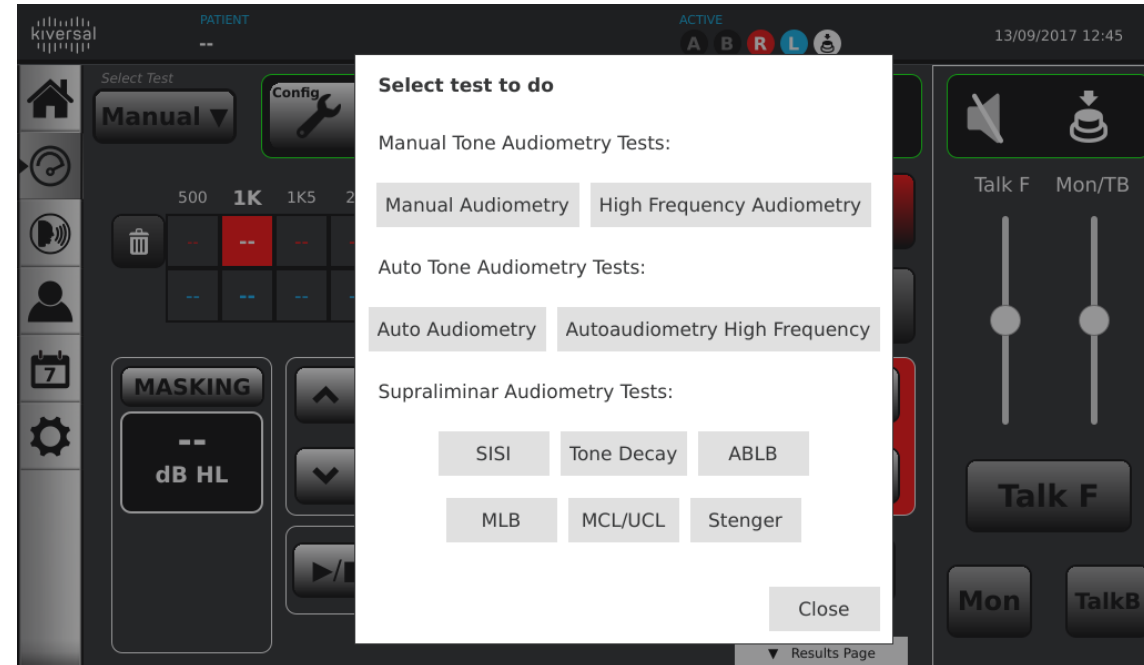
Audixi 10 | OPTIX Module

The ideal companion for your Kiversal Audixi 10 audiometer

OPTIX is our first **Audixi 10 add-on module**. Our new digital control vision system with a remote touch screen console to simplify the control of the instrument from the first use and to guarantee the professional a better working position .

FEATURES:

- Portable: ultra-light (460g.)
- Complete set for eye examination: adjustable examination distance between 40cm and 6m.
- Optotypes presented in a casual way. Wide range of application.
- Remote touch screen console. It simplifies the control of the device.
- Software upgradeable through a simple automatic function.

TECHNICAL SPECIFICATIONS:

- Display technology: IPS TDDI 16.7 M colours | LED backlight | Stereo test in red - cyan mode
- Multilingual interface
- Integration: MB/CIFS, SFTP, DGT, SOAP & REST Web Services, email (SMTP)
- Data format: PDF (report), XML, CSV
- Connectivity: Ethernet, WiFi

REMOTE CONTROL:
Audixi 10 audiometer
10.1" colour multi-touch screen.
Screen resolution of 1024 x 600 pixels.
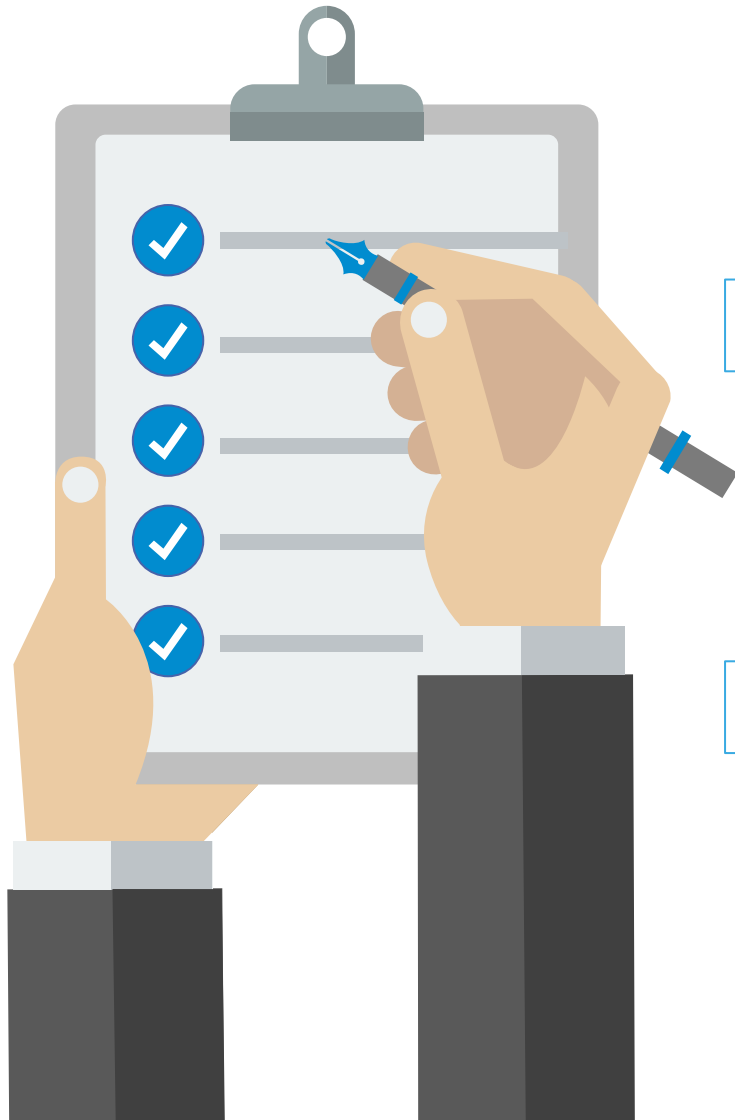*Operating system Linux Embedded.*

SCREEN DISPLAY:
Tablet 10.3": FHD Resolution 1920 x 1200 (220 ppi).
RAM: 2 GB LPDDR4x*.
32 GB Disk (eMCP4x, eMMC)
Dimensions (L x W x H): 244.2 x 153.3 x 8.15 mm.
Weight 460g.
Battery 5000 mAh. Battery life 8.5 hours.

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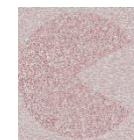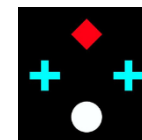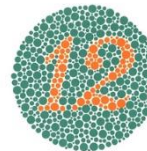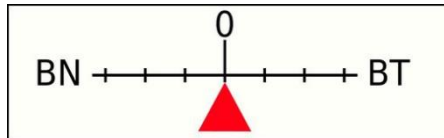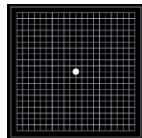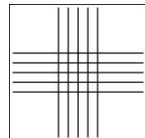
Current Projects

Pilot tests tele-audiometry, new tests and automated speech audiometry (IA)

on-going

1

Pilot test for tele-audiometry with a public Hospital in Barcelona area for Primary care.

Objective: carry out audiometry diagnostic tests in a large area of Catalan territory without the need to transfer audiologists.

In development

2

New tests developed in-house with the collaboration of public Hospitals:

- ✓ Digital Visual Reinforcement Audiometry (VRA) test
- ✓ Pediatric Conditioned Play Audiometry (CPA)
- ✓ Tinnitus test
- ✓ Ability to add more tests

In development

3

Automation of Speech audiometry by using Machine Learning (IA): Project with the collaboration of CREB-UPC.

Objective: to reduce timing in performing the current test (about 2 hours). Industry 4.0

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KiCloud: Our solution

an easy-to-use and efficient solution to solve inefficient,
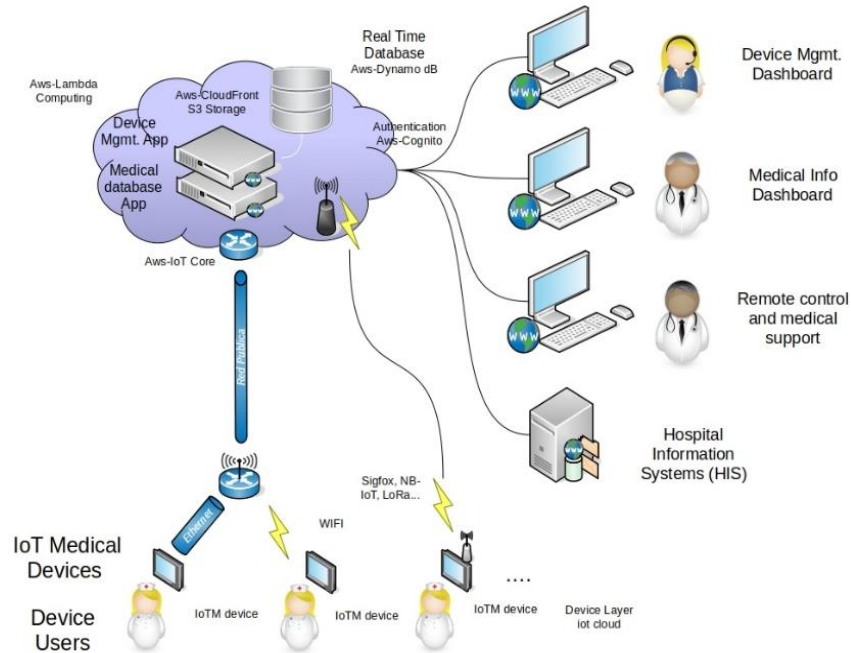analogue medical data processing

In development

Figure 1: KiCloud architecture connecting multiple devices and allowing remote control for recalibration purposes and automated updates

Serverless, SaaS-based Application with an IoT layer that offers data transfer from medical diagnostic devices to any HIS system or any complementary device using a container app.

NO SERVER MANAGEMENT: There is no need to provision or maintain any servers, there is no software or runtime to install, maintain or administer

FLEXIBLE SCALING: The application can be scaled automatically or by adjusting its capacity through toggling the units of consumption (e.g. throughput, memory) rather than units of individual servers

PAY FOR VALUE: Pay for consistent throughput or execution duration rather than by server unit

AUTOMATED HIGH AVAILABILITY: Serverless provides built-in availability and fault tolerance. Clients do not need to architect for these capabilities since the services running the application provide them by default

NOAH compatibility and automated Speech Audiometry testing with speech recognition on the cloud

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Contact us
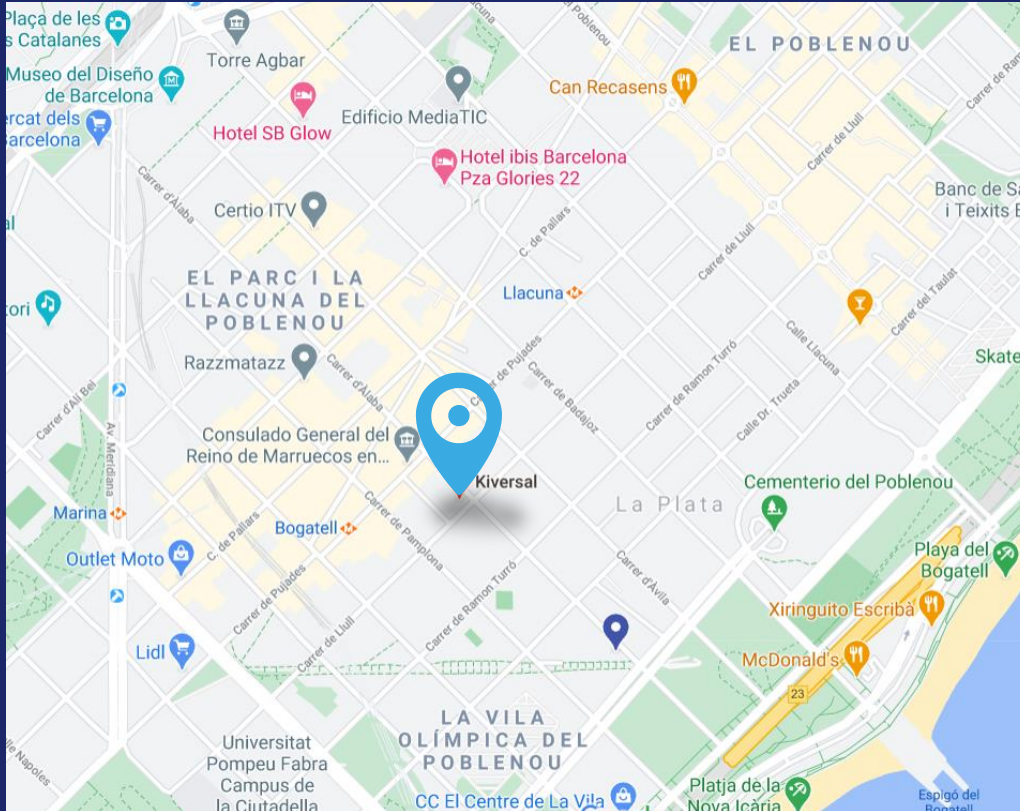
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