Leitwert – Modular IoMT Backbone for Digital Health

Executive Summary

- Leitwert is a Zurich based IoMT company (10 employees) founded in 2014. We create **software for connected biosensors and their integration into research and healthcare processes**.

- Next to a licensable embedded framework for biosensors, we offer gateway software and a vendor-agnostic platform to integrate biosensors, manage the device fleet, aggregate biomarkers and integrate with information management systems and analytics tools. This **enables healthcare proviers and researchers to manage their digital health ecosystem for location-independent, continuous and real-time measurement and analysis of digital biomarkers**.

- Why Leitwert:
  - Open APIs for vendor-agnostic integration of biosensors, IT systems and analytics tools
  - Seamless technology stack from device firmware over gateways to cloud applications
  - Full data sovereignty – you decide where to host the cloud, store data and give access
  - Our innovative technology is already in use for GCP compliant studies, medical grade devices and patient monitoring pilots in hospitals

- Among our customers are leading Swiss wearable manufacturers and research institutions.
  References: Jens Eckstein (CMIO, University Hospital Basel), Walter Karlen (Mobile Health Systems Lab, ETH Zürich)

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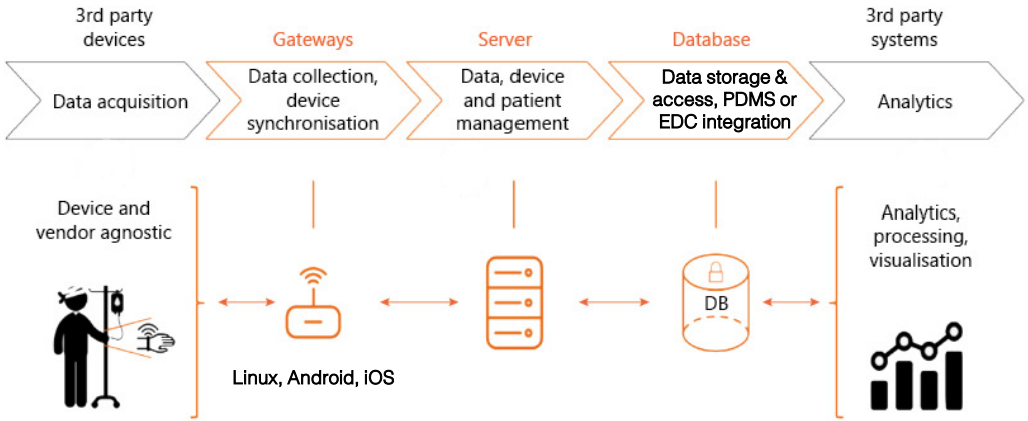
The Vision of Digital Health Relies on Access to Digital Biomarkers

- The typical digital health use case involves measuring large amounts of health data with wearable biosensors and making that data accessible in real-time for data analysis.
- Leitwert addresses two unmet needs of the B2B digital health space:
  - **Interoperability** between data producing sensors and data consuming applications.
  - Enabling device manufacturers, care providers and CROs to **manage the resulting vendor-agnostic IoMT ecosystems**.
- To achieve this, we developed a modular technology platform with open APIs on every level of the IoMT stack, which allows you to integrate with 3rd party systems on device, gateway or cloud level.



Real World Data for Clinical Trials

Continuous Patient Monitoring

Disease Management and Elderly Care

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Digital Health Applications – References

Publication in the Journal of Digital Biomarkers

Device- and Analytics-Agnostic Infrastructure for Continuous Inpatient Monitoring: A Technical Note

Digit Biomark 2020;4:62-68. doi: 10.1159/000509279
Brasier N, Geissmann L, Käch M, Mutke M, Hoelz B, De Ieso F, Eckstein J

https://www.karger.com/Article/FullText/509279

Digital Trial and Intervention Platform

Preferred partner to build a platform for digital health research (Scope: gateways, device hub, frontend application for IoMT)

ETH zürich

Eurostars Project: Smart AF

Preventive screening of atrial fibrillation in high-risk patients

Universitätsspital Basel
Mehr wissen. Alles geben.
eurostars
PREVENTICUS
RHYTHM IS LIFE
European Commission
ascom
112Motion
EUREKA

I-Move Study

Identification of patients requiring early mobilization based on activity data

biofourmis
Universitätsspital Basel
Mehr wissen. Alles geben.

Patient Monitoring: Covid-19 Pilot Operation

Continuous monitoring with medical wearable gathering >5000h of data from Covid-19 patients (HR, SPO2, RR, T)

Universitätsspital Basel
Mehr wissen. Alles geben.

Start-up Award Finalist

at Roche Future X Healthcare 2019 (Top 12 out of 150 applications)

Future X Healthcare
From Science to Patients
Roche

Sleep Study

https://sleeploop.ch/

ETH zürich
UniversitätsSpital Zürich
Der Balgrist
Universität Zürich
UNIVERSITÄTS-KINDERSPITAL ZÜRICH
Psychiatrische Universitätsklinik Zürich

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Device Manufacturers – References

biofourmis.com

greenteg.com

avawomen.com

Open access hardware
by Leitwert

kenzen.com

sleeploop.ch

leitwert.

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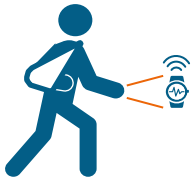
Digital Health Applications

Clinical Study – Continuous Data Capture Anywhere

Features

- Frontend provides workflows for participant registration, assignment of biosensors and monitoring of biosensors and gateways
- Use connected biosensors to conduct ECRIN and GCP compliant studies in clinics and at patient‘s homes
- Integrate with existing EDC and PDMS systems to data storage and synchronization
- Coming soon: Real-time data quality monitoring, alarms & notifications, possibility to deploy 3rd party algorithms for real-time data analysis



1 Register participants (pseudonymized), assign biosensors and gateways.

2 Continuous data capture with automated monitoring of data availability and online status of devices.

3 Granular access management. Export data for post-processing or deploy algorithms for real-time analysis (coming soon).

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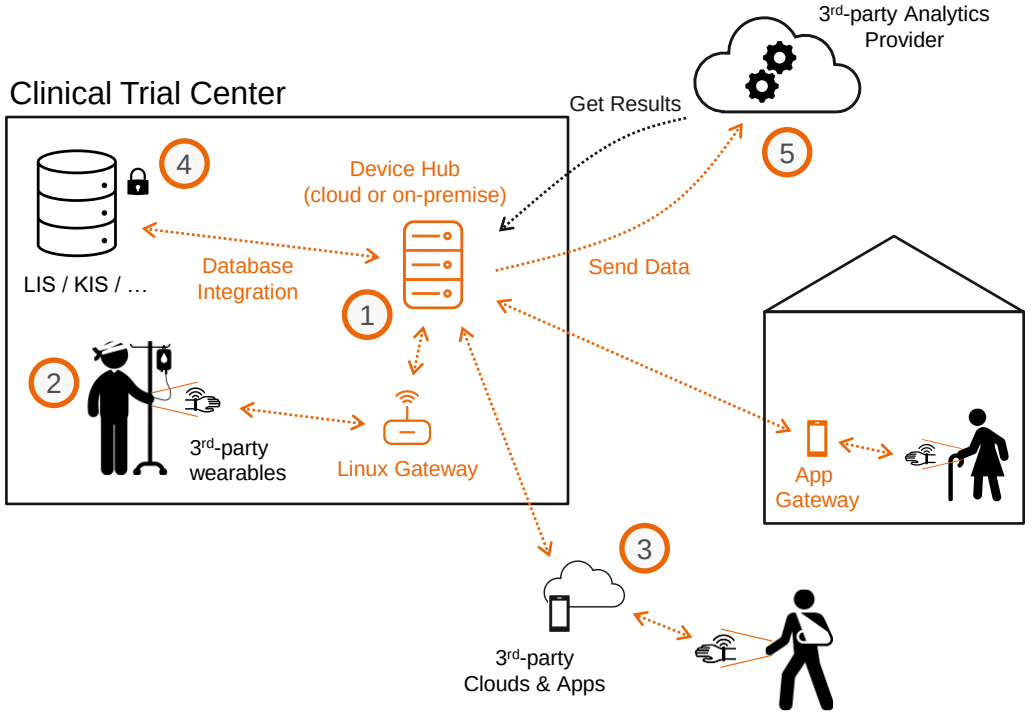
Use Case – Deploy Connected Biosensors in your Study

- Setup Device Hub server (1) hosted on cloud or on premise. It provides frontends for administration and trial workflows (e.g. assign device to trial participant, check data availability).
- Choose any biosensor with open API (2). Leitwert will integrate it with the Device Hub. For Bluetooth devices, we offer Linux, Android and iOS gateway software.
- If your preferred biosensor is part of an end-to-end consumer offering, it usually provides APIs on cloud or app level to synchronize data with the Device Hub (3).
- We integrate your chosen information management system (push or pull) with the Device Hub for data archiving (4).
- Automate data analysis either with your own algorithms or by integrating with analytics providers (5).



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Patient Monitoring[BETA] – Real-time Insights and Prevention

Features

- Early detection of deteriorating health based on continuous real-time monitoring
- Set thresholds for individual patients and parameters
- Flexible deployment across wards, inside and outside of hospitals.
- Use the sensors and algorithms of your choice thanks to open APIs and competent integration support
- Integrate with existing Hospital Information Systems (HIS) and Patient Data Management Systems (PDMS)

Overview on biomarkers for complete ward with individually configurable thresholds and detail views of trend lines. (Medical device certification planned in 2021).

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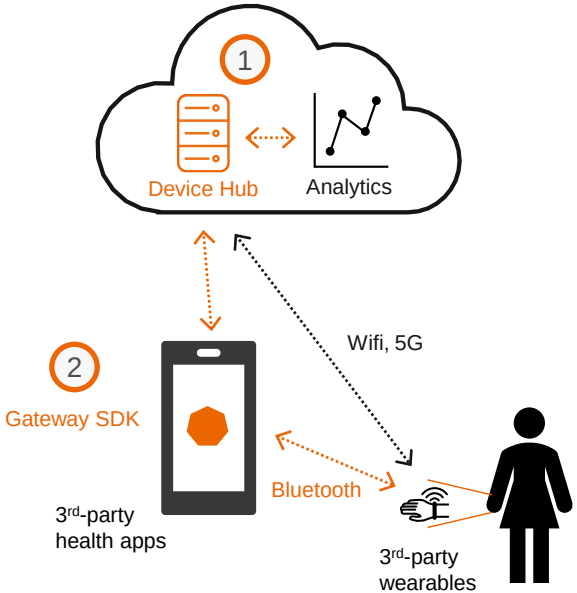
Use Case – Apply Connected Biosensors for your Digital Health App

- Let‘s assume you have – or plan – a mobile application for telehealth or chronic disease management. With our technology stack, you can include objective health data from 3rd-party biosensors as basis for your service or to evaluate outcomes.
- Use the Leitwert Device Hub as SaaS or host it yourself (1). It is your single interface to integrate and manage fleets of biosensors. You can deploy your analytics directly or forward data automatically to your analytics server.
- You can use the Gateway SDK (2) for iOS and Android to enable your application to connect with devices for data synchronization, changing device settings and upgrade device firmware.
- If you build your own device, check out our offering for device manufacturers below:

Jump to slide “Offering for Device Manufacturers”



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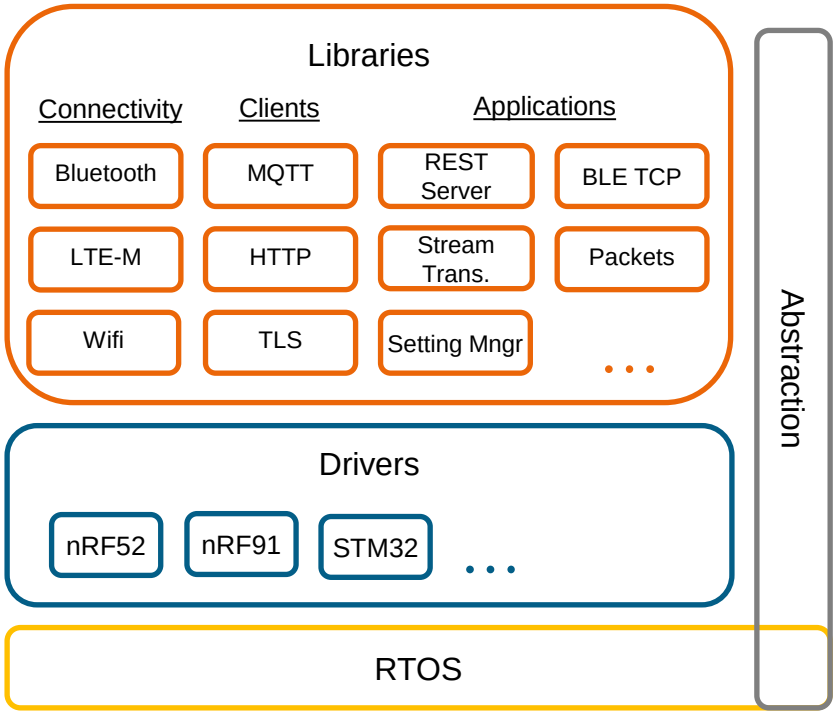
Offering for Device Manufacturers

Embedded Framework – Libraries for Data Processing and Streaming

Features

- Mature libraries for device connectivity via Bluetooth Low Energy, LTE-M and Wifi including end-to-end encryption
- Abstraction layers allow to use these libraries independent of hardware and RTOS and integrate them with existing firmware
- Out-of-the-box firmware for nRF52 (BLE) and nRF91 (LTE-M) – tested (CI, HIL), proven in practice, optimized for efficiency
- Top-notch software team with experience in programming for devices up to medical class C



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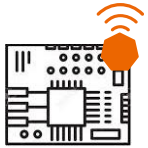
Connectivity – From Retrofit to Integrated Solution

Features

- Connect devices with the tried and tested libraries of our embedded framework
- TLS based end-to-end encryption over Wifi, mobile networks AND Bluetooth Low Energy
- Integration with our gateway software to connect via Bluetooth
- Integration with the Device Hub for device and data management all along the device lifecycle
- The Device Hub enables Bluetooth devices to roam among multiple gateways by coordinating, which gateway connects to the device at any given time

1 Retrofit conventional devices with stand-alone module to track location and usage

2 Retrofit using existing interfaces for complete device management incl. data capture, status, settings and updates (as enabled by device API)



3 Full integration of module or embedded software library for device and data management along device lifecycle

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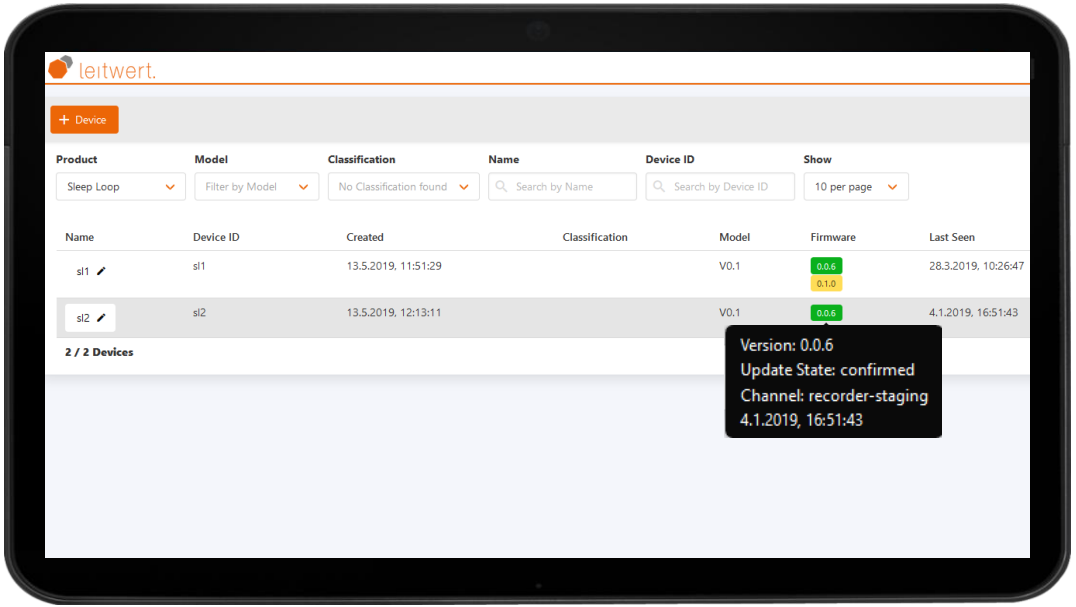
Fleet Management – Firmware Updates, Status and Settings

Features

- Device Hub to manage gateway networks and fleets of 3rd-party devices (vendor-agnostic)
- Monitoring of device status, e.g. battery level, event log, online status
- Change device settings remotely, e.g. measurement mode, weight of patient
- Full control and transparency on distribution of firmware updates
- Immutable audit trail of all user and machine interactions



Register a Digital Twin of every connected device on the Device Hub to manage firmware updates (FOTA), check the device log for technical support, monitor device status and change settings.

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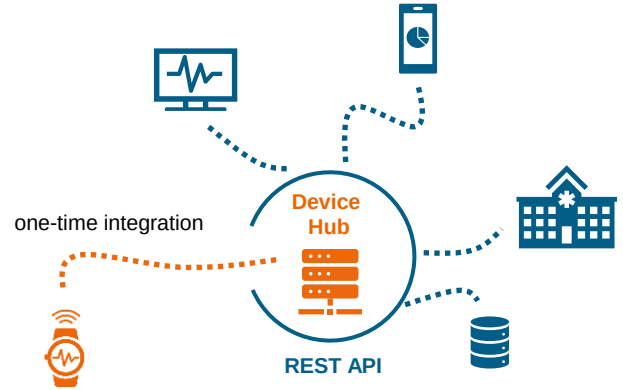
Use Case – Lifecycle Management



1

- Current firmware and device specific key directly at production line or when commissioning device
- Test-Automation
- Create Digital Twin on Device Hub

2

- Encrypted updates and settings management
- Data capture
- Device logs for technical support
- A/B Testing

4

- Integrate once to be compatible with existing tech stack and customer network
- Access to validation studies and digital health pilot applications
- Profit from gateway solutions to deploy your devices

3

- Unlock new features
- Pay-per-use / Device-as-a-Service
- Offer your own applications for digital health and research over Device Hub API

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