








Active implants
From technology to application
through human centered
design

Bart Hermans, Zenso
Joost Thurman, Achilles Design
Hasselt, 18th April 2016



Innovative Electronic System Design House

- Founded in 2007
- Solutions:
 - Feasibility studies
 - Electronic system design
 - Software: embedded & PC
 - Mechanical system design with partners
 - System integration
 - Prototyping
 - Test & validation
 - Documentation
 - Series production via preferred partners
 - Maintenance
- ISO9001 & ISO13485 certified





• Industries:

- Medical
- Consumer
- Industrial
- Automotive










































Strategic product design agency

- Founded 1994
- 20+ product designers & engineers
- Industries
 - Medical
 - Sports
 - Consumer
 - Smart products
 - Industry & construction
 - Retail



- Ideation – Design – Prototyping – Sourcing & Industrialisation





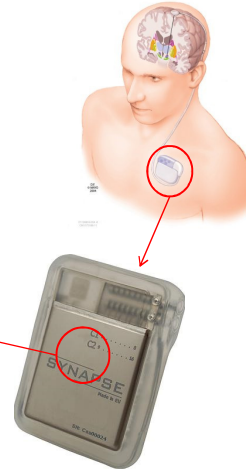
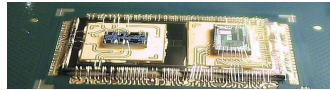
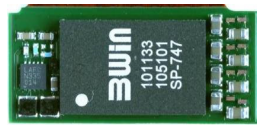
3 Joint Medical Cases Zenso-Achilles Design

- Implantable neurostimulators:
 - Synapse
 - Gecko
- HypoSafe:
 - Active implant to detect and alert diabetics of hypoglycemia
- Nyxoah
 - Active implant for treatment of Obstructive Sleep Apnea

Synapse Case

Implantable neurostimulator

- Brain 'pacemaker' for DBS
- General neurostimulator
- Closed loop stimulation
 - Recording of neural response
 - Optimized patient therapy



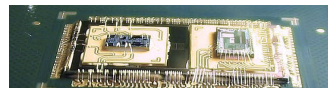
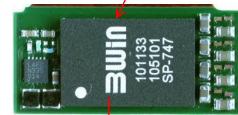
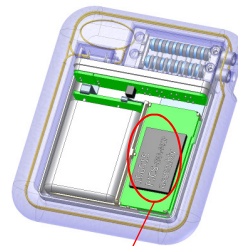
Synapse Case

PICS™* Neurostimulator engine

= A proprietary ASIC that forms the Heart of the Synapse™ Platform

- Can be programmed to deliver an almost random variety of pulses / pulse-shapes
- 32 independent current sources (16 used)
- Each current source individually controllable: Amplitude, Pulse-width, Frequency
- Low power independent current sources
- Max. signal output ranges: 20mA, 1ms, 25 kHz
- Recording capabilities during stimulation as low as 5uV, sampling-FRQ up to 70 kHz

*PICS: Programmable Independent Current Source array



Synapse Case

- Ultra slim IPG
- 1 extension cable connect 2 electrodes
- Extension cable with 15% stretch over complete length



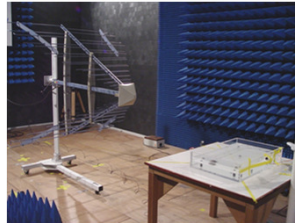
Synapse Case

- Remote control
 - MICS band or ISM band
- Charger
 - Inductive link
 - High efficiency, high range



Synapse Case

- First implantation Q4 2011
- CE label Q4 2012



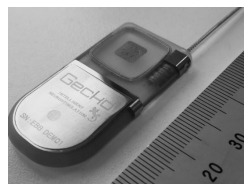
- Testimonial on Zenso website



Gecko Case

Implantable neurostimulator

- Batteryless device for subcutaneous implantation (>2.5cm)
- 4 electrode contacts
- Stimulation and Sensing
- Powering/communication through standard RFID NFC appliances (eg smartphone)
- IoT allows remote therapy/device management (e.g. compliance tracking/efficacy tracking)
- Intuitive and easy to handle wearable power unit (e.g. Velcro on garment)
- Programming & recording through smartphone



HypoSafe Case

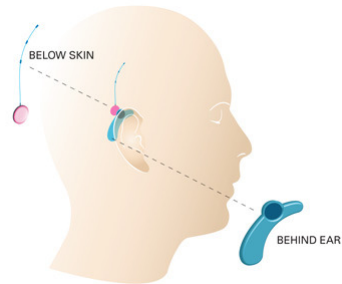
AIMD to detect and alert diabetics of hypoglycemia

Implant

- 2 channel EEG
- Batteryless inductive powered
- Subcutaneous implantation
- 12min local anesthesia

Earhanger part

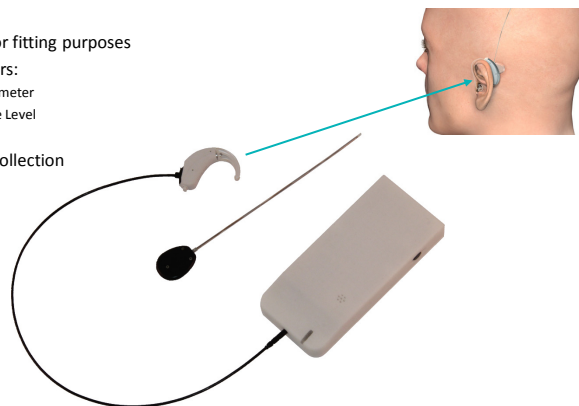
- Powering implant
- 24/7 high quality EEG Monitoring
- Algorithm to detect low blood sugar



HypoSafe Case

Screeener

- External logger for fitting purposes
- Additionnal sensors:
 - 3-axis accelerometer
 - Sound Pressure Level
 - Ambient light
- 2 weeks of data collection



Nyxoah Case

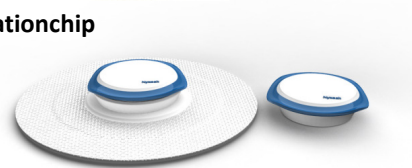


Implant

- Flexible active implant
- Batteryless



Disposable patch & intelligent activation chip



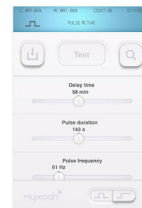
Day-time charging station



Nyxoah Case



App for communication & configuration



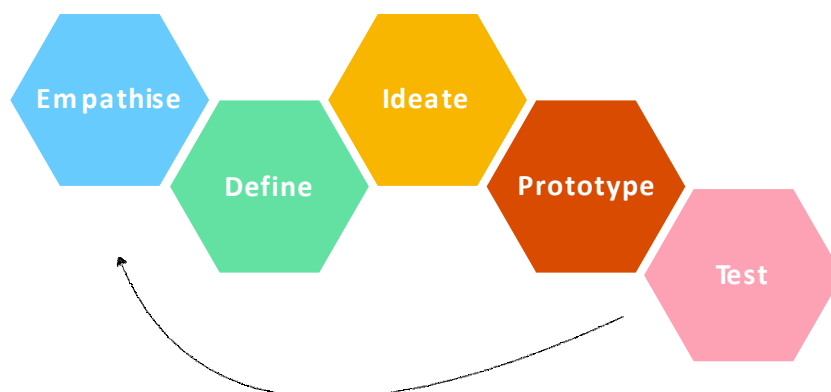
Surgical tool



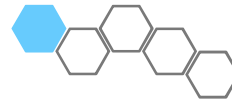
How do we apply human-centered design to active implants?



An iterative cyclic proces



Empathise



Understand the experience, situation and emotion of the patients & stakeholders who you are working for

- Observe patients & caregivers in the context of their situation.
- Engage with users in conversations and interviews. Ask why.
- Watch and listen: ask someone to complete a task and tell you what they are doing



Define



The screenshot shows two user personas. The first is 'Frans', a 72-year-old male who wants to enjoy his retirement. His background includes being retired, having a wife, and being a tennis player. His relation to the system is that he wants to control a watch during what he does. His use pattern is to check the status of battery & connection to a PC once a day. The second persona is 'Tinne', a 40-year-old female who wants to go shopping with her friends. Her background includes being a single mother, a teacher, and a runner. Her relation to the system is that she wants to control a watch during what she does. Her use pattern is to check the status of battery & connection to a PC once a day.

Process and synthesise the findings

Users

Understand the types of person you are designing for (persona's)

Needs

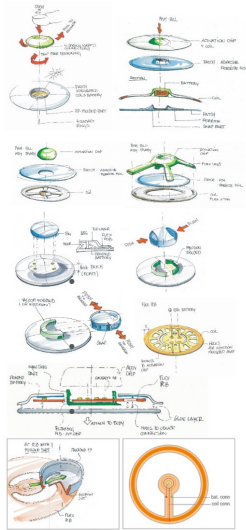
synthesize and select a limited set of needs

Insights

express insights and define principles



Ideate



Idea generation

- Translate problems into solutions.
- Explore a wide variety and large quantity of ideas to go beyond the obvious solutions to a problem.

Creativity

- Combine the un/conscious with rational thoughts and imagination

Group synergy

- Leverage the group to reach out new ideas
Separate the generation and evaluation of ideas



Prototype



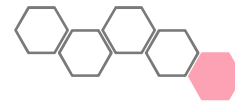
"Build to think"

A simple, cheap and fast way to shape ideas so you can experience and interact with them.

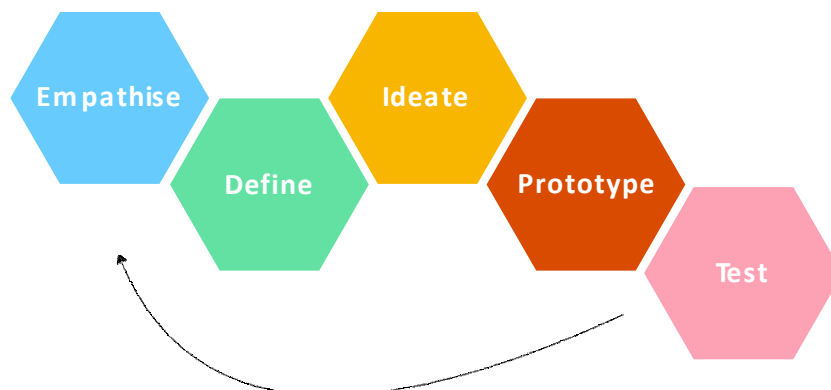
- Start building: Create an artefact in low resolution. This can be a physical object or a digital clickable sketch. Do it quick and dirty.
- Storyboard: create a scenario you can role play in a physical environment and let people experience your solution



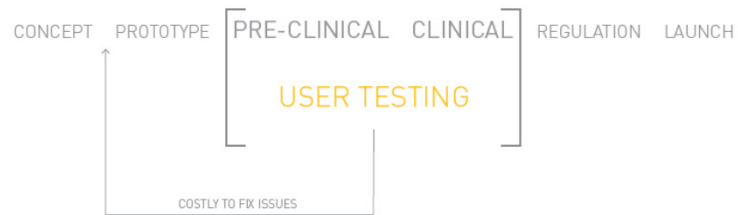
Test



- Ask for **feedback** on your prototypes. Learn about your user, reframe your view and refine your prototype.
- **Show**: let people use your prototype. Give it in their hands and let them use it. Listen to what they say.
- **Create experiences**: let people talk about how they experience it and how they feel



Human Centered Design in Healthcare



Early user interaction is crucial...



Contact



- www.zenso.be
- bart.hermans@zenso.be
- +32 16 404547



- www.achilles.be
- J.thurman@achilles.be
- +32 478201593

