Remote care and clinical solutions
WE ARE PLANEXTA, THE BIOTECH INNOVATIONS COMPANY

SenceBand™ — the world’s first ECG sensor for one hand

Planexta Care — the world’s first BP and HRV monitor for one hand

HealthWatch project — the aim to create the world’s first smart watch with medical grade ECG/HRV, blood pressure and saturation monitoring

PRECISe — universal cloud service for automated ECG interpretation

- Own lab facilities
- 89 specialists engaged
- Solid international experience
- Compliance
<table>
<thead>
<tr>
<th>Products / Technology readiness level</th>
<th>TRL3</th>
<th>TRL4</th>
<th>TRL5</th>
<th>TRL6</th>
<th>TRL7</th>
<th>TRL8</th>
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<td>SenceBand Medical Pro (SCD and MI early detection)</td>
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<td>PlanextaCare (BP, HRV and saturation monitor)</td>
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<td>TBD 10/2018</td>
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<tr>
<td>PlanextaCare Pro (with MI and stroke early detection)</td>
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<td>HealthWatch (medical smart watch)</td>
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TRL6 IN PRE-MARKETING TIMELINE OF A MEDICAL DEVICE

Product Development and Prototyping

- Product Requirements Document
- Project Plan
- Detailed Design Specification
- Engineering Prototype
- Design Freeze
- Critical Design Review
- Verification
- Validation
- Transfer to Production

Market Requirements Document:
- Current state of the universe:
  - Existing/under development products
  - Their strengths & weaknesses
  - User groups and profiles
  - Patient groups and profiles
  - Reimbursement
  - Intellectual property
- The need
- Proposed product:
  - Internal & external requirements (prioritized for "must have" and "nice to have")
  - Features
  - Performance thresholds
  - Constraints
  - Form factors
  - Bill of materials / cost targets
  - Manufacturing and assembly
  - Value proposition (clinical and economic)
- All vs vs safety, quality, reliability, usability, regulatory approvalability and (marketability)

Device Master Record:
- Component, sub-assembly and finished product specifications
- Final bill of materials
- Incoming material/component inspection procedures
- Manufacturing/assembly procedures and schematics
- In-process inspection and testing procedures
- End product inspection and testing procedures
- Packaging and labeling specifications and procedures
- Finished product acceptance criteria

Creation of Scientific Advisory Board of Key Opinion Leaders
Clinical Program Design (assisted by SA and external regulatory counsel)

Pre-Clinical Dev.

- Primary milestone
- Secondary milestone
- Tertiary milestone

(Cadaver Testing)
- In-Vitro & In-Vivo Animal Testing:
  - Biocompatibility testing
  - Safety
  - Final device testing prior to regulatory submissions
  - Initial efficacy/pre-clinical validation (incl. comparison to precursors)

Final Pre-Clinical Report
(Pre-Clinical Validation)
The heart rate variability and P-R intervals monitoring in early detection of sudden cardiac death and myocardial infarction
There is a significant relationship between the autonomic nervous system and cardiovascular mortality, including sudden cardiac death.

Experimental evidence for an association between a propensity for lethal arrhythmias and signs of either increased sympathetic or reduced vagal activity has encouraged the development of quantitative markers of autonomic activity.¹

¹Heart rate variability. Standards of measurement, physiological interpretation, and clinical use. Task Force of The European Society of Cardiology and The North American Society of Pacing and Electrophysiology

²Alex Sarishvili. Risk estimation for Sudden Cardiac Death. Fraunhofer Institute for Industrial Mathematics ITWM
ECG abnormalities of myocardial ischaemia or infarction may be inscribed in the PR segment

Third Universal Definition of Myocardial Infarction, Kristian Thygesen, Joseph S. Alpert, Allan S. Jaffe, Maarten L. Simoons, Bernard R. Chaitman and Harvey D. White: the Writing Group on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction
“I assume that proposed technologies have tremendous potential in the prevention of sudden cardiac death and myocardial infarction. However, the further pre-clinical and clinical trials should be performed due to the Good Clinical Practice and current international regulations. Meanwhile, I wish you good luck in development of solutions, which may save millions of lives worldwide.”

Sergei Gutnikov, MD DPhil (Oxon)
Centre for Prevention of Stroke and Dementia,
Oxford Vascular Study — Nuffield Department of Clinical Neurosciences
PLANEXTA CARE

Provides additionally a constant blood pressure and oxygen saturation monitoring
ADVANTAGES OF CONSTANT AND COMFORTABLE MONITORING OF BLOOD PRESSURE AND SATURATION

HIGH BLOOD PRESSURE IS A MAJOR RISK OF CV DISEASES

Hypertension is a major risk factor for ischaemic and haemorrhagic stroke, myocardial infarction, heart failure, chronic kidney disease, cognitive decline and premature death.

The risk associated with increasing blood pressure is continuous, with each 2 mmHg rise in systolic blood pressure associated with a 7% increased risk of mortality from ischaemic heart disease and a 10% increased risk of mortality from stroke.¹

Constant blood pressure monitoring is the only way for hypertension prevention²

¹Hypertension in adults: diagnosis and management / NICE Guideline November 2016
²http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/KnowYourNumbers/Monitoring-Your-Blood-Pressure-at-Home_UCM_301874_Article.jsp
LOW OXYGEN SATURATION IS A SIGN OF LIFE THREATENING CONDITIONS

- Anemia
- ARDS (acute respiratory distress syndrome)
- Asthma
- Congenital heart defects in children
- Congenital heart disease in adults
- COPD Chronic obstructive pulmonary diseases
- Emphysema
- Interstitial lung disease
- Medications, such as certain narcotics and anesthetics, that depress breathing
- Strained or pulled abdominal muscle
- Pneumothorax (collapsed lung)
- Pulmonary edema
- Pulmonary embolism (blood clot in an artery in the lung)
- Sleep apnea

1 http://www.mayoclinic.org/symptoms/hypoxemia/basics/causes/sym-20050930
Spend more time golfing...

get 7X performance in 10X less time
PROBLEM

Manual ECG interpretation is ineffective and outdated
Most physicians think that they have good interpretation knowledge of ECG, but it's not an easy task\(^1\)

Studies rate non-cardiologist physicians an accuracy of \(36\%\) to \(96\%\) in detecting ECG abnormalities\(^2\)

The emergency department physicians had sensitivities of \(59\%\) and \(64\%\) for ST-T abnormalities\(^3\)

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THE CLINICAL VALUE ADVANTAGES OF AUTOMATED EGG INTERPRETATION:

Standardized processing

- ISO 11073-91064:2009
- Minnesota Code
- Heart rate variability analysis

High precision

- Sensitivity - up to 97.8%
- Specificity - up to 98.2%

1. Health informatics – Standard communication protocol – Part 91064: Computer-assisted electrocardiography
3. Heart rate variability. Standards of measurement, physiological interpretation, and clinical use Task Force of The European Society of Cardiology and The North American Society of Pacing and Electrophysiology (Membership of the Task Force listed in the Appendix)
Clinical guidelines for ECG interpretation
Permanent update on demand from AHA, ESC, ISO with rule-based medical logical modules

Supported ECG formats
SCP-ECG, DICOM-WS 30, HL7 aECG, ecgML, MFER, Philips XML, XML-ECG, mECGml, ecgAware

Free integration into your hospital’s information systems
Easy to use API in compliance with ISO/HL7 and IEC 62304
MOST

❤️ non-cardiac physicians see up to 9 typical patterns
❤️ cardiologists see up to 15 typical patterns
❤️ experienced cardiologists see up to 19 typical patterns

Calculates up to 700 parameters

HOW IT WORKS  SIMPLE AS CALCULATOR

Routine ECG measurement  
EHR sends ECG file to PRECICE  
PRECISE API interpretation  
≤ 1,5 min  
PRECISE PDF report
MAKES THERAPISTS HAPPY

Simply does, what physicians would love to delegate to somebody

- Standardized ECG interpretation: ISO - 11073:91064, Minnesota Code, Heart Rate variability

- Multi language localization support

- Visualization tools

- Adjustable reports
**MEDICAL & SCIENTIFIC RESEARCH**

- occupational physiology
- exercise physiology
- occupational science
- sport science
- psychology
- pharmacology

**TREATMENT AND PREVENTIVE FIELDS**

- cardiology
- intensive care
- endocrinology
- neurology
- occupational medicine
- sports medicine
- obstetrics

Guideline for the application of heart rate and heart rate variability in occupational medicine and occupational science, ASU International issue: 06-2015
UNIVERSAL SOLUTION FOR ALL YOUR NEEDS

Remote / Home Care

Outsource Diagnostic Services
  - PDF reports

Holter Monitoring
  - Tailored dashboards

Inpatient or Outpatient Care
  - Dispatching algorithms

Emergency / Ambulance
  - $18.4B Market
  - 7.4% CAGR
MODERNIZE YOUR ECG DIAGNOSTIC TO IMPROVE ACCURACY, CONTENT, PROCESSING AND COST-EFFECTIVENESS

Raise your standards

- \( x^2 \) accurate\(^{1,2} \)
- \( x^7 \) informative\(^1 \)
- \( x^{10} \) faster\(^3 \)
- \( x^{20} \) cheaper\(^3 \)

2. Jan A. Kors, and Gerard van Herpen. The Coming of Age of Computerized ECG Processing: Can it Replace the Cardiologist in Epidemiological Studies and Clinical Trials?
3. Physician Fee according the Centers for Medicare & Medicaid Services (CMS) 2017 Pricing information HCPCS Code CPT 93010
## Investments to Integration: get free services worth >160’000 euro

<table>
<thead>
<tr>
<th>Service</th>
<th>Cost</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>integration</td>
<td>€30k</td>
<td></td>
</tr>
<tr>
<td>validation</td>
<td>1000 ECGs</td>
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<tr>
<td>24/7 support</td>
<td>€80k</td>
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<tr>
<td>regulatory approval</td>
<td>€50k</td>
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**Average cost of integration on European market**
### ACTIONS

- Term sheet
- Task force creation
- Integration and validation*
- Contract
- Regulatory approval

### TERMS

- ASAP
- 3 weeks
- 10 weeks
- 1 week
- 26 weeks

*On IntoSana example
NEW OPPORTUNITIES

Must have instrument

❤️ Wider range of ECG-based services
❤️ Raise your standards
❤️ Additional revenue streams
❤️ Raise your income
Take it to heart