Partnership for the Heart
– Telemedicine for chronic heart failure
Agenda

- **Aipermon**
  - Telemonitoring Technology used for “Partnership for the Heart” Project
  - Telemonitoring usage example for diabetes

- **PfH - TIM-HF Study (Telemedical Interventional Monitoring in Heart Failure)**
  - System Architecture and measurement parameters
  - Study design
  - Endpoints
  - Results
  - Telemedicine for heart insufficiency patients conclusion
Aipermon GmbH & Co. KG

Who we are

- Founded: 2/2005 as a spin-off from Infineon Technologies AG
- Employees: 22
- Location: Munich/ Germany
- Investor: Dietmar Hopp

What we do

- Development and consulting, production and marketing of systems for Telemonitoring and Activity Monitoring
- Quality approved: ISO 9001 and ISO 13485

• Aipermon Telemonitoring: secure, safe and easy
Telemonitoring Solution Overview

Med. Measurement Devices
- Measurement of vital parameters

Base Station
- Data transmission

Data Service Center
- Secure data delivery

Analysis Software
- Data evaluation and storage

Aipermon
- Use of well-known, best-in-class measurement devices
- Integration of transmission modules (Bluetooth)
- Own activity sensors
- Homebox for analog telephone connection
- IP-Homebox for digital connection
- Mobile device (PDA/mobile phone)
- PC Hub (AiperDock 400)
- Security and reliability management
- Reports, alarms
- Interface for data delivery to external databases (e.g. eHR, ePR, HIS)
- Patient management
- Data visualization
- Device administration

Bluetooth
Analog phone
Web based
Integrated measurement devices

- ECG
- RFID-Scale
- Scale
- Nebulizer
- Peak Flow Meter
- PDA/Handy
- Homebox
- PC-Hub
- IP-Homebox
- Energy balance
- Activity
- Repeater
- SD-card reader
- Emergency button

**Fast** integration of additional measurement devices!
## Base stations

### Homebox 300 HB
- Analog telephone connection
- Zero button operation (no settings)
- Status display (6 LEDs)
- Remote management

### AiperBase 400 IP
- Network connection (Ethernet, DSL/router)
- Zero button operation (no settings)
- Status display (LEDs)
- Remote management

### MMA (PDA)
- GSM/UMTS telephone connection
- Questionnaires (self-evaluation, insulin, …), measuring plan
- Feedback from physician/advisor
- Remote management

### AiperDock 400 (PC Hub)
- Internet Upload
- Additional entries (self-evaluation, insulin, …)
- Feedback from physician/advisor
Telemonitoring application for diabetes: ABC-program

3. Monitoring via telemedicine
Continuous feedback by a personal advisor

1. Magdeburg dual diet
   - Calorie restriction
   - Glycemic Index

2. Activity monitoring
   - Measuring of activity
   - Motivation & mentoring

Prof. Luley, Otto-von-Guericke University Magdeburg, 2007
Study diabetes: Overview

**Objective**
- Medical result: decrease of HbA1c value
- Economical result: cost reduction in medication

**Study**
- Randomized, parallel, controlled
- 88 patients (control group 1:1)
- 6 months of telemedical / according-to-the-guidelines care
- Exchange of care groups after 6 months (sustainability)
- Start Sept. 2008
- Leadership: Prof. Dr. Luley, Otto-von-Guericke University hospital Magdeburg

**Criteria of inclusion**
- Diabetes type 2
- Increased HbA1c and glucose values
- Drug treatment (pills, insulin)

Prof. Luley, Otto-von-Guericke University Magdeburg, 2009
# Study diabetes: Results

<table>
<thead>
<tr>
<th></th>
<th>Start</th>
<th>Results (6 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>223.3 lbs (101.5 kg)</td>
<td>22.6 lbs (-10.3) kg</td>
</tr>
<tr>
<td>HbA1c</td>
<td>7.5 %</td>
<td>-0.9 %</td>
</tr>
<tr>
<td>BMI</td>
<td>35.3 lbs/ins²</td>
<td>-4 lbs/ins²</td>
</tr>
</tbody>
</table>

- **Percentage of patients with HbA1c value > 7.0 % (after 6 months):** from 66% to 27%
- **Decrease of plasmatic glucose (after 6 months):** by 28.8 mg/dl
- **Diabetes medication:** For 68 % of outpatients, the treatment with diabetes medication could either be discontinued or reduced:
  - discontinued: 38 %
  - reduced: 30%
- **Cost reduction/Patient (in 6 months):** 117,- € / 152,- US $

Prof. Luley, Otto-von-Guericke Universität Magdeburg, 2009
The Remote Telemedical System used in TIM-HF

Winkler et al, Int J Cardiol 2010
Project Partner & Aipermon’s responsibilities in PfH

Partner: Aipermon, ICW, Bosch, Charité Hospital, Robert Bosch Hospital

Aipermon:
1. Technical consortia leader for the system architecture
2. Measurement devices and basestation (MMA) equipment
3. Data transfer, integration and management

<table>
<thead>
<tr>
<th>Patient</th>
<th>Meas. devices</th>
<th>MMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG + SpO₂</td>
<td>Blood pressure</td>
<td>How do you feel today?</td>
</tr>
<tr>
<td>Activity</td>
<td>Weight</td>
<td></td>
</tr>
</tbody>
</table>

354 systems in use

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Study Design

- **Randomisation of 710 patients:**
  - 354 (49.9%) telemedical intervention + considered optimally treatment
  - 356 (50.1%) considered optimally treatment (Control group)

- **Main inclusion criteria:**
  - NYHA class II / III
  - Left ventricular ejection fraction LVEF ≤ 35%
  - Decompensation due to HF or LVEF ≤ 25%
  - All patients considered optimally medically treated

- **Main exclusion criteria:**
  - Hospitalization for worsening HF within previous 7 days
  - Planned CRT (cardiac resynchronization therapy - pacemaker) implantation

- **Definition of compliance:**
  - ≥ 70% of possible daily measurements were made (excl. hospitalizations) and no “break” > 30 days
  - **Achieved compliance: 81%**
Participating Telemedical Service Centers

Telemedical center
Berlin
373 patients

Telemedical center
Stuttgart
337 patients

165 medical practices of cardiologists, internists or general practitioners
Endpoints of the TIM-HF Study

- **Primary endpoint**
  - Total mortality

- **Key secondary endpoints**
  - Composite of cardio-vascular (CV) death and hospitalization due to heart failure (HF)
  - Days lost due to death or hospitalization due to HF
  - CV mortality
  - Duration of CV hospitalizations
  - Symptoms & quality of life
Primary Endpoint: All cause mortality

Proportion of patients with event (%)

Remote Telemedical Management
Usual Care

HR 0.97 (0.67–1.41)
P=0.87

Months

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Secondary Endpoint
Composite of CV death and HF hospitalization

Proportion of patients with event (%)

- Remote Telemedical Management
- Usual Care

HR 0.89 (0.67–1.19)
P=0.44
Overview of results for the complete group

1. For stable ambulatory patients with chronic heart failure, remote telemedical management does not reduce:
   - All cause Mortality
   - Rates of hospitalizations

2. Important aspects of physical function and quality of life (i.e. depression) can be improved by remote telemedical management.

Background

- Both groups got the optimal medical treatment
- 50% of the patients had an implanted defibrillator
- => mortality: 8.1% per year in both groups (compared to 20% in other studies)
Conclusion: Identified risk group to benefit from telemedicine

- **Instable patients benefit from telemedicine (profile)**
  - after hospitalization due to HF
  - without depression
  - cardiac output not too low (LVEF >25%)

- **333 (47%) of 710 PfH patients are included in this group**

- **Results of the risk group**
  - ~50% less CV mortality with telemedicine
  - ~50% reduction of the number of days lost due to CV mortality and hospitalizations because of HF
Outlook: HF - total population and prevalence for telemedical application

- **Prevalence:**
  - 1.2 million HF patients in Germany (NYHA I – NYHA IV)
  - approx. 375,000 hospitalizations due to HF

- **Prevalence for telemedicine for HF patients (identified risk group):**
  - approx. 150,000 telemedicine patience per year in Germany
  - reduction of HF hospitalizations of approx. 20 percent
  - (health economy currently being analyzed)
Telemonitoring platform requirements

- Easy to use
- Fast integration of additional measurement devices
- Modular and flexible configurable
- Highest security level
- Proven medical benefit
- End-to-end turn key solution
- Cost efficient
Thank you for your attention!

please visit our stand for further information

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