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Light for Medical Treatments

- **Lighttherapies**: effects via the eyes
  - Blue or white artificial light
    - winter depression (SAD)
    - sleep disorders (circadian rhythms)
    - deficiencies in concentration

- **Phototherapies**: effects via the skin, sometimes combined with drugs
  - Artificial light or natural sun light (Heliotherapy)
    - Infrared Light: rheumatic diseases, (chronic) inflammatory diseases
    - Visible Light: photodynamic therapy (PDT), e.g. of skin cancer
    - Blue Light: neonatal hyperbilirubinemia, Acne
    - UV-Light: Psoriasis (PUVA, NB-UVB, Balneo therapy), Neurodermitis (UVA), Vitiligo, Vitamin D₃ Synthese (UVB)

- **Light Sources**: incandescent & gas discharges lamps, lasers, LEDs (upcoming)
# Societal Trends

## Demographic trend

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 5</td>
<td>15%</td>
</tr>
<tr>
<td>5-14</td>
<td>10%</td>
</tr>
<tr>
<td>15-24</td>
<td>10%</td>
</tr>
<tr>
<td>25-34</td>
<td>10%</td>
</tr>
<tr>
<td>35-44</td>
<td>10%</td>
</tr>
<tr>
<td>45-54</td>
<td>10%</td>
</tr>
<tr>
<td>55-64</td>
<td>10%</td>
</tr>
<tr>
<td>65+</td>
<td>5%</td>
</tr>
</tbody>
</table>


## Health expenditure

### Age groups

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Health Expenditure Per Capita</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-4</td>
<td>Low</td>
</tr>
<tr>
<td>5-9</td>
<td>Low</td>
</tr>
<tr>
<td>10-14</td>
<td>Low</td>
</tr>
<tr>
<td>15-24</td>
<td>Low</td>
</tr>
<tr>
<td>25-34</td>
<td>Low</td>
</tr>
<tr>
<td>35-44</td>
<td>Low</td>
</tr>
<tr>
<td>45-54</td>
<td>Low</td>
</tr>
<tr>
<td>55-64</td>
<td>Low</td>
</tr>
<tr>
<td>65-74</td>
<td>Moderate</td>
</tr>
<tr>
<td>75+</td>
<td>High</td>
</tr>
</tbody>
</table>

Source: NL - RIVM 2007

## Cost effective

Healthcare cost will continue to raise unless cost effective solutions are made available.

Source: Philips

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M Born, J Liebmann Nov 24, 2015; Health Tech Event 2015
Technology Trends

- **Ledification:**
  - Sustainability; energy efficiency
  - New form factors, miniaturization
  - New operation algorithms / treatment modalities

- **Flexible and Stretchable electronics**
  - LEDs on flexible substrates (e.g. textiles)
  - Sensors in textile

- **Digital revolution**
  - Wire less communication
  - Smartphones / Tablets: App developments
  - Tele-health
Healthcare Trends

• Future shortage of healthcare professionals

• Growth in healthcare spend has slowed or fallen in many European countries

• Care is shifting from hospital to lower cost settings, including the home
Trends – impact on phototherapy

- **Societal Trends**
  - Increasing cost of healthcare

- **Technology Trends**
  - Ledification
  - Flexible electronics
  - Digital revolution

- **Healthcare Trends**
  - From hospital to home

The future of phototherapy is phototherapy at home
## Light Therapy – Home use

on the right spot to meet the key healthcare stakeholder needs

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Needs</th>
<th>Light Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients</strong></td>
<td>Effective and convenient treatment</td>
<td>Phototherapy is recommended for specific diseases, and home treatment makes it very convenient</td>
</tr>
<tr>
<td><strong>Providers</strong></td>
<td>Treatment effectiveness and patient adherence</td>
<td>Points validated by clinical trials (important role of ICT, remote monitoring, etc.)</td>
</tr>
<tr>
<td>(Physicians)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Payers</strong></td>
<td>Increase cost-effectiveness of treatments</td>
<td>Home-therapy reduces integral costs, Less costs due to less side effects</td>
</tr>
<tr>
<td>(Insurance companies)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Policy Makers</strong></td>
<td>Safety and efficacy</td>
<td>Chemical / drug free</td>
</tr>
<tr>
<td>(government)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Philips Light & Health Business

- Business that is certified (ISO13485) to develop, market and distribute medical (light therapy) devices.

- Multi-disciplinary team working on portable and wearable light based medical devices.

Visit us on www.blueledtherapy.com
Core competencies

- Solid State Lighting Physics
- Thermal management
- (safety-) Sensors
- Optical modelling and design (light guides, direct lit, side lit, homogeneity)
- LED driver development & Battery and charger circuitry design
- Embedded software development
- Marketing & Sales
- Quality and Regulatory
- Scientific testing and Clinical evaluation
Research: Effects of Light

Influence of UV-free light on human skin cells:

- model system: cell culture of primary keratinocytes
- microvascular endothelial cells
- fibroblasts

Analysis of:
- proliferation $\uparrow\downarrow$
- differentiation
- NO-biosynthesis + protein-nitrosation $\uparrow\downarrow$
- collagen synthesis
- inflammatory mediators (cytokines)

- toxicity
- inflammation

BMBF Final Report, FKZ13N9088 – 13N9095, TIB Hannover, 2010
Research: Effects of Blue Light (1)

- Blue Light is safe (UV-free)
- Blue Light induces Nitric Oxide production in human skin
- Blue Light increases blood flow better than heat alone

Blue Light reduces muscular back pain

- Multi-center clinical investigation (phase 3, 3 sites)
- 172 chronic back pain patients, 5 treatments (2 weeks)
- prospective, randomized, double blinded

Moderate Pain (VAS 4-6 cm)

Upper Back (Neck)

[Graphs showing Delta Baseline (cm) (VAS) for Moderate Pain and Upper Back (Neck) with comparison between Kontrolle (n=42) and PRP* (n=41) for Moderate Pain and Kontrolle (n=23) and PRP** (n=23) for Upper Back (Neck).]

www.clinicaltrials.gov: NCT01528332

J. Keßler et al., The Efficacy and Safety of Blue Light Therapy for Relief of Chronic Musculoskeletal Back Pain: A Prospective, Randomized, Controlled, Double-Blind, Multi-Centre Study, submitted to Physical Therapy, 2015
Philips BlueTouch Pain Relief Patch

- World’s first wearable LED light therapy for muscular back pain
- 2010-2012: developed, manufactured and brought to German-Austrian market by Philips Light and Health Venture
- Since 2013: Product within Philips Consumer Lifestyle Pain Management Category
Research: Effects of Blue Light (2)

- **Reduction of cell proliferation** of keratinocytes and induction of their differentiation\(^1\)
- **Anti-inflammatory action** based on inactivation of immune cells (T-cells, dendritic cells) and reduction of cytokine release\(^2\)

**Keratinocytes**

![Graph showing keratinocyte response to blue light exposure.]

- Reduced proliferation
- Increased differentiation
- Increased apoptosis of T-cells

\(^1\)J. Liebmann, et al: Journal of Investigative Dermatology (2009), Volume 130, pp 259-269
Psoriasis vulgaris

- **Chronic inflammatory skin disease:**
  - hyperproliferation of keratinocytes
    → renewal of epidermal skin in 2-7 days instead of 27 days
  - Infiltration of T-cells into the skin (sustained inflammation)
    → itch, burn, pain sensation

- **Significantly impaired quality of life**

**Existing therapies:**
1st line: topicals, corticosteroids, Vit. D, dithranol, tar preparations
2nd line: UVB narrow-band, PUVA, non-biologic systemics
3rd line: systemic biologics (blocking specific molecular steps)

- **Patient needs:**
  - less side-effects
  - more convenient treatments, e.g. less time consuming and at home
  - feeling less like a patient being in control of the disease
Blue Light for treating Psoriasis: Clinical Trials

Psoriasis 09
- 40 mild to moderate Psoriasis v. patients
- 20 treatments at home (4 weeks)
  2 weeks follow-up, cw. blue light
- Study period: Dec 2009 – Jul 2010

Psoriasis CT02
- 50 mild to moderate Psoriasis v. patients
- 44 treatments at home (3 months)
  1 month follow-up, pulsed blue light
- Study period: Oct 2013 – Sep 2014


Average 50% reduction after 3 months treatment

- treatment compliance 98%
- 3 patients completely cleared during trial
- no device or treatment related side-effects

Psoriasis Treatment

- Device + fixation strap to treat mild to moderate Plaque Psoriasis using **UV-free Blue LED Light**.
- Effectiveness and safety proven in 2 monocenter clinical trials. 
  [www.clinicaltrials.gov](http://www.clinicaltrials.gov): NCT02004847
- Product launched October 2014
- Markets: Netherlands, UK, Germany, France
- Recommended by dermatologists (reimbursement discussions on-going)

**BlueControl**

- Convenient
- Gentle
- Innovative

**BlueControl Gen 2.0**

M Born, J Liebmann Nov 24, 2015; Health Tech Event 2015
• Psoriasis Vulgaris patients with localized plaques
• Aged ≥ 18 years

Untreated & irregular treated Psoriasis vulgaris patients

Over the UV limit Psoriasis vulgaris Patients (that reached the maximal UV dose)

Psoriasis vulgaris patients looking for safer therapy solutions
Philips BlueControl – Device explained

Rechargeable via Micro-USB

Indicator

On / Off

Treatment area
- 40 high power Blue LEDs
- Oval surface ca. 70 x 55mm
- Treatment time 30 minutes per plaque per day

Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rated voltage (V)</td>
<td>100-240</td>
</tr>
<tr>
<td>Rated frequency (Hz)</td>
<td>50-60</td>
</tr>
<tr>
<td>Rated input (W)</td>
<td>15</td>
</tr>
<tr>
<td>Class Medical device</td>
<td>Class IIa</td>
</tr>
<tr>
<td>Classification Risk</td>
<td>Group 1</td>
</tr>
<tr>
<td>Max. daily dose (J/cm²) per plaque</td>
<td>90</td>
</tr>
<tr>
<td>Battery type</td>
<td>Li-Ion</td>
</tr>
</tbody>
</table>

Infrared sensor
- Detecting skin temperature 30° C
- Overheating security at 43 °C
- Easy to clean with alcohol and a cotton bud

Easy to clean surface (damp cloth)
Conclusions

• Light & Health is an innovate research and business area in Philips:
  – build-up of a new product category
  – research, development, clinical validation and introduction of new phototherapy solutions
  – consumer (home) and professional markets

• Light & Health products are medical devices (e.g. in the dermatology domain)
  – proven clinical efficacy & safety
  – supported by healthcare professionals
  – first product examples: Philips BlueTouch, Philips BlueControl

• Many opportunities using different business models and distribution channels (existing or to be build-up).

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