



Scenario M.Light

PRINCE2® in Practice

Practitioner

Version 2018.10

Scenario

Project: **M.Light**

In Germany more than 400,000 people suffer from chronic wounds, with an upwards trend.

The health insurance company Hygeia Ersatzkasse (HEK) published a statistic showing the current annual expenses for treatment and care of this target group being about 4,000 € per patient and year. About 25,000 of HEKs insured people suffer from this kind of disease. Since costs increased by 20% within the last three years there is the threat that the fees have to be raised significantly for the insured.

The Forum of Chronic Wounds society (FCW) sponsored a one-year treatment study by the University of St. Vohlingen. In this study the chronic wounds 250 patients have been irradiated with a newly invented device.

The monitored and documented results for three month were very positive:

- For 25% of the patients the wound healing improved significantly and the costs for treatment and care could be reduced by 50%.
- For 50% of the patients the irradiation had no effect.

The irradiation could be combined optimal with other wound care programs and didn't show any side effects.

The study has recently been presented to the board members of the HEK. As a result the board instructed the programme manager for health care projects to get in touch with the University of St. Vohlingen to gather information on the irradiation device they used. Four weeks later, on the 15th of June, the following project mandate has been submitted to the programme manager.

Project mandate

We hereby commission a project for the development, production and launch of an irradiation device for chronic wounds, as well as the evaluation of representative numbers regarding treatment results.

Working title: M.Light (stands for “Medicus Light”)

- A) The accountability including the budget responsibility for this project will be assigned to the program manager for health care projects. The project will be managed using the method PRINCE2® and all members of the project team have to successfully pass the foundation exam at least.
- B) The developer, producer and publisher will be the company M.Products plc. It's a young and very innovative company with a strong knowledge in medical phototherapy.
- C) The distribution will be handled by Solid Ltd., a medical product distribution company with an excellent market position.
- D) For the development of M.Light a budget of 0.8 Mio. € (+/-5%) has been allocated, up to the start of serial production. The budget for the basic equipment of specific pharmacies and stock is 12 Mio. € (+/-5%). For further project costs a budget of 220.000 € (+/-5%) has been committed. The program manager can dispose over the budget as he sees fit. The development of the M.Light should be completed in 6 month, followed by a 2-month practical usability test phase, one more month for possible re-work and finally the serial production will start. This date must not be delayed more than two weeks, since the education of the sales employees will start in parallel. This project will keep running during the first 12 month of the serial production. During this time a minimum of 500 treatment observations needs to be recorded by the specialist in charge. It has to be verifiable proven that the results of the study from the University of St. Vohlingen are matched.
- E) The M.Products can produce 12,000 M.Light devices with a price of 1,000€ per annum.
- F) The first 6,000 M.Light devices will only be offered to selected pharmacies where preinformed and affected HEK customers can get in touch with. The succeeding target groups will be mobile care services and nursing homes.
- G) The M.Light needs to be registered in the catalogue of therapeutic appliances to enable the prescription usage.
- H) The basis for G) is that the M.Light device gains the declaration of conformity as a medical product according to the Directive 93/42 EWG.
- I) 2 years after the market launch of M.Light the HEK expects a minimum of 10% cost savings for the treatment and care of chronic wounds per annum.
- J) All persons involved in the project have to sign and follow a non-disclosure agreement.

Specifications and costs:

In a meeting with the M.Products senior development engineer the programme manager gets the following information:

The prototype used in the study had the following specifications:

- The emitted radiation is linear polarized and the range comprises lies between 385 and 780nm
- In the underlying study a radiation dose of 40mW/cm² has been applied

Furthermore, the following specifications for M.Light have been agreed:

- A plastic housing resistant to disinfectants
- A circuit board with a digital display
- A laser distance meter to the irradiation field
- Automatic cooling system for cooling of the illuminants
- Zooming function for a variable treatment area
- Mobile irradiation with a wheeled stand

The costs for the development are estimated as follows:

- Injection mould for the plastic housing and parts:	á 100,000€
- Costs for plastic granules:	70,000€
- Approval procedure for medical devices:	50,000€
- Development of circuit board an display:	80,000€
- Development of the user manual:	2,000€
- Development of the wheeled stand:	30,000€
- Additional purchase of 100 silent fans:	10,000€
- Development of the automatic zoom:	40,000€
- Additional purchase of 100 illuminants:	38,000€
- Other development costs:	80,000€

Personnel information:

CEO of the HEK (Hubert Schneid)

A very experienced strategist who was able to balance all the ups-and-downs in health policy and is now able to provide an excellent structure with fair subscription fees for all customers.

Programme manager for HEKs health care project (Helge Pfund)

He started his career at HEK 16 years ago, after he successfully completed his studies on business administration, since then he was able to successfully complete all programmes and projects he managed. To board invites him to their meetings to ensure the programme manager is always aware of the strategic focus of the company. He has a very experienced team of assistants in his PMO (Programme management office).

CFO of the HEK (Linda Herr)

For a while she has been focusing on the exploding costs for wound treatment of the HEK customers and regularly puts pressure on the CEO to initiate appropriate countermeasures. She encouraged the CEO to invest in the M.Light project. Finally she was able to convince the CEO with her conservative, detailed and comprehensible benefit forecast. The CFO has agreed to take at least partial responsibilities for the project.

Head of PR and Marketing of the HEK (Melanie Hell)

She will support the market launch with PR activities. Furthermore she has the order to organize and monitor the documentation of the treatment observations of at least 500 customers of the HEK. She will constantly match the information with the results of the study from the University of St. Vohlingen.

Head of education of the HEK (Torsten Bit)

He will create a webinar and a user DVD and is responsible for the development of the education concept for the sales employees of the Solid.

Chairman of the M.Products (Beat Zuberbühler)

He founded the M.Products Ltd four years ago and has an excellent network to famous scientist of quantum physics. Furthermore he is a board member of the Forum of Chronic Wounds society (FCW). He is very actively collecting donations for further studies and travelling a lot.

Senior development engineer of the M.Products (Urs Weller)

He developed the prototype in cooperation with the doctors of the University of St. Vohlingen and was involved in the study. The specialist and test labs under his control will be able to fulfil this development order. He will also be responsible for the subsequent serial production.

Production manager of the M.Products (Simon Möckli)

He is very experienced in the realization of large-scale production orders. His experienced team and the modern manufacturing plants are suitable for orders of that specification and scale.

Personnel information:

MDB Ltd (Medical Business Development Ltd)

The MDB Ltd is a personnel service provider for interims and project management services in the medical technology sector. Only freelancers with long experience in the management of projects for the development, licensing and market launch of medical products are under contract.

Chair of the Forum of chronic wounds club (Alexandra Luna)

She is an international acknowledged lecturer and instructor for wound management. She will support the HEK as a consultant at the market launch and especially when they receive requests from M.Light users.

Sales manager of the Solid Ltd (Jürgen Wolf)

His responsibility is to place the M.Light in the market and instruct the customers and the attending specialists.

Chairman of the medical association Nord-Ostlummern (Christian Wollschläger)

Nord-Ostlummern is the state with the most nursing homes for the elderly with increasing problems in wound care. The chairman of this medical association follows the M.Light project with great interest.

Chief Editor of the magazine “Apothekenforum” (Helmut Kernwort)

He has a great interest in the success of the M.Light project and will inform his readers immediately of further sustainable positive results from the M.Light users.