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MSF SWEDEN INNOVATION UNIT

PROJECT FACTSHEET

AUTOCLAVE PROJECT

This report details the product and process of an innovative collaboration between Médecins Sans Frontières and external partners, focused on the creation of a new autoclave concept.

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MEDECINS SANS FRONTIERES
LÄKARE UTAN GRÄNSER

MSF SWEDEN INNOVATION UNIT

Introduction

The project includes multidisciplinary collaboration between several actors, with MSF Sweden Innovation Unit as coordinator and biomedical and infection control referents from the MSF Operational Centre in Brussels (OCB) as problem owners.

PROJECT

Many medical devices are reusable and have to be sterilized after use in order to prevent healthcare associated infections. Autoclaves, i.e. sterilizer machines using high-pressure saturated steam, are crucial to achieve effective and safe surgical activities in the field. With surgical activities in MSF requiring increasingly complex surgical instruments – e.g. tubular instruments – the demands on autoclaves continue to grow.

Sterilization quality aside, autoclaves should use less water and energy per cycle, be more time-efficient, and be robust and easy to use and maintain in situations where technical support and training is lacking. This innovation case has explored a new autoclave concept to complement current autoclaves in field settings where power supply is more reliable.

MÉDECINS SANS FRONTIÈRES (MSF)

Médecins Sans Frontières (MSF) is an international medical humanitarian organisation, and was established in 1971 in France with the aim to establish an independent organisation that focuses on delivering emergency medicine aid quickly, effectively and impartially. Nowadays MSF operates all over the world and continues to be independent of both governments and institutions.

This autonomy is used to provide help to people irrespective of gender, race, religion, creed or political convictions. MSF advocates for improved medical treatments and constantly looks for ways to improve its own practices.

MSF SWEDEN INNOVATION UNIT

In the humanitarian sector, where responding quickly to rapidly emerging crisis situations is absolutely crucial, humanitarian organisations struggle to maintain a balance between addressing short-term needs and building the capability to meet long-term challenges.

The MSF Sweden Innovation Unit (SIU) explores a human-centered approach for promoting a culture of innovation within MSF, to more effectively co-create innovations that save lives and alleviate suffering.

For more information, visit msf-siu.org

Our Approach

The SIU takes a human-centered design approach. This means taking the wishes and requirements from the potential users by involving them directly in the design process. In doing this, the product is more likely to fit the needs and wishes of the end-users and the processes in which it has to work.

INNOVATION PROCESS

The MSF SIU uses a three-phase innovation process of initiation, development and implementation. Although these phases principally follow each other, they also often overlap. It is important to highlight that an innovation process is not a linear one, but one that requires iterations in which steps are repeated to improve the product. Iterations improve the design solution to ensure it fits the scenario in which it has to be used.

INITIATION

Framing the challenge, performing research, analyzing insights, defining objectives

DEVELOPMENT

Generating and screening ideas, creating and testing concepts and prototypes

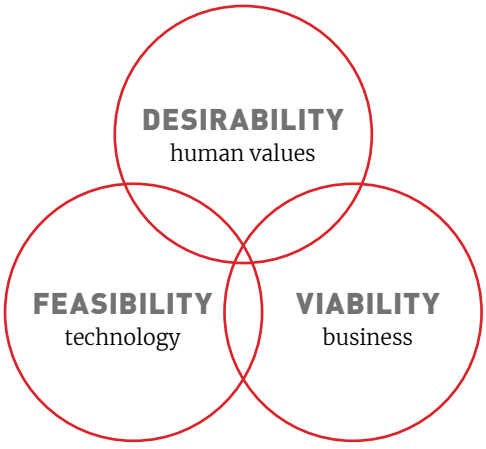
IMPLEMENTATION

Detailed design and implementation, and design of solutions in the field, scaling up and diffusion

COLLABORATION

Many innovation processes are conducted collaboratively. This is done to balance desirability, viability and feasibility, which increases the value of the design solution, as it will be:

- a desirable solution the user really needs.
- a feasible solution that is (technically) possible.
- a profitable solution with a sustainable business model.



This is one of the reasons why the MSF Sweden Innovation Unit operates on a collaborative and open basis. We believe that external actors have value to add through their expertise and aim to harness this added value throughout the design process.

In this project, the partners involved all brought a clear benefit to the project: MSF brought the needs; academia brought the technology; and business brought the viability of bringing the result to market.

MSF can play an important role in the development of new products, because:

- we represent the humanitarian sector by providing the needs and an advocacy platform.
- we provide expertise from the humanitarian perspective, which is very valuable to companies developing products for the sector.
- by being involved at the early stage of development, MSF can ensure new products are designed with their processes in mind.

FROM NEEDS TO SOLUTION PROPOSALS

Along all parts of the innovation process, the needs, ideas and concepts have been continuously iterated with a range of stakeholder and partners to make sure that the prototype tested in the field is based on a solid foundation.

While the design and development partner, Sterimed (later MDS), focused on the technical development and transfer of technical knowledge in this project, MSF focused on the needs and requirements related to user interaction and infection control in the MSF field context. The MSF Sweden Innovation Unit also engaged a student from the TU Delft (a technical university in the Netherlands) to explore the design of new autoclave concepts based on these needs and requirements.

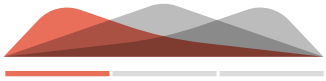
The user-centered design approach used in this project takes needs and requirements from the potential users by involving them directly in the design process. In doing this, the product is more likely to fit the needs and wishes of the end-users and the processes within which it has to work. Moreover, this approach allows the users — or in this case MSF staff — to understand the basis on which changes are made, and it gives them the opportunity to play an important role in shaping them.

Taking into account MSF's needs, wishes and perspective throughout the development process meant not only involving MSF office staff, but also asking field staff for input and feedback, as they will ultimately have to work with the solution produced and integrate it in to their current processes. Hence, an important aspect of this project was field testing prototypes in an MSF mission and collecting feedback from staff coming back from the field.

Training local staff in Haiti on the sterilization process.

01 Initiation

In the initial stages of the project, it was crucial to get a deeper understanding of what the challenge entailed in terms of overall objectives, what the various stakeholders' expectations were, and what they saw as the most critical needs to address.



Step 1 of Innovation process
Initiation

Framing the challenge, performing research, analyzing insights, defining objectives

- 12|2013
  Initial discussions with MSF OCB's biomedical referent on problems with the existing autoclaves, including heater element breakdowns, cumbersome vertical loading, gas requiring constant monitoring, complex valve system, etc.
- 02|2014
  Case proposal presented to MSF Biomedical Working Group and MSF Infection Control Working Group, outlining an initial phase focused on analyzing existing autoclaves, and gaining insight into the needs and requirements of various stakeholders, including end-users, biomedical referents and infection control referents.
- 02|2014
  Thesis project started at TU Delft to explore new autoclave concepts.
- 04|2014
  Lund University's Faculty of Engineering (LTH), Sweden, performed a theoretical analysis of the potential reasons for failing heater elements in existing autoclaves.
- 06|2014
  Questionnaire and interviews to gather needs, requirements and experiences from end-users and other stakeholders at MSF hospitals in Afghanistan, Haiti, Pakistan and Kenya.
- 09|2014
  Register of needs and requirements finalized.

01 Defining objectives

As part of the need analysis, interviews and questionnaires were used to gain insights into the needs of referents, surgeons, nurses, mobile implementation officers, and field workers, along with complementary experiences from resource-constrained Ministry of Health (MoH) settings (e.g. hospitals and health clinics outside NGO activities). The referents from MSF's biomedical working group and infection control working group have taken on the crucial project owner role, grounding the case's ambition, activities and outcomes in the operational realities of MSF.

02 Perform research

Surgeons and nurses were asked to offer their perspectives and expertise on the role of the autoclave in their medical practice, while mobile implementation officers from the biomedical field provided their input on how current autoclaves work and are maintained. End-users at MSF hospitals in Afghanistan, Haiti, Pakistan and Kenya offered useful feedback on advantages and drawbacks of current machines, based on their daily experience from operating the autoclaves in the field.

Experts with MoH experience from field contexts similar to MSF were involved to explore similarities and differences between various field installations.

Representatives of the International Committee of the Red Cross (ICRC) were also involved to contribute with their deep expertise from running autoclaves in an NGO field hospital setting. Academic partners gave us access to expertise in sterilization research, and manufacturing companies contributed with a market scanning capacity, allowing us to better understand which technologies and products were already available on the market and which were emerging.

03 Analyse insights

Critical needs included offering adjustable sterilization temperatures (121°C, 134°C), the ability to sterilize hollow items, giving feedback about the status of the process, allowing the recording of cycles, and allowing users to load horizontally. Sterilization quality aside, the new autoclave concept should also use less water and energy per cycle, be more time-efficient, and be robust and easy to use and maintain in situations where technical support and training is lacking.

Universities were involved to analyze broken heater elements from autoclaves used in the field.

02 Development

Universities were involved to design new autoclave concepts and explore potential failure modes. A manufacturer was brought in to do detail design and prototyping. Sterilization experts with both field and research backgrounds were consulted in the evaluation of the prototype at MSF's training and innovation centre in Brussels, Espace Bruno Corbé (EBC).

Step 2 of Innovation process
Development

Generating and screening ideas, creating and testing concepts and prototypes

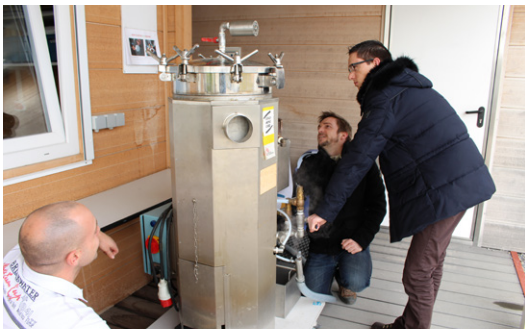
- 10|2014
  Sterimed, Switzerland, was involved to design and manufacture a new autoclave prototype in collaboration with MSF stakeholders.
- 02|2015
  Royal Institute of Technology (KTH), Sweden, performed a material analysis on the broken heater elements from existing autoclaves.
- 05|2015
  A review of the needs, requirements and functional specifications was performed jointly by MSF and Sterimed to inform the design and manufacturing of a first prototype.
- 02|2016
  Assessment of first prototype at Espace Bruno Corbé (EBC), including not only MSF biomedical/infection control referents and mobile implementation officers, but also external experts on sterilization and staff/students working on an autoclave design project at Hogeschool voor Arnhem en Nijmegen in the Netherlands.
- 03|2016
  Assessment of second, updated prototype, at Espace Bruno Corbé (EBC), based on outcomes and re-design proposals from the first EBC assessment.

01 Generating ideas

As the case moved along with a deeper understanding of needs and requirements, a lot of effort was put into creating solution proposals that would address as many of the needs and requirements as possible. To ensure long-term impact while also addressing the immediate needs faced in the operational realities, the conceptual development was organized according to short-term, medium-term and long-term perspectives. For example, finding a replacement heater element model was on the short-term timeline, the material analysis of broken heater elements was on the medium-term timeline, and a completely new autoclave concept was on the long-term timeline.

02 Creating prototypes

Development activities were performed in parallel to explore several potential solutions along each timeline. University partners were involved to both design entirely new autoclave concepts and to explore potential failure modes on existing heater elements, a manufacturer was brought in to do detail design and prototyping of a new autoclave concept, and sterilization experts with both field and research backgrounds were consulted in the evaluation of the resulting prototype at MSF's training and innovation centre in Brussels, Espace Bruno Corbé (EBC).

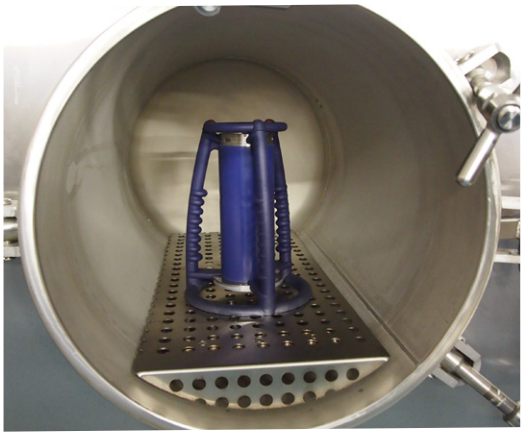


Assessment of traditional autoclave in Espace Bruno Corbé.

03 Testing phase

The work in this phase included translating needs and requirements into technically-oriented functional specifications, which were discussed with the project owner (MSF OCB biomedical referent) to form the basis for the detailed design concept from the manufacturing partner. The first prototype was tested at a Factory Acceptance Test (FAT) at the manufacturer's facility outside of Paris, where MSF representatives from biomedical, infection control and logistic expertise areas took part.

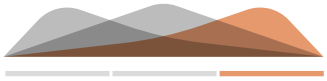
The second prototype was redesigned according to the feedback and results from the FAT, and it was installed and tested at the EBC test site in Brussels, where the participants from the Paris tests were joined by experts in the sterilization process. The machine failed the first EBC test, performed with 3M's Electronic Testing System (ETS), and the sterilization expert then worked together with the manufacturing company to design a sterilization process that would solve the problems identified in the test. At the second EBC test, the machine passed the 3M ETS test, and was thus ready for the field testing phase.



Using the 3M Electronic Testing System at Espace Bruno Corbé in Brussels.

03 Implementation

A pilot study was performed with the autoclave installed in Haiti at the "Centre de références pour les Urgences Chirurgicales et Traumatologiques « N'ap Kembe » de Tabarre", an MSF OCB hospital for traumatology, specialized in ortho-synthesis.



Step 3 of Innovation process
Implementation

Detailed design and implementation of solutions in the field, scaling up and diffusion

05|2016
Presentation and video demo of the autoclave concept at the MSF Scientific Days in London, UK.

09|2016
Installation of third, updated prototype, in Haiti at "Centre de références pour les Urgences Chirurgicales et Traumatologiques « N'ap Kembe » de Tabarre", an MSF OCB hospital for traumatology, specialized in ortho-synthesis.

12|2017
Field-testing phase in Haiti concluded.

Project Completion

01 Pilot Study

After an extensive testing/validation phase at the EBC training center, the autoclave was sent to the Tabarre project for field testing at the end of August 2016. A joint one-week visit with Sterimed (now MDS) was held starting 23rd of September to ensure correct installation and training of the end-users and technicians. At the same time protocols and supporting guidelines were developed together with the field team.

The trainings on site were given to the full sterilization team during the actual shifts in the hospital. Basic information on autoclaving processes like time-temperature and time-pressure curves needed to be included to make the functioning of the device clear to everyone. Rules about which kits and materials to be sterilized by the prototype were set in place, but the overall user friendliness of the device quickly turned it into the preferred autoclave for all sterilization processes. This resulted in turn to an over-use and consequently some breakdowns.

Overall, the device has performed quite well during its short lifespan. The users were satisfied as it not only performed correct sterilization of hollow instruments and surgical drill kits, but also because the autoclave was usually working faster and since they did not have to open/close valves, they could concentrate on packing the instruments. Because the prototype released less heat in the room, the working conditions had improved compared to when they were using four other autoclave models. In total, the autoclave performed over 3000 cycles the first year and downtime was less than 6%.

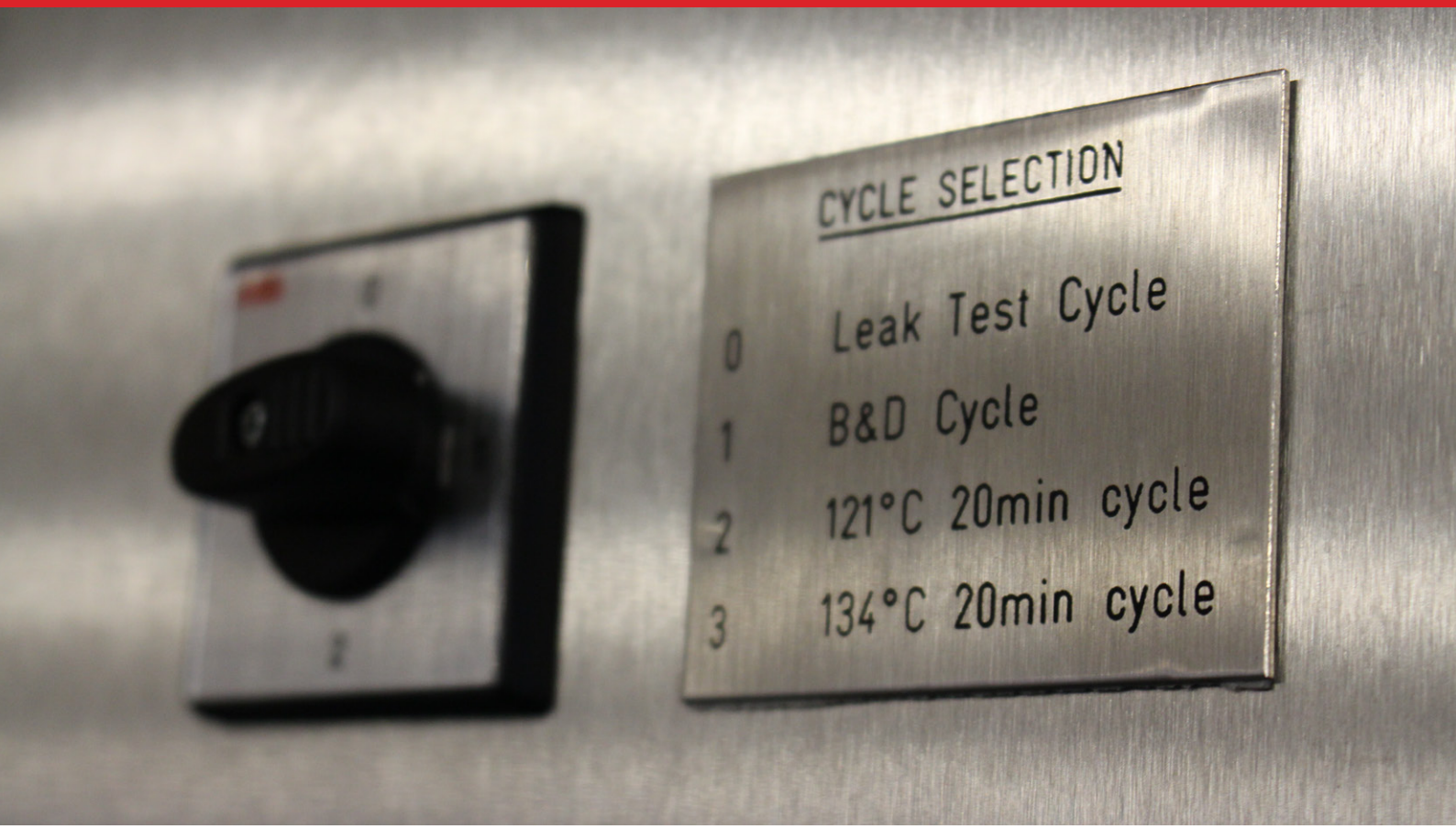
Some breakdowns led to extensive down time. Main causes for those breakdowns were the electro-valves, the pressure regulation and overall lack of experience with the prototype, and finally a critical failure due to a fissure in the sterilization chamber wall.

The electrical valves broke down due to crystal formation, probably due to the high mineral content of the Culligan water used. During a preventive maintenance, the replacement parts were installed incorrectly, making the autoclave unusable for 12 days because the cause was difficult to determine. Luckily MDS had engineers at the ready to fly to the mission and repair the device.

Overall, the field test was definitely useful and increased MSF's knowledge about more complex steam sterilization methods. Apart from some initial engineering flaws such as the peak current draw and the causes of breakdowns, the prototype delivered as expected until the final breakdown.

After revision, the model should preferably be retested in a different setting, as the water savings and relative simplicity of the equipment would remain a big advantage in many settings.

The autoclave prototype being packed during field testing in Haiti.



Lessons Learnt

• There is a clear value in including external actors and experts to challenge established ways of working. For example, bringing Lambda Projects and HEART Consultancy to the tests at Espace Bruno Corbé in Brussels proved to be a critical part of the project success. Not only did we discover that we were not sterilising hollow instruments correctly, we also identified successful ways to mitigate this challenge and design a better solution.

• When setting up pilot studies in the field, it is important to clearly communicate the prototype status. In this case, users did not perceive the autoclave as a prototype, and as they got used to its benefits in their daily work, they were also largely expecting it to be their go-to solution on an everyday basis – which is normally too much to ask from any prototype system.

• Another aspect of field testing is the dynamics between the host organization and the other actors involved in the process, including the prototype manufacturer. The manufacturer might want to spend more time on site, for additional tests and more training sessions with operators and technical team. On the other hand, this can risk putting additional strain on the local field staff. There is an element of volunteering on both sides, both the field staff that are testing and giving feedback on prototype equipment, and the manufacturer that provides equipment and problem-solving capacity. Agreeing on an effective communication process and managing expectations is key.

• A major part of achieving effective communication and expectation management is to plan accordingly. For future projects, we would consider framing the field tests in more detail, including contingency plans, financial commitments and responsibilities when things break down, a process to rely on if additional training is needed, if work profiles need to be updated, etc. In summary, following the standard framework and processes also for the pilot study, so that a clear contract situation leads the way for a more efficient field testing process.

• It is easy to underestimate the time needed to manage the project after the prototype was installed. It is not a ”set and forget” situation, there is a continuous flow of questions back and forth from users and from manufacturers, and in lack of a direct link between these actors, there is a lot of strain on the biomedical referent.

Acknowledgements

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Sterimed, MDS, TU Delft, KTH, Lambda Projects, HEART Consultancy, 3M.

The team testing the 3M Electronic Testing System at Espace Bruno Corbé in Brussels.

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