Disinfection of reusable medical equipment

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Abstract:
Development, implementation and testing of a cleaning and disinfection concept with tracking possibilities for reusable medical equipment, based on the current and future demand and legislation, both measurable and reproducible and which qualifies for ISO standardization.

Focus will be put on the disinfection of systems of anti-decubitus mattresses, because these contain cover, mattress, pipes as well as a pump. When disinfection is developed, the traceability system can be determined and tested, as this needs to withstand the disinfection procedure as well. The project is running.

Introduction

ESRI is a fast-growing SME which has become one of the most important players in market for medical equipment rental. ESRI accordingly wants to expand to arrive at the cutting-edge as regards safety, traceability and guaranteed hygienically clean material in Belgium and Europe. This is a growing market as the use of medical devices in the care world is expanding rapidly. For reasons of complexity and specificity, care-providing bodies are increasingly contracting out these services. Care establishments are hence putting their trust in reusable devices such as pressure redistribution mattresses, and external companies who take responsibility for all the relevant aspects: supply, maintenance (hygiene and/or sterilisation), stock management, etc.

In view of the increasing problems with resistant pathogens, constantly stricter rules concerning hygiene must be complied with. This is as distinct from daily practice where the equipment is manually cleaned and disinfected, with the consequence of these materials being insufficiently cleaned and disinfected with validation of the process being barely possible.

As an example we refer to a press article dating from 21 July 2011:
‘In Maasstad (NL) at least 70 people were infected by the multi-drug resistant Klebsiella bacteria. Twenty-five of these people died.’

Resistance is an additional problem. The use of antibiotics, disinfectants and chemical cleaning results in pathogens becoming increasingly drug-resistant. The consequence is that the illnesses are more difficult to treat, along with a greater spread of the pathogens. This can be illustrated on the basis of the evolution of MRSA (multi-drug resistant Staphylococcus Aureus or ‘the hospital bug’). In 1940 this was still an ordinary pathogen treatable with antibiotics. In 1960 the first methicillin-resistant Staphylococcus Aureus (MRSA) originated, and by 1980 it had become multi-resistant. In 2000 MRSA epidemics originated outside hospitals. The year 2010 heralded the phenomenon of the superbug, whereby today in the United States there is full resistance to the latest antibiotics. Now we have the new resistant hospital bug (CPE). (Carbapenemase-producing Enterobacteriaceae) emerging.

Current registration demonstrates that the majority of these infections occur in Flanders part of Belgium. A total of 23 hospitals have already reported the problem among 175 patients. In Brussels and Walloon hospitals 31 patients have been reported. This contamination also resulted in the infection of sixty persons. For a company such as ESRI it is accordingly crucial to be aware of the current situation of available technologies and to develop an effective procedure.

The question for ESRI is accordingly clear: can a maintenance concept be developed for a supplier of reusable medical equipment that can ensure that goods and products coming into contact with patients can remain free of pathogens that may cause hospital infections in a safe and environmentally friendly manner?

With this project the company seeks support with the following points:
1. What are the disinfection levels of reusable medical devices that can be effectively achieved and measured?
2. What test protocols relating to the cleaning and disinfection of reusable medical devices can be used to monitor the specific cleaning processes?
State-of-the-art cleaning processes

For cleaning mattresses and other devices a comparison can be made with the guidelines for the cleaning and disinfection or sterilisation of instruments, seeing as there are no specific instructions available but such does exist for the use of linen.

As a standard in Europe reference is often made to the guidelines of the WIP (Dutch Working Party for Infection Prevention) in the Netherlands and various NEN standards such as NEN 14065. The CERTEX quality manual includes the requirements ensuing from the NEN-EN 14065 standard. This European standard was drawn up to achieve an agreed level of microbiological quality in conformity with the intended use of the textiles. NEN-EN 14065 is also referred to as RABC (Risk Analysis and Biocontamination Control). Since the end of 2008 all CERTEX-certified companies also have to comply with the RABC standard at the level defined for the company concerned.

The same applies for Belgium, and for the treatment of hospital bedding reference is always made to the various NEN standards which are strictly followed. For the treatment of other devices relative here, at the time of the application no conclusive standards are known. As described in the introduction, the problem of hospital infections is on the increase. For this and other reasons hospitals are increasingly turning to equipment lending services, as this is indeed the case for the much better regulated linen.

Incorporation in the current operating activities

ESRI is currently one of the strongest players in the rental of medical equipment (chiefly for the sale and loan of pressure redistribution mattresses) in Flanders, and ESRI wants to expand to be at the forefront of safe, traceable and guaranteed hygienically clean material in Flanders and the Benelux. This is also why new premises on the research park in Haasrode have been brought into use.

Why the focus on reusable equipment?

The use of medical devices in the care world is growing at pace. This rise is a consequence of different factors such as the greying of the population, the demand for care, and the increasing chronicity of care associated with the ageing of the population. Establishments are also turning to external companies for reusable devices such as pressure redistribution mattresses who take responsibility for supplies, maintenance (hygiene and/or sterilisation), stock management, etc. As a company we want to invest in this growth market to be and remain at the cutting edge.

Purpose of the study

This research yields a double benefit for us: the customer receives a guaranteed safe product, while the company offers its products in a much more efficient way. Finally, this process development prepares for changing market conditions, meaning ESRI is not only ready for the new market and any standard changes, together with Thomas More Kempen the concern can also play a part on standardisation committees for this sector.

Study activities carried out prior to this project

For these topics there have already been various research activities in the past on operating procedures and the implementation of disinfectants in washing programmes, as well as bacteriological testing along with the external monthly bacterial controls (including by Centexbel). The objective of this bacterial control for ESRI is accordingly to be able to guarantee its customers that with their current washing process they are achieving a pathogen reduction as required in, for example, the industrial laundering process for hospitals or the food industry. Elimination of at least 10^6 is the benchmark. This standard is achieved today and controlled monthly (results in the annex).

Problem definition

This research aims to formulate an answer to the search for the most efficient procedure for disinfection and traceability. Both aspects are indeed of importance and are inextricably linked. The primary focus is on
disinfection before traceability is incorporated. Based on the most appropriate disinfection method, the tracing system can then be put in place as it is dependent on the disinfection method.

Hence, in this project we first of all want answers to the following research questions:

- What guidelines/standards/regulations exist in Belgium relating to the hygiene of reusable medical devices?
- What contamination/soiling must be borne in mind?
- How can the high quality of cleaning and disinfection be measured, so also controlled? And how is this workable in practice in an operational environment?
- What protocols and techniques exist relating to cleaning and disinfection and are these effective?
- What tracing technology (that stands up to the washing and cleaning process) can be used so the ‘life history’ of a reusable device can be correctly reproduced.
- What tracing technology allows all the necessary information to be constantly available (such as production cycle, material properties, etc.).

Based on the knowledge gained, we shall set up a pilot study with a full laundry line developed according to all verified knowledge. This set-up is then clinically controlled and tested, as is the methodology developed for tracing the goods.

innovation objective

General objective
The development, implementation and testing of a cleaning and disinfection concept with tracing for reusable medical equipment, based on the current and future demand for care and legislation, that is measurable and reproducible and comes into consideration for ISO standardisation.

Concrete objectives

- Automation of the disinfection process to exclude human error.
- The fully automatic start-up of the disinfection process by computer control for aspects including products and water temperature.
- Development and trial production of a semi-automatic maintenance system to considerably increase production capabilities. The proposed aim is to clean, disinfect and check the operation of more than 100 systems a day.
- Training of personnel for whom a specific manual (scenario) must be developed.
- Traceability of the cleaned medical devices regarding process properties such as the date of processing and control.
- Automated stock management with the implementation of the tracing system.

Concrete criteria

- Building and testing a semi-automatic maintenance system that can clean and disinfect more than 100 systems a day.
- The automatic start-up of the disinfection process by computer control for aspects including products and water temperature.
- All personnel have undergone training on the basis of a specific manual (scenario) developed in the project.
- A tracing system that is resistant to the cleaning and disinfection of the equipment is operational.
- Under the traceability of the cleaned medical devices a system is operational that registers the process properties such as date of bringing into use, date of delivery, date of processing and date of control, etc.
- There is a turnover increase of 30% by 2014.
- Employment increases by 1 FTE per 100 extra systems being loaned (see forecast table for number of employees on pag. 25) to visualise the growth.

Use of the results

When obtaining the intended results ESRI will finally introduce the cleaning and disinfection concept developed in this project at its new location in Research Park Haasrode. The start-up of the activities associated with this project is anticipated for the end of 2013. The expected growth in turnover amounts to 30% in the 3rd year after start-up. When obtaining the intended results this will confirm our position of market leader in this sector and give us an important lead over our competitors. With greater automation of the process it will be endeavoured to work towards ISO standards so ESRI becomes the trendsetter in the sector. As a result, ESRI can develop a new market segment and grow even more strongly by further offering this standardised
application to hospitals and care establishments. (at present exploratory discussions are already taking place with different hospitals)

"Development, construction, testing and validation of the laundry line"

Objectives and criteria:
In this work package we want to:
1. Determine the concept of the maintenance system
2. Achieve the development of the maintenance system
3. Make the maintenance system operational in the form of a prototype
4. Validation of the maintenance system

Intelligent tracing

Objectives
1. Study of the tracing possibilities
2. Setting up of inventory control
   a. assuring that each transfer of equipment from storage site to user and vice versa is recorded (main measuring points)
   b. at set times be able to verify that the stock data is consistent with the data on the movement of the main measuring points and the work statements concerning storage site and processing, and at set times verify that the local work statements are consistent with the central work statements
   c. at set times control the consistency of the information concerning the present equipment with the actual situation
   d. report and resolve discrepancies observed and achieve consistency with other local and central accountancy data.

Interpretation of these objectives.
It is becoming increasingly important to improve the traceability of products and components during and after the production cycle. It is one of the most important considerations in the improvement of supply chain efficiency. Being able to effectively trace products in the supply chain increases reliability and service levels, and helps reduce guarantee costs. There will be the exploration of all possible tracing techniques and their applicability for these materials that can also withstand the process in the laundry line.

Tasks: description of planned tasks, methods, techniques, etc.

Study of traceability by Thomas More Kempen
A distinction is made between different types of traceability which can be used side by side:
1. Tracking: following an object along the supply chain and registering data regarded as relevant
2. Forward traceability: where an article is used is recorded. One article is often used in a number of products
3. Backward traceability: the components used in an article are recorded
4. Active traceability instead of passive traceability: with active traceability a computer system following an object is used to adjust, optimize and control processes in the supply chain. Active traceability further contributes by lowering failure costs and increasing production efficiency.

Making the tracing system operational.
After exploration that can start during the operationalization of the previous work package, all possible tracing systems can be listed and compared to be able to start testing with a carefully considered choice. This testing takes place in two phases: technical laboratory testing of the tracing system and the clinical testing of the tracing system. For clinical testing it is chiefly the management and the personnel of ESRI who will be used. They take responsibility for implementation and also ensure data collection so operational testing is made possible. Corrective action can be taken based on structured feedback from the business manager and his/her personnel.
Milestones
All possibilities will first be studied in the Mobilab laboratory. The tracing possibilities are then considered as regards their characteristics and possible uses inside materials (cover, mattress, pipes, pump). The tracing system must indeed be attached to all these materials. All possible attachment systems and their properties will also be studied. These possibilities are then clinically tested with the undergoing of the disinfection techniques to be used in the laundry line. The results of these tests determine the choice of tracing system (e.g. sprayed ink, RFID, etc.).

Valorisation information
The current trend with respect to the use of reusable medical equipment demonstrates that rental is increasingly being preferred over the purchase of this material. This means the ESRI market will grow. An accelerating factor for this changing market can be the introduction of a certified label. This SME innovation project also creates the basis to go for ISO standardisation after the carrying out of this study. We can refer to FTN in the Netherlands as an example. In their annual report they write the following:

‘Contracting out professional textile care requires sound knowledge in all kinds of fields in the chain. The use of modern textile materials specially developed for use in specific market segments increases the added value for buyers and end users and lowers the costs. Good chain orientation is hence indispensable. Products and services must suffice with regard to (international) norms, standards and guidelines. Against this background FTN initiates, stimulates and facilitates the origination of new developments in textile care. Textile service companies work in an FTN context together with specialists on projects/activities in the field of sustainability, quality management, employment conditions, technological renewal, etc.’ The growing market can also be illustrated by their figures.

Table 2: Forecast for textile care services development 2004 – 2010 (in millions €)

<table>
<thead>
<tr>
<th></th>
<th>2004</th>
<th>2007</th>
<th>2008</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health care</td>
<td>482</td>
<td>529</td>
<td>541</td>
<td>548</td>
</tr>
<tr>
<td>Trade and industry</td>
<td>470</td>
<td>508</td>
<td>492</td>
<td>445</td>
</tr>
<tr>
<td>Hotel, catering and recreation</td>
<td>158</td>
<td>178</td>
<td>169</td>
<td>143</td>
</tr>
<tr>
<td>Total</td>
<td>1110</td>
<td>1215</td>
<td>1202</td>
<td>1136</td>
</tr>
</tbody>
</table>

This table clearly shows the growth in work contracted out for textiles in health care, while there is a downswing in the other sectors.

2.4.1 Importance of the project for the company
As an introduction we can refer to a discussion on 26 September 2012 at the European Commission: ‘Ranging from simple sticking plasters to the most sophisticated life-supporting machines, medical devices and in vitro diagnostic medical devices are central to our health and quality of life.
To ensure that these devices serve the needs and ensure the safety of European citizens, the European Commission today proposed two Regulations which are fit for purpose, more transparent and better adapted to scientific and technological progress. The new rules aim to ensure that patients, consumers and healthcare professionals can reap the benefits of safe, effective and innovative medical devices. The medical device sector is highly innovative, particularly in Europe and has an estimated market value of around €95bn’.

This measure will result in the acceleration of the market trend in the rental of these devices by 100%. This will boost the market share and bring about extra business economic activities at ESRI.
This trend can be bolstered by the introduction of a certified quality label. The results of this project will also be used as input for the adaptation of standards in Belgium, partly for reasons including the involvement of different organisations in this project. Much added value can be achieved with this project, and this as regards insight, standards and certainly economic added value.

**Valorisation stages**

The results of this project will be used to further expand ESRI’s activities. An effectively operating cleaning and disinfection system associated with a high-performance tracing system is the condition for further growth. This growth will manifest itself in a larger market share and more personnel. At present there are already discussions ongoing for an establishment in the Netherlands controlled from Flanders where further R&D and expansion will take place. The possibility is also being studied of setting up a Hub in Flanders (e.g. in Ghent) to be able to serve customers in this region better and faster.

This project will also contribute to the development of an innovative image. ESRI is striving to be the trendsetter in this market segment.

Finally, new research can be put in place using the results from this research. The project results will be offered to our surrounding countries by consulting marketing.

**Side-effects of knowledge and social advantages**

Spill-overs for the company:

- The results of this project form a well-founded basis for further study concerning application to other medical devices
- Tracing other products will also be possible according to the same methodology.
- Fewer pointless movements at ESRI due to more efficient management using tracing
- Trendsetter with the ISO certification application
- In cooperation with Thomas More Kempen: lobbying for regulations on the cleaning and disinfection of equipment

Social advantages

- Patients with problems are offered higher quality and safer products to also contribute to good health, quality of life and savings in costs for the government
- The transparency of labels becomes clear by the drawing up of better and clear procedures as an outcome of this project

**2.4.2 Economic added value**

The results of this project will form the basis of the core activity of ESRI over the coming ten years. And this not only as regards insight and standards, there is also the economic added value.

The results of the project will lead to accelerated market penetration and an expanding market, along with extra business economic activities for the SME and the partners involved in the valorisation value chain.

The advantages of this project for customers of ESRI are the following:

- Patients with problems are offered higher quality and safer products to also contribute to good health, quality of life and savings in costs for the government
  - Easing of the workload of care-providing personnel, including better contact with the patients being enabled (care efficiency).
  - Better motivated personnel.
  - Possibility of carrying out tasks better.
  - A lighter workload.

There is also a number of additional advantages for ESRI:

- Better and clearer procedures, so the transparency of labels is clear
- Fewer pointless movements due to more efficient management with tracing capabilities
Beyond the 10-year estimate this project will have a permanent impact on the whole organisation's operations and service for our customers.

This project also represents a turning point in innovation confirmed by our good performance measured in the innovation audit by the innovation centre on 18 July 2011 in the field of market focus (79.4%), product and service process innovation (53.8%), personnel policy and corporate culture (73.1%) and financial management (70%) and the need for realisation methods (38%).

For employment in Flanders we see the same growth of 100 additional rental systems (average growth 150 each year) needing one logistic employee, one delivery van and 150 more systems (figures included in our submitted annual balance).

Assuming the figures for care demand (2.4.2), knowing that ESRI is at present the rental market leader, both turnover and personnel growth will continue to increase in line with both curves.

Irrespective of mere logistics, technical, commercial and scientific expansion will appear necessary (nursing staff and ergotherapists).