IT-based risk identification: Dynamic data presentation and text mining based classification

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Introduction

Since 2000 the amount of serious incidents related to the application of medical devices reported to the Federal Institute for Drugs and Medical Devices (BfArM) is constantly increasing in numbers (in 2013 approx. 8000 reports). This development in combination with increasing complexity of medical devices leads to increased challenges regarding early and reliable risk identification and assessment. Here modern information technology provides support to the analysis of root causes and the detection of patterns related to systematic device failures.

Methods

Rather than having a standard static view on the data we are currently developing approaches towards a dynamic presentation of the information available. This e.g. means the user shall be able at any moment to see how incidents evolved along a time line visualising the absolute and relative values but even more important the rate of change. As the visualisation is heavily dependent on the appropriate classification of the data but at the same time most of the details about the incident are available only within the narrative description, a substantial amount our research focusses on text mining to identify patterns and to dynamically classify the reports.

Results

The early results show the difficulty in properly classifying incidents by a fully automated system. Even though using synonym catalogues improves the performance, a semi-automated classification process where the user is prompted with the most likely choices but conducts the final classification himself appears to be the most target-oriented approach.

By using dynamical visualisation of incidents the effectiveness to scan large amounts of data can be considerably improved.

Conclusion

Both, the text mining supported classification as well as the dynamic presentation of data, promise to be highly valuable instruments to improve the effectiveness of risk detection and assessment within of the vigilance system even further.
User centered design of a pain assessment app according to IEC 62366

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Introduction

Pain assessment is an important means for healthcare professionals to recognize a patient’s condition and to support medication decisions. The established pain scales make use of patient self-report or observation. However, healthcare professionals still rely on mainly paper-based solutions to gather the data. To facilitate acquisition and exchange of patient related data, we started to create a pain assessment app first primarily for children while following the usability standard for medical devices IEC 62366.

Methods

The regulations of the IEC 62366 prescribe a usability engineering process combined with risk assessment. We have matched our user centered design process to these regulations and apply this medical engineering process to create the app. Therefore, our project starts with a clinical review followed by analysis, design and finalized with a summative evaluation (validation).

Results

The initial ideation phase resulted in a first app concept draft. Subsequently, we took these ideas and conducted a clinical review at Saarland University Medical Center. This allowed us to identify expectations towards the app and which pain scales are considered most important. In order to gather requirements, we conduct focus groups with prospective users. On this basis, we are going to draw up a validation plan and proceed with design and development of a prototype, which will be subject to the summative evaluation (validation). We document the whole process and project results according to IEC 62366 in a Usability Engineering File using our own template.

Conclusion

As an outcome of the clinical review, we were able to confirm our hypothesis, that a pain assessment app could provide an added value. According to the feedback, we consider to extend our concept to people of all ages (e.g. dementia patients) at a later time. Furthermore, we plan to investigate on possibilities to support pain therapy beyond the collection of pain assessments.
Development of a test bench for fatigue strength determination of surgical implants incorporated with magnetic nanoparticles

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Introduction

Surgical mesh implants consisting of PVDF threads with incorporated magnetic nanoparticles (MNP) can be visualized by means of magnetic resonance imaging (MRI). For a high-quality product, the meshes must be strong enough to withstand the forces acting on them after implantation for a long time. In order to test the elastic stress-strain behaviour of threads used for mesh implants, a test bench for fatigue strength determination was developed. The MRI signal alteration caused by local change of MNP concentration due to the elongation of the threads was measured at fixed time intervals.

Methods

The test bench is placed in an isolated chamber to provide defined temperature and air humidity close to physiological conditions. It consists of a holder equipped with tensile grips and loads attached to a eccentric wheel driven ramp. All used materials are compatible in MRI and the holder is filled with 2 w% agarose allowing for safe investigation in MRI. Six different threads are mounted in the grips of the holder, with their long axis perpendicular to an imaginary line joining the points of attachment of the grips to the applied cyclical loading. These exert on the threads half of their breaking strength, which was preliminary investigated with a servo-hydraulic tensile strength testing machine (Zwick, Germany).

Results

The long-term study indicates mechanical stability of the threads. Their ultimate elongation is dependent on the MNP concentration in the threads and the thread thickness. For instance, the elongation for a thread with a diameter of 120 μm and an MNP concentration of 20 mg/g (3 mg/g) was determined to 37.1 mm (30.1 mm) for an applied force of 4.2 N (5.7 N).

Conclusion

The test bench is a suitable and convenient solution for determination of the stress-stain behaviour of threads with incorporated MNP, facilitating at the same time MRI investigation of the weight-loaded threads.
Chunk Controls – An Approach to Increase Usability In The OR

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Introduction

The aim of this study was to analyze the usability of a recently developed prototype for device control (DIORS-Software) in an operation room. In order to make the usage and navigation of the DIORS-Software more easy and harmonious, chunk controls were implemented. Chunks are complex signs consisting of elementary signs of lower order (sub signs) (cf. Schrader, 2013). One central purpose of chunks is to support the human information processing within the human-computer interaction. To assess the usability of the DIORS-Software, it was compared to a clickable Mockup of the Olympus Software (EndoAlpha).

Methods

Participants were 16 surgery nurses who all interacted with each of the two software types. Eight of them started with the EndoAlpha, the others with DIORS. Participants executed one sequence of the laparoscopic colon resection. They had to follow commands by using mock-up versions on a tablet. This simulated scenario was used to test whether providing chunks increases usability compared to sequential commands. After each trial, participants completed the ISONORM 9241-110/S via paper/pencil. Attitudes regarding chunks were assessed via questionnaires.

Independent variables were (1) the type of software (EndoAlpha vs. DIORS) and (2) the type of command (chunks vs. sequential commands). While interacting with the DIORS software, eight of the participants received chunks, eight of them sequential commands.

Results

The DIORS-Software received significantly higher ratings regarding all factors (dependent variables) of the ISO 9141-10/S, which are suitability for the task, self-descriptiveness, controllability, conformity with user expectations, suitability for individualization and suitability for learning. Furthermore, fewer problems in using the DIORS-Software occurred. Chunks revealed high acceptance ratings but did not influence the usability significantly.

Conclusion

A helpful scale to measure attitude towards chunks was developed. Further investigations with an extended experimental group within a real hospital context should take place, as the first results of this simulation seem to be very promising.
Experimental Investigations on Medical Devices for the Development of a Non-Destructive Quality Control

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Abstract

We present the development of two test-setups and the results of our investigations on the flow behaviour of intravenous infusion filters. These activities are milestones to establish a 100% non-destructive quality control (end-of-line test) of the mentioned medical devices. The distinguishing characteristic will be the pressure dependent flow. For this reason we developed two different test-setups which will ensure the similarity between liquid and gaseous flow. First of all we investigate the characteristic flow behaviour of the filters used under realistic conditions and solutions like NaCl 0.9% or Glk 5%. When a gauged filter differs from its characteristic flow rate curve it is assessed as not all right. To get a non-destructive method we replace liquid through high-purity gas. We will show that specific failures can be detected when flown through by liquids and give a forecast of the investigations made with gas. The development of the test-setups and the execution of the experimental investigations can be assessed as successful.

1 Introduction

The function of intravenous infusion filters is to prevent a patient from contamination with glass, plastics, microbes, undissolved drugs and air contained in intravenous infusion solutions. These solutions are given to replace liquid, correct imbalances or to deliver medicine to a patient. Image 1 shows the operating principal and the structure of an infusion filter. The hydrophilic membrane filters harmful contents, the hydrophobic membrane filters air which is contained in the solution. Infusion filters are dedicated to single use. A patient can be connected with various filters at the same time. The given liquids get into the human body with gravity infusion or syringe pumps (Image 2).

The filtering membranes of the infusion filters are made of porous media. These materials are widely used in different industries like water treatment and the (bio-) pharmaceutical industry. Integrity testing as a form of quality control of membranes is divided into destructive and non-destructive methods. Furthermore non-destructive testing can be done before and after use. Also integrity testing can be done with direct or indirect methods [3,4]. Currently the Bubble Point Test is used. It is a direct, non-destructive but contaminating procedure before use.

2 Methods

To develop the quality control the investigated infusion filters are presented and the conditions under which the investigations are made are illustrated. After this the functional requirements of the two different test-setups are described and how the resulting problems were solved. Furthermore the theoretical backgrounds of the presented investigations are explained.
2.1 Materials and Experiments

Object of the investigations are the infusion filters and their specific flow behaviour. They are produced more than a million times per year and are dedicated to single use. The product range includes types of different geometries, different hydrophilic membrane materials and different pore sizes. They all have the same hydrophobic ventilation membrane material. The investigated infusion filters are shown in Table 1.

Table 1 parameters of investigated infusion filters

<table>
<thead>
<tr>
<th>Filter</th>
<th>Pore Size [µm]</th>
<th>Type of Material</th>
<th>Surface Area [cm²]</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPM</td>
<td>0.2</td>
<td>Nylon</td>
<td>2.3</td>
</tr>
<tr>
<td>RPM</td>
<td>0.2</td>
<td>PET</td>
<td>2.3</td>
</tr>
<tr>
<td>RPM</td>
<td>1.2</td>
<td>PET</td>
<td>2.3</td>
</tr>
</tbody>
</table>

The used fluids are an isotonic saline solution and high purity synthetic air.

The experimental investigations are made under the conditions shown in Table 2.

Table 2 conditions: pressure, temperature, fluid

<table>
<thead>
<tr>
<th>Pressure [mbar]</th>
<th>Temperature [°C]</th>
<th>Fluids</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 2000</td>
<td>21 (const.)</td>
<td>NaCl 0.9%</td>
</tr>
<tr>
<td>0 – 200</td>
<td>synth. air 5.0</td>
<td></td>
</tr>
</tbody>
</table>

Of each type of filter a multiple number were investigated.

The process of the measurement is as follows. At first the filter was connected with the fluidic system. The 2/2 way valve has been closed and the pressure was regulated at a specific value. After this the valve were opened and the flow has been measured at a specific moment in time. The value of volume flow at the liquid system has been taken five seconds after the valve was opened. The evaluation of the measurement values is presented as volume flow over pressure.

2.2 Test- Setup

The development of the test-setups has to meet several functional requirements. These requirements are: comparable flow conditions, precise regulation of flow and pressure, minimal leak losses, a high level of purity, application as “End-of-Line”-quality control, high sensitive sensors, minimum measurement uncertainties, the use of 3 different gases and a good repeatability.

To satisfy these requirements we have undertaken the following efforts. First of all two separate systems have been established. One system is only used with liquids, the other is only used with gas. To get comparable flow conditions and precise regulation of flow and pressure some preliminary studies have been done, the pressure and flow control were dimensioned accordingly and if it worked the same components were selected.

Furthermore the components are connected by stainless steel tube fittings with gastight sealing and tube-gripping action as well as every component of the systems like pipes, fittings and instruments was cleaned to remove oil, grease and loose particles.

In order to use the assembly as a “End-of-Line”-quality control in a clean room production facility it is ensured that the completed infusion filters are connected with luer-lock connectors and that it can be handled from one person in a short time frame from at least 10 seconds for a multiple number of filters at the same time.

The sensors in the systems have a high resolution, are precise and have a good repeatability. The used sensors measure the pressure and volume flow rate, temperature and the dew point in the gas system. They are shown in Table 3.

Table 3 manufacturer and type of the used sensors

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Parameter</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wika</td>
<td>pressure</td>
<td>P-30</td>
</tr>
<tr>
<td>Siemens</td>
<td>liquid flow rate</td>
<td>SITRANS F C MASS</td>
</tr>
<tr>
<td>Alicat</td>
<td>gas flow rate</td>
<td>M Series Whisper</td>
</tr>
<tr>
<td>Wika</td>
<td>temperature</td>
<td>TR40</td>
</tr>
<tr>
<td>Vaisala</td>
<td>dew point</td>
<td>DMT 132</td>
</tr>
</tbody>
</table>

Both systems meet the requirements of an intended uncertainty budget from maximum 5%, are robust and have a good repeatability.

2.2.1 Liquid Flow System

The system for liquid flow consists of a regulated pressure source, a pressure vessel, sensors to measure the fluid temperature, the pressure and flow, a metering valve and the infusion filter. The system is shown in the following image.

Image 4 experimental setup for water

The pressure vessel is filled with cleaned water, NaCl 0.9% or Glk 5%. The biggest challenge of the development of this system existed in the choice of the flow sensor. The whole system is configured to measure volume flow between 0 – 1 litre per minute and 0 – 250 mbar pressure.
2.2.2 Gaseous Flow System
The gas system consists of the same components and has the same structure like the liquid flow system. It is distinguished in the choice of a different flow sensor and has an additionally dew point sensor. It is used with high purity gases like synthetic air, argon or nitrogen.

2.3. Theoretical background
To describe the flow behaviour and calculate the pressure drop, volume flow rate or velocity the geometric dimensions have to be known and the Bernoulli-Equation, especially the Hagen-Poiseuille Law have to be used. Due to the use of only relative low pressure liquid and gas are assumed to be incompressible. Since the filtering membrane is a porous media, the calculation of the mentioned values is not possible. For this it is necessary to know some specific information like the i.e. the average pore size and the contact angle between the material, the fluid and the atmosphere. To get these parameters extensive studies are necessary which is not part of this project.

3 Results
The measurement values of different filter types flown through by different fluids, the identification of a non-conforming filter and the time dependent behavior of liquid flow at constant pressure are shown.

3.1. Liquid
In image 5 the pressure dependent volume flow rates of three different filter types with same dimensions but different filtering membranes and pore sizes are shown.

Image 5  example of the mean volume flow of different filter types with the same surface area [NaCl 0,9%; 2,3 cm²]

The presented values are mean values of several filters of the same type. The different filter types distinguish clearly from each other. They show a nonlinear behaviour depending on the inlet pressure.
In the following image the integral aspect of the quality control is presented. Three different measurement series from the same filter type are shown.

Image 6  example of the volume flow of different filters of same type [NaCl 0,9%; 2,3 cm² surface area]

Two volume flow curves are close together in contrast to the third.
First of all it gets obvious that measuring a multiple number of filters of the same type a characteristic flow behaviour can be identified. Secondly a deviation from that norm is detected through its specific flow over pressure graph when it is investigated under the same conditions and in the same way. This deviating filter is identified as non-conforming and will be sorted out.

Image 3  SEM-picture of a 0,2 µm Nylon + membrane

Image 3 shows the cross section of a 0,2 µm Nylon + membrane which can be found in one of the investigated infusion filter types. The porous structure is clearly visible.
In image 7 the decreasing time dependent behaviour of an infusion filter while through-flown by liquid at constant inlet pressure is presented.

### Image 7  example of the time dependent behavior of liquid flow [const. pressure]

This knowledge leads to the decision that the measured volume flow has to be obtained at a concrete moment in time after the valve was opened to get comparability between the measurements of different filters.

### 3.2. Gas

On the second system the flow behavior of the infusion filters through-flown by gas have been investigated. Again filters of the same type were measured to get the mean volume flow dependent from the inlet pressure. In the following image three flow curves of different filter types are illustrated. They have the same geometry but differ from each other in the used porous membrane. The same types of filters used in image 5 and explained in table 1 were taken.

### Image 8  example of the mean volume flow of different filter types [synth. Air; 2,3 cm² surface area]

The inlet pressure was regulated within 50 – 200 mbar. The flow curves differ from each other clearly as well. The filter system with the largest pore size has also the highest volume flow rate. The investigations have shown no time dependent behavior and a linear inlet pressure dependency.

### 4 Conclusion

We have illustrated the development of two test-setups. These systems are engineered to meet the specific requirements of the prospective quality control and its methodology. They fulfil every specification and have shown its qualities in the explained experimental investigations.

These measurements have been performed with liquid and gas. We used different filter types and showed their inlet pressure dependent volume flow behavior. The investigations performed explicit and promising results. These are: every filter type shows a unique inlet pressure dependent flow characteristic, these characteristics are independent from the fluid, the flow of liquid has a time dependent behavior whereas the flow of gas does not behave the same way and non-conforming filter systems can be easily identified.

Considering these perceptions we will do the next steps to develop the designated quality control. Therefore we will examine extensive experimental investigations of the gas flow through the filter systems and take into account which production faults we are able to detect. Furthermore we will refine the methodology of the measurement process to meet the requirements of a quality control at the end of an assembly process from a medical device.

The submitted experimental investigations and the development of the two test-setups have been essential milestones to reach this goal. The entire non-destructive quality control and its methodology will be presented upon completion at a future date.

### 5 Acknowledgement

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### 6 References


Bugs! iPad-Hygiene in Healthcare

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² Hannover Medical School, Institute for Medical Microbiology and Hospital Epidemiology

Abstract

Nowadays, mobile electronic devices such as tablet PCs are frequently being used directly at the patient’s bedside. Thus, as for all other tools and devices used in such settings, there is a need for proper reprocessing (disinfection) after use in order to prevent pathogen transmission. However, manufacturer’s commonly only allow cleaning the devices with a dry fleece, although this approach certainly does not live up to the demands of infection control.

1 Introduction

With the increasing adoption of mobile technologies by physicians and other health care personnel, old issues regarding hygiene are resurfacing: any transmission of infectious agents by mobile devices that act as a carrier must be avoided. As seen in previous studies, bacterial contamination of mobile phones of hospital employees is a potential threat [1,2,3]. Other highly mobile tools such as tablet-PCs give additional food to the debate about “clean hands” [4] and instruments [5] in healthcare settings.

Starting with the recent introduction of iPads in several clinical departments and wards at Hannover Medical School, we proposed standardized disinfection measures for using these devices in a clinical setting, e.g. to clean them with isopropanol-wipes once a day on a regular basis or after obvious contaminations. To train the users how to properly apply the standard procedure of cleaning and to be able to track and document the whole process, we developed an interactive cleaning guide in form of an app that leads users through the whole process in an interactive manner.

1.1 Debac-app

In a cooperative project of the Institute for Medical Microbiology and Hospital Epidemiology, the Peter L. Reichertz Institute for Medical Informatics, both based at the Hannover Medical School (MHH), and Frobese GmbH (Hannover, Germany), an interactive and easy to use disinfecting guide, called “deBac-app”, was developed for the iPad®. In six iterative steps, the app guides users through the standardized cleaning procedure. During each step, the user is asked to interact with the device: “deBac-app” tracks the various parts of the cleaning process and logs the results using its internal protocol function. Later on, this protocol may be emailed to any interested recipient. A timer can be set to remind users to clean the device on a daily basis. Currently, the app is available free of charge (in both German and English language) in the usual app stores for Apple’s App Store® (for iPads®) as well as Google’s PlayStore® (for both tablets and smartphones). deBac-app is currently in use at Hannover Medical School.

1.2 Objective

In a previously published study, we were able to show that a standardized disinfection procedure with isopropanol wipes as it can be performed aided by deBac can significantly reduce the microbiological load in medical as well as non-medical settings [6]. Since this initial study, we received many requests by other clinical centers who voiced an interest in using deBac for devices deployed at their centres and we are currently in the process of preparing a preparing a larger scale multicenter trial with some of these newfound partners. Of course, this necessitates an appropriate method for tracking whether disinfection is successful. In the aforementioned small scale study, the amount as well as species of microorganisms found on the surface of the devices (before and after disinfection) was determined based on an evaluation of contact agar plates that were used on 13 locations (6 on the front, 7 on the back). Although the evaluation of the agar plates applied in this manner lead to valuable results, it is a relatively time consuming and expensive process (due to both material costs as well as working time) and this may prove prohibitive for using the same setup at a larger scale. Therefore, in preparation for the future multicentre trial, we were interested in whether a reduced number of sample locations – which will certainly lead to lower expenditures of time and money – can still adequately capture the success of the disinfection procedure. In addition, we were interested in whether regular and properly executed disinfection of the devices can lead to an overall reduced microbial load over time (even for devices that are not freshly disinfected).

2 Methods

In this evaluation, isopropanol wipes (mikrozid® AF, Schülke & Mayr GmbH, Germany) were used disinfecting the surfaces of five devices (iPad®, Apple, USA). Five members of the care staff (who all use their devices regularly in their daily routine) were asked to use them as they usually do, including a regular disinfection process as guided by “deBac-app” as they saw fit. The tablet PCs were sampled for microbiological contamination by the using contact plates (CASO agar, Heipha, Germany) on
four locations: two on the front, and two on the back side. Sampling was performed by staff of the infection control laboratory before and after performing the standardized disinfection procedure (as described in deBac) and this took place over a course of four weeks, once per week, at the end of the individual shifts. Following standard (certified) in-house laboratory procedures, the number of colony forming units (CFU) was determined and the specific pathogens that were found were identified up to the species level.

Descriptive statistics included calculation of the median and standard deviation for the CFU found on the devices, stratified for the time when the samples were taken (before vs. after disinfection), the side of the device where the samples were taken from (front side vs. back side) and the types of bacteria that were determined (gram positive vs gram negative) (Table 1).

The elimination of CFU by disinfection was calculated for each week (1 through 4) for the devices and stratified for the sampled side (front side vs back side). In addition, the percentage of reduction in microbial load was calculated (Table 2).

Also, the types of bacteria and their frequency of occurrence were determined before (Table 3) and after disinfection (Table 4), again stratified for gram positive and gram negative species.

### Results

In total, before disinfection, 2,033 CFU were counted on the five devices during the four week monitoring period (median: 416, IQR 118). Gram positive bacteria that are part of the physiological human skin flora were the main types that were identified, amounting to 1,950 CFU (median: 398, IQR 87) vs 83 CFU for gram negative bacteria (median: 4, IQR 20). The aluminium back side of the devices carried a much higher load of bacteria than did the glass surface on the front: Gram positive bacteria were found 2.8 times more often on the back than on the front (front: 507 CFU, back: 1,443 CFU) and for gram negative bacteria, the load was 3.6 times higher on the back than on the front (front: 13 CFU, back: 65 CFU). After disinfection, a total of 87 CFU (median: 20, IQR 17) could be found over the four week monitoring period, with 86 CFU being gram positive and only 1 CFU belonging to gram negatives (Table 1).

Stratified for each week, the CFU reduction was between 94.99% (min, week 2) and 96.58% (max, week 1). Before disinfection, the amounts of CFU of the devices back sides were during the observation period at least 2.11 (week 2) times higher than the amount on the front sides (Table 2 and Figure 1). The best elimination could be demonstrated on the front sides of the devices with a maximum elimination of 98.96% (week 1) compared to the minimum elimination of 94.49% (week 4) on the back side.

### Table 1. Number of CFU, median and interquartile ranges (IQR) stratified for the disinfection (before vs. after), the side samples were taken from (front side vs. back side) and type of bacteria (gram positive vs. gram negative).

<table>
<thead>
<tr>
<th>Gram positive bacteria</th>
<th>Before disinfection</th>
<th></th>
<th></th>
<th>After disinfection</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total CFU</td>
<td>Median CFU</td>
<td>IQR</td>
<td>Total CFU</td>
<td>Median CFU</td>
<td>IQR</td>
<td></td>
</tr>
<tr>
<td>both sides</td>
<td>1,950</td>
<td>398</td>
<td>87</td>
<td>86</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td>front</td>
<td>507</td>
<td>100</td>
<td>50</td>
<td>15</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>back</td>
<td>1,433</td>
<td>316</td>
<td>57</td>
<td>71</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Gram negative bacteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>both sides</td>
<td>83</td>
<td>4</td>
<td>20</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>front</td>
<td>18</td>
<td>1</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>back</td>
<td>65</td>
<td>4</td>
<td>10</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>2,033</td>
<td>416</td>
<td>118</td>
<td>87</td>
<td>20</td>
<td>17</td>
</tr>
</tbody>
</table>

### Table 2. CFU stratified for week (1 to 4), disinfection (pre vs. post) and side of the device (front vs. back).

<table>
<thead>
<tr>
<th>Week</th>
<th>Both sides</th>
<th></th>
<th></th>
<th>Front</th>
<th></th>
<th></th>
<th>Back</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Reduction (%)</td>
<td>Pre</td>
<td>Post</td>
<td>Reduction (%)</td>
<td>Pre</td>
<td>Post</td>
</tr>
<tr>
<td>1</td>
<td>702</td>
<td>24</td>
<td>96.6</td>
<td>193</td>
<td>2</td>
<td>98.9</td>
<td>509</td>
<td>22</td>
</tr>
<tr>
<td>2</td>
<td>539</td>
<td>27</td>
<td>94.9</td>
<td>173</td>
<td>7</td>
<td>95.9</td>
<td>366</td>
<td>20</td>
</tr>
<tr>
<td>3</td>
<td>361</td>
<td>15</td>
<td>95.8</td>
<td>73</td>
<td>4</td>
<td>94.5</td>
<td>288</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>431</td>
<td>21</td>
<td>95.1</td>
<td>86</td>
<td>1</td>
<td>98.8</td>
<td>34</td>
<td>19</td>
</tr>
</tbody>
</table>
Before disinfection, on arrival at the laboratory, a variety of microorganisms could be found on the surface on the iPads®, many of them belonging to the physiological human skin flora (e.g., various staphylococci, Bacillus spp. or Corynebacterium spp.), but some of them were pathogenic microorganisms (e.g., Staphylococcus aureus (non-MRSA¹), Pseudomonas spp. or Acinetobacter spp.) that pose a greater risk.

Table 3. Types of bacteria found before disinfection and frequency of their occurrence over the course of four weeks (before disinfection).

<table>
<thead>
<tr>
<th>Type</th>
<th>CFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram positive</td>
<td></td>
</tr>
<tr>
<td>coagulase-negative staphylococi</td>
<td>1,642</td>
</tr>
<tr>
<td>Corynebacterium spp.</td>
<td>192</td>
</tr>
<tr>
<td>Bacillus spp.</td>
<td>87</td>
</tr>
<tr>
<td>alpha-hemolytic streptococci</td>
<td>18</td>
</tr>
<tr>
<td>Staphylococcus aureus (non-MRSA¹)</td>
<td>10</td>
</tr>
<tr>
<td>non hemolytic streptococci</td>
<td>1</td>
</tr>
<tr>
<td>Gram negative</td>
<td></td>
</tr>
<tr>
<td>Acinetobacter johnsonii</td>
<td>31</td>
</tr>
<tr>
<td>Enterobacteriaceae</td>
<td>25</td>
</tr>
<tr>
<td>Neisseria spp.</td>
<td>21</td>
</tr>
<tr>
<td>Moraxella spp.</td>
<td>2</td>
</tr>
<tr>
<td>Acinetobacter spp.</td>
<td>3</td>
</tr>
<tr>
<td>Pseudomonas spp.</td>
<td>1</td>
</tr>
</tbody>
</table>

¹ MRSA: methicillin resistant Staphylococcus aureus

After disinfecting the devices in the manner described by deBac-app’s interactive disinfection guide, numbers for microorganisms found on the devices were greatly reduced and only one potentially pathogenic microorganism (Acinetobacter spp.) could be identified.

Table 4. Types of bacteria found before disinfection and frequency of their occurrence (before disinfection).

<table>
<thead>
<tr>
<th>Type</th>
<th>CFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram positive</td>
<td></td>
</tr>
<tr>
<td>coagulase-negative staphylococi</td>
<td>51</td>
</tr>
<tr>
<td>Bacillus spp.</td>
<td>27</td>
</tr>
<tr>
<td>Corynebacterium species</td>
<td>8</td>
</tr>
<tr>
<td>Gram negative</td>
<td></td>
</tr>
<tr>
<td>Acinetobacter spp.</td>
<td>1</td>
</tr>
</tbody>
</table>

Over the course of the four week observation period, it was noticeable that baseline contamination seemed to decline with only a small increase in the last week (Figure 1). Although not certain, this effect may possibly be attributed to the regular and meticulously performed disinfection.

Figure 1. CFU stratified for side of the devices before and after disinfection

4 Conclusion

If not properly disinfected, tablet PC surfaces may serve as a potential source of spreading pathogens. Especially in the age of multi-resistant strains that are often found in clinical environments and pose a high risk, in particular for seriously ill patients. Thus, special care must be taken to reduce transmission of such pathogens by all available means. The responsibility for this should not solely remain with the end users which is the healthcare staff who use mobile devices for their daily work. Rather, technical and administrative staff included in the planning processes for projects where mobile devices may potentially be used in the context of caring for patients also needs to be made aware of the necessity for the implementing proper hygiene protocols for any such devices.

A standardized alcohol-based surface disinfection following a standardized protocol as included in the deBac-app is appropriate for decontamination of tablet PCs and should be carried out regularly as a part of patient safety in the bed-side digital information era.

4 References


