

**Report from the Cortrium3 test University Hospital Zealand, Oncology Department and palliative Units, Naestved  
2016-2017**

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InnoCan

Report from the Cortrium3 test  
University Hospital Zeeland,  
Oncology Department and palliative  
Units, Naestved

2016-2017



Slagelse December 2018

Lead Partner for the projectet,. NH Holländer, University Hospital Zeeland, Oncology Department and palliative Units, Naestved, Denmark

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# Interreg

Deutschland - Danmark



EUROPEAN UNION

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## **Summary**

The device Cortrium C 3, provided by the company Cortrium, was tested at University Hospital Zeeland, Oncology Department and palliative Units, Naestved. The Department of Clinical Oncology and Palliative Care ensures treatment and care for patients with cancer as well as specialized palliative care for terminal patients.

The purpose of the study was to evaluate measurement properties and feasibility of using a Vital sign Monitoring System for cancer patients under treatment. Patients at the oncology ward were asked to participate during their admission to hospital.

The test, including patients indicated that: The measurements conducted were constant. The advantages for introducing a vital sign measurement to oncology patients is to reduce the constant disturbance of measuring vital signs day and night ensuring the patients rest to recover as well as easing the workflow for the healthcare professionals conducting measurements. During the test interviews were conducted with healthcare professionals (nurses) as well as patients which could describe their experience of using healthcare devices such as the C 3 during their treatment and care of the patients. Subsequently the interviews with the patients described their experience of using the device.

## **Innocan and Interreg**

This clinical test of the C 3 device is part of the Innocan project. Innocan is funded by "Interreg Deutschland-Danmark" with funds from the European Regional Development Fund. The project started in January 2015 and runs for 3 years with a budget of 4,3 mio. Euro. The project has 10 partners from the region of Zealand, the region of Southern Denmark and the German region Schleswig-Holstein. The partners are hospitals, innovation centres, educational institutions, patient associations and a private company. See for more information on [www.innocan.org](http://www.innocan.org) and [www.interreg5a.eu](http://www.interreg5a.eu).

This clinical test is one of the four innovative technologies that will be tested within the Innocan project. Experiences from the test will be used for the development of a cross border test centre. The overall goal of the Innocan project is to preserve and improve the quality of cancer treatment. A fact that people are living longer means that the ratio of elderly cancer patients will increase by a far amount. Within the next decade the number of new cancer patients will be increased with 30 percent within the geographic region of Interreg Deutschland-Danmark (south Denmark & northern Germany).

The sub goals in the Innocan project were:

- Test of 4 innovative technologies in cancer treatment in the region. Companies must be offered easier access to evaluation and testing of their new innovative technologies. The goal is to reduce the time it takes for the new technology to penetrate into the health care sector.
- Development and establishment of a test centre for innovative monitoring technology. The test centre will function cross-border and have employees in both Denmark and Germany. The test centre will be a portal to the health care sector for companies with innovative solutions.

- Development of shorter and more gentle treatment methods with same effect but less side effects for 5 well defined cancer types.
- Creation of a common database for the big cancer types. Data will be updated continuously, and it will be possible to monitor improvements in treatment, including service and patient satisfaction. In depth analysis of register data will support long term improvement of quality of treatment.

## **Participating parties**

### **Manufacturer**

Cortrium  
Galionsvej 37  
DK-1437 Copenhagen

### **Test sites**

University Hospital Zeeland,  
Oncology Department and palliative Units,  
University Hospital Zeeland,  
DK-4700 Naestved

### **Other Parties**

University College Absalon  
Slagelsevej 7  
DK-4180 Sorø

Design School Kolding (DSKD)  
Ågade 10  
DK-6000 Kolding

Production, Research & Innovation (PFI), Region Sjælland  
Alléen 15  
DK-4180 Sorø

Universitetsklinikum Schleswig-Holstein  
Campus Lubeck and Kiel  
Ratzeburger Allee 160  
23538 Lubeck  
Germany

## **Role of the participating parties**

Cortrium had developed the C3 device. The C3 device contains sensors that monitors Electrocardiogram (ECG), Respiratory rate (breathes per minute), and Body surface temperature. Also, the C3 device contains an accelerometer for registration of the body posture.

The following thesis were aimed to be tested:

Thesis 1) Pulse: The C3 device produces clinically validated pulse data.

Thesis 2) Respiratory rate: The C3 device produces clinically validated respiratory rate data (breaths per minute).

Thesis 3) Infection: With no justified statistic significant correlation between skin and body temperature, the study is exploring how to prevent aggravated or lethal outcomes of cancer treatment, e.g. chemotherapy, by using vital signs measurements combined with accelerometer data to detect infection levels.

Thesis 4) The qualitative study: The study will report the advantages and disadvantages regarding new technological solutions, and the change in workflow and healthcare provision as it is experienced by the healthcare personnel and the patients. The data validation studies (thesis 1-3) will be tested in comparison with golden standard measurements methods and/or data validated medical equipment.

Cortrium provided the 10 C3 devices for this test. Accessories like plastic covers, Ipads, cords were provided.

University Hospital Zeeland in Naestved were chosen as the first test site involving the oncology ward. The research nurse from the Oncology ward acted as a responsible for the in-house testing on the ward. University College Absalon were responsible for the test as a joint venture with the Innocan local team who were residents at the Naestved site. The research nurse was on daily bases overlooking the test site and monitoring the progress during the test in Naestved.

University College Absalon had the responsibility of the actual test as well as the final report. However, the Oncology department at Næstved oncology department played an overall coordinating role concerning the actual testing at the hospital. University College Absalon were active players on collecting test data through observation and interviewing participating patients and healthcare professionals as well as analysing data afterwards. Health Innovation Regional Zealand (PFI) acted as a work package leader and coordinated communication between the involved partners and the lead partner (Naeststved Hospital). PFI further had a role in the communication between the company Cortrium and the InnoCan project group. The project group intended to incorporate learnings from this clinical test in their evaluation of all the C3 test sites and in the development of future research.

## **Background**

In cooperation with, Health Innovation Regional Zealand, Kolding Design School, University College Absalon, Universitetsklínikum Schleigswig-Holstein at Campus Lubeck and Campus Kiel wanted to test a medical healthcare device to get an understanding of how to select and implement

new healthcare solutions for continuous monitoring of vital measurements. This in order to enhance patient safety, experience, treatment, mobility and rehabilitation.

This test has been one leg of a series of tests on patients admitted to hospitals in Denmark and Germany under EU's INTERREG 5a program.

This rapport represents the test at the oncology department University Hospital Zeelan, Næstved Hospital. The purpose was to test measurement of vital signs with the newly developed wireless monitoring technology, the C3 device developed by the company Cortrium. The purpose was to compare parallel measurements of pulse, respiratory rate and temperature, respectively measured according to current clinical practice at Næstved University Hospital and by the newly developed wireless monitoring technology the C3 device. Similarly, the aim was to get insight into patients' experience wearing and being monitored by the C3 device, and furthermore how health care professionals experience involvement of the C3 device in the care and treatment practice.

### **The Medical device**



Healthcare technology is an overall focus in healthcare practice - and particular solutions that are cheap, small and easy to use, and in that perspective can monitor patients in their homes, as well as in the hospital.

The company Cortrium has developed a wearable cost effective medico device, the C3 device (picture above), for measuring a number of vital signs. The C3 device is placed above the sternum with three standard ECG electrodes attached. The C3 sensors allows the measurement of 3-channel ECG, surface temperature, respiratory rate and accelerometer data. In addition to this, several measurements can be extracted from to the sensors e.g. heart rate, variation in heart rhythm, pace count, falls and body position. The C3 device connects wirelessly via Bluetooth to a phone or a tablet, where the measured parameters can be read. If so desired, data can be transmitted in real-



time via the internet, opening up for telemedical use. In this project, the C3 device communicates with iPad Mini (Apple).

### **Clinical context**

The C3 device was tested on patients with cancer at an in-house test at University Hospital Zeeland, Oncology Department and palliative Units, Nested. The Department of Clinical Oncology and Palliative Care ensures treatment and care for patients with cancer as well as specialized palliative care for terminal patients.

The treatment modalities include a wide range of non-surgical oncological modalities focusing on cancer chemotherapy, biologically targeted drugs, and radiotherapy. University Hospital Zeeland, Oncology Department and palliative Units, Naestved complies with international accepted guidelines and standards and is one out of five oncological expert Centers in Denmark.

The patients were included in the project by the clinical research nurse and the research nurse as well as the nurses on duty managed the C3 device during the trial period Medical Doctor. In case of technical problems such as corrections with the device itself the manufacturer Cortium supervised and managed potential errors. In the future the C3 device can potentially be used to react if vital signs are changing in patients with cancer, and then treatment can be initiated at a much earlier stage.

In addition, the patients do not experience being disturbed all the time during admission to hospital when using the C3 device. Furthermore, the device can ease the workload of nurses in their daily routines. However, it can be a challenge to ensure correct measurements. It must be emphasised that the clinical eye of a nurse working with cancer patients cannot be replaced by a measuring device and the technology measurements must never replace the physical as well as clinical assessment of a patient with cancer.

### **Aim of the test**

The aim of the clinical test with the C3 device was

- To evaluate the paired measurement of the C3 device, by comparing the test results of the vital sign measurements
- To explore the possibilities of enhancing the treatment, care and wellbeing for patients with cancer by interviews with healthcare professionals as well as patients

The C3 test have great potentials for the future care and treatment of cancer patients as the product could improve the quality of life for this patient group by allowing continuous monitoring during hospital admission instead of being monitored manually which creates disturbances both night and day. By introducing a device such as the C3 patients with cancer may experience a more flexible day with less disturbances.

### **Why did the company Cortrium want to test the product?**

The company Cortrium aimed to find out if there are potential opportunities for a device like the C3 to measure vital signs whilst admitted to hospital. They want to explore the usability of the C3 device at the hospital as well as understand what the healthcare professionals and the patients think of the device.

### **Why are the hospital interested in the test?**

University Hospital Zeeland, Oncology Department and palliative Units, Naestved, was investigating new methods to care and treat elderly patients with cancer with the focus on closely increasing quality of life, reducing days of hospital admission as well as innovative solutions in order to shift the healthcare professionals work in a more effective way.

By participating in this test, University Hospital Zeeland, Oncology Department and palliative Units, Naestved, wanted to investigate if the C3 device could be used by cancer patients in cancer treatment admitted to hospital. The hospital wished to participate in the test verifying if the C3 device measures precise during use, if the technology worked and how it was received by healthcare professionals as well as patients.

Further the project is part of already existing research on oncology and elderly care.

### **Test design**

The study was of explorative character and aimed to consist of a quantitative cross-sectional-study with paired results of vital signs measured in the clinical praxis as well as on the C3 device. Furthermore, qualitative interviews and ethnographical observational studies of the healthcare professionals as well as the patients were conducted.

The recruitment was conducted from newly admitted patients at University Hospital Zeeland, Oncology Department and palliative Units, Naestved. In total 37 patients were included in the project. Seven of the patients were interviewed about their experience of being introduced and using the C3 device. Ten C3 devices and ten iPad Minis were included. The Ipad Minis were pared to the C3 device with a numeric code (1-10).

**Inclusion criteria:** Able persons, >18 years of age with a cancer diagnosis and in treatment at the oncological Department. The patients must be admitted with fever (temperature > 38,5 degrees) at the University Hospital Zeeland, Oncology Department and palliative Units, Naestved.

**Exclusion criteria:** Pregnant women and fertile women who were not using contraception. Patients with a known heart condition. Patients who do not speak German.

**Informed consent:** The clinical research nurse in cooperation with the Professor in charge was responsible for the recruitment of the participants and forwarding the oral and written information about the project. Dependent of the medical condition of the patient the information was forwarded right after admission to University Hospital Zeeland, Oncology Department and palliative Units, Naestved.

In case the admission happened during evening and night shifts the oral and written information were given the next day. Apart from the written patient information describing the test purpose and design, a folder about patient rights in research was forwarded, written by the Ethical Committee of Research. As the test consisted measurement of vital signs during the acute phase of admission the immediate consent of participation was important. The patients were informed that participation in the project was voluntary, and that they could withdraw from the project at any time without any consequences for their further treatment.

## **Ethical considerations**

Ethical considerations were kept both at University Hospital Zeeland, Oncology Department and palliative Units, Naestved. No biological material was gathered as part of the clinical trial and thus no authorization was needed both including patient data as well as data from the interviews with patients and healthcare professionals.

In the test of the C3 device on the ward the clinical test was conducted using Internet access. Data was stored on the C3 device and the individual iPads as well. Data transmission from the C3 device for iPads was encrypted. The clinical trials are conducted in compliance with the Guidelines for "Good Clinical Practice" DS / EN ISO 14155: 2011 ", and the collected scientific data was handled in accordance with the " Law concerning the processing of personal data.

Qualitative interviews were conducted with patients as well as nurses. The interviews were digital recorded and transcribed verbatim. The recordings were stored and handled on a secure server at University Absalon with only access from the researchers involved in the test According to the EU Data Protection Regulation (GDPR). Digital recorded interviews and transcripts were destroyed 30 days after completion of the test.

The patients participating in the C3 test received written information about the test. The patients were offered an additional interview about participation in the test and that they had time to consider their participation before signing up for the test. Consent were given by the patient themselves.

The participant information and the template patient consent form were forwarded the patient and each patient were asked to sign a document (proxy statement) that allowed the Medicines Agency and the relevant foreign health authorities' access to the patient records for inspection and control of the test. Included patients in the test could at any time during the trial testing period withdraw his or her inclusion - without facing a deterioration of their planned treatment.

The patient data from the C3 device was analyzed only in connection with the clinical test. The data was not subject to any clinical decisions made during the patient's admission to hospital or causing delay in the treatment of the patient. The C3 device were medically certified approved. The clinical test did not bring forward or postpone any planned treatment by the healthcare personnel.

## **Test perspectives**

Several perspectives were included in the test.

First and foremost, the company Cortrium was interested in the functionality of their C3 device. Would the device be usable in a clinical setting? And most important, were the measurements accurate?

As previously mentioned the user perspective was of great importance. Did implementation of a healthcare device measuring vital signs improve the experience and life quality of patients admitted with fever? Further the nursing perspective was explored. Would implementation have any impact on the nurses` workload

Subsequently it was important to explore the ethical considerations and the patients` autonomy when implementing a new technological device. When implementing new tests on patients with cancer some resistance to participation is expected from the patients, the healthcare professionals as well as relatives.

Economy is a continuous subject in healthcare and this project could elaborate of the economical perspectives of introducing online monitoring of patients with fever on a Department of Oncology. Finally, the test and the planned framework can give an insight into the interaction between technology and organization of the medical practice.

## **Test process**

The protocol for the test was conducted by University Hospital Zeeland, Oncology Department and palliative Units, Naestved, University College Absalon, The Design School Kolding, Region Zeeland and the company Cortrium. The protocol was accepted for research in May 2015. The first patient was included in the project February 2016 and the inclusion of patients ended ultimo August 2016.

## **Test implementation**

After the initial acceptance of the protocol the test design was developed in cooperation between the partners involved in the project. The project was further approved by the health authorities and regional Scientific Ethical Committee.

Observational studies were conducted by The Design School Kolding and University College Absalon prior to the test start and during the test to ensure the facilities were suitable for conducting the test as well as storing and cleaning the C3 device.

Prior to the implementation of the patients the clinical research nurse ensured that the physical location was prepared for the tests. This included storing of the devices, loading of devices and iPads. Ensuring the hygienic regulations were enforced.

The manual with guidelines for using the device were updated. Furthermore, the healthcare professionals were informed and instructed about their roles in the test.

The data from the C3 device were collected on an iPad Mini. At the same time data from a manual collection of vital signs were collected by the nurses on University Hospital Zeeland, Oncology Department and palliative Units, Naestved

The 7 patients who were involved in the project were interviewed by the clinical research nurse from Naestved. Additional observational studies were conducted.

Interviews with 10 nurses, and the clinical research nurse at University Hospital Zeeland, Oncology Department and palliative Units, Naestved were conducted with researchers from University College Absalon and Kolding Design School.

Qualitative and quantitative data analysis were conducted by researchers from University College Absalon.

### **Procedure**

The framework of the initially planned test was followed. However due to start issues with the technology corrections needed to be resolved. Furthermore, the administration and management were dependent of the Danish public holidays and festive season. Working with patients who are in treatment for cancer obstacles occurred such as patients being too ill to participate, or they were send home before the test could start. There were no other initial problems. The management decided when the nurses were free to be interviewed and due to this the period was extended according to the original plan.

The paired quantitative data was collected as planned and generated a satisfying number of inclusions of measurements.

### **Methodology**

Qualitative and quantitative methods have been applied during this test.

#### **Qualitative methods to collect and analyse data**

- Observation. Location were observed by trained researchers to gather data on how the test site were suitable.
- Semi structured interviews. Patients were interviewed by trained researchers about their experience with the C3 device and implementation of health care technology as part of their care and treatment.
- Semi structured interview. Health care professionals were interviewed individually about their view on the use of new technologies in the care of oncology patients.

Data from the interviews were analysed using a thematic analysis approach. Thematic analysis is the process of identifying patterns and themes within qualitative data.

## Test results

In the following section the test results and the data collected will be presented in the following order, quantitative results followed by qualitative results.

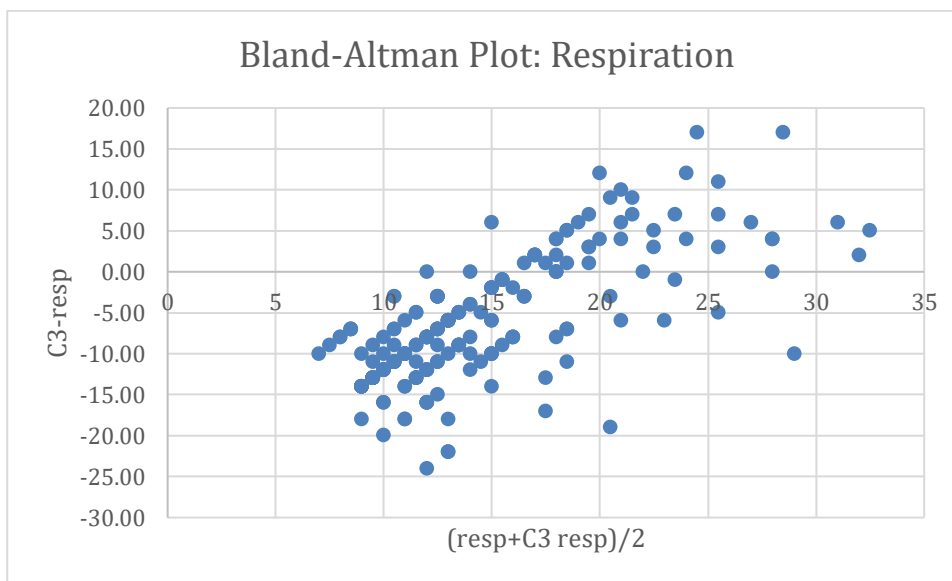
All data from the C3 device was collected and provided by Cortrium.

In order to test the difference between measurements from the C3 device and standard methods of testing a Student's t-test were performed. A value of  $P \leq 0,05$  was found for measurements of pulse, and a P value  $< 0,001$  was found for all remaining test pairs.

For instance, when P values = 0 (respectively pulse and respiratory), a Student's t-test were performed on data both including and excluding the value 0, and this did not change the results, as P values were still statistically significant, below 0,05.

These results indicate that there was a difference between the vital signs measured by the C3 device and the manually methods.

In the Bland Altman plots (fig. 1-7), the differences between the C3 device and standard measurements are illustrated.



*Figure 1 : The Bland Altman Plot shows the C3 has a negative tendency at low respiratory rates and positive at high respiratory rates*

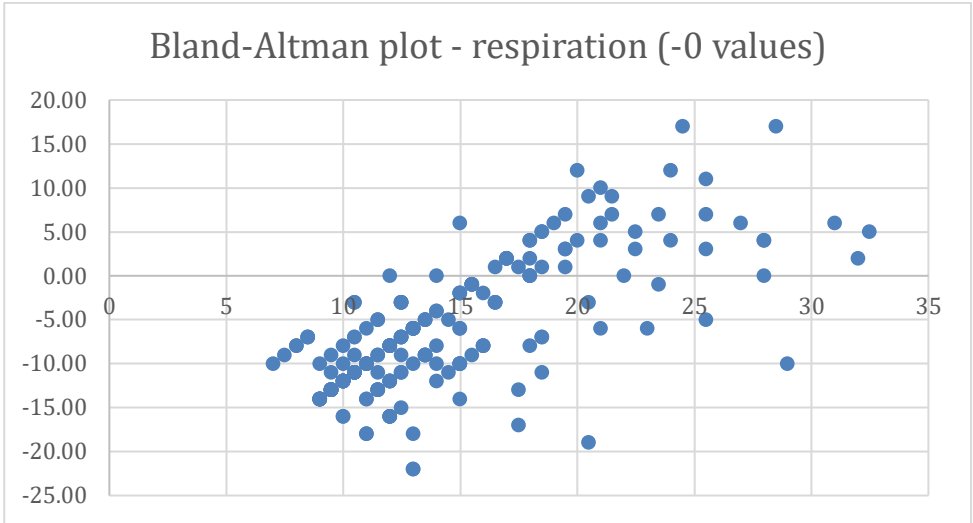


Figure 2: The Bland Altman Plot for respiration measurements does not differ much if values of 0 are removed

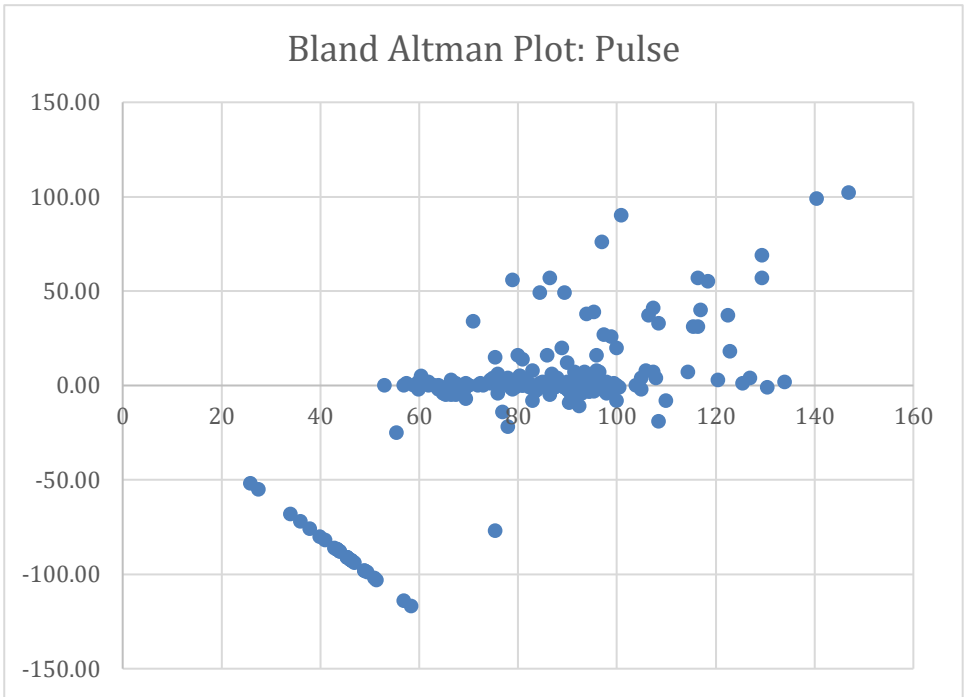


Figure 3: The Bland Altman Plot for pulse shows the biggest differences at low and high pulse. The correlation between the two methods are greatest in the normal range for pulse.

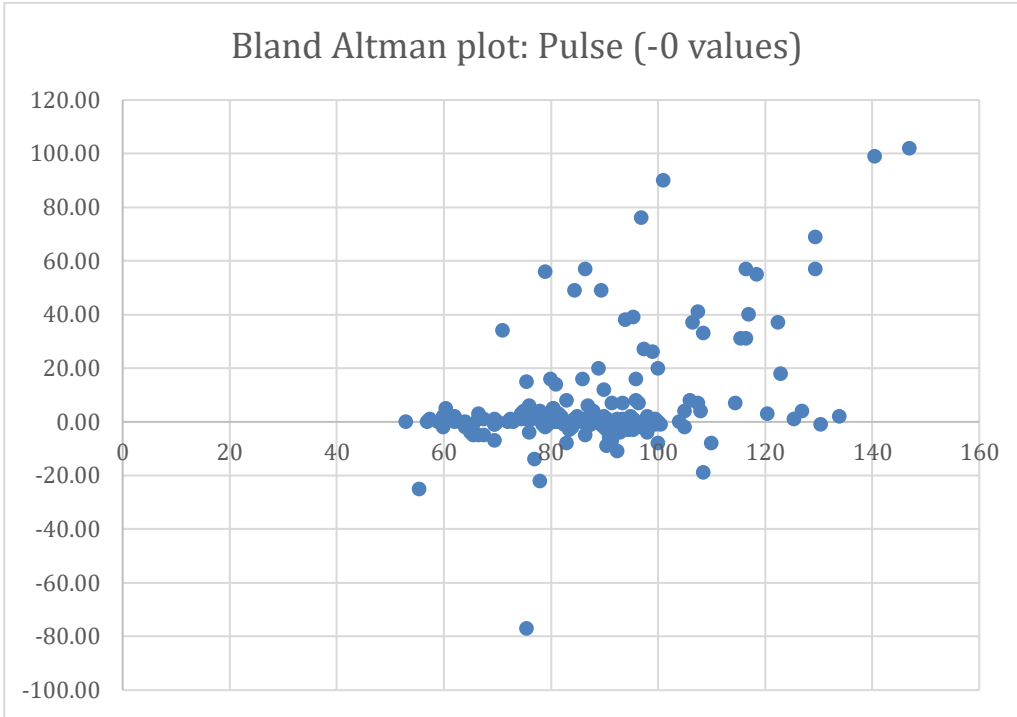


Figure 4: The Bland Altman Plot for pulse where values of 0 have been removed shows the negative difference almost removed

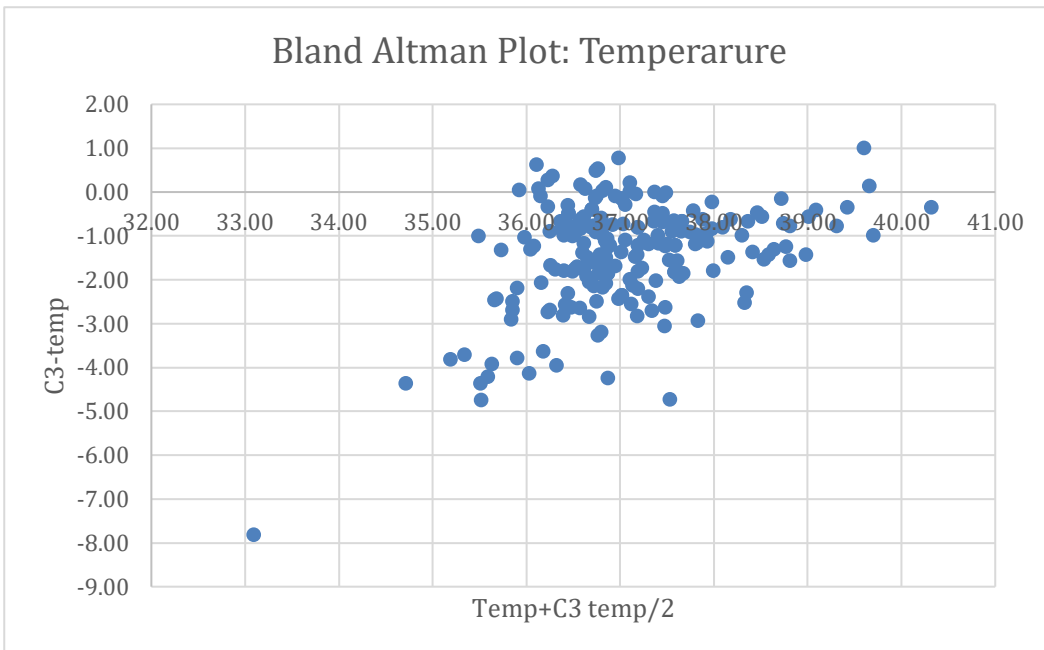


Figure 5: The Bland Altman Plot for temperature shows a general negative tendency for the measurements taken from the C3 device. This is aggravated at lower temperatures



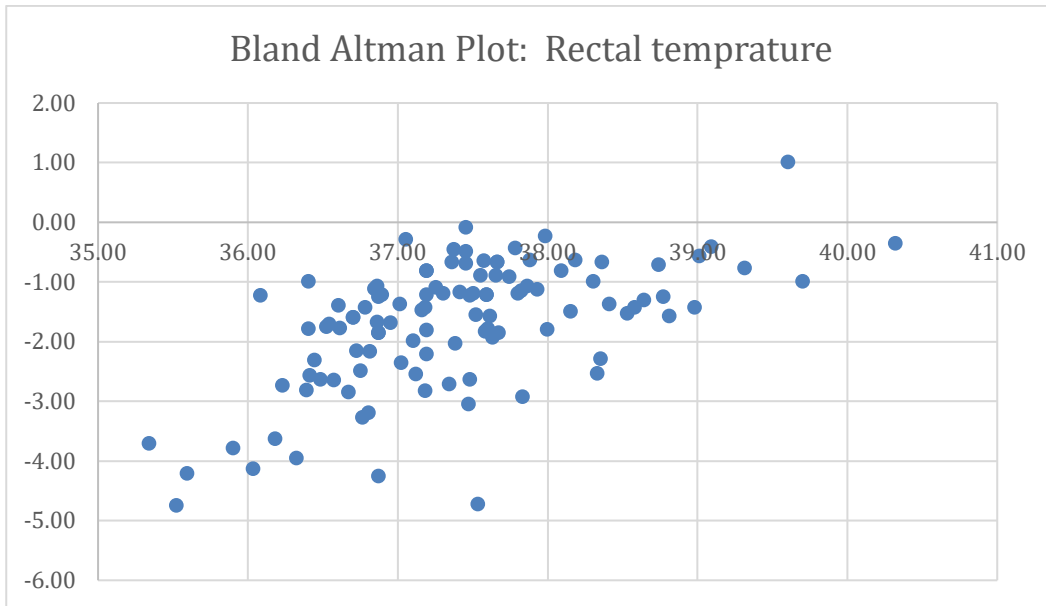


Figure 6: The Bland Altman Plot shows, that when temperature is taken rectally the negative tendency for difference between the standard method and the C3 is more pronounced

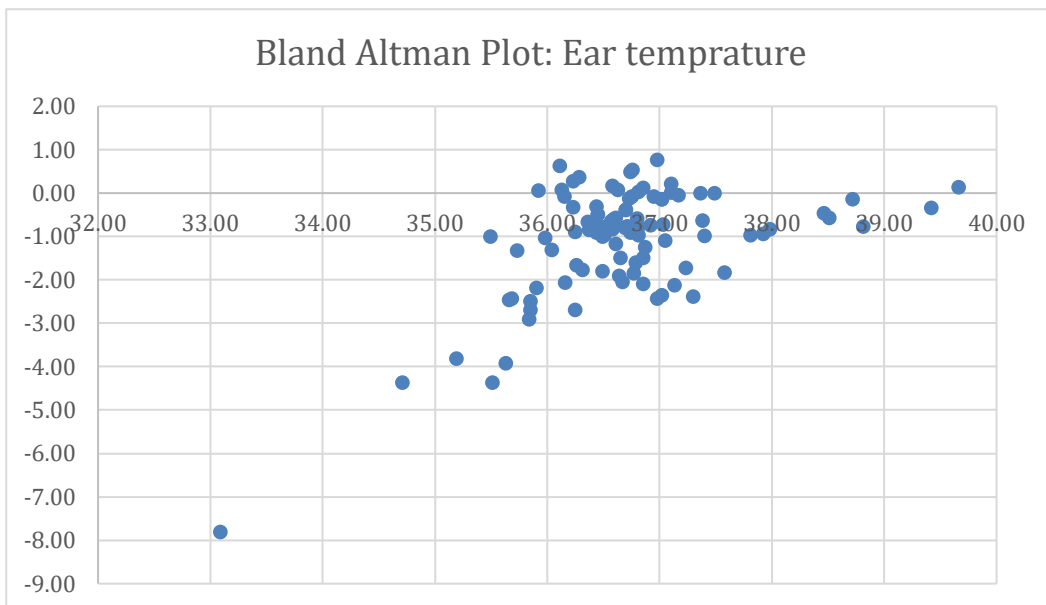


Figure 7: The Bland Altman Plot shows, that when the C3 measurements are compared only to temperature measured in the ear the difference is less pronounced.

To investigate the relationship between the two types of measurement (the standard and the C3 device) an regression analysis was performed. All results show a significant correlation between the standard and the C3 method ( $P \geq 0,001$ ).

Quantitative results (summary by University College Absalon)

From the measurements the following results emerged.

- The difference between the temperature measured using the C3 device and a digital (rectal) thermometer indicated with a strong significance that the C3 device was measuring the temperature too low as compared with digital rectal thermometer.
- The difference between the temperature measured using the C3 device and using a digital (ear) thermometer indicate that on average the C3 device measured 1,08 °C lower than the digital ear thermometer. It is more evident when measuring low temperatures.
- The difference between the pulse measurements using the C3 device and using a pulse oximeter based on 182 observations indicated that there was a significance that the C3 device measured the pulse at a too high frequency. There was a tendency that the C3 device had a negative deviation at low pulse measurement and a positive deviation at high pulse measurement.
- The difference in respiration frequency measurement using the C3 device and by counting the respiration frequency physically indicated that the C3 device on average counts 6,33 too low with a high significance (average is 6,33). There was a tendency that the C3 device had a negative deviation at low respiration measurement and a positive deviation at high respiration measurement.

## **User perspective**

The user perspective was evaluated from qualitative interviews with seven patients and ten nurses at the University Hospital Zeeland, Oncology Department and palliative Units, Naestved. In the following excerpts of the experienced by the patients and nurses are presented. The experiences are presented under the following themes.

### **The patient perspective:**

#### **Introduction to the C3 test:**

Generally, all the patients who participated in the project expressed that they were well informed, and one patient mentioned that it was interesting to participate in the project.

#### **The healthcare professionals' management of the device:**

One of the patients mentioned that it was observed, that some of the health care professionals were more engaged in using the device than others. Some nurses got irritated. Another patient mentioned that it was difficult to read the instruction of using the device when you were not familiar with the process. However, the same patient said that the nurses were eager and that no measurements were skipped.

A patient mentioned that there was a clear difference between how the younger nurses handle the device comparing to the older nurses. The patient further observed, that the younger did not need the instruction each time they used the device measurements – the older nurses had to use the instruction each time, and they carried the instruction with them.

A third patient described that the nurses were uncomfortable using the iPad. The patient further described how the nurses' helped each other instead of using the instruction for the C3 device. The measurements were registered each time.

Two of the patients who had used the C3 device for 24 hours emphasised that they had not experienced any problems. Another two patients mentioned that they experienced problems in the beginning. However, the nurses' helped each other.

### **How do the patients experience the C3 device?**

All the patients describe, that they had not been disturbed wearing the C3 device. In fact, two of the patients stated that they even forgot they were wearing the device. One patient experienced that one of the electrodes had detached itself due to hair growth on the chest, which had not been removed prior to the attachment. Another patient experienced a rash where the attachment of the plaster had been and subsequently left the test. This patient had not been bothered by the device in general. Two of the patients had the electrodes falling off due to perspiration. One patient was wearing the C3 device when it was very warm and started itching due to the heat.

Generally, the C3 device did not bother the patients at night. The patients were sleeping on their backs or on their sides. However, one patient mentioned that the C3 device lightened up at night.

### **Benefits using the C3 device**

Five of the seven patients stated that using the C3 device was an advantage for the nurses as they saved time. One patient said that it subsequently assisted the nurses in their workload. One of the patients thought it was an advantage that the temperature was measured electronically and not by rectal thermometer. Yet another patient stressed that it was easier to keep an eye on the patients this way. Another patient stated that the C3 device was an advantage as he had a presumption about the hospital being High Tech. And using the C3 device was a way to ensure the patients that in the hospital everything was in control. Lastly a patient stressed that with the C3 device the patients avoided numerous disturbances, because nurses did not have to attend to the patients all the time.

### **Disadvantages using the C3 device**

One of the patients mentioned that it was a disadvantage using the C3 device as the patients missed the contact and the relation with the nurses if vital signs were measured automatically. The patient stated that regardless of how ill you are, some patients see the contact with the nurses as the highlight of the day. The measurements are also a way of being in touch with the nurses. Two of the patients mentioned that they would call the nurses if they needed them for e.g. answering questions.

### **The future and possible use in the patients` own homes**

Generally, all seven patients interviewed could see themselves using the C3 device at home. Two of the patients stated that using the C3 device at home might prevent them from being admitted to hospital. One patient suggested that the nurses could call them when admission to hospital was needed.

### **Continuous monitoring:**

Two of the patients mention that they did not feel more ill when being continuous monitored. Four of the patients thought it was acceptable to be monitored and one patient stated it was genius.

### **The Nurses perspective**

#### **Results from the interviews with the nurses:**

#### **Difficulties paring the C3 device and iPad**

Some nurses had the experience, that the C3 device and the iPad did not connect to one another. One of the nurses said, it was the nurses own fault, that the C3 device and the iPad did not connect to one another, because they had taken the wrong C3 device after recharging.

#### **Reliability takes focus - first of all temperature:**

Almost all the nurses were concerned about the validity of the measurements of the C3 device. The nurses main focus was whether the C3 device measured the vital signs correctly. Many of the nurses assumed, that a rectal-measurement, was the most correctly method measuring the patients temperature. There were references to the research literature and an indication that more research are needed for the C3 device to guarantee correct measurements.

#### **Patient Information - and concerns about inclusion:**

The nurses had the experience, that the patients were generally interested in the project and that they wanted to participate. One thing was getting oral information as a research patient, another thing is reading the written information as a cancer patient. One of nurses had the reflection that highly febrile cancer patients might not wanted to use their time reading an extensive patient information about a research test

#### **Nurses Information:**

The overall perspective was good. The material used was approved off and especially the key persons guide to the iPad and work flow were good. However, most off the nurses would have liked a more detailed introduction, for instance an introduction day. Not all of the nurses felt comfortable about the C3 test in the beginning, but after a while they got used to it.

#### **Research nurse in charge:**

The research nurse had been central to the test and the whole project at Naestved University Hospital, managing the test, ensuring "things" were done and often been at the ward every day, taking responsibility of:

- The Test
- The Inclusion
- The Cleaning of the C3 devices
- The Loading of the iPad Minis and the C3 devices
- Being available on the ward and in the evening for questions and help

#### **Patient Interest:**

The nurses had the experience, that the patients had a positive attitude to the test and wanted to help testing the implementation of new "things" [technology] . In the beginning, the inclusion was difficult, and therefore more nurses were included in the test- start up.

#### **Differences between working in day shifts and night shifts:**

Nurses in night shifts had the experience that there were not as many resources in the night. The inclusion was primarily done during the day shifts.

#### **Economy**

No economical compensation was given in the project to either healthcare professionals or patients participating in the project. The completion of the project was conducted by the nurses and doctors University Hospital Zeeland, Oncology Department and palliative Units, Naestved. The C3 devices as well as the iPad Minis used in the project were sponsored from external sources. The Oncology Department had sponsored 8 Ipads Mini's themselves.

Subsequently implementing healthcare technology in general may have an economical benefit such as monitoring the patients at home during treatment and care. However, in this test of the C3 device the focus has not been on the economic benefit but on assessing the use of the device for patients submitted to oncology treatment and care. Further the experience of nurses caring for as well as monitoring the patients whilst using the device has been the focus. More research is needed with focus on the economic benefit in this area.

#### **Interaction between technology and organization of the health care practice**

Resistance to new technology and resistance to change is a potential threat from employees, healthcare professionals, patients and relatives. However, this test has proven that there is an opening in implementation technology into the treatment and care of patients with cancer and potentially others. Although the quantitative data indicated an error in measuring the vital signs using the C3 device -the error was consistent and an adjustment of the C3 device is necessary and required in order to be implemented as a healthcare technology tool when measuring vital signs in patients generally.

### **Summing up on the process**

The C3 test at University Hospital Zeeland, Oncology Department and palliative Units, Naestved was the first prototype testing of the C3 device. Introducing the device proved obstacles, however only to be expected when testing a new medical solution on patients who are hospitalized.

The test needed two steps. Step one, that the nurses are trained in using the device and familiarize themselves in the technology, the manual and the communication with the patient. The step two, recruiting patients suitable to be included in the test.

Recruiting patients for the test turned out to be very easy. Patients were very willing to participate. Testing on patients admitted to hospital showed that it is necessary to have nurses and doctors from the hospital to take an active role in the test. In future tests, awareness of time and resources would be recommended. Further acknowledging that nurses have different approaches to working with health care technology.

Interviews with nurses and patients participating the test were conducted in order to get the nurse and patient perspective working with and around the C3 device.

The paired measurements from the C3 devices as well as manual data taken by the nurses were analysed and produced a data set.

### **Recommendations to manufacturer**

Generally, the overall results from the test of the C3 device were positive. The tests were seen from the healthcare professionals` perspective and from the patient`s perspective as positive.

As this test was a pilot test, errors and difficulties introducing the device occurred along the way. These were presented for the manufacturer Cortrium.

Feedback was reported back to the manufacturer, as adjustments were needed during the test or other problems needing immediate attention occurred. An example could be hygienic regulation problems due to crack in the surface material of the C3 device.

A recommendation for further development of design, were the size of the C3 device as it needs to fit on the chest of the patient without the patient feeling uncomfortable (e.g. large breasted women). Or it could be adjusting the light on the C3 device as patients noticing the lights on the device disturbing their sleep.

Recommendations were sent to the manufacturer Cortrium at the end of the test in enabling the manufacturer making adjustment. These recommendations are being held confidential due to the agreement between the manufacturer and Innocent.

### **Recommendations to the hospital**

As the use of healthcare technology increasingly are being introduced to the hospitals recommendations as well as best practice is needed. The pilot test of the C3 device was tested on a very few patients as well as the follow up interviews made with both nurses and patients.

It is indicated that using the C3 device monitoring vital signs in patients with cancer generally had been successful. In order to facilitate the best care and treatment for the patients during their cancer treatment recommendations has been made to the manufacturer. An example could be the C3 device being too bright during the night when the patients are trying to sleep. Another recommendation is the size of the C3 device as it needs to fit on the chest of the patient without the patient feeling uncomfortable.

Storing the C3 device and the IPad Mini in a convenient and safe place on the ward where there is space for as well as access to charging is important. Further attention to continuous cleaning of all the devices used is important in order to follow the hygienic regulation of the hospital.

Implementation of healthcare technology is generally new for nurses. In this test the nurses were interviewed about the pro and cons of using the C3 device caring and treating patients with cancer. A thorough introduction of the nurses to the background and the use of the device is vital when implementing new healthcare technology. The manual for the nurses is recommended to be easily read and understood. In case of errors on the devices help must be easily accessible on the ward.





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InnoCan has the following partners





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## C3 protocol

'Clinical testing on newly developed monitoring technology for continuous measurements of vital signs in patients with cancer'

Marie Bruun Nielsen  
[August 24<sup>nd</sup>, 2016]

Protocol

## **Clinical testing on newly developed monitoring technology for continuous measurements of vital signs in patients with cancer**

### **Purpose**

The purpose is to test measurement of vital signs with the newly developed wireless monitoring technology, the C3 unit developed by Cortrium (Annex 1). The purpose is to compare parallel measurements of pulse, respiratory rate and temperature, respectively measured according to current clinical practice at an oncology department (Næstved Hospital) and by the newly developed wireless monitoring technology the C3. Similarly, the aim is to gain insights into how patients experience wearing the C3 and being monitored by the C3, and furthermore how health professionals experience involvement of the C3 in the care and treatment practices.

### **Background**

In Denmark, 80 % of the total health care costs are used on treatment and care for persons with chronic diseases, this including cancer. The number of chronically ill persons with one or several diagnoses is increasing and at the same time, the demographic development implies a considerable increase in the part of the population of 60+ years (1). These facts together are expected to lead to increased health care costs (1, 2) in an already economically pressured health care system with continuous rising costs.

New technology is seen as one of the future solutions of demographic and economic challenges of the health care system regarding treatment of chronic diseases (3). In the Danish national plan of action for the deployment of telemedicine, '*National handlingsplan for udbredelse af Telemedicin*', new technology is especially emphasized as a solution in treatment of chronic conditions (4). New technology is assumed to bring more welfare, better everyday life for citizens, a reduction in hospitalizations and readmissions (5,6), although research in the field indicates that new technology not necessarily will have the expected effect (4,7).

A necessary element in the diffusion of telemedical solutions is the use of units and sensors, which are small, cheap and simple to use and allow for monitoring of persons and patients in their home, as well as in the hospital. Many of these technologies are based on technology widely used within fitness and self-tracking. These units are known as "wearable devices" (units worn on the body) or the more general term "wearable technology". Common to these products is that they are computers or electronics built into clothing or equipment that can be worn on the body. The products range from small activity meters to glasses with advanced technology. Within the health care system the term "mobile Health" or "mhealth" is used. Attention around this field along with the number of publications has accelerated in recent years (Figure 1).

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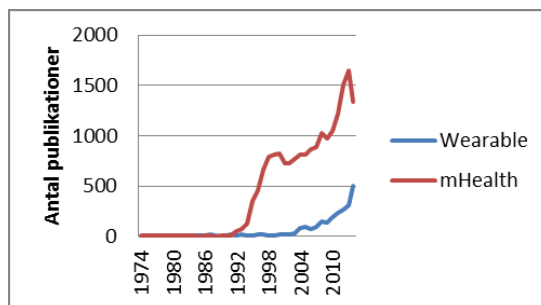


Figure 1: PubMed distributed over years, with search on "Wearable" and "mHealth". (Antal publikationer = Number of publications).

Cortrium has developed a wearable medico device, the C3, for measuring of a number vital signs. The C3 is placed above the sternum with three standard ECG electrodes attached. The C3 sensors allow measuring of 3-channel ECG, surface temperature, respiratory rate and accelerometer data. In addition to this, several measures can be extracted due to the sensors e.g. heart rate, variation in heart rhythm, pace count, falls and body position. The C3 communicates wirelessly via Bluetooth with a phone or tablet, where the measured parameters can be read. If so desired, data can be transmitted in real-time via the Internet, opening up for telemedical use. In the project, communication to the C3 is done with iPad Mini (Apple). Reference is made to annex 1 for further technical specifications.

The Oncological Department at Næstved Hospital, wish to test the C3 in collaboration with 'Sundhedsinnovation' (Health innovation), Region Zealand and University College Zealand to get a better understanding of how to choose and implement new solutions for continuous monitoring of vital signs. This in order to provide patients with greater security and mobility, and increase the quality of the clinical quality, as well as the user perceived quality of treatment and rehabilitation. This project will form the basis of experience for a more extensive test of the C3 on patients hospitalized in partner hospitals in Denmark and Germany under the EU INTERREG 5a program, where the design will include elements corresponding to a 'Medicinsk Teknologi Vurdering' ( in English 'Health Technology Assessment') (8).

Patients recruited for the project are patients with cancer (primarily lung and colorectal cancer), who are hospitalized in the Oncological Department, Næstved Hospital, because of complications (often *peni* or *sepsis*).

The patients themselves monitor temperature in the home. It is often fever ( $> 38.5$  °C) that triggers hospitalization. When the patient is hospitalized, a number of vital signs are measured cf. the current clinical practice (9) – including pulse and respiratory rate selected to test the functionality and measuring quality of the C3 in a clinical context. Furthermore, registrations of temperature will be included to examine the coherence between the clinical registration (digital thermometer, rectal measurement) and the C3 registrations of the surface temperature and the ambient temperature.

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In literature there seem to be no studies on surface temperature measured by IR-thermometer (no contact) specifically on sternum in adults. Relevant articles will best be identified individually from references in other studies. A study from 1936 established evidence that surface temperature ranges from 33.5 to 36.9 °C in general, and that temperature on the torso and the head is least impacted by the ambient air temperature (10). At the same time a more recent study, which measured surface temperature 1.5 cm below the navel, found obese persons to have a significant lower surface temperature, compared to persons with a normal weight (11). A direct relationship between surface - and body temperature of adults seems not to be described in literature. A review from 2014 (12) identifies a number of problems and necessary assumptions regarding surface temperature in relation to the core temperature, including ventilation of the skin surface, ambient temperature, body build and the degree of vascular dilation in the measured skin area. At the same time, it is estimated, that if you want measurements with the least possible bias, a "no-contact" technology, as is found in the C3 unit, should be used. The measures will however be dependent on the persons clothing. A study on 167 children aged 1 to 48 months has proven that IR measurements on the forehead is strongly correlated to rectal temperature ( $r = 0.952$ ), with a sensitivity and specificity of 97%, and a negative predictive value of 99% for fever (13). However, results on children cannot be expected to be directly transferable to adults and elderly people. Thus, the use of data for the various temperature measures of this project is explorative in nature.

New technologies vary in quality and studies show that more empirical evidence is needed to either support or refute the advantages of using intelligent technologies in the social- and health care system (14-17). According to KORA (the Danish National Institute for Analysis and Research in Communities and Regions), the key areas for a successful implementation are *user acceptance, organization, technology, politics and legislation, financing* and *a sustained strategy* (4). The implementation must meet the quality standards which the health care system is subject to and it must be continuously monitored (18-20) and thus consequently adjusted (18-20). The Danish health care system is assessed and accredited based on WHO's recommendations for quality standard in health, according to the Danish Model for Quality (Den Danske Kvalitetsmodel, DDKM), by indicators of the clinical, organizational and patient-perceived quality. As health care is measured up against the quality of the delivered health care, the quality of health care using new technological solutions must meet the same quality standards (22). In addition to the study of the C3's actual measuring quality, it is therefore important to uncover how patients experience quality in relation to the use of new technology in care and treatment, as well as perspectives from health professionals.

### **Participants and design**

The study is explorative of nature and will consist of a quantitative as well as a qualitative part. The quantitative part will be a cross-sectional study of paired measures of vital signs (pulse, respiratory rate and temperature) measured respectively by standard hospital equipment used at the Department of Oncology and by the C3. The qualitative study is based on semi-structured interviews and ethnographic studies of monitored patients, as well as health professionals who have been involved in the care of monitored parents. Recruitment is carried out amongst patients recently hospitalized at the oncology department. The plan is to include about 40 patients during the period August 24<sup>th</sup> -

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October 10<sup>th</sup> 2015, or until saturation of data. A total of ten C3 monitoring units and their corresponding tablets will be included in the study. A number (no. 1 – 10) pairs them.

### **Inclusions criteria**

Legally competent patients aged 18 or older with a cancer diagnosis, in treatment at the Department of Oncology, and febrile (> 38.0 °C) when hospitalized at the Department of Oncology, Næstved Hospital.

### **Exclusion criteria**

Pregnant and fertile women, who do not use contraceptives. Patients with known heart disease.

### **Informed consent**

During hospitalization, patients will receive verbal and written information about the study by a nurse responsible for recruitment of participants. The information will be given to the patient immediately following admission, depending on the condition of the patient. A patient hospitalized during the evening and night shift, will receive information about the study on the next day shift. Besides the written information to the patient, which in brief describes the aim and design of the study, the patient receives the pamphlet on “*The Legal Rights of Test Persons when participating in a Research Project within Health Sciences*”, issued by The National Committee on Health Research Ethics in Denmark. The participants will have the possibility of having an observer present. Since the aim of the study is to evaluate vital signs in the acute phase, patients will be asked to give informed consent during the first 24 hrs. of admission. Throughout the admission time, patients can get further information about the project from the charge nurse and two named nurses allocated to the project. The participants are informed, that participation is voluntary and that they can withdraw their consent at any time with no consequences for their further treatment.

### **Qualitative part:**

The Department of Oncology is responsible for recruiting informants amongst patients and health professionals. During the admission, a representative sample of patients (by age and gender) will receive written and oral information about the qualitative part of the study. The informants' participation in the qualitative interviews and ethnographical observational studies occurs after delivering independent written consent for this part of the project. Informants, who have difficulties understanding or expressing themselves due to language or communication issues are excluded. When preparing the written patient-information the wording must be considered, since the information, which the informant receives prior to the interview, can bias the informant's answers and attitudes.

### **Methods**

Participation in the study begins as soon as the patient has given informed consent, after which the C3 is placed on the patient. Then, the patients will be monitored according to the current clinical guidelines at the Department of Oncology, Næstved Hospital (9). After the termination of the clinical monitoring of vital signs, the C3 unit is removed. This will most often be at the end of hospitalization.

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### Quantitative part:

Paired measurements of vital signs measured, respectively, according to current clinical practice (basic observation score; BOS-scoring) (9) and with the C3, will be compared. The three parameters selected for the clinical validation of the C3 are: Heart rate, respiratory rate and temperature cf. table 1.

Parameter	Current Clinical Practice (BOS-scoring)	C3
Pulse /heart rate (beats per minute)	Pulse oximeter placed on finger	Derived from ECG-signal by use of Open Source analysis software (23)
Respiratory rate (number of breaths per minute)	Measured at rest by counting the number of times the chest rises for 15-30 seconds. Rate is multiplied as equivalent to one minute.	Respiration signal is based on impedance changes measured between two ECG electrodes. The frequency is derived from fluctuations in the signal.
Temperature (estimate for core temperature in degrees Celsius)	Digital thermometer, measured rectal or in ear according to current guidelines for temperature measurement (Annex 5)	An IR thermometer on the sternum measures surface temperature. A digital thermometer placed in the C3 unit measures ambience temperature. Both sensors have 0.02 °C accuracy.

Table 1: Vital signs measured in the present study

### Practical implementation

All patients are risk assessed according to current clinical practice (BOS-scoring) (9), upon hospitalization. The readings are done by the nurse responsible for the patient, and are administered three times during the first 24 hours after admission. The patient's BOS-score determines the range of subsequent risk assessments, which however, as a minimum, will take place once a day, until the patient is discharged. The readings (including time of the readings) are manually transferred to the preprinted BOS-tables and are subsequently transferred to the patient's electronic journal (Opus).

Regarding the readings of the C3 a nurse allocated to the project will several times a week read and manually transfer the BOS data from the patient's journal as well as the time-identical data from the C3 measures on the corresponding iPad Mini. These readings will take place in a room unconnected to the patients and the development nurse has thus no direct contact to or knowledge of the patients. The values from the clinical measurements (BOS-table) and the C3 readings are introduced into a data sheet for each patient. Similarly, the development nurse will extract data from the included patients' electronic records on the following background variables: gender, age, weight, height and diagnoses. The readings will continue during the entire hospital admission.



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Besides the recruitment procedure and the placement and removal of the C3 on the patient, the project will not mean any changes in the daily routines of the personnel in relation to the care and treatment of the included patients. However, the C3 will have to be charged once a day, which will be taken care of by the nurse responsible for the patient.

After the C3 has been removed from the patient, it will be cleaned and prepared for use on a new patient. Preparation includes cleaning and disinfection, the transfer of relevant data to the data sheet and charging of the C3 to 100 %.

### **Statistical considerations:**

The paired measurements are analyzed with difference plots (Bland-Altman plots), allowing for identification of outliers and systematic differences between the two methods. 98 % "limits of agreement" will be calculated (mean difference  $\pm$  1.96 standard deviation for the difference), which will provide information on how far apart the two methods are for most individuals. If this difference is of no clinical significance, the two methods could be used arbitrarily (25-27). Similarly, estimates (confidence intervals) for "limits of agreement" will be calculated.

The inclusion of 200 paired measurements ( $n=200$ ) yields a 95% confidence interval of  $\pm 0.24s$ , where  $s$  is the standard deviation of the difference between the two methods), which is considered appropriate for this project.

### **Number of patients:**

Based on the above statistical considerations to make 200-paired measurements for all parameters, calculations show that each C3 unit shall provide an average of 20 recordings for each of the ten C3 monitoring units.

The following calculation is an estimate of how many patients that allegedly must be included in the project to achieve the required 200-paired measurements: Since the patients hospitalized at The Department of Oncology, Naestved Hospital have their vital signs measured at least once a day, it will take a at least twenty days to obtain the required number of measurements. The project is scheduled to run over 48 days in total. The department has approximately 22-28 new admissions per week with an approximate admission time of 5.4 days. This means that in those 48 days approximately 90 patients could be inquired ( $48 \text{ days} / 5.4 \text{ days} / \text{patient} * 10 \text{ C3 units}$ ). Of this population, it is expected that about 60 % are hospitalized with fever (above 38.5 °C) and therefore meet the project's inclusion criteria. With an estimated dropout rate of 25 %, the final population thus include about 40 patients. However, it is the goal of 200-paired measurements, which will determine the final number of patients included in the study.

### **Qualitative design:**

The purpose of the qualitative part of the study is to investigate 1) how patients experience wearing and continuously being monitored with the C3 unit, and 2) which challenges health professionals experience in their work, when new technologies are involved in care and treatment and which meaning it has to the delivery of their work.

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### **Semi-structured interviews:**

The qualitative studies are based on semi-structured interviews with 12 patients, who have been or are being monitored with the C3 for at least 24 hours during their hospital admission. The interviews are conducted by a clinical development nurse who through his/her relation to The Department of Oncology, Næstved Hospital has specialized clinical knowledge but no knowledge of the individual patients. The interviews are conducted during the admission of the patients. In addition, qualitative semi-structured interviews will be conducted with 10 of the health professionals (primarily nurses and social and health care assistants), who have been involved in the care of those patients who have participated in the project. These interviews are conducted by PhD Students from Research and Innovation, University College Zealand, and are not known by the health professionals.

A semi-structured interview guide is prepared, where interview questions are based on the thematic research questions (Annex 3 and 4) in relation to interviews with both patients and health professionals. The interview starts with some small talk and a briefing where the informant is told about the project and what is to be examined. This is to make the informant comfortable, while at the same time being fully aware of what is to be examined. The interview questions are written in everyday language. The initial open question can give spontaneous descriptions, rich on information, where the informant concludes on what has been central to the informant's own experience. Next can follow extended questions through an inquisitive and critical approach to the informant's answers (28).

The interview is recorded with a dictaphone for the purpose of transcription as well as analysis and interpretation.

### **Ethnographic observation study:**

Ethnographic observational study of health professionals, involved in the care and treatment of patients monitored with the C3, will also be carried out. This is to examine which challenges health professionals experience in their work, when new technologies are implemented in care and treatment and which meaning it has to the delivery of their work.

The observational study is carried out prior to the semi-structured qualitative interviews with the health professionals. During the interviews, it will then be possible to ask in more detail about the observations, which could pose potential challenges or affect the roles and relationship between the patient and the health professional. This way the insights from the observational study are deepened through the interviews.

The three methods: ethnographical observational studies, qualitative semi-structured interviews with health professionals and interviews with patients will be triangulated. Data from analysis will be processed theoretically and discussed.

### **Side effects, risks and inconveniences**

No side effects are expected in relation to wearing and being monitored by the C3. A slight discomfort may be associated with the ECG electrodes' skin contact. A discomfort, which may be compared to the irritation or the removal of an ordinary band-aid. With regard to potential irritation or allergy, multiple commercial ECG electrodes will be available in order

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to meet patients' individual needs (E.g. sensitive skin, allergy etc.). Moreover, the C3 is CE-classified, which means, that the unit complies with EU requirements on safety, health and environment.

## Ethics

The study includes the current clinical praxis for measuring vital signs in the Oncology Department at Næstved Hospital, supplemented with testing of the cordless monitoring unit the C3. The C3 will be attached to the patient's chest with standard electrodes and is thus non-invasive. Apart from the previously mentioned possible discomfort in relation to the ECG electrodes' contact with the skin, it is estimated, that overall, there are no significant risks associated with participating in the project.

In the quantitative part of the project, no biological material is gathered and therefore, the project will not give rise to a biobank. It must be underlined that these tests are carried out without connection to the Internet. Data is stored on, and can only be retrieved from, the individual iPads in the test. In the qualitative part, identifiable data, such as recordings of interviews, transcriptions etc. will be destroyed, when they are no longer needed. Overall, the study will be carried out according to the guidelines for Good Clinical Practice. Likewise, the collected scientific data will be handled according to "Lov om behandling af personoplysninger<sup>1</sup>"

## Reportings

Since the project involves testing of medical devices, the project has been reported to the Danish Health Authority. The project has also been reported to the Danish Data Protection Agency.

## Financing

The involved parties will not receive economical compensation for their work in the project. The actual completion of the project is expected to be conducted by the staff in the Oncology Department at Næstved Hospital, as part of their daily routine. The C3 monitoring units belong to Næstved Hospital. Likewise, the hospital has access to the included mini iPads.

## Publications

Findings, both positive and negative, will be submitted to international peer-reviewed journals. Since the project will form the basis of experience for a larger testing of the C3 on hospitalized patients in partner hospitals in Denmark and Germany under the EU INTERREG 5a program, which we expect will be approved, the publication will be included in the overall publication, once the larger project is finished.

## Perspectives

The C3 represents a type of solution, capable of supporting automatic readings of vital signs, hereby relieving hospital staff compared to the current manual measurements, involving risks concerning typing errors. Likewise, hospitalized patients can be spared repeated measurements of vital signs and ensured quick interventions through continuous, rather than punctate monitoring of a potential aggravation of the patient's condition.

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<sup>1</sup> A Danish law on handling personal data.

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Ultimately, this will prevent unintended deaths. Furthermore, the C3 represents (in a more mature version) a type of monitoring solution, that in the long run could be used at home and thus e.g. support early intervention at the deterioration of the patient's condition or spare the patients for outpatient consultations during treatment. The present analysis of the functionality and measuring quality of the C3 in a clinical design will be essential in relation to further development of these types of solutions. Likewise the data collected, on how nursing staff and patients incorporate these new vital signs technologies successfully in both their work organization and in their lives and homes, will help reduce the barriers for the introduction of other health technologies. This knowledge can become a lever for the implementation of several types of health technologies in hospitals and in the patients' own home.

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Protocol

## References

1. Sundhedsstyrelsen. Det danske sundhedsvæsen i internationalt perspektiv. Sundhedsstyrelsen, 2010
2. Vallgård S, Krasnik A (red). Sundhedsvæsen og sundhedspolitik, Munksgaard 2010
3. Ballegaard SA, Thorsen M, Bro LL, Wentzer HS. Hjemmeteknologi til patienter med KOL. Patient, professionelle og organisatoriske perspektiver. KORA, Det Nationale Institut for Kommuner og Regioners Analyse og Forskning, 2012
4. Danske Regioner, Kommunernes Landsforening, Ministeriet for Sundhed og Forebyggelse, Social- og Integrationsministeriet, Erhvervs- og Vækstministeriet, Økonomi- og Indenrigsministeriet & Finansministeriet. National handlingsplan for udbredelse af telemedicin. Fonden for Velfærdsteknologi, 2012
5. Regeringens handleplan for sundhed: Jo før – jo bedre. Tidlig diagnose, bedre behandling og flere gode leveår for alle. Regeringen, 2014.
6. Department of Health. Whole System Demonstrator Programme Headline Findings – December 2011
7. Accelerating innovation: the power of the crowd. Global lessons in eHealth implementation d Documents/ehealth-implementation. KMGP International Cooperative, 2012
8. Metodehåndbog for Medicinsk Teknologivurdering. Kristensen FB, Sigmund H (red.). Sundhedsstyrelsen, Enhed for Medicinsk Teknologivurdering, 2007
9. Observation og opfølgning på kritiske observationsfund. D4, Regionale sygehusdokumenter.
10. Bierman W. Temperature of the skin surface. JAMA, 1936; 106:1158-62
11. Savastano DM, Gorbach AM, Eden HS, Brady SM, Reynolds JC, Yanovski JA. Adiposity and human regional body temperature. Am J Clin Nutr 2009; 90:1124-31
12. Teran CG, Torrez-Llanos J, Teran-Miranda TE, Balderrama C, Shah NS, Villarroel P. Clinical accuracy of a non-contact infrared skin thermometer in paediatric practice. Child Care Health Dev 2012; 38:471-6
13. Taylor NA, Tipton MJ, Kenny G3. Considerations for the measurement of core, skin and mean body temperatures. J Therm Biol 2014;46:72-101

## Protocol


14. McGowan J, Grad R, Pluye P, Hannes K, Labrecque M, Welch V, Tugwell P. Electronic retrieval of health information by healthcare providers to improve practice and patient care. *Cochrane Database Syst Rev* 2009. The Cochrane Collaboration. Published by John Wiley & Sons Ltd, 2010
15. Dudley L, Garner P. Strategies for integrating primary health services in low- and middle-income countries at the point of delivery. The Cochrane Collaboration. Published by John Wiley & Sons Ltd, 2011
16. Martine S, Kelly G, Kernohan GW, McCreight B, Nugent C. Smart home technologies for health and social care support, *Cochrane Review*, 2009
17. Obstfelder A, Engeseth KH, Wynn R. Characteristics of successfully implemented telemedical applications. *Implement Sci* 2007; 2:25
18. Den Landsdækkende Undersøgelse af patientoplevelser, revideret udgave august 2011. Enheden for Brugerundersøgelser, Region Hovedstaden, 2011.
19. Regionernes Kliniske Kvalitetsudviklingsprogram. Rammebeskrivelser for anvendelse af kvalitetsdata fra de landsdækkende kliniske kvalitetsdatabaser. Databasernes fællessekretariat, 2012
20. Patientombuddet, Årsberetning 2011, Danske Patientsikkerhedsdatabase. Patientombuddet, Frederiksberg, 2012
21. Quality of care. A process for making strategic choices in health systems. WHO, 2006
22. Stevnshøj AL (red.) Den danske kvalitetsmodel. Kvalitet i bevægelse. Institut for Kvalitet og Akkreditering i Sundhedsvæsenet (IKAS), 2014
23. Hamilton PS. Open source ECG Analysis Software Documentation. E.P. Limited, 2002
24. Rengøring og desinfektion af medicinsk flergangsudstyr, der ikke anvendes til invasive og operative indgreb. D4, sygehusdokumenter
25. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; 1:307-10
26. Bland JM, Altman DG. Applying the right statistics: analyses of measurement studies. *Ultrasound Obstet Gynecol* 2003; 22:85-93

## Protocol

27. Bland JM, Altman DG. Agreement between methods of measurement with multiple observations per individual. *Biopharm Stat* 2007;17:571-82
28. Kvale S, Brinkmann S. Interview – introduktion til et håndværk. Hans Reitzels Forlag, 2009

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### Annex 1: Technical specifications for Cortrium's C3



# Cortrium

Introducing the C3 device

The **Cortrium C3** device is developed to meet the demand for a **modern, reliable, and open medical grade vital sign monitoring system**. The device is based on **state-of-the-art technologies** while remaining **inexpensive** as it is fabricated from high quality off-the-shelf components.

**Specs:**



- **Weight:** ~24 grams.
- **Dimensions (L x H):** ~ 50 mm x ~ 9 mm.
- **Battery:** 3.5V rechargeable Li-ion battery. ~ 72 hours battery life when recording and ~ 24 hours when live streaming. Recharged using standard micro USB port.
- **Internal memory:** 4 GB microSD card for > 17 days of continuous recording.
- **Connectivity:** Bluetooth 4.0 Low Energy (BLE) and live streaming to cloud service. Open RESTful API available.
- **Placement:** Worn on the chest using inexpensive off-the-shelf standard ECG electrodes.

**Metrics:**

1. **ECG:** 3 channels at 16 bit @ Fs=250 Hz
2. **Respiratory rate:** 16 bit @ Fs=250 Hz
3. **Body surface temperature:** 16 bit @ Fs=25 Hz
4. **Device temperature:** 16 bit @ Fs=25 Hz
5. **Accelerometer:** 3 axis at 12 bit @ Fs=25 Hz

**Derived metrics:**

- Heart rate
- Heart rate variability (HRV)
- Heart rate recovery
- Core temperature estimate
- Body position/posture
- Fall detection
- Sleep analysis
- Calorie count
- Step count



The smartphone screen shows the following data:

Heart Rate	Respiration	Temp	Device Temp	Posture
69 bpm	23 bpm	36.0 °C	33.4 °C	Upright

The screen also displays three ECG waveforms labeled ECG I, ECG II, and ECG III. At the bottom, there are controls for 'Pause' and 'Grid'.



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Annex 2: Table for BOS measures

Observationsskema

Label

Nøgle til risikoscore 0 1 2 3 Skema nr: \_\_\_\_\_

REGION SJÆLLAND

AFDELING / AFSNIT	DATO														
ÅR	KL														
RESPIRATIONS-FREKVENS	≥25														
	21-24														
	12-20														
	9-11														
	≤8														
Acceptabel kronisk værdi															
SpO <sub>2</sub> %	96-100														
	94-95														
	92-93														
	≤91														
Acceptabel kronisk værdi															
O <sub>2</sub> TILSKUD kronisk tilskud	l/min														
TEMPERATUR	≥40°														
	39°														
	38°														
	37°														
	36°														
	≤35°														
MARKÉR MED PRIK															
BLODTRYK	≥220														
	210														
	200														
	190														
	180														
	170														
	160														
	150														
	140														
	130														
	120														
	110														
	100														
	90														
80															
70															
60															
60															
DIASTOLISK BT: SKRIV VÆRDI															
PULS	≥160														
	150														
	140														
	130														
	120														
	110														
	100														
	90														
	80														
	70														
	60														
	50														
≤40															
MARKÉR MED PRIK															
Bevidsthed	A = vågen / orienteret														
Acceptabelt niveau	V/P/U = påvirket														
<b>Total risikoscore</b>															
Total score minus kronisk værdi midlertidig værdi															
Vandledning anfar +/- eller ml. Ved <50 ml/ 4. time = Enkeltscore 3															
Scoringshyppighed (timer)															
INITIALER: Plejepersonale / Læge															

Version: 3. Date: May 12<sup>th</sup>, 2015

## Overvej Sepsis

Ved BOS  $\geq 2$  og/eller mistanke om bakteriel infektion:



### Vejledning til risikoscorening af patienten

Alle nyindlagte patienter skal have vurderet behovet for observation af vitale værdier og målt BOS **mindst 3 gange indenfor de første 24 timer**. På baggrund af den sammentalte BOS observeres patienten fremadrettet jf. anbefalede handlingsalgoritme:

Samlet BOS	Minimum observations hyppighed	Tværfaglig Handlingsalgoritme	
0	Hver 12. time	Fortsæt rutine observation	
1-2	Hver 6.-8. time	ABCDE optimering	
3-4	Hver 3.-4. time	ABCDE optimering. Sygeplejersken vurderer om lægen skal orienteres eller tilkaldes. Kontaktes lægen tager denne stilling til behandlingsplan inkl. til-ladelig score.	Enkeltscore på 3: <b>Kald MAT</b> (hvis et så-dant system ikke haves, vagthavende læge).
5-6	Hver 3.-4. time	ABCDE optimering. Sygeplejersken tilkalder straks lægen, som lægger plan som ovenfor.	
7-8	Hver 1.-2. time	ABCDE optimering. Sygeplejersken tilkalder straks vagthavende læge. Lægen tilser patienten akut og lægger plan som ovenfor. Plan konfereres med bagvagt.  Overvej <b>MAT/ anæstesiologisk assistance</b> .	
9 eller derover	Hver 30. minut	ABCDE optimering. Sygeplejersken tilkalder straks vagthavende læge. Lægen tilser patienten indenfor 15. minutter. Konferer med bagvagt eller kald <b>MAT/ anæstesiologisk assistance</b> . Læg plan som ovenfor.	

**Vigtigt!** Ved pludseligt fald eller stigning i en enkelt vital parameter, orienteres vagthavende læge. Uanset BOS værdi kan vagthavende læge eller MAT tilkaldes, hvis der er bekymring for patientens tilstand.

**MAT – Kaldekriterier** uforandret, så husk: **Samlet diurese < 50 ml på 4 timer = Enkeltscore på 3**

BOS værdi videregives ved vagtskifte (Safety Briefing) og overflytning af patient til anden enhed.

AVPU vurdering af bevidsthedsniveau
<b>A</b> lert - vågen og orienteret
<b>V</b> erbal - reagerer på tiltale
<b>P</b> ain - reagerer på smertestimuli
<b>U</b> nresponsive - ingen reaktion, bevidstløs

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**Annex 3: Interview guide for interviews with health professionals**

This interview is estimated to last approximately 30 minutes.  
I would like to interview you on your experiences of including the C3 in care and treatment practices as tested here in the Department of Oncology during the last 4 weeks.

	<b>Interview questions</b>	
Briefing	Thorough information for the participant on the use of data and the purpose of the interview	
How have you experienced working with the C3?		
What changes and challenges, do you experience in working with the C3 in care and treatment of patients?		
What advantages and disadvantages, do you think including the C3 in care and treatment could bring in the future?		
In your opinion, how does the C3 affect your relationship with the patients?		
Thank you for participating		

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**Annex 4: Interview guide for interviews with patients**

<b>Research questions:</b>	<b>Interview questions:</b>	
<p><i>Briefing</i></p> <p><i>Small talk</i></p>	<p><i>Information is briefly given on the interview that is estimated to last approximately 5-10 minutes:</i></p> <p>The purpose is to gain insight into how you as a patient are experiencing wearing and being monitored by the C3. Your experiences are important insights for us, as they can contribute with important knowledge, as well as help improve quality and process.</p>	
<p>What is your experience of wearing the C3 on your body? And how do you experience the fact that the C3 continuously transfers data on your body temperature, pulse and breathing to the health professionals?</p>	<p>Possible additional questions:</p> <ul style="list-style-type: none"> <li>• What is it like wearing the C3?</li> <li>• How does the C3 stick?</li> <li>• How is your movability?</li> <li>• Can you feel the C3 when wearing it?</li> <li>• Does the C3 affect your sleep at night?</li> <li>• Does the C3 irritate you at night?</li> <li>• What is it like showering with the patches attached?</li> <li>• Does the C3 still stick if you are sweating?</li> </ul> <p>Could you imagine wearing the C3 at home? And what advantages and disadvantages would this give you?</p>	
<p>Debriefing</p>	<p>Thank you for participating. Rounding off the interview</p>	

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### Annex 5: Instructions on temperature measurement

Onk NAE - Temperaturmåling, ver. 1

Side 1 af 2

Sygehusvæsen - Somatik - Medicinske specialer - Onkologi Næstved - Generelle - Behandling og pleje af bivirkninger af sygdom og behandling

Niveau:	Onkologi Næstved Lidkrævet er dokumentet ikke dokumentstyret.				REVISOR EILAND - us er det for sig
Type:	Instrukser m.v. <b>Temperaturmåling</b>				
Redaktør:	Fagligt ansvar:	Ledelsesansvar:	Dokumentnummer:	Version:	Godkendt af:
aclo	jjae	Onkologi NAE afd.ledelse	337597 /	1	hmrc, nhho
14.01.2013					
Dokumentbrugere Næstved, Onkologi, Læge, SOSU asc./hj. og sygehj., Sygeplejerske, Onk nse alle, Onkologi NAE, internet					

- 1) Formål
- 2) Anvendelsesområde
- 3) Fremgangsmåde
- 4) Ansvarsforhold
- 5) Dokumentation
- 6) Definitioner/Søgeord
- 7) Referencer

#### 1) Formål

Formålet er at indlagte patienter får foretaget en individuel vurdering af temperaturmåling afhængig af indlæggelsesårsag.

#### 2) Anvendelsesområde

Gælder indlagte patienter.

#### 3) Fremgangsmåde

Alle nyindlagte patienter skal det første døgn have målt rektal temperatur i forbindelse med BOS-måling.  
Desuden skal patienter med svær leucopeni/neutropeni (leukocytter < 1,0 og neutrofile < 0,5) og som samtidig er højfebril (øre-temperatur over 38,5) have målt temperatur rektalt. (Ref. Dokumentnr. 21834 i D4).  
Undtaget er patienter, der er rectumamputeret og/eller i trombocytopeni (trombocytter < 20). I disse tilfælde, samt hvis patienten nægter at få målt temperatur rektalt, dokumenteres dette på BOS-skemaet med et lille "ø" (øre) ud for temperaturen.

Efter et døgn indlæggelse skal lægen til stuegang tage stilling til følgende:

- Om patienten fortsat skal have målt rektal temperatur, og i givet fald skal det ordineres i patientjournalen.
- Hvor mange gange i døgnet patienten skal have målt temperatur.

Efter 1 døgn overgås der til øre temperaturmåling, medmindre andet er ordineret i lægejournalen.

Der skal imidlertid løbende foretages en vurdering af, hvorvidt patienten fortsat kan bibeholde øre temperaturmåling.

Adskillige patienter på onkologisk afdeling er indlagt pga. f.eks smerter, obstruktion, ascites- og/eller pleuradrænage, eller fordi ambulat behandling ikke er muligt, som ved eksempelvis strålebehandling, Cytozarbehandling el.lign. I sådanne tilfælde vil der ofte være indikation for at overgå til øre temperatur måling efter 1 døgn indlæggelse.

Som udgangspunkt er rektalmåling den mest præcise måde at måle temperatur på (ref. Center for Kliniske Retningslinier). Ved uoverensstemmelse mellem sundhedspersonalets faglige skøn og temperaturen på øretermometret, skal temperaturen kontrolleres rektalt.

Det er endvidere vigtigt at observere patientens kliniske almen tilstand og være opmærksom på øvrige parametre som blodtryk, puls, respirationsfrekvens og saturation.

Desuden er udviklingen i temperaturen ofte af større betydning end selve temperaturen.

<http://d4.tessi.intern/D4Doc/book/RSJ/dokument.asp?DokID=337597&sText=temper...> 12-05-2015

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Onk NAE - Temperaturmåling, ver. 1

Side 2 af 2

hvorfor det er vigtigt at sammenligne patientens tidligere temperaturmålinger.  
Ved temperaturmåling i øret er det vigtigt, at termometeret håndteres korrekt (ref. Dokumentnr. 310076 i D4).

Fordelene ved øretemperaturmåling kontra rektalmåling er bl.a.:

- At sikre patientens integritet.
- Hvis patienten selv måler rektal temperatur, er der en risiko for, at termometeret glider ud af rectum og dermed ikke angiver en nøjagtig temperatur.
- Større sikkerhed for korrekt placering af termometeret, da det altid er sundhedspersonalet, der måler temperaturen.
- Lettere adgang til at måle temperatur på alle patienter, uanset om de er immobile, smertepåvirkede, cerebralt påvirkede m.v.
- Mere hygiejnisk, da rektal termometeret kan kontaminere patientens hænder, tøj, sengebord etc.

- 4) **Ansvarsforhold**
- 5) **Dokumentation**
- 6) **Definitioner/Søgeord**
- 7) **Referencer**

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## InnoCan has the following partners



*Partners are responsible solely for their own statements and presented results in the project.*