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Innovation Report

Transforming in-clinic post-operative and intermediate care with cosinuss°

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ABSTRACT

Continuous, mobile patient monitoring plays a critical role in healthcare, particularly for post-surgery, intermediate care in clinics. The implementation of vital signs monitoring technology enables healthcare professionals to triage patients effectively by maintaining real-time awareness of their health status and allowing for prompt intervention when necessary. This technology supports early mobilization and facilitates the detection of potential complications such as post-surgical sepsis. cosinuss° technology has been evaluated in various studies, in terms of its accuracy in capturing vital parameters and its usability, emphasizing its potential to enhance intermediate patient care and outcomes. This report outlines the design and implementation of cosinuss° Health patient monitoring solution for use in intermediate, postoperative clinic settings. It presents the results and insights from three recent, in-clinic applications, discussing both technical and practical aspects, clinical processes, and the reported satisfaction from both patients and medical caregivers. The findings highlight the promising potential of cosinuss° Health on improving patient monitoring and overall clinical outcomes.

Contents

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1. Summary

Continuous, mobile patient monitoring plays a critical role in healthcare, particularly for post-surgery, intermediate care in clinics. The implementation of vital signs monitoring technology enables healthcare professionals to triage patients effectively by maintaining awareness of their health status and intervening promptly when necessary. Moreover, such technology allows early mobilization and the detection of potential complications such as sepsis post-surgery. cosinuss° technology has been evaluated in various studies [1–4] in terms of its accuracy in captured vital parameters and usability, emphasizing its potential to enhance intermediate patient care and outcomes.

2. Challenges in hospital intermediate and postoperative care

Intermediate and post-surgery care in hospitals faces significant challenges due to rising demand for intensive care resources, coupled with limited human and financial capacities [5]. This situation hampers the delivery of critical care to seriously ill patients and compromises the monitoring of high-risk individuals. Hospital-acquired infections further exacerbate these issues, straining healthcare resources and increasing the risk of complications during postoperative recovery when detected too late [6]. Globally, postoperative complications are the third leading cause of death [7], highlighting the urgent need for innovative monitoring solutions to improve patient outcomes.

The occurrence of postoperative complications is often unavoidable. However, timely diagnosis and treatment can significantly mitigate the impact of these complications on morbidity and mortality, effectively preventing “failure to rescue” [8,9]. By promptly addressing complications, the adverse effects on the patient can be minimized, and potential life-threatening situations can be averted. Anticipating the need for intensive therapy with the help of continuous vital signs monitoring can further enhance patient outcomes, potentially leading to shorter ICU stays for less severely affected patients [10]. In contrast, unplanned readmissions to ICUs due to significant postoperative complications extend hospital stays and increase morbidity and mortality rates [11,12]. Thus, early detection and intervention are critical, necessitating continuous monitoring of vital signs.

The nursing shortage exacerbates challenges such as increased mental load on staff, poor documentation practices, and avoidable patient complications, all contributing to higher rates of “failure to rescue” [13–15]. Due to demographic changes and medical advancements, the number of surgical patients with complex comorbidities requiring intensive postoperative monitoring is increasing [16]. However, the growing demand for monitoring beds has not been matched by an expansion in ICU capacity due to resource constraints. This leads to delayed surgeries, the transfer of emergency patients over long distances, or the relocation of high-risk postoperative monitoring to regular wards [17,18]. Notably, over 70% of postoperative deaths occur on regular wards without ICU admission, underscoring the need for improved monitoring solutions [19].

Current monitoring methods are labor-intensive, costly due to manual data documentation and restrict patient mobility, potentially leading to preventable complications. Mobile, postoperative, and therapeutically efficient monitoring options remain limited. Major postoperative complications such as bleeding, hypoxemia, delirium, and sepsis, often manifest through changes in vital signs [20], with nonspecific symptoms appearing 8-12 hours before the onset of life-threatening events [9,21]. Continuous monitoring of heart rate (HR), blood oxygen saturation (SpO2), body temperature, blood pressure, respiratory rate, and consciousness, while preserving patient mobility, is essential for timely detection and intervention to support recovery [22,23].

Expanding postoperative care in general wards with mobile, continuous patient monitoring technologies fosters a more patient-centric approach, can improve the patient experience and quality of care through early complication detection [24–26], and ultimately contributes to the stabilization of critically ill emergency management.

3. Objectives

The purpose of this report is to outline the design and implementation of cosinuss° Health patient monitoring solution for its use in the intermediate, postoperative clinic setting. It presents the results and learnings from three recent, in-clinic applications. The paper also discusses technical and practical aspects, clinical processes, and reported satisfaction from both patients and medical caregivers.

4. Technology in a nutshell

cosinuss°s approach to patient monitoring is the wireless and continuous measurement of all relevant vital parameters in one sensor, worn in the external ear canal (Fig. 1). cosinuss° in-ear sensors enable multiple measurements per minute automatically, instead of one measurement every four to six hours and real mobile monitoring, which simplifies and secures patient therapy.

The in-ear sensors measure vital signs based on photoplethysmography (PPG), which is a non-invasive, optical measurement method that evaluates blood volume variations [27]. Various information can be extracted from the PPG signal, typically including HR and SpO2. More complex derivatives include respiration rate, heart rate variability (HRV), and blood pressure, which provide additional insights into the patient’s overall condition. Based on these vital signs data, together with an assessment of the movement frequency and movement patterns, postoperative complications can be evaluated timely.

4.1. The in-ear sensor: c-med° alpha

The c-med° alpha is the first in-ear, wearable pulse oximeter, for which the medical standard for SpO2 measurement could be proven by a low deviation from blood gas analyses in an indirect comparison [4]. Thus, the c-med° alpha fulfills the regulatory requirements set by the EN ISO 80601-2-61 and has the European medical CE certificate as a Class IIa device. The c-med° alpha measures SpO2 and heart rate based on two PPG signals, red and infrared, and body temperature through an infrared sensor, continuously and in real time. The in-ear sensor also calculates the perfusion index (PI) for the infrared PPG, which is used to assess the quality of the measured SpO2 values.

Additional raw data such as the PPG signals and the 3D acceleration, and further vital parameters such as respiration rate and blood pressure changes are available in combination with the cosinuss° Gateway and

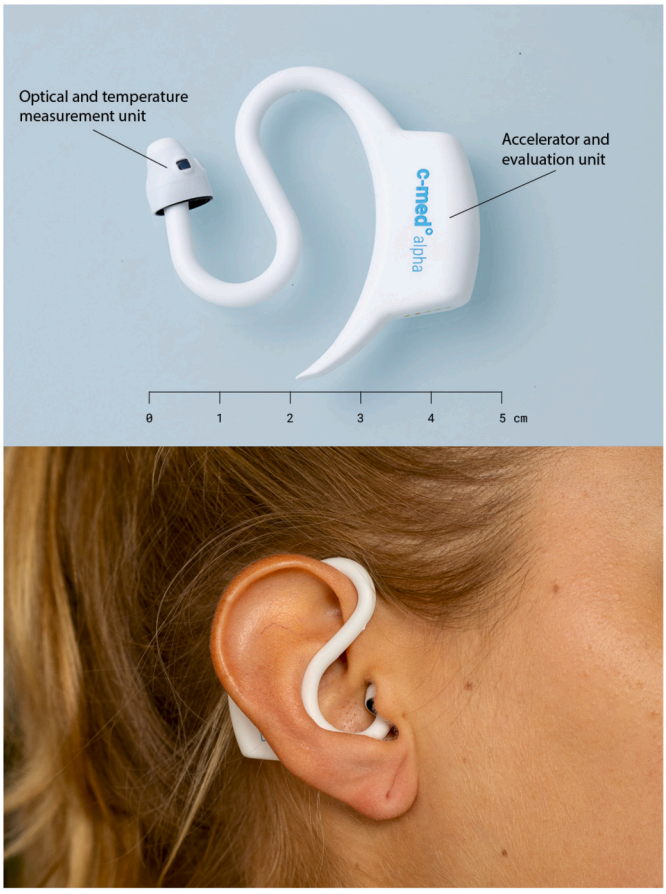

Fig. 1. Top: c-med° alpha in-ear wearable sensor. The ultra lightweight sensor consists of two following units: (Left side) Optical PPG sensor and infrared thermometer and (Right side) Three-dimensional linear accelerometer and the evaluation unit, including embedded board, battery and charging contacts. Bottom: Volunteer is wearing the c-med° alpha in the right ear.

cosinuss° Health platform (see Fig. 2, Section 4.2). The device continuously measures and visualizes the vital parameters of healthy or sick persons, from the age of 18-years old. It is intended to be used as a medical measuring device both at-home and in-clinic environments. Recent studies demonstrate its usability also in outdoor conditions, especially in emergency situations, such as mountain rescue and air rescue. In a recent technical feasibility study conducted by Ludwig Maximilian University of Munich in collaboration with the Bavarian Mountain Rescue Service, the in-ear sensors have been tested and positively evaluated for their reliability in monitoring vital signs of accident victims, even under extreme weather conditions and during transport, including in helicopters (MoReTech: Mountain Rescue Technology Study). The study findings are in preparation for publication (Benkert et al., 2024). The technical specifications of the c-med° alpha can be seen in the Table 1.

4.2. In-clinic patient monitoring solution: cosinuss° health

cosinuss° offers a complete solution starting from continuous data acquisition, through data transmission, data access and further data analysis. The core competence of the solution lies in the high quality data acquisition, which is the essential basis for all further processing and reliable health insights. The solution includes the hardware components as well as the service of data transmission, storage and data display. The entire system is planned to be certified as a Class IIa product in Europe.

cosinuss° Health has been developed to offer a total solution that is paid for by the clinics on a monthly basis. The system is completely modular and customizable according to specific needs of a clinic.

Table 1
Technical specifications of the c-med° alpha.

Vital signs	Heart Rate, Body Temperature, SpO2, RR-intervals (HRV)
Medical product classification	Class IIa
Certification	Medical CE, FCC & Bluetooth
Size (WxHxD)	58.6 x 55.2 x 10.0 mm
Weight	Approx. 7 grams
Material	Silicone rubber, USP class VI, medical grade
Battery life	Continuous measurement: approx. 15 h Periodical (3 min every 15 min): approx. 48 h
Protection type	IP47
PPG Sensor	Red LED, infrared LED and photodiode
Thermometer	Infrared and contact thermometer
Accelerometer	3-axis, linear
Sampling rate	PPG: variable, up to 200 Hz

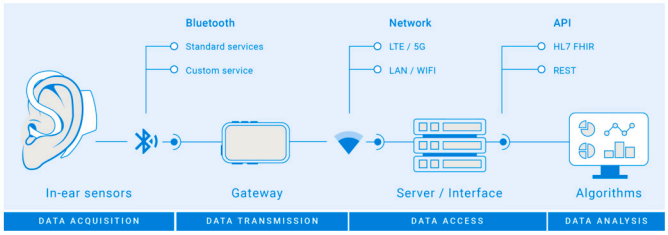

Fig. 2. cosinuss° Health platform solution for patient monitoring. The data are transferred from the in-ear sensor via the gateway to the server/interface using Bluetooth Low Energy (BLE) and network connections. Application programming interface enables seamless data integration into hospital IT systems.

5. In-clinic applications of cosinuss° health: innovations in patient monitoring

5.1. Case 1. DiAssCo study: in-clinic monitoring of COVID-19 patients

The rapid and dynamic pandemic with the SARS-CoV-2 between 2020-2021 had presented the German healthcare system with unprecedented challenges. The allocation of intensive care treatment capacities played a central role, especially when the dynamics of the spread and infection among older people was increasing. The DiAssCo study was conducted in 2021 at the Klinikum Großhadern of LMU, Munich, with the aim of digital assessment of COVID-19 patients using the cosinuss° in-ear sensor technology [28]. The study was coordinated by PD Dr. Roman Schniepp (Clinic of Neurology) and Dr. Ines Speck (Clinic of Anaesthesiology).

Hospitalized COVID-19 patients suffering from COVID-19 were equipped with the in-ear sensor in parallel to any treatment they were receiving at the clinic. The patients' medical condition spanned a wide spectrum of disease severity and outcomes. Data were collected in the first half of 2021, during the height of the COVID-19 pandemic, where at-home testing kits were not yet widely available and personal interaction with patients was very limited, due to time resources and the infection hazard.

Patient cohort

Patients were recruited from the Central Emergency Department of Klinikum Großhadern and from various inpatient units, including wards and intensive care units. Recruitment was directly supervised by physicians belonging to the study team, who were also responsible for sensor fitting and charging. Patients were included in the study if they had a COVID-19 infection at the time of their hospital admittance, as determined by a positive detection of the SARS-CoV-2 virus.

5.1.1. Study goals

The primary objective of the study included predictive modeling of the COVID-19 disease progression, based on cardio-respiratory param-

eters, body temperature and body movement, recorded continuously long-term with the in-ear sensor technology.

Heart rate variability (HRV) holds promise as a valuable tool for patient monitoring, particularly in diseases like COVID-19, which can have acute and lingering symptoms. While continuous health monitoring is currently primarily confined to intensive care wards, expanding its use to other stages of hospitalization could offer broader oversight of cardiovascular health in hospital settings. As such, a secondary objective of the study was to investigate the potential of HRV measurements, derived from the in-ear sensor PPG data, as a means of assessing patients' conditions. Analysis of the study data set is ongoing, and a master's thesis focusing on the potential of HRV features in predicting COVID-19 outcomes based on the DiAssCo data set is available upon request [28].

5.1.2. Monitoring setup

The DiAssCo study employed the prototype version of the c-med° alpha in-ear sensor, the cosinuss° Two, to continuously record cardiocirculatory and respiratory vital parameters, in addition to body temperature and body movements of COVID-19 patients. The main functional difference of cosinuss° Two from the c-med° alpha is that it measures the body temperature via contact thermometer, instead of an infrared sensor. As the °Two was the only sensor that could measure crucial vital parameters for COVID–19 with high data quality and sampling rate in a single device, the longitudinal objective data on disease were collected using °Two.

Patient monitoring setup included the in-ear sensor °Two, the cosinuss° Gateway and the initial version of the cosinuss° Health web interface. Recorded vital parameters were heart rate, respiratory rate, body temperature and blood oxygen saturation. Through the three-axis accelerometer embedded in °Two, the movement parameters of COVID-19 patients were also recorded. The in-ear sensor alternated between a 12-minute measurement phase and a 3-minute data transfer phase. The measured data was transmitted via BLE to a gateway in the same room and subsequently sent to cosinuss° Health server for storage and display. This alternating recording mode was chosen to strike a balance between the sensor battery life and continuous recording.

5.1.3. Outcomes

Patient population

The study encompassed 149 patients, approximately 38% of which were women. The average age was around 62 years. The majority of patients in this study were experiencing acute and serious illness. A subset of patients (around 20%) was admitted to the ICU.

Vital signs data

Automatic, high sampling rate (200 Hz PPG signal, 1 Hz vital signs, 0.1 Hz body temperature) 12-min recordings in every 15 minutes were set for the study. The total wearing time of the cosinuss° Two sensor was 29871.2 hours, with 200.5 hours of wearing time per patient. In total, 25165.0 hours of data was recorded, leading to 57055.6 million data points, including the PPG and acceleration data, in addition to the vitals. The most used sensor size was medium, followed by small and large sizes (S: 56, M: 77, L: 16).

Staff survey feedback

After the study, medical staff involved in the study were asked about the experience they had using the in-ear sensor °Two for measuring vital parameters of the COVID-19 patients. Three participants (one physician, two doctoral students) completed the questionnaire. Overall, the respondents' assessment of the system and its use was good. Two respondents rated the usability of the cosinuss° Health Platform as easy to use. This is an important aspect in order to avoid complicating the work processes of nursing staff and doctors.

One feedback was that the changing of the sensor twice a day due to battery charging was inconvenient. In the clinic, with older patients, the sensor wearing and dislodgement process could be very cumbersome, mostly due to lack of technological understanding. However, with younger patients and active participation, it was uncomplicated. Overall, patients found it uncomfortable to wear the cosinuss° Two for extended periods, which led to relatively low acceptance. This feedback informed the design of the c-med° alpha afterwards, to improve its ergonomics. For more details about the qualitative feedback, see Section 6 and Table 2

Table 2
Summary of key results from the medical staff survey (n = 14), pooled from the three in-clinic cases described above. Questions 1–5 were rated on a scale from 0 (not satisfied) to 10 (satisfied). For the full questionnaire, see Appendix.

Survey results overview	
Survey questions	**Average rating**
1. How would you rate the usability of the cosinuss° Health Platform?	6,79
2. How was the acceptance of the cosinuss° sensor among patients?	6,29
3. How satisfied were you with the training on the cosinuss° system?	7,23
4. How satisfied were you with the cosinuss° support regarding use of the system?	7,50
5. How do you rate the ease of use of the in-ear sensor?	6,00
6. How much time did you need to set up the cosinuss° sensor on a patient and link it to the cosinuss° Health platform?	71%: < 5 min 29%: 5 to 10 min

5.2. Case 2. hospital pilot project: in-clinic postoperative patient monitoring

In 2023, together with an innovative, medium-sized German hospital, cosinuss° conducted a pilot project to monitor the vital parameters of patients after surgery. The hospital has a strong focus on quality, innovation, and patient satisfaction, and part of one of the largest healthcare providers in Germany. It has a capacity of over 350 beds and specializes in cardiology, general and visceral surgery, and particularly orthopedic surgery for comprehensive patient care concerning the cardiovascular and musculoskeletal system. The hospital's aim is to continuously provide high-quality care to patients through innovation and technology.

5.2.1. Project goals

The project aimed to achieve various enhancements in patient, clinic, and employee aspects by implementing the cosinuss° Health patient monitoring system.

For patients, the objectives included enhancing safety, fostering a sense of security and well-being, and minimizing disruptions from routine, in-clinic measurements. The clinic sought to enhance monitoring for recently operated patients, improve patient safety, digitally document vital data, and establish remote monitoring for outpatient care. Additionally, adopting state-of-the-art medical technology aimed to boost the clinic's reputation. Employee benefits focused on streamlining routine tasks, enhancing responsiveness and staff morale, and reducing administrative documentation burdens.

5.2.2. Solution setup

cosinuss° Health system, including the c-med° alpha in-ear sensor, the Gateway and the cosinuss° Health web platform was implemented for various stations of the hospital, such as otorhinolaryngology, urology, hand and trauma surgery and internal medicine. The gateways were connected to the hospital network and the vital data were displayed on the web interface of the cosinuss° Health platform. Automatic 5 minutes vital signs recordings in every 15 minutes were set. Measured vital parameters were heart rate, blood oxygen saturation, body temperature and respiration rate.

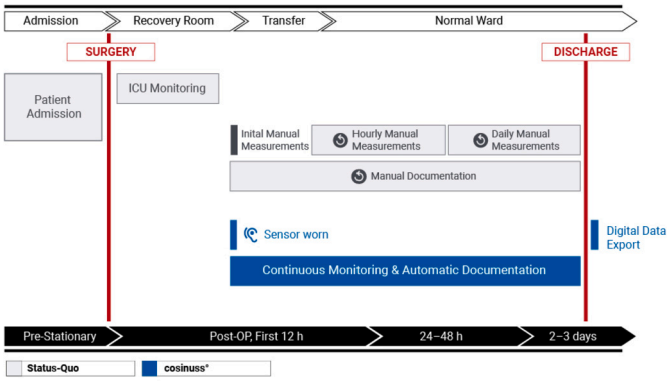

Fig. 3. Visual comparison of conventional post-operative patient monitoring (in grey) and automated continuous monitoring with cosinuss° Health (in blue). Conventional monitoring relies on manual vital sign checks during ward rounds, while the c-med° alpha in-ear sensor enables continuous monitoring and automated documentation until discharge.

5.2.3. Process before-vs-after cosinuss° health integration

The usual procedure for patients and medical staff after an operation at the hospital is as follows: Immediately after the operation, the patient is transferred to the recovery room, where their vital signs are monitored using conventional, stationary monitoring measures. If necessary, a printout of the monitoring data is placed in the patient's file. Within the first 12 hours after the operation, the patient is transferred from the recovery room to a normal ward by the nursing staff. Here, the staff takes the first manual measurement of vital parameters. This is documented by hand and stored in the patient file. In the following 24 to 48 hours, regular manual vital signs checks are carried out at least once a day by the nursing staff and during doctors' rounds. The patient is usually discharged two to three days after the operation. No final vital data recording takes place before discharge (see Fig. 3).

In order to improve these processes and implement continuous, digital monitoring, the cosinuss° system was integrated in the following process steps: Before the patient is transferred from the recovery room to the ward by the nursing staff, the patients wear c-med° alpha sensor. The first incoming measured values are documented by the staff in the patient file. In the hours and days that follow until the patient is discharged, the vital signs are now automatically and continuously recorded and documented in the cosinuss° Health platform (see Fig. 3). All recorded data is exported from the cosinuss° Health web interface before the patient is discharged and stored in the patient file.

Patient population

In total 89 patients were monitored after surgery with the cosinuss° Health system. 54 patients were from otorhinolaryngology, urology, hand surgery patients, while 35 of them were from internal medicine, trauma surgery patients.

Vital signs data

For the first group of patients, the total wearing time of the c-med° alpha sensor was 209.2 hours, with 3.9 hours wearing time per patient. In total, 75.7 hours of data was recorded, leading to 255 million data points, including all PPG and acceleration data, in addition to vitals. The most used sensor size was small, with a small difference to medium size (S: 30, M: 24). It is noteworthy that 20-40% of patients had surgeries around the ear, therefore in-ear monitoring was not possible for those patients.

The total wearing time for the latter group of patients was 317.5 hours, with 9.1 hours wearing time per patient. In total, 113.1 hours of data was recorded, leading to 381 million data points, including all PPG and acceleration data, in addition to vitals. The most used sensor size was small, with a small difference to medium size (S: 19, M: 16).

Staff survey feedback

After the pilot project, the medical staff involved were asked about the implementation of the new process in a qualitative survey (for further details, see Section 6, Table 2). Overall, the acceptance of c-med° alpha sensor by the patients was evaluated as good to very good with an average of 7.1, on a scale from 0 to 10, from not satisfied to very satisfied, respectively.

5.3. Case 3. UMG - cosinuss° project: in-clinic hemodynamic monitoring of cardiac surgery patients

The maintenance of cerebral perfusion is essential for optimal outcomes in patients requiring surgery with a heart-lung machine. In order to ensure adequate cerebral perfusion, it is important to carry out extended hemodynamic monitoring, which is commonly used in critical care settings. The recent study, started in September 2023, aimed for prospective evaluation of the c-med° alpha, in-ear temperature- and oxygen saturation measurements, on cardiac surgery patients for hemodynamic monitoring. The study was initiated and led by PD Dr. med. Martin Friedrich and Prof. Dr. med. Anselm Bräuer, at the University Medical Center Göttingen (UMG).

5.3.1. Challenges in the status quo

The insertion of a catheter into the femoral artery remains the gold standard for measuring body temperature, blood pressure, and for obtaining arterial blood gas analyses. Alternatively, a probe for temperature measurement can be placed in the bladder. However, both methods are invasive. Furthermore, during cardiac surgery, measuring SpO2 in a region closely correlated with cerebral perfusion is obligatory. Common practice for that is to use two electrodes that measure oxygen saturation in the forehead region via near-infrared spectroscopy (NIRS). This method is well-established and supported by clinical data. However, with this method, postoperative measurements in the normal ward setting is not standard practice.

5.3.2. Study goals

c-med° alpha in-ear sensor is a promising, non-invasive, alternative option for measuring the required vital signs during surgery. However, c-med° alpha has not been evaluated in the context of cardiac surgery patient population. Therefore, the main objective of the study was to analyze whether there are clinically relevant differences in measurement accuracy between the c-med° alpha and conventional methods used to measure SpO2, heart rate, and body temperature. Additionally, the study aimed to test the technical robustness of the cosinuss° Health patient monitor during each step of the procedure, from anesthesia induction to postoperative monitoring in the normal ward (see Fig. 4).

5.3.3. Monitoring solution & procedure

As a Class IIa medical device, c-med° alpha technically provides the ability to continuously and non-invasively capture reliable data: heart rate, SpO2, body temperature, a quality index, and perfusion.

The monitoring setup was similar to described in the Case 2, Section 5.2. The cosinuss° Health system, including the c-med° alpha in-ear sensor, the Gateway and the cosinuss° Health web platform was implemented in various stations of the hospital, in which the cardiac surgery patients (≥ 18 years-old) were operated and monitored post-surgery.

During the surgical anesthesia induction, the c-med° alpha sensors were placed in both ears of the patient. The attachment of the NIRS electrodes and the placement of the arterial catheter were also carried out under anesthesia as part of the surgical induction. The vital data were collected and recorded during:

5.3.4. Outcomes

Patient population

In total 32 patients were monitored with the cosinuss° Health system from the surgical induction step to postoperative monitoring in the normal ward.

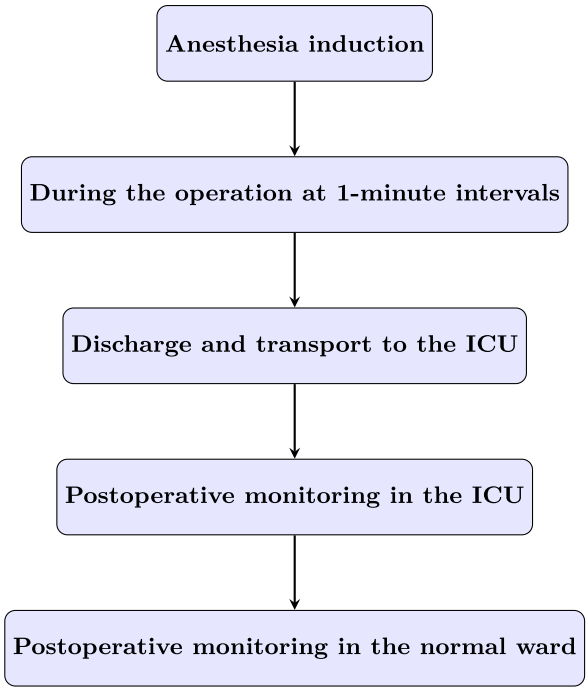

Fig. 4. The flowchart of the study procedure: continuous monitoring of the patient's vital data is tested in each step via the wearable c-med° alpha sensor.

Vital signs data

Automatic continuous recordings with high sampling rate (200 Hz PPG signal, 1 Hz vital signs, 0.1 Hz body temperature) was set for the study. The total wearing time of the c-med° alpha sensors, which was also the net recording time, has been 777.6 hours, with 24.3 hours recordings per patient. 4384.8 million data points have been recorded, including the PPG and acceleration data, in addition to the vitals. The most used sensor size was small, with a small difference to medium size (S: 18, M: 14).

Staff survey feedback

We received feedback on the use of the c-med° alpha and cosinuss° Health from one of the medical staff involved in the study. The cosinuss° Health solution was rated as user-friendly, with relatively satisfying data quality (6, on a scale from 0 (= not satisfied) to 10 (= very satisfied)). Setting up the c-med° alpha was considered to be a quick process, taking less than five minutes to set up the sensor and link it to the system. Overall feedback was that mobile and automated vital data recording in medical care is to be helpful in the future. For details of the received feedback, see Section 6.

6. Results & learnings

Data and measurement quality:

An important aspect of monitoring critically ill patients is the precise measurement of their vital signs. After all, the medical staff must be able to rely on the measured data. In the DiAssCo study (see Section 5.1), achieving high data quality was crucial for accurately predictive modeling of the COVID-19 disease progression. When asked how satisfied the medical staff were with the data quality of the cosinuss° Two compared to common measurement devices, the answers were very diverse. They ranged from not very satisfied, fairly satisfied to mostly satisfied. Here it is important to note that, in this study, a prototype of the c-med° alpha in-ear sensor, the cosinuss° Two, was used. The °Two has a sensor housing that is not designed for medical use. As the measurement quality depends very much on a good sensor fit [2], the causes for relatively poor data quality could be, for example, an incorrectly selected sensor size, intermittent sensor attachment and thus, suboptimal sensor fitting.

Furthermore, the unique circumstances of the peak of the COVID-19 pandemic in early 2021 led to less frequent patient contact, strongly differing from typical hospital conditions. Therefore, the issue of a deteriorating PPG signal quality could not be mitigated by readjusting the in-ear sensor. cosinuss° has developed an indicator for the PPG signal's quality, which displays whether the derived heart rate of the current measurement is reliable or not. If the signal quality indicator drops below a certain threshold, which is determined individually for every application, the sensor sends data with higher uncertainty. Implementing a live data quality indicator and other metrics such as the current number of pulses classified as "valid" or a live view of pulse waves, are in progress and could greatly improve the data acquisition quality [28].

"Continuous vital signs monitoring saves lives. We saw it happening in our COVID-19 study inside the hospital."
PD Dr. Roman Schniepp,
Klinikum Großhadern (LMU)

In addition, although the data quality satisfaction from the UMG project (see Section 5.3) was high, respondents from both the DiAssCo study (Section 5.1) and the UMG project stated that they had to interrupt patient monitoring three or more times. The reasons given were connection problems, particularly the Gateway disconnecting from Wi-Fi and measurements aborted at the patient's request, often due to pressure sensation or discomfort in hearing.

Ease of use:

When using innovative patient monitoring technologies, one central aspect of the in-clinic process optimization is to reduce the effort required from medical staff. An important question in this context was how much time nurses needed to insert the in-ear sensor into the patient's ear and connect it to the application platform. Another important aspect is how time-consuming the application of the in-ear sensor is perceived to be.

Overall, the respondents rated the insertion and use of the sensor as medium to low effort. When asked how much time it took to set up the sensor on a patient and link it to the cosinuss° Health platform, 71% of all respondents stated that it took less than five minutes. The time required depended heavily on the age of the patient, with older patients the process taking longer, and also on how open or familiar the patients were to new technologies.

The respondents were also asked how many attempts they had to make to put on and set up the sensor for the first time. The DiAssCo study (Section 5.1) respondents stated that they had to do this relatively frequently (more than twice). This is mainly due to the fact that the predecessor model of the c-med° alpha, the cosinuss° Two, was used in this study. Due to considerable improvements in ergonomics and design, the c-med° alpha was evaluated as easy to insert into the patient's ear.

With regard to cleaning the sensor, the most respondents found the process to be fairly time-consuming, especially if the sensors have to be replaced frequently or reused between patients. It became clear that the cleaning process could be made more efficient in the future, depending on the application and the number of patients being monitored. Accordingly, development of disposable sensor heads are planned to enhance the usability of the in-ear sensor specifically for in-clinic use.

In the future, it would also be conceivable that the in-ear sensors could be equipped with additional functions, depending on the area of application. Some of the medical staff mentioned, for example, the function of integrating an audio and telephone function could increase the patient acceptance of wearing the sensor over a longer period of time. Indeed, cosinuss° is currently collaborating with industry and academic partners to develop a novel sensor system combining the in-ear sensor with voice assistant capabilities [29].

Overall, the usability of the cosinuss° Health monitoring solution rated to be satisfying, with relatively high acceptance of the c-med° alpha among patients (see Table 2).

Sensor size selection:

Both cosinuss° Two and c-med° alpha come in three different sensor head sizes (S, M, L). In an ideal scenario, the sensor perfectly fits into the ear canal and has a reliable contact to the skin tissue, which ensures optically robust measurements and high data quality. The respondents were asked what criteria they used to select the right size of sensor for each patient. The survey revealed that selecting the right sensor size is no easy task. It is not clear to many users which factors they should consider. Most respondents stated that they used the size of the pinna or ear lobe as an indicator for the right sensor size, although, there is no correlation between the size of the pinna and that of the ear canal.

Four respondents stated that they used the perfusion index as one of their criteria. This, together with the signal quality index, is in fact an important indicator that the sensor fits correctly and that the size of the sensor head matches the size of the ear canal. Then, in communication with the patient, the wearing comfort needs to be taken into account, especially for long-term monitoring. Here, the learning was that the importance of the correct sensor size and thus the correct fit in the patient's ear canal must be communicated more clearly to users. This aspect is now more clearly incorporated into the user training and the instructions of the cosinuss° sensor, together with information on which factors need to be considered to estimate the right size for a patient.

Training & support:

Detailed training is essential for the correct use of the cosinuss° mobile patient monitoring system, in order to avoid possible application errors and achieve the best possible measurement quality. The medical staff survey, therefore, also focused on the evaluation of the training. In addition to theoretical instruction, practical exercises also play an important role here: The first attempt at inserting and setting up the sensor worked immediately for three people, and for seven people the second time (out of 14).

In general, respondents were quite satisfied with the training on the cosinuss° sensors and the support they received from cosinuss°, in response to their questions and issues they faced (see Table 2). It also became clear from the survey that extensive training and sufficient time for practice, is necessary for the users to test the sensors and the system, and to feel confident enough to use it.

Potential for in-clinic adoption:

The respondents see two major advantages of using the cosinuss° system in clinical practice: it could save time and, through the automated continuous measurement of vital data, could increase patient outcomes. For instance, in the DiAssCo study (see Section 5.1), automated continuous monitoring enabled the timely detection and treatment of developing infections in a patient in the regular ward, who experienced high fever at various time points during the night, but remained stable in the morning. During the COVID-19 pandemic, another particular relief was that medical staff did not have to go into the isolation room with the patients to collect and record the vital data.

Furthermore, all respondents stated that they consider mobile and automated vital data recording in nursing practice to be helpful in the future. They reported that it would make their daily work easier, if the cosinuss° system were to replace the daily recording of vital signs. Based on the survey and the direct exchange with medical staff, there are a number of areas in which further development and optimization of the cosinuss° technology would be useful. First, in order to replace the conventional, stationary monitoring, also including the recording of blood pressure is essential. Indeed, cosinuss° has already been working towards implementing a blood pressure monitoring algorithm (Technical white paper on blood pressure is available at request). Second, integration of the data flow into the hospital system is another crucial aspect for the adoption of the cosinuss° monitoring system for intermediate care.

7. Discussion

Open gaps in continuous monitoring:

Continuous mobile monitoring of vital parameters via wearable technology offers a promising potential to improve clinical outcomes. However, its effectiveness and benefits have yet to be confirmed in large-scale randomized clinical trials [30–32]. Currently, there is limited understanding of how individual vital signs fluctuate during acute illness or post-surgery recovery in hospital settings [33]. A recent study with COVID-19 patients explored the feasibility of continuous vital sign monitoring in home isolation [34]. This study was the first to demonstrate reliable, continuous tracking of biosignals relevant to the progression of an infectious disease, enabling immediate hospital admission in the event of critical health deterioration. Nevertheless, the clinical value of continuous monitoring in predicting hospital outcomes remains to be established.

One of the main challenges in continuous monitoring is ensuring the accuracy and reliability of vital sign data obtained from wearable sensors, especially in mobile use [35]. Previous studies have shown that inaccurate or unreliable readings can raise concerns among nursing staff, potentially undermining the system's credibility and adoption [36,37]. Another significant issue is the interpretation of continuous real-time data, as excessive false alarms can overwhelm staff and hinder effective clinical decision-making [32,36,38]. To address this, it is essential to redefine 'normal' individual vital sign trends during post-surgery recovery to reduce false alarms. Additionally, continuous monitoring often requires changes to established clinical workflows and hospital information systems [32,39]. Healthcare staff must adapt to these new systems, which should be designed to complement existing practices without adding unnecessary burdens. Ensuring proper training and motivation for staff to effectively use and incorporate the technology into their routines is critical for successful implementation [32,36].

Competing approaches for in-clinic continuous monitoring:

Many wearable devices on the market can continuously and wirelessly measure vital signs such as heart rate and blood oxygen saturation [40]. However, most are not medically certified, limiting their use to consumers. Additionally, the majority of these devices are wrist-worn, making them susceptible to motion artifacts [40,41]. Another limitation is their lack of integration with hospital information systems, which restricts their clinical utility. Current in-clinic continuous monitoring methods include: (1) Patches (e.g., Vital Connect), which allow mobile, continuous monitoring but do not directly measure body temperature or integrate with other platforms; (2) Standalone devices (e.g., Masimo and Nonin), which are often interoperable and usable in mobile settings, but generally do not support continuous data collection; and (3) Hospital monitor systems (e.g., Philips, Dräger, GE Healthcare), which provide continuous, highly accurate measurements but lack mobility and are not cost-efficient.

The c-med° alpha offers minimal restrictions for the patient, promoting fast-track recovery and early mobilization. It is the first in-ear pulse oximeter to achieve medical-grade accuracy for measuring oxygen saturation and heart rate, as validated against clinical-grade finger pulse oximeters [4]. Unlike other wearables, such as wrist-worn devices or medical patches that estimate body temperature from skin temperature, often leading to significant inaccuracies [42], the c-med° alpha directly measures body temperature with clinical grade accuracy [3] (see also Langenhorst et al. 2024, submitted). It also measures respiratory rate [34] and acceleration [1] and indirectly provides estimates of blood pressure, providing information on all six vital parameters [43]. Moreover, recent studies have demonstrated reliable data transmission via the cosinuss° Health platform and seamless integration of recorded data into the hospital's central monitoring system with minimal technical effort [4,39]. By storing health data in the HL7-FHIR standard, it ensures interoperability at all times. The integration of the HL7 system is currently undergoing testing. Collectively, these features, along with its clinical accuracy, position the c-med° alpha as a better alternative to established continuous monitoring devices.

In recent years, cosinuss° has concentrated its R&D efforts on developing a cuffless, PPG-based in-ear blood pressure monitoring solution with clinical-grade accuracy. Although the algorithm is currently under development, initial comparisons with a reference electronic cuff device show promising results. By expanding the cosinuss° Health system to include additional vital parameters, such as blood pressure, along with real-time evaluation, the solution aims to evolve into a comprehensive monitoring system capable of reliably predicting postoperative complications.

8. Conclusion

This report describes the design and implementation of the cosinuss° Health patient monitoring solution across three in-clinic applications for monitoring patients with acute illnesses and postoperative care. Data from these use cases suggest that the c-med° alpha, combined with cosinuss° Health, is feasible for use in low-intensity care settings, such as general wards. The system has been well-accepted by both patients and clinical staff, serving as a bridge between intermittent manual observations and traditional ICU-grade wired monitoring systems. It provides a sense of safety and reassurance for both nurses and patients. Nurses acquired the necessary skills to operate the system and offered valuable feedback for improving its usability, functionality, and training. Medical staff demonstrated strong interest in adopting efficient digital solutions that could benefit patients, healthcare workers, and clinical practice.

While full-scale integration into routine healthcare settings has yet to be achieved, these example projects underscore the potential of cosinuss° Health to cost-effectively improve postoperative and intermediate care. However, further evidence is needed to confirm its impact on clinical outcomes and cost-effectiveness. In conclusion, cosinuss° Health holds significant promise for enhancing diagnostic care in hospitals, optimizing, and personalizing postoperative therapy through mobile, continuous in-ear monitoring of vital signs.

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CRediT authorship contribution statement

Incinur Zellhuber: Writing – review & editing, Writing – original draft, Investigation, Conceptualization. **Melanie Schade:** Writing – original draft, Investigation. **Tim Adams:** Formal analysis, Data curation. **Manfred Blobner:** Writing – review & editing, Conceptualization. **Michael Weber:** Writing – review & editing, Project administration. **Catherina A.B. Bubb:** Writing – original draft, Conceptualization.

Declaration of competing interest

The technology used in this study is a commercial product of Cosinuss GmbH (Munich, Germany), which is the employer of co-authors IZ, MS, TA and MW. Corresponding author MB received fees for consultancy or lectures from GE Healthcare™ (Helsinki, Finland), Grünenthal™ (Aachen, Germany), and Senzime™ (Landshut, Germany). MB is a medical consultant to HW Pharmaconsulting (Moosbach, Germany). Co-author CABB declares no competing interests.

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Appendix A. Supplementary material

Supplementary material related to this article can be found online at https://doi.org/10.1016/j.csbj.2024.10.002.

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