Article Identifier
DOI: 10.22032/dbt.58880
URN: urn:nbn:de:gbv:ilm1-2023isc-050:5

CONCEPT FOR THE MEASUREMENT OF VITAL PARAMETERS DURING THE USE OF AN INFRARED CABIN TO INVESTIGATE PHYSIOLOGICAL EFFECTS AND TO INDIVIDUALIZE THE SAUNA SESSION

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ABSTRACT

Infrared sauna bathing has positive effects on body and mind. Quantifying these effects helps to make sauna use more efficient and safer and to increase the user-observed wellness effects. Currently, there are no practical solutions for a comprehensive and user-friendly monitoring of the physical impact of sauna bathing. This paper focuses on the concept development to investigate which measurement setups are suitable to record and evaluate changes in vital parameters. Based on prioritized vital parameters and requirements a pre-selection of devices in form of wearables is made, which is going to be examined in detail for their suitability. An investigation with ten test persons is planned, in which the wearables' measurement accuracy and the user acceptance outside and inside the infrared cabin are quantified. The result is a concept for the test procedure and the evaluation of the wearables in order to integrate a suitable device into the overall system.

Index Terms – infrared sauna, individualization, vital parameter measurement, wearable

1. INTRODUCTION

Sauna bathing is a tradition that goes back thousands of years and its positive effects on body and mind have been known since around 2000 BC [1]. Similar to physical training, a regular sauna session stresses the cardiovascular system [2]. Heating the skin surface and the body core can have various effects, including improving blood circulation [3], strengthening the immune system [4], relieving pain from rheumatic diseases [5], lowering blood pressure [5], accelerating wound healing [5], and releasing 'happy hormones' [6]. It can also support controlled weight loss programs, especially for very heavy patients, to prevent excessive stress on joints.
Instead of a traditional steam sauna, the use of infrared radiation in the sauna offers the advantage that the air temperature rarely rises above 60 °C and thus the cardiovascular system is less stressed [6]. The wavelength of infrared radiation is in the range between 780 nm and 1 mm and therefore outside the spectrum of visible light. Depending on the wavelength, the radiation penetrates the skin to different depths and can also reach blood vessels close to the skin. In these areas the radiation is converted into heat, which is distributed throughout the body via the blood and thus increases the body core temperature. [5] Therefore, compared to the traditional sauna, almost no heat is imposed from the outside, but is generated in the body itself. In the sauna, infrared radiators made of carbon or ceramic are typically installed as surface heating elements in the walls of the cabin [6]. Currently, when using an infrared sauna, users decide on the temperature, length and frequency of the sauna sessions based on their own

sensations or experience. In order to make the use of an infrared sauna more efficient, the aim of the project EWIVIKIS ("Development of an intelligent infrared heat cabin as an instrument to measure and improve vitality on the basis of an AI recommendation system") is to individually design the sauna session. The sauna duration and temperature should be controlled by the cabin system in such a way that the body reacts optimally and the user is highly satisfied. The individualisation of the sauna experience can enable the targeted use of infrared saunas in prevention and therapy.

In order to enable individualisation, various parameters of the user have to be recorded. The focus of this work is the investigation of a possibility to record the change of the user's vital parameters during the sauna session. The aim is to find a suitable measurement sensor setup that can be integrated into the overall design of an intelligent infrared cabin. The concept for the development of this setup is explained below.

2. SELECTION OF MEASURING DEVICES

2.1 Vital parameters

By measuring vital parameters during the sauna session, the direct reaction of the body to the application of infrared radiation is to be recorded and evaluated. Examples of changes in such parameters during a sauna session (traditional and infrared) are shown in Table 1.

Table 1 Changes in vital parameters during a sauna session and their integration in the concept

Category	Parameter	Change	Integration
thermoregulatory	Skin temperature	Increase [7]	Yes
thermoregulatory	Body core temperature	Increase [8–10]	Yes
thermoregulatory	Sweat rate	Increase [11]	No
thermoregulatory	Sweat composition	Changes in electrolyte ratios [12]	No
cardiovascular	Vessel diameter	Increase [13]	No
cardiovascular	Heart rate	Increase [11, 14–16]	Yes
cardiovascular	Heart rate variability	Increase [17]	Yes
cardiovascular	Stroke volume	Increase [11]	No
cardiovascular	Blood pressure	Decrease [7, 8, 11, 16]	Yes
cardiovascular	Blood velocity	Increase [13]	No
haematological	Hormones	Various changes [18]	No
haematological	Acid-base balance	Respiratory alkalosis [19]	No
haematological	Blood composition	Various changes, e.g. increase in lymphocytes [8, 9, 19, 20]	No
haematological	Heat shock proteins	Increase in amount [11]	No
haematological	Oxidative status	Various changes, e.g. in antioxidants [21, 22]	No
respiratory	Respiratory rate	Increase [23]	Indirect
respiratory	Minute volume	Increase [23]	No
respiratory	One-second capacity	Increase [23]	No
respiratory	Vital capacity	Increase [23]	No
respiratory	Blood oxygen saturation	Increase [19]	Indirect
other	Immune response	Change in gene expression [24]	No
other	Spermatogenesis	Decrease in sperm count [25]	No

Based on their properties and possible measurement methods, seven vital parameters were selected for monitoring during the sauna session in this concept:

- *Skin temperature* (ST) and *body core temperature* (BCT) increase as a direct result of radiation application. Monitoring the temperature is a safety mechanism to avoid overheating of the body.
- The *heart rate* (HR) is an indicator of cardiovascular stress and can serve as a guide for achieving various sauna goals. This is accompanied by *heart rate variability* (HRV) as an indicator of cardiovascular health and the body's ability to adapt to stressful situations.
- High *blood pressure* (BP) is an acute health risk. A decrease in BP may therefore represent a reduction of cardiovascular stress and should be monitored.
- The *respiratory rate* (RR) is not a prioritised parameter, but accrues as an additional calculable parameter in some methods and can provide additional information on the state of exertion.
- The *blood oxygen saturation* (SpO_2) is not a prioritised parameter, but accrues as an additional calculable parameter in some methods. In users with healthy lung function, this value should always be in the normal range. Monitoring can thus serve as a safety mechanism.

Due to its special temperature and radiation conditions, the infrared sauna represents a challenging field to record vital parameters. Research into this application is limited. Devices described in literature to capture vital parameters in the sauna include the following:

- Simple heart rate monitors and running trackers (often measuring HR only) [14, 16, 20]
- Rectal temperature measurement [10, 26]
- Digital hand-held infrared thermometers [27, 28]
- Sphygmomanometer with arm cuff [16, 20, 26–28]
- Ultrasound devices for vascular examination [13]

The technology used here is mainly for study purposes only and does not claim to be integrated into the concept of a wellness application because its use lacks comfort or is impractical for home application.

2.2 Requirements

Since the measurement of vital parameters during an infrared sauna session is a special application, specific requirements must be placed on the measurement technology to be used. The requirements focus on functionality and aspects of usability. The main requirements for the measurement technology are shown in Table 2.

The suitability of devices is measured against these requirements. Due to the simplicity of acquisition and applicability, commercially available wearables have proven to be an adequate option. The measurement methods used by the wearables are often contact or infrared thermography, photoplethysmography (PPG), pulse oximetry and the estimation of vital parameters such as blood pressure based on the PPG signal and user characteristics. These methods are all non-invasive and can be implemented with little effort on the part of the user. Disadvantages are predominantly the susceptibility to interference with movements and the indirect estimation of certain vital parameters.

Table 2 Requirements catalogue for measurement equipment to record vital parameters in an infrared cabin

ID	Description	Type
U.1	The measurement must be non-invasive	Usability
U.2	The measurement must be automatic.	Usability
U.3	The measurement must be mobile and must not restrict the user's movements. Likewise, the measurement quality must not be significantly negatively influenced by movements.	Usability
U.4	The measurement technology must be adaptable to different anatomical conditions. It should have a firm fit that is not influenced by external circumstances (e.g. perspiration).	Usability
U.5	The measurement should have a high level of comfort and should not negatively influence the relaxation caused by the wellness application	Usability
U.6	The materials used in contact with the body must be biocompatible and non-allergenic.	Usability
U.7	The measurement should not take place on surfaces in contact with the sauna environment (e.g. back).	Usability
U.8	The measurement technology must be reusable.	Usability
U.9	The measurement technology must be easy to disinfect.	Usability
U.10	The measurement technology should have a battery life of 12 h.	Usability
U.11	The measurement technology should have a max. price of 200 €.	Usability
U.12	The measurement technology should not pose a safety risk to the user and should include measures e.g. against electric shock.	Usability
F.1	The measurement technology used in the sauna must have a temperature resistance of up to 70 °C.	Functionality
F.2	The measurement technology used in the sauna should have a water protection class of at least IPX4.	Functionality
F.3	The measurement technology used in the sauna must be shielded against IR radiation or must not show any negative reaction to the application of IR radiation.	Functionality
F.4	The measurement method should not be light sensitive.	Functionality
F.5	The measurement technology should be corrosion resistant.	Functionality
F.6	All desired measurement functions should be accommodated in one device and implemented with the desired methods.	Functionality
F.7	The measurement technology should allow compensation of changes in environmental conditions (e.g. temperature, perspiration).	Functionality
D.1	Data acquisition and processing should be performed in real time.	Data
D.2	The equipment used must provide high signal quality and should include artefact suppression capabilities.	Data
D.3	Bluetooth Low Energy should be used for communication. The range should be at least 10 m.	Data
D.4	The data export should be simple and e.g. in the form of text files.	Data

2.3 Wearables

Due to the limited financial situation and time available, only a selection of wearables can be examined for their suitability for use in the sauna. A broad market research was conducted and three wearables were selected for examination. The pre-selection (Table 3) was prioritised according to the range of possible measurable vital parameters, the price, the commercial availability and the possibility of data processing. The information in Table 3 is based on data sheets, see Appendix A, and manufacturer websites. The price is as of 06/2023 and was determined via the manufacturer's own web shops.

Table 3 Technical specifications of the selected wearables and their expected advantages and disadvantages in use (Functions in brackets are possible with the device but the parameter values are not available for further processing due to various reasons)

Aspect	Samsung Galaxy Watch 5 (= GW5)	Oura Ring Generation 3 (= O3)	Cosinuss° c-med alpha (= C-med)
Price (€)	239,00	314,00	583,10
Adaptability	Wristband	8 sizes	3 sizes
Function	HR, (HRV), BP, SpO_2	(ST), (BCT), HR, HRV, (RR), (SpO_2)	BCT, HR, (HRV), (BP), RR, SpO_2
Temperature	MIL-STD-810H	-10 to 52 °C	15 to 40 °C
Water	IP68, 5ATM	Up to 100 m	IP47
Battery Life	Up to 40 h	Up to 7 d	Up to 12 h
App	Samsung Health	Oura App	Cos. Lab App
API	yes	yes	Health Platform
Advantages	BP measurement without arm cuff	Aesthetics Association with wellness sector	Range of accessible vital parameters Medical product
Possible disadvantages	Availability and processing of sensor data	Limited range of parameters Price	Price

As can be seen in Table 3, the data sheets do not specify operating temperatures above 52 °C for any of the wearables, so that use in the sauna would have to be ruled out here. Nevertheless, the wearables are checked for their suitability on the basis of the following reasons:

- Oura Ring Generation 3: information on website for use in the sauna (https://support.ouraring.com/hc/de/articles/360025428394-Produktsicherheit-und-Nutzung, as of 16.06.2023, paragraph "Allgemeine Verwendung")
- Cosinuss° c-med alpha: Consultation with the Cosinuss° development team
- Samsung Galaxy Watch 5: pre-test in climate chamber at 70 °C, which showed no safety risks for the user

It is suspected that the heating of the wearables in the sauna is limited, as the user acts as a heat dissipator and the air temperature can also only reach a maximum of 60 °C - 70 °C. Thus, the specified operating temperatures could be adhered to or be only slightly exceeded.

3. METHODOLOGY

3.1 Experimental setup and procedure

3.1.1 Measurement setup

In order to be able to evaluate the measurement accuracy of the wearables, the reference devices listed in Table 4 are used. The patient monitor has a three-wire ECG lead via button electrodes, a pulse oximeter with a rubber sleeve for the finger and an upper arm cuff for blood pressure measurement. The reference devices are medically certified and determine the vital parameters directly and not via estimation. Overheating of the equipment can be ruled out, as it will not be permanently placed in the cabin during the examination.
There is no reference device for the recording of ST and HRV in this examination, so that the accuracy with regard to these parameters cannot be assessed.

Table 4 Specifications of reference devices

Device	Parameter	Method	Counterpart
Patient monitor Philips M3046A	HR, SpO_2, RR, BP	ECG, pulse oximetry, oscillometrical BP measurement	GW5, C-med, O3
Ear thermometer Beurer FT 58	BCT	Infrared thermography	C-med

The measurement setup with wearables and reference devices inside and outside the cabin is shown schematically in Figure 1.

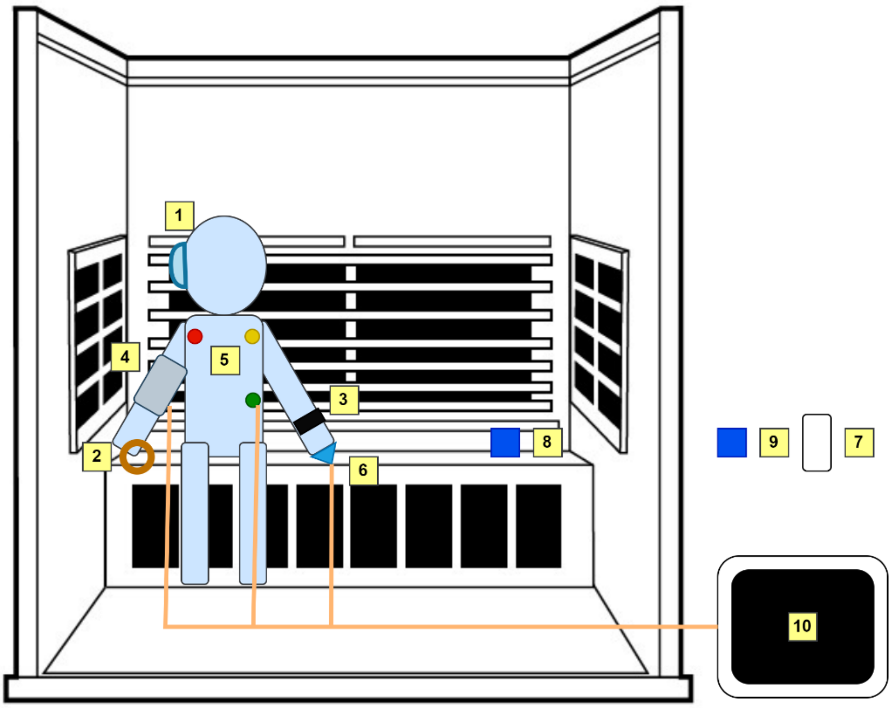

Figure 1 Schematic measurement setup for the wearables, inside and outside the infrared cabin (1 – Cosinuss° c-med alpha, 2 – Oura Ring Generation 3, 3 – Samsung Galaxy Watch 5, 4 – Blood pressure cuff, 5 – ECG electrodes, 6 – SpO_2 finger sleeve, 7 – Infrared ear thermometer, 8 - Logger for air temperature and humidity inside of the sauna, 9 - Logger for air temperature and humidity outside of the sauna, 10 – Patient monitor with connectors)

3.1.2 Procedure

The principle of the study is based on the simultaneous measurement of vital parameters with all selected wearables and the reference devices. In order to be classified as acceptable, the wearables may have a maximum average deviation of 5 % from the reference value.

The investigation is divided into a series of measurements at room temperature for 15 min and a series of measurements under sauna conditions for 30 min. For the sauna, an air temperature of 60 °C is set in the infrared cabin. The combination of *60 °C* and *30 min* is based on the extreme application case specified by the cabin manufacturer. After preheating the cabin, the air temperature is approximately 45 °C and only warms up to 60 °C after the user enters the sauna, so that a temperature increase takes place during the examination.

In addition to the vital parameters, the humidity and temperature in the room and sauna are also recorded in order to quantify environmental influences. In addition, the test subjects fill out a questionnaire, which is explained in more detail in section 3.1.3. The test procedure is as shown in Figure 2.

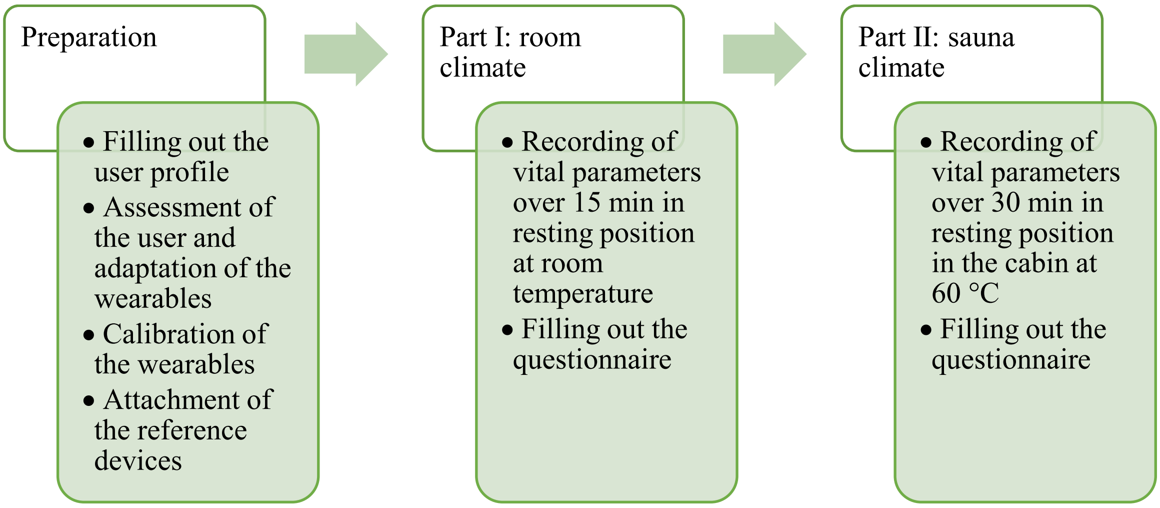

Figure 2 Test procedure

The recording intervals for the measured values are shown in Table 5. The intervals of the wearables are partly determined by internal programming and the measurement modes used.

Table 5 Measurement intervals for vital parameters (man = manual measurement, arbitrary interval)

Parameter	GW5	C-med	O3	M3046A	FT 58
HR	1 s	1 s	5 min	0,5 s	-
HRV	-	-	5 min	-	-
ST	-	-	-	-	-
BCT	-	10 s	-	-	man: 3 min
BP	man: 3 min	-	-	man: 3 min	-
SpO_2	man: 3 min	1 s	-	0,5 s	-
RR	-	random	-	0,5 s	-

3.1.3 Questionnaire

In order to obtain a subjective assessment of the wearables from the user, a questionnaire is handed out. The questionnaire, like the study itself, is divided into three parts. The first part, which is filled out by the test person at the beginning of the study, contains questions about the user profile and sauna habits. The second part is answered after Part I and contains an assessment of various user acceptance aspects in regard to each wearable. In the third part after Part II, an assessment of the wearables under sauna conditions is requested.

A 5-point Likert scale is used to evaluate the wearables, in which the agreement with a statement is indicated, see Table 6. The questionnaire contains statements with positive and negative connotations in order to avoid an imprinted tendency of the test person.

Table 6 Example question from the questionnaire for the usability of the selected wearables (5-point Likert scale)

Samsung Galaxy Watch 5					
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
In room climate, the wearable has an appropriate wearing comfort.					

At the end of the examination, the test persons rate on a 10-point scale how likely they are to use the wearable again in the sauna. If desired, the reason for the specific rating should also be explained.

3.2 Evaluation criteria

Based on the requirements catalogue, a list of subjective and objective aspects can be drawn up that allow a statement about the suitability of the wearables. The various aspects are given a weighting based on personal assessment, see Table 7. There are three evaluation levels that an aspect can receive and which are assigned a certain number of points: FULFILLED - 1 point, PARTLY FULFILLED - 0.5 points, NOT FULFILLED - 0 points. Points are awarded based on the study results. The evaluation level and the weighting then add up to a final score that can be compared between the wearables. The wearable with the highest score will be deemed the most suitable and will be integrated into the concept.

Table 7 Aspects for the evaluation of the suitability of the selected wearables with corresponding weighting (W – weighting, S – subjective assertion, O – objective assertion)

Aspect	W	S/O	Aspect	W	S/O
Function – Heart Rate	1,00	O	Real-time data	0,50	O
Function – Heart Rate Variability	0,75	O	Accessibility of data	1,00	O
Function – Blood pressure	1,00	O	Commercial availability	1,00	O
Function – Skin temperature	0,75	O	Price	0,50	O
Function – Body temperature	1,00	O	Battery Life	0,50	O
Function – Respiratory Rate	0,25	O	Usability – Adaptation	1,00	O/S
Function – Blood Oxygen Sat.	0,50	O	Usability – Comfort	1,00	S
Temperature resistance	1,00	O	Usability – Limited Mobility	1,00	S
Water resistance	0,75	O	Usability – Disinfection	0,50	O
Infrared radiation resistance	1,00	O	Usability – Biocompatibility	1,00	O
Measurement – continuous	0,75	O	Usability – Operation	0,50	S
Measurement – non-invasive	1,00	O	Usability – Fit	0,75	O/S
Measurement – automatic	0,75	O	Usability – Flexibility	0,50	S
Measurement – high resolution	0,50	O	Usability – Heat development	1,00	S
Measurement – accuracy	2,00	O	Usability – Size and weight	0,25	S
			Usability – Aesthetics	0,25	S

The measurement accuracy is emphasised here as an aspect with a weighting of 2.00, since it is the central object of the study. An exact mapping of the physical reaction to the sauna conditions is the basis for the development of a high-quality system. It is possible that this aspect will be split up so that the accuracy for different vital parameters can be rated separately. For the study, a test person number of 10 persons is aimed for. The mean value of the deviations of the individual test persons is determined as the resulting measurement deviation for the wearable. In addition, the standard deviation is calculated. The latter can indicate, for example, whether various characteristics of the test persons have influenced the measurement deviation and thus whether the scattering is greater.

3.3 Theoretical concept for the sauna system

As mentioned in the introduction, the aim of the development is a sauna system that adapts the sauna duration and temperature individually to the user and thus offers an optimal sauna experience. In the concept of the system, in addition to the vital parameters, a static (e.g. age, gender) and dynamic (e.g. daily state of mind) user profile and the subjective evaluation of each sauna session are included. The use case for the system is shown in Figure 3.

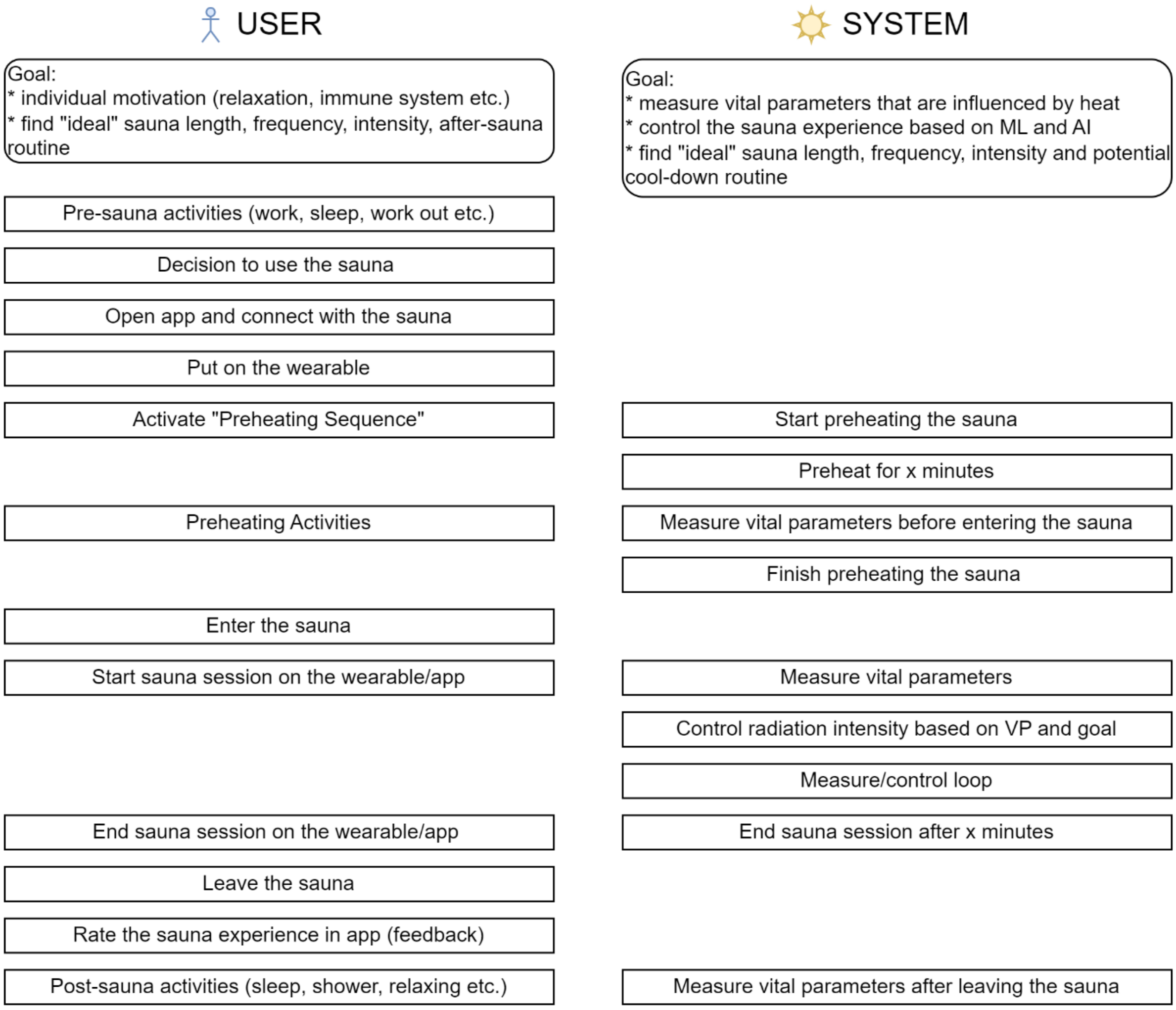

Figure 3 Use Case (ML- Machine Learning, AI – Artificial Intelligence)

Ideally, the wearable should be worn by the user at all times in order to record as much vital data as possible, which can then be related to the sauna session. In any case, it must be worn shortly before and after the sauna session, i.e. it is also used during activities such as showering or sports. Problems can arise here if the wearable does not match one's own aesthetics and is thus not worn voluntarily outside the sauna. Furthermore, the users themselves are responsible for disinfecting and maintaining the wearable (e.g. charging).

In the sauna, the temperature and humidity in and around the cabin are also recorded via integrated sensors. High temperature differences can have an influence on the thermoregulation of the body and the subjective feeling of the user. However, with the help of the data, these factors can be taken into account and integrated into the system via compensation algorithms. In this case, it is not possible to manipulate the wearables themselves.

Vital data, user data and environmental data are collected by the system. The collection happens automatically, without the user having to perform more actions than putting on the wearable and switching the infrared cabin on and off. A machine learning algorithm is used to analyse the data. The algorithm searches for correlations between the static and dynamic user attributes and the sauna session. The principle of federated learning is used here, in which neural networks are trained on the local end devices of the users without the user data having to be transmitted to a central server. Only the trained network parameters are integrated into the central network. This protects the sensitive health data of the users.

4. DISCUSSION

The study described here is only a concept. The procedure has not yet been fully tested in reality, which means that problems can arise during the final implementation that pose a risk to the success of the study. On the one hand, in any study with real people, there is the possibility that a sufficient number of test subjects cannot be found or that the test subjects will terminate the study before the measurement is completed, whether for personal or health reasons (e.g. too high a circulatory load due to the sauna session). With regard to the wearables themselves, problems that may arise include the following, which as a result hinder concept development:

- None of the wearables can withstand the high temperatures in the sauna and a loss of function occurs.
- The wearables do not have sufficient measurement accuracy in the sauna, i.e. the measured vital parameters cannot be trusted.
- The comfort of the wearables is lacking in such a way that the test persons do not want to use them at all.
- The wearables show interindividual differences in quality, which cannot be correlated with the user characteristics and therefore cannot be compensated.

It can be equally difficult to decide for one of the wearables if too many compromises must be made. For example, a wearable may have very good measurement quality, but exceed the price range and be intolerable in comfort. At this point, the weighting of the individual aspects may need to be reconsidered.

It should also be noted that not all measurement and evaluation influences can be taken into account in the study. The measurement chain includes a multitude of other factors for which the significance of their influence is not known. The selection of wearables to be tested is also limited due to time and cost-related reasons, so that the study does not cover the entire market. It should also be mentioned that the market for wearables and fitness trackers is constantly evolving at a fast pace. Findings and evaluations from this study may no longer correspond to the state of the art in a few years and may be irrelevant because better wearables with more functions have been released. This paper still provides a concept that can be reused to evaluate different devices if the evaluation parameters are adjusted.
In addition, the number of test persons is limited, so that no exhaustive statistical evaluation of the results can be carried out. A larger number and a diverse composition of test persons allows a more comprehensive view of the suitability of the wearables in relation to the total user base of infrared saunas.

5. CONCLUSION

This paper presents a concept to investigate the suitability of wearables for use in an infrared cabin. The focus is on the evaluation of the measurement accuracy as well as the user acceptance. The consideration of subjective and objective aspects can allow a comprehensive statement on the use of wearables.
The next step is to implement the study concept. If no wearable turns out to be suitable, the in-house development of a sensor setup with all desired requirements is an alternative.

In any case, the use of infrared cabins and their effects on the human body is a fascinating field of research that has not been worked on intensively at the moment. The recording of vital parameters in the sauna represents a possibility to make the sauna session more efficient and safer. A possible extension of the application beyond the wellness area to therapy and prevention measures underlines the importance of the planned project and the upcoming results.

6. ACKNOWLEDGEMENTS

This work is funded and done as part of the project “Entwicklung einer intelligenten Wärmekabine als Instrument zur Vitalitätsmessung und -verbesserung auf Basis eines KI-Empfehlungssystems“ of the “Zentrales Innovationsprogramm Mittelstand (ZIM)“ of the Federal Ministry for Economic Affairs and Climate Action managed by „VDI/VDE Innovation + Technik GmbH“. This project is a cooperation of the Biomechatronics Group at Technische Universität Ilmenau, Clearlight Saunas Europe GmbH, and Hamburger Informatik Technologie-Center e.V (HITeC).

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APPENDIX

A. Datasheets

Samsung Galaxy Watch 5

Technische Daten: Galaxy Watch5 & Galaxy Watch5 Pro[1 2]

	Galaxy Watch5	Galaxy Watch5 Pro
Materialien & Farben	Aluminium-Gehäuse und Sportarmband - 44 mm: Graphit, Sapphire, Silber - 40 mm: Graphit, Pink Gold, Silber	Titangehäuse mit D-Buckle Sportarmband - 45 mm: Black Titanium, Gray Titanium
Abmessungen[3] & Gewicht[4]	- 44 mm: 43,3 x 44,4 x 9,8 mm, 33,5 g - 40 mm: 39,3 x 40,4 x 9,8 mm, 28,7 g	45 mm: 45,4 x 45,4 x 10,5 mm, 46,5 g
Display	Saphirglas 24 Gpa - 44 mm: 1,4" (34, 6mm) 450 x 450 Super AMOLED, Full Color Always On Display - 40 mm: 1,2" (30,4 mm) 396 x 396 Super AMOLED, Full Color Always On Display	Saphirglas 29 Gpa - 1,4" (34,6 mm) 450 x 450 Super AMOLED, Full Color Always On Display
Prozessor	Exynos W920 Dual-Core 1,18 GHz	
Speicher	1,5 GB RAM + 16 GB interner Speicherplatz (davon 7,5 GB frei verfügbar)	
Akku (typisch)[5]	- 44 mm: 410 mAh - 40 mm: 284 mAh	590 mAh
Ladeleistung	Schnellladen (WPC - unterstützter drahtlose Ladestandard)	
Betriebssystem	Wear OS Powered by Samsung (Wear OS 3.5)[6]	
UI	One UI Watch 4.5	
Sensoren	Samsung BioActive Sensor (Optische Herzfrequenz + elektrisches Herzsignal[7] + bioelektrische Impedanzanalyse[8]), Beschleunigungsmesser, Barometer, Gyroskop, geomagnetischer Sensor, Lichtsensor	
Anschlüsse	LTE[9], Bluetooth 5.2, Wi-Fi 802.11 a/b/g/n 2.4+5GHz, NFC, GPS/ Glonass/ Beidou/ Galileo	

[1] Verfügbarkeit kann je nach Land, Modell und kompatiblen Smartphones variieren.
[2] Alle Funktionalitäten, Features, Spezifikationen und weitere Produktinformationen in diesem Dokument, einschließlich aber nicht begrenzt auf Produktvorteile, Design, Preisangaben, Komponenten, Leistungsdaten, Verfügbarkeit und Produkteigenschaften können unangekündigten Änderungen unterliegen.
[3] Ohne Gesundheitssensoren gemessen.
[4] Ohne Armband gemessen.
[5] Tatsächliche Akkulaufzeit kann je nach Netzwerkumgebung, Nutzungsverhalten und anderen Faktoren variieren.
[6] Wear OS Powered by Samsung läuft auf Smartphones mit der neuesten Android-Version (Go Edition and Smartphones ohne Google Play Store ausgenommen). Unterstützten Funktionen können je nach Plattform und Markt variieren und unterliegen möglichen Änderungen.
[7] Bei der Samsung Health Monitor App, die das Messen des Blutdrucks und eine EKG-Aufzeichnung ermöglicht, handelt es sich um ein Medizinprodukt. Die Verwendung der Funktionen setzt eine Verbindung mit einem kompatiblen Samsung Smartphone voraus. Für die Kalibrierung der Blutdruckfunktion ist ein MFDS-genehmigten Manschetten-Blutdruckmessgerät für den Oberarm erforderlich. Die Blutdruckmessung kann dabei unterstützen, Folgen von zu hohem Blutdruck vorzubeugen und Anzeichen eines normabweichenden Blutdrucks rechtzeitig zu erkennen. Die Blutdruckmessung dient nicht dazu, einen Bluthochdruck oder andere Erkrankungen zu diagnostizieren oder die Werte des Nutzers auf Anzeichen eines Herzinfarkts zu prüfen. Für eine größere Genauigkeit sollten Nutzer ihr Gerät mindestens einmal im Monat kalibrieren. Die EKG-Funktion sucht niemals nach Anzeichen für einen Herzinfarkt. Die EKG-Funktion kann bei der Feststellung von Herzrhythmusstörungen unterstützen. Die Funktionen sind nicht dazu gedacht, eine ärztliche Diagnose oder eine Behandlung durch einen Arzt zu ersetzen. Bei Bedenken um die Gesundheit sollten Nutzer unbedingt einen Arzt aufsuchen. Die Funktion ist nicht für Nutzer bestimmt, die jünger als 22 Jahre sind. Weitere wichtige Hinweise findest Du in der Bedienungsanleitung. Bitte lies die Bedienungsanleitung und Hinweise gründlich vor dem Erstgebrauch durch.
[8] Die BIA-Analyse dient nur für Fitness und Wellnesszwecke. Die Funktion ist nicht zur Erkennung bzw. Diagnose und Behandlung von Erkrankungen oder körperlichen Erfassungen und auch nicht Verhütung, Überwachung, Behandlung oder Linderung von Krankheiten oder der Kompensierung von Verletzungen oder Behinderungen oder andere medizinische Zwecke gedacht. Wenn du dir Sorgen um deine Gesundheit machst, suche einen Arzt auf. Die Funktion ist nicht für Nutzer bestimmt, die jünger als 20 Jahre oder älter als 80 Jahre sind oder, wenn du schwanger bist oder einen Herzschrittmacher sowie ein anderes medizinisches Gerät trägst. Um das beste Ergebnis zu erzielen, führe die Messungen immer zur gleichen Tageszeit auf nüchternen Magen durch.
[9] LTE-Konnektivität nur für LTE-Modelle verfügbar.

Wasserfestigkeit	5 ATM[10] + IP 68[11] / MIL-STD-810H[12]
Kompatibilität	Android 8.0 oder höher mit 1,5GB RAM[13]

[10] Bietet Wasserschutz bis 5 ATM nach ISO Standard 22810. Nicht geeignet für Aktivitäten wie Springen in das Becken, Sporttauchen, Wasserski oder ähnliche Wasseraktivitäten mit hoher Geschwindigkeit und/oder Aktivitäten in tiefem Wasser.

[11] Schutz bei dauerhaftem Untertauchen bei 1,5 m Wassertiefe für 30 Minuten und ausschließlich in klarem Wasser. Kein Schutz bei Salzwasser und anderen Flüssigkeiten, insbesondere Seifenlauge, Alkohol und/oder erhitzter Flüssigkeit.

[12] US Militärstandard (MIL-STD-810H). Schutz gegen folgende äußere Einflüsse: Direkte Sonneneinstrahlung, Temperaturen im Bereich von 71°C bis zu -40°C, gefrierenden Regen, bis zu 72 Stunden Staub, Widerstand gegen mechanische Stöße und Vibrationen.

[13] Geräteaktivierung ist erst nach Herstellen einer Verbindung mit einem Smartphone möglich, das Google Mobile Services unterstützt. Kompatible Geräte können je nach Markt, Mobilfunkanbieter und Gerätemarke variieren.

Cosinuss° c-med alpha (extraction from data sheet 1603891941)

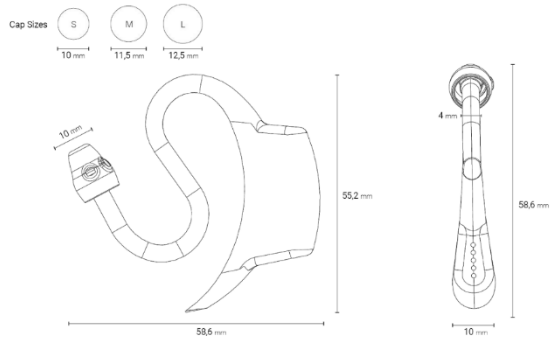
Document ID: 1603891941
Basic UDI-DI:426046302CMED4F

c-med° alpha - data sheet

cosinuss°
Vital signs . mobile . continuous . convenient

c-med° alpha

Medical wearable for continuous vital signs measurements



Features

- Continuous measurement of key vital signs:
  - heart rate
  - core body temperature
  - blood oxygen saturation (SpO2)
  - more raw data available
- Medically certified
- Approx. 15 hours of battery life when measuring continuously, longer battery life when measuring periodically.
- IP47 protected
- Operating temperature range: 15 °C – 40 °C

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c-med° alpha - data sheet

cosinuss°
Vital signs . mobile . continuous . convenient

General

Product specification

Type number	MS01
Generation	1
Device type	Continuous vital sign monitor
Usage	Measuring key vital signs continuously in the outer ear canal
Measuring position	Outer ear canal
Measured values	Heart rate, oxygen saturation (SpO2), core body temperature, RR-intervals.
Medical product classification	IIa
Certification	Medical CE & FCC, Bluetooth
Status indicators	RGB-LEDs
Size, **H** x W x D	55.2 mm x 58.6 mm x 10.0 mm
Weight	Approx. 7 g
Material	Silicone rubber, medical grade - ISO 10993-5 /-6 /-11 - USP class VI
Color	White
Battery life	Continuous: approx. 15 h Periodical (3 min every 15 min): approx. 48 h Standby: approx. 1 year
Environmental temperature for usage	15 °C – 40 °C
Barometric pressure for usage	700 – 1060 hPa (700 – 1060 mbar)
Storage temperature	-20 °C – 60 °C
Storage relative air humidity	≤ 95 % (non condensing)
Protection type	IP47

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c-med° alpha - data sheet

Appliance class	II
Power supply requirements	BF
Service life	2 years
Scope of delivery	c-med° alpha device, charging box, charging cable, power supply, manual

Radio transmission

Radio data transmission

Type	Bluetooth Low Energy (BLE)
Version	5.0 (backwards compatible to 4.2)
Frequency	ISM band 2.4 – 2.485 GHz
Transmitting power	0 dBm
Services	Battery Service, Device Information Service, Health Thermometer Service, Heart Rate Service, Pulse Oximeter Service, Custom Profile
Encryption	AES
Transmitting range	approx. 10 m

Power supply

Rechargeable battery

Type	Lithium battery, rechargeable
Capacity	60 mAh
Charging time	approx. 1 h

Sensor technology

Sensor types	Infrared and contact thermometer, optical measurement (LEDs and photodiode), accelerometer
Raw data	PPG (red, infrared and ambient light), acceleration

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c-med° alpha - data sheet

Quality indexes	Heart rate quality, perfusion index
Vital signs	Heart rate, core body temperature, blood oxygen saturation (SpO2),
Further derived parameters	Breathing rate

Photoplethysmography (PPG) sensor

Type	Red LED, infrared LED and photodiode
Method	Photoplethysmography (PPG)
Resolution	19 bit
Sampling rate	Variable, standard 200 Hz

Thermometer

Type	Infrared sensor
Measuring range	Measuring range: 34 °C – 43 °C Measuring limits: -25 °C – 50 °C
Resolution	0.1 °C
Technical accuracy	Inside of the measuring range ± 0.3 °C Outside of the measuring range ± 0.5 °C
Sampling rate	Variable, standard 0.1 Hz

Accelerometer

Type	3-axis, linear
Measuring range	Up to ±156,96 m/s^2
Resolution	16 bit
Technical accuracy	± 0.002 m/s^2
Sampling rate	Variable, standard 100 Hz

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Basic UDI-DI:426046302CMED4F

c-med° alpha - data sheet

Vital Signs

Core body temperature

Type	Infrared thermometer
Measuring range	Measuring range: 34 °C – 43 °C Measuring limits: -25 °C – 50 °C
Resolution	0.1 °C
Technical accuracy	Inside of the measuring range ± 0.3 °C Outside of the measuring range ± 0.5 °C
Interval	Variable, standard 0.1 Hz

Heart rate

Type	PPG
Measuring range	35 bpm – 220 bpm
Resolution	1 bpm
Accuracy	± 2 bpm
Interval	Variable, standard 1 Hz

Oxygen saturation (SpO2)

Type	PPG
Measuring range	70 % – 100 %
Resolution	1 %
Accuracy	± 3 %
Interval	Variable, standard 1 Hz

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Produktunterstützung und Fragen

Solltest du Fragen zur Einrichtung des Rings, zur Nutzung der App oder zu anderen Services von Oura haben oder sollten Probleme mit dem Produkt auftreten, schau dir zuerst die Antworten auf häufig gestellte Fragen an, die du unter ouraring.com/faq findest. Wenn du dort das Gesuchte nicht findest, erstelle ein Support-Ticket unter support.ouraring.com und unser Team hilft dir gern weiter.

Sicherheitsinformationen

Bitte beachten Sie, dass die Oura-Dienste nicht dazu bestimmt sind, Krankheiten oder Gesundheitszustände zu diagnostizieren, zu behandeln, zu heilen oder zu verhindern. Die Informationen und Ratschläge in den Oura-Diensten dienen nur zu Informationszwecken und können die Dienstleistungen von Ärzten und anderen medizinischen Fachkräften nicht ersetzen. Wenden Sie sich mit Fragen zu einer Erkrankung oder zu Veränderungen, die Sie aufgrund von Informationen oder Ratschlägen der Oura-Dienste an Ihren Schlaf- oder Aktivitätsgewohnheiten vorzunehmen beabsichtigen, immer zuvor an einen Arzt/eine Ärztin. Ignorieren Sie ärztliche Ratschläge unter keinen Umständen aufgrund von etwas, das Sie in den Oura-Diensten gelesen haben, und schieben Sie auch keine ärztlichen Konsultationen aus diesem Grund auf.

Wir sind nicht für gesundheitliche Probleme verantwortlich, die sich aus Informationen oder Ratschlägen ergeben, die Sie von den Oura-Diensten erhalten haben. Wenn Sie aufgrund der Rückmeldungen der Oura-Dienste Änderungen an Ihren Schlaf- oder Aktivitätsgewohnheiten vornehmen, erkennen Sie dadurch an, dass Sie dies allein auf Ihr eigenes Risiko tun. Es ist wichtig, auf die Reaktionen des eigenen Körpers zu achten. Wenn Sie zum Beispiel unerwartete, wiederholt auftretende oder lang anhaltende Schmerzen, Müdigkeit oder Beschwerden verspüren, weil Sie Änderungen an Ihren Schlaf- oder Aktivitätsgewohnheiten vorgenommen haben, wird empfohlen, einen Arzt zu konsultieren, bevor Sie diese Änderungen beibehalten. Die Informationen und Ratschläge in den Oura-Diensten können unangemessen sein, wenn Ihre Körperfunktionen und -reaktionen aufgrund von medizinisch relevanten Zuständen oder seltenen angeborenen Merkmalen erheblich von Durchschnittswerten der Bevölkerung abweichen.

Bitte achten Sie darauf, dass der Ring oder ein anderes Oura-Produkt, das Sie tragen, nicht an festen Strukturen oder schweren Gegenständen hängen bleibt, wenn Sie sich oder besagte schwere Gegenstände bewegen.

Wenn Sie aufgrund des Rings oder eines anderen Oura-Produkts Rötungen oder Hautreizungen an Ihrem Finger feststellen, entfernen Sie den Ring/das Produkt sofort. Wenn die Symptome länger als 2 bis 3 Tage andauern, während derer Sie Ihr Oura-Produkt nicht verwendet haben, wenden Sie sich an einen Hautarzt/eine Hautärztin.

Anwendung, Pflege und Wartung

Der Fingerumfang kann je nach Tageszeit variieren, und manchmal kann es schwierig sein, den Ring vom Finger abzuziehen. Wenn der Ring festsitzt:

→ Befeuchten Sie den Finger mit kaltem Wasser und milder Seife, und drehen Sie den Ring langsam, um ihn abzustreifen.

→ Halten Sie die Hand hoch (über Herzhöhe), bis der Blutdruck im Finger sinkt. Versuchen Sie dann, den Ring abzuziehen.

→ Suchen Sie in Notfällen und/oder bei Beschwerden – wenn Sie den Ring nicht selbst entfernen können – unverzüglich einen Arzt auf.

Reinigen Sie den Ring mit einem weichen Tuch oder waschen Sie ihn mit milder Seife und Wasser von Hand ab.

Der Oura-Ring kann beim Duschen, Baden, Schwimmen und Schnorcheln getragen werden.

Vermeiden Sie es nach Möglichkeit, den Ring beim Krafttraining, bei der Arbeit mit einer Schaufel oder anderen schweren Geräten oder beim Tragen schwerer Gegenstände aus Metall, Keramik oder Stein zu tragen. Vermeiden Sie außerdem, den Ring neben anderen Ringen oder Gegenständen zu tragen, die aus Metall, Keramik, Steinen oder Diamanten bestehen. Der Oura-Ring kann zerkratzt werden und

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kann seinerseits Schmuck aus weicherem Metall oder andere Gegenstände bei engem Kontakt zerkratzen, wie z. B. Handyhüllen aus Gold, Silber oder Aluminium. Auch manche keramischen Handyhüllen mit weicher Beschichtung könnten verkratzt werden.

Halten Sie den Ring von Kindern fern. Dieses Produkt ist nicht für Personen unter 18 Jahren bestimmt. Wenn Sie wissen oder vermuten, dass ein Kind den Ring verschluckt hat, bringen Sie das Kind sofort zu einem Arzt/einer Ärztin. Schützen Sie den Ring vor Hitze. Lassen Sie ihn z. B. nicht im Auto oder in der Sonne liegen. Durchstechen Sie den Ring oder seinen Akku nicht.

Bitte vermeiden Sie den Umgang mit Batterien/Akkus sowie die Arbeit an Geräten und mit Maschinen, die Batterien/Akkus enthalten, während Sie Ihren Oura-Ring tragen. In bestimmten Fällen, in denen sowohl die Kathode als auch die Anode einer Batterie/eines Akkus den Ring berühren, besteht – ähnlich wie bei herkömmlichen Metallringen – die Gefahr eines Kurzschlusses. Dies kann zu einem potenziell gefährlichen Stromschlag führen. Bitte treffen Sie entsprechende Vorsichtsmaßnahmen, um diese Situationen zu vermeiden.

Sicherheits- und Produktinformationen

Technische Daten

→ **Material der äußeren Oberfläche:** Titan, je nach Farbe mit PVD-Beschichtung (PVD = Physikalische Gasphasenabscheidung) oder diamantähnlicher Kohlenstoffbeschichtung (DLC).

→ **Materialien der Oberfläche an der Innenseite:** Nichtallergenes, nichtmetallisches, nahtloses Innenformteil

→ **Speicherkapazität:** Es wird empfohlen, die Daten des Rings täglich mit der Oura-App zu synchronisieren. Der Ring kann je nach Art und Häufigkeit der Ringnutzung Daten von bis zu eine Woche speichern.

→ **Akku:** wiederaufladbarer LiPo-Akku, je nach Ringgröße mit einer Leistung von 15 mAh bis 27 mAh, nicht austauschbar.

→ **Akkulaufzeit:** In der Regel 4–7 Tage. Die Akkulaufzeit hängt von den aktivierten Funktionen sowie von der Art und Häufigkeit der Ringnutzung ab.

→ **Aufladen:** Kabelloses Laden mit dem Oura-Ladegerät

→ **Ladezeit:** typischerweise zwischen 20 und 80 Minuten, je nach Anfangsladezustand des Rings

→ Die im Produkt verwendeten roten und grünen Leuchtdioden (LED) liegen im sichtbaren Farbbereich. Sie sind sicher für den Benutzer und Personen in der Umgebung.

→ **Konnektivität:** Bluetooth Low Energy (Bluetooth Smart®)

→ **Aktualisierbarkeit der Ring-Firmware:** Automatische Firmware-Aktualisierungen über die Oura-App

→ **Verfügbarkeit der Oura-App:** App Store, Google Play

→ **Kompatibilität der Oura-App:** Siehe https://support.ouraring.com/hc/de/articles/360025578613-Oura-Device-Compatibility.

→ **Sicherheit:** Zwischen dem Ring und der App wird verschlüsselte Bluetooth-Kommunikation verwendet.

→ **Der Ring ist wasserdicht** bis 100 m.

→ **Das Ladegerät ist nicht wasserdicht** und nur für den Innenbereich geeignet.

Das Ladegerät nicht in feuchten Umgebungen wie z. B. einem Badezimmer verwenden oder aufbewahren.

→ **Betriebstemperaturbereich:** –10 bis +52 °C

→ **Bei Raumtemperatur laden.**

→ Ladegerät-Eingangsanschluss und -spannung USB-Typ-C-Anschluss. USB-Nennspannung 5 V.

Das Gerät ist für die Versorgung durch eine externe 5-V-Gleichstromquelle vorgesehen, die der Norm IEC 62368-1 entspricht. Die dem Gerät bereitgestellte Leistung darf 15 W nach 3 Sekunden nicht überschreiten.

→ Das Ladegerät entspricht der internationalen