Corsano Health Cardiowatch 287 USA Usability Study

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Abstract

Objectives: Regulations and standards put the emphasis on usability and human factor design in the development of medical device and risk management. This paper explains the main challenges for wearable devices by showing how usability and human factors study was performed on the Corsano Cardiowatch 287 bracelet for body metrics monitoring.

Method: The Corsano Cardiowatch 287 bracelet was designed and developed based on risk management and usability engineering operating procedures, including risk analysis, formative and summative evaluations, according to harmonized standards.

Results: Risk analysis, event database study and product safety testing demonstrated the need of increasing mechanical and electrical protection, especially to protect users against misuse. Studies showed that the Bluetooth pairing process is the main source of unsatisfaction and early failure in using the device. The risks in using the device and measuring body metrics is low and resides mainly in the stress of the user about his/her health condition and the lack of information.

Conclusion: The usability engineering process and human factors testing enabled to evaluate the risks linked to use and misuse of the device, eliminate or reduce them, and demonstrate the safety of the device in daily use, by professional or lay persons. Summative evaluations demonstrated that the Corsano Cardiowatch 287 bracelet is easy to use and comfortable. The mobile APPs were also perceived as easy to use, easy to navigate and giving valuable information.

Keywords: cardiowatch – usability study – wearables

1 Introduction

The Corsano Cardiowatch 287 bracelet is a wrist wearable device, monitoring multiple sensors including, PhotoPlethysmography (PPG), accelerometer, temperature and others, measuring multiple body metrics and raw data, in continuous or spot measurements.

The Device internally runs a firmware. It connects to a mobile application (APP), and syncs to the cloud.

The device is rechargeable thanks to a magnetic USB cable to connect the device to a 5V power source.

Severity Level	Definition	Description
SL1	Negligible	Inconvenience or temporary discomfort
SL2	Minor	Results in temporary injury or impairment not requiring professional medical intervention
SL3	Serious	Results in injury or impairment requiring professional medical intervention
SL4	Critical	Results in permanent impairment or life-threatening injury
SL5	Catastrophic	Results in Patient Death

Operating principle

The Cardiowatch 287 consists of an accelerometer and a photoplethysmogram (PPG) sensor. The PPG sensor consists of an LED and a photodiode and measures fluctuations in the light reflected from the arteries and arterioles in the subcutaneous tissue. From the light fluctuations measured the actual heart rate and potential cardiac arrhythmias can be detected. In addition to the PPG sensor the accelerometer provides data on the activity level of the wearer.

Description of interfaces

The device is composed of an electronic enclosure attached to the wrist with an adjustable strap. To charge the battery of the device, a cable is provided with a USB-A connector on one side and a magnetic holding connector on the other side, that connects in a safe and error-free manner to the electronic enclosure (magnet poles prevent from connecting the wrong way). The cable also includes a short-circuit protection.

Cardiowatch 287 device

The user can use the device through the mobile APP. The APP has simple functionalities, basically enabling the user to start and stop a measurement. But the user needs to pair the device to the APP and register to the cloud account. The pairing process was shown to be the most problematic step in the use of similar devices, this is why it was considered with attention.

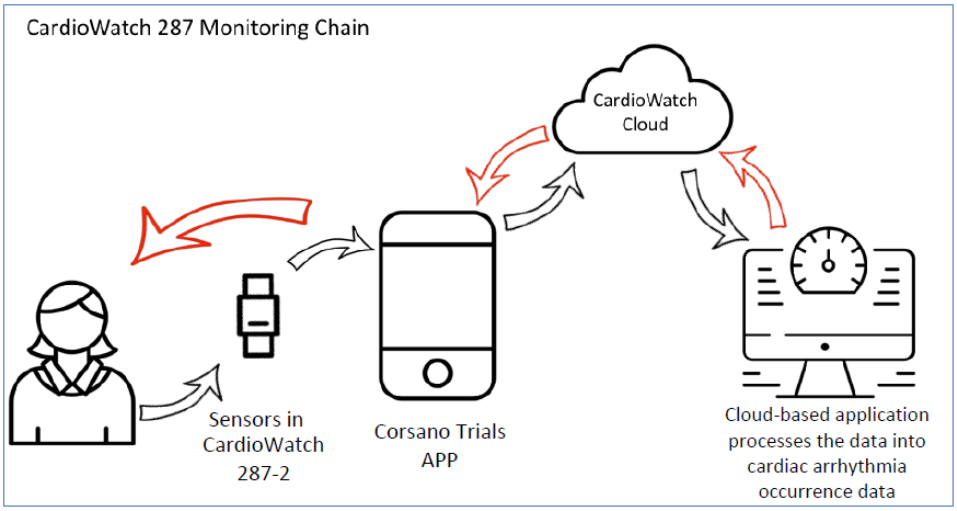
2 Study execution

Intended use

The Cardiowatch 287 System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals.

Intended population can be anybody over 18 years old. Since the device is suited for cardiac screening by third-party medical applications,

there is a special interest in target population over 55 years old.



Cardiowatch 287 System

Title of user group	Demographic data	Expected/Intended qualification, job experience, skills	Anticipated tasks and their frequency (related to the medical device)
Health care personnel (Physicians, nurses)	20-60, M/F (professional workers)	Limited knowledge in wearable technologies	• Instruct patients how to wear the device • Check the wearable is tight on wrist • Connect the device to the mobile APP • Enter personal data

Customer	18+, any customer (special interest over 55)	Can have no knowledge of wearable devices	• Download the mobile APP
			• Pair their device
			• Create User Account
			• Enter User Profile data
			• Use the APP to check
			  ○ Activity
			  ○ Sleep
			  ○ HRM
			  ○ SpO2

Intended user groups

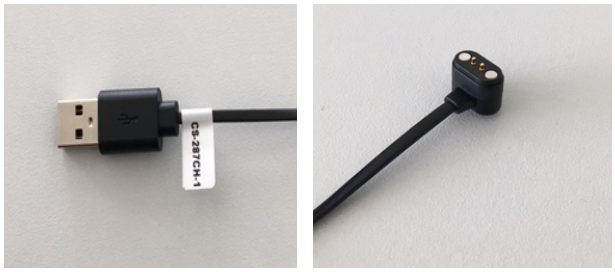
Use Environment	Lighting	Sound/Noise (ambient and intermittent)	Climate	Typical equipment used (in conjunction with the medical device)	Furnishing
Hospital, Clinic, Health Care center	Normal hospital light conditions	Typical public place noise environment	15-30 degC	Smartphone, mobile APP, system gateways	Chair, bed
Home	Light can be dimed	Home noise environment	15-30 degC	Smartphone, mobile APP	Chair, bed

Intended environments

Cardiowatch 287 strap

The strap is in contact with the skin. It is important that the strap is tightly adjusted for the quality of the measurement. This is explained in IFU and taken into account in the risk analysis.

The charge cable is a potential source of misuse. It was taken into account in risk management, device design to lead to a safe use. This was validated in the Product Validation process, in the Product Safety testing.



Charging cable

The Instruction For Use is provided to the user and is available from the APP.

The device is packaged in a box. The label information is applied in the internal part of the packaging and on rear-side (barcode label).

Cardiowatch 287 Label

Cardiowatch 287 package box

3 Analysis of hazards and risks associated with use of the device

The usability risks were taken into account as part of the risk analysis of the device and covered by the risk management process.

Risk analysis

Preliminary analysis was performed in the risk management process and in the preliminary phase of the usability engineering process, especially during formative evaluation.

The risk analysis demonstrated an unacceptable risk with the charging cable that was mitigated by design and validated in Product Safety testing.

Known problems are EMC problems and stress generated by false positive detection. Difficulties in pairing the device is also a known issue but does not generate a hazard.

Other known issues are linked to the rechargeable batteries but they are not particularly use related. This point is mentioned here and covered by the risk management process.

The device has a magnetic charge cable. When plugged in the mains, it can connect to a metal surface and create a short. This risk of potential harm was removed by designing a short-cut protection. This is also covered by the risk management process and the device validation.

Previous device analysis

Summative evaluation of the previous generation device was performed and demonstrated that the product is easy to wear and has no interference with their sleep.

It is well-known that the pairing process for Bluetooth devices is a critical step in the user experience. Previous evaluations were performed to evaluated it. It showed that the pairing process had to be improved. Further evaluation demonstrated the efficiency of the change and the improvement of the pairing process.

Formative evaluation

A formative evaluation of the Corsano Trial APP, based on a heuristic approach was performed and showed satisfactory results for the interface design of the APP.

Conclusion of preliminary analysis

Based on existing design, the device is safe and effective for the user.

After preliminary analysis, no critical tasks were identified, where potential harm related to the use of the device, could happen.

Nevertheless, Human Factors Validation Testing was conducted to demonstrate that the device can be used in an efficient and error-free manner, in representative environments, with representative users, and took in the USA to follow FDA guidance.

Description and categorization of critical tasks

The process used to identify the critical tasks was the following:

- Consider all UI characteristics related to safety/use error and analyze severity
- Since no high severity hazardous situation were identified, the choice of so-called critical tasks was based on effectivity more than safety. So common tasks were selected: charging the device, registering a cloud account, pairing the device and performing a measurement. Scenarios for the Human Factors Validation Testing include these tasks.
- Scenarios were defined for Lay persons and Healthcare workers

User Interface Characteristics Related to Safety and Potential Use Errors

To identify the critical tasks, all UI characteristics related to safety/use error were considered and severity analyzed.

UI-characteristic related to safety/use errors (primary operating functions)	Possible use error with respect to UI-characteristic	Root cause	Hazardous situation	Harm and severity level (SL)
Wearable PPG interface	PPG sensor not able to properly read the PPG signal	Band not tightly attached to the wrist	Bad PPG data monitored leading to missing diagnostics	No particular Harm (SL 1: Negligible). Risk is mitigated by the providing of a data quality factor when data are unreliable
Case, band	Skin irritation	Allergy to material	User cannot use the device	User needs to change the strap (SL 1: Negligible). Device is validated for biocompatibility
Charging cable	Plug the cable wrongly	No indication or not foolproof	Power cable can be short-cut, get hot and burn user	The risk is mitigated. A fuse is placed on the cable to prevent short-circuit. The cable is validated for product safety for short-circuiting (SL 3: Serious) This risk must be mitigated by a short-cut current limiter in the cable. After mitigation the severity is reduced to 1 (SL1: Negligible)
LEDs	Misunderstand display information	User does not read IFU	User might not be able to use the device properly	User might not be able to use the device properly (SL1: Negligible)
Transport and storage	Device under bad environment conditions during transport or storage	Device is stored in extreme conditions (temperature or humidity)	Device can be damaged, or service life impacted	User might not be able to use the device properly (SL1: Negligible)
Disposal	Device is disposed with general waste	User is not aware it should be recycled	Impact on environment	No harm for user (SL1: Negligible)
Maintenance	Maintenance is mainly software updates. The user may update the wrong software	The user has no technical knowledge of the system	The user gets proposed a wrong software update	The user cannot use the device anymore (SL1: Negligible) This risk is managed by the software. Easy and safe updates are considered in SW requirements.
Repairs	When devices are sent for repair, employees can be infected if device is not clean.	The device is worn by infected patient	The employee manipulates an infected device	During transport, the infectious agent decreases. Device is produced by ISO13485 company. Return procedures include disinfection of devices. (SL1: Negligible)
Abnormal use (intentional misuse)	The user may wear the bracelet on a different part of the body, on the upper arm for example.	Intentional misuse.	The data may not be accurate.	Quality of collected data is bad, can create confusion in data analysis. (SL1: Negligible) This risk cannot be mitigated but warning information is present in IFU

Foreseeable hazards and hazardous situations

4 Details of human factors validation testing

The study was a series of in person simulated use sessions with 33 participants to learn more about the Corsano Health's Cardiowatch 287 device.

The system uses software running in the mobile APPs. Due to the low risks related to the use of the device, finding 90% of all problems is acceptable. According to Faulkner (2003), the usability shall be performed on 15 people to reach this target. Each user group will be tested on 15 people.

No. users	Min. % Found	Mean % Found	*SD*
5	55	85.55	9.2957
10	82	94.69	3.2187
15	90	97.05	2.1207
20	95	98.4	1.6080
30	97	99.0	1.1343

Faulkner Scale

Users who have no prior experience with the device are recruited. They representative of each user group, 15+ people for each group, Lay Persons and Healthcare Workers. Each user undergoes the process individually to simulate use of the device. Each user signs an informed consent.

A user is provided with a packaged device (including final labelling), asked to unpack, set up and prepare to use the device. The user will leave with the device and resume their normal life. They will be wearing the device for a day and night, then return the device.

Users are observed by a researcher. Individual participant behaviors, commentary and response to post set up questions are recorded for further analysis.

In April and May 2022, the researcher Dr. Baran Erdik, M.D. conducted a series of 1-on-1 in person usability interviews with 33 participants to learn more about the Corsano Health's Cardiowatch 287 device.

Given the device's indications, the researcher tested it with consumers in the following two audience segments in the Metro Atlanta area and Norfolk, Nebraska:

15 Lay persons
18 Healthcare workers

The research included a mix of male and female users ages 24-66 with no prior experience with this particular device. It was recorded if users have prior experience with similar devices.

Any issues that arose during the study which may have been caused by user profile characteristics, have been recorded and analyzed as appropriate.

In order to understand a realistic and independent user device setup experience, we incorporated observational time and then asked detailed questions about the experience.

A user was provided with a packaged device (including final labelling), asked to unpack, set up and prepare to use the device. The user left with the device and resume their normal life. They were asked to wear the device for 24-hour period including the night, then returned the device.

Users were observed by the researcher. Individual participant behaviors, commentary and response to post set up questions were recorded onto Test Case Records to ascertain if there had been sufficient understanding of the instructions for use.

Results and user experience details were presented to all product design stakeholders and resulted in further development and implementation as applicable.

Test Environment

All of the users were visited by the researcher in their home, a mutually acceptable location such as Starbucks or Library, or their place of work in case of healthcare workers to receive the equipment. They were presented an unopened device in the presence of the researcher. Users downloaded the Corsano App from the AppStore or Google Play, paired the device and wore it during a 24h period overnight. Users were asked to complete the survey.

The user studies were carried out in isolation, no prior training or knowledge of the device mechanics or use interface was addressed. The aim of the study was to validate an intuitive and self-explanatory device both mechanically and in its use. During recruitment the device was explained like a simpler Apple Watch without providing additional details.

The following document was accompanied the device:

– Cardiowatch 287 User Guide

5 Test results

User Errors Record

Researcher focused on the following:

Task	Criteria
Clean device	Device properly cleaned
Charge the device	Green light blink
Download the app	APP installed
Pair the device to the app	Device paired
Start measurement	Measurement started
Wear device	Device properly worn (tight)
Stop measurement	Measurement stopped and synchronized

Operational Sequences

Analysis of results

Device

The surveys show that the wearability of the device is good.

- More than 80% of people are sometimes aware, only sometimes or not aware, of wearing the bracelet. Only 2.8% say it is frequently irritating. 0% of people find it is frequently interfering with sleep.
- 0% of people find the device hard to charge.
- 6.1% find it is hard to use.

We can conclude that the usability and the comfort in wearing of the device are very good.

APP

The pairing process is good.

- 0% of people find it is hard to pair the device and APP.
- 6.7% find the navigation in APP is hard.
- 12.8% find the information in the APP is not useful. This is 20% in lay persons and 5.6% in healthcare professionals. This is explained that the APP monitors health metrics, for analysis by physicians. Lay persons may not be interested in such data.
- 6.7% of people find the APP difficult to use. This is low and coherent with points above.

A specific point about the APP was raised. The metrics selection for weight and height should be automatically pre-set to Imperial when using a phone in the USA. This was subsequently implemented in the APP.

6 Risk-benefit analysis

The purpose of the Human Factors Validation was to demonstrate the effectivity of the interface of the device.

No critical tasks leading to potential harm was identified in the usability engineering process.

There are residual risks related to failure of the device (like battery leaks) and use error (like strap not tight) but they were reduced to minimum and have low severity. So, the risk is low. The benefit is high, since the device enables to easily, efficiently and continuously measure several body metrics, like heart rate. This enables physicians to diagnose cardiac problems. So, the benefit-risk ratio is very high and thus, the risks related to the device are acceptable.

7 Conclusion

The Corsano Cardiowatch 287 device has been found to be safe and effective for the intended users, uses and use environments.

First, the user interface characteristics related to safety were identified to highlight potential use errors. The analysis was performed by company experts based on known errors, foreseeable errors and their own experience. As part of the Risk Management process, the identified risks were removed by safe design, reduced to minimum or mitigated.

Then, the analysis of use scenarios did not identify a critical task leading to potential harm.

Nevertheless, to demonstrate an effective use of the device, formative and summative evaluations were performed in Europe (Switzerland and The Netherlands) on the device interface and on the APP interface. Studies on previous devices showed the importance of the pairing process. This was particularly evaluated in the summative evaluation, improved and gave satisfactory results. The pairing process is found hard by 0% of patients and health care workers.

Some risks were removed, and the other usability risks, even though reduced to minimum, are remaining. Their severity is low and they are acceptable. The benefit of the device is high since it enables comfortable, noninvasive, and continuous monitoring of vital signs. So, the benefit-risk ratio is clearly favorable.

In April and May 2022, Human Factor Validation Testing was performed in the USA, in the Metro Atlanta area and Norfolk, Nebraska, by HFE expert, Dr, Baran Erdik (MD/MPHA).

The testing showed no risk and no major error in using the device.

The surveys confirmed that the device is easy to use, to charge and comfortable to wear.

The surveys also confirmed the device is easy to pair with the APP, the APP is easy to use, to navigate and gives valuable information.

8 Discussion

Technological advancements, particularly over the last 20-30 years have enabled monitoring of both basic biological data such as heart rate, as well as more advanced data like SpO2 levels and heart rate variability. Though the optimal use of this data is debated, literature so far supports use of wearable health monitors particularly in the diagnosis of Atrial Fibrillation as well as whether a change in pulse rate is demonstrated in cases of syncope, and sports/exercise related metrics and tracking (Turakhia MP, Desai M, Hedlin H, et al. Rationale and design of a large-scale, app-based study to identify cardiac arrhythmias using a smartwatch: The Apple Heart Study. Am Heart J. 2019;207:66-75). Furthermore, recent data have also supported these versatile biomonitoring devices offering clues for early diagnosis of SARS-CoV-2 offering another avenue to help mitigate transmission and break off transmission chains (Natarajan A, Su HW, Heneghan C. Assessment of physiological signs associated with COVID-19 measured using wearable devices. npj Digit Med. 2020;3(1):156).

Moreover, exercise plays a crucial role in both prevention and treatment of Diabetes and Obesity. Two major chronic illnesses, that cause excessive

burdens on the society as a whole, both from a financial standpoint as well as years of productivity/life lost. Although it is easy to prescribe exercise, it is hard to actually have patient's keep up with it. Several studies including a major systematic review have demonstrated that pedometers are associated with significant decreases in BMI as well as blood pressure (Bravata DM, Smith-Spangler C, Sundaram V, et al. Using pedometers to increase physical activity and improve health: a systematic review. JAMA. 2007;298(19):2296-2304). Several studies have also shown that use of apps to track exercise were associated with an increase of daily steps close to 2000 per day (Chaddha A, Jackson EA, Richardson CR, Franklin BA. Technology to help promote physical activity. Am J Cardiol 2017; 119:149). It is thus not unreasonable that Corsano device could be integrated with clothing, as well as other technological devices to provide patients an easy solution that would assist in exercise as a both preventative measure as well as treatment.

Corsano Cardiowatch 287 offers a solution that is proprietary yet can be integrated easily with different devices and watches, offering flexibility that is hard to find from competitors in the current landscape. As can be seen from the usability study, the comfort of the device is extremely personal, and as such flexibility of integration of similar biomonitoring devices will nevertheless be of crucial importance. Furthermore, the best use case scenarios for the Corsano device as well as similar devices are yet to be elucidated, and the regulatory landscape will need to catch up to the pace of technological developments, as thanks to big data and AI, it will get easier to diagnose and detect different conditions but to warn the end user of such changes, while forgoing liability and ensuring regulatory compliance will be the crucial step. Finally, further studies that bridge the data with the clinical landscape are particularly needed for usability of some data such as HRV (as clinical usability of HRV is not well established), as well as data that is outside of 2SD, for example bradycardia in extremely fit athletes, as this indicates an extreme but perfectly healthy scenario.

Annex A – Summary of Surveys

1. Where you aware of wearing the sensor?				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Not aware	25.0%	33.3%	16.7%
2	Only sometimes aware	27.8%	33.3%	22.2%
3	Sometimes aware	27.2%	26.7%	27.8%
4	Usually aware	14.4%	6.7%	22.2%
5	Continuously	5.6%	0.0%	11.1%
2. What was the extend of irritation skin?				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Does not irritate	73.3%	80.0%	66.7%
2	Not really irritating	23.9%	20.0%	27.8%
3	Not irritating at first, but after a while	0.0%	0.0%	0.0%
4	Frequently irritating	2.8%	0.0%	5.6%
5	Always irritating	0.0%	0.0%	0.0%
3. What was the extend of interference sleep?				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Not interfering	73.3%	80.0%	66.7%
2	Not really interfering	15.6%	20.0%	11.1%
3	Sometimes interfering	11.1%	0.0%	22.2%
4	Frequently interfering	0.0%	0.0%	0.0%
5	Always interfering	0.0%	0.0%	0.0%
4. Did bracelet stay in place in case of sweating?				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Stays in place	76.7%	86.7%	66.7%
2	Hardly loosens	20.6%	13.3%	27.8%
3	Sometimes loosens	2.8%	0.0%	5.6%
4	Frequently loosens	0.0%	0.0%	0.0%
5	Always loosens	0.0%	0.0%	0.0%

5. Was bracelet easy to charge?				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Really easy	58.3%	66.7%	50.0%
2	Easy	30.0%	26.7%	33.3%
3	Took some time, but acceptable	11.7%	6.7%	16.7%
4	Hard to charge	0.0%	0.0%	0.0%
5	Hard and cumbersome	0.0%	0.0%	0.0%
6. Overall user-friendliness				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Very easy to use	27.8%	33.3%	22.2%
2	Easy to use	51.7%	53.3%	50.0%
3	Neither easy to use, nor hard to use	14.4%	6.7%	22.2%
4	Difficult to use	6.1%	6.7%	5.6%
5	Very difficult to use	0.0%	0.0%	0.0%
7. How do you evaluate the pairing process?				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Really easy	29.4%	20.0%	38.9%
2	Easy	50.0%	66.7%	33.3%
3	Took some time but acceptable	20.6%	13.3%	27.8%
4	Hard	0.0%	0.0%	0.0%
5	Hard and cumbersome	0.0%	0.0%	0.0%
8. How do you evaluate the registration process?				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Really easy	30.6%	33.3%	27.8%
2	Easy	45.0%	40.0%	50.0%
3	Took some time but acceptable	21.1%	20.0%	22.2%
4	Hard	3.3%	6.7%	0.0%
5	Hard and cumbersome	0.0%	0.0%	0.0%
9. How do you evaluate the navigation in the APP?				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Really easy	27.2%	26.7%	27.8%
2	Easy	32.8%	26.7%	38.9%
3	Took some time but acceptable	33.3%	33.3%	33.3%
4	Hard	6.7%	13.3%	0.0%
5	Hard and cumbersome	0.0%	0.0%	0.0%

10. How do you evaluate the information provided by the APP?				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Very useful	24.4%	26.7%	22.2%
2	Useful	36.1%	33.3%	38.9%
3	Sometimes useful	26.7%	20.0%	33.3%
4	Rarely useful	6.1%	6.7%	5.6%
5	Not useful	6.7%	13.3%	0.0%
11. Overall user-friendliness of the APP				
Answer	ID	Percentage total	Percentage lay persons	Percentage healthcare workers
1	Very easy to use	27.8%	33.3%	22.2%
2	Easy to use	38.3%	26.7%	50.0%
3	Neither easy to use, nor hard to use	27.2%	26.7%	27.8%
4	Difficult to use	6.7%	13.3%	0.0%
5	Very difficult to use	0.0%	0.0%	0.0%

Annex B – Critical Tasks and Scenarios

Lay persons

Tasks	Use error (User)	Reactions (User interface)	Root cause	Hazardous situation (HS)	Harm and severity of harm („SL“)	Critical task (hazard-related)	Risk control measures applied for the safe use
Unpack device	User throws away the package	None	User does know there is important information on package	None	No harm (SL 1)	☐ Critical; ☒ Not critical	Sign on package and IFU
Charge the device	User does not connect the cable to the right plug. The user may create a short	Device does not charge Cable gets hot	User has no basic knowledge of USB and rechargeable devices	Cable cannot get in short-circuit User may not be able to use the device	No harm (SL 1)	☐ Critical; ☒ Not critical	Explained in IFU
Download the APP	User cannot download the APP	None	Link to download the APP is not provided	Patient/Customer cannot use the APP	No harm (SL 1)	☐ Critical; ☒ Not critical	Indicate link in IFU Keywords in stores
Sign-in / Sign-up	User presses the wrong button	Goes to wrong page	User does not understand Sign-in/Sign-up	Patient/Customer will not be able to create an account	No harm (SL 1)	☐ Critical; ☒ Not critical	Indicate steps in IFU
Pairing	User skips steps or kills the APP	APP proposes the pairing when reopen	User has no time to finish process	Patient/Customer cannot use the device	No harm (SL 1)	☐ Critical; ☒ Not critical	Indicate in IFU Step by step in APP, explained with animated images
User starts a measurement	User does not press right button	Measurement does not start	User cannot see the button	Patient/Customer cannot get a measurement	No harm (SL 1)	☐ Critical; ☒ Not critical	Clear interface
User wears the device	User does not wear the device well	Bad quality signal are recorded	User has not read the IFU and does not know the strap must be tight	Patient/Customer cannot get a good measurement	No harm (SL 1)	☐ Critical; ☒ Not critical	Explained in IFU APP receives a quality index for

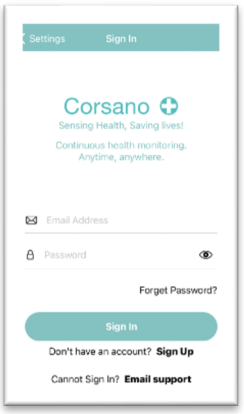
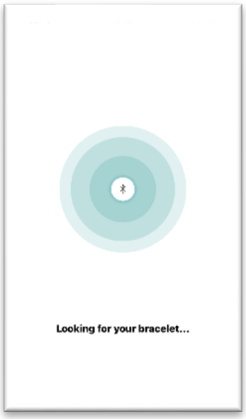
Tasks	Use error (User)	Reactions (User interface)	Root cause	Hazardous situation (HS)	Harm and severity of harm („SL“)	Critical task (hazard-related)	Risk control measures applied for the safe use
							signal measured
User stops a measurement	User does not press right button	Measurement does not stop	User cannot see the button	Patient/Customer may not get a measurement	No harm (SL 1)	☐ Critical; ☒ Not critical	Clear interface to avoid mistakes

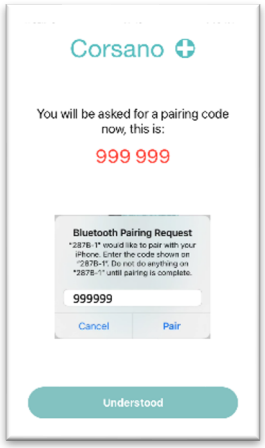
Healthcare workers

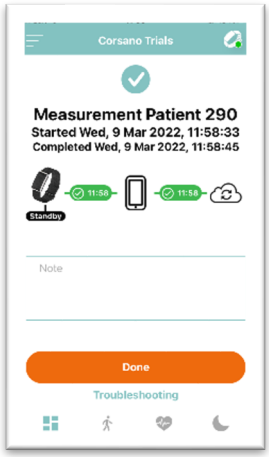
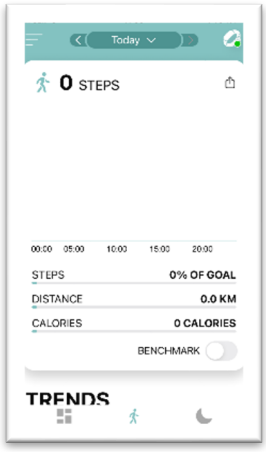
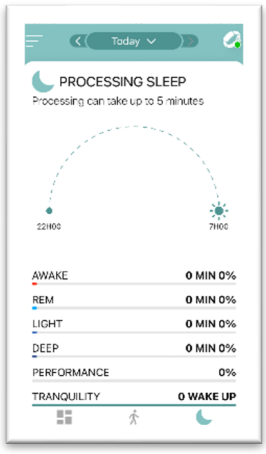
Tasks	Use error (User)	Reactions (User interface)	Root cause	Hazardous situation (HS)	Harm and severity of harm („SL“)	Critical task (hazard-related)	Risk control measures applied for the safe use
Clean the device	User uses aggressive cleaning agent	None	User uses wrong agent	None	No harm (SL 1)	☐ Critical; ☒ Not critical	Sign on package and IFU
Charge the device	User does not connect the cable to the right plug. The user may create a short	Device does not charge Cable gets hot	User has no basic knowledge of USB and rechargeable devices	Cable cannot get in short-circuit User may not be able to use the device	No harm (SL 1)	☐ Critical; ☒ Not critical	Explained in IFU
Put device in the package	User does not put the charging cable	There is an empty position in the package	Human error	None	No harm (SL 1)	☐ Critical; ☒ Not critical	Dedicated position in package for cable
Give device to patient	None	None	None	None	None	None	None
Let patient download the APP	Patient cannot download the APP	None	Link to download the APP is not provided	Patient/Customer cannot use the APP	No harm (SL 1)	☐ Critical; ☒ Not critical	Indicate link in IFU Keywords in stores
Patient Sign-in / Sign-up	Patient presses the wrong button	Goes to wrong page	User does not understand Sign-in/Sign-up	Patient/Customer will not be able to create an account	No harm (SL 1)	☐ Critical; ☒ Not critical	Indicate steps in IFU

Tasks	Use error (User)	Reactions (User interface)	Root cause	Hazardous situation (HS)	Harm and severity of harm („SL“)	Critical task (hazard-related)	Risk control measures applied for the safe use
Patient pairs the device	Patient skips steps or kills the APP	APP proposes the pairing when reopen	User has no time to finish process	Patient/Customer cannot use the device	No harm (SL 1)	☐ Critical; ☒ Not critical	Indicate in IFU Step by step in APP, explained with animated images
Patient starts a measurement	Patient does not press right button	Measurement does not start	User cannot see the button	Patient/Customer cannot get a measurement	No harm (SL 1)	☐ Critical; ☒ Not critical	Clear interface
Patient wears the device	Patient does not wear the device well	Bad quality signal are recorded	User has not read the IFU and does not know the strap must be tight	Patient/Customer cannot get a good measurement	No harm (SL 1)	☐ Critical; ☒ Not critical	Explained in IFU APP receives a quality index for signal measured
Patient stops a measurement	Patient does not press right button	Measurement does not stop	User cannot see the button	Patient/Customer may not get a measurement	No harm (SL 1)	☐ Critical; ☒ Not critical	Clear interface to avoid mistakes

Annex C – APP sequences

Screen page	Comment
	Starting page
	Signing Page
	Pairing Sequence

	Pairing – found device
	BLE Security Code Page
	Start measurement

	Stop measurement
	Activity display Page
	Sleep display Page