# Conceptual redevelopment of an existing ECG Patch

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***Abstract*—The Electrocardiogram (ECG) is one of the most important biomedical signals for monitoring the cardiac activity and the health status of a human. In recent years an increasing number of wearable ECG devices were developed to enable continuous and ambulatory monitoring, which should lead to early detection of cardiological diseases, reduction of heart failures and health care costs. This paper aims to redevelop an adhesive ECG patch compatible with the Movesense MD sensor to offer a cheaper alternative on the market. It involves selecting new materials and building prototypes to determine the required amount of silver and to test their electrical functionality and compliance with ANSI/AAMI EC12:2000/(R)2020 standard. The measurement performance of the prototype is validated by statistical evaluations of ECG measurements recorded on the prototype and the existing ECG patch during different movement patterns. Material changes were primarily made to the backing material, for which TPU is used, to the contact elements, which are made of silver-printed carbon foil, and to the flat snaps, whose design was modified to allow a mechanical attachment. The results show that the redeveloped patch requires a silver volume of 0.165 $mm^3$ per electrode, the patch provides good electrical performance and meets all the requirements of ANSI/AAMI EC12:2000/(R)2020 for an application time of 72 h. A positive linear correlation exists between the measurement performance of the patches with a Pearson's r of 0.98. Whereby a slightly higher correlation in rest positions than in active movement was detected. With the developed concept, the required amount of silver is reduced by 91% and the selling price by 65%. Consequently, a concept for a more cost-effective alternative to ambulatory and wireless measurement of ECG signals with the Movesense MD sensor is developed. Following this study, the final product and production design should be specified and sample production should be run to conduct further tests with machine-made prototypes.**

***Index Terms*—Electrocardiography (ECG), Wearable medical device, single-lead.**

## I. Introduction

THE demand for wearable medical devices that record and process physiological signals have increasingly grown in recent years [1]. Factors influencing this development include a rising trend towards personalised and continuous healthcare monitoring, as well as technological advances and the pressure to reduce healthcare costs [2]. One of the most important biosignals for monitoring the health status of an individual is the electrocardiogram (ECG) [3], [4]. It records the electrical activity of the heart and therefore offers the possibility of diagnosing cardiovascular diseases. Continuous monitoring in particular can promote the early detection of these diseases and thus significantly reduce the number of heart failures. [5], [6]

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Today, there are several methods for recording ECG signals, which include, for example, the standard 12-lead ECG or Holter monitoring for long-term measurements. Since conventional 12-lead ECGs miss cardiac arrhythmias that occur outside of their recording period and Holter monitoring devices are often very uncomfortable for long-term measurements, the trend in ECG monitoring moves towards portable and wireless systems that can compensate for these limitations and also allow measurements in a non-clinical setting. [4], [7], [8]

The ongoing research focuses on the development of adhesive ECG sensor patches for continuous, wireless measurement of ECG signals in real-time [4]. Thereby, the focus lies on the development of cost-efficient and easily available solutions that are intended to promote both user-friendliness and comfort [8]. ECG patches are applied to the chest to provide continuous long-term monitoring of heart rhythm via two electrodes which are connected to a sensor unit that processes the ECG signals and allows them to be retrieved in real-time via a mobile phone or computer. In recent years, several new devices were developed that provide advances such as miniaturisation, efficient energy use and longer monitoring, which can improve diagnostic accuracy [9]. One device that is frequently mentioned in the literature is the Zio Patch (iRhythm Technologies, San Francisco, CA, USA), for example, which is already FDA approved [10]. It is a single-channel ECG monitoring device that attaches to the patient's left anterior chest and can continuously monitor the ECG signal for up to 14 days [11]. The results of the studies by Barrett et al. and Yenikomshian et al. have shown that the Zio Patch has a higher diagnostic yield in detecting cardiac arrhythmias with long-term continuous monitoring compared to 24-hour Holter monitoring [9], [12]. Another example is the ATP-100 patch (ATsens Co., Gyeonggi-do, Republic of Korea), which according to a study by Choi et al. provides comparable results to conventional ECG systems. In addition to these two examples, other research results indicate that the use of such ECG patches will become more important in the future, as they both enable continuous ambulatory monitoring of cardiac activity and provide good results compared to conventional ECG systems. Moreover, these systems have a higher detection rate of pathologies that would otherwise go unnoticed during normal routine examinations [13].

The company Movesense has developed a further sensor, the so-called Movesense Medical Device (MD) Sensor, and a compatible single-lead ECG patch. A key difference between this sensor and the previously described products is that it is not permanently attached to the patch but connects to a compatible one or chest belt via flat snaps. It is a wireless, programmable sensor which allows real-time information about a patient's heart activity to be accessed via an app. The Movesense MD

sensor is registered as a class IIa medical device, in conformity with the EU medical device directive 93/42/EEC for single-channel ECG, HR, and RR interval detection. [14]

The compatible ECG patch consists of five different components. The carrier material is a red non-woven fabric to which a PET foil is glued. Two silver electrodes with an volume of $3.8\,mm^3$ silver are printed onto this foil for recording the heart signals. In the holes in the carrier material and the plastic strip two flat snaps are placed with the use of conductive adhesive. To prevent a short circuit between the two electrodes, an insulator is needed. For this purpose Polyethene (PE) foam is used, which is glued on the back of the flat snaps. The two electrodes are fully covered with a solid gel layer for measuring the biomedical signals of the heart. To protect the contact surface of the patch, a transparent cover sheet is placed on the bottom of the patch. In a study by Rogers et al, the Movesense MD sensor was attached to a chest belt and its measurement results were validated against a conventional 12-lead ECG. Results showed, that both systems provide comparable data. [15]

Studies to validate the compatible ECG patch on the market could not be found. Since the offered patch is very expensive, it is to be redeveloped within the scope of this study so that it can be offered more cheaply on the market. By developing an alternative, cheaper ECG patch, a contribution is made to enabling the usage of the Movesense MD sensor more widely for the continuous and ambulatory measurement of cardiac activity and thus promoting the early detection of cardiovascular disease.

## II. Methods

This paper focuses on the following key points. Firstly, a selection of materials is made. Secondly, tests will be carried out to validate the electrical performance of the materials and to compare the measurement performance of the prototype with the existing patch.

### A. Material and Design

As a backing material a thin polymer material, which is characterised by high ductility, good hydrolysis resistance, excellent biocompatibility and high abrasion resistance, is selected [16]. Due to these material properties, it is applied for many medical applications nowadays. Its high flexibility allows it to adapt well to different body shapes, which is an important requirement for the ECG patch. The gel provides the electrically conductive connection between the skin and the electrode. For the Patch, a solid hydrogel is chosen. Hydrogels are transparent, biocompatible and ionically conductive materials. They reduce skin resistance and thus ensure good signal quality. In addition, compared to liquid gel, it can be applied to the skin for a longer period before skin irritation occurs. [17], [18] For attaching the Movesense sensor to the patch, the stainless-steel flat snaps of the existing patch are chosen as it is thinner than most conventional snap buttons and therefore more comfortable. To avoid the use of conductive adhesive, an alternative mechanical attachment method is developed. This involves changing the design of the existing flat snap. A silver printed conductive foil is chosen as the contact element. The silver surface picks up the electrical signal and the foil provides the conductive connection between the silver electrode and the flat snap. An insulator is needed for preventing the occurrence of a short circuit that is glued over the contact points of the flat snaps with the carbon material. Therefore conventional PE foam is chosen. It is coated with an adhesive surface so that it cleaves well to the skin and holds the electrode in place in addition to the adherence of the gel. A conventional grid-printed PET film is used as the cover sheet.

The design of the patch remains similar to the existing one and can be seen in Figure 1. The adhesive surface has a similar size, as this has proven to be suitable for long-term use. Only the shape of the patch is slightly changed by rounding the edges so that the risk of it detaching easily is kept low. The distance between the electrodes is not changed and remains at 100 mm, as reducing the distance between the electrodes could lead to a deterioration of the signal quality [17]. The centre distance between the Flat Snaps is 27 mm for the attachment of the Movesense MD Sensor.

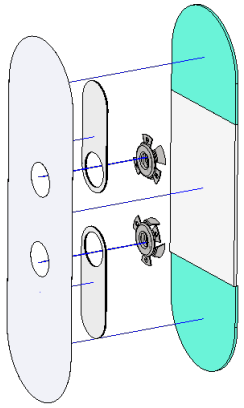

Fig. 1. Exploded view of the redeveloped ECG patch.

### B. Methods for evaluating the functionality of the concept

To test the selected materials, the following two test procedures are chosen. (1) The electrical functionality of the materials and the required amount of silver on the contact element are determined based on the ANSI/AAMI EC12:2000/(R)2020 for disposable ECG electrodes. This test is chosen as this standard must be fulfilled anyway for clinical usage approval. (2) The functionality of a prototype is validated in comparison to the existing patch by performing ECG measurements with both patches and the Movesense MD sensor.

*1) Electrical Performance Test:* Measurement procedures are performed using the SEAM ECG electrode test platform. Prototypes with the selected silver-coated conductive material and the hydrogel are built to determine the electrical performance and to evaluate the ANSI/AAMI EC12:2000/(R)2020. For the measurement, the gel surfaces of the electrodes are attached and connected to the SEAM ECG electrode test platform via cables. Each channel of this device contains

circuits to perform the following reference tests to determine compliance with the requirements defined in EC12. [19]

*Bias current tolerance:* During the bias current tolerance measurement, 200 nA DC is applied to the electrodes for a period of 72 h. Thereby, the offset change in the silver area is measured which must not exceed a value of 100 mV. [20]

To establish the required silver surface area for the functionality of the electrode, this measurement is performed with silver surfaces of different sizes. Of all the measurements provided in the ANSI/AAMI standard EC12, the electrodes are stressed the most in this one, so the electrodes are likely to pass all other tests in the standard if the bias tolerance is maintained. Therefore, this measurement is well suited to determine the amount of silver required for the fulfilment of the electrical performance of the electrode. The different silver and corresponding gel areas tested are listed in Table 1.

TABLE I
TESTED SILVER AND GEL SURFACES ON BIAS CURRENT TOLERANCE MEASUREMENT

| Silver surface in $mm^2$ | Gel surface in mm |
|---|---|
| 99.2 | 25 x 45 |
| 110 | 35 x 45 |
| 120 | 35 x 45 |
| 130 | 35 x 45 |
| 140 | 35 x 45 |
| 150 | 35 x 45 |
| 200 | 40 x 45 |
| 250 | 45 x 45 |
| 300 | 50 x 45 |

*Internal Noise:* As part of the bias measurement, the internal noise is measured by connecting the electrode to a test circuit. After a stabilisation time of 1 min, the pair of electrodes must not generate a voltage exceeding $150\,\mu$Vpp in the passband of 0.15 to 100 Hz for 5 min.

After the required silver area is determined, the following measurements of the EC12 standard are performed. For each test, a required amount of 12 electrodes is used. [20]

*DC offset Voltage:* The DC offset voltage is the voltage of a gel-to-gel electrode pair due to the difference in their electrode half-cell potentials. It is measured by connecting the electrode to a circuit with a DC voltmeter. The meter applies a current of less than 10 nA. Subsequently, the offset voltage must not exceed a value of 100 mV after a stabilisation time of 60 s and before 90 s have elapsed. [20]

*AC impedance:* To measure the AC impedance of an electrode, a sinusoidal current with known amplitude and a value of $10\,\mu$A is applied to the electrode. The amplitude of the resulting voltage is then determined. To meet the requirements of the EC12 standard, the resulting voltage for a single pair of electrodes must not exceed $2\,k\Omega$. [20]

*Defibrillation overload recovery:* In this measurement, the electrodes are exposed to four capacitor discharges. Thereby a $10\,\mu$F capacitor is charged to 200 V and discharged in series across the pair of electrodes with $100\,\Omega$. During a 30-second interval after each measurement, the rate of change of the residual polarisation potential must not exceed $\pm 1$ mV/s. After the electrode pair is checked for compliance with this requirement, the AC impedance is measured again, which must not exceed $2\,k\Omega$. [20]

*2) Measurement Performance:* To evaluate the functionality and measurement performance of the developed concept the compliance of the ECG signals of a handmade prototype is determined in comparison to the existing patch. The prototype is therefore defined as the test electrode, the existing patch represents the reference electrode.

*Experimental setup and data aquirisation*

As shown in Figure 2, the two patches are applied to the skin surface of a test person, using the V1 and V4 positions of the six-chest wall lead as attachment points. The corresponding skin areas of the test person were shaved before the measurement. A Movesense sensor is attached to each of the flat snaps of the patches and connected to the Movesense Showcase App (version 1.1.0) on two different mobile phones with IOS operating system. The test person is male, 26 years old and has no pre-existing medical conditions. The measurements are taken simultaneously to allow a statement about the consistency of the values. Since the patch is designed for daily use, the measurement focuses on different movement patterns that simulate people's daily activities. Three scenarios are defined: resting position, movement of the upper body and movement of the whole body. 15 measurements are carried out which are illustrated in Table 2. Each of them has a duration of 60 s with a frequency of 125 Hz. Thus, 7500 paired data points are generated per measurement series.

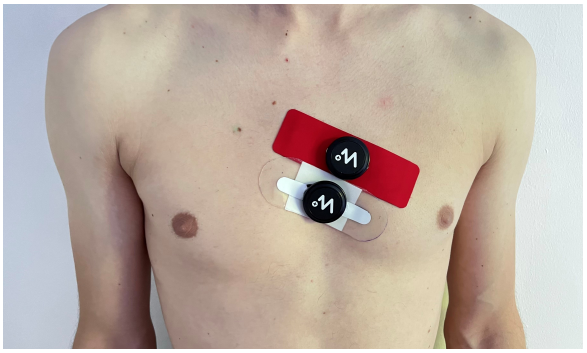

Fig. 2. Placement of electrodes for measurement performance test. Reference electrode on the top. Prototype electrode on the bottom.

*Data processing*

The measured ECG signal curves are not suitable for evaluating and assessing the functionality of the prototype in comparison to the reference patch, as the heart signals can show significant differences in their amplitude due to the different electrode placements [21]. So for a meaningful comparison, the RR intervals of the measured ECG signals are determined and the resulting heart rates (HR) for each patch are calculated. This is done by exporting the ECG .csv files from the Movesense Showcase app and using the Python toolbox NeuroKit2 [22].

*Statistics*

To evaluate the compliance of the HRs and conclude on the measurement performance of the prototype in comparison to the reference electrode, statistical evaluations are carried

TABLE II
TEST SCENARIOS OF THE MEASUREMENT PERFORMANCE TEST

| **Scenario 1 - Resting position** | |
|---|---|
| *Measurement number* | *Position* |
| 1 | Seated position |
| 2 | Seated position |
| 3 | Standing position |
| 4 | Standing position |
| **Scenario 2 - Movement of the upper body** | |
| *Measurement number* | *Position* |
| 5 | Sitting and horizontal movement of arms up and down |
| 6 | Sitting and vertical movement of arms up and down |
| 7 | Standing and arms extended to the side |
| 8 | Standing and horizontal movement of arms up and down |
| 9 | Standing and vertical movement of arms up and down |
| 10 | Standing and rotation of the upper body |
| **Scenario 3 - Movement of the whole body** | |
| *Measurement number* | *Position* |
| 11 | Slow walking |
| 12 | Moderate walking |
| 13 | Fast walking |
| 14 | Alternate: walking for 10 s and standing still for 10 s |
| 15 | Alternate: sitting for 10 s and standing for 10 s |

out. To determine the deviations of the paired HRs, the mean percentage deviation is calculated for each measurement series. The standard deviation is then calculated to analyse the the dispersion of the percentage deviation of the paired HRs per measurement series. To investigate the compliance of the HR of the prototype electrode with the HR of the reference electrode, a correlation analysis is performed. Using this analysis, a conclusion can be drawn about the direction and the strength of the correlation between the two values. The size of Pearson's r correlations is evaluated as follows: $0.00 \leq \mathrm{r} < 0.10$ no correlation, $0.10 \leq \mathrm{r} < 0.30$ low correlation, $0.30 \leq \mathrm{r} < 0.50$ medium correlation, $0.50 \leq \mathrm{r} < 0.70$ high correlation, $0.70 \leq \mathrm{r} < 1.00$ very high correlation. To perform this analysis, the data set is reduced to one HR value per second for each of the 15 series. The Pearson's r is then calculated with the software Minitab, Inc 20.

## III. RESULTS

### A. Materials and design of new ECG patch

The main changes were made to the carrier material and the contact elements. A flexible thin polymer material is chosen as the carrier material instead of woven polyester. For the contact element, two silver-printed conductive foils are used instead of the PET film with fully printed silver electrodes. The new contact element has a silver volume of 0.33 $mm^3$ in total. Furthermore, a modification is made to the design of the flat snaps so that it is possible to attach them to the patch using a mechanical attachment method. In this way, the use of conductive adhesive can be avoided. Regarding the design, the basic structure has remained the same, only the edges of the patch are more rounded. Table 3 compares the original and new materials of the individual components of the ECG patch.

TABLE III
MATERIAL COMPONENTS OF ORIGINAL AND NEW PATCH.

| **Component** | **Material original patch** | **Material new patch** |
|---|---|---|
| Coversheet | PET-Foil | Grid-printed PET-Foil |
| Backing material | Woven polyester | TPU |
| Foam | PE-Foam | PE-Foam |
| Contact Element | Silver-printed PET foil | Silver-coated carbon foil |
| Flat snap | Stainless steel | Stainless steel |
| Gel | Hydrogel | Hydrogel |

### B. Electrical performance

The bias measurement with the different silver areas has shown that a silver area larger than 110 $mm^2$ and a silver thickness of 1,5 $\mu$m provides sufficient electrical performance to meet the ANSI/AAMI EC12:2000/(R)2020 for disposable ECG electrodes for an application time of 72 h. Since silver is an expensive raw material, from an economic point of view it is reasonable to keep the amount of silver as small as possible. So, the smallest determined silver area of 110 $mm^2$ is used for the further development process. The results of the noise measurement showed that the internal noise of the electrode pairs does not exceed the limit of 150 $\mu$Vpp after 360 s on all silver surfaces. The DC offset voltage measurement resulted that all 12 electrodes meeting the requirements and none of the electrodes exceeds the limit value of 100 mV after 20 s, 40 s and 61 s. After 20 s the AC impedance lies between 492.2 $\Omega$ and 650.3 $\Omega$. Therefore none of the twelve prototypes reaches or exceeds the limit value of 2 $k\Omega$ and passed the test. During the defibrillation overload recovery test, neither in the four iterations nor during the AC impedance measurement was the limit reached or exceeded by any of the electrodes. In summary, electrodes with a silver-printed carbon foil with a silver area of 110 $mm^2$ and a layer thickness of 1.5 $\mu$m meet all the requirements of the ANSI/AAMI EC12:2000/(R)2020 for disposable ECG electrodes in combination with the selected hydrogel. So these electrodes are successful for measuring biopotentials on the body surface.

### C. Measurement performance

The results of the measurement performance are divides into (1) descriptive statistics and (2) correlation analysis.

*1) Descriptive statistics:* Within the framework of descriptive statistics, the mean percentage deviation of the HR of the prototype compared to that of the reference electrode is determined. Results have shown that the mean percentage deviation of measurement series 15 with a value of -0.897 % deviates significantly from the other measurement series which show a mean percentage deviation in the range of -0.009 % to 0.069 %. This indicates a small deviation between the measured HRs of the two electrodes. The results of the standard derivation of measurement series 10, 11 and 15 also show high values compared to the others. Measurement 10 has a standard deviation of 3.34 %, measurement 11 of 1.53 % and measurement 15 of 6.11 %. For all other series, the standard deviation is less than 1 %, which indicates a low dispersion of the percentage deviation between the HRs.

*2) Correlation analysis:* A positive linear correlation between the two HRs is shown in each of the three scenarios. Their diagrams are illustrated in Figures 3, 4 and 5. In other words, an increase in the HR values of the prototype electrode is accompanied by an increase in the HR values of the reference electrode. A few outliers are detected, which all occur in a HR range above 90 bpm. The results of Pearson's r show a value of 0.999 for the first scenario, a value of 0.994 for the second scenario and a value of 0.943 in the third scenario. Therefore all correlation coefficients show a value of $0.70 \leq \mathrm{r} < 1.00$. Consequently, according to Kuckarts et al., it can be concluded that a very strong correlation exists between the measured values of the two electrodes in all three scenarios. Since the data sets of the measurements were reduced to one HR per second, the correlation coefficient was additionally calculated across all measurement points for more comprehensive conclusions. This result shows a value of 0.980, which confirms the very strong correlation between the HRs of the prototype with those of the reference electrode. [23]

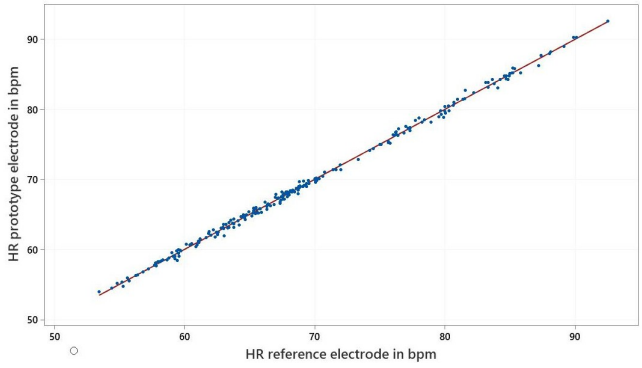


Fig. 3. Scatterplot of scenario 1 - Resting position: HR of prototype electrode on $y$ axis, HR of reference electrode on $x$ Axis. $r = 0.999$.

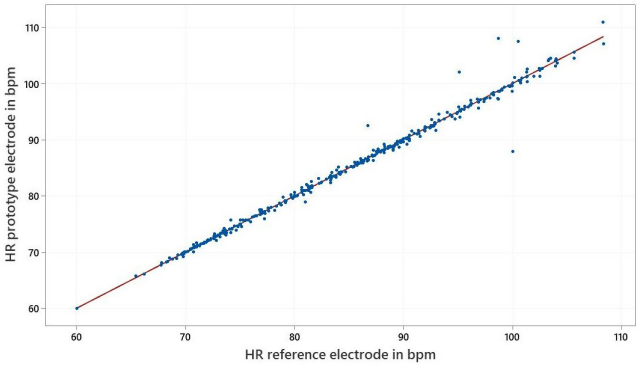


Fig. 4. Scatterplot of scenario 2 - Movement of upper body: HR of prototype electrode on $y$ axis, HR of reference electrode on $x$ Axis. $r = 0.994$.

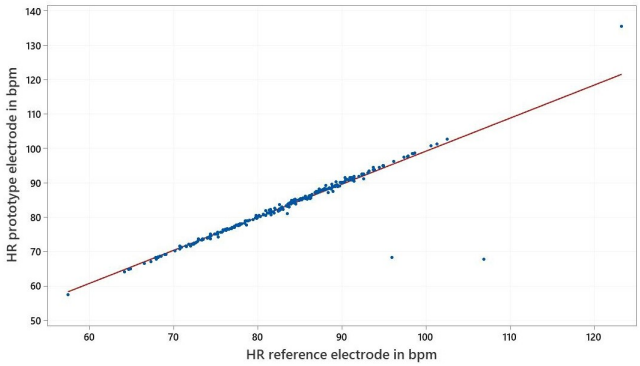


Fig. 5. Scatterplot of scenario 3 - Movement of whole body: HR of prototype electrode on $y$ axis, HR of reference electrode on $x$ Axis. $r = 0.943$.

## IV. Discussion

This paper aims to redevelop an existing ECG patch that is compatible with the Movesense MD sensor so that a more cost-effective alternative can be offered on the market. The improvements regarding the material and the design are discussed in the following. Then the results of the electrical performance are evaluated, and the results of the measurement performance are examined regarding their outliers and reasons for possible artefacts. Finally, the Production and cost optimisation, as well as the limitations, are mentioned.

### A. Improvements in terms of material

The comparison of the materials used for the original and the new patch has shown that changes primarily relate to the carrier material, the contact element, and the flat snap. By choosing the flexible and thin polymer material as a backing material, good ductility and hydrolysis properties are achieved with the new ECG patch. It has a film thickness of 50 µm and is, therefore, thinner and more flexible than the woven polyester of the existing patch. The availability of this material in different colours makes it easy to offer the product in different designs. The silver-printed conductive foil reduces the required amount of silver material by 91.35%. This reduction is achieved by replacing some of the silver with a conductive foil. The results of the electrical performance measurement

show that this ensures sufficient electrical conductivity for ECG signals. The design modification of the flat snaps enables a mechanical attachment to the patch, which eliminates the need for conductive adhesive. This offers a considerable advantage, as conductive adhesives are on the one hand very expensive and on the other hand difficult to process. During the application, hydrogel and foam are in direct contact with the skin. These materials are also used in other electrodes and as no serious discomfort is recommended during the application, they are suitable for the ECG Patch. Hydrogel also offers the advantage of being self-adhesive and therefore no additional adhesives are required. As silver and conductive adhesives are expensive raw materials with the reduced amount of silver and the mechanical attachment of the flat snap costs can be saved.

### *B. Evaluation of electrical performance*

The electrical performance test based on ANSI/AAMI EC12:2000/ (R)2020 for disposable ECG electrodes verified all measured values to be within the specified limits, which indicates good electrical functionality. It is to be considered that in the experimental set-ups the measuring device was directly connected to the conductive material. Whereas in the patch, the connection to the carbon material is made via the flat snaps. Therefore, it is expected that the impedance of the finished electrode will be slightly higher. Since all values are well below the limits, it can be assumed that the finished, machine-made electrode also meets all requirements. The bias measurement performed for 72 h has shown that electrodes with a silver area of 110 $mm^2$ and a silver thickness of 1,5 $\mu$m fulfil all electrical requirements for this application time. Although the selected hydrogel material is approved for an application time of up to 14 days according to the manufacturer, the experience shows that skin irritation occurs in most patients after 72 h. To be able to assess this more precisely for the specific case of the patch, wear tests or clinical trials with a machine-made prototype would have to be carried out.

### *C. Evaluation of measurement performance*

The results of the measurement performance test showed that the values of the developed prototype correlate with those of the patch currently offered on the market. However, some small deviations were found in the statistical evaluations.

An important factor influencing the result of the measurement performance is the occurrence of artefacts. Artefacts are false measurement data that do not originate from the heart but are caused by interference during signal recording or transmission [24]. When measuring ECG signals, artefacts can be caused by muscle contractions or body movements, which affect the contact between the skin and the electrode and thus disturb the signal transmission. Akintola et al. have shown that the risk of artefacts increases with physical activity due to higher body movement. Another impact could be the preparation of the skin. Before long-term ECG measurements, the skin is usually prepared with alcohol or potassium chloride to remove the non-conductive skin layer that reduces skin impedance, thus improving signal quality. In this measurement, the skin was only shaved. [6]

As the HR from the RR intervals of the respective ECG signal curves was evaluated using Phyton and the Neurokit2 toolbox to determine the measurement performance, miscalculations due to incorrectly identified RR intervals can also lead to incorrect results.

For the descriptive results, the mean percentage deviation in measurement series 15 is increased compared to the others. This can be attributed to the occurrence of an artefact at the reference electrode. At this point, the HR of the reference electrode increases to a value of above 130 bpm for a few seconds, while the HR of the prototype remains at about 78 bpm. Since the mean value reacts very sensitive to extreme values, it can be assumed that the comparatively high mean percentage deviation is due to this outlier of the reference electrode [25]. When calculating the standard deviation, differences are observed in measurement series 10, 11 and 15. The reason for the outliers in measurement series 10 is likely to be found in four artefacts at the prototype electrode which can be attributed to the rotational movement of the upper body. This rotating movement causes alternating tensions and motions of the skin in the chest area, which can lead to reduced skin-electrode contact. Since more artefacts occurred on the prototype than on the reference electrode, it can also be assumed that the placement of the prototype electrode is not optimally suited. Further investigations of this movement pattern and different attachment points of the prototype would have to be carried out to provide a general conclusion on this. In series 11 an outlier occurred at the beginning of the recording on both patches, causing the HR to rise to about 140 bpm for a few seconds. The high value of the standard deviation can be attributed to this artefact. It is seen that it appears first at the prototype electrode and with a slight delay at the reference electrode. This delay causes the deviation of the HR of the two electrodes to increase sharply for a short moment which is reflected in the value of the standard deviation. Since the standard deviation determines the scatter around the calculated mean value, it is only representative if the mean value nearly equals the desired position parameter [25]. For this analysis, the ideal position parameter would be a mean value of 0%, which implies that no deviation exists between the HR of the prototype and the reference electrode. Since the calculation of the mean percentage deviation has shown that measurement series 15 has a high deviation from the value of 0%, the calculation of the standard deviation is not suitable for this series, so this result is not further considered. The correlation analysis has proven a strong linear relationship between the HR values of the two electrodes with a value of 0.98 over all measurement points. In scenarios 2 and 3, some outliers were observed in a heart rate range above 90 bpm. A further question that arises in the context of the deviations is whether the HF of the prototype tends to have a higher or lower value compared to the reference electrode. For this purpose, the signs of the percentage deviation are considered. This shows that in 50.01% of the deviations the HF of the prototype is higher than the HF of the reference electrode measured in parallel. For 49.99%, the HR of the prototype is lower. This indicates

that there is no trend in the direction of the deviation. In summary, this experiment showed that as the physical activity of the test person increases, the outlier load also rises and thus the correlation of the measurement performance of the two patches slightly decreases. This corresponds to the statement by Akintola et al. Furthermore, in none of the three scenarios significant outliers were identified in the heart range below 90 bpm, so it can be assumed that there is a higher correlation between the data at lower heart rates. Furthermore, it can be concluded that the measurement performance and functionality of the developed patch are consistent with the existing patch for normal daily activities.

### *D. Production and costs*

For reasons of confidentiality, no further information about the costing and production is provided. However, it should be mentioned that it is possible to produce the developed patch on existing machines which results in cost savings. A price reduction of 65% can be achieved compared to the existing patch. However, the economic feasibility of the concept depends on the number of patches to be produced. If the number of units produced is small, the retooling of the machines and the associated downtimes could have a higher cost impact on the patch than if it is produced in large quantities [26].

### *E. Limitation*

Due to the handmade prototypes, inaccuracies cannot be excluded. This applies to the tested silver surfaces as well as to the prototype used for the measurement performance test. Another limitation in determining the measurement performance relates to the fact that a handmade prototype was tested on a healthy test person. For a more comprehensive statement on this, further studies with several test persons and different population groups are necessary, e.g. with elderly people or patients with known heart diseases. However, this would have exceeded the scope of this study and the results would not have been as meaningful if all measurements had been carried out with a handmade prototype. Thus, this study showed that the developed concept, the chosen materials, and the chosen design are functional. For further conclusions, the production would have to be set up and studies with machine-made prototypes would have to be conducted. In addition, it is only possible to make a limited statement about the quality of the measured ECG signal. It is only possible to state the quality in comparison to the existing patch. As this patch is available and approved on the market and the measurement of the electrical performance also provided good values, it can be assumed that the quality of the signal of the ECG patch is sufficent. However, it would be useful to carry out measurements with the redeveloped patch in comparison to a conventional ECG device to be able to evaluate the quality more accurately.

## V. Conclusion

In conclusion, with this study, a concept for a new ECG patch for the measurement of ECG signals with the Movesense sensor is developed, which fulfils the ANSI/AAMI EC12:2000/(R)2020 for ECG disposable electrodes, has a comparable measurement performance to the existing patch and can be offered at a lower price on the market. All defined requirements are conditionally or completely fulfilled with this concept. In addition, the research question could be answered. Following this thesis, according to a product development concept defined by Günter et al., the next step is to specify the final product design. This means defining the exact product specifications, including material requirements, permissible tolerances, etc., and working out process plans for production [27]. Subsequently, it is recommended to run sample productions to perform further measurements with machine-produced prototypes and larger study populations over the entire application period.

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