TELECARE-CENTER ULM GMBH

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THE ASSESSMENT COVERED

#170608-0000643 1980 Peter Schmidt Gender male Report number Year of birth Name Taken on 2017/05/30 4:23 pm Assessment on 2017/06/08 4:21 pm at at



TELECARE CENTER SERVICES

A pulse curve was recorded using the "Preventicus Heartbeats" smartphone app and tested to reveal cardiac arrhythmias, such as atrial fibrillation. Afterwards, the Telecare Center performed a medical-technological analysis of the recordings taken by the app. Please observe the additional notes overleaf.



DETAILS OF ASSESSMENT

1. User comment:

Palpitations

2. Quality of the recording:

Excellent: No or less than 5% disruptions were identified in the signal.

3. Automatic heart rate assessment findings

Your heart rate is normal and averages 79 beats/minute (bpm).

4. Automatic rhythm assessment findings:

Your cardiac rhythm is regular.

5. Assessment by Telecare:

At minute 1 between 0 - 11 seconds, abnormalities were identified when compared to our database that are comparable with: Bigeminy.

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^{*} The result presented is statistical in nature and has been generated by comparing the measurement with a database.



CONCLUSION

Abnormalities* were identified. You should discuss them with your physician.

Your pulse curve shows a bigeminy (regular occurrence of ectopic beats). A bigeminy can be triggered by certain situations in life (e.g. stress, caffeine consumption, pregnancy). If it becomes manifest on a regular basis, it may be indicative of a cardiac rhythm disorder or heart disease. It is recommended that you clarify this finding with your attending physician to establish whether a further examination or quantification over a longer period by Holter-ECG recording is needed.



NOTES FOR ATTENDING PHYSICIANS

Abnormalities* were identified. Further details can be found in section "Details of assessment".

DESCRIPTION OF THE STRUCTURED SCREENING PROGRAM FOR SPECIFIC DETECTION OF SPORADIC CARDIAC ARRHYTHMIAS

This program was designed with the technical objective of employing the user's own smartphone or smartwatch to detect sporadic cardiac arrhythmias occurring in outpatient settings under non-acute circumstances. The "Preventicus Heartbeats" applied for this purpose is a medical device for cardiac arrhythmia screening in conformity with the Essential Requirements of Directive 93/42/EEC or its respective national transpositions. Clinical studies have demonstrated that this app's underlying algorithm is capable of distinguishing cardiac arrhythmias (like atrial fibrillation) from regular heart rhythms with an accuracy of approximately 95%.

As part of this assessment, the medical-technical assistant staff of the Telecare-Center UIm 6mbH analyzed the recordings generated by the "Preventicus Heartbeats" app. As far as possible, measurement and data collection errors were identified and the recorded data compared against a reference database. The aim was to determine the extent to which the analysis matched the statistical results. This assessment does not render—nor is it intended as a substitute for—any medical services.

LEGAL BASIS; TREATMENT AND EXCEPTION CLAUSE FOR DOCTORS

The medical-technical and statistical assessment and possible correction of the data by the Telecare-Center Ulm GmbH is conducted by its medical-technical assistant staff who are specifically trained in the rhythmological assessment of pulse-related data. However, this analysis is not a formal medical service, and as such, in not intended for decision-making in acute conditions or for real-time monitoring of vital functions, nor does it intervene in any existing guideline compliant diagnostic pathways or therapeutic interventions. This assessment does not involve a diagnosis, but rather exclusively suggests a tentative suspicion with qualified informational intent. Under no circumstances should it be used as a substitute for any person-related diagnostics, consultation, care or treatment rendered by a physician.

The user releases the Telecare-Center Ulm GmbH from all liability caused by any possible misinterpretation. The Telecare-Center Ulm GmbH and its staff and/or partners assume no responsibility whatsoever for decisions that the user or the physician bases on the data generated by this product.

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The result presented is statistical in nature and has been generated by comparing the measurement with a database.



Heart rhythm analysis verified by the Telecare Center



Pulse wave:

they merely symbolize the trigger point of a detected heartbeat.

Irregular heartbeat (e.g. ectopic beat) tremely irregular heartbeat (absolute arrhythmia) **Eliminated disruptions:**

If present

Rhythmical abnormalities:



Further details can be found in section "Details of assessment, 5. Assessment by Telecare"

The R-spikes projected in the pulse waves have been artificially generated and do not correspond to the original shape of an ECG curve;





Report heart rhythm analysis via 5-minute pulse measurement

Name: Peter Schmidt Gender: male Year of birth: 1980 **Record:** 2017/05/30 4:23 pm Remark: Palpitations Heart rhythm **Heart rate Proposal** Your heart rhythm is regular. Your heart rate is normal and averages 79 No abnormalities were observed. Repeat the measurement at regular intervals. beats/minute (bpm). Heart rate time curve Reportnummer: #170608-0000643 Minute 1 Minute 2 Minute 3 Minute 4 Minute 5 120 240 300 Pulse measurement 10s 20s 40s 50s Minute 1 Minute 2 Minute 5 **Eliminated disruptions:** Pulse wave: **Symbolized R-spikes:** ↑ Regular heartbeat Irregular heartbeat (e.g. ectopic beat) Extremely irregular heartbeat (absolute arrhythmia) If present The R-spikes projected in the pulse waves have been artificially generated and do not correspond to the original shape of an ECG curve: they merely symbolize the trigger point of a detected heartbeat.



Intended use and disclaimer: By using this app, users agree and acknowledge that they have read and understood the following policy: This app constitutes a class I medical device that is in conformity with the Essential Requirements of Medical Device Directive 93/42/EEC or its respective national transpositions. Intended use: This app is designed to detect cardiac arrhythmias in out-patient settings under non-acute circumstances and not in emergencies. The app is not designed to be an aid in either decision-making for acute states or for real-time monitoring of vital functions: Neither does this app encroach upon any existing guideline-compliant diagnostic pathways or therapeutic measures in place. The results do not constitute a diagnosis, but rather suggest a potential suspicion that is exclusively intended for informative purposes; under no circumstances does it replace personalized diagnosis, consultation, consultation, consultation, and regular heart replace personal replaced by a physician, healthcare professional or medically trained personnel. Clinical trials have demonstrated that the algorithm on which this app is based can detect the difference between irregular cardiac rhythms (e.g. atrial fibrillation) and regular heart rhythms with an accuracy of up to 95 cm. The user hereby releases Preventicus GmbH from any liability arising from a possible misinterpretation. Preventicus GmbH, including its employees and/or affiliates, shall assume no responsibility whatsoever with regards to decisions users make based on the information generated by this product. Medication or drugs affecting the heart rate or pacemakers can potentially falsify the results of the rhythm analysis. For more informationen visit www.preventicus-heartbeats.com