apoplex medical technologies

SRA®

Instructions for Use

Content

Overview of further instructions for use in connection with our Service **SRA®**:

SRA®transfer Manual

SRA®viewer Manual

CE

SRA® Instructions for Use
Version 2.4 / Issue date: 20-02-2025
These instructions for use replace all previous versions.

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1 General information about **SRA®**

Intended Purpose

The **SRA®** software is used for the fully automated analysis of ECG data with the aid of an algorithm for the following features:

1 Episodes of manifest atrial fibrillation (AF) (absolute arrhythmia),

2 Changes in heart rhythm that provide evidence of possible paroxysmal atrial fibrillation (pAF) without episodes of manifest atrial fibrillation being detected.

Users

SRA® is commissioned by the following users:

- Stroke units (certified and non-certified)
- ICUs for the treatment of stroke and TIA patients
- Neurological rehabilitation clinics
- General practitioners and specialists
- Trade partners

If the users are not qualified for cardiological diagnosis (e.g. in cooperation with trade partners), this is offered by apoplex medical technologies GmbH in the form of a telemedical service.

Intended patient group

The patient group is high-risk patients with a stroke risk (CHA2DS2-VASc score >1).

Indication

SRA® is used for the following patient groups:

- Patients with risk factors for atrial fibrillation (primary prevention) and

- Stroke and TIA patients (secondary prevention / cause clarification of atrial fibrillation).

Contraindication

There are no contraindications against the use of the **SRA®**.

Warnings

The following warnings and necessary precautions must be observed in connection with the use of the **SRA®** :

ECGs of patients with the following characteristics cannot be analysed or can only be analysed to a limited extent:

- Pacemaker,
- Bundle branch block,
- Severe ventricular extrasystoles,
- Condition after pharmacological cardioversion.

It should also be noted that SRA® may only be used on patients of legal age (18 years and older).

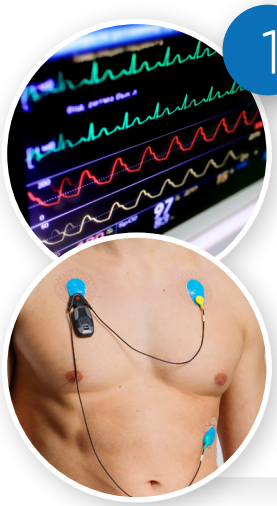
The result of the analysis may only be used for the diagnosis of atrial fibrillation or for further risk stratification.

The analysis system **SRA®** must never be used as the sole basis for diagnosis and treatment decision. In particular, any positive analysis result must be verified using the 5-minute ECG interval (part of the **SRA®** report), as there is a residual risk of a false positive / false negative result.

Classification according to MDD

Class I according to MDD appendix IX, Council Directive 93/42/EEC

Procedure



1

Automatic ECG measurement
from the patient monitor

or:

Classic ECG lead
via a Long-Term ECG recorder

2

The data is sent via an encrypted and secured connection to our **SRA®** Cloud and analysed

3

Transmission of the analysis report
as a PDF file

4

Create diagnosis
independently by checking the ECG interval provided in the analysis report (**SRA®**)

or:

through the physicians' network of apoplex medical technologies (**SRA®+**)

Compatible systems

Patient monitoring systems Draeger and Nihon Kohden

In conjunction with patient monitoring systems from Dräger and Nihon Kohden, the transmission of analysis reports is fully automated once a day. In this case, you will receive the complete analysis of the previous day from all patients for whom an identification number was entered on the monitoring system.

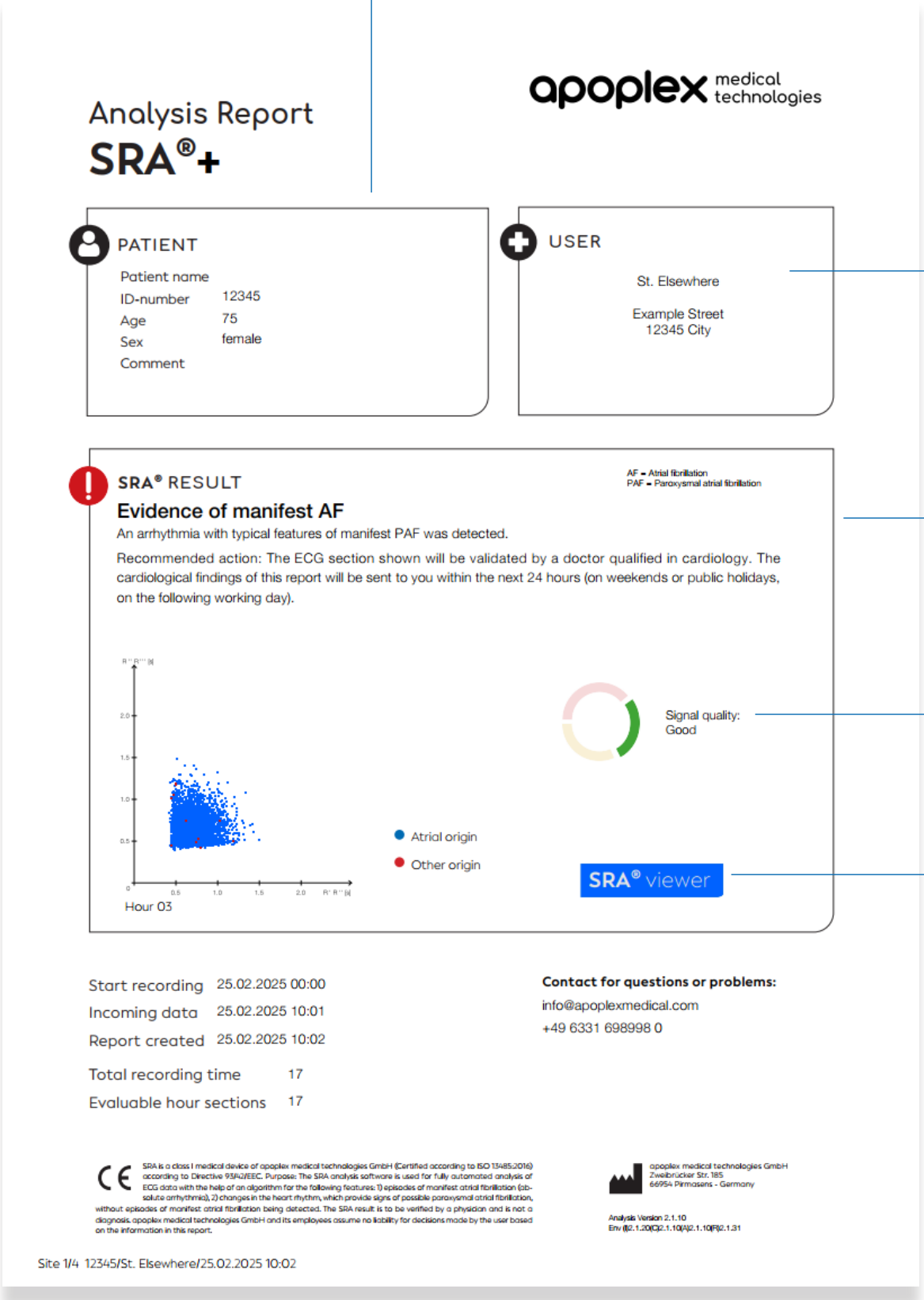
Philips patient monitoring system

In conjunction with a Philips patient monitoring system, the ECG data of the selected patients is transmitted manually once a day. The time of data transmission is freely selectable, but it has been shown in practice that a transmission in the morning makes sense. The analysis includes max. the last 24 hours.

Long-Term ECG recorders

SRA® analyses up to max. 7 days of ECG recordings if LT-ECG recorders are used. After sending in the ECG via the transfer app **SRA®**transfer, an analysis report is created for the recorded period and then transmitted.

2 The analysis report



Analysis Report
SRA®+

apoplex medical technologies

PATIENT

Patient name
ID-number 12345
Age 75
Sex female
Comment

USER

St. Elsewhere

Example Street
12345 City

SRA® RESULT

AF = Atrial fibrillation
PAF = Paroxysmal atrial fibrillation

Evidence of manifest AF

An arrhythmia with typical features of manifest PAF was detected.

Recommended action: The ECG section shown will be validated by a doctor qualified in cardiology. The cardiological findings of this report will be sent to you within the next 24 hours (on weekends or public holidays, on the following working day).

Hour 03

Signal quality:
Good

Atrial origin
Other origin

SRA® viewer

Start recording 25.02.2025 00:00
Incoming data 25.02.2025 10:01
Report created 25.02.2025 10:02

Total recording time 17
Evaluable hour sections 17

Contact for questions or problems:
info@apoplexmedical.com
+49 6331 698998 0

CE SRA is a class I medical device of apoplex medical technologies GmbH (Certified according to ISO 13485:2016) according to Directive 93/42/EEC. Purpose: The SRA analysis software is used for fully automated analysis of ECG data with the help of an algorithm for the following features: 1) episodes of manifest atrial fibrillation (absolute arrhythmia), 2) changes in the heart rhythm, which provide signs of possible paroxysmal atrial fibrillation, without episodes of manifest atrial fibrillation being detected. The SRA result is to be verified by a physician and is not a diagnosis. apoplex medical technologies GmbH and its employees assume no liability for decisions made by the user based on the information in this report.

apoplex medical technologies GmbH
Zweibrücker Str. 185
66954 Pirmasens - Germany

Analysis Version 2.1.10
Env (I)2.1.20(C)2.1.10(A)2.1.10(R)2.1.31

Site 1/4 12345/St. Elsewhere/25.02.2025 10:02

PATIENT

Information about the patient is listed here. For data protection reasons, information on the patient's name is not transmitted for analysis. The 'ID number' is to be assigned by the user and is used for allocation. When sending data with **SRA**®transfer , information on 'age' and 'gender' is mandatory.

USER

This field contains the address of the user.
This can be changed on request.

SRA® RESULT

In this field, the result of the analysis is displayed with the corresponding explanation and recommendation for action in text form. The Lorenz Plot is used for graphical representation (see explanation on page 12).

SIGNAL QUALITY

In the 'Signal quality' field, the user receives an indication of the value of the ECG data sent. The levels 'good', 'medium' and 'poor' are displayed. For poor signal quality, see explanation page 10.

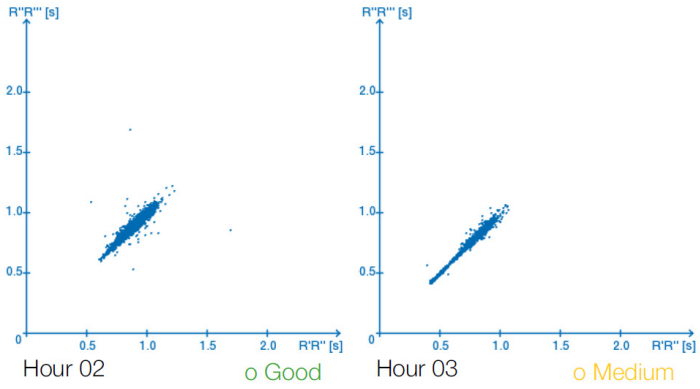
SRA®viewer

With the **SRA**®viewer, all details of the original ECG recording can be accessed easily and quickly. In particular, conspicuous segments from the Lorenz Plot can be traced back to the corresponding ECG data with the click of a mouse.

Signal quality

A successful analysis requires high quality ECG data.

The signal quality display in the analysis report allows you to check the recording quality of the ECG data. The following signal qualities are displayed:



If **SRA®** is combined with poor signal quality, it can occasionally lead to incorrect detection of the QRS complexes (R-waves) and detection of ventricular extrasystoles (PVCs), which affect the result classification. It may happen that **SRA®** cannot always reliably distinguish between disturbances and PVCs, or does not detect all RR intervals. Disturbances often manifest themselves in randomly distributed points in the Lorenz Plot. Missing R-waves are manifested by further lobes with double spacing in x- and y-direction. The detection of the PVCs is based on a review of the morphology of the QRS complexes. This can be influenced by disturbances in the signal, placement of the electrodes, position type of the heart or by strongly widened QRS complexes in atrial beats (e.g. in bundle branch blocks). If the QRS complexes are very widened and there is evidence of manifest fibrillation, PVC detection is not performed. If the signal quality is poor or if you have doubts about the QRS detection (abnormalities in the Lorenz Plot), you should check the ECG recording for plausibility using the **SRA®**viewer and repeat the recording if necessary. If the recording is repeated, there are no additional costs, but the additional effort due to reapplying the electrodes, waiting time for the patient, etc. can be avoided in most cases.

If an analysis could not be carried out due to poor signal quality, the user receives a report with corresponding instructions on how to successfully repeat the recording.

SRA® Analysis results

No evidence of pAF

At the time of recording, no evidence of manifest AF was detected, nor was there an increased likelihood of pAF.

Recommendation for action

This is just a snapshot in time. AF may still develop and should continue to be monitored in conjunction with other conditions.

Increased probability of pAF

As the ECG shows features comparable to those of patients with proven pAF in fibrillation-free phases, this suggests an increased likelihood of pAF.

Recommendation for action

Previous study results show that further screening after pAF at this result level will be significantly more successful than without pre-screening. The time and effort required for this depends on the screening time already completed as well as many other diagnostic parameters.

Indication of manifest AF (at **SRA®+**)

An arrhythmia with typical features of manifest AF was detected.

Recommendation for action

The ECG interval shown will be validated by a physician qualified in cardiology. The cardiological findings of this report will be sent to you within the next 24 hours (on weekends or public holidays, on the following working day).

Indication of manifest AF (with **SRA®**)

An arrhythmia with typical features of manifest AF was detected.

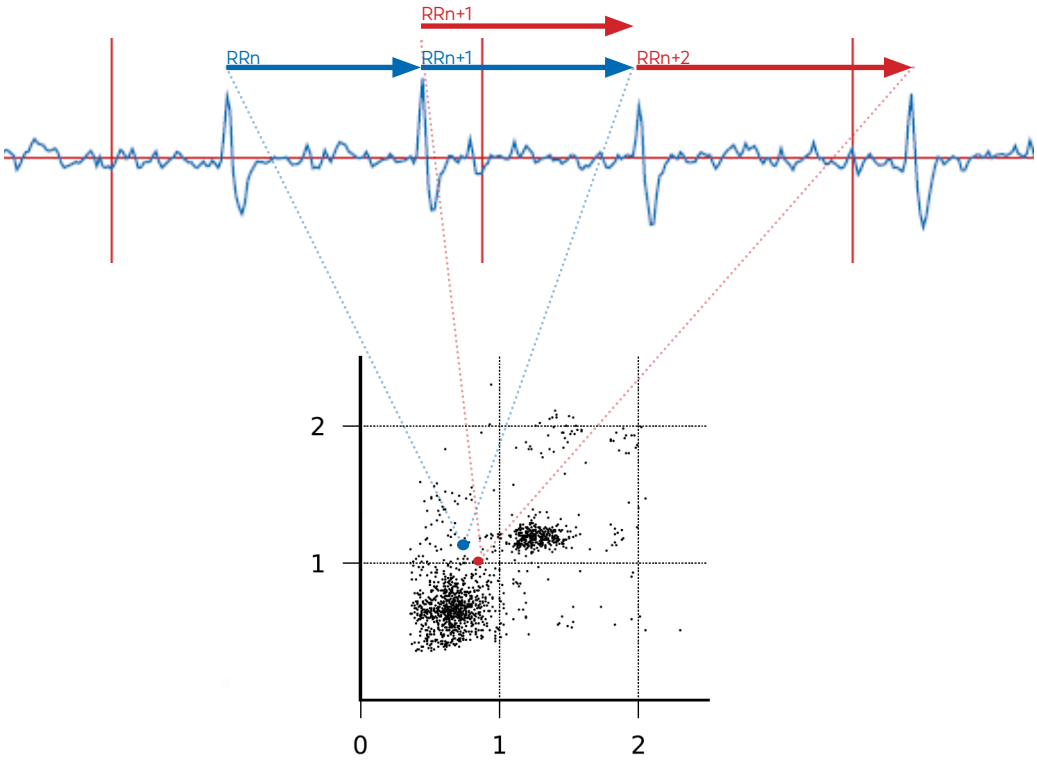
Recommendation for action

Although the specificity is high, the possibility of a false positive result cannot be excluded. The ECG interval shown must be validated by a physician.

The Lorenz Plot

The Lorenz Plot, often called the Poincaré Plot, is an excellent method for visualising the dynamics of the heartbeat. Here, the times between two QRS complexes (RR interval) are represented in such a way that one interval is plotted against the next in a coordinate system. This can take place in two dimensions (x,y), as shown in the next diagram.

Example of a Lorenz Plot



Representation of the individual hourly Lorenz Plots in the report

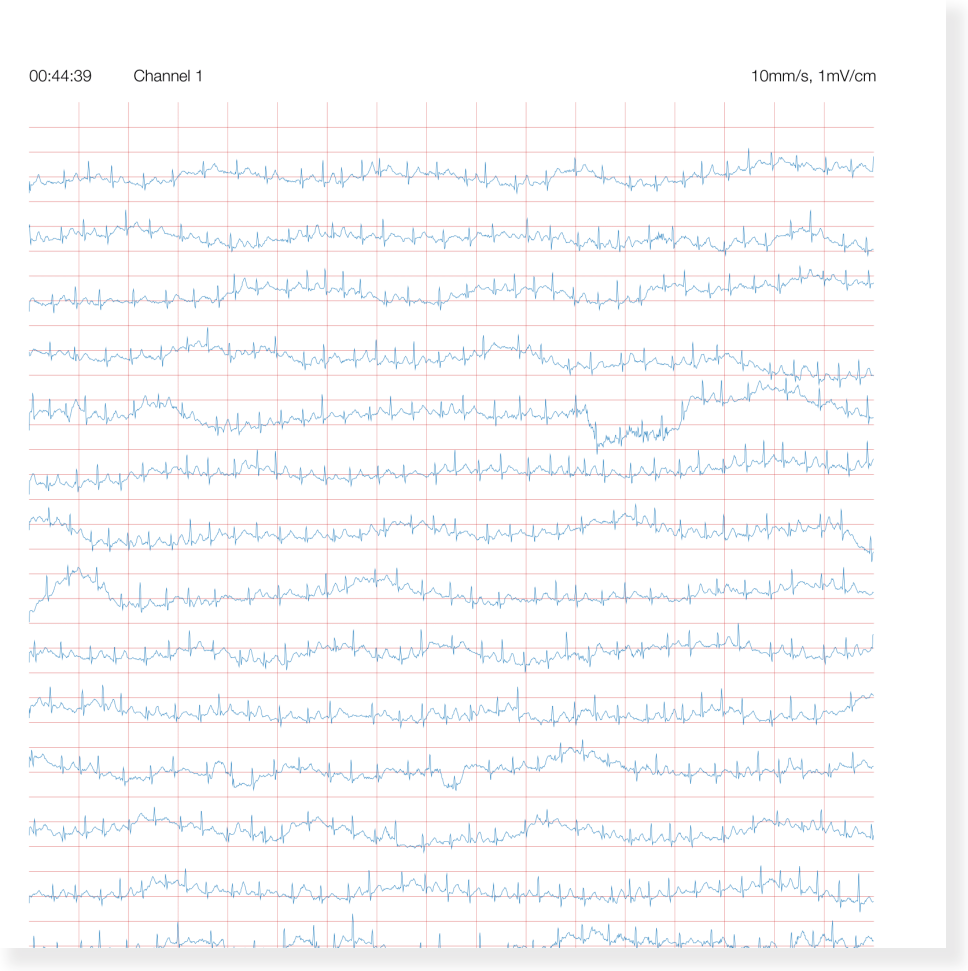
- Lorenz Plots of the individual hours in order from left to right and from top to bottom.
- Below each Plot, the hour and the signal quality are indicated.
- Empty coordinate systems are a sign of ECG data that cannot be evaluated.
- Hour intervals without content (no coordinate system) at the end of the overview mean the ECG recording has ended.
- The analysis is based on many different mathematical parameters. Properties of the Lorenz Plot represent only a part of these parameters. Therefore, the Lorenz Plot alone cannot be used to derive the analysis result.
- The Lorenz Plot offers the possibility to visually gain information about heart rate variability.

The 5-minute ECG interval

If one or more manifest episodes of atrial fibrillation are detected through **SRA®** , the two ECG channels of the same, particularly typical time interval are displayed separately on pages 2 (channel1) and 3 (channel 2).

In order to ensure a high level of reliability for finding atrial fibrillation episodes, great importance was attached to a very high sensitivity (even for short episodes) at the request of many users. This can also cause false positives, but these are rare and relatively easy to assess using the 5-minute ECG interval provided. This approach has been confirmed as beneficial by many users, especially cardiologists. If the 5-minute ECG interval is false positive, there are no atrial fibrillation episodes in the rest of the ECG either.
The 5-minute ECG interval is provided in sufficient resolution and can be enlarged up to 400% with a PDF reader without loss of quality.

With **SRA®+**, the 5-minute ECG interval serves as the basis for the findings by our network of physicians.

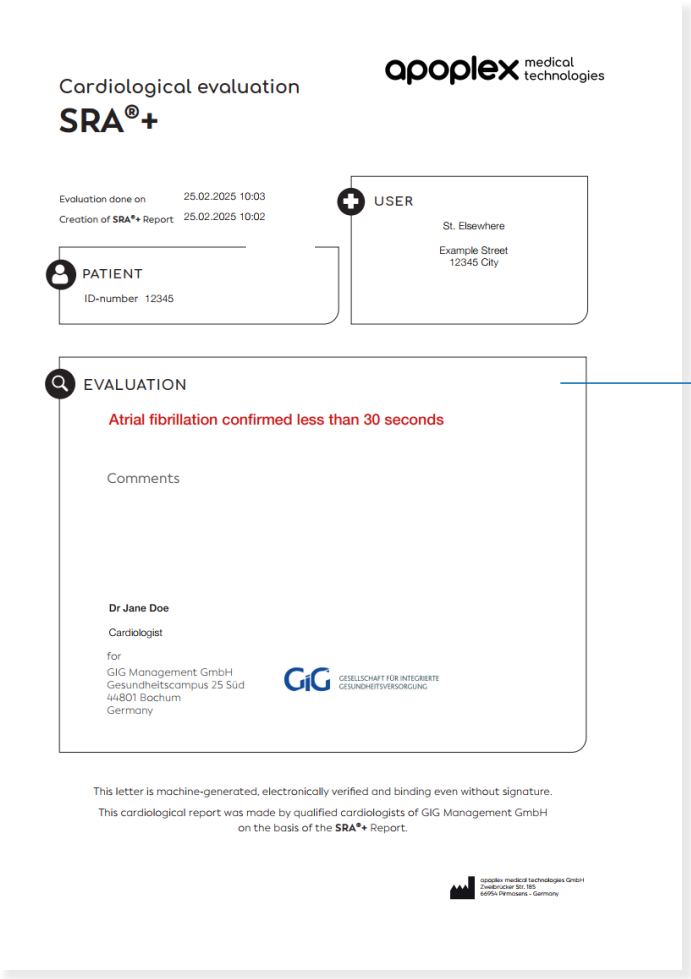


3 The cardiological evaluation

If the **SRA®** algorithm detects an indication of manifest atrial fibrillation, the report – including the 5-minute ECG interval – is automatically forwarded to our network of physicians. There, the report is examined by cardiologically qualified physicians within 24 hours (at weekends or on public holidays, on the following working day) for the diagnosis of atrial fibrillation. The user then receives the evaluation by email. Once atrial fibrillation greater than 30 seconds has been cardiologically confirmed, the corresponding patient will not receive any findings from further analysis reports.

Possible evaluation:

- Atrial fibrillation confirmed, less than 30 seconds
- Atrial fibrillation confirmed, greater than 30 seconds
- No atrial fibrillation confirmed
- No evaluation (comments required)
- Other (comments required)



Cardiological evaluation
SRA®+

apoplex medical technologies

Evaluation done on 25.02.2025 10:03
Creation of SRA®+ Report 25.02.2025 10:02

USER
St. Elsewhere
Example Street
12345 City

PATIENT
ID-number 12345

EVALUATION
Atrial fibrillation confirmed less than 30 seconds

Comments

Dr Jane Doe
Cardiologist
for
GIG Management GmbH
Gesundheitscampus 25 Süd
44801 Bochum
Germany

GIG GESELLSCHAFT FÜR INTEGRIERTE GESUNDHEITSVERSORGUNG

This letter is machine-generated, electronically verified and binding even without signature.
This cardiological report was made by qualified cardiologists of GIG Management GmbH on the basis of the SRA®+ Report.

apoplex medical technologies GmbH
Zweibrücker Str. 185
66954 Pirmasens - Germany

Evaluation

This field contains the cardiological evaluation of the corresponding analysis report. In the 'Comments' section, the examining physician can record further information on abnormalities or irregularities. In the lower section, the name of the reporting physician is written.

4 Service & Support

Our aim is to provide you, at any time and anywhere, with the best possible support and comprehensive competent care for the successful use of our service.

If you have any technical problems or questions, our qualified staff will be happy to find a solution together with you.

You can reach our service team at

Tel.: +49 6331 69 89 98 66
Email: service@apoplexmedical.com

You can find our current service hours on our website: www.apoplexmedical.com

Note to the user and/or the patient:

All serious incidents related to the device shall be reported to the manufacturer and to the competent authority of the member state where the user and/or the patient is practicing/resident.

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