apoplex medical technologies

SRA Pro

Instructions for Use

,

,

Software
2024.39.X
IFU Version
1.0

Table of Contents

SRA Pro Instructions for Use
Version 1.0 / Issue date: 15.03.2026
This is the currently valid version. All previous versions remain accessible in the archive.

MD CE 0483

UDI 4260701590071

apoplex medical technologies GmbH
Neufferstr. 57
66953 Pirmasens
Germany
PRRC: Albert Hirtz

E-mail: info@apoplexmedical.com
Web: https://www.apoplexmedical.com
Tel.: +49 6331 698998 0
Fax: +49 6331 698998 19

Notices in This Document

The following types of notices are used in these instructions for use:

> **Note**
>
> **Note** — General information or explanation that is helpful for understanding or correct use.

> **Warning**
>
> **Warning** — Indicates a situation that, if disregarded, may lead to erroneous results or misinterpretation.

1 General Information on SRA Pro

Intended Purpose

Medical device software that aids medical professionals in the analysis of ECG signals.

The product is designed to:

- provide information that supports the user in deciding on further diagnostics,
- analyse ECG data for patients in non-serious situations or conditions where treatment is normally not expected to be time-critical.

Analysis results must never be used as the sole basis for diagnosis and treatment decisions.

> **Warning**
>
> The results of the SRA Pro analysis must never be used as the sole basis for diagnostic or treatment decisions.

Abbreviations

Abbreviation	Meaning
ECG	Electrocardiogram
pAF	Paroxysmal atrial fibrillation
AF	Atrial fibrillation
PVC	Premature ventricular contraction
TIA	Transient ischaemic attack

Users

SRA Pro is used by the following user groups:

- Stroke units (certified and non-certified)
- Acute-care hospitals treating stroke and TIA patients
- Neurological rehabilitation clinics
- General practitioners and specialists
- Distribution partners

Use Environment and Qualification Requirements

Use environment: SRA Pro is intended exclusively for use in professional clinical settings (e.g. stroke units, acute-care hospitals, neurological rehabilitation clinics, physician practices). Operation requires a stable internet connection and suitable IT infrastructure as specified in the “Minimum Hardware and Software Requirements” section. SRA Pro must be operated exclusively on non-safety-critical IT infrastructure (i.e. systems whose failure does not directly endanger patients, e.g. clinical workstation PCs — not on systems that control or monitor life-sustaining devices).

Qualification requirements: Users must be licensed healthcare professionals (physicians or equivalently qualified clinical staff). Specific cardiology expertise is not mandatory.

Training: Before initial use, an introduction by trained personnel from apoplex medical technologies GmbH or an authorised distribution partner is required.

Intended Patient Population

The intended patient population is adults over 18 years of age.

Indication

SRA Pro is used for the following patient groups:

- Patients with risk factors for atrial fibrillation (primary prevention) and
- Stroke and TIA patients (secondary prevention / aetiology workup: I48.0 Atrial fibrillation, paroxysmal; I48.1 Atrial fibrillation, persistent; I48.2 Atrial fibrillation, permanent).

Contraindications

The following contraindications apply to the use of SRA Pro:

- Patients with a cardiac pacemaker
- Patients under 18 years of age

> **Warning**
>
> ECGs from patients with the following characteristics cannot be analysed, or can only be analysed to a limited extent:
>
> - bundle branch block,
> - severe ventricular extrasystoles,
> - status after pharmacological cardioversion.
>
> SRA Pro must be operated exclusively on non-safety-critical IT infrastructure.
>
> The analysis result may only be used for the diagnosis of atrial fibrillation or for further risk stratification.
>
> The SRA Pro analysis system must never be used as the sole basis for diagnosis and treatment decisions. In particular, every positive analysis result must be interpreted by the attending physician in the overall context of the patient's presenting symptoms, other test results, and the 100-second ECG segment (part of the SRA Pro report), since a residual risk of a false-positive remains.

Clinical Performance and Benefit

Performance: Sensitivity ≥ 98 %; specificity ≥ 95 % for the detection of manifest atrial fibrillation. These values refer to a comparison with adjudication by experienced cardiologists in a clinical validation study.

The software provides healthcare professionals with information that supports further diagnostic decision-making, enables timely clinical interventions, and thereby contributes to reducing the patient's stroke risk.

> **Warning**
>
> The analysis result may only be used for the diagnosis of atrial fibrillation or for further risk stratification.
>
> The SRA Pro analysis system must never be used as the sole basis for diagnosis and treatment decisions. In particular, every positive analysis result must be interpreted by the attending physician in the overall context of the patient's presenting symptoms, other test results, and the 100-second ECG segment (part of the SRA Pro report), since a residual risk of a false-positive remains.
>
> SRA Pro must be operated exclusively on non-safety-critical IT infrastructure.

Limitations and Suitability

SRA Pro is suitable for clinical use when the following conditions are met:

- Minimum ECG recording duration: 5 minutes 30 seconds.
- Signal quality: Sufficient signal quality is required for a reliable analysis (see Signal Quality section in the analysis report).
- Patient population: Adults over 18 years of age.

The following clinical conditions limit the reliability of the analysis:

- Cardiac pacemaker (contraindication — do not use)

SRA Pro is not suitable for the analysis of ECGs from paediatric patients.

Classification per MDR

Class IIa per MDR Annex VIII, Rule 11

File Formats

The following file formats are supported:

Format	Description	Files
EDF (European Data Format)	Open standard for storing multi-channel biosignal data	.edf
MIT/WFDB (MIT-BIH / WaveForm DataBase)	PhysioNet format for physiological signal data, consisting of a header file and a binary signal file	.hea, .dat
RFV	Proprietary ECG data format by Philips, developed for the Philips Information Center	.rfv

Minimum Hardware and Software Requirements

- A standard computing device with an available internet connection.
- Supported web browsers: Google Chrome, Mozilla Firefox, Microsoft Edge, Apple Safari (latest version recommended in each case).
- Minimum screen resolution: 1280 × 800 pixels (recommended: 1920 × 1080).
- A PDF reader is required to view the analysis report (e.g. Adobe Acrobat Reader, built-in browser PDF viewer).
- Unsupported file formats are rejected by the system. Feedback is provided via the upload interface.

Storage and Handling

SRA Pro is a cloud-based software without physical components. No special storage or handling conditions apply. Access credentials must be kept confidential and protected against unauthorised access.

IT Security Measures

- All data transfers are conducted exclusively over HTTPS/TLS-encrypted connections.
- Patient data may only be transmitted in pseudonymised form. The user assigns a patient ID that does not allow identification of the patient (no real names, dates of birth, or case numbers). The mapping between patient ID and patient identity remains exclusively with the user and must be documented and secured in accordance with the institution's data protection policies.
- Access credentials for the SRA Pro API gateway must not be shared with unauthorised persons.
- The operating system and browser must be kept up to date by the user to ensure security updates are applied.
- SRA Pro must be operated exclusively on non-safety-critical IT infrastructure.

2 Workflow

SRA Pro is a cloud-based analysis service for long-term ECG recordings. Users upload their ECG data via the SRA Pro API web transfer service. The data are transmitted to the analysis server of apoplex medical technologies over an encrypted and secured connection and analysed automatically. After the analysis is complete, users receive the analysis report as a PDF file by e-mail.

Commissioning

Initial commissioning of SRA Pro takes place during a personal onboarding session conducted by apoplex medical technologies GmbH or an authorised partner (see section “Qualification Requirements and Training”). During this session, access credentials for the SRA Pro API gateway are provided and correct operation is verified.

Access credentials for the API gateway are assigned per user. Organisational rules for use within an institution (e.g. shared use by multiple physicians) are established during the onboarding session.

Starting the Device

1. Open the SRA Pro API gateway at https://gateway-int.srapro.com/ in a web browser.
2. Log in with the username and password provided by apoplex medical technologies GmbH.

Data Upload

To securely transmit your ECG data to SRA Pro, you can use the API web transfer service:

1. Enter the pseudonymised patient ID.
2. Upload your ECG files.
3. Verify the successful transmission of your data using the confirmation displayed.
4. Your data are analysed automatically and the analysis report is delivered to you by e-mail.

> **Note**
>
> The analysis report is delivered by e-mail after the analysis is complete. For 24 hours of ECG data, processing time is typically less than 10 minutes after a successful upload. During periods of high analysis volume, delivery may take up to 12 hours.

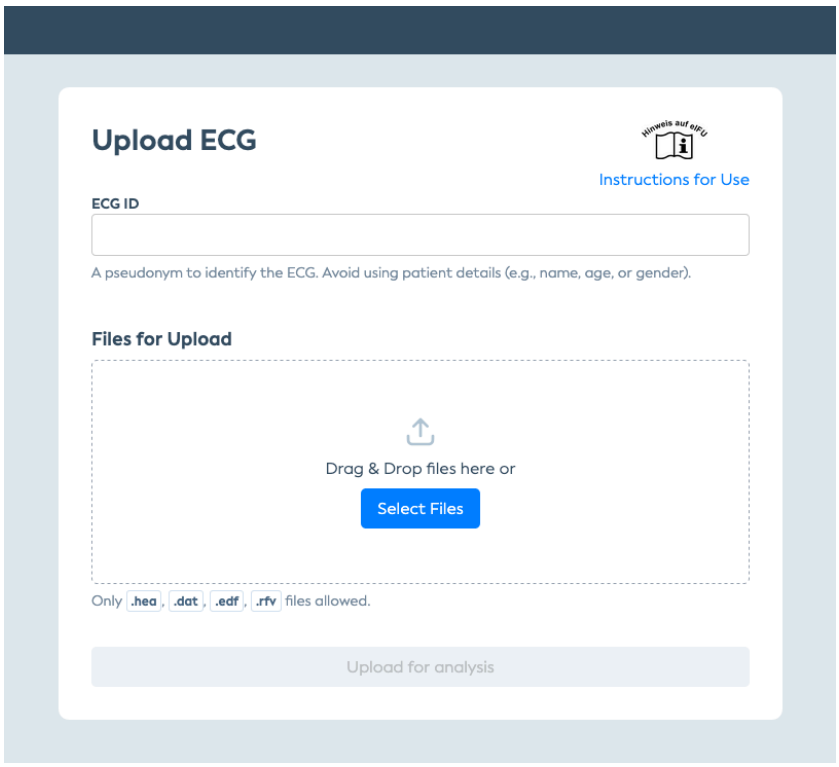


Fig. 1: Upload form of the SRA Pro API web transfer service. The “Patient ID” and “Select file” fields are mandatory.

3 The Analysis Report

After the analysis is complete, SRA Pro generates a multi-page PDF report. This report contains:

- the **analysis result** (classification into one of three categories, see following pages),
- an **overview of signal quality** per channel,
- the **hourly Lorenz plots** for visual assessment of heart rate variability,
- for a positive finding, a **100-second ECG segment** of the most representative episode for physician verification.

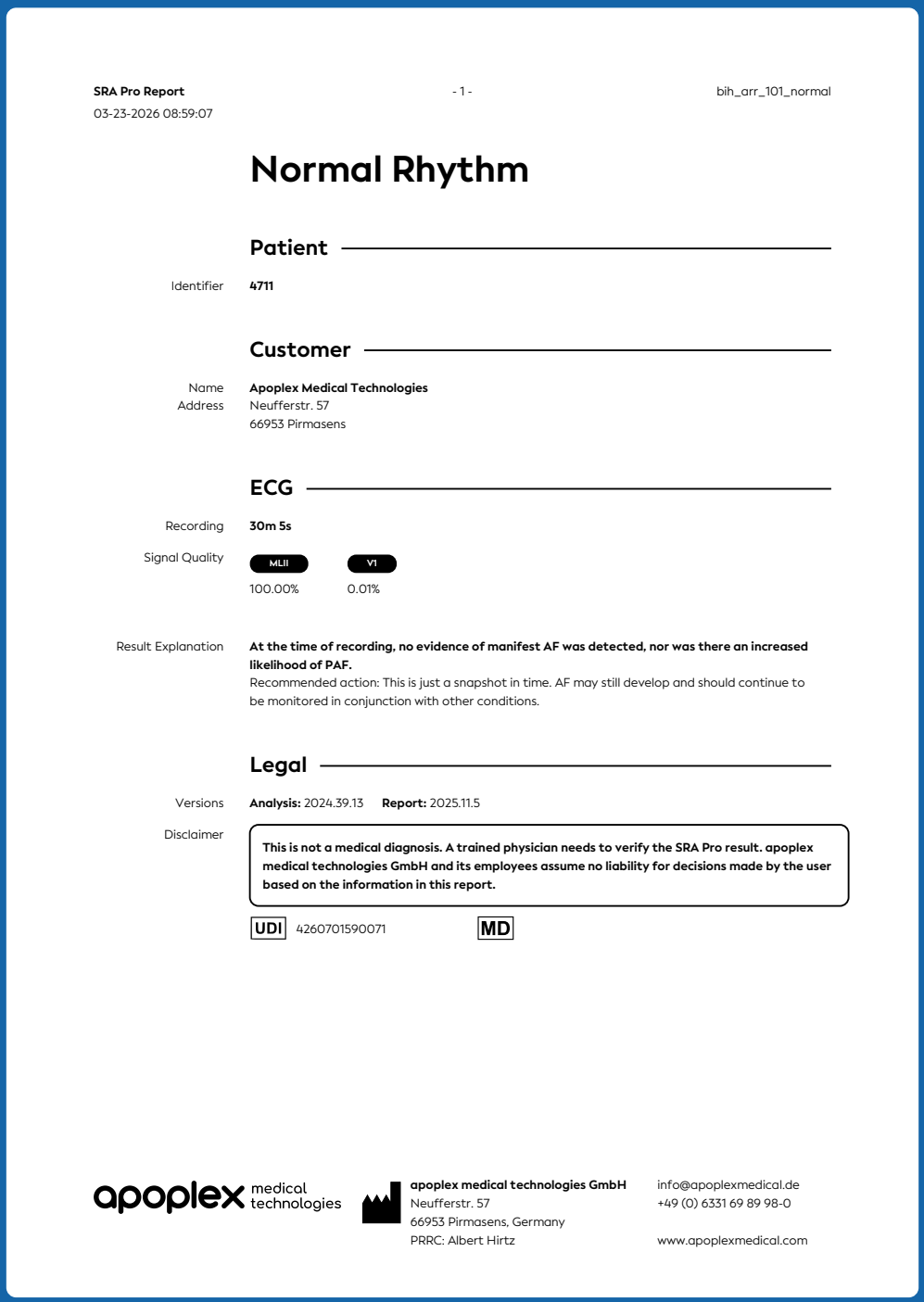
The report is delivered to the user by e-mail as a PDF file. A PDF reader is required to view the report (see section “Minimum Hardware and Software Requirements”).

> **Note**
>
> A complete example report is provided during the onboarding session by apoplex medical technologies (see section “Commissioning”).

No Indication of pAF

At the time of recording, SRA Pro detected neither indications of manifest AF nor an increased probability of pAF.

Recommended action: This result is a snapshot in time. AF can develop over time and should continue to be monitored in conjunction with other conditions.



SRA Pro Report - 1 - bih_arr_101_normal
03-23-2026 08:59:07

Normal Rhythm

Patient

Identifier **4711**

Customer

Name **Apoplex Medical Technologies**
Address Neufferstr. 57
66953 Pirmasens

ECG

Recording **30m 5s**

Signal Quality MLII 100.00% V1 0.01%

Result Explanation **At the time of recording, no evidence of manifest AF was detected, nor was there an increased likelihood of PAF.**
Recommended action: This is just a snapshot in time. AF may still develop and should continue to be monitored in conjunction with other conditions.

Legal

Versions **Analysis:** 2024.39.13 **Report:** 2025.11.5

Disclaimer **This is not a medical diagnosis. A trained physician needs to verify the SRA Pro result. apoplex medical technologies GmbH and its employees assume no liability for decisions made by the user based on the information in this report.**

UDI 4260701590071 MD

apoplex medical technologies

apoplex medical technologies GmbH
Neufferstr. 57
66953 Pirmasens, Germany
PRRC: Albert Hirtz

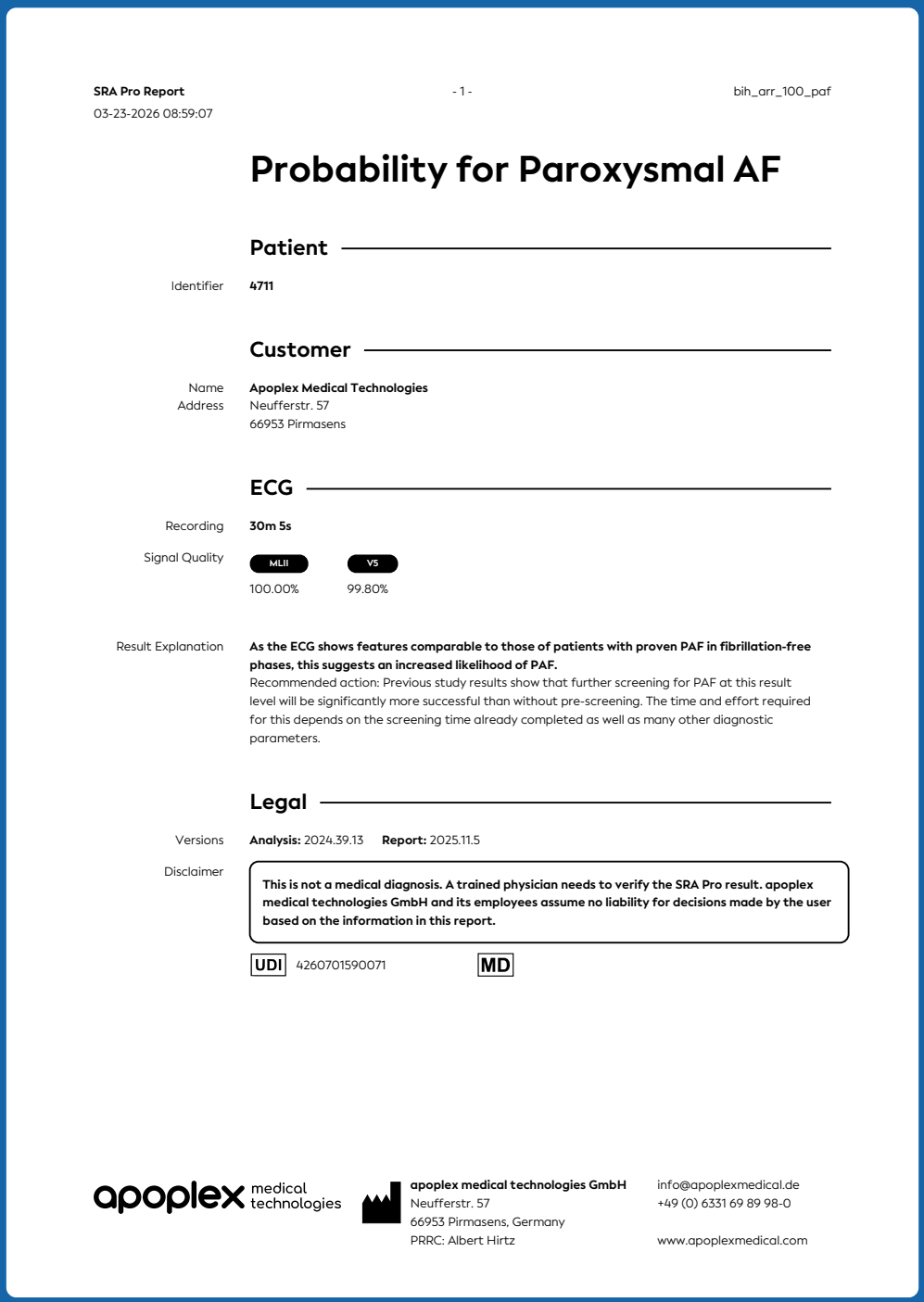
info@apoplexmedical.de
+49 (0) 6331 69 89 98-0
www.apoplexmedical.com

Fig. 2: Example — SRA Pro analysis report — No indication of pAF

Increased Probability of pAF

The ECG exhibits features comparable to those of patients with confirmed pAF during fibrillation-free phases, indicating an increased probability of pAF.

Recommended action: The treating physician should initiate extended rhythm monitoring (e.g. repeated long-term ECG over ≥ 72 h or implanted loop recorder). In previous studies, pre-selection by SRA Pro increased the detection rate of pAF compared with untargeted screening. The physician determines the scope and type of follow-up diagnostics based on the duration of screening to date, the CHA_2DS_2-VASc score, and other clinical findings.



SRA Pro Report - 1 - bih_arr_100_paf
03-23-2026 08:59:07

Probability for Paroxysmal AF

Patient

Identifier **4711**

Customer

Name **Apoplex Medical Technologies**
Address Neufferstr. 57
66953 Pirmasens

ECG

Recording **30m 5s**

Signal Quality MLII 100.00% V5 99.80%

Result Explanation **As the ECG shows features comparable to those of patients with proven PAF in fibrillation-free phases, this suggests an increased likelihood of PAF.**
Recommended action: Previous study results show that further screening for 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.

Legal

Versions **Analysis:** 2024.39.13 **Report:** 2025.11.5

Disclaimer **This is not a medical diagnosis. A trained physician needs to verify the SRA Pro result. apoplex medical technologies GmbH and its employees assume no liability for decisions made by the user based on the information in this report.**

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+49 (0) 6331 69 89 98-0
www.apoplexmedical.com

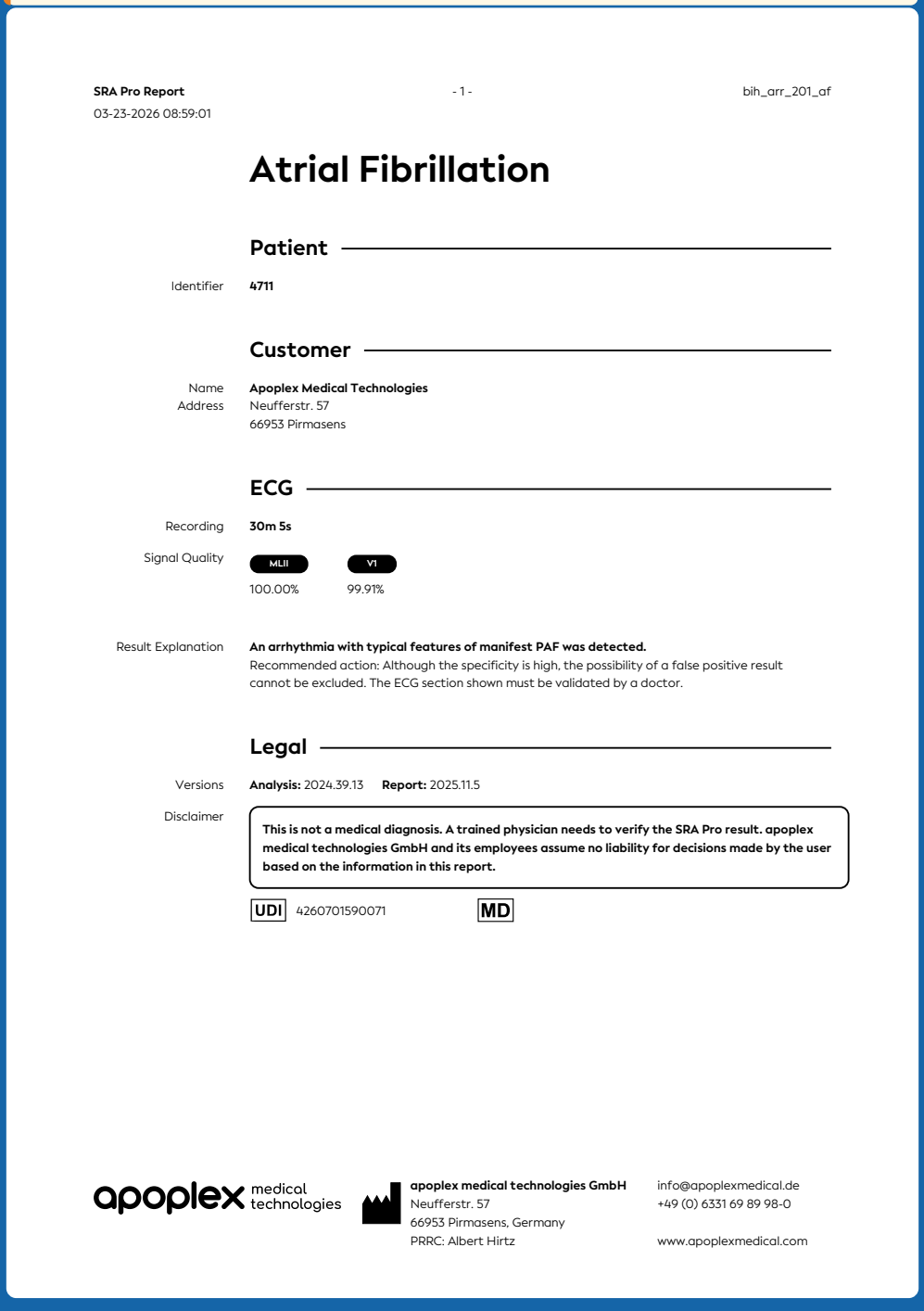
Fig. 3: Example — SRA Pro analysis report — Increased probability of pAF

Indication of Manifest AF

SRA Pro detected an arrhythmia with features typical of manifest AF.

Recommended action: Despite high specificity, a residual risk of false-positive results remains. A physician must validate the ECG segment shown.

> **Warning**
>
> **The SRA Pro analysis system must never be used as the sole basis for diagnosis and treatment decisions.** In particular, every positive analysis result must be interpreted by the attending physician in the overall context of the patient's presenting symptoms, other test results, and the 100-second ECG segment (part of the SRA Pro report), since a residual risk of a false-positive remains.



SRA Pro Report - 1 - bih_arr_201_af
03-23-2026 08:59:01

Atrial Fibrillation

Patient

Identifier **4711**

Customer

Name **Apoplex Medical Technologies**
Address Neufferstr. 57
66953 Pirmasens

ECG

Recording **30m 5s**

Signal Quality MLII 100.00% V1 99.91%

Result Explanation **An arrhythmia with typical features of manifest PAF was detected.**
Recommended action: Although the specificity is high, the possibility of a false positive result cannot be excluded. The ECG section shown must be validated by a doctor.

Legal

Versions **Analysis:** 2024.39.13 **Report:** 2025.11.5

Disclaimer **This is not a medical diagnosis. A trained physician needs to verify the SRA Pro result. apoplex medical technologies GmbH and its employees assume no liability for decisions made by the user based on the information in this report.**

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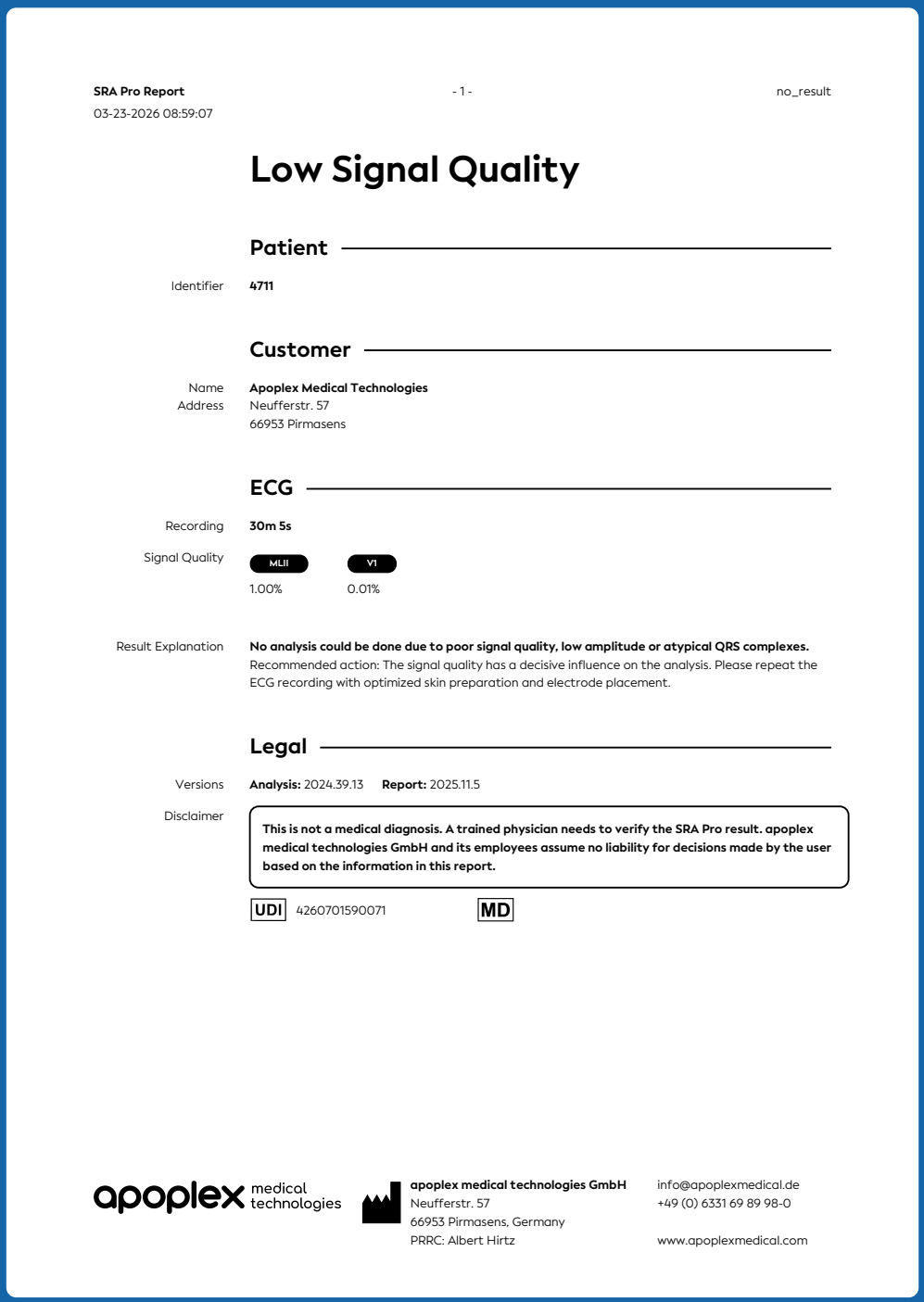
Fig. 4: Example — SRA Pro analysis report — Indication of manifest AF

Low Signal Quality

SRA Pro was unable to perform the analysis due to low signal quality, low amplitude, or atypical QRS complexes.

Recommended action: Repeat the ECG recording with improved skin preparation and electrode placement. Ensure that the electrodes have secure skin contact and that artefact sources (e.g. muscle movement, loose cables) are minimised.



SRA Pro Report - 1 - no_result
03-23-2026 08:59:07

Low Signal Quality

Patient

Identifier **4711**

Customer

Name **Apoplex Medical Technologies**
Address Neufferstr. 57
66953 Pirmasens

ECG

Recording **30m 5s**

Signal Quality MLII 1.00% V1 0.01%

Result Explanation **No analysis could be done due to poor signal quality, low amplitude or atypical QRS complexes.** Recommended action: The signal quality has a decisive influence on the analysis. Please repeat the ECG recording with optimized skin preparation and electrode placement.

Legal

Versions **Analysis:** 2024.39.13 **Report:** 2025.11.5

Disclaimer **This is not a medical diagnosis. A trained physician needs to verify the SRA Pro result. apoplex medical technologies GmbH and its employees assume no liability for decisions made by the user based on the information in this report.**

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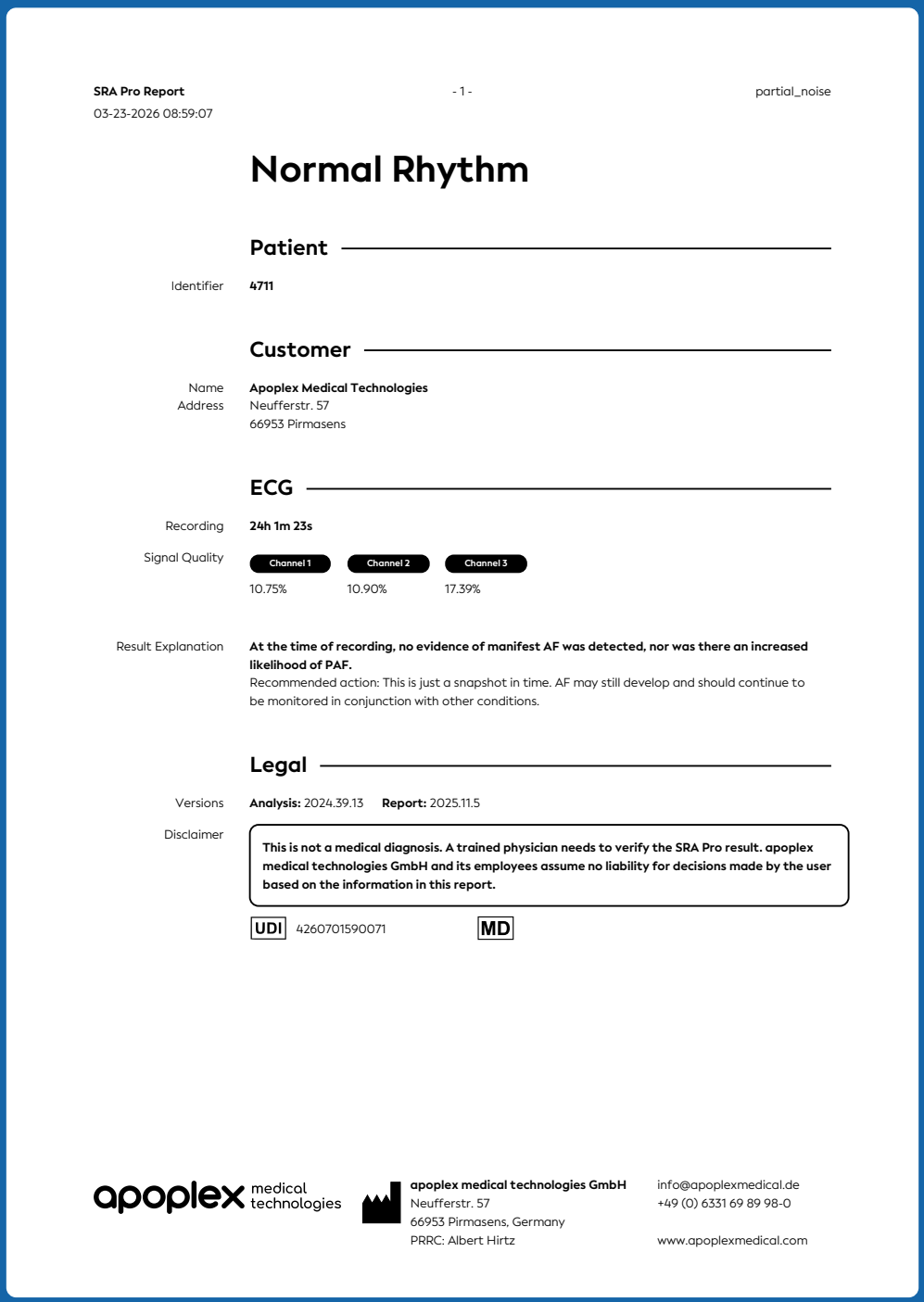
www.apoplexmedical.com

Fig. 5: Example — SRA Pro analysis report — Low signal quality

Limited Signal Quality

In a 24 h recording, substantial segments exhibited limited signal quality. SRA Pro produced a result whose reliability depends on the proportion of evaluable recording time. Warning symbols on the hourly Lorenz plots indicate the affected segments.

Recommended action: The treating physician should assess the proportion of evaluable recording time. If this proportion is insufficient, the recording should be repeated with improved skin preparation and electrode placement.



SRA Pro Report - 1 - partial_noise
03-23-2026 08:59:07

Normal Rhythm

Patient

Identifier **4711**

Customer

Name **Apoplex Medical Technologies**
Address Neufferstr. 57
66953 Pirmasens

ECG

Recording **24h 1m 23s**

Signal Quality

Channel 1	Channel 2	Channel 3
10.75%	10.90%	17.39%

Result Explanation **At the time of recording, no evidence of manifest AF was detected, nor was there an increased likelihood of PAF.**
Recommended action: This is just a snapshot in time. AF may still develop and should continue to be monitored in conjunction with other conditions.

Legal

Versions **Analysis:** 2024.39.13 **Report:** 2025.11.5

Disclaimer **This is not a medical diagnosis. A trained physician needs to verify the SRA Pro result. apoplex medical technologies GmbH and its employees assume no liability for decisions made by the user based on the information in this report.**

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www.apoplexmedical.com

Fig. 6: Example — SRA Pro analysis report — Limited signal quality

Signal Quality

A successful analysis requires high-quality ECG data.

The signal quality display in the analysis report enables you to check the recording quality of the ECG data. At this point, the quality of the transmitted data is shown in detail for each channel. An example display:

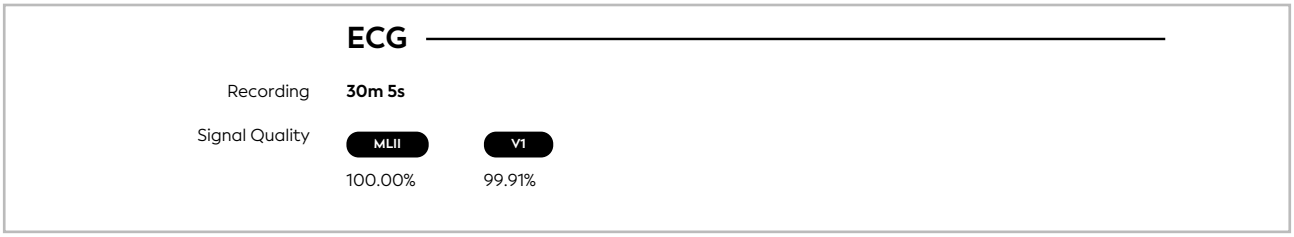

Fig. 7: Signal quality in the report

> **Note**
>
> The designation and number of channels correspond to the data of the original ECG.

With poor signal quality, **SRA Pro** may produce erroneous detection of QRS complexes (R waves) and detection of premature ventricular contractions (PVCs), which influence the result classification. SRA Pro does not reliably distinguish between artefacts and PVCs in all cases and does not detect all RR intervals. Artefacts manifest as randomly distributed points in the Lorenz plot. Missing R waves manifest as additional lobes at double distance in both the x and y directions. PVC detection is based on an assessment of QRS complex morphology. Signal artefacts, electrode placement, the electrical axis of the heart, or significantly widened QRS complexes in atrial beats (e.g. in bundle branch blocks) influence PVC detection. SRA Pro does not perform PVC detection in the presence of significantly widened QRS complexes or indications of manifest fibrillation.

> **Warning**
>
> ECGs from patients with the following characteristics cannot be analysed, or can only be analysed to a limited extent:
> - bundle branch block,
> - severe ventricular extrasystoles,
> - status after pharmacological cardioversion.

The Lorenz Plot

The Lorenz plot, also known as the Poincaré plot, visualises the dynamics of the heartbeat. It plots the time between two QRS complexes (RR interval) against the subsequent interval in a coordinate system. The following figure shows this representation in two dimensions (x, y).

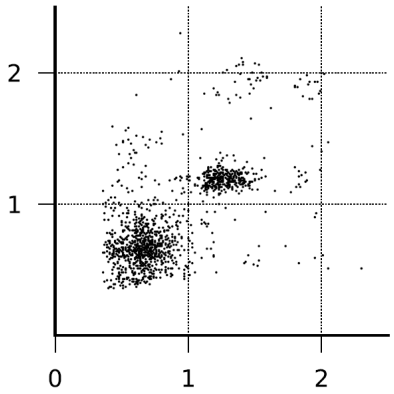

Fig. 8: Example Lorenz plot

Display of individual hourly Lorenz plots in the report

- Lorenz plots for individual hours are arranged from left to right and top to bottom.
- Below each plot, the hour and signal quality are indicated.
- Empty coordinate systems indicate non-evaluable ECG data.
- Hourly segments without content (no coordinate system) at the end of the overview indicate that the ECG recording was terminated.
- The analysis is based on various mathematical parameters. Characteristics of the Lorenz plot represent only a subset of these parameters. Therefore, the analysis result cannot be derived from the Lorenz plot alone.
- The Lorenz plot visually displays heart rate variability.

The 100-Second ECG Segment

If **SRA Pro** detects one or more manifest episodes of atrial fibrillation, the report presents the two ECG channels of the most representative time segment separately on pages 2 (channel 1) and 3 (channel 2). The channel designations correspond to the channels of the transmitted ECG recording. Which leads are displayed depends on the configuration of the long-term ECG recorder used.

SRA Pro prioritises high sensitivity (including for short episodes) in order to reliably detect atrial fibrillation episodes. This may result in false-positive findings. The physician evaluates these using the accompanying 100-second ECG segment. If the 100-second ECG segment proves to be a false positive, the remainder of the ECG also contains no atrial fibrillation episodes.

The 100-second ECG segment has a resolution that allows lossless magnification with a PDF reader up to 400 %.

Fig. 9: 100-second ECG segment (channel II)

4 Service & Support

Software Updates

Updates to SRA Pro are applied server-side by the manufacturer; no action on the part of the user is required. Safety-related updates are communicated to registered users.

Verification

The user confirms correct operation after each upload by checking for receipt of the analysis report by e-mail. If the report is not received, service support should be contacted.

Maintenance

As a cloud-based service, SRA Pro requires no user-side maintenance. The availability and integrity of the service are monitored by the manufacturer. In the event of technical issues, contact the service team.

Error Messages and Malfunctions

The following situations may occur during upload:

Situation	Action
Unsupported file format	The system rejects the file and displays an error message in the upload interface. Check whether the file format is supported (see section “File Formats”).
Upload error	Check your internet connection and repeat the upload. If the problem persists, contact service support.
No report received	If the analysis report has not arrived after more than 12 hours, contact service support (see section “Support”).
Service availability	SRA Pro is a cloud-based service. Registered users are notified in advance of planned maintenance.

Support

For technical issues or questions, contact the service team at:

Tel. +49 6331 698998 66
Fax +49 6331 698998 19
E-mail service@apoplexmedical.com

Current service hours are available on our website: https://www.apoplexmedical.com

Note

Notice to the user and/or the patient:
Any serious incident that has occurred in relation to the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

Frequently Asked Questions

Question	Answer
The file format is not accepted.	Ensure that your ECG files are in one of the supported formats (see section “File Formats”). The system displays an error message for unsupported formats.
I would like to have the same data analysed again.	Upload the ECG data again via the API gateway. A running analysis cannot be cancelled.
The report has not arrived.	Check the spam/junk folder of your e-mail programme. If the report does not arrive, contact service support.

apoplex medical technologies GmbH
Neufferstr. 57
66953 Pirmasens
Germany

Tel. +49 6331 698998 0
Fax. +49 6331 698998 19
https://www.apoplexmedical.com
info@apoplexmedical.com