PREVIA SEPSI SCORE

INSTRUCTION FOR USE (ENGLISH)

HEALTHCARE PHYSICIANS

This Instruction for Use is intended for Healthcare Physicians who receive PREVIA SEPSI SCORE alerts within their usual hospital information system (for example, the EHR). PREVIA SEPSI SCORE has no user interface of its own; alerts and related information are displayed through the hospital's existing clinical applications configured by the hospital IT team and Integrator.

Product Name	Model Number	Software version
PREVIA SEPSI SCORE	SEPSI-200	2.0.0

Software versions covered: Version 2.0.0 and subsequent minor versions within the 2.Y series that do not require this Instructions for Use to be updated, in accordance with PREVIA MEDICAL's change control process.

Symbols

	CE marking		Consult instructions for use or consult electronic instructions for use
	Medical Device		Medical device manufacturer
	Unique device identifier		Date of manufacture

An electronic copy of this document is available to view/download at: https://www.previa-medical.com/en/user-manual/.

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1. Device Description

PREVIA SEPSI SCORE is a medical device software intended for use in the prediction of risk of developing sepsis in hospitalized adult patients. This software analyses structured clinical data from the Electronic Health Record (EHR) to calculate a sepsis risk score for hospitalized patients.

1.1. Intended purpose

PREVIA SEPSI SCORE is a medical device software intended for use in the prediction of risk of developing sepsis in hospitalized adult patients. This software is intended to be used by Healthcare Physicians who operates in general hospital settings. This software, developed using a machine learning model, analyses structured clinical data from the Electronic Health Record (EHR) to calculate a sepsis risk score for hospitalized patients. When this score exceeds a predefined threshold an alert is generated. These outputs are risk-based insights to assist healthcare physicians in the monitoring of patients who may be at risk of developing sepsis. This device is not intended to diagnose sepsis or replace clinical judgement but serves as a decision-support tool for healthcare physicians.

1.2. Indication

PREVIA SEPSI SCORE is indicated for adult patients hospitalized in general settings.

1.3. Contraindications

PREVIA SEPSI SCORE is contraindicated in pediatric patients (under 18 years old).

1.4. Intended Users

PREVIA SEPSI SCORE is intended to be used by Healthcare Physicians who apply their clinical expertise to analyze sepsis risk scores and make informed decisions, they are the end users.

Support users:

- Integrators are responsible for enforcing the hospital's IT policy. They are responsible to integrate the software into their information system and make the alert available to healthcare physicians,
- PREVIA technical support is responsible to manage software installation and updates.

1.5. Intended target population

The patient population for the PREVIA SEPSI SCORE encompasses adult patients of all genders who are currently hospitalized.

1.6. Clinical Benefit

- Highlights patients that may be at risk of developing sepsis
- Early detection of the risk of developing sepsis

1.7. Intended condition of use

The PREVIA SEPSI SCORE system is software designed to operate on hospital computer infrastructure (physical or virtual servers) within hospital settings. The medical device comprises two software units (back-previa and ai-previa) deployed as containerized services on hospital-managed infrastructure.

The PREVIA SEPSI SCORE solution integrates into the hospital's existing information system through deployment performed by a designated Integrator. Once integration is completed, alerts generated by the PREVIA algorithm are written to the hospital FHIR repository as Communication resources and are then displayed by the hospital's clinical applications within existing workflows already used by healthcare staff (e.g., electronic health records). Healthcare physicians access the alerts directly in their routine working environment without the need to launch or manage a standalone application.

Technical Prerequisites:

- Hospital IT infrastructure with FHIR-compliant APIs exposing necessary data elements
- Local network connectivity to access the hospital FHIR repository and identity provider
- Internet connectivity for non-clinical operational telemetry to the manufacturer (device functions clinically without internet connection)
- All integration and updates performed by IT personnel must comply with healthcare facility policies and regulatory requirements to ensure safe and effective use

As a software-only medical device, PREVIA SEPSI SCORE has no physical storage or environmental condition requirements.

The PREVIA SEPSI SCORE solution is not intended:

- for use outside hospital settings (e.g., home monitoring).
- to replace clinical judgment; alerts should always be interpreted within the context of the patient's overall clinical condition.
- for use in limited environments where the necessary data is not reliably accessible; offline or disconnected operation is not supported.

1.8. Principles of operation and its mode of action

PREVIA SEPSI SCORE is a medical device software (SaMD) intended for monitoring the risk of sepsis in hospitalized adult patients. Its purpose is to support earlier clinical assessment by

providing a real-time risk score derived from routinely collected electronic health record (EHR) data. PREVIA SEPSI SCORE does not diagnose sepsis and does not replace clinical judgment; it merely provides additional information to support clinicians in their decision-making process.

The medical device comprises two software units that form the device boundary: back-previa (orchestration and data processing) and ai-previa (machine learning inference). The hospital FHIR repository, identity provider, and display systems are outside the device boundary and remain under hospital responsibility.

1.8.1. Principle of Operation

PREVIA SEPSI SCORE operates exclusively from structured EHR data. It does not rely on any external sensors, hardware components, or alternative data sources. All input data originate from information that healthcare professionals routinely review during standard patient management. The input source is unique and consists solely of structured demographic, physiological, and medical information available in hospital EHR systems. These data originate from known, validated sources that do not introduce new or altered risks when integrated into the software. Healthcare professionals would naturally access and interpret these same data elements to form an independent clinical opinion if the software were not available.

The software uses three main categories of input data. The first category includes temporal clinical data such as vital signs (heart rate, respiratory rate, systolic and diastolic blood pressure, oxygen saturation and temperature), laboratory values (creatinine, lactate, white blood cell count, platelets, bilirubin, diuresis, partial pressure of oxygen and fraction of inspired oxygen), and the level of consciousness as assessed by the Glasgow Coma Scale. The second category encompasses medical history and comorbidities derived from ICD-10 code groups. The third category includes demographic information such as age, gender and the month of admission. The selection of these variables was based on a review of existing scientific literature, complemented by expert clinical input, and guided by the relevance, quality and availability of each variable within EHR systems.

1.8.2. Data Processing

On an hourly cadence (approximately every 60 minutes), the system processes available data using predictive models to identify abnormal patterns or trends that might indicate a potential risk of developing sepsis. To identify these patterns or trends, the data is first processed to ensure that there are no disparities in the units used. For temporal data, the last value of each full hour is selected to define the patient's condition according to that variable at that precise time. For example, if 2 heart rate measurements are available at 16:23 and 16:47, then only the one at 16:47 is used to qualify the patient's heart rate at 17:00. These hour-binned measurements are then propagated forward up to the current time to create dense time series. For example, with heart rate measurements 62, 75 and 84 available respectively at 13:00, 15:00 and 18:00, for a score computation at 21:00, the time series for heart rate will hold the following values : 62, 62, 75, 75, 75, 84, 84, 84, 84. Afterwards, the last 12 timepoints, as specified by the time windows length parameter of the AI model, are selected to compute the mean, standard deviation, minimum, maximum, median and last value of this window. These

6 metrics computed for each of the 15 temporal variable windows accounts for 90 input features of the AI model. The gender variable is binarized such that a 0 represents a female patient and a 1 a male patient. The age variable is given as is. The month of hospital admission is given as an integer. Patient's comorbidities history is given through binary groups, if the patient has an ICD-10 code corresponding to a group, the value of this group is set to 1, otherwise it stays at 0. The 15 comorbidities groups were determined following the work of Shimabukuro et al., 2017.

1.8.3. Model Operation

The predictive model used within PREVIA SEPSI SCORE is an XGBoost classifier. It consists of a series of decision trees that iteratively split features at learned thresholds to estimate the probability that a patient's condition may evolve toward sepsis. All parameters, splits and thresholds within the model are learned during training. Once the probability is computed, it is compared with a predefined threshold. If the threshold is exceeded, PREVIA SEPSI SCORE generates a FHIR Communication resource that is transmitted to the hospital information system. Clinicians are then presented with an alert consisting of the risk score, the date and the time of generation. Alongside the risk probability, the system provides explainability information identifying the most influential clinical variables contributing to the risk assessment, supporting clinician interpretation. This alert merely indicates a potential risk of clinical deterioration. Before initiating any clinical intervention, a qualified healthcare professional must confirm the patient's condition through standard clinical assessment, and all subsequent medical decisions remain entirely under clinician responsibility.

PREVIA SEPSI SCORE integrates seamlessly into the clinical environment through HL7 FHIR interoperability, enabling automated data collection, structured data exchange and continuous hourly score computation. It is compatible with commonly used electronic health record systems and analyzes patient information in real time. The software relies on computationally derived features (statistical summaries of temporal vital signs and laboratory values) to estimate sepsis risk.

1.8.4. Mode of Action

The mode of action of PREVIA SEPSI SCORE is purely algorithmic and informational. The software acts by analyzing trends, patterns and deviations in routinely collected EHR data using a machine-learning model trained to recognize associations with sepsis outcomes. Based on these learned associations, PREVIA SEPSI SCORE estimates the probability that a patient may be progressing toward sepsis and provides this information to clinicians in the form of a risk score and, when applicable, an alert. PREVIA SEPSI SCORE does not act on the patient, does not influence or alter physiological processes and does not initiate or trigger any automated clinical intervention. Its effect is strictly limited to processing data and generating information intended to support, but never replace or drive, clinical decision-making. Clinicians are required to confirm any suspected condition through standard clinical examination, and PREVIA SEPSI SCORE does not modify existing clinical workflows but rather provides supplementary information that may assist in earlier recognition of potential deterioration.

2. Performance characteristics

Unless otherwise specified, the following performance characteristics summarize validated study results and associated targets; site-specific performance will be documented in the Site Configuration Report.

PREVIA SEPSI SCORE has demonstrated the following performances:

Performance characteristics		**Definition**
Clinical	Sensitivity	Mean sensitivity ± SD = 0.74 ± 0.02
	Specificity	Mean specificity ± SD = 0.93 ± 0.01
	Precision	Mean precision ± SD = 0.52 ± 0.03
Safety	False negative rate	Mean False negative rate ± SD = 0.26 ± 0.02
Technical	System Availability	The software is available 99.5% of the time (excluding scheduled maintenance). In case of critical issues, response and resolution time is under 60 minutes.
	Patient Data Protection	Patient identifiable information is fully protected and never included in system logs. All data processing follows secure validation procedures with no bypass allowed.
	Maintenance and Updates	Scheduled maintenance requires minimal downtime. All software updates are verified and tested before deployment to ensure system integrity.
	Clinical Data Standards	All clinical outputs use the international FHIR healthcare data standard. Patient clinical data from the EHR (including vital signs, labs data) is not stored locally on hospital servers, ensuring centralized data governance and security.
	Alert Management	Sepsis alert frequency is configured according to your hospital's agreement. The system ensures only one active alert per patient to avoid duplicate notifications. Alert logic is validated during system integration.
	Hospital Department Coverage	The software analyzes data from all patient departments agreed upon with your hospital.

2.1. Cybersecurity

PREVIA SEPSI SCORE operates entirely within the hospital network.

PREVIA SEPSI SCORE is designed to run entirely inside the hospital's IT environment and uses the hospital's usual login systems. Data exchanged with the software is protected by encrypted connections, and user accounts are restricted to the minimum access needed for their role. The software does not open new external access to patient data; only anonymized, aggregated technical information may be sent to PREVIA for maintenance and performance monitoring. System components are regularly updated and monitored for security, and technical logs are configured to avoid identifiable patient data while still allowing hospital IT teams to detect issues, investigate incidents, and restore normal operation safely.

Cybersecurity configuration (for example, network segmentation, access control, monitoring and incident response) is the responsibility of the hospital IT team and Integrator and is outside the control of Healthcare Physicians.

2.2. Compatibility

Compatibility is ensured in environments where the hospital IT infrastructure exposes the necessary data elements using FHIR-compliant APIs.

3. Warnings and precautions

The following warnings and precautions are provided to support safe clinical use of PREVIA SEPSI SCORE alerts by Healthcare Physicians.

Clinical responsibility and limits

- PREVIA SEPSI SCORE provides decision-support information only it does not replace clinical judgment. It does not confirm or exclude a diagnosis of sepsis.
- Alerts and scores must always be interpreted by qualified healthcare professionals within the full clinical context of the patient.
- The responsibility for patient care decisions remains with the healthcare provider at all times.
- The artificial intelligence model has been developed and validated on specific patient populations and clinical practices. Changes in patient characteristics, care protocols, or hospital information systems may affect device performance and require clinical reassessment of the relevance of generated alerts.
- While the model has been designed to generalize from training data, it may exhibit reduced performance in rare or atypical clinical situations that were not sufficiently represented during its development. The clinician's judgment must always take precedence over generated alerts.

Population limits

- The device only analyses data from adult patients.
- PREVIA SEPSI SCORE must not be used for paediatric patients.

Data quality and availability

- The quality of the data collected can influence the alerts generated. Incomplete, delayed or incorrect data in the electronic health record may lead to missing alerts or inappropriate alerts.
- In case of doubt about the patient's condition or about the plausibility of the alert, always prioritize a complete clinical assessment over the absence or presence of a PREVIA SEPSI SCORE alert.

System availability

- If you suspect that alerts are missing, delayed or not visible in your usual clinical system, follow your local hospital procedure for IT incidents and inform PREVIA technical support via the contact provided in section 9 or via your local IT team.

Cybersecurity

- Use of the software is only possible via the hospital intranet connection. PREVIA SEPSI SCORE does not support offline or disconnected operation.

4. User guide

4.1. Typical clinical workflow for Healthcare Physicians

Healthcare Physicians access PREVIA SEPSI SCORE alerts by logging into their usual hospital clinical information system; no additional PREVIA-specific user account or password is required, as user access is managed by the hospital's existing identity provider.

The steps below describe a typical use of PREVIA SEPSI SCORE alerts within a hospital information system. The exact visual appearance may differ depending on your local EHR or clinical application.

For detailed instructions on how to log in, access the alert inbox, or navigate within your local clinical application, please refer to the user guides of the interfaces (for example, EHR or alert dashboard) used in your hospital.

1. A PREVIA SEPSI SCORE alert is generated when the patient's sepsis risk exceeds the configured threshold. The alert is made available in your usual clinical system (for example, in a sepsis worklist, notification panel or patient banner) according to local configuration.

2. You open the patient's record from the alert entry in your clinical application. The alert context typically includes at least the risk score, the date and time of generation and the patient's identification and location.
3. You review the patient's clinical context (vital signs, laboratory results, medical history, current treatments and any other relevant information available in the EHR) together with the sepsis risk score.
4. Based on your clinical judgment and local sepsis protocols, you decide on appropriate actions (for example, clinical examination, additional investigations, initiation or adjustment of treatment, closer monitoring, or no immediate change).
5. You document your clinical assessment and the actions taken in the patient's record, following your hospital's usual documentation and sepsis management procedures. If your hospital system allows, you may also update the alert status according to local workflow.

4.2. Alert status and how to use it

The alert status indicates where the patient is in the sepsis work-up and treatment pathway. The exact labels in your clinical system may vary slightly, but they should follow the meanings below.

Healthcare Physicians should use alert statuses in a way that reflects their actual clinical decisions and actions and remains consistent with local sepsis protocols and documentation rules.

Status	What it means	When to use it (by Healthcare Physicians)
unknown	New alert created when PREVIA SEPSI SCORE detects a high risk of sepsis. No formal clinical review has been documented yet.	Initial status when an alert appears. Normally set automatically by the system when the risk score is above the alert threshold.
preparation	High-priority alert where PREVIA SEPSI SCORE has detected a high sepsis risk together with additional signs highly suggestive of sepsis (for example, criteria compatible with SEPSIS-3).	Treated as more urgent than unknown. Typically set automatically when predefined criteria are met. Use local sepsis protocol to guide rapid assessment and response.
in-progress	Sepsis work-up and/or treatment is underway. The alert has been acknowledged by healthcare physicians and active management for	After reviewing the alert and clinical context and starting appropriate actions (for example, clinical examination, investigations, antibiotics, ICU referral), change the alert to in-progress to indicate that sepsis management has started.

	suspected or confirmed sepsis is in progress.	
on-hold	The patient has been reviewed and, at this time, sepsis is not considered likely or no immediate action linked to the alert is required. The alert is parked but remains visible for follow-up.	After clinical review, when you judge that sepsis is unlikely or ruled out and no sepsis-specific intervention is started, set the alert to on-hold to show that it has been reviewed without triggering active sepsis management.
completed	The sepsis episode associated with the alert has been fully managed according to local protocol and no further sepsis-specific actions are expected.	When you have completed the planned sepsis work-up and treatment and consider that no further specific action related to this alert is required, change the status to completed so the alert can be archived as resolved.
not-done	The expected sepsis management pathway was not fully completed (for example, due to time elapsed without follow-up or changes in goals of care).	Often set automatically after a defined delay or at encounter end. If your local workflow allows manual use, set not-done only when you need to close an alert that cannot reasonably be taken further (for example, change of care objectives), in line with hospital governance.
stopped	The alert is no longer clinically active because the encounter ended before the sepsis episode was fully managed.	Usually set automatically when the encounter ends while the alert is still in an early state (unknown, preparation, or on-hold). Physicians normally do not need to change an alert to stopped manually.
entered-in-error	The alert was created by mistake (for example, test configuration, incorrect patient, or technical issue) and should not be interpreted as part of clinical sepsis management.	Used only in exceptional administrative situations and according to hospital procedures. If you suspect an alert was generated in error, follow local incident or IT processes rather than modifying this status yourself, unless explicitly authorised.

5. Handling abnormal situations, errors and failures/Malfunction of the device

If you encounter behaviour suggesting a malfunction (for example, unexpected absence of alerts in a clinical context where sepsis risk is suspected, repeated technical error messages in the clinical system related to PREVIA SEPSI SCORE, or apparently inconsistent scores),

follow your hospital's procedure for reporting IT or medical device incidents and contact PREVIA support at: support@previa-medical.com

5.1. General troubleshooting steps

Restart your clinical application: Close the application or browser you use to access patient records or alerts and reopen it to see if the issue resolves.

5.2. Error messages and their meanings

Depending on how PREVIA SEPSI SCORE is integrated, some technical error messages may be displayed by the hospital information system. Examples below are indicative; your local system may use different wording.

1. Error 404: Page Not Found
    - **Signification**: The requested resource could not be found on the server.
    - Measures to Take:
        - Check that you accessed the correct function in your clinical system (for example, patient record or alert list).
        - Try again or navigate back using your usual application controls
        - Contact local IT support or PREVIA support if the issue persists.

2. Error 500: Internal Server Error
    - **Signification**: An unexpected condition was encountered on the server.
    - Measures to Take:
        - Try repeating the action after a short delay.
        - If the problem persists, report the issue to your hospital IT support and mention that PREVIA SEPSI SCORE functionality may be affected.

3. Network Error
    - **Signification**: There was a problem with the network connection.
    - Measures to Take:
        - Check that you are connected to the hospital network according to local procedures.
        - If connectivity is confirmed but the problem persists, contact IT support.

4. Data Sync Error
    - **Signification**: The module failed to retrieve or sync data with the server.
    - Measures to Take:
        - Ensure that the clinical application you are using is functioning correctly.
        - If patient data or alerts appear incomplete or outdated, contact your IT support team and indicate that data synchronization with PREVIA SEPSI SCORE may be affected.

6. Maintenance, updates, and lifecycle information

Software installation and updates are under the responsibility of PREVIA MEDICAL. Software integration into hospital`s network is under the responsibility of the IT Integrator. A dedicated Instruction for Use is available for the Integrator.

Security updates and patches required to maintain the safety and performance of PREVIA SEPSI SCORE are mandatory. When PREVIA MEDICAL notifies your hospital of a security update, the hospital IT team and Integrators must apply it promptly in accordance with hospital change-control procedures, in order to minimize exposure to known vulnerabilities and to maintain compliant operation of the device.

The expected lifetime of PREVIA SEPSI SCORE, under the conditions described in this IFU and with regular updates and maintenance, is 3 years from initial deployment

End of life is reached when this version is no longer supported by the manufacturer (for example, after replacement by a newer major version or withdrawal from the market). Continued clinical use after end of support is not recommended. Your hospital IT team will be informed of supported versions and is responsible for coordinating upgrades with PREVIA MEDICAL.

7. Deinstallation

Uninstallation of PREVIA SEPSI SCORE is under the responsibility of the hospital IT service and IT Integrators. Any uninstallation or decommissioning activity must follow the hospital’s IT policies, change control procedures and data protection rules.

For technical uninstallation procedures, refer to the PREVIA SEPSI SCORE IFU for IT Integrators.

PREVIA SEPSI SCORE does not store clinical data outside the hospital FHIR server. Uninstallation of the software does not delete or modify patient data or clinical outputs already written to the hospital FHIR repository; these data remain governed by the hospital’s own retention, access and audit policies. If your hospital intends to remove or archive historical PREVIA SEPSI SCORE outputs, this must be managed according to local governance and regulatory requirements.

8. Data protection, privacy, and information management

All personally identifiable health data are read from and written to the hospital FHIR server; the device does not persist such data outside that server.

Identifiable patient data remain under the control of the hospital. PREVIA SEPSI SCORE may transmit anonymized and aggregated technical telemetry to PREVIA MEDICAL for maintenance, performance monitoring and post-market surveillance, in accordance with applicable data protection requirements and contracts between PREVIA MEDICAL and the hospital.

IT Integrators are responsible for enforcing the hospital's IT policy when configuring and operating PREVIA SEPSI SCORE within the hospital information system.

Clinical outputs produced by the device (RiskAssessment and Communication) are written to the hospital FHIR repository and are governed by the hospital’s retention, access, and audit policies.

9. Incidents

9.1. Serious Incident

Any serious incident that as occurred in relation to the device shall be reported to PREVIA MEDICAL and the competent authority of the Member State in which the user and/or the patient is established.

PREVIA MEDICAL must be contacted at the following email address:

- ⇨ complaints@previa-medical.com

The contacts points of the competent authorities are available on the website of the European Commission:

- ⇨ https://ec.europa.eu/tools/eudamed

In the event of a suspected or confirmed serious incident involving PREVIA SEPSI SCORE (for example, missing or delayed alerts, clearly inappropriate alerts, or a suspected security incident), Healthcare Physicians must continue to manage patients using standard clinical assessment and the hospital’s usual sepsis detection and treatment protocols, without waiting for or relying on PREVIA SEPSI SCORE alerts.

At a minimum, when reporting a serious incident or suspected serious incident related to PREVIA SEPSI SCORE, please provide through your hospital's usual escalation channels and to PREVIA MEDICAL:

- **Type of incident** (for example, missing alerts, false alerts, technical error, suspected security issue),
- **Product identification** (PREVIA SEPSI SCORE, model SEPSI-200, software version if known),
- **Clinical context of use** (department, approximate date and time, type of patients concerned), and
- **Brief description of the impact on clinical workflow** (for example, need to revert to manual monitoring or change in sepsis work-up or treatment).

In case of any doubt about a potential serious incident, please contact PREVIA MEDICAL at info@previa-medical.com.

9.2. Security Incident

In case of a suspected security incident (for example, suspected unauthorized access, data integrity concerns, abnormal behavior of alerts), you must also follow your hospital's information security incident procedures and, if there is any doubt about the reliability of PREVIA SEPSI SCORE alerts, rely on standard clinical practice until the situation has been clarified.

Healthcare Physicians and the hospital shall remain available to PREVIA MEDICAL to provide any additional information reasonably required to investigate the incident and to implement any corrective or preventive actions recommended by PREVIA MEDICAL or by the competent authority.

10. Paper copy

These instructions for use are provided in electronic format. A paper copy can be supplied on request free of charge.

It is possible to obtain a paper copy of these instructions for use in 7 calendar days by contacting us at support@previa-medical.com.

In the mail, you will need to provide us:

- A physical address to send this notice

- A contact name
- The following mention in the title: “Request for Paper Copy of Instructions for Use”

The paper copy contains the same content as the electronic instructions for use in effect on the date of printing.

For any questions about the content of this IFU or its availability to Healthcare Physicians through hospital systems, please contact your local PREVIA SEPSI SCORE Integrator or PREVIA MEDICAL via the support contact above.

11. Other Informations



Electronic Instruction for use
https://www.previa-medical.com/en/user-manual/



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A Privacy Policy is available at https://www.previa-medical.com/en/user-manual/

If you have any questions or concerns, please contact PREVIA MEDICAL at info@previa-medical.com

Features released in the latest software versions that may not be described in this document are covered in our release notes. In the event of any conflict between this document and the release notes, the release notes shall prevail.