PREVIA SEPSI SCORE

Instruction for Use (English)

IT Integrators

This document uses the term "IT Integrators" consistently to refer to hospital IT personnel responsible for technical integration of PREVIA SEPSI SCORE.

This instruction for use is intended for IT Integrators. This IFU provides instructions on how to integrate PREVIA SEPSI SCORE into the hospital's information system and make the sepsis risk alert available to healthcare physicians.

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. Key Terminology

- **SEPSI Score**: Proprietary machine learning-derived sepsis risk probability (0.0 to 1.0)
- **RiskAssessment**: FHIR resource recording calculated sepsis risk score
- **Communication**: FHIR resource representing an alert to clinicians
- **Encounter**: Hospital admission or visit during which monitoring occurs
- **Explainability**: AI-generated information identifying factors contributing to risk score
- **back-previa**: Orchestration software unit handling data retrieval, transformation, and FHIR writes
- **ai-previa**: AI inference software unit executing XGBoost model
- **PREVIA Monitor**: Cloud-based telemetry platform for post-market surveillance (operated by PREVIA MEDICAL)
- **Threshold**: Probability cutoff above which alerts are generated
- **MTTR**: Mean Time To Repair (average restoration time after incidents)

3. Technical 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 Characteristic	Definition
Algorithm Type	XGBoost gradient boosting classifier
Data Integration	FHIR R4 compliant
Analysis Cadence and Timeliness	One scheduled run per clock hour for all active inpatient encounters in connected departments. If a run is interrupted by restart, it is not retried; the next run starts at the next clock hour. Hourly cadence when healthy; no catch-up for interrupted hours.
FHIR Write Correctness	≥99% successful writes per month for RiskAssessment (scores) and Communication (alerts). Duplicate write detection enabled; duplicates do not impact clinical display as integrators filter by Communication status.

FHIR Read Conformance	Reads for Patient/Encounter/Observation/Condition conform to FHIR R4 profiles; ≥99% successful validated reads per month with zero profile/schema violations.
IAM and Transport Security	OAuth2/OIDC least-privilege scopes; 100% TLS 1.2+ with certificate validation for all FHIR calls; zero unauthenticated calls.
Availability and MTTR	≥99.5% monthly availability (excluding planned maintenance); continuous operation 24/7 when properly maintained. Availability measured on uptime and on-time start of the next hour, not on retro-processing missed windows. Missed hourly runs are not retro-processed; clinical behavior is based on prospective hourly execution only.
Endurance and Stability	Continuous operation without performance degradation or memory leaks; stable p95 latency and resource usage over extended periods.
Data Protection and Integrity	No local clinical database; logs contain no patient identifiers (zero PII in sampled logs); FHIR profile validation at write; read-modify-write updates to avoid lost updates; all clinical outputs persisted only in hospital FHIR repository.
Maintenance and Updates Integrity	Live update or minimal downtime; supply-chain integrity with digest pinning and provenance checks; optional egress via approved repositories or mirrors.
System-of-Record Convention	Persist clinical outputs only in hospital FHIR repository (RiskAssessment for scores, Communication for alerts); no local clinical data storage in database.
Alert Policy and Deduplication	Enforce single active alert per encounter at application level; alert rate monitored within site-agreed parameters.
Department Coverage	100% of hospital-agreed inpatient departments included in hourly score computation; department scope and exclusions (e.g., paediatrics, specialty units) documented in site configuration agreement.

3.1. Cybersecurity

3.1.1. General cybersecurity controls

PREVIA SEPSI SCORE implements defense-in-depth security controls:

Transport Security: All external communications use TLS 1.2 or higher to protect data in transit between back-previa, the hospital FHIR API, and the identity provider.

Access Control: OAuth2/OpenID Connect authentication with least-privilege scopes. Tokens are scoped to minimum permissions required for reading clinical inputs and writing RiskAssessment and Communication resources.

Network Isolation: back-previa and ai-previa communicate over an isolated container bridge network that is not routable from external segments. The device requires no inbound exposure from external networks.

Data Residency: All patient data remain within the hospital FHIR server. The device does not persist patient data outside the hospital's system of record.

Secrets Management: Operational credentials (API tokens, client secrets) are supplied through protected configuration mechanisms approved by the hospital. These credentials are stored on hospital-controlled, encrypted storage with restrictive file permissions, excluded from source control, and rotated according to hospital policy. Secrets are never embedded in container images or source code.

Logging without Patient Data: System logs exclude patient identifiers by design. Security-relevant events (authentication failures, repeated errors, abnormal patterns) are surfaced for review.

Vulnerability Management: Third-party components are monitored for known vulnerabilities with periodic scanning and remediation according to established timelines.

3.1.2. Network connectivity between back-previa and ai-previa

PREVIA SEPSI SCORE is deployed as two containerized software units (back-previa and ai-previa) that communicate over an isolated container network managed within the hospital infrastructure. This internal communication is part of the medical device boundary and must not be directly exposed to external network segments.

PREVIA Technical Support is responsible for installing and configuring the PREVIA SEPSI SCORE containers, including the internal connectivity between back-previa and ai-previa, as well as the associated technical health checks. During installation and software updates, PREVIA Technical Support verifies that back-previa can successfully reach the ai-previa endpoint before enabling routine clinical operation. If these internal checks fail, PREVIA SEPSI SCORE does not enter normal scoring mode and must not be considered operational.

The IT Integrator is responsible for providing a secure network environment that allows this internal communication to function correctly. In particular, the IT Integrator shall:

- ensure that the container runtime (for example, Docker or Kubernetes) can create and maintain an isolated bridge network between back-previa and ai-previa, without additional firewall blocking on the host;
- avoid introducing firewall or routing rules that would intermittently block or reroute traffic on this internal network;

- include the PREVIA SEPSI SCORE services in the hospital's standard supervision tools, so that loss of availability reported by PREVIA health checks is detected and escalated according to local procedures.

PREVIA SEPSI SCORE internal health checks are described in PREVIA Technical Support procedures and do not require any configuration by the IT Integrator, beyond the secure network environment described above.

3.1.3. IT Integrators Responsibilities

It is the responsibility of the IT Integrator to:

- Follow cybersecurity best practices to defend against potential attacks.
- Implement a robust backup plan and procedure to prevent server downtime and data loss.
- Conduct regular virus scans to protect the operating system from malware infections.
- Enforce a strong password policy to prevent unauthorized access.
- Implement encryption and data protection measures to safeguard sensitive information.
- Develop secure data transfer procedures to prevent loss of critical data.
- Adhere to privacy policies and data protection protocols to maintain patient confidentiality.
- Implement authentication best practices to prevent unauthorized system access.
- Establish a Distributed Denial of Service (DDoS) protection procedure to mitigate attacks.

4. Warning and precautions

The following warnings and precautions are provided to support safe installation and integration of PREVIA SEPSI SCORE.

Clinical responsibility and limits

- PREVIA SEPSI SCORE provides decision-support information only it does not replace clinical judgment.
- 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.

Population limits

- PREVIA SEPSI SCORE is intended only for adult patients (≥18 years).
- It must not be activated on paediatric populations.

Data quality, availability

- The quality, completeness, and timeliness of data in the hospital FHIR server directly affect alerts and scores. IT Integrators must ensure that required resources, codes, and units are available and consistent with Section 5.4.1, and that any major change to the FHIR API or coding systems triggers the verifications described in Section 6.1.

Cybersecurity

- PREVIA SEPSI SCORE is intended for use within hospital environments with secure intranet connectivity to the hospital FHIR server. Offline or disconnected operation is not supported.
- Unauthorized access to the deployment environment or FHIR API can compromise patient safety and data protection. IT Integrators must enforce hospital security policies (network segmentation, access control, monitoring, incident response) as described in the cybersecurity Section 3.1.
- In case of suspected malfunction of PREVIA SEPSI SCORE (for example, unexpected absence of alerts, repeated errors, or abnormal patterns), follow the troubleshooting steps in Section 6 and contact PREVIA technical support at support@previa-medical.com.
- In case of suspected virus or malware contact PREVIA technical support at support@previa-medical.com.

5. Software Installation and Integration

5.1. Responsibilities

PREVIA technical support is responsible to manage software installation.

IT Integrators are responsible to integrate the software into their information system and make the alert available to healthcare physicians.

The label is distributed by mail during the installation process to the Integrator (in PDF format). IT integrators shall ensure that the device label provided by Previa Medical is displayed within the user interface and remains accessible to end users.

5.2. Technical prerequisites

5.2.1. Hosting and Infrastructure

The hospital must provide:

1. **Virtual Machines**: Two on-premises Linux virtual machines (Ubuntu 20.04 LTS or 22.04 LTS):
    - Pre-production environment VM
    - Production environment VM
    - Minimum 8 GB RAM per VM
    - Minimum 100 GB disk space per VM
    - Cloud-based (Bare Metal) or self-hosted server
2. **Network Segmentation**:
    - Secure network segment for the application tier (back-previa) and model runtime tier (ai-previa)
    - Isolated container bridge network for communication between back-previa and ai-previa (not routable from external segments)
    - No inbound exposure from external networks required
    - Outbound access limited to: hospital FHIR API, hospital identity provider, and PREVIA Monitor (telemetry only)

5.2.2. FHIR R4 API Requirements

The hospital must provide a FHIR R4 compliant API with:

1. **Read Access** to the following clinical input resources:
    - Patient (identity linking)
    - Encounter (in-scope hospitalizations)
    - Observation (vital signs and laboratory values and blood culture results)
    - Condition (comorbidities and diagnoses)
    - MedicationRequest (relevant therapies)
    - DiagnosticReport (microbiology and blood culture results)
2. **Write Access** for device outputs:
    - RiskAssessment (computed sepsis risk scores)
    - Communication (alerts and lifecycle management)
3. **Authentication:** OAuth2/OpenID Connect authentication with least-privilege scopes. Access tokens are scoped to the minimum permissions required for reading clinical inputs and writing RiskAssessment and Communication resources, and are renewed per site policy to maintain service continuity.

4. **Data Availability**: Required clinical data elements must be available in structured, coded format through the FHIR API.
5. **Compatibility:** Compatibility is ensured in environments where the hospital IT infrastructure exposes the necessary data elements using FHIR-compliant APIs. Pre-production and production environments must expose structurally equivalent FHIR resources and coding for all PREVIA SEPSI SCORE inputs and outputs, even if pre-production operates on a reduced data set.

5.3. Software Installation

Installation is performed by PREVIA technical support. The Integrator's role is to prepare the environment and coordinate integration.

5.3.1. Alert Threshold Calibration (Site-Specific)

Purpose: The alert generation threshold determines when PREVIA SEPSI SCORE creates a Communication resource to notify clinicians of elevated sepsis risk. Threshold calibration balances sensitivity (detecting true sepsis cases) against positive predictive value (minimizing false alerts).

Calibration Process:

During installation, PREVIA technical support performs retrospective score calculation on historical patient data (typically 3-6 months) from the hospital. Based on this analysis:

1. **Sensitivity Target**: Threshold is set to achieve minimum 70% sensitivity
2. **PPV Optimization**: Among thresholds meeting sensitivity target, the value with highest positive predictive value is selected
3. **Typical Threshold Range**: 0.70 to 0.90 probability

Performance Trade-offs at Different Sensitivity Thresholds as indication value:

Sensitivity	Threshold (approx.)	Expected Sensitivity	Expected Specificity	Expected PPV	Alert Volume	Clinical Impact
90%	~0.60-0.70	≥90%	~93-95%	0.40-0.50	High	Maximum case detection; higher false alert burden on healthcare physicians
80% (Target)	~0.70-0.80	≥80%	~96-97%	0.55-0.65	Moderate	Balanced sensitivity/PPV; meets regulatory requirement
70%	~0.80-0.90	~70-75%	~98%	0.65-0.75	Low	High precision; some missed

						cases; below regulatory target

Post-Deployment Adjustment:

After 3-6 months of clinical use, PREVIA technical support may recommend threshold re-calibration based on:

- Observed false positive rate and clinical feedback from healthcare physicians
- Alert acknowledgment patterns
- Changes in patient population or data quality

Threshold adjustments require configuration update and PREVIA technical support coordination.

Integrator Notification:

The calibrated threshold value will be documented in the Site Configuration Report provided after installation. The Integrator should retain this documentation for reference.

5.3.2. Recommended OAuth2 / OpenID Connect configuration and FHIR scopes

PREVIA SEPSI SCORE accesses the hospital FHIR server via a technical account (client) configured in the hospital's identity provider (IdP) (for example, Keycloak, Azure AD, or another OpenID Connect / OAuth2 server). To limit security risks, PREVIA SEPSI SCORE should be granted only the minimum set of permissions (least-privilege principle) required to operate.

5.3.2.1. Technical client for PREVIA SEPSI SCORE

The hospital IT Integrator shall create a dedicated confidential client (for example, previa-sepsi-score) in the IdP:

1. Authentication method: client credentials or another server-to-server flow agreed with the hospital.
2. Redirect URIs: not applicable for pure server-to-server flows, unless required by the IdP.
3. Client secret: generated and stored according to the hospital's security policy (encrypted store, restricted access).

5.3.2.2. Recommended read permissions (FHIR scopes)

Grant only the scopes required to read input data:

1. patient.read – access to the patient's administrative identifiers required for identity matching, as well as certain patient data (age, sex, and date of death where applicable.
2. encounter.read – access to encounter metadata (admission/discharge dates, wards).
3. observation.read – access to vital signs and laboratory results used by PREVIA SEPSI SCORE.
4. condition.read – access to existing comorbidities/diagnoses (for example, ICD-10).
5. medicationrequest.read (if applicable) – access to medication orders when part of the input set.
6. diagnosticreport.read (if applicable) – access to relevant diagnostic reports (for example, blood cultures).

These scopes must be aligned with the actual FHIR server implementation. If the server uses different scope naming, an equivalent least-privilege set must be defined in collaboration with the hospital IT Integrator.

5.3.2.3. Recommended write permissions (FHIR scopes)

PREVIA SEPSI SCORE only needs to write the following resources:

1. riskassessment.write – for SEPSI, SOFA and SEPSIS-3 RiskAssessment resources.
2. communication.write – for sepsis Communication resources containing the alerts and their status.

No write permission is required on core clinical resources such as Patient, Encounter, Observation, Condition, MedicationRequest, or DiagnosticReport.

5.3.2.4. Scope verification and testing

Before go-live, the IT Integrator should:

1. Configure the technical client with the recommended scopes (or their local equivalent).
2. Use the provided installation test scripts or health-check endpoints to verify that read access is possible only on the expected resources, and that PREVIA SEPSI SCORE can successfully create and update RiskAssessment and Communication resources.
3. Confirm that any broader or unnecessary scopes are not granted to the PREVIA SEPSI SCORE technical client.

5.3.3. Pre-Installation Phase (IT Integrator Responsibilities)

The IT Integrator is responsible for preparing the environment before PREVIA SEPSI SCORE is installed:

1. Ensure all technical prerequisites are met:
   - VMs provisioned with correct specifications
   - FHIR R4 API accessible with required read/write permissions
   - OAuth2/OpenID Connect or Active Directory authentication configured
2. Provide PREVIA technical support with:
   - Necessary credentials and access tokens (stored on encrypted, hospital-controlled storage)
   - FHIR API base URL and identity provider endpoints
   - Network access to FHIR API and identity provider
3. Coordinate with hospital IT security, network, and clinical teams

5.3.4. Installation Phase (PREVIA Technical Support Responsibilities)

PREVIA technical support will:

1. Deploy containerized services (back-previa and ai-previa) from GitHub Packages to hospital VMs
2. Configure the protected configuration mechanism with:
   - Hospital-specific endpoints (FHIR API, identity provider, PREVIA Monitor)
   - Model selection parameters (model_name, model_version, feature set identifier)
   - Threshold policy for alert generation (calibrated to achieve ≥70% sensitivity)
3. Execute **FHIR API - Structure Control**:
   - Verify presence of required FHIR resources
   - Verify structural compatibility with FHIR R4 standard
   - Test API routes for search, read, and write operations
4. Execute **FHIR API - Data Quality Control**:
   - Verify compatibility with international coding standards (ICD-10, LOINC, etc.)
   - Assess presence and quality of data required for score calculation
   - Validate value ranges, frequencies, and units
5. Perform **retrospective score calculation** to validate performance in the facility context
6. **Calibrate alert threshold** based on local retrospective data to ensure minimum 70% sensitivity
7. Install and configure monitoring agent for PREVIA Monitor telemetry

5.3.5. Post-Installation Phase (Integrator Responsibilities)

After installation, the IT Integrator is responsible for ensuring that PREVIA SEPSI SCORE outputs are correctly integrated and that the environment remains operational:

1. **Configure downstream integration**: Ensure RiskAssessment and Communication resources created by PREVIA SEPSI SCORE are accessible to healthcare physicians through:

   - EHR display integration
   - Clinical workflow applications
   - Alert notification systems (as appropriate)

2. **Coordinate operational monitoring**: Establish communication channels with PREVIA technical support to receive alerts when:

   - System availability drops below 99.5% target (excluding planned maintenance)
   - Authentication failures occur repeatedly
   - Data quality issues are detected
   - Performance anomalies are identified

   The Integrator should respond promptly to system health alerts, coordinate troubleshooting and root cause analysis, and escalate to hospital IT security, network, or clinical informatics teams as needed.

3. **Provide end-user guidance**:

   Ensure healthcare physicians understand how to:

   - Interpret sepsis risk scores (RiskAssessment resources)
   - Read alerts (Communication resources)
   - Escalate technical issues

4. **Maintain operational environment**:

   - Enforce hospital IT security policies
   - Maintain network connectivity and firewall rules
   - Ensure backup and disaster recovery procedures are in place

PREVIA MEDICAL recommends conducting verification tests following device integration and maintaining records of these tests to ensure proper operation.

5.4. FHIR Resource Specifications for Integration

5.4.1. Required Clinical Data Elements and Coding Standards

PREVIA SEPSI SCORE requires specific clinical data elements to be available through the hospital FHIR API. The following tables specify required FHIR resources, data elements, and expected coding standards.

Observation Resources (Vital Signs):

Data Element	LOINC Code	Expected Unit	FHIR Profile
Heart Rate	8867-4	beats/min (bpm)	vital-signs
Respiratory Rate	9279-1	breaths/min (/min)	vital-signs
Systolic Blood Pressure	8480-6	mmHg (mmHg, mm[Hg] or mercury millimeter)	blood-pressure
Diastolic Blood Pressure	8462-4	mmHg (mmHg, mm[Hg] or mercury millimeter)	blood-pressure
Oxygen Saturation (SpO2)	2708-6	% (% or percent)	oxygen-saturation
Body Temperature	8310-5	°C (°C or degree Celsius or Cel or °F)	body-temperature
Glasgow Coma Scale	9270-0	score (3-15)	observation

Observation Resources (Laboratory Values):

Data Element	LOINC Code	Expected Unit	Notes
Creatinine	2160-0	mg/L (mg/L or µmol/L or mg/dL)	Serum/Plasma
Lactate	2518-9	mg/L (mmol/L or mg/L)	Serum/Plasma/Blood
White Blood Cell Count	6690-2	/mm3 (/mm3 or K/mm3)	-
Platelet Count	777-3	/mm3 (10^9/L or 10^3/µL or /mm3 or K/mm3)	-
Bilirubin (Total)	1975-2	mg/L (mg/dL or µmol/L or mg/L)	-
Urine Output (Diuresis)	9192-6	mL (mL or L)	-
Partial Pressure of Oxygen (PaO2)	2703-7	mmHg (mmHg, mm[Hg] or mercury millimeter)	Arterial blood
Fraction of Inspired Oxygen (FiO2)	3150-0	% (% or percent)	-

Unit Conversion:

PREVIA SEPSI SCORE automatically converts units to standardized internal representations. Supported conversions include:

- Temperature: °F → °C
- Lactate: mmol/L → mg/L
- Creatinine: µmol/L → mg/L, mg/dL → mg/L
- Bilirubin: µmol/L → mg/L, mg/dL → mg/L
- Diuresis: L → mL

Data Quality Requirements:

For optimal performance:

- Vital signs updated at least every 4 hours for hospitalized patients
- Laboratory values available within 24 hours of collection
- Comorbidity history (ICD-10 codes) documented in patient record
- Missing data: The system uses forward-filling to handle missing values in the 12-hour temporal window

FHIR API Data Verification:

During installation, PREVIA technical support performs data quality verification per Section 6.1. The Integrator should coordinate with clinical informatics teams to:

- Ensure LOINC codes are correctly mapped in the hospital system
- Verify units are consistently reported
- Validate that required data elements are being captured

5.4.2. RiskAssessment Resource Structure

5.4.2.1. RiskAssessment resource types and purpose

PREVIA SEPSI SCORE creates HL7 FHIR RiskAssessment resources to record calculated sepsis risk scores for each patient evaluation cycle. The system generates **three types of RiskAssessment resources**:

1. **SEPSI Score RiskAssessments**: Proprietary machine learning-derived sepsis risk probability (method code: "SEPSI_SCORE")
2. **SOFA Score RiskAssessments**: Sequential Organ Failure Assessment score for clinical severity evaluation (method code: "SOFA_SCORE")
3. **SEPSIS-3 Detection RiskAssessments**: Clinical sepsis confirmation based on SOFA score ≥2 points combined with positive blood culture (method code: "SEPSIS-3")

These three types cover all sepsis-related scoring outputs in current PREVIA SEPSI SCORE deployments.

All RiskAssessment types created by PREVIA SEPSI SCORE share the same core fields and method.coding convention and are generated hourly for each eligible patient encounter in the hospital FHIR repository.

5.4.2.2. Core RiskAssessment resource structure, method and performer

5.4.2.2.1. RiskAssessment Resource Structure

Mandatory Fields:

- resourceType: "RiskAssessment"
- id: Unique identifier assigned by the hospital FHIR server
- status: "final" (score calculation completed)
- subject: Reference to Patient resource
- encounter: Reference to Encounter resource
- occurrenceDateTime: Timestamp when score was calculated (ISO 8601 format)
- performer: Reference to PREVIA SEPSI SCORE device
- method: Distinguishes between score types:
    - SEPSI Score: method.coding.code = "SEPSI_SCORE"
    - SOFA Score: method.coding.code = "SOFA_SCORE"
    - SEPSIS-3 Detection: method.coding.code = "SEPSIS-3"
- prediction: Array containing:
    - outcome: CodeableConcept ("Sepsis risk" for SEPSI Score, "SOFA score" for SOFA Score, "SEPSIS-3 detected" for SEPSIS-3 Detection)
    - probabilityDecimal: Score value
        - SEPSI Score: 0.0 to 1.0 (probability)
        - SOFA Score: 0 to 24 (integer severity score)
        - SEPSIS-3 Detection: 0.0 or 1.0 (binary: criteria not met / criteria met)
    - rationale: JSON payload describing the explainability data for the score (contributing clinical factors and their impact, see Section 5.4.5 for more details)

Optional Fields (Explainability):

- basis: Array of references to input Observation and Condition resources used for score calculation

5.4.2.2.2. Method coding convention for all PREVIA SEPSI SCORE RiskAssessments

For all RiskAssessment resources created by PREVIA SEPSI SCORE, the primary method.coding element uses the following convention for its code value:

RETROSPECTIVE/SEPSI_SCORE_v2.0.0 or PROSPECTIVE/SEPSI_SCORE_v2.0.0, where:

- The prefix indicates the study type: RETROSPECTIVE/ or PROSPECTIVE/
- The suffix indicates the software version (e.g. v2.0.0)

In current production deployments, PROSPECTIVE/SEPSI_SCORE_v2.0.0 is used for live scoring; retrospective prefixes are reserved for study configurations.

5.4.2.2.3. Performer (device identification):

For all RiskAssessment resources created by PREVIA SEPSI SCORE, the performer element references the PREVIA SEPSI SCORE device (for example, Device/PREVIA_SEPSI_SCORE). This ensures that downstream systems can consistently identify the medical device that produced the score and align it with the corresponding Communication.sender.

5.4.2.3. SOFA Score Calculation

The SOFA (Sequential Organ Failure Assessment) score is calculated based on six organ system dysfunction parameters:

- **Respiratory**: PaO2/FiO2 ratio
- **Cardiovascular**: Blood pressure and vasopressor requirements
- **Hepatic**: Bilirubin level
- **Coagulation**: Platelet count
- **Renal**: Creatinine or urine output
- **Neurological**: Glasgow Coma Scale

Each parameter is scored from 0 (normal) to 4 (most abnormal), resulting in a total SOFA score ranging from 0 to 24.

5.4.2.4. SEPSIS-3 Detection

PREVIA SEPSI SCORE automatically detects SEPSIS-3 criteria, defined as:

- **SOFA Score ≥ 2**: one SOFA score ≥ 2 AND

- **Positive Blood Culture**: Confirmed positive blood culture result (retrieved from DiagnosticReport resources)

When both conditions are met during the same encounter, the system identifies SEPSIS-3 and may adjust alert priority from unknown to preparation status (see Section 5.4.4).

5.4.2.5. Integration Requirements for RiskAssessment consumption

Integrators should ensure that downstream clinical applications can:

- Distinguish between SEPSI Score, SOFA Score, and SEPSIS-3 Detection RiskAssessments using the method field
- Display the sepsis risk probability (SEPSI Score) prominently
- Display SOFA scores for clinical severity context
- Highlight SEPSIS-3 detection when criteria are met
- Show the calculation timestamp for both score types
- Link to associated Communication resources (alerts)
- Display explainability information to healthcare physicians (see Section 5.4.5)
- Provide context by linking to input clinical data referenced in basis field

5.4.3. Communication Resource (Alerts)

PREVIA SEPSI SCORE creates and updates HL7 FHIR Communication resources to represent sepsis risk alerts. These resources follow the Communication lifecycle and contain structured clinical information for integration into hospital systems.

5.4.3.1. Communication Resource Structure

Communication resources created by PREVIA SEPSI SCORE represent sepsis alerts for a given patient encounter. Each alert instance is stored as a FHIR Communication resource on the hospital FHIR server with the following mandatory content.

Mandatory Fields:

- **resourceType**: "Communication"
- **id**: Unique identifier assigned by the hospital FHIR server
- **status**: Alert lifecycle status (see Section 5.4.4)

- **category**: CodeableConcept with coding system for alert type
- **topic**: CodeableConcept describing the clinical topic of the alert
- **priority**: "routine" | "urgent" | "asap" | "stat"
- **subject**: Reference to Patient resource
- **encounter**: Reference to Encounter resource
- **recipient**: At least one reference to the intended clinical service or recipient
- **sender**: Reference to the PREVIA SEPSI SCORE device (for example, Device/PREVIA_SEPSI_SCORE)
- **reasonReference**: Reference to the associated RiskAssessment resource (the SEPSI Score on which the alert was based when it was created)
- **medium**: At least one element describing the communication medium (for example, "EHR inbox" or equivalent local term)
- **sent**: Timestamp when alert was generated (ISO 8601 format)
- **payload**: Alert content including:
    - **contentString**: Human-readable alert message

Optional Fields:

- **note**: Free-text comments or additional information related to the alert
- **received**: Timestamp when the alert was received by the down

These elements ensure that downstream systems can reliably identify PREVIA SEPSI SCORE alerts, link them to the corresponding patient encounter and RiskAssessment, and display them in clinical workflows.

5.4.3.2. Sender (device identification)

For all Communication resources created by PREVIA SEPSI SCORE, the sender element is set to the PREVIA SEPSI SCORE device (for example, Device/PREVIA_SEPSI_SCORE). This allows downstream systems to reliably identify alerts originating from the PREVIA SEPSI SCORE medical device and to distinguish them from other alert sources.

5.4.3.3. Alert detection mechanisms (polling vs subscriptions)

PREVIA SEPSI SCORE writes Communication resources to the hospital FHIR server. Hospital systems may detect these alerts either by periodic polling of the Communication endpoint or

by using FHIR Subscriptions or equivalent push mechanisms supported by the local FHIR server. The choice of mechanism is under the responsibility of the hospital and its IT Integrators.

5.4.3.4. Recommended polling interval and example queries

IT Integrators are responsible for configuring how downstream systems detect new or updated Communication resources written by PREVIA SEPSI SCORE. When FHIR Subscriptions or equivalent push mechanisms are not available or not used, PREVIA recommends implementing periodic polling with an interval of 5–15 minutes, balancing timeliness of alert display with load on the hospital FHIR server.

Typical polling strategy:

- Query only Communications created or last updated since the previous poll (for example, using _lastUpdated and a sliding time window with a small overlap, such as 1–2 minutes) and/or
- Filter by sender to restrict to PREVIA SEPSI SCORE alerts and/or
- Filter by status to focus on active alerts (for example, unknown, preparation, in-progress).

Example FHIR queries (to be adapted to local server capabilities):

- GET [base]/Communication?sender=Device/PREVIA_SEPSI_SCORE&_lastUpdated=gt{timestamp_minus_15min}&status=unknown,preparation,in-progress
- GET [base]/Communication?encounter={encounterId}&sender=Device/PREVIA_SEPSI_SCORE&status=unknown,preparation,in-progress

When the hospital FHIR server supports Subscriptions or equivalent mechanisms, IT Integrators may instead configure push notifications on new/updated PREVIA SEPSI SCORE Communications. In that case, the recommended alert timeliness target (5–15 minutes from Communication creation to clinician visibility) remains applicable.

5.4.3.5. Integration test scenarios for alert visibility

Before go-live, IT Integrators shall verify that alerts generated by PREVIA SEPSI SCORE are reliably visible in clinicians' usual applications within the expected delay. At minimum, the following test scenarios should be executed in the pre-production environment and, where feasible, in production with test patients:

1. **End-to-end alert creation and display (happy path):**

- PREVIA SEPSI SCORE creates a test Communication resource for a test encounter (for example, using a controlled test configuration or a known retrospective case).
- The Integrator confirms that the alert appears in the clinician UI (EHR inbox, worklist, or banner) within the configured polling interval (target: ≤15 minutes).

2. **Filtering and status handling:**

   - Verify that only PREVIA SEPSI SCORE alerts (sender = Device/PREVIA_SEPSI_SCORE) appear in the dedicated sepsis alert view or worklist.
   - Change Communication.status (for example, to in-progress or on-hold) via the clinician UI and confirm that the updated status is reflected correctly in both the UI and the underlying FHIR resource.

3. **Multiple alerts and noise control:**

   - Generate multiple test alerts across different encounters and confirm that the UI displays them in a way that remains usable (sorting, grouping, or filtering), consistent with local workflow design.

The completion of these scenarios and their expected results should be documented in the site-specific test report or Site Configuration Report, and retained with the hospital's integration documentation.

5.4.3.6. Integration Requirements for Communication consumption

Integrators must ensure that downstream systems (EHR displays, alert notification systems) can display and manage Communication resources. For detailed alert status lifecycle information, see Section 5.4.4 Alert Status Management.

5.4.4. Alert Status Management

PREVIA SEPSI SCORE implements a structured alert lifecycle through the FHIR Communication resource. Each alert progresses through defined statuses based on clinical review and automatic time-based rules. Understanding these statuses is essential for proper integration and display in hospital systems.

Communication Resource Status Values:

Status	Display Term	Description	Trigger	Expected Integrator Action

unknown	Pending Review	Alert created when SEPSI Score exceeds threshold without Sepsis-3 criteria	Automatic: Score > threshold, no Sepsis-3	Display to healthcare physicians for initial assessment
preparation	Pending Verification	Alert created when SEPSI Score exceeds threshold with Sepsis-3 criteria met	Automatic: Score > threshold + Sepsis-3 present	Display to healthcare physicians with elevated priority
on-hold	Deferred	Healthcare physician assessed and determined no immediate sepsis risk	Manual: Healthcare physician action OR Automatic: 72h elapsed without action	Display with lower priority; may be reactivated
in-progress	Active	Healthcare physician confirmed sepsis risk and initiated clinical response	Manual: Healthcare physician confirmation	Display prominently; track response actions
completed	Resolved	Healthcare physician completed sepsis management protocol	Manual: Healthcare physician completion	Archive; retain for audit and reporting
not-done	Incomplete	Alert closed without full protocol completion	Automatic: 30 days in in-progress OR encounter ended while in-progress	Archive; flag for quality review
stopped	Cancelled	Alert closed due to encounter termination before clinical action	Automatic: Encounter ended while in unknown, preparation, or on-hold	Archive; no action required
entered-in-error	Error	Alert created in error (rare, administrative correction only)	Manual: Administrative correction	Remove from clinical display; retain in audit log

Alert Lifecycle Workflow:

PREVIA SEPSI SCORE currently uses only the Communication.status values listed in the table above; the device does not set any other status codes.

1. **Initial Creation** (Automatic and managed by PREVIA SEPSI SCORE):
   - If SEPSI Score > alert_threshold AND Sepsis-3 criteria NOT met → Status: unknown
   - If SEPSI Score > alert_threshold AND Sepsis-3 criteria met → Status: preparation
2. **Healthcare Physician Assessment** (Manual actions):

- Healthcare physician reviews alert → Can change to on-hold (no risk) or in-progress (risk confirmed)
- Healthcare physician completes protocol → Changes to completed

3. **Time-Based Transitions** (Automatic and managed by PREVIA SEPSI SCORE):

- 72 hours without action: unknown or preparation → on-hold
- 48 hours in on-hold + new score > threshold → Reset to unknown or preparation
- 30 days in in-progress → not-done
- Encounter ends: Pending alerts → stopped; Active alerts → not-done

Integrator Implementation Guidance:

- Hospital clinical applications that display PREVIA SEPSI SCORE alerts enforce required fields and confirmation steps for alert status changes.
- Role-based access in these applications ensures only authorised users can change alert status.
- An audit trail of alert status changes is maintained by the hospital information system.
- Poll Communication resources or implement push notifications for status changes
- Display active alerts (unknown, preparation, in-progress) prominently in healthcare physician workflows
- Provide healthcare physicians with interface controls to update status (on-hold, in-progress, completed)
- Archive terminal statuses (completed, not-done, stopped, entered-in-error) for audit and reporting
- Configure alert aging policies that are consistent with the automatic status transitions at 72 hours and 30 days, defining when an alert moves from an active state (unknown / preparation / in-progress) to an archived state (on-hold, completed, not-done, stopped, entered-in-error) and how it is removed from clinical worklists.

Status groupings for display:

or display purposes, alerts SHOULD be grouped as follows:

- **New alerts to be handled as a priority**: unknown, preparation
- **Alerts under follow-up**: in-progress
- **Pending alerts**: on-hold
- **Other alerts**: completed, not-done, stopped, entered-in-error (optional display, and grouping may be adapted according to the hospital's needs).

Only new alerts to be handled as a priority and alerts under follow-up SHOULD be displayed in high-priority worklists.

Use of additional Communication.status values (out of scope of this device):

PREVIA SEPSI SCORE uses the status values listed in this section. Healthcare facilities MAY configure additional local alert lifecycle states or mappings (for example, EHR-specific "acknowledged" or "reviewed" flags) as part of their own clinical workflow design. Such local extensions are outside the scope of this IFU and remain under the responsibility of the healthcare facility and its IT Integrators.

5.4.5. Explainability Information in RiskAssessment Resources

PREVIA SEPSI SCORE provides AI-generated explainability information that identifies which clinical factors and score components contributed most significantly to the calculated sepsis risk score. This information supports healthcare physician understanding and clinical decision-making.

Explainability Data Structure:

Explainability information is stored in the RiskAssessment resource's prediction.rationale sub-property for SEPSI Score and SOFA Score RiskAssessments. No additional explainability information is stored for SEPSIS-3 Detection RiskAssessments.

- For **SEPSI Score RiskAssessments**, prediction.rationale contains a structured representation of SHAP (SHapley Additive exPlanations) values for the main input features (for example: lactate, heart rate, blood pressure, respiratory rate, temperature, white blood cell count, creatinine, bilirubin).
- For **SOFA Score RiskAssessments**, prediction.rationale contains the detailed decomposition of the SOFA score by component (respiratory, cardiovascular, hepatic, coagulation, renal, neurological).

Example: SHAP-based explainability for SEPSI Score:

For SEPSI Score RiskAssessments, PREVIA SEPSI SCORE uses SHAP values to quantify the contribution of each feature to the predicted risk. A typical explanation includes, for the current patient and time window, a ranked list of features with their direction and magnitude of impact on the score (for example, elevated lactate and tachycardia increasing risk, normal blood pressure decreasing risk).

Example: Component-level explainability for SOFA Score:

For SOFA Score RiskAssessments, PREVIA SEPSI SCORE records the contribution of each SOFA organ system component in prediction.rationale (respiratory, cardiovascular, hepatic, coagulation, renal, neurological). This allows downstream systems to display both the total SOFA score and its decomposition by organ system.

Integration Recommendations:

IT Integrators should:

- Parse and display explainability structures from RiskAssessment prediction.rationale for SEPSI Score and SOFA Score RiskAssessments
- Present top contributing factors (typically 3-5) alongside the sepsis risk score
- Use human-readable display_name values for healthcare physician-facing displays
- Provide visual indicators (e.g., arrows, color coding) for contribution direction
- Link contributing factors to current patient values in the EHR for context

Clinical Interpretation Guidance:

Healthcare physicians should use explainability information to:

- Understand which clinical observations are driving the risk score
- Validate that the model's assessment aligns with clinical judgment
- Identify specific areas for clinical intervention
- Recognize potential data quality issues (e.g., erroneous lab values)

5.4.6. Clinical Information Content in Output Resources

This section describes the complete clinical information workflow from score calculation through alert generation and healthcare physician action.

RiskAssessment Resource (Score Recording):

PREVIA SEPSI SCORE creates three types of RiskAssessment resources hourly:

SEPSI Score RiskAssessment (when above recording threshold):

- **Sepsis Risk Probability**: Decimal value (0.0 to 1.0) representing likelihood of sepsis development within 48 hours
- **Calculation Timestamp**: Exact date/time when score was computed
- **Patient Context**: References to Patient and Encounter resources
- **Input Data References**: Links to Observation and Condition resources used in calculation (via basis field)

- **Explainability Data**: Top contributing clinical factors with LOINC codes and contribution scores (see Section 5.4.5)

SOFA Score RiskAssessment:

- **SOFA Score Value**: Integer value (0 to 24) representing organ dysfunction severity
- **Organ System Subscores**: Breakdown by respiratory, cardiovascular, hepatic, coagulation, renal, and neurological systems (stored in rationale field)

SEPSIS-3 Detection RiskAssessment:

- **SEPSIS-3 Criteria Status**: Binary value (0.0 = criteria not met, 1.0 = criteria met)
- **Detection Logic**: SEPSIS-3 criteria are met when BOTH conditions are satisfied:
  - **SOFA Score ≥ 2**: one SOFA score ≥ 2 AND
  - **Positive Blood Culture**: Confirmed positive blood culture result (retrieved from DiagnosticReport resources)
- **Clinical Impact**: When SEPSIS-3 criteria are met during an encounter, the system may adjust Communication alert priority from unknown to preparation status (see Section 5.4.4)

Communication Resource (Alert Generation):

When the sepsis risk score exceeds the alert threshold, PREVIA SEPSI SCORE creates a Communication resource containing:

- **Alert Status**: Current lifecycle state (see Section 5.4.4 for complete status table)
- **Priority Level**: Clinical urgency indicator (routine, urgent, asap, stat)
- **Alert Message**: Human-readable text describing the sepsis risk
- **Associated Score**: Reference to the RiskAssessment resource
- **Patient and Encounter Context**: References for clinical workflow integration
- **Timestamp**: When the alert was generated

Workflow Integration:

1. **Score Calculation** (hourly): RiskAssessment created for each patient with sufficient data
2. **Alert Generation** (threshold-based): Communication created when score exceeds calibrated threshold
3. **Healthcare Physician Display**: Integrator systems display active alerts (status: unknown, preparation, in-progress) in EHR

4. **Clinical Review**: Healthcare physician reviews alert, score, and explainability data
5. **Action and Documentation**: Healthcare physician updates alert status based on clinical assessment and intervention
6. **Lifecycle Management**: System automatically transitions alerts based on time rules and encounter status

Required Integrator Capabilities:

To fully support healthcare physicians, the Integrator must ensure downstream systems can:

- Retrieve and display RiskAssessment resources with current scores
- Retrieve and display Communication resources with appropriate urgency indicators
- Show explainability information from RiskAssessment notes
- Link alerts to associated scores and input clinical data
- Provide healthcare physicians, through hospital clinical applications, with controls to update Communication status in a guided and auditable way (for example, stepwise workflow, confirmation prompts, role-based access)
- Update displays in near real-time when new alerts or scores are created
- Archive completed/cancelled alerts while retaining audit trail

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

If you require any support please contact us at: support@previa-medical.com

6.1. FHIR API Verifications

To ensure safe and interoperable use of PREVIA SEPSI SCORE, PREVIA technical support performs FHIR API verifications in collaboration with the hospital IT Integrator and, where applicable, clinical informatics / data teams. These checks MUST be completed during initial installation (see Section 5.3) and whenever the hospital FHIR API, coding systems, or infrastructure undergo significant changes.

6.1.1. FHIR API – Structure Control

The objective of Structure Control is to confirm that the hospital FHIR API exposes all resources and operations required by PREVIA SEPSI SCORE, with structures compatible with the FHIR R4 profiles used by the device.

PREVIA technical support, with support from the IT Integrator, shall verify that:

- The FHIR API exposes the resources required by PREVIA SEPSI SCORE as specified in Section 5.3.2.2 (Patient, Encounter, Observation, Condition, MedicationRequest, DiagnosticReport, RiskAssessment, Communication).
- The structure of these resources (profiles, mandatory elements, data types) is compatible with the FHIR R4 standard and with the requirements described in Section 5.4.
- All required API routes are accessible with the PREVIA SEPSI SCORE technical account, including:
    - Search and read operations for input resources.
    - Create and update operations for RiskAssessment and Communication resources.
- Authentication and authorization are correctly configured (OAuth2/OpenID Connect) with least-privilege scopes limited to the operations and resources required by PREVIA SEPSI SCORE.

Any incompatibility identified during Structure Control shall be documented and resolved collaboratively between PREVIA technical support and the hospital IT teams before clinical use.

6.1.2. FHIR API – Data Quality Control

The objective of Data Quality Control is to confirm that the clinical data exposed through the FHIR API is present, coded, and formatted in a way that allows PREVIA SEPSI SCORE to operate within its validated performance range.

PREVIA technical support, in collaboration with the IT Integrator and clinical informatics / data teams, shall verify that:

- Coding systems and value sets used for key variables (in particular LOINC and ICD-10) are consistent with the expectations described in Section 5.4 and the data specifications referenced therein.
- Required data elements for score calculation are present with sufficient completeness and timeliness (for example, vital signs updated at least every 8 hours and key laboratory values available within 24 hours of collection).
- Units for numeric observations are consistent with those described in Section 5.4.1 or can be reliably converted using the unit conversion rules implemented by PREVIA SEPSI SCORE.
- Basic distribution and range checks (for example, minimum/maximum values, plausible ranges for vital signs and laboratory values) do not reveal systematic data quality issues that would invalidate model assumptions. Where needed, these analyses are carried out by PREVIA technical support and/or the hospital's data teams.

If significant data quality issues are identified (for example, missing key variables, inconsistent units, or implausible value ranges), PREVIA SEPSI SCORE shall not be used clinically until

corrective actions have been implemented and the Data Quality Control has been re-performed.

6.2. System-Level Errors

Error Type	Description	Integrator Action
FHIR API Unreachable	back-previa cannot connect to hospital FHIR server	Verify network connectivity, firewall rules, FHIR server status
Authentication Failure	OAuth2 token expired or invalid	Check identity provider status, verify credentials not expired per hospital policy
Data Drift Detected	Incoming data patterns deviate from training distribution	PREVIA technical support will investigate; may require model recalibration
Model Loading Failure	ai-previa cannot load XGBoost model	Contact PREVIA technical support immediately (critical error)

7. Maintenance, updates, and lifecycle information

PREVIA technical support is responsible to managing maintenance and updates, including security updates and patches required to maintain compliance with the manufacturer's post-market surveillance and vulnerability management procedures.

Security-relevant updates communicated by PREVIA MEDICAL are mandatory and must be applied by the IT Integrator within the timelines specified by PREVIA MEDICAL (for example, emergency security fixes may need to be applied within days). The Integrator shall ensure that local change-control processes allow these security updates to be executed without undue delay.

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). After end of support, continued clinical use is not recommended.

7.1. Integrator Responsibilities for Maintenance

The IT Integrator shall:

- Monitor system availability and alert PREVIA technical support of any disruptions
- Maintain secure network connectivity and firewall rules
- Plan PREVIA SEPSI SCORE maintenance windows outside peak clinical activity periods, in coordination with clinical leadership and PREVIA technical support, to minimise impact on patient care
- Ensure backup and disaster recovery procedures are in place according to hospital IT policies
- Report any technical issues or anomalies to PREVIA technical support at support@previa-medical.com
- Coordinate software updates with PREVIA technical support
- Maintain documentation of local configuration and integration settings

7.2. Integrator Coordination

PREVIA technical support monitors system health through PREVIA Monitor and will contact the IT Integrator if:

- System availability drops below 99.5% target (excluding planned maintenance)
- Authentication failures occur repeatedly
- Data quality issues are detected
- Performance anomalies are identified

The IT Integrator should:

- Respond promptly to system health alerts from PREVIA technical support
- Coordinate troubleshooting and root cause analysis
- Escalate to hospital IT security, network, or clinical informatics teams as needed

7.3. Operational Monitoring and Performance Metrics

PREVIA technical support is responsible for performance monitoring through PREVIA Monitor.

PREVIA Monitor Telemetry:

PREVIA SEPSI SCORE transmits anonymized and aggregated operational metrics to PREVIA Monitor on a monthly basis. This telemetry supports:

- Post-market surveillance per (EU) 2017/745 MDR requirements
- Performance monitoring and quality assurance
- Proactive identification of technical issues

Telemetry Data Transmitted (No PHI):

Metric Category	Examples	Purpose
System Availability	Uptime percentage, downtime events	Reliability monitoring
Scoring Activity	Total scoring cycles, encounters processed per service	Usage patterns
Alert Generation	Alert count, alert rate trends	Performance tracking
Error Frequencies	Authentication failures, timeout counts by type	Issue detection
Data Quality	Missing data rates by variable, unit conversion counts	Data quality trends

PHI Protection:

"PHI" stands for *Protected Health Information*. In this document, PHI refers to any information that relates to an identified or identifiable patient's health, care, or payment for care (for example: name, medical record number, encounter identifier, date of birth, or any combination of clinical and administrative data that can directly or indirectly identify a patient).

Per GDPR requirements:

- Telemetry contains ZERO patient identifiers (no names, MRNs, encounter IDs)
- All data is aggregated (counts, percentages, frequencies)
- Transmission uses HTTPS/TLS encryption
- Data is stored on health-certified hosting server (HDS certification)

8. Deinstallation

Deinstallation of PREVIA SEPSI SCORE must be coordinated between the hospital and PREVIA technical support and is performed only at the hospital's written request.

8.1. Scope and Responsibilities

Uninstallation activities are performed by PREVIA technical support, following the procedures provided in PREVIA Technical Documentation and in coordination with the hospital IT teams.

PREVIA SEPSI SCORE operates entirely on hospital-managed infrastructure; deinstallation does not remove any clinical data from the hospital FHIR server.

8.2. Pre-Uninstallation Requirements

Before PREVIA SEPSI SCORE is uninstalled, the following prerequisites MUST be fulfilled:

- A written notification from hospital stakeholders (including IT and clinical leadership) to PREVIA MEDICAL requesting uninstallation of PREVIA SEPSI SCORE. This notification can be sent via support@previa-medical.com. A notice period of 30 days is recommended to allow for scheduling, coordination with clinical stakeholders, and completion of pre-uninstallation checks.
- Archival of operational activity logs (which contain no personally identifiable information) for regulatory retention. These logs must be preserved for at least 10 years in accordance with (EU) 2017/745 MDR Article 10(8) and PREVIA MEDICAL's quality management system procedures.
- Verification by the hospital that no PREVIA SEPSI SCORE alerts are pending clinical review or action at the time of deinstallation.
- Documentation of final system status and any open technical or clinical incidents related to PREVIA SEPSI SCORE.

PREVIA technical support and the hospital IT Integrator shall coordinate to agree on the deinstallation date and maintenance window, taking into account potential service interruptions.

8.3. Technical Uninstallation Procedure

The technical uninstallation procedure is executed by PREVIA technical support in accordance with PREVIA Technical Documentation and PREVIA MEDICAL’s internal deinstallation procedures, in alignment with hospital change-control policies. The following responsibilities apply during the procedure.

PREVIA technical support responsibilities:

- Execute all software deinstallation steps on the PREVIA SEPSI SCORE components, as defined in PREVIA Technical Documentation (service shutdown, removal of containers and configuration, verification that no PREVIA SEPSI SCORE processes remain active).
- Preserve and hand over, where applicable, archived operational activity logs in accordance with agreed retention arrangements (Section 8.4).
- Provide a deinstallation report or certificate to the hospital summarizing the date, actions performed, and final system status.

Hospital / IT Integrator responsibilities:

- Revoke or disable all authentication credentials, technical accounts, and network access permissions that were used exclusively for PREVIA SEPSI SCORE (for

example FHIR API client credentials, identity provider client registrations, PREVIA Monitor telemetry endpoints), in accordance with hospital IT security policies.

- Remove or disable any custom integrations implemented to display PREVIA SEPSI SCORE alerts in local clinical applications (for example EHR widgets, dashboards, or notification rules), ensuring that no clinical user interface continues to refer to PREVIA SEPSI SCORE after deinstallation.
- Update local configuration and operational documentation (architecture diagrams, asset inventories, security documentation) to reflect the removal of PREVIA SEPSI SCORE from the hospital information system.

8.4. Data Retention and Post-Market Surveillance

Clinical data produced by PREVIA SEPSI SCORE (including RiskAssessment and Communication resources) remain stored in the hospital FHIR server and continue to be governed by the hospital's data retention, access, and audit policies. PREVIA SEPSI SCORE does not store patient data outside the hospital FHIR server.

Operational activity logs (without personally identifiable information) that were archived prior to deinstallation are retained for a minimum of 10 years to support regulatory obligations, incident investigation, and post-market surveillance.

These logs contain only anonymised, aggregated technical and statistical information and do not include any patient-identifiable clinical content.

No other data than such statistical follow-up information is retained by PREVIA MEDICAL.

PREVIA MEDICAL records the deinstallation of PREVIA SEPSI SCORE for device tracking and post-market surveillance in accordance with (EU) MDR Article 83 and the PREVIA MEDICAL quality management system. The hospital retains access to all historical PREVIA SEPSI SCORE outputs in its FHIR repository after the device has been uninstalled.

The hospital IT team remains responsible for removing or disabling any custom integrations implemented to display PREVIA SEPSI SCORE alerts in local clinical applications (for example EHR widgets, dashboards, or notification rules) once PREVIA SEPSI SCORE has been deinstalled.

9. Data protection, privacy, and information management

IT Integrators are responsible for enforcing the hospital's IT policy.

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.

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.

PREVIA MEDICAL is responsible for the design and performance of PREVIA SEPSI SCORE and for ensuring that the device does not persist personally identifiable patient data outside the hospital FHIR server. The hospital is responsible for data governance, access control, and retention policies applied within its information system.

Data protection and information management measures described in this section shall be read in conjunction with the cybersecurity controls (Section 3.1) and telemetry / post-market surveillance arrangements (Sections 7.3 and 8.4).

Data retention and GDPR compliance

Clinical data produced by PREVIA SEPSI SCORE and stored in the hospital FHIR server are retained by the hospital in accordance with applicable data protection law, including GDPR, and with the hospital's own retention policies for medical records.

PREVIA MEDICAL does not define or enforce the retention period for patient-level clinical data; it only retains anonymised, aggregated technical and statistical information for post-market surveillance and device quality monitoring, as described in (Sections 7.3 and 8.4).

10. Incidents

10.1. Serious incident

Any serious incident that has occurred in relation to the device shall be reported without undue delay to PREVIA MEDICAL and to the competent authority of the Member State in which the user and/or the patient is established, in accordance with applicable vigilance requirements (including (EU) 2017/745 MDR Article 87).

PREVIA MEDICAL must be contacted at the following email address:

- ⇨ complaints@previa-medical.com

IT Integrators shall follow the hospital's internal incident and vigilance procedures and promptly inform PREVIA MEDICAL when they become aware of a potential serious incident involving PREVIA SEPSI SCORE.

Technical malfunctions or service interruptions that do not result in or contribute to a serious deterioration in a patient's state of health should still be reported to PREVIA MEDICAL as technical incidents via support@previa-medical.com, in line with the troubleshooting and maintenance sections.

For European Market, the contact points of the competent authorities are available on the website of the European Commission:

⇨ https://ec.europa.eu/tools/eudamed

10.2. Expected behavior in case of loss of communication or incident (fail-safe)

In case of loss of communication between PREVIA SEPSI SCORE and the hospital FHIR server, or in case of a technical incident affecting score computation or alert generation, the system behaves in a fail-safe manner:

- PREVIA SEPSI SCORE does not generate partial or unreliable alerts.
- Existing Communication resources already written in the FHIR server remain available for clinical review in the EHR.
- No retrospective “catch-up” processing is performed for the period of unavailability; clinical workflows remain based on prospective execution only.

The hospital is responsible for applying its own contingency procedures to ensure that clinical teams are aware of the temporary unavailability of new alerts and can adapt their workflows accordingly.

10.3. Minimum information to provide for incident analysis

When reporting an incident or suspected malfunction to PREVIA MEDICAL, the IT Integrator shall provide at least the following information:

- **Type of incident:** e.g. loss of communication, unexpected absence of alerts, abnormal alert rate, authentication failure, suspected data corruption, suspected security incident.
- **Software version and configuration:** PREVIA SEPSI SCORE version (e.g. v2.0.0), deployment environment (pre-production / production), relevant local configuration (e.g. alert threshold policy, services in scope).
- **Context of use:** date and time of the incident, affected hospital services, approximate number of patients or encounters concerned, recent infrastructure changes (e.g. FHIR upgrade, network change, OS or VM update).
- **Technical evidence where available:** relevant log extracts (without patient identifiers), screenshots or error messages, ticket references from internal IT systems.

The IT Integrator shall remain available to PREVIA MEDICAL for follow-up questions, provision of additional technical elements, and participation in joint root-cause analysis as needed.

10.4. Recovery of essential functions after incident

After an incident (e.g. hardware failure, network outage, or software fault), the hospital and PREVIA technical support shall coordinate to restore essential functions of PREVIA SEPSI SCORE in a controlled manner, in line with the maintenance and coordination principles described in Section 7.

The following principles apply:

- **Clinical continuity:** During recovery, the hospital shall maintain continuity of clinical workflows using existing tools (e.g. standard sepsis screening protocols, existing clinical dashboards) and clearly communicate any temporary limitation of PREVIA SEPSI SCORE alerts to clinical teams.
- **Stepwise technical recovery:** PREVIA technical support and the IT Integrator shall restore infrastructure, connectivity, and PREVIA SEPSI SCORE services in a stepwise manner, verifying at each step that the system behaves as expected before returning to normal operation.
- **Verification before return to service:** Before resuming routine use, basic technical and functional checks shall be performed (e.g. health-checks, test scoring on synthetic or test patients, verification that new RiskAssessment and Communication resources are correctly written and visible in the EHR).

Roles and responsibilities for recovery:

- **Hospital operator / clinical teams:** Inform clinical teams of the incident, apply local clinical contingency procedures, and avoid relying on PREVIA SEPSI SCORE alerts until normal operation is confirmed.
- **IT Integrator:** Restore the hosting environment (VMs, network, certificates, FHIR connectivity), apply any corrective actions communicated by PREVIA MEDICAL, and verify that integration paths (EHR displays, alert worklists) are functional.
- **PREVIA MEDICAL (manufacturer):** Analyse incident reports, provide technical guidance and corrective actions, support the IT Integrator during recovery, and confirm when the device can be considered operational again.

10.5. Contingency planning and security incidents

Hospitals shall maintain contingency plans in case of temporary downtime or reduced performance of PREVIA SEPSI SCORE, including:

- Procedures to inform clinical teams that PREVIA SEPSI SCORE alerts are temporarily unavailable or unreliable.
- Alternative monitoring or screening processes for sepsis risk during the outage period, as defined by the hospital's clinical governance.
- Clear criteria for returning to normal operation once PREVIA SEPSI SCORE has been restored and verified.

In case of a **suspected or confirmed security incident** involving PREVIA SEPSI SCORE (e.g. compromise of credentials, unauthorized access to the hosting environment, or abnormal traffic patterns):

- The IT Integrator shall immediately apply the hospital's security incident response procedures (e.g. revoking credentials, isolating affected systems, increasing monitoring), while preserving evidence relevant for investigation (see also Section 3.1 Cybersecurity).
- PREVIA MEDICAL shall be informed without undue delay via support@previa-medical.com and, where applicable, via complaints@previa-medical.com if the incident may have impacted patient safety.
- The IT Integrator shall remain available to PREVIA MEDICAL to support containment, investigation, and implementation of corrective or preventive actions.

These security incident procedures complement, and do not replace, the hospital's own information security policies, maintenance and monitoring arrangements described in Section 7, and applicable regulatory reporting obligations.

11. 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.

12. Other Informations



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



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PREVIA MEDICAL
107 rue Béchevelin 69007 Lyon, France
Website: https://www.previa-medical.com/

Date of issue of the IFU: 21 SEPT 2026
Version of the IFU: v4.0

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.

The solution complies with GDPR regulations and is hosted on a server approved as a health data host. It guarantees that the data transmission complies with current regulations.

