Instructions for Use

Salus.Tech Medical Scribe - AI-powered clinical documentation platform

MEDICAL DEVICE - Class I, Rule 11(c), MDR Annex VIII

CE

Manufacturer	Salus.Tech S.r.l.
Address	Viale Monte Nero 80, 20135 Milano (MI), Italy
Contact	support@salustech.io / +39 338 350 7705
UDI-DI	(01)08053695060011
AIDC	none - the electronic displays carry the human-readable UDI only (MDR Annex VI Part C 6.5.4(d))
Software Version	v1.0.0
Release Date	2026-11-01
Instructions for Use	English edition, revision 1.3, 2026-10-29

Intended purpose. Salus.Tech Medical Scribe is a software-based medical device intended to assist healthcare professionals in generating clinical documentation (transcription, coding, report generation) from patient interaction data. The device processes audio and text input to produce draft clinical notes, ICD-9-CM code suggestions, and automated follow-up schedules. All AI-generated outputs are drafts and require mandatory physician review before validation. The device is intended for use in healthcare facilities and by authorized healthcare professionals.

1. Device Overview and Intended Use

1.1 Device Name and Purpose

Salus.Tech Medical Scribe - AI-Powered Clinical Documentation

This device is a software-based clinical documentation tool intended to assist healthcare professionals in creating clinical notes, generating diagnostic and procedural codes, and automating administrative tasks. It is **not** intended to:

- Replace physician clinical judgment
- Provide independent diagnosis or treatment recommendations
- Generate final clinical documents without physician review
- Make autonomous clinical decisions
- Diagnose patients or conditions

Use context and patient population: the software may be used to document clinical activity in ambulatory, specialist and hospital settings, delivered in person or by telemedicine. There is no restriction by patient age, pathology or specialty: the software performs documentation functions only and does not interact with or affect the patient directly. **Excluded from the intended use: urgency and emergency visits** - the device is not intended for use in urgent or emergency care. Contraindications: none identified.

> **WARNING - conditions that degrade the spoken input.** Neurological or physical speech disorders, phonation through tracheostomy, malformations altering speech sounds, and non-native speakers do not exclude a patient from the intended use: use in those encounters is at the physician's discretion. These conditions are not represented in a controlled way in the test samples, so the manufacturer claims no measured performance for them.

1.2 Intended Users

User Profile	Role	Intended Use
Healthcare Professional (PS)	Physician	Use transcription, coding, report generation, and appointment scheduling features to document patient care
Administrative User (AU)	Practice manager, administrative staff, medical assistants	Register patients, manage appointments and scheduling on behalf of the physician or facility; no access to clinical data

1.3 Key Features and Functional Modules

Module	Feature	Description
MOD-01	Live Transcription	Transcribes the physician-patient conversation in real time during the encounter (streaming ASR)
MOD-02	Batch Transcription	Transcribes uploaded audio recordings
MOD-03	Report Generation	Creates structured draft clinical reports from the transcript (three-stage AI pipeline), including drug-name audio corrections and ICD-9-CM administrative code suggestions; physician selects final codes
MOD-05	Pre-briefing Aggregator	Summarizes prior records and uploaded documents for context (data aggregation, not clinical interpretation)
MOD-06	Document Management	Stores and retrieves reports and uploaded patient documents; PDF export
MOD-08	Follow-up Scheduler	Proposes follow-up appointments based on explicit physician instructions

Module	Feature	Description
MOD-09	Administrative Functions	Patient registration, appointment management and scheduling (non-clinical)
MOD-10, MOD-11	FSE 2.0 Integration (future interoperability feature - out of the Class I scope)	Publication to / consultation of the Italian Fascicolo Sanitario Elettronico (data transport/display only)
MOD-12	B2B Enterprise Integration	API-based integration and embedded visit experience for healthcare facilities (data transport)

1.4 What This Device Does NOT Do

- Does NOT diagnose patients or medical conditions
- Does NOT recommend treatment or medications
- Does NOT make clinical decisions
- Does NOT replace physician responsibility for patient care
- Does NOT validate clinical documentation (physician must do so)
- Does NOT interpret pre-briefing data; pre-briefing is data aggregation only
- Does NOT correct grammatical or clinical errors automatically; physician review is required
- Does NOT check drug interactions or provide medication alerts (not part of the certified device)
- Does NOT generate simplified patient-language summaries of reports (not implemented in the certified device)
- Does NOT provide long-term data archival; records are retained per healthcare facility policy and GDPR requirements. Audio recordings and data are encrypted in transit (TLS) and at rest in cloud storage

1.5 Performance Characteristics

The accuracy of the AI draft was measured on 270 consultation transcripts in Italian, each compared with a reference report (the reference campaign, 13 September 2026). The acceptance criteria bind every later release, measured on the same test set.

Characteristic	Measured in the reference campaign	Acceptance criterion for every release
Factual accuracy of the draft (FAS)	97.30%	at least 96.65%
Factual accuracy in the critical fields (medications, allergies, diagnosis, treatment plan)	99.29%	at least 98.73%
Structural completeness (SCS)	92.42%	at least 91.02%
Composite accuracy score (CAS)	96.42%	at least 95.82%
Content omitted from the draft (omission rate)	6.10%	at most 7.30%
Invented content (hallucination), share of the clinical facts in the draft	0.55%	at most 0.72%
Reports with at least one invented fact	11.85%	at most 15%
Visits with at least one invented fact in a critical field	4.81%	at most 5%
Visits with at least one omitted fact in a critical field	5.56%	at most 8%
Service availability	-	target 99.0% per month

- The drafts were scored by an automated evaluator against the reference reports. The critical-field events are counted on that automatic classification and have not yet been reviewed by a physician; that review is carried out after placement on the market.
- Transcription (speech-to-text) has no acceptance criterion of its own. The figures above are measured on the text of the consultations, so they do not include the effect of transcription errors; the word error rate is measured after placement on the market.

- The conditions that degrade the spoken input (sec. 1.1) and the recording conditions (sec. 2.1) are not represented in a controlled way in the test samples; no measured performance is claimed for them.
- In the reference campaign 11.85% of reports contained at least one invented fact, and some reports left out facts said during the consultation. Review the whole report every time before you press **Save** (sec. 4.1).

1.6 Expected Clinical Benefits

The device claims no direct, measurable patient outcome. Its expected benefits are indirect, through the clinical documentation it helps produce:

- Documentation completeness - the draft report captures the content of the consultation, with omitted content within the acceptance criteria of sec. 1.5.
- Documentation accuracy - the draft report reproduces the content of the consultation, with invented content within the acceptance criteria of sec. 1.5.

These benefits apply only to a report the physician has reviewed, corrected where needed and saved (sec. 4.1). No comparison with manual documentation has been measured, and none is claimed.

---

2. Getting Started

2.1 System Requirements (Technical Prerequisites)

Declared minimum requirements. The browser, operating-system, connectivity and hardware values below are the manufacturer's DECLARED minimum IT-environment requirements under MDR Annex I sec. 17.4 (minimum requirements concerning hardware, IT networks characteristics and IT security measures necessary to run the software as intended), with the sec. 17.3 mobile-platform consideration covering use on tablets and, through the mobile web version in a web browser, on phones. **They are NOT presented as a tested compatibility matrix:** no device/browser lab campaign is run on the Class I path; the executed campaign evidence was produced on documented desktop Chromium-based environments (build ids recorded per case). Environment-related complaints are monitored against these declared minimums under post-market surveillance.

Minimum Hardware & Connectivity:

- **Browser:** Chrome 90+, Firefox 88+, Safari 14+, Edge 90+ (latest versions recommended)
- **Internet Connection:** broadband, with at least **1.5 Mbps** available while a transcription is running. This is the declared minimum. The device's own continuous demand is the audio it sends - uncompressed PCM at 16 kHz, 16-bit, mono, about 0.26 Mbit/s - and the declared figure covers that with headroom for protocol overhead, network variation and the rest of the application. It is derived from what the device sends and set by the manufacturer, not measured on a test network. Below it, a live transcription session may interrupt or degrade.
- **Audio Input Device (for voice transcription):** Microphone (built-in or external)
- **Microphone placement:** keep the microphone close to the people speaking. As a general indication, about **2 metres**; the workable distance depends on the microphone, so a good external microphone tolerates more and a built-in laptop microphone less. This matters because of how the recording fails: as distance grows, an ambient recording tends to omit clinical facts silently rather than transcribe them wrongly, and an omission is harder to catch on review than an error. The figure is an average working distance, not a tested specification - individual microphone models are not qualified (see the declared-minimums note at the head of this section).
- **Operating System:** Windows 10+, macOS 10.14+, iOS 14+, Android 10+

Recommended Environment:

- Modern, auto-updating browser
- Stable internet connection (wired preferred for clinical settings)
- External microphone for voice quality (USB headset recommended)
- 27-inch or larger display for clinical workflows
- Display of 13 inches or larger for report review (tablet or desktop); the device can also be used on phones, through its mobile web version in the phone's web browser

2.2 Data Security and Privacy

- **AWS Data Center:** eu-central-1 (Frankfurt, Germany) - all EU data residency
- **AI Processing Services:** speech transcription (live and uploaded recordings) by a self-hosted OpenAI Whisper (`faster-whisper large-v3-turbo`) service on AWS GPU EC2; report drafting by Anthropic Claude via AWS Bedrock - all within AWS eu-central-1.
- **Encryption in Transit:** TLS 1.2 minimum, enforced on every deployed surface - the API Gateway HTTP APIs and the WebSocket API (AWS-managed `execute-api` endpoints, no custom domain), client-to-edge delivery (HSTS plus upgrade-insecure-requests), the RDS databases (`rds.force_ssl = 1` with `ssl_min_protocol_version = TLSv1.2`) and the five clinical S3 buckets (`DenyInsecureTransport` over the S3 service floor). TLS 1.0 and TLS 1.1 are not accepted anywhere; TLS 1.3 is accepted where the endpoint offers it. Pinned value.
- **Encryption at Rest:** AES-256 (patient data encrypted in AWS storage)
- **Access Control:** Cognito-based authentication with separate user pools per profile. Multi-factor authentication is not enabled on any portal.
- **Automatic logoff:** The application signs you out automatically after **2 hours of inactivity**. Separately, your access credential expires on a fixed schedule and is renewed silently while you are working: **2 hours** for the physician portal, **1 hour** for the assistant workspace. Closing the browser does not by itself end the session - use **Log out** when leaving a shared or unattended workstation.
- **Notifications:** service notifications may be delivered in-app, by email, and by SMS (your phone number is used for appointment reminders; no clinical content is sent by SMS). The SMS channel carries no clinical and no GDPR Art. 9 special-category data. The enforcing control is not a routing guarantee but data minimization at the source: every outbound SMS body is drawn from a closed inventory of 14 predefined templates and is rendered strictly by substitution into that template, so a sending component cannot inject arbitrary fields. The maximum personal data any live SMS body can carry is the recipient mobile number, a first name, a doctor name, an appointment date, time and location, a short-lived numeric code, and an opaque HTTPS link. No diagnosis, ICD-9-CM or SNOMED code, medication, laboratory value, vital sign, symptom or report text appears in any template.
- **Audit Logging:** All user actions logged for compliance and investigation

- **GDPR Compliance:** Data handling per Article 5 principles (lawfulness, fairness, transparency, etc.)
- **Data Retention:** Per healthcare facility policy and GDPR retention requirements
- **Right to Access/Deletion:** Patient data retrieval and deletion workflows available

2.3 Initial Setup (Administrative User)

Steps:

1. Contact Salus.Tech support to obtain login credentials
2. Log in with administrative account
3. Your tasks in the device are patient registration and appointment management (sec. 3.2 A and B). Facility configuration, EHR-integration setup and the system test are done in the institute admin console, outside the certified device

2.4 User Onboarding (Healthcare Professional)

Healthcare Professional:

1. Receive login credentials from your practice administrator
2. Log in and review required training/orientation (mandatory on first use)
3. Accept terms of use and AI transparency statement
4. Perform initial setup: link microphone, test audio quality, set default preferences
5. Create first patient record or search for existing patient in practice system

---

3. User Instructions by Profile

3.1 Healthcare Professional (Physician)

One validation act. The product has a single finalization control, a button labelled "Save" in the English interface and "Salva" in the Italian interface. There is no separate control to validate the transcription, approve the codes, preview the report or sign it. Workflows A, B and C describe this single-act validated-save workflow; the physician's responsibility attaches to the Save act.

A. Transcription Workflow (MOD-01)

Purpose: Convert spoken clinical notes into text.

Steps:

1. Open the patient record in Salus.Tech Medical Scribe
2. Click **"Start Transcription"** button
3. **Audio Recording Notice:** Confirm you understand audio is being recorded and transmitted to the AI engine
4. Speak naturally; the AI will transcribe your words in real-time or near-real-time
5. Pause between sections (e.g., "History of Present Illness," "Physical Exam," "Assessment and Plan")
6. Once complete, click **"End Transcription"**
7. **Review Phase (MANDATORY):** The transcribed text appears in editable fields. Review for accuracy:
    - Correct any misheard words (e.g., "diastolic pressure 120" should be "80")
    - Verify patient names, medication names, and dosages
    - Add missing clinical details if the AI missed information
    - Delete any extraneous or erroneous text
8. When satisfied, proceed to code review and report generation. There is NO separate per-stage validation control: the reviewed transcription is carried into the report draft, and ALL content - transcription, codes and report sections - is validated together by the single **Save** act on the report (workflow C, step 5)
9. The reviewed transcription is used for subsequent coding and report generation

Key Warning:

> **MANDATORY PHYSICIAN REVIEW:** Do not carry a transcription forward without careful review, and do not save the report without having reviewed it. The AI may have misheard clinical terms, drug names, or patient information. You are clinically and legally responsible for the accuracy of the final document.

B. ICD-9-CM Code Suggestion (within MOD-03)

Purpose: Suggest diagnostic and procedural codes for administrative use (billing and classification), not for clinical diagnosis.

Steps:

1. After validating the clinical transcription, click **"Generate Code Suggestions"**
2. The device retrieves candidate codes from the ICD-9-CM catalogue by keyword and synonym search; an AI step then orders the candidates and estimates a confidence value for each, and candidates scoring below 70 are discarded. If the AI step is unavailable, candidates are shown without that confidence gate, with a confidence equal to their text-search score and a floor of 10. The suggestions are:
    - **Diagnostic Codes** (ICD-9-CM) - up to 10 suggestions ranked by confidence
    - **Procedure Codes** (ICD-9-CM) - suggestions based on documented procedures
3. Review each suggested code:
    - Hover over code to see AI's reasoning
    - Accept the code by clicking ✓
    - Modify/select a different code by searching the ICD-9-CM reference (search field provided)
    - Reject the code if it doesn't match documented clinical content
4. For codes you reject, the system suggests alternatives or allows free-text entry
5. When selection is complete, the selected codes are part of the report draft. There is NO separate code-approval control: codes are validated together with the whole report by the single **Save** act (workflow C, step 5)
6. The selected codes are stored with the report when the report is saved
7. **Items the device does not code.** Some of what you say is recorded in the visit but is deliberately not turned into an ICD-9-CM code: occupation, social circumstances, family history, and substance or lifestyle references. The device does not search for a code for these, even when a medical term appears inside the phrase - a family history of a disease is recorded, not coded. Such items appear beneath the code list as excluded items, each with its reason, and they are read-only: they are the device's decision for you to review, not a suggestion to accept. **An empty code list does not always mean the same thing.** If excluded items are

shown, the device chose not to code them. If the list is empty and nothing is excluded, the device searched and found no code. Check which before concluding that a code is missing.

Key Warnings:

> **These are suggestions only.** You must verify each code matches the patient's actual diagnosis and procedures. The AI may suggest incorrect codes based on misheard or ambiguous clinical language. You are responsible for final code selection.
>
> **ICD-9-CM codes are administrative.** They are used for billing and classification, not for clinical diagnosis. The physician's clinical assessment always takes precedence.

C. Report Generation (MOD-03)

Purpose: Create a formatted clinical note/report for the patient record.

Steps:

1. After validating transcription and approving codes, click **"Generate Report"**
2. Select report template (Clinic Note, Hospital Discharge, Specialty Report, etc.)
3. The AI structures the transcription into standard sections:
    - Chief Complaint
    - History of Present Illness
    - Past Medical History
    - Medications
    - Allergies
    - Physical Exam
    - Assessment
    - Plan
    - Billing Codes
4. Review the report in editable format:
    - Rearrange sections if needed (drag-and-drop)
    - Edit text for clarity, completeness, or accuracy
    - Add missing clinical elements
    - Remove extraneous content

5. When your review of the ENTIRE report - transcription, codes and every section - is complete, click the single **Save** control. The control is labelled "Save" in the English interface and "Salva" in the Italian interface. Saving is one act - measured at 1 click and 0 confirmation dialogs from draft to stored record. There is NO preview stage, NO per-section confirmation and NO signature control
6. Saving stores the report as the validated clinical record and it becomes part of the patient's official medical record

Key Warning:

> **PHYSICIAN VALIDATION - THE SINGLE SAVE ACT:** Clicking **Save** stores the report as the validated clinical record. By saving, you confirm that you have reviewed the entire report - transcription, codes and all sections - verified its accuracy, and take clinical responsibility for its contents. Do not save any report you have not personally reviewed. The device enforces the explicit act (a report is not finalized without it); it does NOT enforce the review itself: no forced preview, no per-section confirmation and no minimum review time exist. The review duty rests entirely on you.

F. Pre-Briefing Aggregator (MOD-05)

Purpose: Summarize prior visits and patient history for context.

Steps:

1. When opening an existing patient record, the Pre-Briefing panel appears on the right side
2. It displays:
    - Last 3-5 prior visit notes (with dates)
    - Active medication list
    - Known allergies
    - Chronic conditions
    - Last lab results (if available in EHR integration)
3. Use this to:
    - Recall the patient's medical history quickly
    - Note recent changes in medications or symptoms
    - Identify patterns (e.g., recurring complaints)
4. The pre-briefing is searchable (click "Find" and enter term)

Key Warning:

> **Pre-Briefing is Data Aggregation, not Clinical Interpretation:** The system simply collects prior documentation; it does NOT analyze whether findings are clinically significant or unexpected. You must personally review the pre-briefing and integrate it with current clinical assessment. Do not rely on the pre-briefing for clinical decision-making without independent review.

G. Follow-up Scheduling (MOD-08)

Purpose: Automatically schedule follow-up appointments based on physician instructions.

Steps:

1. After completing and validating a visit note, click **"Schedule Follow-up"**
2. Enter your follow-up instructions in natural language, e.g., "Follow up in 3 weeks to check blood pressure" or "Return if symptoms worsen"
3. The system suggests appointment times based on:
    - Healthcare facility's available time slots
    - Any standing follow-up protocols (e.g., "Post-op check at 2 weeks")
4. Review the suggested appointment(s) and confirm or modify
5. The appointment is sent to the patient via email

Key Warning:

> **Follow-up Scheduling Uses Physician Instructions, not AI Clinical Judgment:** The system does not determine medical necessity for follow-up. It schedules appointments based on what you instruct. You are responsible for deciding when and how often a patient should be seen.

H. Data Export & Integration (MOD-06 export / MOD-12 B2B)

Purpose: Export documented information to the patient's electronic health record (EHR).

Steps:

1. After the report is saved as the validated clinical record (workflow C, step 5), click **"Export to EHR"**
2. Select export format (HL7, CDA, PDF, or proprietary EHR format)

3. Confirm patient identifier and EHR system destination
4. Click **"Send"** - the report is encrypted and transmitted to the EHR system
5. EHR system receives the export and integrates it into the patient record

Note: Export functionality requires pre-configured integration with your EHR vendor. Contact your practice administrator if export is not available.

I. Report Templates and Questionnaires (MOD-03)

Purpose: Create and edit your own report templates and questionnaires.

Steps:

1. When you choose, create a report template or a questionnaire, or edit one of your own
2. The AI that drafts your reports checks each template for completeness and tells you what to change
3. Decide which changes to make, and make them
4. Approve the template: no template is generated or used without your final approval

---

3.2 Administrative User (Practice Manager, Administrative Staff)

A. Patient Registration

Purpose: Register patients.

Steps:

1. Log in with Administrative User credentials
2. Click **"User Management"** or **"Settings"**
3. To **Add a New Patient:**
    - Click **"Add Patient"** -> **"New Patient"**
    - Enter basic demographics (name, DOB, phone, email, insurance info)
    - Assign to a primary care provider

B. Appointment Management

Purpose: Schedule and manage patient appointments; coordinate with healthcare professionals.

Steps:

1. Click **"Appointments"** or **"Calendar"**
2. View weekly or monthly calendar of all healthcare professionals' schedules
3. To **Schedule an Appointment:**
    - Click **"New Appointment"**
    - Select patient (search by name/ID)
    - Select healthcare professional
    - Select date and time (system shows available slots)
    - Add notes (if needed)
    - Click **"Create"** - appointment is saved and patient is notified
4. To **Reschedule:**
    - Click the appointment on the calendar
    - Click **"Reschedule"**
    - Select new date/time
    - Click **"Save"** - patient is notified of change
5. To **Cancel:**
    - Click appointment
    - Click **"Cancel"**
    - Optionally add cancellation reason
    - Patient receives cancellation notice

D. Reporting and Analytics

Compliance-report downloads are done in the institute admin console, outside the certified device.

---

4. Warnings and Precautions

4.1 Mandatory Physician Review (Human-in-the-Loop)

WARNING - CRITICAL:

All AI-generated outputs (transcriptions, codes, reports, summaries) are DRAFT and require mandatory physician review before clinical use.

The AI may make errors, including misheard words, incorrect code suggestions, missing clinical data, or grammatical errors. The physician MUST review, edit, and explicitly validate every output before it is used clinically or entered into the medical record.

Failing to review AI outputs may result in:

- Incorrect clinical documentation
- Medical errors in patient care
- Billing fraud or compliance violations
- Patient harm

The physician is clinically and legally responsible for the accuracy and appropriateness of all documentation.

4.2 Drug Name Corrections

WARNING:

The AI may misheard or suggest incorrect drug names. Before validating any documentation:

- Verify every drug name is spelled correctly (e.g., "lisinopril", not the misspelling "lysinopril")
- Confirm the drug is appropriate for the patient's condition
- Check the dose and frequency are correct
- Use the built-in drug reference to verify spelling and strength

Drug name errors can result in serious harm if the patient receives the wrong medication.

4.3 ICD-9-CM Codes Are Administrative, Not Diagnoses

WARNING:

ICD-9-CM code suggestions are **administrative codes for billing**, not clinical diagnoses.

- The AI suggests codes based on documented clinical information, but you must verify each code matches the patient's actual diagnosis and procedures.
- Final code selection is your responsibility.
- Do not use ICD-9-CM codes as the basis for clinical decisions; use your clinical assessment and the patient's clinical findings.
- The device also does not code non-medical content - occupation, social circumstances, family history, substance or lifestyle - even where a medical term appears inside the phrase. Those items are listed as excluded beneath the codes rather than coded.

4.4 Pre-Briefing Is Data Aggregation, Not Clinical Interpretation

WARNING:

The Pre-Briefing panel aggregates prior visit notes and patient history for quick reference. It does **not** analyze the clinical significance of findings.

- Do not assume prior findings are still clinically relevant (patient's condition may have changed).
- Do not use pre-briefing alone to make clinical decisions; integrate it with your current clinical assessment.
- Always review the full prior note if you need detail about a past finding.

4.5 AI Corrections Are Not Clinical Recommendations

WARNING:

When the AI corrects a word while it writes the draft report (e.g., a misspelled drug name), the correction is part of the AI draft, not a clinical recommendation.

- Review every correction before you save the report.
- The AI may replace a word with a similar one that is not clinically appropriate (e.g., correcting "captopril" to "enalapril").
- You are responsible for verifying that the correction matches your intent.

4.6 Follow-up Scheduling Is Based on Physician Instructions, Not AI Clinical Judgment

WARNING:

The Follow-up Scheduler automatically schedules appointments based on your instructions (e.g., "Follow up in 2 weeks"). It does **not** determine medical necessity.

- Only schedule follow-ups if clinically appropriate.
- Do not rely on the scheduler to recall that a patient needs follow-up; you must explicitly instruct it.
- Verify that the scheduled appointment date/time is appropriate before confirming.

4.7 Audio Recording and Data Transmission

WARNING:

When you use the Voice Transcription feature:

- Your audio is recorded and transmitted to the AI transcription engine (a self-hosted OpenAI Whisper service on AWS GPU EC2, used for both live encounters and uploaded recordings - hosted on AWS eu-central-1)
- Audio is transmitted over encrypted connections (TLS) and stored encrypted at rest in cloud storage
- Audio retention follows the manufacturer's data-retention policy
- By using the voice feature, you consent to this recording and transmission
- Do not record privileged information (attorney-client communications, discussions with others not part of the care team) in voice notes

4.8 System Availability and Backup

WARNING:

- Salus.Tech Medical Scribe is hosted in the cloud. Internet connectivity is required to use the device.
- If internet is unavailable, you cannot access the system or patient data.
- System maintenance may occur during off-hours; the application may be temporarily unavailable.
- Backup your critical workflow: if the system is unavailable during a patient visit, use paper notes and enter documentation later when the system is restored.
- Do not delay patient care if the system is unavailable; see patients using alternative documentation methods (paper chart, EHR if available).

4.9 Data Security and Confidentiality

WARNING - GDPR:

- Patient data is encrypted in the AWS database and in transit (TLS 1.2 minimum - pinned value, see sec. 2.2).
- Your login credentials grant access to patient data; do **not share your login** with colleagues.
- Always log out when you step away from your computer, especially in a clinical setting where others may be present.
- If you suspect unauthorized access or a data breach, contact regulatory@salustech.io immediately.
- The practice is responsible for compliance with GDPR and healthcare privacy regulations; use the device in a GDPR-compliant manner.

---

5. Residual Risks and Risk Controls

The following residual risks are managed through control measures. Users must understand these risks and the mitigations:

Hazard	Residual Risk	Risk Control (Required User Action)
AI transcription errors (misheard words)	Incorrect clinical documentation	Mandatory physician review of all transcriptions before validation
Incorrect ICD-9-CM code suggestions	Billing fraud, incorrect clinical classification	Physician verifies each code matches documented clinical content

Hazard	Residual Risk	Risk Control (Required User Action)
Unauthorized access to patient data	GDPR violation, patient privacy breach	User authentication (enforced password policy: a password of at least 8 characters including an upper-case letter, a lower-case letter, a number and a symbol; temporary passwords expire after 7 days - see sec. 6.1); user responsibility to log out and secure credentials; encryption at rest and in transit
Incomplete patient history in pre-briefing	Missed clinical findings, adverse drug interaction	Physician reviews full prior note for context; does not rely on pre-briefing alone
Audio recording transmitted over internet	GDPR breach, unauthorized recording disclosure	Audio encrypted in transit (TLS 1.2 minimum, pinned - see sec. 2.2) and at rest; user consent obtained before recording
System unavailability during patient visit	Delay in care documentation, patient care disruption	User falls back to paper notes or EHR; documentation entered retroactively when system restored

Key Point: The primary risk mitigation for all AI-related hazards is **mandatory physician review** (Human-in-the-Loop). All outputs are drafts requiring physician validation before clinical use.

---

6. Cybersecurity Responsibilities for Users

Users of Salus.Tech Medical Scribe share responsibility for maintaining cybersecurity:

6.1 Your Responsibilities

- **Protect Your Login Credentials:**
  - Do not share your username/password with colleagues

    - The system requires a password of at least **8 characters** including an upper-case letter, a lower-case letter, a number and a symbol. Use at least **12** for a clinical account - longer is the single most effective thing you control. Temporary passwords issued by an administrator expire after 7 days.
    - Change your password regularly (every 90 days recommended)
- **Secure Your Workstation:**
    - Always log out of Salus.Tech Medical Scribe when you step away from your computer
    - Lock your workstation (Windows: Ctrl+Alt+Delete -> Lock; Mac: Control+Command+Q)
    - Do not leave patient data visible on your screen when unattended
    - Use a privacy screen if working in a shared clinical area
    - Do not use Salus.Tech Medical Scribe on a shared, public or unmanaged computer (internet point, hotel or waiting-room terminal, a device you do not control). Use a workstation managed by your practice, and always log out before leaving it.
- **Report Security Concerns:**
    - If you suspect unauthorized access, contact your IT/Security team immediately
    - Report any suspicious emails claiming to be from Salus.Tech asking for your credentials (phishing)
    - If you inadvertently share a password, change it immediately and notify your administrator

6.2 Manufacturer's Responsibilities

Salus.Tech provides:

- Secure hosting on AWS with encryption at rest (AES-256) and in transit (TLS 1.2 minimum, pinned - see sec. 2.2)
- Regular security audits and penetration testing
- Compliance with GDPR and applicable EU healthcare data protection requirements
- Data retention and secure deletion per the manufacturer's data-retention policy
- User authentication and access control

- Audit logging of all user actions

6.3 Healthcare Facility Responsibilities

Your practice is responsible for:

- Network security (firewalls, intrusion detection, antivirus software)
- User access management (who has login credentials, role-based access)
- Physical security (locked computer room, secure workstations)
- Compliance with GDPR (data processing agreement with Salus.Tech, privacy policy, etc.)
- Training staff on cybersecurity best practices
- Incident response plan (procedure if data breach occurs)

---

7. Complaint and Feedback Channels

7.1 How to Report a Problem

If you experience any issue with Salus.Tech Medical Scribe, please report it:

Option 1: In-App Feedback

- Click **"Help"** -> **"Report a Problem"** or **"Feedback"**
- Describe the issue and upload screenshots if relevant
- Your feedback is sent to Salus.Tech's quality team

Option 2: Email

- Send email to: regulatory@salustech.io (complaints and safety reports; for general, non-safety questions use support@salustech.io)
- Subject line: "Complaint" or "Adverse Event" (if safety-related)
- Include: Your name, user ID, date/time of incident, what happened, what you expected to happen

Option 3: Phone

- Call: +39 338 350 7705
- Speak with a support agent or leave a detailed voicemail

7.2 What Constitutes a Complaint?

Report any of the following:

- Device malfunction (crashes, freezing, data loss)
- Inaccuracy in AI output (transcription errors, incorrect codes, missing data)
- Security concerns (unauthorized access, data breach, suspicious login attempts)
- Patient harm or near-miss (example: AI suggested wrong dose, you caught it during review)
- User interface usability issue (confusing, difficult to navigate)
- Data privacy concern (patient data shared with wrong person, unauthorized access)

7.3 What Happens After You Report?

1. Your complaint is logged in Salus.Tech's complaint database (unique complaint number assigned)
2. Salus.Tech's quality team investigates:
    - Determine if the issue is a device malfunction or user error
    - Assess if the issue poses a safety risk
    - Identify root cause
    - Decide if corrective action is needed
3. You are notified of the outcome (email or phone)
4. If the incident is a serious incident - one that led, might have led or might lead to a death, a serious deterioration in a person's state of health or a serious public health threat (MDR Art. 2(65)) - Salus.Tech reports it to the competent authority, as MDR Art. 87 requires
5. Corrective actions are tracked and verified

7.4 Adverse Event Reporting (If Patient Harm Occurred)

If a problem with Salus.Tech Medical Scribe resulted in or could have resulted in patient harm:

1. **Stop using the affected feature immediately**
2. **Contact your practice's compliance/quality officer**

3. **Report to Salus.Tech (via Help or email) with "ADVERSE EVENT" in the subject**
4. **Provide:**
    - Patient ID (de-identified if possible)
    - What went wrong (transcription error, code error, system crash, etc.)
    - When it happened (date, time)
    - What patient harm resulted or could have resulted
    - What you did to mitigate harm
5. **Reporting to the competent authority.** In Italy, healthcare professionals are required to report a serious incident to the Ministero della Salute without delay and no later than 10 days (DM 31 marzo 2022), and to Salus.Tech (step 3). Elsewhere, you may report a suspected serious incident to the competent authority of your country

Note: Salus.Tech reports serious incidents involving the device to the competent authority, as MDR Art. 87 requires, under its vigilance procedure.

7.5 Manufacturer Contact Information

Salus.Tech S.r.l.

- **Address:** Viale Monte Nero 80, 20135 Milano (MI), Italy
- **Legal name:** SALUS.TECH S.R.L.
- **VAT number:** IT14293820966 (partita IVA 14293820966) | **Codice Fiscale:** 14293820966 (the two numbers coincide for an S.R.L.)
- **Email - General Support:** support@salustech.io
- **Email - Quality/Compliance, complaints and safety reports:** regulatory@salustech.io
- **Phone:** +39 338 350 7705
- **Website:** https://salustech.io

---

8. Troubleshooting

Problem	Possible Cause	Solution
Cannot log in	Wrong password, account deactivated, browser issue	Reset password via "Forgot Password" link; contact administrator to reactivate account; try different browser
Microphone not working	Microphone not connected, browser permissions not granted, device blocked	Check microphone is connected and powered on; go to browser Settings -> Privacy -> allow site to use microphone; restart browser
Transcription is inaccurate	Noisy environment, speaker talking too fast, accented speech, microphone too far from the people speaking	Move to quieter location; speak slowly and clearly; use external microphone with better audio quality; keep the microphone close to the people speaking - about 2 metres as a general indication, less for a built-in laptop microphone (see sec. 2.1, Microphone placement)
AI code suggestions seem wrong	Transcription error, ambiguous clinical language, AI doesn't understand context	Review transcription first to ensure it's accurate; manually search ICD-9-CM code if suggestion is clearly wrong; mark as complaint if issue is systematic
No ICD-9-CM codes are suggested	The visit contained nothing codable, or what you said was non-medical content the device does not code (occupation, social circumstances, family history, substance or lifestyle)	Look beneath the code list. If excluded items are shown, the device chose not to code them and that is by design - nothing is missing. If nothing is excluded either, the device searched and found no code: check the transcription is accurate, and search the ICD-9-CM reference manually if you still expect one

Problem	Possible Cause	Solution
Slow system response	Network congestion, server load, browser cache issues	Check internet connection; try refreshing browser; clear browser cache (Ctrl+Shift+Delete) and reload
Cannot export to EHR	EHR integration not configured, EHR system down, wrong credentials	Contact IT/Administrator to verify EHR integration is set up; check if EHR system is down for maintenance; verify export credentials are correct

9. AI Act Transparency Obligations (MDR Annex I §23 + EU AI Act Art. 50)

9.1 Notification That Content Is AI-Generated

Required Statement (Display to All Users):

> "**AI-Generated Content Notice:** This document or content was generated by artificial intelligence. It is a draft and requires human review before use."

Where It Appears:

- On every AI-generated transcription or draft report (header or footer)
- In the application interface whenever an AI output is presented

User Acknowledgment: Users must acknowledge they understand content is AI-generated before first use of AI features.

9.2 Notification of Audio Recording

Required Statement (Displayed before Voice Transcription Begins):

> "**Audio Recording Notice:** By clicking 'Start Transcription,' you consent to recording your audio input. Your audio will be transmitted to the AI transcription engine (hosted on AWS, eu-central-1) for processing. Audio is encrypted in transit and stored encrypted at rest; retention follows the manufacturer's data-retention policy. Do you consent?"

User Action Required: User must click **"I Consent"** before recording begins. If user declines, transcription feature is disabled.

9.3 Description of AI Processing

Statement (Accessible in Help / About Section):

> **How the AI Works:**
>
> 1. **Audio Input (Live and Batch Transcription - MOD-01/MOD-02):**
>   - You speak during the encounter (live) or upload an audio recording (batch)
>   - Live and uploaded audio are transcribed by a self-hosted OpenAI Whisper (`faster-whisper large-v3-turbo`) service on AWS GPU EC2 - all within AWS eu-central-1
>   - The AI converts speech to text using automatic speech recognition (ASR) with speaker identification
>   - Transcribed text is returned to you for review and editing
>   - Audio is stored encrypted; retention follows the manufacturer's data-retention policy

2. **Text Processing (Report Generation, Coding - MOD-03):**
    - The transcript is processed by a large language model (Anthropic Claude via AWS Bedrock, eu-central-1) through a three-stage quality pipeline (structured prompting -> AI self-feedback -> deterministic structural validation)
    - The AI extracts conditions the physician explicitly named and suggests ICD-9-CM administrative codes: candidates are retrieved from the ICD-9-CM catalogue by keyword and synonym search, then an AI step orders them and estimates a confidence value, and candidates scoring below 70 are discarded. If that AI step is unavailable, candidates are shown without the confidence gate, with a confidence equal to their text-search score and a floor of 10 - neither the search nor the AI ordering step makes a diagnostic inference
    - The AI structures information into standard report sections and highlights drug-name audio corrections
    - All suggestions are presented to you for review and approval
3. **Data Aggregation (Pre-briefing - MOD-05):**
    - Prior visit notes, uploaded documents, and patient history are retrieved and summarized
    - The AI organizes them for reference (no clinical interpretation or prioritization)
4. **Appointment Scheduling (Follow-up - MOD-08):**
    - The physician's explicit follow-up instructions are extracted from the transcript
    - The AI suggests appointment dates/times based on calendar availability
    - The appointment is scheduled only upon physician approval

Important: All AI outputs are suggestions or drafts. Final clinical decisions rest with the healthcare professional.