

Instructions for Use (IFU)

Document ID	DEN-IFU-001
Version	0.1
Date	07 Apr 2026
Regulatory Reference	Article 13

Table of Contents

- 1 Introduction
 - 1.1 Purpose and scope
 - 1.2 Device identification and regulatory information
 - 1.3 Intended purpose
 - 1.4 Intended users, patient population, and use environment
 - 1.4.1 Intended users
 - 1.4.2 Patient population
 - 1.4.3 Use environment
 - 1.5 Indications for use
 - 1.6 Expected clinical benefits
 - 1.7 Performance characteristics and operating limits
 - 1.7.1 Working performance baseline
 - 1.7.2 Operating limits
 - 1.8 Contraindications and not intended use
 - 1.9 System requirements and setup
 - 1.9.1 Supported environment

1.9.2 Minimum hardware and browser baseline

1.9.3 Network requirements

1.9.4 IT security requirements

1.9.5 Microphone permission and browser access

1.9.6 Microphone selection and device changes

1.9.7 Account provisioning and onboarding

1.9.8 Initial setup

1.9.9 Installation verification checklist

1.10 Operating instructions

1.10.1 Access the system

1.10.2 Select patient and session context

1.10.3 Before starting a documentation session

1.10.4 Start a documentation session

1.10.5 Pause, resume, or stop capture

1.10.6 Upload approved audio input where the released workflow permits file upload

1.10.7 Generate document-specific draft outputs

1.10.8 Template selection and context-text workflow

1.10.9 Review generated transcript and structured content

1.10.10 Correct, approve, and transfer

1.11 Warnings, precautions, and residual risks

1.11.1 Use-related hazard traceability (`DEN-US-001`)

1.11.2 Human review is mandatory

1.11.3 AI limitations

1.11.4 Automation bias warning

1.11.5 Patient identity and context warning

1.11.6 Completeness and submission warning

1.11.7 Correction and editability warning

1.11.8 Scope limitations

1.11.9 Audio quality limitations

1.11.10 Capture-state and device warning

1.11.11 Data privacy and confidentiality warning

1.11.12 Integration and transfer precautions

1.11.13 Residual risks

1.12 Troubleshooting and fallback

1.13 Data handling, cybersecurity, decommissioning, and privacy

1.13.1 Decommissioning and data deletion

1.14 Maintenance, updates, and version management

1.15 Electronic labeling and access to the IFU

1.16 Incident reporting and support

1.17 Revision control

1 Introduction

Field	Value
Document ID	DEN-IFU-001
Document title	Instructions for Use
Product	Dentio Practice Automation System
Product code	DEN-PAS
Software version	1.7.0
MDR classification	Class I
Classification rule	Annex VIII Rule 11
Effective date	To be decided before release approval
Status	Draft working version
Manufacturer	Dentio AB
Manufacturer address	Norrtullsgatan 6, 113 29 Stockholm, Sweden
UDI-DI	07350183430006
Basic UDI-DI	735018343Dentio_v1AM
SRN	SE-MF-000051592
Author	Lukas Sjögren
Reviewer	Anton Li, CTO
Approver	Anton Li, CTO

1.1 Purpose and scope

This Instructions for Use document explains the intended use, safe operation, limitations, and user responsibilities for the Dentio Practice Automation System.

This working draft is intended to seed or rewrite the controlled document **DEN-IFU-001** . It should be treated as a Dentio-specific baseline, not as release-ready text.

This IFU must stay aligned with:

- DEN-IP-001 for the intended purpose and explicit exclusions
- DEN-IP-002 for device description and architecture context
- DEN-RM-004 for risk-derived warnings and residual risks
- DEN-US-001 for use-related safety and usability assumptions
- DEN-LAB-001 for label / About-screen / electronic IFU presentation
- DEN-UDI-001 for device identification values and UDI rules
- DEN-CY-008 and DEN-CY-009 for operator-side network and IT assumptions

1.2 Device identification and regulatory information

The Dentio Practice Automation System is a browser-based cloud software medical device intended for professional dental-care use.

Current identification values for this release baseline:

- product name: Dentio Practice Automation System
- product code: DEN-PAS
- software version: 1.7.0
- UDI-PI (production identifier for this software release baseline): 1.7.0
- MDR classification: Class I under Annex VIII Rule 11
- UDI-DI: 07350183430006
- Basic UDI-DI: 735018343Dentio_v1AM
- manufacturer: Dentio AB
- manufacturer address: Norrtullsgatan 6, 113 29 Stockholm, Sweden
- support contact: support@dentio.com
- general contact: info@dentio.com
- website: dentio.com
- application access: app.dentio.com
- EU Declaration of Conformity reference: DEN-DOC-001

Dentio bears the CE mark in accordance with Regulation (EU) 2017/745 for a Class I medical device. No notified body number should be shown for the self-declared Class I configuration.

The controlled CE-mark symbol presentation for the final IFU release is to be decided before release approval and must remain aligned with `DEN-LAB-001` and `DEN-DOC-001` .

EUDAMED registration status for this release baseline must be verified against the current controlled registration record before release.

If any identification value changes, this IFU and `DEN-LAB-001` must be updated together.

1.3 Intended purpose

Dentio is medical software intended to support licensed dental professionals in the safe and effective management of patients' oral health through AI-assisted clinical documentation drafting. The software captures and structures explicitly stated clinical information from dental encounters and presents draft clinical documentation for clinician review, editing, and approval. Its intended benefit is to improve the quality, completeness, and consistency of clinical documentation and related record-keeping workflows, and to reduce documentation burden on clinicians.

Dentio is intended only for documentation support. All generated output remains a draft until it has been reviewed and explicitly approved by a licensed dental professional. Dentio does not replace professional clinical judgment.

1.4 Intended users, patient population, and use environment

1.4.1 Intended users APPROVED

Dentio is intended for use by:

- licensed dentists
- dental hygienists
- dental nurses
- other authorised dental professionals who are trained and permitted to review and approve clinical documentation

Users are expected to:

- understand routine dental documentation workflows
- meet the baseline user-profile assumptions in `DEN-US-001`, including licensed professional training with at least 3 years of higher education and basic-to-advanced routine IT use in clinical systems
- complete Dentio onboarding or equivalent organizational training before first independent use

- review the current IFU and applicable local workflow instructions before using the released system
- review AI-generated outputs before clinical use
- recognize when software output is incomplete, inaccurate, or unsuitable for the clinical situation

Dentio is not intended for use by patients or laypersons.

1.4.2 Patient population APPROVED

The intended patient population comprises patients receiving routine dental care within the intended dental-clinic setting. This includes adult and pediatric dental-care populations where the use case remains documentation support rather than direct treatment or diagnosis by the software.

The software does not interact directly with the patient and does not itself provide treatment.

1.4.3 Use environment

Dentio is intended for use in:

- public and private dental clinics
- general dentistry and specialist dental practices
- indoor professional care environments with suitable audio capture conditions
- workflows where the clinician can review generated text before it is used in the patient record

The software is intended to be used during or immediately after a patient consultation in environments where the clinic has the required internet connectivity, workstation setup, and local access controls. The released market baseline covered by this IFU is Sweden only. The controlling release-market IFU language is Swedish. A controlled English supporting version may be maintained where Dentio releases an English-language UI variant, but it does not replace the Swedish release version for the Sweden market. The released configuration may support clinician-controlled export or transfer of clinician-reviewed unsigned draft documentation to supported third-party journal systems. Such integrations are limited to transfer of unsigned draft information and do not finalize, sign, or autonomously enter documentation into the patient record.

1.5 Indications for use APPROVED

Dentio is indicated for AI-assisted drafting of clinical documentation and related record-keeping during or immediately after dental encounters. It may be used to transcribe and structure explicitly stated consultation content into draft record content for clinician approval.

The device is intended to support documentation activities performed by dental professionals. It is not intended to autonomously finalise documentation or determine clinical actions.

1.6 Expected clinical benefits APPROVED

When Dentio is used as intended and all generated content is reviewed by a qualified dental professional before final use, the expected clinical benefits are:

- improved completeness and consistency of clinical documentation
- reduced risk of documentation-related omissions in routine dental workflows
- support for maintaining accurate and up-to-date oral health records
- support for timely clinician review, correction, and completion of consultation documentation
- improved consistency of structured documentation that supports patient management and continuity of care

These benefits are indirect and depend on correct user review and approval. Dentio does not create clinical benefit by replacing clinician judgment.

1.7 Performance characteristics and operating limits

This section addresses MDR Annex I Section 23.4(e) and should remain aligned with the approved validation evidence in `DEN-AI-003` , `DEN-VV-004` , `DEN-CE-001` , and the released product specification.

1.7.1 Working performance baseline IN REVIEW

The following performance characteristics are working draft values and must be verified against the latest approved validation package before release:

- Word Error Rate (WER) for general clinical speech: $\leq 5\%$
- Dental Terminology Accuracy Rate: $\geq 95\%$
- Clinical Entity Recognition accuracy: $\geq 95\%$

- Diarization Error Rate (speaker attribution): < 5%
- Field-Match Accuracy for structured output: use the currently approved validated value from the released performance specification

1.7.2 Operating limits **APPROVED**

Performance can degrade when:

- audio quality is poor
- speakers overlap or interrupt each other frequently
- regional accents, dialects, mixed-language speech, or unclear diction differ materially from validated operating conditions
- microphones are poorly positioned or the room has strong background noise
- the user attempts to rely on output without completing the required review
- patient context or integration context is selected incorrectly before transfer

Users must treat generated content as draft content until review is completed.

1.8 Contraindications and not intended use **APPROVED**

No device-specific clinical contraindications are identified for Dentio when it is used within its intended professional documentation workflow and all output is reviewed before use in the patient record.

Dentio is not intended to:

- independently diagnose, detect, screen, or predict any disease or condition
- assign clinical findings or evaluate clinical risk
- generate patient-specific diagnostic or therapeutic recommendations, clinical warnings, or alerts
- perform automated clinical decision-making or influence clinical actions without human intervention
- analyse radiographs, measurements, physiological signals, or other diagnostic data
- monitor physiological parameters or vital signs
- finalise, sign, or enter documentation into the patient record without explicit clinician approval

Experimental or non-released integration work is outside the intended purpose and is not part of the released device configuration unless it is formally documented and validated.

1.9 System requirements and setup

This section supports MDR Annex I Section 23.4(ab) and should remain aligned with DEN-IP-002 , DEN-CY-008 , and DEN-CY-009 .

The device is ready for safe use only when the released Dentio environment, the user's account access, the active browser, the microphone path, and the destination workflow used for transfer have all been confirmed as available and appropriate for the intended documentation task.

1.9.1 Supported environment APPROVED

The clinic or user organization must provide:

- a desktop computer or laptop suitable for professional documentation review
- a supported web browser
- a functioning built-in or external microphone suitable for consultation audio capture
- an internet connection capable of stable real-time or near-real-time use
- a consultation environment in which the primary speaker can be heard clearly enough for reliable transcription and review

Supported browser baseline:

- Dentio is validated for use with the current and two most recent major versions of Google Chrome, Microsoft Edge (Chromium-based), Mozilla Firefox, and Apple Safari
- desktop and laptop use only; tablet and mobile platforms are not part of the released device configuration
- minimum supported display resolution: 1440 x 900 at standard browser zoom
- JavaScript, secure cookies/local browser storage, and microphone permissions enabled
- HTTPS/TLS connectivity to Dentio services available without interception that breaks application function

1.9.2 Minimum hardware and browser baseline APPROVED

Minimum hardware and browser baseline:

- device capable of running a supported browser without visible interface truncation during review workflows
- Dentio is intended for use on desktop and laptop computers running Windows (x64), macOS (Intel or Apple Silicon), or Linux (x64)
- microphone capable of intelligible speech capture in the intended clinic environment

- speaker or headset available where audio playback or verification is required
- operating system and browser still receiving current security updates from the platform vendor

The clinic and user are responsible for ensuring that the selected microphone and workstation setup are suitable for the intended consultation workflow. Dentio is not intended to compensate for persistently poor audio capture conditions.

1.9.3 Network requirements APPROVED

The operating environment must provide:

- stable outbound internet connectivity to Dentio services
- minimum upload speed of 1 Mbps
- sufficient bandwidth and latency characteristics for audio transmission and review workflows
- firewall settings that do not block required audio upload or application traffic
- reliable connectivity throughout the documentation workflow so the user can complete review and approval before transfer

Dentio is a cloud-hosted service. No on-premise infrastructure is required. No inbound firewall rules are required. A stable internet connection with a minimum upload speed of 1 Mbps is required. A wired or reliable Wi-Fi connection is recommended. Dentio buffers audio data locally and retransmits automatically if connectivity is briefly interrupted. If the clinic uses a web filtering proxy, it must allow WebSocket connections and must not strip authentication headers.

1.9.4 IT security requirements APPROVED

To use Dentio safely, the operator should ensure:

- only authorized users have access to Dentio accounts
- each clinician uses their own individual account
- user credentials are protected and not shared
- clinic devices and browsers are maintained with current security updates
- access to patient data is limited according to role and need
- local organizational controls are in place for secure workstation use
- devices are protected by screen lock, local access control, and malware protection according to clinic policy
- users sign out or otherwise end access when leaving a shared workstation

- Dentio automatically terminates inactive sessions to reduce the risk of unauthorized access

1.9.5 Microphone permission and browser access APPROVED

Dentio requires browser-level microphone permission for live audio-capture workflows.

Before first capture, the user must:

- allow microphone access in the browser when prompted
- confirm that the browser still shows microphone access as enabled for the Dentio application route
- stop and resolve the issue if microphone access is denied, blocked, or unavailable

If microphone access is denied or blocked:

- do not start or continue a live recording workflow
- retry the permission request only after confirming that the user intends to allow access
- recheck the browser permission state before retrying capture
- follow the browser-specific permission instructions approved for the released environment if manual permission reset is required

1.9.6 Microphone selection and device changes APPROVED

Dentio may show more than one available microphone or audio-input device. The user remains responsible for confirming that the active device is the correct microphone for the current consultation.

Users must:

- verify the active microphone before starting a recording workflow
- recheck the active microphone after connecting, disconnecting, or changing audio devices
- confirm that the selected device captures the primary speaker clearly enough for the intended workflow
- stop and correct the selection if the wrong device, no device, or an unsuitable device is active

Where the released configuration presents a recommended Dentio microphone or automatically prefers a newly connected recommended device, the user must still confirm that the active selection is appropriate before recording.

1.9.7 Account provisioning and onboarding

Dentio accounts for clinical use must be provisioned before first independent use.

For the released clinical workflow baseline:

- user access is expected to be created and authorized through Dentio onboarding or an authorized clinic administrator
- the user must receive the approved authentication method and any required access permissions before first use
- the user must complete the applicable Dentio onboarding or organizational training before independently approving or transferring documentation
- self-registration is not part of the controlled clinical-release workflow unless Dentio has explicitly approved that route for the released environment

1.9.8 Initial setup APPROVED

Before first use:

1. access Dentio through the current approved application route at `app.dentio.com` or the organization-controlled access path for the released environment
2. confirm that the user has appropriate authorization, has completed required onboarding or local training, and is permitted to approve clinical documentation
3. confirm microphone access and browser permissions and resolve any blocked-permission state before capture
4. confirm that the selected microphone captures the user's speech clearly in the intended room setup
5. if the released workflow includes a separate capture overlay or dedicated recording surface, confirm that the correct session, patient, and audio device are selected before starting capture
6. confirm connectivity and any required integration setup for the released workflow used by the clinic
7. confirm that the user understands the review obligation for AI-generated content
8. confirm that fallback documentation procedures are available if Dentio is unavailable

1.9.9 Installation verification checklist APPROVED

Before first clinical use of the released system, the responsible operator or administrator should confirm all of the following:

- the approved Dentio access route loads without browser security errors
- the user can authenticate successfully with the released access method
- the browser version is supported for the released baseline
- microphone permission is granted and a short audio-capture test confirms intelligible speech capture
- the correct patient/session selection workflow is available where the released configuration requires it
- the software version shown in Dentio matches the approved release baseline referenced by the current labeling and IFU
- the released transfer destination, if used, is available and the user understands the fallback process if transfer fails

1.10 Operating instructions

This section describes the released core documentation workflow for Dentio.

For the current released documentation workflow baseline, the output types covered by this IFU are:

- journal draft output
- odontogram / status output
- parodontal output (parod)

Other workspace, account, analytics, support, or administrative pages are not part of the safe-use workflow described in this IFU. Any additional document type or user-facing workflow that materially affects documentation safety must be added to this IFU before release approval.

This section describes the released core documentation workflow for Dentio:

1. access the system
2. select the correct patient and session context
3. capture or upload the relevant consultation content using an approved released workflow
4. generate and review the relevant draft output type
5. correct, approve, and transfer only the final clinician-reviewed draft

If a user-facing workflow materially affects documentation safety and is released to end users, this IFU must be updated before release approval so the released workflow is described here.

1.10.1 Access the system

1. sign in using an authorized Dentio account
2. open the relevant consultation or documentation workflow
3. verify that the correct patient and encounter context are selected, where applicable

1.10.2 Select patient and session context

1. confirm that the consultation is associated with the correct patient
2. if the released workflow uses a selectable session list, choose the correct planned or newly created session before recording
3. if the released workflow uses a separate capture overlay, verify that recording is enabled only for the selected valid session
4. stop and correct the workflow immediately if the wrong patient, session, or encounter context is shown

1.10.3 Before starting a documentation session

1. confirm that the consultation is associated with the correct patient
2. confirm that the microphone is active and positioned appropriately
3. confirm that the environment is suitable for intelligible speech capture
4. reduce background noise where reasonably possible
5. avoid parallel conversations, speaker overlap, or room activity that makes the primary speaker difficult to hear
6. confirm that fallback documentation procedures are available if capture fails

1.10.4 Start a documentation session

1. start audio capture according to the user interface instructions
2. speak clearly and follow the normal documentation workflow intended for the consultation
3. avoid overlapping speakers where possible
4. if several people speak, ensure that the clinically relevant speaker can still be heard distinctly
5. stop the capture when the relevant consultation content has been completed

1.10.5 Pause, resume, or stop capture

1. use pause only when the consultation workflow is temporarily interrupted and the user intends to continue within the same documentation session
2. before resuming, confirm again that the correct patient, session, and microphone are still active
3. if the interruption creates uncertainty about whether relevant content was captured, repeat or manually document the missing portion rather than assuming the recording is complete
4. when stopping capture, wait for the software to show that processing has started or completed before moving to generation or transfer
5. do not treat a paused, interrupted, or still-processing capture as final documentation content

1.10.6 Upload approved audio input where the released workflow permits file upload

1. use uploaded audio only if the clinic's released Dentio workflow permits audio-file upload for the intended documentation purpose
2. confirm that the uploaded file corresponds to the correct patient and consultation before submission
3. wait for the system to complete upload, finalization, and processing before relying on the generated output
4. if upload, finalization, or processing fails, use the fallback documentation process or repeat the upload only after reconciling what has and has not been received by the system

1.10.7 Generate document-specific draft outputs

1. select the intended output type before generation or review
2. for journal output, use the standard draft-generation workflow
3. for odontogram / status output, review the generated tooth findings and chart information as a separate document-specific output
4. for parodontal output, review the generated periodontal findings as a separate document-specific output
5. if the user enters extra instructions, context text, or template-guided instructions before generation, treat the resulting output as influenced by both the source consultation

content and the user-entered guidance

6. review each active document type separately before approval or transfer; do not assume that review of one document type also validates another

1.10.8 Template selection and context-text workflow

1. select a template only when it is appropriate for the current consultation type and the user understands the structure it will apply to the generated output
2. review the selected template before generation if the user is unsure what headings, phrases, or structure it will introduce
3. if the user enters extra instructions or context text, keep the text limited to relevant documentation guidance for the current consultation
4. do not use template or context-text input to introduce unsupported findings, diagnoses, treatment decisions, or patient information that was not established in the consultation workflow
5. after generation, verify that the resulting output still reflects the actual consultation and not an overly broad or outdated template expectation

1.10.9 Review generated transcript and structured content

1. review the transcript for omissions and inaccuracies
2. review structured outputs for formatting and content correctness
3. confirm that no unsupported diagnostic or treatment conclusions were introduced
4. confirm that all clinically relevant spoken content is represented correctly
5. confirm that patient identity and encounter context remain correct throughout the workflow
6. confirm that the generated draft is complete enough for the intended documentation step before moving to approval or transfer
7. pay particular attention to any word, tooth number, diagnosis, or other element marked with a question mark (?) or similar uncertainty marker; Dentio may use this to indicate uncertainty in the transcription or structuring
8. when an uncertainty marker is present, verify the source consultation content and correct, remove, or re-document the uncertain content before approval or transfer
9. until a dedicated visual uncertainty highlight is implemented in production, the user must not rely on color cues and must actively identify (?) markers during review
10. where extra instructions, context text, or templates were used, confirm that the final output still accurately reflects the consultation and does not add unsupported content

11. where more than one document type was generated, review each generated output independently before transfer

1.10.10 Correct, approve, and transfer

1. edit or reject inaccurate content
2. approve only the content that correctly reflects the consultation
3. confirm patient identity again in the destination record or journal system before export, copy, or transfer
4. verify that any confirmation dialogue, status indicator, or completion state shown by the system matches the user's intended action before submission, export, or transfer
5. where the released workflow allows document selection for transfer, confirm that only the intended reviewed document types are selected
6. for the current released workflow baseline, transfer or upload only the clinician-reviewed journal, odontogram, and parod outputs supported by the destination workflow
7. verify the final transferred or copied text in the destination record
8. if destination-system validation or upload errors occur, resolve them before repeating the action so that duplicate, partial, or conflicting entries are not created
9. use export or transfer only after the final review has been completed and only for unsigned draft information

Dentio must not automatically finalize, sign, or accept clinical documentation into the patient record without clinician review and explicit user action.

1.11 Warnings, precautions, and residual risks IN REVIEW

The warning, precaution, and residual-risk sub-sections below must be read together before the device is used clinically. They implement Dentio's current information-for-safety controls and should remain aligned with `DEN-RM-003` , `DEN-US-001` , and the formal risk-management file when completed.

1.11.1 Use-related hazard traceability (`DEN-US-001`) IN REVIEW

The following warning and workflow controls provide direct traceability to the current use-related hazards in `DEN-US-001` :

DEN-US-001 risk ID	Use-related hazard	IFU control
UR-01	User accepts incorrect transcription without review	Human review is mandatory, AI limitations, Automation bias warning, and review/approval workflow steps
UR-02	Confusion regarding which patient's data is displayed	Select patient and session context, Patient identity and context warning, and transfer verification steps
UR-03	Unintentional submission of incomplete document	Completeness and submission warning, installation/setup confirmation, and transfer validation checks
UR-04	Difficulty correcting erroneous AI-generated text	Correct, approve, and transfer, troubleshooting guidance, and fallback documentation instructions
UR-05	Misinterpretation of system messages	Capture-state and device warning, troubleshooting guidance, and plain-language review of warnings/confirmation states before proceeding

1.11.2 Human review is mandatory APPROVED

All AI-generated output must be reviewed, corrected where necessary, and consciously approved by a qualified user before it is relied upon or transferred into the patient record. This warning is a primary information-for-safety control for **UR-01**.

1.11.3 AI limitations APPROVED

Dentio may produce:

- omissions
- transcription errors
- AI hallucinations, meaning fabricated clinical content that has no basis in the source consultation content
- incorrect structuring
- wording that does not fully match the spoken consultation
- content that appears plausible but does not correctly reflect the encounter

- uncertain words, tooth numbers, diagnoses, or other elements that Dentio may mark with a question mark (?) when confidence is low
- Incorrect connection between clinical notes and rules by Försäkringskassan

Users must not assume that generated output is complete or correct without review. Any content marked with (?) or another uncertainty marker requires heightened manual review and correction before approval or transfer.

Pending production improvement requirement: uncertainty-marked content should be made visually prominent in the review UI, for example with a yellow highlight, so low-confidence content is easier to identify before approval or transfer. Until that is implemented, the (?) marker itself remains the active uncertainty indicator.

1.11.4 Automation bias warning APPROVED

Users must actively guard against automation bias. Output that appears fluent, plausible, or well-structured may still be incomplete, attributed to the wrong patient context, or clinically unsuitable.

The user must make an independent professional judgment and must not approve text only because it appears polished or because it was generated by the software.

1.11.5 Patient identity and context warning APPROVED

Documentation associated with the wrong patient creates a significant safety risk.

Users must:

- verify the correct patient before starting capture
- verify the patient and encounter context again before approval, export, or transfer
- stop and correct the workflow immediately if the wrong patient, wrong encounter, or wrong destination record is suspected

This warning directly supports mitigation of UR-02 .

1.11.6 Completeness and submission warning APPROVED

Users must not treat a generated draft as complete only because the workflow appears to have progressed normally.

Before approval, export, or transfer, the user must confirm that:

- the generated content is complete for the intended documentation step
- required corrections have been applied

- the system status or confirmation dialogue matches the user's intended action
- no partial, duplicate, or unfinished content is being submitted

This warning directly supports mitigation of UR-03 .

1.11.7 Correction and editability warning APPROVED

If the user cannot confidently correct, reject, or re-run inaccurate output, the generated draft must not be approved or transferred.

If editing controls, undo behavior, or document switching do not behave as expected:

- stop the workflow before approval
- preserve the correct patient context
- use the fallback documentation process if accurate correction cannot be completed safely

This warning directly supports mitigation of UR-04 .

1.11.8 Scope limitations APPROVED

Dentio only supports documentation of information that is explicitly stated during the configured consultation workflow.

The software must not be used as evidence that an unstated clinical conclusion has been established.

1.11.9 Audio quality limitations APPROVED

Performance may degrade when:

- background noise is high
- multiple speakers overlap
- microphones are poorly positioned
- the user speaks unclearly
- unsupported languages or terminology variants are used
- strong accents, dialect variation, or mixed-language statements fall outside validated operating conditions

If the speaker cannot be heard clearly, or if the environment does not allow reliable capture of the relevant consultation content, the user must not rely on Dentio output without heightened manual checking and correction. If reliable capture cannot be achieved, the user must use the fallback documentation process.

1.11.10 Capture-state and device warning APPROVED

Users must not assume that the capture workflow is safe to continue only because the interface remains open.

Users must stop and correct the workflow if:

- microphone permission is denied, blocked, or lost
- no suitable microphone is available
- the wrong microphone or audio-input device is selected
- recording is paused, interrupted, or disconnected and the user cannot confirm what content was captured
- the system is still uploading, finalizing, or processing and the final state has not yet been confirmed

This warning directly supports mitigation of **UR-05** where system status, warning, or confirmation messages may otherwise be misunderstood.

1.11.11 Data privacy and confidentiality warning

Dentio workflows may involve audio recordings, transcripts, structured drafts, and destination-transfer content that contain patient-identifiable health information.

Users must:

- protect credentials, active sessions, and workstation access throughout the workflow
- avoid recording, displaying, or transferring patient information where unauthorized persons can observe or access it
- use only approved Dentio access routes, approved devices, and approved transfer workflows for patient data
- report suspected unauthorized access, unintended disclosure, or data-integrity issues to Dentio without delay

Detailed handling, security, and decommissioning instructions are provided in **Data handling, cybersecurity, decommissioning, and privacy**.

1.11.12 Integration and transfer precautions

Supported third-party journal-system integrations are limited to clinician-controlled transfer of unsigned draft information.

Users must verify that transferred or copied text appears correctly in downstream documentation systems.

If integration or transfer fails, the user must resolve the issue before relying on the generated output as completed documentation.

1.11.13 Residual risks

Residual risks expected for Dentio include:

- transcription errors
- omission of spoken information
- AI hallucinations, including fabricated clinical findings, medications, tooth numbers, or recommendations not supported by the consultation content
- incorrect structuring of information into the wrong field or note context
- delayed detection of plausible but incorrect AI-generated wording
- documentation being associated with the wrong patient if the user does not verify context during review and transfer
- privacy or confidentiality harm if patient-identifiable information is exposed through unauthorized access, display, or transfer failure

These risks are mitigated primarily through mandatory clinician review and approval, usability controls, cybersecurity controls, and information-for-safety controls in this IFU. The substantive AI/ML hazard categories used for this warning set are currently aligned to **DEN-RM-003** ; formal residual-risk entry recording and final acceptability confirmation remain part of the controlled risk-management file workflow in **DEN-RM-004** when completed.

1.12 Troubleshooting and fallback

Representative user-facing message examples may include:

- No microphone found
- Failed to Detect Microphones
- Microphone System Not Ready
- Upload Failed

For contact details, see **Incident reporting and support** .

Situation or message type	User action	Escalation path
Microphone permission denied or blocked	Do not start or continue recording. Recheck browser permission state, request access again if appropriate, and confirm that microphone access is granted before retrying.	Contact the local administrator for browser/device policy issues, then use the Dentio support contact in Incident reporting and support if the problem persists.
No microphone found, Failed to Detect Microphones, or the wrong microphone is selected	Recheck the active audio-input device, reconnect the intended microphone if needed, and confirm that the correct device is selected before retrying.	Contact the local administrator if the device is unavailable or unstable, then use the Dentio support contact in Incident reporting and support if Dentio does not recognize an available microphone.
Recording paused unintentionally or capture interrupted	Stop and verify patient/session context, microphone state, and what content was actually captured. Repeat the missing portion or use fallback documentation rather than assuming continuity.	Contact Dentio support if the interruption recurs or creates uncertainty about documentation integrity.
Upload Failed, uploaded audio, finalization, or processing appears stuck	Do not assume the upload completed. Verify whether the file was received, wait for the final processing state, and avoid duplicate resubmission until the current state has been reconciled.	Contact Dentio support if the state does not resolve or if duplicate/partial processing is suspected.
Generated journal, odontogram, or parad output appears incomplete or incorrect	Check audio quality, patient context, selected document type, and any user-entered instructions or templates. Manually correct the output or repeat the workflow before use. Do not approve the output until it is accurate and complete enough for the intended documentation step.	Contact Dentio support if the issue persists or creates a safety risk.
Odontogram or parad generation fails	Confirm that the correct consultation content and document type were	Contact Dentio support if the dedicated document-generation

Situation or message type	User action	Escalation path
	selected, then retry only after checking that the underlying session state is complete enough for the requested output.	workflow continues to fail.
System status, warning, or confirmation message is unclear	Stop and read the message fully before proceeding. Verify patient context, workflow state, and whether the action being confirmed matches the user's intent. If uncertain, do not approve, export, or transfer the draft.	Contact the local administrator or Dentio support if the meaning remains unclear.
Session times out, the user is logged out automatically, or an unsaved draft may be lost	Sign in again, verify the correct patient/session context, and confirm what content has and has not been saved before resuming work. Do not recreate or retransmit content until duplicate-entry risk has been checked.	Contact Dentio support if draft state cannot be reconciled safely.
Integration, upload, or destination-system validation fails	Verify whether the content was saved or transferred successfully. Avoid duplicate or partial entry into the patient record. Reconcile the destination record before repeating the action.	Escalate according to local workflow and contact Dentio support if the issue affects documentation integrity.
Software unavailable or connectivity interrupted	Use the organization's fallback documentation process. Do not assume unsaved or partially generated text is complete. Re-enter the workflow only after access is restored and the current state has been verified.	Contact Dentio support if the interruption persists or affects patient-documentation integrity.
Login or access fails	Verify account status, browser compatibility, and that network policies are not blocking access.	Contact the local administrator first, then Dentio support as appropriate.

1.13 Data handling, cybersecurity, decommissioning, and privacy

Data handling, retention, deletion, and privacy behavior must remain aligned with the approved Dentio privacy, retention, and security documentation.

Users and operators should assume the following baseline responsibilities:

- use supported browsers and managed devices where possible
- protect account credentials and session access
- follow local patient-data handling rules and Dentio-approved workflows
- report suspected security events, data integrity issues, or unauthorized access without delay

Baseline controls that apply to safe use of the released system include:

- use only supported browsers, supported operating systems, and organization-approved devices
- maintain current operating-system and browser security updates
- use individual user accounts and protect credentials from sharing or reuse by other staff
- ensure secure workstation access controls, screen lock, and sign-out practices for shared devices
- use Dentio only over approved network paths that preserve secure application connectivity and required authentication behavior

The following cyber / privacy claims are still to be verified against the current approved Dentio security and privacy documentation before release and must not be finalized in this IFU until verified:

- hosting-location wording
- encryption wording
- authentication-method wording, including any MFA / SSO claims
- retention-period wording
- controller / processor role wording
- patient-information / consent wording specific to the released market

Do not publish market-specific data-hosting, retention, privacy, or security claims in the final IFU unless those values have been validated against the current approved Dentio data-protection documentation.

1.13.1 Decommissioning and data deletion

When a clinic or user organization stops using Dentio on a workstation or account, the operator should:

1. end active sessions and remove local access from shared devices
2. confirm that required patient documentation has been reviewed and transferred according to the approved workflow
3. remove downloaded files, browser-stored data, or temporary local copies according to clinic policy
4. deprovision user access according to the organization's access-control process
5. follow the approved Dentio data-retention and deletion procedure for account or service termination

1.14 Maintenance, updates, and version management

Dentio is maintained through controlled software updates.

Dentio does not rely on a fixed public release cadence. Updates may be deployed when needed for maintenance, security, workflow improvement, or safety correction, and users should treat the current approved labeling and the in-product version display as the authoritative release baseline.

Users should:

- use supported versions of browsers and client devices
- follow organizational instructions for software access and account lifecycle management
- review important update notices that may affect workflow or safety
- verify whether a change in version or labeling requires retraining or process updates
- check the software version shown in Dentio and compare it with the current approved label / IFU baseline when a release change is announced
- verify the running version in the released user interface through the current Help -> About Dentio or equivalent released labeling path
- review updated IFU or labeling material before using a newly released workflow that changes documentation behavior

Planned maintenance expected to cause significant downtime should be communicated in advance through controlled release communication. Safety-relevant updates should be communicated through controlled release communication, such as in-product notice, release

communication from Dentio, or updated labeling / IFU material before or at rollout of the changed workflow.

If a workflow change, maintenance event, or release notice indicates that safe use conditions have changed, the user must review the new instructions before continuing clinical use.

Major changes may require updated device-identification or UDI handling in accordance with **DEN-UDI-001**.

1.15 Electronic labeling and access to the IFU

The current approved IFU should be accessible through the software labeling / About-screen flow defined in **DEN-LAB-001**.

Working navigation assumption:

- Help -> About Dentio

The final released Dentio labeling should make the following items available through the electronic label or About screen:

- product name
- software version
- manufacturer details
- UDI information
- CE-mark display
- intended purpose summary
- link or download path to the current approved IFU

Users should always verify that they are consulting the latest approved revision.

1.16 Incident reporting and support **APPROVED**

Users should report:

- serious incidents related to the device
- significant malfunctions affecting safe use
- persistent inaccuracies or failures that could create a safety risk
- suspected cybersecurity or data-integrity issues that could affect safe use
- suspected serious incidents to Dentio immediately
- users and healthcare professionals in Sweden may also report suspected serious incidents to the Swedish Medical Products Agency (Läkemedelsverket)

- users and healthcare professionals established in other EU member states should also report suspected serious incidents to the competent authority in the member state where they are established

Dentio assesses manufacturer reportability and performs any required manufacturer vigilance reporting under the applicable MDR Article 87 process after receiving and assessing the event information. Users should therefore report suspected serious incidents to Dentio without delay and should not wait for a scheduled review cycle.

Support contacts:

- Dentio support: support@dentio.com
- Dentio general contact: info@dentio.com
- Dentio vigilance and paper-copy requests: support@dentio.com
- Swedish Medical Products Agency (Läkemedelsverket):
registrator@lakemedelsverket.se

Urgent safety-related contact currently follows the established Dentio support route and the vigilance procedure in DEN-PM-005 . A separate public telephone number for vigilance contact is to be decided before release approval.

The Swedish-market reporting and support wording in this IFU should remain aligned with the current DEN-PM-005 vigilance procedure.

1.17 Revision control

Field	Value
IFU revision	0.1 draft working version
Date of issue	To be decided before release approval
Latest approved revision	To be decided before release approval
Change description	Working revision updated to address current IFU audit findings for intended purpose alignment, UDI-PI traceability, setup verification, use-related risk traceability, warning terminology, troubleshooting detail, maintenance wording, and incident-reporting wording.
Label / About-screen alignment checked against DEN-LAB-001	Yes - reviewed against the current live draft on 2026-04-06

Software version identifies the released product build or release family. **IFU revision** identifies this controlled document version. They must remain traceable to each other but are not necessarily identical values.

Approval Signatures

Role	Name	Signature	Date
Author			
Reviewer			
Approver			