Vidd

Instructions for Use

Vidd Software (VM-01)

Vidd Medical AS

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Software version v1.1.0 · Date of issue 21 August 2026, revision 2 · English

1 About This Document and the Device

These Instructions for Use describe how Vidd Software is intended to be used, who may use it, what it does well and less well, and the warnings and limitations that apply.

Read Section 2 before you use Vidd Software for the first time. Keep this document available for reference.

FIELD	INFORMATION
Product name	Vidd Software
Internal reference	VM-01
Software version	v1.1.0
Release date (date of manufacture)	21 August 2026
Date of issue	21 August 2026, revision 2
Language	English
Manufacturer	Vidd Medical AS, Trondheimsveien 184, 4th floor, 0570 Oslo, Norway
Contact	post@viddmedical.com — www.viddmedical.com
Single Registration Number (SRN)	NO-MF-000049999
Device type	Software that is a medical device in its own right (MDSW)
Components	Software only. No hardware, no accessories
Declared MDR risk class	Class I
Classification rule	MDR Annex VIII, Chapter III, Section 6.3, Rule 11, final paragraph (“all other software”)
Notified body	Not applicable for the current Class I declaration
Conformity assessment	Manufacturer self-declaration under MDR Article 52(7)
EMDN code	V92 — Medical device software, not included in other classes
Basic UDI-DI	PP14321VIDD20251083
UDI-DI	112093808512
UDI issuing entity	IFA GmbH
Markets where made available	Norway

The software version is the production identifier (UDI-PI) required for traceability under MDR Annex VI Part C. This document applies to software version v1.1.0. For each subsequent release, Vidd Medical AS assesses whether a revised Instructions for Use, a new UDI-PI and/or a new UDI-DI is required, under the applicable change-control and UDI procedures. The version in use is shown in the software.

These Instructions for Use are supplied in electronic form, not on paper. They are published at **www.viddmedical.com/instructions-for-use**, where the current version and previously issued versions are available, and can also be opened from within Vidd Software. To find the correct document, use the product name Vidd Software with Basic UDI-DI PP14321VIDD20251083 or UDI-DI 112093808512, together with the software version shown in the application. A paper copy is supplied free of charge within seven calendar days of receipt of a request sent to post@viddmedical.com.

The document is available in Norwegian and English. The Norwegian version applies to the Norwegian market. Its content follows MDR Annex I, Section 23.4, and it forms part of the technical documentation under MDR Annex II.

2 Read This First

Four rules govern safe use of Vidd Software. Everything else in this document supports them.

⚠ **Everything the software produces is a draft.** Read it in full and approve it yourself before it enters the medical record. The software may add content that was never said, omit content that was, and attribute a statement to the wrong speaker.

⚠ **Verify the patient before you start and before you transfer.** A patient from an earlier session may still be in context.

⚠ **Check every citation against its source.** A citation may point to the wrong note, and content in a note you selected may be missing from the draft.

⚠ **Confirm in the medical record that the note is there.** A transfer confirmation is not proof that the content was stored.

3 Intended Purpose

Vidd Software is intended to assist authorised healthcare professionals in producing draft clinical documentation from patient consultations, clinical dictation and clinical documents selected by the user from the patient record, by:

- transcribing speech to text;
- extracting, assembling and structuring existing clinical content into a draft document of the type selected by the user; and

- allowing the user to ask questions about the current draft and, where available, the consultation transcript, and to request changes based on content contained in those inputs, for the user's review and acceptance or rejection.

All output must be reviewed, corrected where necessary and approved by the healthcare professional before it is finalised in the electronic health record or used for any clinical or administrative purpose.

Vidd Software is not intended to:

- diagnose a disease or condition;
- screen, predict or provide a prognosis for a disease or condition;
- monitor a patient's health or physiological parameters;
- recommend or select treatment;
- provide clinical alerts or scores;
- interpret symptoms;
- provide clinical decision support; or
- replace the healthcare professional's clinical judgement.

Vidd Software reproduces, organises and reformats information that the user has provided. It does not apply clinical rules, calculate values or compare the input against clinical criteria, and it is not intended to add clinical information that is absent from the input.

4 What the Software Does

FUNCTION	WHAT IT DOES
Speech-to-draft (Tale-til-utkast)	Transcribes speech from a consultation or dictation, and produces a draft note in the structure of a documentation template you select.
Text-to-draft (Tekst-til-utkast)	Produces a draft clinical document based on clinical notes **you select** from the patient record. The software extracts, assembles and structures content from the selected notes, with citations to the sources. Relevant information may be omitted; check the whole draft against the source material.
Vidd Assistent	After a draft has been generated, you can ask questions about it and request changes in natural language. It works on the consultation transcript and the current draft only, and keeps no conversation history between sessions. Changes are proposals you accept or reject.

Text-to-draft and your access rights. The function reads only the notes you select, and only notes you already have access to in the electronic health record. It gives you no access beyond your own rights, and your access to each note is logged. Before a note is used as a source, you confirm that you have read it and are familiar with its content.

The automated source check. After the draft is written, the software checks the link between the generated content and the notes you selected. This check is not a guarantee that a citation is correct. You verify each citation against the original note.

Generation and regeneration. On first generation the draft is added to the workspace without overwriting existing medical-record content. If you regenerate the draft, the previously generated draft is replaced, and manual edits made since the previous generation may be lost.

What the software does not reach. The language model does not browse the internet and does not retrieve information from clinical knowledge sources or look-up services. Patient data may be processed by approved data processors providing technical services for Vidd Software, under the applicable data-processing agreements and the approved deployment configuration.

Documentation templates determine the structure of the generated document and are controlled by Vidd Medical AS.

5 Using Vidd Software

STEP	ACTION
1	Log in with your personal account. In the embedded configuration you are logged in through the host clinical application.
2	Confirm the correct patient and encounter. Patient assignment can be deferred, but content cannot be transferred until a patient has been assigned and verified.
3	Inform the patient in accordance with your organisation's procedures and legal basis for recording and processing personal data.
4	Check that the microphone works and the audio indicator responds.
5	Provide the input. For speech-to-draft, start the recording. For text-to-draft, select the notes the draft is to be based on and read them. Text may also be entered or pasted directly. Select document type and template.
6	Wait for the draft to be generated.
7	**Read the whole draft.** Check that nothing has been added that was not said or written, that statements are attributed correctly, and that nothing relevant is missing.
8	For a text-to-draft document, check each citation against its source note, and check that nothing relevant from the selected notes has been left out.
9	Correct the draft, and add information from other sources that belongs in the record. You may use Vidd Assistent to propose changes; read each proposal before accepting it.
10	Approve the documentation. In the non-integrated configuration you copy or export it manually; in the EHR-integrated configuration Vidd Software publishes it; in the embedded configuration Vidd Software transmits it to the host application, which writes it into the record.

STEP	ACTION
11	Confirm in the receiving system that the documentation is present and complete, then log out.

Complete and transfer documentation in the same working session. Audio is deleted once the draft has been generated. Transcripts and drafts that have not been transferred are deleted automatically after the retention period configured for your installation, stated in the deployment documentation. A draft cannot be relied upon to be available later.

6 If Something Goes Wrong

SITUATION	WHAT TO DO
The wrong patient or encounter is selected	Do not approve or transfer. Correct the selection, or discard the draft. If content already reached the wrong record, follow your organisation's correction procedure and report it.
A recording was started for the wrong patient	Stop and discard it. Do not move it to another patient. Start again with the correct patient selected.
The microphone is not capturing	Check the connection and the browser's microphone permission, and confirm the audio indicator responds. Do not assume a session was captured because recording looked active.
The connection drops during a consultation	Do not assume recording continued. Check what was actually captured before you continue, and be ready to document by another method.
Generation fails or stalls	Wait for the software to report the outcome, then generate again. If it fails repeatedly, document by another method and report the fault.
The draft does not match the source notes — a citation points to the wrong place, or content you selected is missing	Do not approve on the basis of the citation. Verify against the source note, correct or complete the draft, and report it.
Manual edits disappeared after regeneration	Regeneration replaces the generated text. Re-apply your corrections before approving.
Transfer to the medical record fails	The draft is preserved. Check whether the note already reached the record, then retry.
Transfer is confirmed, but the note is missing from the record or appears twice	Do not close the session assuming the record is complete. Follow your organisation's correction procedure, document by another method if needed, and report it.

SITUATION	WHAT TO DO
A recording or draft is missing	Recordings and drafts are deleted after the retention period for your installation and cannot be recovered. A recording may also stop if you leave the page while it is paused. Document again, or by another method.
The browser is unsupported, or a warning about the environment appears	Switch to a supported browser or version, and check that content produced beforehand is complete.
You suspect unauthorised access	Log out and report it immediately to the responsible function in your organisation and to Vidd Medical AS. Access history is not available within the software.
An error is found after the note has been filed	Correct the record under your organisation's procedures. Once approved, the note is part of the record and no longer under the control of Vidd Software. If the error came from the software, report it.
The software does not respond	Document by your organisation's normal method and report the fault.

Report faults, incorrect output and security events to the responsible function in your healthcare organisation and to Vidd Medical AS at post@viddmedical.com. Serious incidents are reported as described in Section 20.

7 Further Warnings

The four rules in Section 2 apply at all times. In addition:

⚠ **Do not rely on generated output alone.** You remain responsible for what is recorded.

⚠ **Do not use the software for clinical decisions.** It provides no diagnoses, prognoses, treatment recommendations, alerts or interpretation of symptoms.

⚠ **Read every change Vidd Assistent proposes before accepting it.** Vidd Assistent is subject to the same limitations as the rest of the software.

8 Precautions

- Allow time to review. Transcription and summarisation introduce errors, omissions and wording that needs correction.
- The draft is generated from what you provide during the session, including any clinical notes you select. Nothing else is retrieved automatically; add other information where relevant.
- Never copy unreviewed content into the medical record or another system.

- Check the microphone and the audio indicator before recording. Speak clearly and avoid background noise.
- Follow your organisation's procedures and legal basis for informing the patient and for processing audio and personal data. Where you cannot, document by another method.
- Place the screen so the consultation is not disturbed and the content cannot be read by others. Keep hands-on use to a minimum during the consultation.
- In the non-integrated configuration, copied content stays on the clipboard after transfer. Check the patient context before pasting.
- Log out yourself. The automatic timeout does not replace it, and an active session must not be left unattended.
- Use the software only in the environment described in Section 11 and under your organisation's information-security and data-protection policies.

9 Performance, Languages and Evaluated Scope

Languages. Speech input and transcription: Norwegian and English. Generated written content: Norwegian Bokmål, Norwegian Nynorsk and English. Standardised section headings in clinical notes are produced in Norwegian regardless of the language of the body text, so a document with English body text is not wholly in English.

Accuracy. Vidd Medical AS states no numeric transcription accuracy figure, and does not claim uniform performance across consultations of differing complexity. Transcription is intended to be adequate as a basis for documentation that a healthcare professional reviews — not to be correct without review.

Conditions that reduce quality. Background noise, poor room acoustics or several people speaking at once; poor microphone quality or placement; unclear speech, strong dialect or an unsupported language; an unstable network connection; and specialised terminology, abbreviations or proper names uncommon in the language used.

Situations that have not been specifically evaluated. Consultations conducted through an interpreter; consultations where the language changes during the session; consultations with several simultaneous or overlapping speakers; patients with speech or communication difficulties; and young children. Output produced in these situations should be reviewed with particular care.

Document types. Draft transcriptions, draft clinical notes and summaries, and structured draft documents including discharge summaries, referrals, medical certificates and letters to patients. Which document types and templates are available to you is configured for your organisation.

How you can tell the software is working as intended. The recording indicator and audio level respond while recording; generation progress is shown; the draft remains marked as a draft until you approve it; and after a transfer attempt the software shows whether a technical confirmation was received or the transfer failed. A technical confirmation does not establish that the content was stored correctly in the right record — that is checked in the receiving system.

10 Configurations

Vidd Software is available in three configurations. All three have the same intended purpose and user group. Which functions are enabled is determined by the deployment. In all configurations the content is generated, presented and approved in Vidd Software, and nothing is transferred before you have reviewed and approved it.

CONFIGURATION	HOW IT IS USED
Non-integrated	You provide all patient context yourself. You review and approve the draft, then copy or export it manually into the medical record.
EHR-integrated	Patient and encounter information, and the notes you select, are retrieved from the electronic health record. You review and approve the draft, which Vidd Software publishes to the record through an approved integration.
Embedded	A host clinical application logs you in, provides your practitioner identity and supplies patient and encounter context, launches Vidd Software and displays it inside its own surface. You review and approve the draft, which Vidd Software transmits to the host application, which writes it into the record.

Patient and encounter information — retrieved from the electronic health record or supplied by the host application — is used for identification and transfer only. It is not used to generate clinical content.

In the embedded configuration, storage of the content and any subsequent processing after successful transmission are performed by the host clinical application, under the responsibility of its manufacturer. Confirm there that the content has been stored correctly.

Integration with a specific electronic health record system or host application is established for each deployment and documented by the manufacturer. The systems covered by your deployment are stated in the deployment documentation. Use with a system not covered by an approved deployment is outside the intended purpose.

11 Technical Requirements and Use Environment

Vidd Software is a web-based application used within authorised healthcare IT environments, deployed in an approved cloud-hosted or on-premises configuration.

REQUIREMENT	DESCRIPTION
Device	Desktop computer, laptop or tablet
Browser	Google Chrome, Microsoft Edge, Apple Safari or Mozilla Firefox — the current major version or the one immediately preceding it, with security updates installed
Operating system	The operating system and browser combinations approved for your installation are stated in the deployment documentation

REQUIREMENT	DESCRIPTION
Browser permissions	Microphone access must be permitted for the site
Network	A connection that is stable for the duration of a consultation
Audio	A functioning microphone, positioned so that the speakers are captured clearly
Access control	Individual user accounts issued and managed by the healthcare organisation. In the embedded configuration, users are authenticated by the host clinical application
Session timeout	The session ends automatically after a period of inactivity configured by your organisation, between 1 and 60 minutes. Individual users can neither extend nor disable it
Deployment	Approved cloud-hosted or on-premises configuration only
Data processing	Under a written data-processing agreement in accordance with Regulation (EU) 2016/679 (GDPR)

Network prerequisites specific to your installation — including addresses that must be reachable and any firewall or proxy configuration — are stated in the deployment documentation.

Minimum IT security measures to be provided by the healthcare organisation: controlled user provisioning, authentication and de-provisioning; protection against unauthorised access to the devices used; security updates for operating systems and browsers installed as released; and network protection in accordance with national and institutional requirements.

Vidd Software requires no physical maintenance. Updates and configuration changes are developed, verified and released under Vidd Medical AS's Quality Management System and distributed through secure channels. Users are informed of changes that affect use.

12 Indications for Use

Vidd Software is indicated for use by authorised healthcare professionals to transcribe patient consultations and clinical dictation into text, and to produce draft clinical documents from clinical notes selected by the user. It is not indicated for any specific disease, condition, clinical specialty or patient group.

13 Intended Users

The intended users are healthcare professionals who are authorised by their healthcare organisation to create or manage clinical documentation, hold the professional competence required for their role, have received the necessary information or training, and are able to review and correct the generated output. Users may include physicians, nurses, psychologists, physiotherapists and other qualified healthcare professionals.

Selection of the source notes used by text-to-draft is performed by the healthcare professional.

Patients are not intended users and do not operate the software.

14 Patient Population

Vidd Software is not intended for a specific disease, condition, clinical specialty or patient group. There is no restriction on patient age. The software does not assess patients and does not provide patient-specific clinical recommendations. No documentation templates or workflows specific to paediatric care are provided in this release.

Patient consultations, clinical dictation and clinical notes selected by the user form the input to the software.

15 Expected Benefit

Vidd Software supports the timely production of clinical documentation that the healthcare professional reviews, corrects and approves for the patient's medical record.

No claim is made that the software improves the clinical quality or the completeness of the medical record.

16 Contraindications and Limitations

No disease-specific contraindications have been identified, because Vidd Software is not intended for a specific disease, condition or patient group.

The following uses are outside the intended purpose:

- using generated output without review and approval;
- transferring unreviewed output to the electronic health record;
- using the output as the only source of clinical information;
- using the software to make or support diagnostic or treatment decisions;
- using the software for patient monitoring, triage or clinical alerts;
- using the software as a replacement for professional clinical assessment;
- using the software by an unauthorised person;
- using the software in an unsupported technical environment; and
- using the software when the healthcare professional cannot review the draft before it is finalised.

17 Residual Risks

Identified risks have been reduced as far as possible without adversely affecting the benefit-risk ratio, in accordance with MDR Annex I. The following residual risks remain and have been evaluated as acceptable:

- The software may produce content that was not present in the input.
- The software may omit information that was present in the input.

- The software may attribute statements to the wrong speaker or role.
- Content in a text-to-draft document may be cited to the wrong source note.
- Content present in a selected source note may be omitted from the draft.
- Documentation may be attributed to the wrong patient if the patient in context is not verified.
- A transfer confirmed by the software may not result in the content being stored correctly in the receiving system.
- Content approved in the non-integrated configuration may reach an unintended destination, because the transfer is performed manually.
- A note may be filed twice in the medical record if a failed transfer is retried without first checking the record.
- A recording may be lost if the session is left while a recording is paused.
- Manual edits may be lost if the draft is regenerated.
- Audio recordings are deleted after the draft has been generated. Transcripts and drafts that have not been transferred are deleted after the configured retention period and cannot be recovered.
- Unauthorised access may occur if login and logout procedures are not followed.

These risks are controlled through technical and organisational risk controls, verified workflows, information presented in the user interface, and the healthcare professional's review and approval of all output before use. The residual-risk evaluation is documented in the Risk Management Report.

No physiological side effects are associated with the use of Vidd Software.

18 Symbols

The following symbols are used on the product label and in the labelling, in accordance with EN ISO 15223-1:2021.

SYMBOL	MEANING
⚠	**Caution.** Indicates that caution is necessary, or that the situation requires the operator's awareness or action to avoid an undesirable consequence.
CE	**CE marking of conformity.** Indicates the manufacturer's declaration that the product complies with the applicable European legislation.
MD	**Medical device.** Indicates that the item is a medical device.
	Manufacturer. Indicates the medical device manufacturer.
UDI	**Unique Device Identifier.** Carries the UDI-DI and the UDI-PI. The Basic UDI-DI is not part of the UDI carrier; it is stated in Section 1 and in the EU Declaration of Conformity.
	Consult instructions for use. Indicates the need for the user to consult the instructions for use.

19 Abbreviations

ABBREVIATION	FULL TERM
AI	Artificial Intelligence
CE	Conformité Européenne (European Conformity)
DMP	Direktoratet for medisinske produkter (Norwegian Medical Products Agency)
EHR	Electronic Health Record
EMDN	European Medical Device Nomenclature
GDPR	General Data Protection Regulation (Regulation (EU) 2016/679)
IFU	Instructions for Use
LLM	Large Language Model
MD	Medical Device
MDR	Medical Device Regulation (Regulation (EU) 2017/745)
MDSW	Medical Device Software
QMS	Quality Management System
SRN	Single Registration Number
UDI-DI	Unique Device Identifier — Device Identifier
UDI-PI	Unique Device Identifier — Production Identifier

20 Reporting of Serious Incidents

Any serious incident that has occurred in relation to Vidd Software should be reported to Vidd Medical AS and to the competent authority of the Member State in which the user and/or the patient is established.

RECIPIENT	CONTACT
Manufacturer	Vidd Medical AS — post@viddmedical.com
Competent authority (Norway)	Norwegian Medical Products Agency (DMP) — report via Melde.no

A serious incident is any incident that directly or indirectly led, might have led or might lead to the death of a patient, user or other person, to a temporary or permanent serious deterioration of their state of health, or to a serious public health threat.

21 Manufacturer and Regulatory Compliance

Vidd Medical AS, Trondheimsveien 184, 4th floor, 0570 Oslo, Norway — post@viddmedical.com — www.viddmedical.com

Vidd Software is classified as a Class I medical device under MDR Annex VIII, Rule 11, final paragraph. Conformity is declared by the manufacturer under MDR Article 52(7); no notified body is involved in the conformity assessment. The EU Declaration of Conformity is available from the manufacturer on request. Vidd Software is developed and maintained under a Quality Management System compliant with EN ISO 13485:2016.

22 Related Documents

Supplied to your healthcare organisation together with the software:

- Deployment and installation documentation for your installation
- Quick guide for daily use
- Information on the processing of personal data
- EU Declaration of Conformity, on request

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