Instructions for Use

Software Version / Serial Number (SN): v1.0.0
Release Date (Date of Manufacture): 14 October 2025

For Vidd Software, the software version number serves as the serial number for traceability purposes.

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1. Device Identification

Product Name: Vidd Software
Type: Software as a Medical Device (MDSW), Class I in accordance with Regulation (EU) 2017/745 (MDR)
Manufacturer: Vidd Medical AS
Manufacturer Address: Trondheimsveien 184, 0570 Oslo, Norway
Basic UDI-DI: PP14321VIDD20251083

This IFU is provided in English. Translations will be made available in official EU languages where the device is marketed.

2. Intended Purpose

Vidd Software is an AI-assisted Software as a Medical Device (MDSW) intended to support healthcare personnel and individuals authorised by healthcare organisations in the creation, review, and management of clinical documentation within healthcare workflows.

All data processing occurs within secure and authorised healthcare IT environments or within certified data-processing infrastructures operated under formal agreements that ensure compliance with GDPR and applicable cybersecurity standards.

The software provides two primary functionalities:

Speech-to-text:

Conversion of spoken consultations and dictation into draft textual documentation through automated transcription supported by AI-based language processing.

Text-to-text:
Generation of structured draft summaries or reformatted documentation from existing clinical texts to support accurate and consistent patient records.

Vidd Software is intended solely as a documentation support tool. The device facilitates efficient and standardised record-keeping, and is not intended to analyse clinical information, interpret symptoms, establish diagnoses, or provide therapeutic recommendations.

All content generated by the software constitutes draft documentation and must be reviewed, validated, and approved by an appropriately qualified person within the healthcare organisation before inclusion in the patient's official record or for any other clinical or administrative use.

3. Indications and Users

Indications for Use:
Clinical documentation and administrative workflows in healthcare settings.

Contraindications: -

Intended Patient Population:
Not specific to any disease or condition.

Intended Users:
Individuals authorised by healthcare organisations to create, review, or manage patient documentation within clinical or administrative workflows.

4. Expected Clinical Benefits

When used as intended, Vidd Software may provide the following benefits:

- The software contributes to enhanced patient safety by improving the consistency of clinical documentation.
- Vidd Software accurately transcribes clinical consultations from speech to text, ensuring reliable documentation of patient interactions
- The software effectively generates a comprehensive summary of the consultation, reducing the risk of missing crucial information.
- Vidd Software allows clinicians to review and edit the generated content, ensuring the accuracy of the information stored in the patient's electronic medical record.
- The software contributes to enhanced patient safety by improving the consistency of clinical documentation.
- Vidd Software reduces the time spent on documentation, potentially increasing the time available for direct patient care.

All expected benefits are conditional upon correct use of the software and require that all outputs are reviewed and approved before inclusion in the EHR.

5. Warnings and Precautions

Vidd Software is a documentation support tool and must be used with care.

**The software uses artificial intelligence based on large language model (LLM) technology to assist in generating draft summaries. The output may occasionally contain inaccuracies, omissions, bias or fabricated ("hallucinated") information due to the inherent limitations of probabilistic, "black-box" models. All AI-generated content is therefore considered a draft and must be carefully reviewed, corrected, and approved by an authorised user within the healthcare organisation before it is stored in the EHR, communicated to patients, or used for any administrative purpose. The software must never be relied upon as a substitute for clinical judgement, diagnosis, or treatment decisions.*

Warnings

- All text generated by the software constitutes draft documentation and must be reviewed, validated, and, where necessary, corrected before it is stored or used within the electronic health record (EHR).

- Do not rely solely on automatically generated text. The authorised user remains responsible for verifying that all information recorded is complete and appropriate.
- Ensure that the correct patient is selected before recording or saving any documentation.
- Risk of temporary software malfunction or data-processing interruption may, in rare cases, result in incomplete or delayed output. Users shall verify that documentation has been properly saved and exported before closing a session.

Precautions

- Automated transcription or summarisation may introduce errors*, omissions, or phrasing that requires user adjustment.
- Do not copy or transfer unreviewed or unapproved draft content into official medical records or downstream systems.
- Operate the software only within authorised and secure IT environments, in accordance with institutional data-protection and cybersecurity policies.
- Verify microphone and system functionality before each use.
- Log out or close the session after use to prevent unauthorised access.

All identified risks related to the device have been reduced as far as reasonably possible. See Section 6 for information on residual risks.

6. Residual Risks

Despite implemented safety and quality controls, certain residual risks remain:

- Potential transcription or summarisation inaccuracies, resulting from inherent limitations of AI-based language processing (e.g., omission or misinterpretation of information)*.
- Incomplete documentation, if draft notes are not reviewed, approved, or successfully exported to the electronic health record (EHR).
- Risk of unauthorised access, if institutional login and logout procedures are not correctly followed.

All identified risks have been reduced as far as reasonably possible through design and process controls.

7. Compatibility and Deployment

Vidd Software operates as a web-based application within authorised healthcare IT environments.

The software may be deployed in authorised on-premises or cloud-hosted configurations, managed under formal data-processing agreements that ensure compliance with GDPR and institutional information-security requirements.

Temporary operational data may be stored securely for processing and system-performance purposes in accordance with local regulations and organisational policies.

Stable network connectivity and a modern, compliant web browser are required for operation.

A functional microphone is necessary for real-time speech-to-text use.

No physical maintenance is required.

Software updates and configuration changes are distributed under validated change-control procedures, in accordance with the manufacturer's Quality Management System (QMS), and released through secure channels.

8. Symbols and Abbreviations Used on Product Label and Documentation

Symbol	Description
	CAUTION: Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequence.
	CE Marking of Conformity: Indicates European conformity (CE) and the manufacturer's declaration that the product complies with applicable European regulations.
	Medical Device: Indicates that the item is a medical device.

	Basic UDI-DI: PP14321VIDD20251083
	Manufacturer: Indicates the medical device manufacturer.

9. Incident Reporting

In accordance with Article 87 of Regulation (EU) 2017/745, any serious incident related to the use of Vidd Software must be reported without undue delay to:

Manufacturer: Vidd Medical AS - post@viddmedical.com
Competent Authority (Norway): NOMA - meddev-no@noma.no

Report incidents both to the manufacturer and to the competent authority in your country.

10. Contact Information

For technical assistance or further information about the EU Declaration of Conformity:
Vidd Medical AS | Trondheimsveien 184, 0570 Oslo, Norway
post@viddmedical.com www.viddmedical.com

11. Regulatory Compliance

Vidd Software is classified as a Class I medical device in accordance with Regulation (EU) 2017/745 (MDR).
The device has been developed and is maintained under a Quality Management System compliant with ISO 13485:2016.
All identified risks have been reduced as far as reasonably practicable, and the overall residual risk has been evaluated and determined to be acceptable.
No physiological side effects are associated with the use of this device.