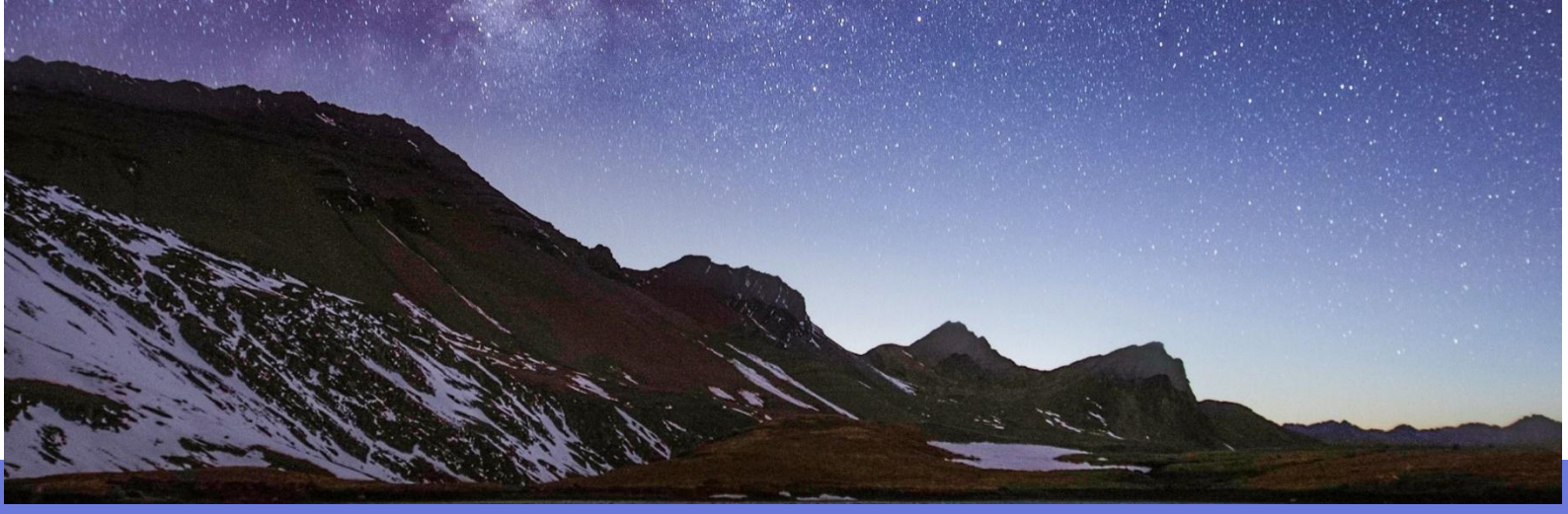

# DIKTAMEN DCB 0129 Clinical Safety Case Report

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| **Author(s): Rebecca Wilson CSO GPHC 5024799** | **Version issue date: 18/04/25** |

# Document Management

## Revision History

| Version | Date | Summary of Changes |
|---|---|---|
| 0.1 | 18/03/25 | Drafted |
| 0.2 | 07/04/25 | Amended following hazard workshop |
| 1.0 | 18/04/25 | Published |

## Reviewers

This document must be reviewed by the following people:

| Reviewer name | Title / Responsibility | Date | Version |
|---|---|---|---|
| Rebecca Wilsom | Senior Clinical Safety Officer | 18/04/25 | 1.0 |
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## Approved by

This document must be approved by the following people:

| Name | Title | Date | Version |
|---|---|---|---|
| Rebecca Wilsom | Senior Clinical Safety Officer | 18/04/25 | 1.0 |
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## Related Documents

These documents provide additional information and are specifically referenced within this document.

| Reference Number | Title | Version |
|---|---|---|
| Ref 1 | DCB0129 | 4.2 |
| Ref 2 | DCB0160 | 3.2 |
| Ref 3 | Diktamen Clinical Risk Management Plan | 1.0 |
| Ref 4 | Hasard Log | 1.0 |

| Glossary of Terms and Abbreviations | | |
|---|---|---|
| Clinical Risk | | The combination of the severity (impact) and likelihood (chance) of harm to a patient, including the probability of that harm occurring. |
| Clinical Risk Analysis | | The systematic use of available data to recognise and assess clinical risk. |
| Clinical Risk Control | | The process of making decisions and implementing actions to reduce clinical risks within acceptable levels. |
| Clinical Risk Estimation | | The process of assigning values to the severity (impact) of harm to a patient and the likelihood (chance) of that harm occurring. |
| Clinical Risk Evaluation | | The process of comparing clinical risk against established criteria to determine its acceptability. |
| Clinical Risk Management | CRM | The systematic application of management policies, procedures, and practices to analyse, evaluate, and control clinical risk. |
| Clinical Risk Management (CRM) Process | | A set of interrelated or interacting activities to meet the DCB 0129/0160 standard requirements, ensuring clinical safety in the development, deployment, and use of the digital health solution. |
| Clinical Risk Management File | CRMF | A repository containing all related Clinical Risk Management Documentation and Evidence for Safety Arguments. |
| Clinical Risk Management Plan | CRMP | A document outlining the implementation and any variations to the Clinical Risk Management System, describing how Clinical Risk Management will be conducted to ensure patient safety and meet DCB 0129/0160 requirements. |
| Clinical Safety | CS | Assessment of clinical risk to patients. |
| Clinical Safety Case Report | CSCR | A report presenting arguments and supporting evidence to make a compelling, comprehensible, and valid case that a system is or is not safe for a given application in each environment. |
| Clinical Safety Officer | CSO | An accredited clinician responsible for ensuring the safety of the digital health solution through clinical risk management as set out in the NHSE DCB 0129/0160 Standards. |
| Data Co-ordination Board | DCB | The DCB NHS standards, specifically DCB 0129 and DCB 0160, are guidelines issued by NHS England that require health IT system manufacturers and healthcare organisations to conduct risk assessments to ensure the clinical safety of their products before they are deployed. |
| Digital Health System | | A product used to provide electronic information for health or social care purposes, which may be hardware, software, or a combination. |
| Harm | | Death, physical injury, psychological trauma, and/or damage to the health or well-being of a patient. |
| Hasard | | A potential source of harm to a patient. |
| Hasard Log | HL | A mechanism for recording and communicating the ongoing identification of system hazards associated with a Digital Health system. |
| Health Organisation | HO | The organisation where the digital health system is deployed or used for healthcare purposes. |
| Initial Clinical Risk | | The clinical risk derived during clinical risk estimation. |
| Intended Use | | The use of the digital health system according to the specifications, instructions, and information provided by the Manufacturer to its Clients for its intended use. |
| Likelihood | | A measure of the occurrence of harm (probability). |

| | | |
|---|---|---|
| Manufacturer | | Responsible for the design, manufacture, packaging, or labelling of a Digital Health system, assembling a system, or adapting a Digital Health System before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party. |
| Patient Safety | | Prioritisation of minimising harm to patients. |
| Residual Clinical Risk | | Clinical risk remaining after the application of risk control measures. |
| Safety Management System | SMS | Key processes undertaken to ensure that Digital Health systems are designed and developed to minimise any potential clinical risk arising from their application within clinical care environments or healthcare-related activities. |
| Severity | | A measure of the possible consequences of a hazard. |
| Quality Management System | QMS | A structured framework of policies, processes, and procedures required for the design and manufacture of medical devices to ensure they consistently meet regulatory requirements and customer expectations. |

# Contents

# Document Control

This document is available in two forms, controlled and uncontrolled. The controlled variant is maintained electronically and accessed by authorised persons of Diktamen UK LTD and associated Healthcare Organisations who have or will deploy the Diktamen product. Uncontrolled variants are all other electronic and printed copies. The author of this document is Rebecca Wilson GPHC: 5027499, appointed Clinical Safety Officer, outsourced from DigiSafe Compliance LTD.

## Intended Audience

This document will be made available to all key stakeholders involved in the design, development, test and implementation and on-going maintenance of Diktamen.

## Executive Report

### Purpose

This Clinical Safety Case Report (CSCR) for Diktamen developed and maintained by Diktamen UK LTD, summarises the evidence required to demonstrate compliance with DCB 0129.

The CSCR includes the identification of hazards related to Diktamen, a detailed risk assessment through systematic evaluation and structured activities like Hasard Workshops, communication of risk control measures to mitigate any hazards, and where appropriate the transfer of risk and mitigation responsibilities.

The CSCR's validity is restricted to the functional scope and clinical contexts defined within the document and depends on the maintenance of defined mitigations by specified Hasard owners. Any changes to the system, its scope, or clinical use context necessitate a review and update of the Clinical Safety Case and CSCR. For the purpose of this CSCR the Diktamen product version number is 4.0.

### Compliance and Best Practices

The deployment of the product is planned to meet compliance and adhere to best practices in clinical safety standards, specifically DCB0129 and DCB0160. These standards ensure that digital health technology products are safe for use in clinical environments and that it meets the necessary regulatory requirements. By aligning with these standards, the

deployment process aims to minimise risks and enhance patient safety, ensuring that the product is both effective and reliable.

## Re-iterations

The CSCR will be revised and re-issued prior to the release of any new system version and updated post-deployment if the original safety case assumptions and risk evaluation do not reflect the actual clinical risk observed during practical use. Revisions will also occur during system maintenance stages, such as when extending the system's scope or using it outside the bounds covered by the original safety case. All iterations of the CSCR will be stored within the Clinical Risk Management File (CRMF), which is managed by the CSO and Top Management, with updates maintained in line with any changes throughout Diktamen's design and development life cycle.

The Clinical risk management file is stored in Diktamen UK Document management system.

## Assessment Overview

An experienced Clinical Safety Officer conducted a thorough assessment of the product and its associated documentation. This comprehensive evaluation included a detailed review of the product's design, functionality, and safety features. The assessment process was rigorous to ensure that the product meets all necessary safety and performance criteria. The Clinical Safety Officer's expertise was crucial in identifying potential issues and ensuring that the product is ready for deployment.

## Hasard Identification

The methodology used to identify potential hazards related to the product involved a structured approach, utilising risk assessment techniques such as Structured What-If Technique (SWIFT). This approach allowed for a systematic examination of potential risks and their impacts. By employing SWIFT, the assessment team was able to identify and document various hazards, ensuring that all potential risks were thoroughly evaluated and addressed.

## Risk Management Approach

The risk control approach adopted for this product deployment was based on the "As Far as Possible (AFAP)" method. This method involves assessing individual hazards and

implementing mitigations to minimise risk to the lowest practicable level. By applying AFAP, the team ensured that all identified risks were managed effectively, with appropriate controls and safeguards put in place to protect patient safety and product integrity.

## Assurance and Recommendations

The assessment conducted by the accredited Clinical Safety Officer provides assurance that the product has been fully reviewed and assessed for deployment. The thorough evaluation process confirms that Diktamen does meet all necessary safety and performance standards. The Clinical Safety Officer has provided several recommendations for consideration, including ongoing monitoring and periodic reviews to ensure continued compliance and effectiveness. These recommendations aim to support the safe and successful deployment of the product in clinical settings.

***In conclusion, the overall assessment of the product has been satisfactory, with no increased harm to patient safety identified. A total of four key hazard themes were recognised during the evaluation, each involving multiple contributing factors. However, through the implementation of appropriate initial controls, both the initial and residual risk scores were effectively reduced to a level of 2 or below – indicating low risk.***

***A key point to acknowledge is that two-factor authentication is not enabled by default; however, it can be activated if required by NHS organisations. Additionally, it is important to note that the Diktamen product is not currently integrated with the NHS Personal Demographics Service (PDS) or any electronic patient record (EPR) systems within the UK. While the product is functionally capable of supporting such integration, this has not been evaluated as part of this assessment. The evaluation has been based on the use of Diktamen as a standalone product, with no connectivity to medical records.***

# The DCB Standards

In England, manufacturers and deployers of Health IT systems, including software and apps, must comply with clinical safety standards DCB0129 and DCB0160, established under the Health and Social Care Act 2012. These standards provide a framework for Clinical Risk Management (CRM), requiring rigorous and systematic analysis to ensure technologies used in health and social care settings do not pose increased risks to patients. This report provides an overview of the Diktamen, manufactured by Diktamen UK LTD and deployed in NHS health and Care organisations, addressing clinical safety, governance arrangements, and other relevant information to support the mitigation of clinical risks associated with the product.

The Clinical Safety Case Report (CSCR) is the third document in a series required to support compliance with the DCB standards, following the Clinical Risk Management Plan and the Hasard Log. This report aims to demonstrate that the application complies with NHS clinical safety standards, ensuring it is clinically safe and fit for purpose. Together, these documents provide assurance that the application meets the necessary safety standards within NHS England's framework.

As the manufacturer Diktamen UK LTD are responsible for meeting the requirements of DCB 0129.

The Clinical Safety Objectives for the deployment include monitoring hazard identification and assessments, ensuring the solution's clinical safety, assessing changes to design and use, and implementing assurance activities for safety-critical functionality.

# Diktamen Overview

## Background

Healthcare professionals are often under pressure to balance intensive clinical duties with extensive documentation responsibilities. Time constraints, the demand for accurate record-keeping, and growing patient loads frequently contribute to documentation fatigue. These challenges not only impact operational efficiency but may also compromise the accuracy and timeliness of patient information. Diktamen has been implemented as a solution to alleviate these pressures by offering a digital dictation platform that streamlines the transcription process. By enabling clinicians and care professionals to dictate notes directly into a secure system—supported by priority settings, annotations, and file attachments—Diktamen allows healthcare teams to redirect their time and attention back to patient care while maintaining high-quality clinical documentation standards.

The deployment of Diktamen has been shaped by meaningful collaboration between several key stakeholders. Clinical staff were central to the process, providing practical insights into user interface preferences and workflow requirements. IT teams facilitated the secure setup, validated system performance, and ensured that infrastructure needs were met. Administrative staff contributed significantly to configuring access levels, designing user pathways, and managing queue-based workflow allocation. These stakeholders' input helped tailor the platform to meet the practical and regulatory demands of the clinical environment, ensuring that the deployment was not only technically sound but also aligned with day-to-day operational needs and expectations.

# System Overview

Diktamen is a comprehensive digital dictation and transcription platform designed to streamline clinical documentation workflows for health and care professionals. It facilitates efficient voice-to-text conversion, enabling clinicians to focus more on patient care and less on administrative tasks.

**Key Features and Functionalities**

- Multi-Device Dictation- Clinicians can record dictations using various devices, including desktop applications and mobile apps, providing flexibility and convenience.
- Secure Data Handling- All dictations are encrypted during transmission and at rest, ensuring compliance with data protection regulations like GDPR and ISO 27001 standards.
- Workflow Management- Dictations are automatically routed through a structured workflow—from the author to secretarial staff and then to transcriptionists—enhancing efficiency and reducing turnaround times.
- Priority Tagging and Annotations- Users can assign priority levels to dictations and add notes or instructions, facilitating better task management and communication among staff.

- Speech Recognition Integration- The platform incorporates advanced speech recognition technology to expedite the transcription process, reducing reliance on manual typing.
- Real-Time Monitoring- Managers and team leads have access to real-time status updates of dictations, enabling effective oversight and resource allocation.

Diktamen is an advanced and efficient transcription management system designed to streamline the process of converting audio dictations into accurate, complete, and well-organised text documentation. It serves as a crucial tool for healthcare organisations, offering flexibility and scalability to meet the needs of different users. With a focus on precision, ease of use, and workflow optimisation, Diktamen addresses the needs of multiple roles within healthcare documentation teams, including authors, secretarial staff, transcriptionists, and administrators.

**Key Features and Benefits of Diktamen**

**Author Role**

Authors, typically healthcare professionals such as doctors and clinicians, play a vital role in the process. With Diktamen, authors can quickly and easily record their patient care dictations using voice-recording devices or mobile applications. The platform supports various audio formats, enabling integration with existing devices.

Diktamen allows authors to:

- Dictate patient notes in real-time with the ability to pause, resume, or skip sections as necessary.
- Record detailed patient information, medical histories, treatment plans, and other vital data with ease.
- Streamline the process by eliminating the need for manual data entry, saving time and reducing the chance for errors.

This feature ensures that healthcare professionals can focus on patient care rather than spending excessive time on documentation, while still maintaining high-quality and accurate medical records.

**Secretarial Staff**

Once dictations are recorded, the secretarial staff steps in to manage the dictation queue. Diktamen offers an intuitive and user-friendly interface for secretaries to track, assign, and prioritise tasks. By ensuring a clear overview of the entire workflow, Diktamen helps secretarial staff:

- **Organise and prioritise dictation tasks**: Assign dictation jobs to transcriptionists based on urgency, complexity, and the availability of resources.
- **Ensure timely processing**: With real-time updates and notifications, secretarial staff can ensure that no dictation task is overlooked or delayed.
- **Monitor progress**: Secretaries can track the status of each dictation in the system, providing updates and notifications to authors or transcriptionists when necessary.

This role ensures that dictation tasks are processed efficiently, reducing bottlenecks and ensuring that documentation is completed within the required timeframe.

**Transcriptionists**

Transcriptionists play a crucial role in transforming audio dictations into accurate text. Diktamen's platform is designed to support transcriptionists with powerful tools that ensure high accuracy and productivity. Some key benefits for transcriptionists include:

- **Voice recognition technology**: Diktamen's advanced transcription system uses voice-to-text software to assist transcriptionists, enhancing speed and accuracy while reducing the risk of errors.
- **Easy navigation**: With features like timestamping, pausing, and adjusting playback speed, transcriptionists can easily navigate through complex recordings, ensuring precise transcription.
- **Error detection and correction**: Diktamen's built-in error-checking mechanisms help transcriptionists identify discrepancies in the text, ensuring that the final output matches the author's dictation without any medical inaccuracies.

By ensuring that each transcription is accurate, complete, and properly formatted, transcriptionists can deliver high-quality documentation that meets the medical industry's rigorous standards.

**Administrators: System Configuration and Workflow Optimisation**

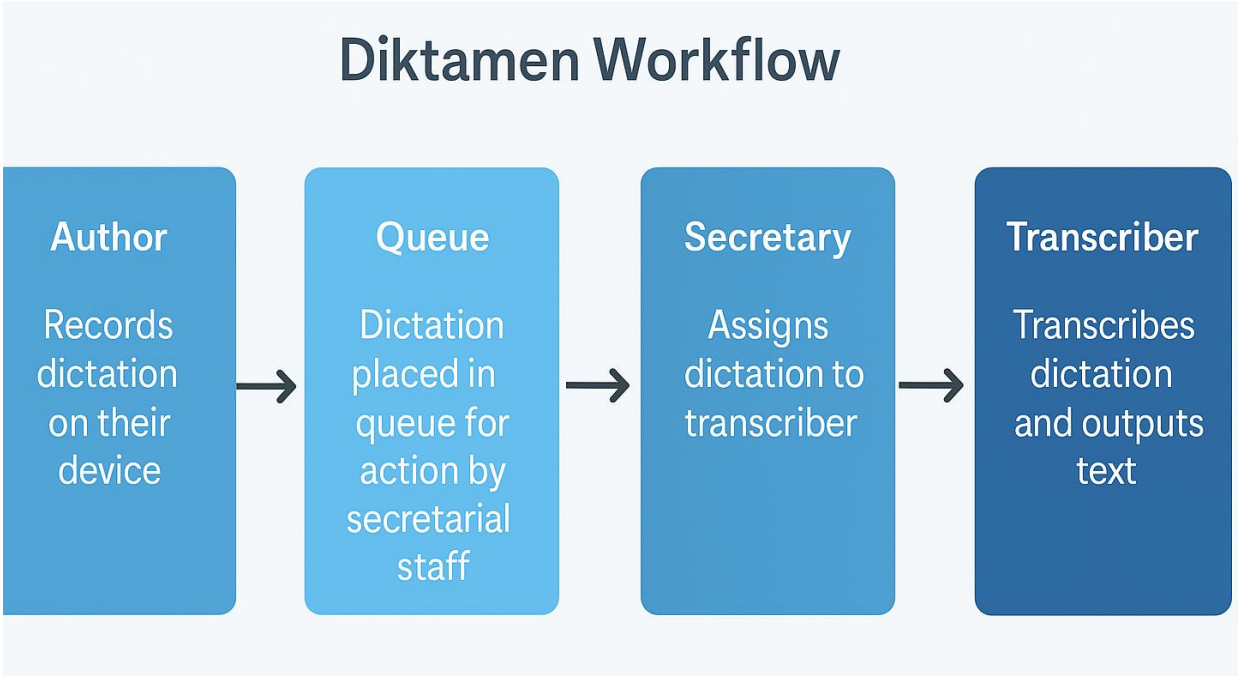
Administrators are responsible for the overall management and configuration of the Diktamen system. They ensure that the platform is running smoothly, optimising workflows, and maintaining a secure, reliable system for all users. Key responsibilities include:

- **User management**: Administrators can assign and manage user roles, ensuring that each individual has access to the necessary tools and resources according to their responsibilities.
- **System configuration**: Administrators can customise the system settings to meet the specific needs of the healthcare organisation, including workflow rules, notification preferences, and document templates.
- **Performance monitoring**: With real-time analytics and reporting, administrators can monitor the performance of the system, track user activity, and optimise resources for greater efficiency.
- **Security and compliance**: Diktamen ensures that all documentation and patient information are securely stored, in compliance with healthcare regulations such as HIPAA and GDPR.

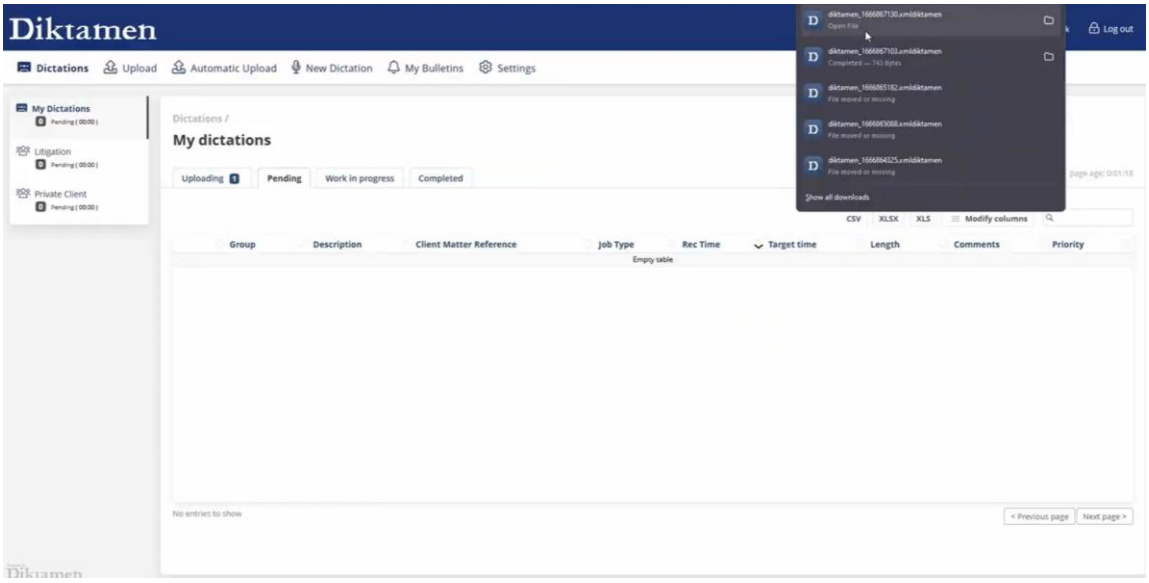
The system supports cloud-based storage, ensuring that documentation can be accessed from anywhere, at any time, enabling collaboration and improving patient care.

**User Roles and Responsibilities**

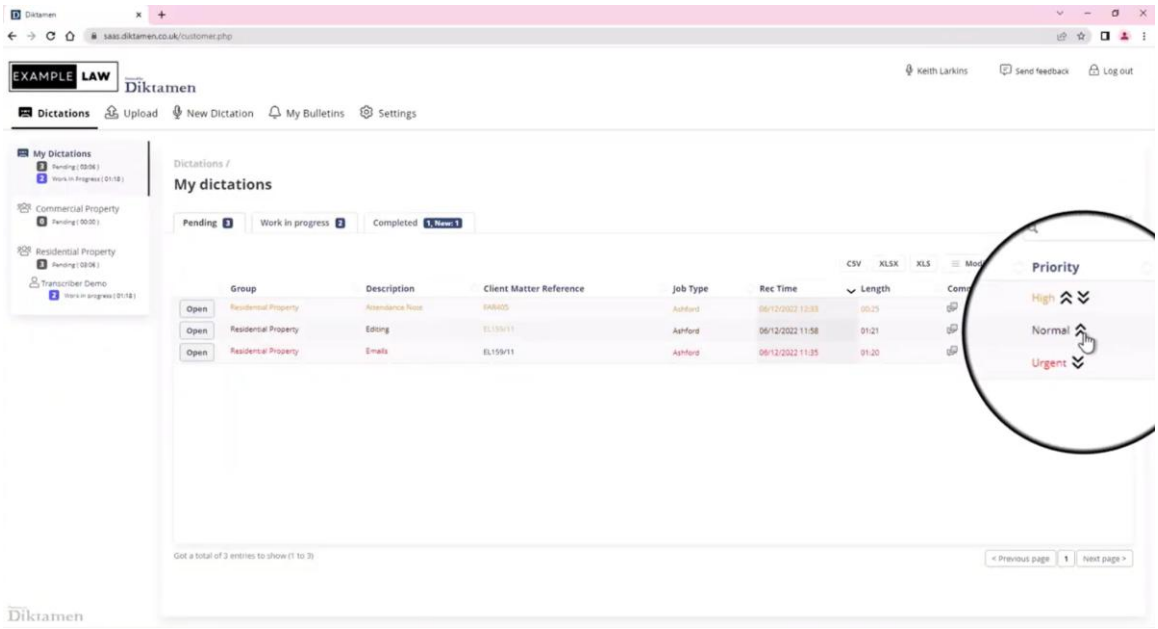
- **Authors**: Typically, healthcare professionals who record dictations related to patient care.
- **Secretarial Staff**: Manage the dictation queue, assign tasks, and ensure timely processing.
- **Transcriptionists**: Convert audio dictations into text, ensuring accuracy and completeness.
- **Administrators**: Oversee system configuration, user management, and workflow optimisation.



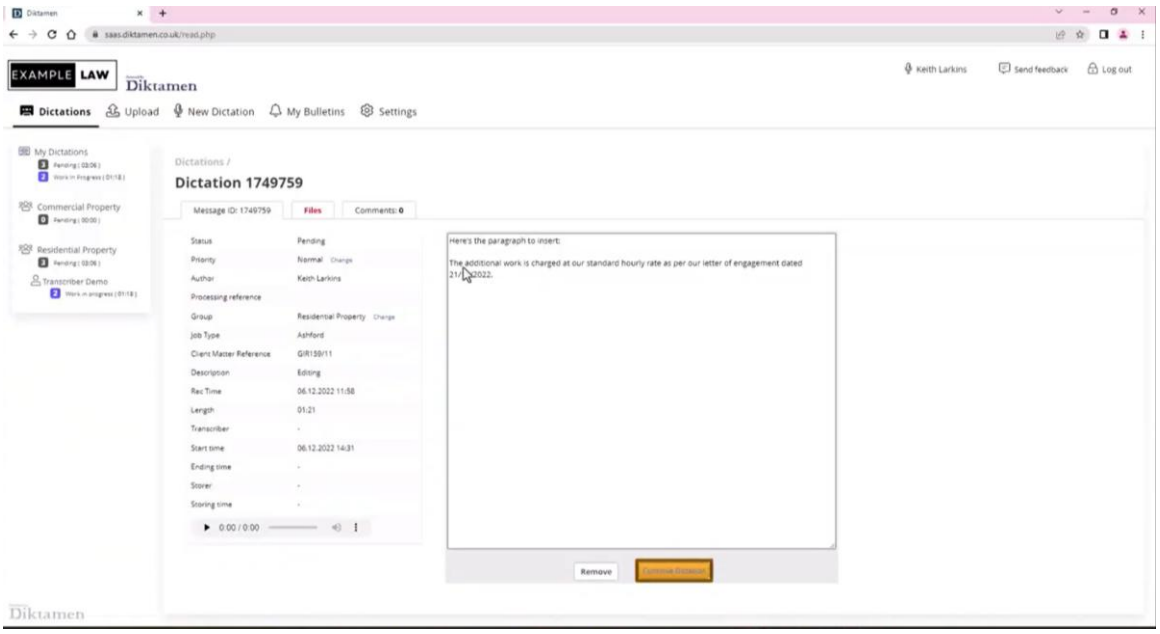
Below are some screenshots of the user interface.



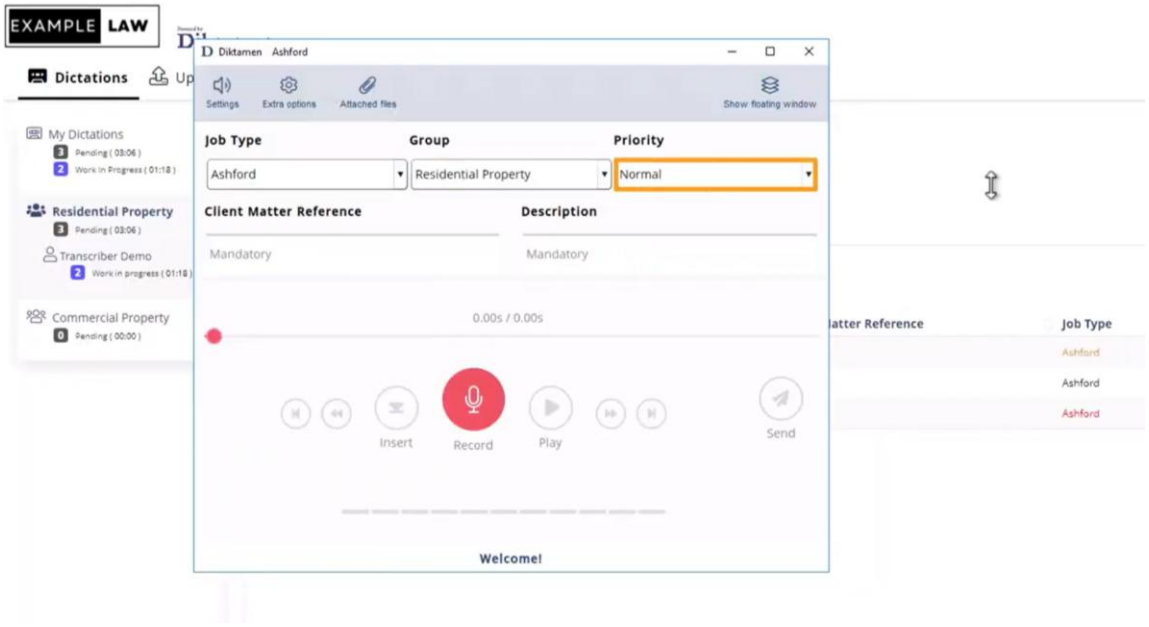

This pop up is displayed to the user at first time of use, they should ensure this is set to always open file so that the software auto launches, if they do not there could be a risk that the user cannot access the system and therefore, lead to a delay in dictation.




The author is presented with a dashboard, here they can easily see their dictations, they can also see any comments from other staff and the priority of the dictation recorded.




Within the dictation itself, authors can add notes and files.

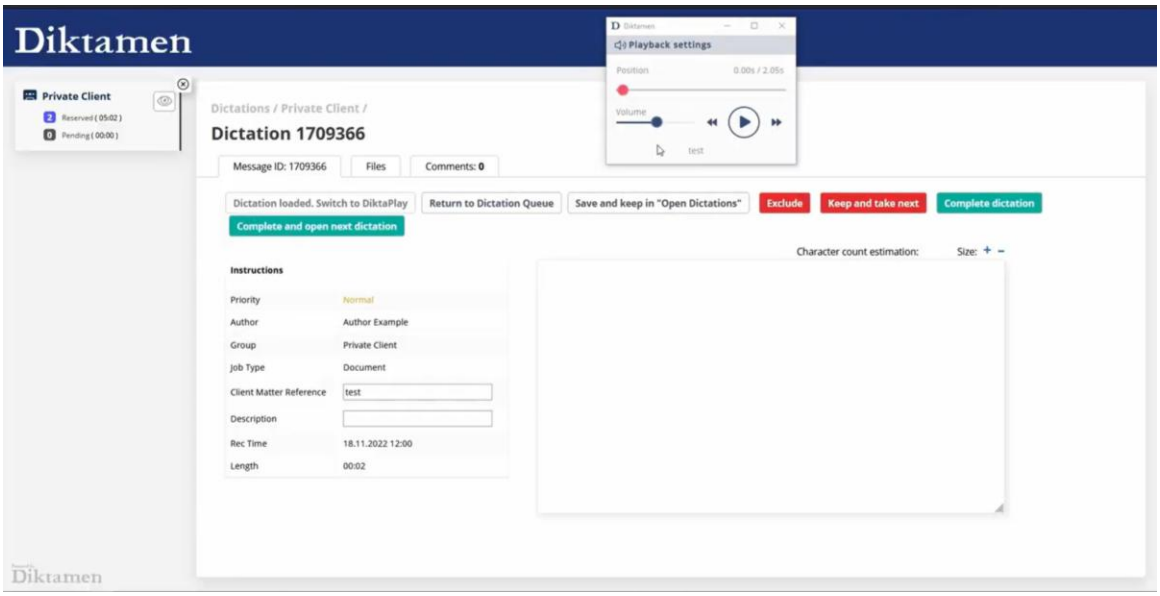



The above example shows how the author dictates, the field named ‘client matter reference’ is where the author would enter the details of the patient, these fields can be and will be configured with each deploying organisation to ensure that the correct data fields are captured for the patient, it is important to note that a minimal data set will be required to capture the patient details, this will include :

- First name
- Last name
- Date of Birth
- and/or NHS number

as minimum.

These demographics at a minimum will be required to capture the correct patient details and then the dictations to be safely recorded and transcribed. It is also important to note that the deploying organisations are required to ensure correct workflow processes are in place to match the dictation, files and any other documentation. Information for the patient must be recorded within the core primary medical record.

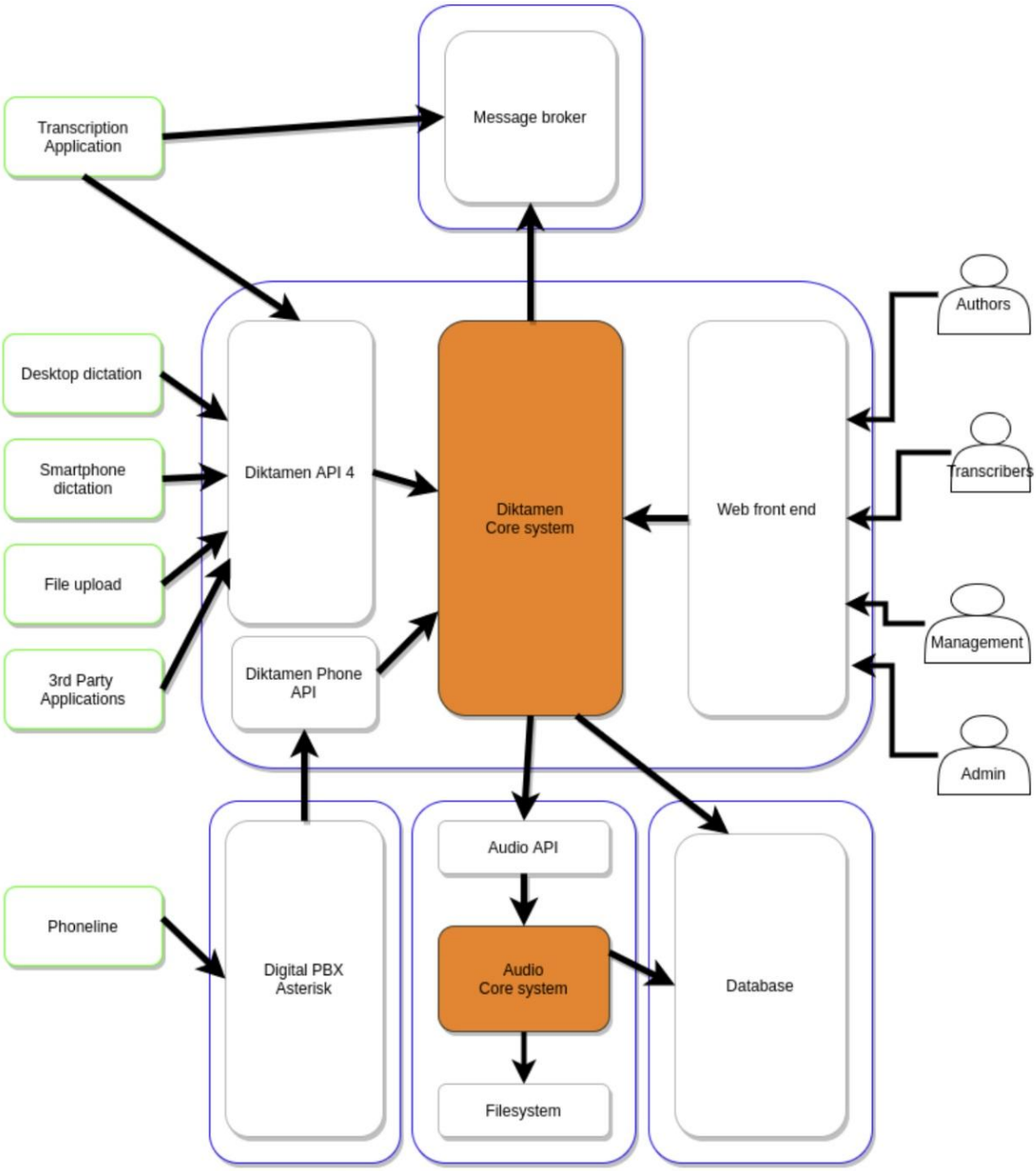



The transcribers see a similar dashboard to the author however, with the playback functionality, here the user can open, action, exclude and complete the transcriptions for the dictations.

Again, the users must ensure the launch is set up correctly, they are trained on where to look for notes, files, priorities and all notifications are set up accurately.

The Diktamen product has built in system design to ensure information is not discarded in error and pop-up boxes display throughout the system when certain actions are performed. There is also the ability to un-do an action and this is fully audited.

## Architecture Diagram




Picture 1. Architecture overview.

# Intended Use

Diktamen is a comprehensive transcription management system designed to streamline the process of converting audio dictations into accurate, complete, and organised text documentation within the health and care sector. The system is specifically intended for use by healthcare professionals—such as doctors, nurses, medical secretaries, transcriptionists, and administrators—who are responsible for creating, managing, and processing medical documentation.

The primary purpose of Diktamen is to improve the efficiency and accuracy of medical transcription workflows. By providing an intuitive interface for dictation, real-time task management, and advanced transcription features, Diktamen enables healthcare professionals to focus on patient care while maintaining high-quality documentation standards.

**Target Users:**

- Authors (healthcare professionals such as doctors, specialists, and nurses) who dictate patient care information.
- Transcriptionists who convert audio recordings into written documents.

- Secretarial Staff who manage the task queues, assign transcription jobs, and monitor the workflow.
- Administrators who oversee system configuration, user roles, and security.

**Key Functionalities:**

- Dictation Recording- Authors dictate patient information, diagnoses, treatment plans, and other medical details directly into the system.
- Task Management- Secretarial staff manage, assign, and track dictation tasks for transcriptionists.
- Transcription Tools- Transcriptionists convert audio files into accurate text with features like voice recognition and error-checking tools.
- System Administration- Administrators configure user roles, manage system settings, and ensure compliance with healthcare regulations.

Diktamen is applied in healthcare settings, such as hospitals, outpatient clinics, and private practices, where medical documentation is a critical part of patient care. The system ensures that patient data is documented accurately, efficiently, and securely, complying with necessary privacy standards (e.g., HIPAA).

## Test Plan

Diktamen has outlined a robust and structured approach to testing that supports the safe and reliable deployment of its clinical dictation and transcription platform within NHS and healthcare environments. Their testing practices are aligned with the expectations of DCB0129 and DCB0160 clinical safety standards, ensuring that any system introduced into the patient care pathway is thoroughly validated for function, safety, and integration readiness.

For every system release, Diktamen conducts Operational Acceptance Testing (OAT) and User Acceptance Testing (UAT) as part of the deployment project. These tests are performed to verify that the dictation and transcription workflows function as intended in the live clinical environment. The acceptance testing process is structured around core functionalities such as user authentication, integration with Electronic Patient Record (EPR) systems, and the accurate flow of clinical information through the system.

In addition to high-level acceptance testing, Diktamen also performs end-to-end functional testing. This includes both client-side components—such as the local workstation dictation client and speech recognition features—and server-side backend components, which handle data submission, validation, and logging. These tests ensure that the system behaves as expected across different environments and user scenarios, from recording a dictation to its successful submission, logging, and transcription.

Diktamen also confirms that integrity and validation checks are part of their routine system testing. Automated checks are in place to detect issues such as missing patient identifiers or failed submissions, which trigger alerts and logs for further review. These mechanisms help ensure that invalid or incomplete dictations are flagged early, preventing data corruption or loss.

The product supports site-specific configuration, and as part of deployment, custom workflows are tested to ensure compatibility with local clinical operations. This means that different departments or organisations using tailored workflows and settings will have their unique configurations validated through the testing process before go-live.

While Diktamen confirms ongoing product development and the inclusion of hotfixes when needed, the slide deck does not elaborate on the use of regression testing or automated test frameworks, nor does it mention the frequency or structure of these internal QA activities. However, the fact that all deployments undergo structured testing tied to NHS clinical safety compliance indicates a systematic and responsible approach.

- OAT and UAT conducted for every system release as part of deployment.
- End-to-end testing includes:
- Dictation client (recording and speech recognition)
- Backend and submission pathways
- User authentication
- System integration with EPRs verified during acceptance testing.
- Automated validation checks for data completeness and submission integrity.
- Custom workflows are tested per site as part of configuration.
- Monitoring and alerting systems are validated for real-time issue detection.
- Maintenance and updates occur biannually, with hotfixes as required.

## Training Plan

Diktamen has developed a comprehensive and flexible training approach to support successful adoption and ongoing use of its clinical dictation and transcription system. Their training plan is designed to ensure that users across deploying sites—including clinicians, secretaries, transcribers, and IT staff—are fully confident and competent in using the system, while maintaining clinical safety, data integrity, and workflow efficiency.

Training is coordinated closely with the deploying organisation and includes both in-person and remote options to accommodate diverse operational needs and geographical locations. This flexible delivery model supports scalable rollouts across multiple departments, sites, or even entire trusts. The training delivery is tailored on a case-by-case basis, ensuring relevance to specific team structures, workflows, and local priorities.

As part of the deployment project, Diktamen provides a suite of comprehensive training materials, including user guides, step-by-step instructions, FAQs, and training slides. These materials are role-specific and designed to reinforce correct usage, system navigation, and escalation procedures. In addition to written guidance, Diktamen offers guided workflows and in-system tooltips, which help users address common errors like incomplete submissions or failed validations.

Hands-on training workshops are delivered to introduce users to the platform's full functionality and to answer site-specific questions. These workshops may be delivered directly by Diktamen trainers or through a train-the-trainer model, where designated super users or clinical champions receive advanced training and subsequently support their local teams. These champions act as frontline support during both go-live and day-to-day use, helping ensure knowledge is retained and applied effectively within clinical settings.

All training activities and test outcomes are formally documented. This includes records of attendance, participant feedback, issues encountered during training, and the resolutions applied. Lessons learned are incorporated into future sessions to continuously improve the training process and support consistent system use across organisations.

- In-person and remote training options for flexibility across deployment sites.
- Tailored delivery based on each site's workflows and team structure.
- User guides, step-by-step slides, and tooltips provided to reinforce learning.
- Train-the-trainer model empowers local super users to support their teams.
- Workshops and Q&A sessions address practical usage and site-specific queries.
- Training includes alert interpretation, error resolution, and escalation SOPs.

- Documentation of test/training results, feedback, and lessons learned for improvement.

## Regulatory Compliance

Diktamen has built its platform in accordance with established health IT regulations and international standards to ensure safety, data protection, and compliance across NHS and broader healthcare environments. The company clearly articulates the intended use of its system as a digital health solution supporting clinical dictation and transcription workflows—not performing diagnostic, therapeutic, or direct clinical decision-making functions. This distinction is critical for regulatory purposes and confirms that Diktamen does not qualify as a Software as a Medical Device (SaMD) under MHRA or EU MDR classification.

As such, the product has not been designated a medical device and does not fall under classifications such as Class I, IIa, IIb, or III. Instead, Diktamen has aligned its compliance strategy with non-device digital health standards, particularly those required for NHS deployment. This includes strict adherence to DCB0129 (manufacturer compliance) and DCB0160 (user site compliance), both of which are mandated under Section 250 of the Health and Social Care Act 2012. These standards govern the safe design, implementation, and operation of digital health systems that influence clinical workflows or patient care pathways.

In support of information governance and cybersecurity, Diktamen is ISO/IEC 27001 certified, demonstrating a mature Information Security Management System (ISMS). This includes protocols for secure data handling, storage, and transmission, with strong encryption measures in place. The system does not transmit patient-identifiable data to external services, and all data is encrypted both in transit and at rest, in line with NHS Digital guidance and UK GDPR.

While Diktamen is not certified under ISO 13485 (medical device quality management) or ISO 14971 (risk management for medical devices)—which are not required given the product's classification—it does maintain an internal quality management structure appropriate to its scope. This includes rigorous processes for product testing, clinical

safety assurance, and version-controlled software updates. Regular testing, issue resolution, and controlled maintenance cycles further support product reliability and regulatory confidence.

Training and documentation processes are also aligned with compliance goals. During deployment, all relevant governance documentation—including DCB0129 submissions and clinical safety case reports—are shared with the deploying organisation's Clinical Safety Officer (CSO). This collaboration ensures a shared understanding of risk, operational expectations, and audit readiness.

- Product does not qualify as a medical device and is therefore not assigned a Class I–III designation.
- Not SaMD: No diagnostic or therapeutic function; used solely for documentation.
- DCB0129 and DCB0160 compliant, supporting clinical safety during deployment and use.
- ISO/IEC 27001 certified: Full ISMS in place for data protection and cybersecurity.
- Not ISO 13485 or ISO 14971: Not required due to non-medical device classification.
- QMS practices maintained internally, including structured testing, updates, and traceability.
- No transmission of patient data to third parties; all data is encrypted and securely stored.
- Clinical Safety Officer involvement ensures regulatory oversight during onboarding and operation.

# Clinical Governance Structures

Key governance activities involve approving the Clinical Risk Management Plan to ensure it is appropriate and achievable within the context of Health IT System development, modification and deployment. This includes ensuring that clinical risk management activities are completed according to the plan, reviewing and approving all safety documentation such as Clinical Safety Case Reports and the Hasard Log, and examining evidence in the Clinical Risk Management File to support the Clinical Safety Case Report. Additionally, these activities encompass providing recommendations to the project team as needed and escalating any unacceptable safety risks to management.

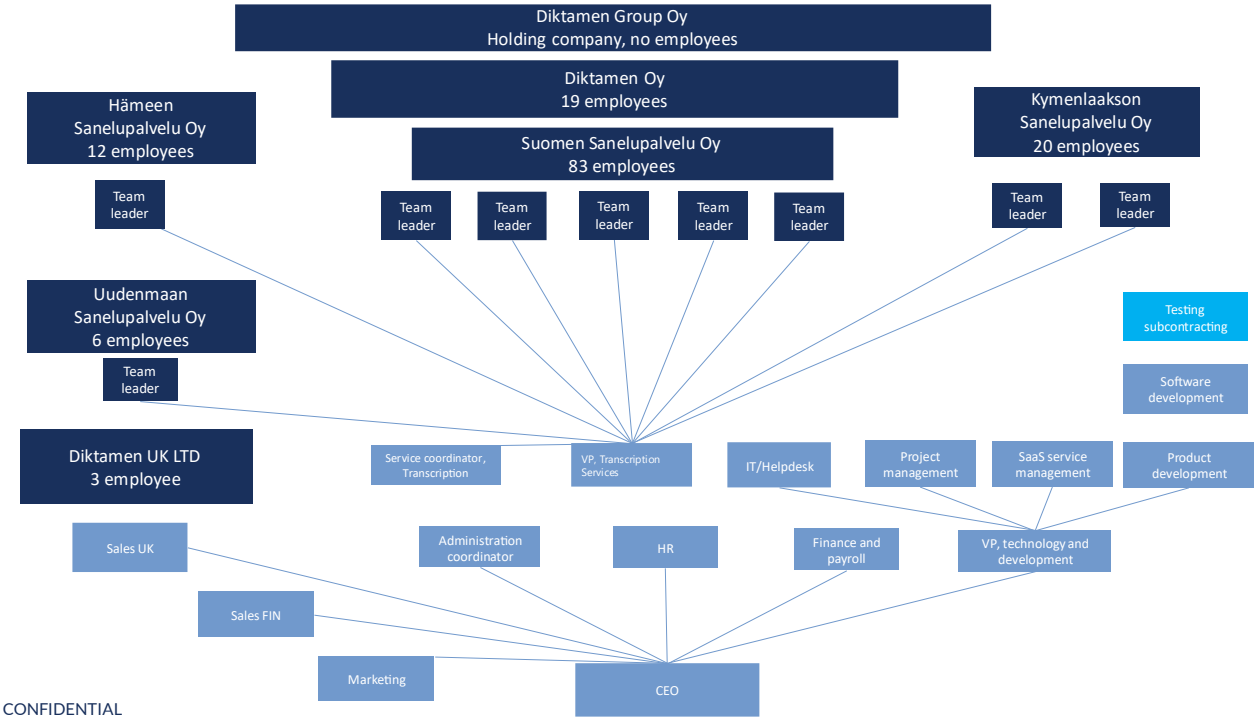
A formal governance structure has been established to oversee both the deployment and ongoing management of the Diktamen system. Rebecca Wilson outsourced Clinical Safety Officer (CSO) and Senior Pharmacy Technician with over ten years' clinical-safety experience. The governance framework brings together:

- **Clinical Leads and Champions**, responsible for ensuring that system workflows align with patientcare requirements;
- **IT and Infrastructure Teams**, accountable for technical deployment, integration, and system performance;
- **Operational Management**, charged with coordinating logistics, training, and day-to-day delivery; and
- **Diktamen's Product Team**, whose members are deeply versed in clinical risk management

During the initial deployment phase, meetings occur biweekly, transitioning to monthly once the system reaches steady state. Attendees include the CSO, product managers, IT representatives, operational managers, and Diktamen specialists. Standard agenda items cover:

1. Project milestones and status updates
2. Clinical-safety reports and any new hasard logging
3. Issue and risk reviews, with actions tracked to closure
4. Strategic decisions, configuration changes, and resource needs

## 5. End-user feedback and lessons learned

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## Service Management & Incident Reporting

Diktamen has established a comprehensive incident management framework to ensure that any system-related issues—ranging from user-reported errors to potential clinical safety events—are captured, assessed, and resolved in a timely and transparent manner.

**Incident Reporting Channels**

To capture feedback from all stakeholders, Diktamen provides multiple, easily accessible channels for reporting incidents:

- Helpdesk Ticketing System- 24/7 support via phone and email, logged in a central ticketing tool.
- Formal Complaints- Escalated via email to the account management.
- User Observations- In-platform "Report Issue" button and guided feedback prompts.
- Survey Feedback- Periodic user surveys to capture qualitative insights.

All channels feed into a unified incident register, ensuring no report is overlooked.

Detailed guidance on incident reporting is distributed to every deploying organisation:

- A quick-reference guide outlining required information (timestamp, patient context, screenshots/logs).
- An escalation flowchart showing whom to contact for each priority level.
- In-system tooltips and onboarding slides that demonstrate how to use each reporting channel.

# Clinical Risk Identification and Analysis

## Hasard Identification

Diktamen conducts hasard identification workshops, facilitated by a Clinical Safety Officer, to identify potential hasards associated with the deployment and use of a digital health system. These workshops employ methodologies such as HASID and SWIFT to identify risks, with minutes taken and stored in the Clinical Risk Management File (CRMF). If third-party components are involved, they will be included in the hasard identification and risk assessment scope.

All identified hasards are recorded in the Hasard Log. Hasard identification considers end-to-end clinical and non-clinical processes, with details documented in the CRMF and

Clinical Safety Case Report. Any changes to the digital health system's scope or content will prompt a hazard identification review.

## Models of Hasard Identification

### HASID (Hasard Identification)

HASID is a qualitative risk analysis technique used to identify potential hazards through a workshop-based approach. The primary goals are to review the process early to ensure the design accommodates credible hazardous scenarios and to assess safeguards intended to mitigate risks for these scenarios. A successful HASID workshop requires a multidisciplinary team familiar with the process and its operation. It should be led by an experienced chair, with a scribe to document all identified hazardous scenarios, their likely consequences, safeguards, and actions.

#### SWIFT (Structured What If Technique)

This technique uses targeted questions to explore the consequences of unintentional actions across functions, information, and users. The analysis is documented in a simple table, making the process straightforward and easy to follow, quickly identifying significant issues.

#### Additional Sources of Hasard Identification

Hazards may also be identified during the development, deployment, and use of the digital health system through:

- Discovery activities during the design of a solution.
- Testing of amended functionality of the product in different configurations.
- Ad hoc testing of live service functionality and end-user feedback/insights.
- Reporting of an incident, near miss, or problem within the live service.
- Identification by a third-party supplier or user base.


*Clinical Risk Management Lifecycle*

## Hasard Log

The Hasard Log includes hazard identification, descriptions of patient safety consequences, explanations of hazard causes and contributory conditions, identification of existing mitigating controls, and estimation of clinical risk. It also identifies participating personnel. For each identified hazard, the Hasard Log records the hazard number, name, description, potential clinical impact, possible causes, existing controls, and additional recommendations to reduce the risk score. The Clinical Safety Officer has estimated clinical risks, evaluated and managed clinical risk control, with hazards scored and residual risks assessed. Hazards are categorised as open, closed, or transferable between the solution, deploying sites, and end users, with controls applied as needed in each setting.

## Hasard Workshop

Hasard Workshops were held with the Diktamen and the CSO to review the baseline Hasard Log and identify additional hazards. These workshops systematically examined the solution design and supported workflow, focusing on identifying hazards, their main causes, controls to reduce residual risk, and assigning ownership of outstanding actions. The Clinical Safety Officer facilitated these workshops, aiming to capture and review existing and new potential hazards, and to agree on initial risk ratings based on the system workflow.

Follow-up sessions with key team members were conducted to refine hazards and identify controls. These meetings focused on validating system mitigations, re-estimating residual risk, and setting timescales for the review, write-up, and publication of the CSCR.

# Clinical Risk Analysis

Clinical risk identification and analysis was conducted using the Structured What If Technique (SWIFT) to consider potential consequences, causes, clinical safety impacts, existing controls, and recommendations to improve patient safety. Consideration was given to potential hazards such as inappropriate use, infrastructure or software failures, and user training issues. These scenarios may contribute to a series of failures that could result in a patient safety issue.

Key activities in the clinical risk analysis included reviewing the product scope, clinical context, workflow, existing safety documentation, interfacing dependencies, and conducting structured hazard workshops and ad-hoc review sessions.

The nominated Clinical Safety Officer (CSO) assessed the solution, associated workflows, and all relevant supporting evidence, enabling the identification of hazards, their effects, potential harm, and causes. These findings were documented within the Hasard Log (ref 4), reviewed by the project team, and discussed in a hazard workshop. They should be reviewed prior to deployment. The clinical risk associated with each hazard has been scored based on the severity of harm and the likelihood of occurrence, considering existing mitigations. The assessment criteria and risk acceptability matrix are detailed in appendices.

The attitude towards undesirable risk has evolved with increasing digital awareness. Previously go-lives would be halted if undesirable risks exist, however the scoring mechanism now serves as guidance to highlight high-risk areas where further controls should be implemented.

## Clinical Risk Estimation and Evaluation

All identified hazards were evaluated using a "Cause, Effect, Hasard, Harm" approach to explore potential consequences, considering contributory factors and existing mitigating controls from health IT design, end-user training, and business processes.

The clinical risk associated with each hazard was scored based on the severity of harm and the likelihood of occurrence, considering existing mitigations. The criteria used for assessment are detailed in Appendix 1-4.

This defined the initial risk score, and further recommendations led to the Clinical Risk Analysis Process, ensuring that residual risk ratings are accurate and justified. The table outlines the number of identified hazards and their respective residual risk ratings following the initial risk score and recommendations. These will continue to be evaluated, and further mitigation will be applied as the risk management process dictates during ongoing risk assessment. Hasard identification is a continuous activity throughout the product's lifecycle, conducted by the CSO.

The risk scoring system, as described in the Clinical Risk Management Plan and Clinical Risk Classification Matrix, is based on grading the severity and likelihood of patient harm occurring which gives a resulting Clinical Risk Rating (Appendix 1-3).

The initial risk of the system overall low with 4 hazards identified as having an Initial Risk Rating of 1-2 (acceptable) and 0 hazards with an undesirable risk rating of 3, requiring further evaluation and risk control.

0 hazards were identified with a Risk Rating of 4/5.

The Clinical Risk Estimation ratings from the Initial Clinical Risk Evaluation process were used to identify and prioritise hazards for further mitigations, as outlined the Residual Risk Acceptance Criteria table used during the evaluation process

(Appendix 4). Further risk control measures will reduce the clinical risk rating further and form the Residual Risk Rating.

| Initial Risk Rating | | | | | | |
|---|---|---|---|---|---|---|
| **Initial Risk Score** | 1 | 2 | 3 | 4 | 5 | Total |
| **Number of Hasards Identified** | 1 | 3 | 0 | 0 | 0 | 4 |

## Control Option Analysis & Control Measure Implementation

Verification of control measures is critical to ensuring the accuracy of Residual Risk Scores. For all identified hazards, clinical risk control options were considered. Controls are interventions that reduce the likelihood of a hazard occurring and can be categorised as follows:

- System design or functional change
- System testing and validation of effective control implementation.
- Targeted user training and/or instruction
- Additional workflow process, modification or business process controls

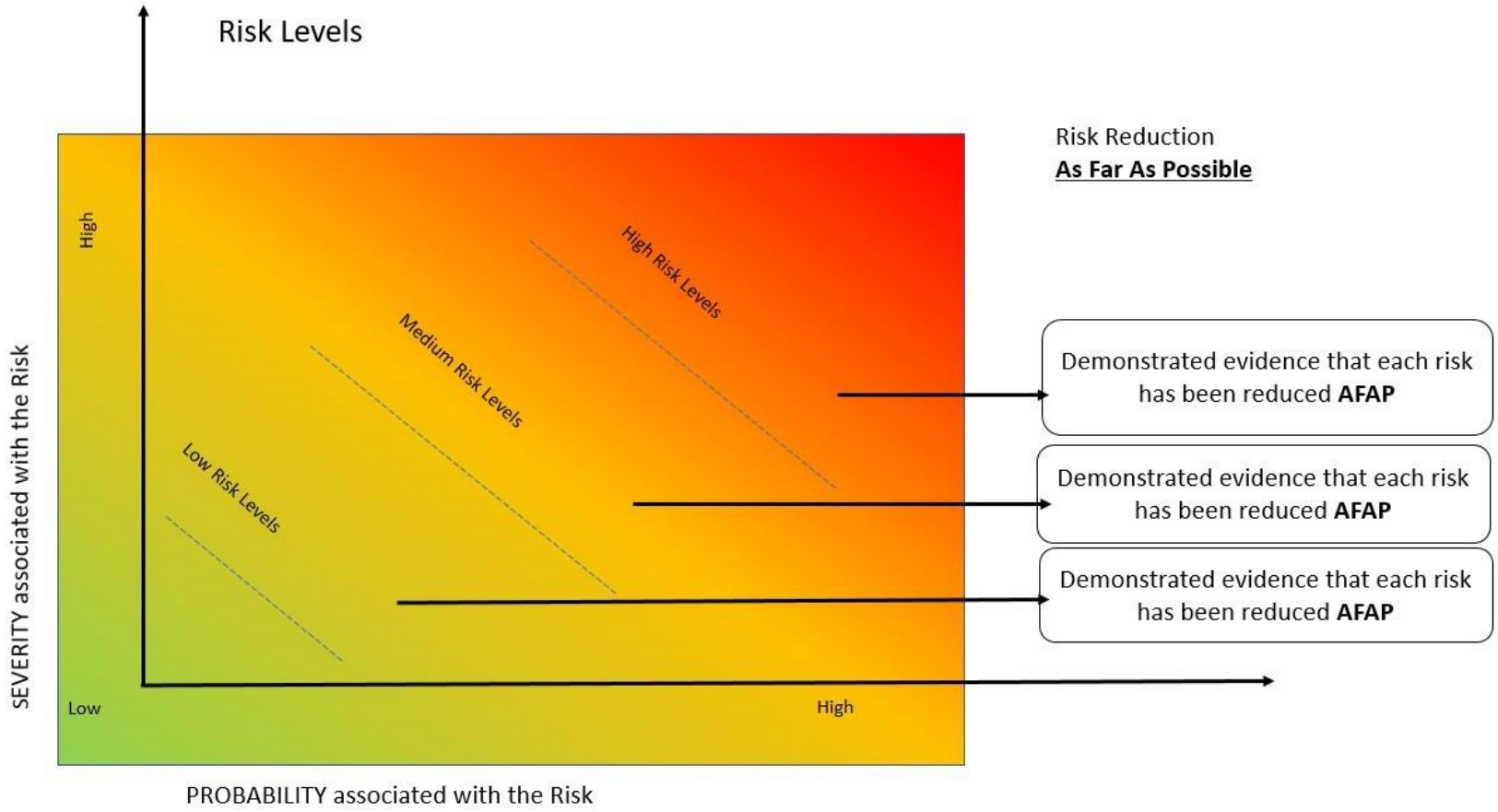
Following the application of these additional mitigations, residual risk scores were determined and reviewed against the Residual Risk Acceptance Criteria (Appendix 4). This process ensures that all potential risks are managed effectively, maintaining the safety and reliability of the product.

# Clinical Risk Control and Residual Risk

The As Far As Possible (AFAP) approach assesses individual risks and applies mitigations to reduce their likelihood. This principle forms the foundation of the DCB Standards.

After control measures implementation, Residual Risk Rating of Diktamen are as follows:

| Residual Risk Rating | | | | | | |
|---|---|---|---|---|---|---|
| **Residual Risk Score** | 1 | 2 | 3 | 4 | 5 | Total |
| **Number of Hasards Identified** | 1 | 3 | 0 | 0 | 0 | 4 |




*The As Far as Possible principle*

## Transferred Hazards

Transferrable hazards are defined by the DCB Standards as those not directly linked to the product's functionality but arise from end-user interactions and human interventions. These hazards must be managed by the deploying Healthcare Organisations, ensuring that appropriate mitigations are implemented and maintained to comply with DCB 0129 and DCB 0160 standards.

A Hasard can be transferred once all manufacturer control measures have been implemented, and further risk mitigation is only realistically achievable from the healthcare organisation.

| | | |
|---|---|---|
| End user at deploying site is unable to view information using the system, therefore, the dictation is not available for the secretary or transcriber and therefore cannot be completed | End User at deploying organisation does not receive data or it is not visible within the platform. | The patient may not receive the appropriate level of care due to the information not being available at the time to the end user. This could lead to a delay/lack in treatment which could lead to inconvenience or harm.<br><br>They may be a delay to patient care if the dictations cannot be completed in a timely manner due to an issue meaning the user cannot complete their dictations/letters |

**HS1-Recommendations:**

- Users are advised to familiarise themselves with the system before use.
- Care should be taken when amending configurations. Testing should be completed to ensure configurations are done correctly and any changes are correctly completed.
- Sites should ensure their connections are working as intended, if any issues are identified this should be reported locally following local business process.
- If any system issues are identified they should be reported to the organisation following the agreed process. This will then be prioritised, ranked and dealt with by the product team.
- Workflow Process maps should be created by each site and these should be included in local Standard Operating Procedures. (Review of any historic material which included decommissioned systems)
- Communication to all end users regarding updates, configurations or issues of the system should be disseminated.
- Fallback solution adopted where required when the system is down/unavailable.

| | | |
|---|---|---|
| The end user bases their decision or pathway on incorrect , conflicting or missing information. | Data displayed to the end user in the system is incorrect, conflicting or missing. | The end user could base their decision and treatment plan/pathway on the information provided/displayed through the system. Incorrect, conflicting or missing information could lead to harm if the end user acts upon it or does not have a clear picture of the patients true health. A situation where incorrect or conflicting information is presented to the user may lead to incorrect diagnosis, incorrect treatment or no treatment being provided. |

**HS2 Recommendations-**

- Provision of healthcare should be based on latest up to date information. End users decisions based on historical information which has not been updated can be harmful to patients therefore, users should always check the information with other sources. These include- the patient, letters, other systems etc. It is the end users responsibilities to ensure they are making appropriate decisions and gathering all necessary information before treating or making a triage/pathway choice.

- If any issues are identified which are relating to the system this should be reported to the support team via the agreed route. This will then be prioritised and ranked and dealt with by the product team. If data is identified which appears to be incorrect or conflicting this should be raised immediately through the reporting mechanism.

- If incorrect data is suspected it is recommended a fall-back solution is adopted, this should be communicated to top management to assess and communicate.

| | | |
|---|---|---|
| End Users unintentionally or intentionally use the system in a different way than intended or by general human error intervention(s). | End User error leads to incorrect use of the system | Patients could come to psychological upset, inconvenience , trauma or harm. There could be a delay in treatment, incorrect treatment or no treatment provided to the patient. |

**HS4 Recommendations**

- Users should be familiar with current access regulations and policies. Professional responsibility to access patient information appropriately and safely.
- The system should be implemented from top level down at each deploying site, a champion is recommended per site to fully understand the full functions and capabilities. This person can be used to show others and support them where needed.
- User feedback should be collated and shared with the organisation to enable future developments.
- End users should be advised on the intended use and limitations of the system.

**For all hasards-**

- User Acceptance Testing should be completed where applicable by each site using the system prior to release to end users. Test scenarios and reports should be completed this includes any new functionality and configuration changes.
- Users should be aware to right click on the pop up when first using the software so that it continues to auto open on launch.
- Once a dictation is accepted it stays in open que and cannot be completed by other secretaries or users, it is important these are completely in a timely manner or returned to the que.
- Users should be trained on appropriate use of the system, advised on access, audit control and encouraged to use the system respectively.
- Where available workshops, demonstrations, user guides should be completed by the end users to fully engage, learn and share experiences with others, End users should seek advice if they are not sure on how to use the system.

## Manufacturer Recommendations

The following recommendations have been developed with both clinical and non-clinical users in mind. Implementing these recommendations will help reduce clinical risk to As Far As Possible (AFAP) and ensure the product is safe for use in clinical settings.

*The Clinical Safety Officer (CSO) has reviewed the standalone nature of the Diktamen dictation system and highlighted its reliance on end-users to manually enter and reconcile patient details with the primary EPR record. To reduce the risk of data-entry errors and associated clinical hasards, the CSO has proposed three key enhancements.*

*Recommendations for Diktamen*

- *Enable Default Multi-Factor Authentication (MFA)*

  *• Enforce MFA by default for all user accounts to strengthen access security and reduce the risk of unauthorised or accidental logins.*
- *Integrate with the PDS Service*

  *• Connect directly to the NHS Personal Demographics Service to automatically populate and verify patient identifiers (e.g., NHS number, demographics), eliminating manual lookup and entry.*
- *Support EPR Integration*

  *• Build interfaces to major Electronic Patient Record systems so that dictations—and any associated metadata—flow automatically into the patient's primary clinical record, ensuring consistency and reducing reconciliation steps for users.*

*Implementing these measures will mitigate manual-process errors, enhance patient safety, and streamline the overall dictation workflow.*

# Healthcare Organisation Recommendations

General Recommendations to Healthcare Organisation to encourage the safe use of the digital healthcare system:

- Incidents should be reported following the outlined processes, with patient information recorded in the primary medical record, and a fallback solution available if the solution is inaccessible.
- Clear and detailed patient communication is crucial, with up-to-date and accurate patient details to minimise errors. All staff, including new starters and bank staff, should be fully aware of the process and patient engagement expectations.
- Clinicians will use professional judgment in interpreting clinical information, considering the full patient context.
- Users will verify patient identity against system records and other materials.
- Healthcare organisations will contact patients by other means if they fail to respond or interact with the system as expected.
- Healthcare professionals will have access to demographic and clinical data from various sources.

## Deploying Organisation Responsibilities

To ensure ongoing safety and compliance, the deploying organisation should:

- **Understand the Intended Use**
  Ensure all users fully grasp the product's scope and limitations.
- **Mitigate Manual-Entry Implications**
  Put in place robust processes to verify that manually entered patient details match the correct individual.
- **Acknowledge No UK-PDS/EPR Integration Yet**
  Recognise that, at present, Diktamen does not link to the NHS Personal Demographics Service or any UK Electronic Patient Record systems.
- **Auto-Population Setup**
  Configure the software so the software auto-populate at each new session launch.
- **Notes, Document Upload & Priority Features**
  Train users where to add free-text notes, upload supporting documents, and set transcription priorities correctly, and, also where to retrieve them.
- **Comprehensive Training for All Roles**
  Mandate completion of role-specific training (authors, secretaries, transcriptionists, administrators) before go-live.
- **Define & Document Workflows in an SOP**
  Develop, approve, and maintain a Standard Operating Procedure that captures local task-flows, escalation paths, and audit trails.

It is important that patient information and data is stored in the primary medical record, therefore any information which is captured in the Diktamen product should be transferred to the EPR/PMR for the patient. It is also important for deploying organisations to ensure that any dictations that require transcribing are completed and sent to the patient or health care professional correctly and within a timely manner. It is the responsibility of the deploying organisation to ensure the full end to end process is defined and completed by all staff.

# Safety Summary Statement

A clinical safety assessment of the Diktamen product was conducted in alignment with DCB 0129 standards established by NHS England. The assessment was led by an experienced Clinical Safety Officer and utilised structured risk analysis methodologies, including hazard identification workshops and the Structured What If Technique (SWIFT). This process ensured evaluation of potential clinical risks and provided a robust understanding of the product's safety profile.

The scope of the assessment included an evaluation of the product's intended use, target user groups, and clinical context within health and care settings.

The assessment identified a total of 4 hazard groups/themes, with many possible causes, all of which were classified with initial risk scores of 1–2, indicating low and acceptable clinical risk. No hazards were identified with an undesirable risk rating (score of 3 or above). Hazards were prioritised based on their severity and likelihood, and each was carefully analysed for potential safety implications.

There are no hazards that remain at undesirable risk levels following the application of control measures. However, certain low-risk, user-dependent hazards (e.g., manual patient detail entry) were transferred to the deploying healthcare organisation, with specific recommendations documented in the Hasard Log and Clinical Safety Case Report. These should be addressed as part of the DCB 0160 clinical risk assessment process by the organisation's Clinical Safety Officers (CSOs).

A defined incident management framework has been established. This includes:

- A 24/7 helpdesk ticketing system
- In-platform issue reporting tools
- Clear escalation protocols

These mechanisms ensure that any post-deployment clinical safety issues are captured, prioritised, and resolved swiftly, maintaining continued regulatory compliance and patient safety.

The clinical safety assessment provides satisfactory assurance that the Diktamen product, is safe for use in the health and care environments although it should be noted that Diktaman have some recommendations from the CSO and the deploying organisations should acknowledge and adopt the recommendations listed in this report and supporting hazard log.

# Appendices

## Appendix 1: Assessment of Severity

| Severity Classification | Interpretation | Number of Patients Affected |
|---|---|---|
| **Catastrophic** | Death | Multiple |
| | Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term | |
| **Major** | Death | Single |
| | Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term | |
| | Severe injury or severe incapacity from which recovery is expected in the short term | Multiple |
| | Severe psychological trauma | |
| **Considerable** | Severe injury or severe incapacity from which recovery is expected in the short term | Single |
| | Severe psychological trauma | |
| | Minor injury or injuries from which recovery is not expected in the short term | Multiple |
| | Significant psychological trauma | |
| **Significant** | Minor injury or injuries from which recovery is not expected in the short term | Single |
| | Significant psychological trauma | |
| | Minor injury from which recovery is expected in the short term | Multiple |
| | Minor psychological upset; inconvenience | |
| **Minor** | Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible consequence | Single |

*Table 1: Severity Classifications*

# Appendix 2: Assessment of Likelihood

| Likelihood Category | Interpretation | Number of Patients Affected | Frequency |
|---|---|---|---|
| **Very High** | Certain or almost certain; highly likely to occur. | 1 in 10 | Daily |
| **High** | Not certain but very possible; reasonably expected to occur in the majority of cases | 1 in 100 | Weekly |
| **Moderate** | Possible | 1 in 1,000 | Monthly |
| **Low** | Could occur but in the great majority of occasions will not. | 1 in 10,000 | Yearly |
| **Very Low** | Negligible or nearly negligible possibility of occurring | 1 in 100,000 | Once in a lifetime |

*Table 2: Likelihood Classifications*

# Appendix 3: Assessment of Risk

| Likelihood | | | | | | |
|---|---|---|---|---|---|---|
| | Very High | 3 | 4 | 4 | 5 | 5 |
| | High | 2 | 3 | 3 | 4 | 5 |
| | Medium | 2 | 2 | 3 | 3 | 4 |
| | Low | 1 | 2 | 2 | 3 | 4 |
| | Very Low | 1 | 1 | 2 | 2 | 3 |
| | | Minor | Significant | Considerable | Major | Catastrophic |
| | | **Severity** | | | | |

*Table 3: Risk Matrix*

# Appendix 4: Risk Evaluation

| | |
|---|---|
| 5 | Unacceptable level of risk |
| 4 | Mandatory elimination of hazard or addition of control measure to reduce risk to an acceptable level |
| 3 | Undesirable level of risk. Attempts should be made to eliminate the hazard or implement control measures to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical |
| 2 | Acceptable where cost of further reduction outweighs benefits gained or where further risk reduction is impractical |
| 1 | Acceptable, no further action required |

*Table 4: Risk Evaluation Summary*