HEALTH HERO

CE

Symptom Assessment

Instructions for Use

Department:	Quality and Compliance	**Version No:**	5. 0
Responsible Executive:	Director of Quality and Compliance	**Review Due:**	24-Nov-26
Owner:	Quality Officer	**Review Date:**	24-Nov-25

Version	Amendment Details	Date Issued
1	Document created	18-Mar-22
2	Moved to new branded format. Update as part of Doctorlink integration into HealthHero Solutions. Change of document name to 'Instructions for Use' combining former 'Product Terms' and 'Intended Use' documents. Reference to NHS Clinical standards DCB0129 and DCB0160 removed.	31-Jan-24
3	Update to new branding, document table info, manufacturer name and age of user. Update to include symbols and glossary too.	27-Jul-25
4	Regulatory section added and symbols updated. Table of contents added. Warnings and cautions expanded.	27-Oct-25
5	Clinical Benefits and Performance Characteristics expanded	24-Nov-25

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Table of Contents

1. Device Identification

Software Name	Symptom Assessment
Version	2025.002
Unique Device Identifier (UDI)	(01)04262543120003(8012)2025.002
Description	The Symptom Assessment is a B2B clinical decision support (CDS) application classified as Software as a Medical Device (SaMD). User access is governed by customer-defined configurations and contractual agreements, in line with the software's intended use and risk classification. The application is accessible via two integration models: • HealthHero-hosted front-end platform, or • Customer-hosted and configured front-end platform. The software uses intelligent algorithms, grounded in published best practice and underpinned by Bayesian logic, to triage users to the most appropriate level of care based on their reported symptoms. This enables users to access clinically informed guidance 24/7, at a time and place convenient to them—empowering timely decision-making and improving access to care In accordance with ISO 13485:2016, the software is validated to ensure it performs consistently and safely as intended. Validation activities are proportionate to the risk associated with the software's use, and all processes are documented to meet regulatory and quality management system (QMS) requirements
Device Classification	The software is CE marked under the EU Medical Device Directive 93/42/EEC as a Class I medical device. It is registered with the UK MHRA as a Class I device, with conformity assessed against the Essential Requirements and supported by a self-declaration of conformity. The device is considered a legacy device under Article 120(3) of Regulation (EU) 2017/745 (MDR), and as a result is subject to the transitional provisions of the Medical Device Directive (MDD) during its ongoing migration to MDR as outlined in Article 120(3). The device will be considered Class IIa under MDR, Rule 11.
Intellectual Property	The underlying technology is protected by patents held by Doctorlink Innovations, part of HealthHero Solutions: ○ US Patent No. 7,516,110 ○ EU Patent No. 1,686,513

2. Labelling

The device label is hosted on the HealthHero website and is presented at start-up as a printable PDF. The label includes the Unique Device Identifier (UDI) for the Symptom Assessment software. Users can also access the label at any time via: Symptom Assessment Label. The label is version-controlled and updated promptly to reflect the latest approved version.

3. Intended Purpose

Medical Purpose	Symptom Assessment is decision support software intended for digital clinical triage, to guide people to the right care at the right time through intelligent algorithms that represent published best practice.
Target Patient Population	Individuals who are symptomatic and requiring assessment of their condition to help them decide when and where to seek care.
Intended User	The Symptom Assessment is intended only for use by individuals aged 16 years and older. It is designed to assess the symptoms of individuals aged 3 to 120 years. Users may complete assessments on behalf of dependents under the age of 16, provided they reside in the same household.
Environment of Use	Symptom Assessment is a Business to Business (B2B) product where Users and their access to the product are determined by the Customer requirements and contractual terms agreed. Users access the Symptom Assessment software application either via: • a HealthHero front end hosting platform or, • a customer configured front end hosting platform The User completes the assessment by answering a series of questions on an electronic device in their chosen environment.
Clinical Benefits	When used as directed, the Symptom Assessment enables users to access timely, clinically informed triage recommendations based on their reported symptoms. The software supports improved access to care by guiding users to the most appropriate level of care, helping to reduce unnecessary emergency visits and optimize clinician time. Clinical benefits include increased awareness of urgent symptoms, prompt identification of red-flag

	conditions, and support for earlier intervention, which may contribute to improved health outcomes and patient safety.
Performance Characteristics	• The software generates triage recommendations by applying validated Bayesian algorithms and clinician-approved logic to user-reported symptoms and medical history. • Outputs include recommended care pathways (e.g., emergency care, GP appointment, pharmacy/dental care, self-care) and a PDF traversal record for clinical review and integration into EMR systems. • Limitations: Recommendations are based solely on the information provided by the user and are intended to support, not replace, clinical judgment. Accuracy depends on truthful and complete input; the tool is not intended for use in emergencies or as a substitute for professional medical advice.

4. Regulatory

Overview	The Symptom Assessment is developed under a Quality Management System (QMS) certified against ISO 13485:2016. The product is currently in transition to the Regulation (EU) 2017/745 (MDR) framework and is subject to the transitional period applicable to legacy devices. The QMS requirements outlined in Article 10(9) of Regulation (EU) 2017/745 (MDR) are adhered to.
Technical Documentation	HealthHero maintains technical documentation in accordance with MDD requirements, supplemented by MDR requirements for Post Market Surveillance, Clinical Evaluation and vigilance. Documentation is readily accessible for review by competent authorities and Notified Bodies.
Transitional Arrangements	During the MDR transitional period, no significant changes to the design or intended purpose of the device are permitted.
Serious Incident Reporting	Any serious incident that has occurred in relation to this device should be reported to the manufacturer who shall notify the competent authority of the Member State in which the user and/or patient is established. In the EU, HealthHero will notify the relevant EU Competent Authority via MIR within 15 days of awareness, within 10 days for death or unanticipated serious deterioration, and within 2 days for a serious public health threat. Trend reporting is performed per MDR Article 88. Users may also report incidents via national reporting schemes where available.

Cybersecurity and Access Controls	The software must be operated on secure devices and networks. Customers are responsible for ensuring that only authorized users have access to the application and that devices are protected by appropriate security measures, including user authentication, device encryption, and regular software updates.
Language and Instructions for Use Access	This Instructions for Use (IFU) is presented to all users at first use, in English for the UK and ROI. For use in other countries, a localized and translated version will be provided as required by local regulations. In the European Union, a paper copy of the IFU is supplied to all lay users as a printable PDF accessible via the device and the HealthHero website (https://www.healthhero.com/hubfs/Symptom Assessment Instructions for Use.pdf). Users may print the IFU directly from this website. Additional paper copies are available free of charge upon request from the manufacturer within 7 calendar days, in accordance with Commission Implementing Regulation (EU) 2021/2226 (consolidated 2025). The IFU is version controlled and updates are promptly reflected on the website.

5. System Requirements

Operating Systems	Modern web browsers on Windows, macOS, iOS, and Android platforms (e.g., Chrome, Safari, Edge, Firefox).
Hardware Requirements	Internet-enabled device such as a smartphone, tablet, or computer with a stable connection
Internet Connection	Minimum 3G connection; broadband recommended for optimal performance
Security	Device should support HTTPS and TLS 1.2 or higher for secure data transmission

6. Installation and Activation

Instructions for downloading, installing and activating the software	HealthHero's Symptom Assessment software is delivered as a web-based application and does not require installation on end-user devices. Access and activation are managed through the following steps: The software is deployed via:

	• A HealthHero-hosted front-end platform, or • A Customer-hosted and configured front-end platform. Users access the application through a secure web link provided by the Customer or HealthHero.
Account setup and licensing information	User access is governed by the Customer's configuration and licensing agreement. If authentication is required, user credentials are issued by the Customer's system administrator or HealthHero support team

7. Operating Instructions

Usage Instructions	Users complete a structured, algorithm-driven questionnaire on a personal electronic device. Questions are primarily multiple choice and relate to the user's symptoms. Upon completion, the system provides a clinically appropriate disposition, which is the most urgent level of care that cannot be safely excluded.
Descriptions of features and Functions	<u>Symptom Questionnaire Engine</u> • Users complete a structured, algorithm-driven questionnaire. • Questions are primarily multiple choice and tailored to the user's reported symptoms. • The system dynamically adjusts the question flow based on previous answers. <u>Clinical Triage Logic</u> • The software uses Bayesian logic and evidence-based, clinician approved algorithms, to determine the most appropriate level of care. • Final output is a disposition—the most urgent level of care that cannot be safely excluded. <u>Disposition Categories</u> • Emergency care (e.g., A&E / 999) • GP appointment within 24 hours • GP appointment within 3 days • Pharmacy or dental care within 3 days • Self-care at home <u>Red-Flag Detection Module</u> • Identifies potentially life-threatening symptoms (e.g., cardiac or respiratory distress, stroke). • If triggered:

	• The assessment is immediately terminated.
	• A clear emergency directive is presented to the user (e.g., “Call 999”).
	
	<u>Safeguarding Logic</u>
	• Optional feature that detects non-clinical risks (e.g., safety, welfare, or social concerns).
	• When enabled:
	  • Generates a safeguarding profile based on user responses.
	  • Profile is securely transmitted to a designated healthcare professional or safeguarding lead.
	  • Not visible to the user.
	<u>Traversal Record Generation</u>
	• A digital record of the completed assessment (the “traversal”) is generated.
	• Includes:
	  • User responses
	  • Final triage outcome
	• Provided in PDF format for:
	  • Clinical review
	  • Integration into EMR systems
	  • Secure storage
	  • User access upon completion
	<u>Customisation and Integration</u>
	• Can be deployed via:
	  • HealthHero-hosted front-end platform
	  • Customer-hosted and configured front-end
	• Configurable features include:
	• Safeguarding logic
	• Branding and user interface
	• Integration with third-party systems
	• Info icons that provide contextual guidance explaining questions and how to answer them to help users feel confident and informed throughout their assessment.

Input and output data explanation	<u>Input Data</u> Users interact with a structured, algorithm-driven questionnaire. Questions are primarily multiple choice and dynamically adapt based on previous responses. Inputs include: • Presenting symptoms • Duration and severity • Demographic information (e.g., age, sex) • Relevant medical history or risk factors <u>Output Data</u> The system generates a clinically appropriate disposition, defined as the most urgent level of care that cannot be safely excluded. Possible dispositions include: • Emergency care (e.g., A&E / 999) • GP appointment within 24 hours

	• GP appointment within 3 days
	  • Pharmacy or dental care within 3 days
	  • Self-care at home
	<u>Safety and Risk Controls</u>
	Red-Flag Detection Module:
	• Detects potentially life-threatening symptoms.
	• Terminates the session and prompts an emergency directive (e.g., “Call 999”).
	Safeguarding Logic (if enabled):
	• Identifies non-clinical risks (e.g., welfare concerns).
	• Generates a safeguarding profile for review by a designated professional.
	
	<u>Assessment Record (Traversal)</u>
	A PDF record of the completed assessment is generated.
	• Includes:
	  • User responses
	  • Final triage outcome
	• Intended for:
	  • Clinical review by authorised healthcare professionals
	  • Integration into electronic medical record (EMR) systems
	  • Secure storage
	  • User access upon completion

How to interpret results or alerts	Upon completion of the assessment, the software generates a clinically appropriate disposition, indicating the most urgent level of care that cannot be safely excluded. This outcome is determined solely based on the information provided by the user during the structured, algorithm-driven questionnaire. Where configured, customers may receive a digital record of traversal which includes the user’s responses and the final triage outcome. This record is delivered in PDF format and is intended for: • Clinical review by authorised healthcare professionals, and • Integration into EMR systems or secure data storage environments, in line with applicable data protection and interoperability standards. Dependent on configuration, a copy of the traversal can also be made available to the user upon completion of the assessment.

8. Warnings and Precautions

Warnings	• This device does not replace professional medical advice and should not be solely relied on for health decisions. • Incorrect or incomplete answers can lead to inaccurate recommendations, ensure information provided is truthful and complete. • Some questions may be emotionally triggering. Stop use and seek support if you feel distressed. • Recommendations may differ from local clinical practice if the device is used outside the intended region.
Contraindications	• Do not use this device in emergency situations such as chest pain, severe breathing difficulty, or uncontrolled bleeding. • The device is not intended for routine health checks or preventive screening in individuals without symptoms. • The device is designed for English language use. Misinterpretation of questions in other languages may affect accuracy. • Users under 16 years should not complete assessments independently. Adults completing assessments for dependents must ensure accuracy.
Residual Risks	• Incomplete or inaccurate information entered by the user will affect device accuracy • Using the device without understanding English or validated translations may lead to misinterpretation. • Access may be interrupted due to technical or third-party failures. • Certain questions may cause emotional discomfort • Accessibility limitations may lead to misinterpretation.
Limitations	As a standalone product, the Symptom Assessment software does not provide medical advice, diagnosis, or treatment. It functions as a clinical decision support tool, offering a triage recommendation based on the combination of symptoms entered by the User. The output is intended to guide Users to the most appropriate level of care and should be interpreted within the context of broader clinical judgment by the healthcare professional.
Customer Precautions	The Customer agrees to operate the Symptom Assessment software in accordance with the terms of the license agreement and the associated fair use policy. The software generates a clinically appropriate triage pathway based solely on the information provided by the User. If the Customer modifies, overrides, or disables any standard functionality, configuration, or clinical recommendation—whether through technical integration or operational policy—HealthHero disclaims all responsibility and liability for any

	resulting inappropriate clinical outcome, including but not limited to: • Incorrect service or provider recommendations • Inaccurate urgency or timeframe guidance • Misdirection to inappropriate clinician types or third-party services To ensure continued safety, performance, and compliance, customers are responsible for: • Implementing updates in a timely manner, especially those related to clinical safety or regulatory requirements • Validating updates within their environment where custom configurations exist • Maintaining compatibility with integrated systems and customer-hosted platforms • Collaborating with HealthHero to plan and support update deployment Delays in adopting critical updates may affect system performance and clinical accuracy.
User Precautions	The tool must be used strictly for its intended purpose as described in the IFU. It is not a substitute for professional medical advice, diagnosis, or treatment. Users should ensure they:- • Provide accurate and complete information • Interpret results appropriately and seek advice from a healthcare professional if unsure • Monitor for warnings or alerts (e.g. urgent care alerts, red flag symptoms, age or demographic restrictions, legal and consent notices) • Report Adverse Events or Malfunctions • Use the tool in a secure environment to protect personal health information. • Do Not Modify, tamper or attempt to alter, reverse-engineer, or misuse the software in any way.
Measures in the event of malfunction	If the software fails to load, displays an error, or becomes unavailable, stop use and seek professional medical advice.

9. Development, Maintenance and Updates

Software Updates	HealthHero releases periodic updates to the Symptom Assessment software to maintain clinical accuracy, safety, and regulatory compliance. These updates may include: • Algorithm enhancements • Safety feature improvements (e.g., safeguarding logic) • Regulatory or standards-based changes

	Customers are required to accept and implement each update within six (6) months of its release to production. Continued use of outdated versions beyond this period may compromise clinical safety and will invalidate HealthHero's indemnification obligations.
Algorithm Maintenance and Validation	Clinical algorithms are reviewed and updated on a rolling cycle to ensure alignment with the latest evidence-based guidelines, including those published by NICE and other national safety standards. Urgent clinical updates are deployed as hot-fixes, prioritised and approved by the Clinical Governance Team based on risk and clinical impact. All algorithms are subject to independent validation and ratification by an External Review Panel comprising licensed General Practitioners, following a standardised clinical protocol.
Troubleshooting	The Customer is required to promptly notify HealthHero of any: • Identified quality issues • Adverse events or feedback related to the use of the software This obligation supports post-market surveillance and continuous improvement in accordance with ISO 13485:2016 and applicable regulatory requirements.

10. Storage and Handling

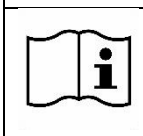
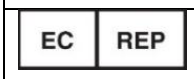
Data Use	HealthHero uses traversal data from both completed and incomplete assessments to support the ongoing maintenance and improvement of the Symptom Assessment algorithms. This activity forms part of the organisation's post-market surveillance and continuous improvement processes, as required under ISO 13485:2016. All data used for this purpose is fully anonymised prior to analysis, ensuring that no personally identifiable information (PII) is retained. Personal data is not used for direct marketing or any commercial outreach activities.
Digital Storage Requirements	Symptom Assessment leverages secure cloud infrastructure for digital data storage. Where cloud storage is employed, HealthHero ensures full compliance with ISO 13485:2016 (Quality Management Systems for Medical Devices) and IEC 62304 (Software Lifecycle Processes for Medical Device Software). In addition, all cloud-based data handling is designed to be fully GDPR-compliant, incorporating robust data encryption, access control mechanisms, and user consent protocols to safeguard personal health information in compliance with HealthHero

	Solutions ISO27001 certified Information Security Management Systems.
Data Retention	HealthHero retains all technical documentation for a minimum of 10 years following the placement of the device on the market, in accordance with MDR requirements. Personal data is processed and retained per GDPR and our Privacy Notice; retention periods vary by purpose and jurisdiction. Archived data is maintained in a manner that ensures it remains readily accessible, retrievable, and searchable, as stipulated in MDR Annex II.

11. Provision of Product

Provision of product outside of UK	Symptom Assessment is a UK indemnified product available in English language and conforming to UK clinical standards of care. Where Symptom Assessment is to be utilised outside of the UK, then a statement of work will be created to establish responsibilities for any localisation and translation to support use of Symptom Assessment in a non-UK country, as well as any certification or regulation requirements in order to meet local health care provisioning.
Geographic Scope and Localisation	The Symptom Assessment software is an indemnified UK product, developed in accordance with UK clinical standards of care and available in the English language. For deployment outside the United Kingdom, a formal Statement of Work (SoW) will be established to define: • Responsibilities for localisation (e.g., clinical content adaptation, language translation), • Any regulatory or certification requirements applicable in the target jurisdiction, • The scope of clinical governance and indemnity arrangements for non-UK use. Localisation activities will be conducted in compliance with applicable regulatory frameworks and quality management system requirements under ISO 13485:2016 and Regulation (EU) 2017/745 (MDR).

12. Symbols and Glossary

Symbol	Meaning	Standard Reference
	Refer to Instructions for Use (IFU)	ISO 15223-1:2021, 5.4.3
	Manufacturer	ISO 15223-1:2021, 5.1.1
	Translation	ISO 15223-1:2021, 5.6.3
	Authorised Representative in the European Community	ISO 15223-1:2021, 5.1.2.
	Medical Device	ISO 15223-1:2021, 5.7.7.
	Unique Device Identifier (UDI)	ISO 15223-1:2021,
	CE Mark – indicates conformity with EU Medical Device Directive (legacy use)	EU MDR

Glossary Term	Definition
Symptom Assessment (SA)	A Software as a Medical Device (SaMD) that replicates an initial clinical consultation to triage users to the most appropriate level of care based on reported symptoms.
Software as a Medical Device (SaMD)	Software intended to be used for medical purposes without being part of a hardware medical device.
Clinical Decision Support (CDS)	A system that provides clinicians, staff, patients, or other individuals with knowledge and person-specific information to enhance health and healthcare.
User	A lay person aged 16 years and older, who may complete assessments on behalf of dependents under the age of 16, provided they reside in the same household.
Customer	The organisation or entity that contracts with HealthHero to deploy the Symptom Assessment software.

Traversal	A digital record of a completed symptom assessment, including the user's responses and the final triage outcome.
Disposition	The recommended level of care based on the user's symptoms (e.g., emergency care, GP appointment, self-care).
Red-Flag Detection Module	A safety feature that identifies potentially life-threatening symptoms and prompts emergency action.
Safeguarding Logic	A configurable feature that detects non-clinical risks (e.g., welfare concerns) and alerts designated professionals.
GDPR	General Data Protection Regulation – a legal framework that sets guidelines for the collection and processing of personal information.
ISO 13485:2016	An international standard that specifies requirements for a quality management system for medical devices.
IEC 62304	A standard that defines the life cycle requirements for medical device software.
MHRA	Medicines and Healthcare products Regulatory Agency – the UK regulator for medical devices.
Intended Use	The purpose for which the software is designed, as defined by the manufacturer.
Intended User	The demographic or professional group for whom the software is designed.
Environment of Use	The setting in which the software is used.

13. Contact and Support

General Support and Queries:	HealthHero Solutions Limited Email: support@healthhero.com Phone: +44 (0)20 3966 1122 Website: https://www.healthhero.com
Data Protection Officer:	dpo.epc@healthhero.com
Incident and Feedback reporting:	Use the 'contact us' button within the application. Customers can contact their account manager Or email InternalTechSupport@healthhero.com
Yellow Card Reporting	Users and healthcare professionals can report suspected adverse events, product issues, or safety concerns related to medical devices via the MHRA Yellow Card Scheme. Submit a report at: https://yellowcard.mhra.gov.uk