

Document Control

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Product

- **Name:** Pathpoint® eDerma
- **Version:** 1.1
- **UDI-DI:** 5061042820013

Intended Use

Pathpoint® eDerma is a cloud-based dermatology platform designed to assist healthcare professionals in documenting and managing dermatological conditions. It is intended for use as a fully interoperable application on compatible computing devices with electronic healthcare records (EHRs) and other referral systems, such as e-RS and GP Connect.

Pathpoint® eDerma is intended to be used by qualified healthcare professionals, including dermatologists, dermatology speciality trainees, and other medical practitioners involved in diagnosing and triaging skin conditions. The software provides a digital platform for capturing, storing, and displaying patient information related to dermatological examinations, assessments, and treatments.

Intended Medical Indication

Pathpoint® eDerma is intended to support the diagnosis and management of various skin conditions including but not limited to melanoma, basal cell carcinoma, squamous cell carcinoma, eczema, and contact dermatitis. The software is designed to facilitate comprehensive documentation, assessment, treatment planning, and monitoring of patients with diverse dermatological needs.

Mapping of Requirements to Document Sections

Reference	Section	Document Section
EU MDR 2017	Annex II, 1.1 a) - d), h), i)	(All)
UK MDR 2002	Part II of Schedule 2A to the UK MDR 2002	(All)
European Directive 93/42/EEC	Annexes	(All)

ISO 14971:2019 Section	Document Section
5.2	(All)

IEC Section	62366-1:2015	Document Section
5.1		(All)

Contraindications

Pathpoint® eDerma is not intended to replace healthcare professionals' independent judgement or clinical expertise. It is designed to be used as a tool to enhance the efficiency and accuracy of dermatological documentation and support clinical decision-making processes.

Users should be aware that the software does not provide definitive diagnoses or treatment recommendations. The final responsibility for patient care rests with the healthcare professional, who should rely on their training, experience, and any other available relevant information sources when making clinical decisions.

It is important for users to review and comply with all applicable regulations, guidelines, and legal requirements governing the use of medical software in their respective jurisdictions. Pathpoint® eDerma should only be used by individuals with the necessary qualifications and training to interpret and utilise the information provided through the software effectively.

Device Description

Pathpoint® eDerma is a cloud-based dermatology platform meticulously crafted to streamline the documentation and management of dermatological conditions for healthcare professionals. It serves as a fully interoperable application, seamlessly integrating with compatible computing devices equipped with electronic healthcare records (EHRs) and other referral systems, including e-RS and GP Connect.

This innovative software solution is specifically designed for use by qualified healthcare professionals, such as dermatologists, dermatology speciality trainees, and other medical practitioners involved in diagnosing and treating skin conditions. Pathpoint® eDerma facilitates efficient and comprehensive documentation of dermatological examinations, assessments, and treatments by providing a digital platform for capturing, storing, and displaying patient information.

Device Usage

The primary intended use of Pathpoint® eDerma is to aid healthcare professionals in the following activities:

1. **Clinical Triage and Dermatological Documentation:** Pathpoint® eDerma serves as a pivotal tool for qualified healthcare professionals, including dermatologists,

dermatology speciality trainees, and other medical practitioners involved in diagnosing and treating skin conditions. The software facilitates clinical triaging, allowing professionals to assess and prioritise cases based on urgency and severity efficiently. Additionally, it enables detailed dermatological documentation by recording and storing comprehensive patient information. This includes medical history, clinical observations, images, and notes related to dermatological examinations.

2. **Image Viewing:** The platform empowers users to import and view digital images of skin conditions. This feature aids in accurate diagnosis and enables healthcare professionals to monitor changes over time, enhancing the overall assessment process.
3. **Treatment Planning:** Healthcare professionals can leverage Pathpoint® eDerma to create meticulous treatment plans. The software allows the documentation of prescribed medications, procedures, and recommendations for managing dermatological conditions. This ensures a streamlined and effective approach to patient care.
4. **Communication and Collaboration:** Facilitating seamless communication and collaboration, the software provides a secure digital environment for sharing patient data, images, and treatment plans among healthcare professionals. This collaborative aspect enhances the collective understanding of cases and promotes interdisciplinary approaches to patient care.

User Profile

The typical user of Pathpoint® eDerma would be a healthcare professional, such as a dermatologist, nurse, administrator, or medical photographer. These users would have the qualifications and prior training in their respective healthcare fields. They would have a good understanding of patient care and treatment protocols. Regarding technical proficiency, Pathpoint® eDerma users would be comfortable using software applications and have basic computer skills. They would also have a moderate level of proficiency in navigating and using the software's features. The time spent using the software would vary depending on the specific healthcare setting and the frequency of patient assessments, but users would be expected to spend at least 1 hour per week.

Use Environment Including Software/Hardware

The software can be run on multiple devices, including desktop computers, laptops, and tablets. It is not limited to a specific operating system, as it is a web-based application that can be accessed through a browser. The use environment can vary depending on the healthcare setting, but it is typically quiet and controlled, such as a clinic or hospital office. The lighting is typically adequate for computer use.

Pathpoint® eDerma does not require any additional software or hardware. However, users will need access to a device with internet connectivity and a compatible web browser to use the software. This can include smartphones with compatible operating systems, such as iOS or Android, as long as they have a browser that can access the web application.

Diagnostic and Treatment Focus

While the Pathpoint® eDerma supports healthcare professionals in understanding the disease state of patients and planning for diagnosis, it is essential to highlight that the device is not intended for standalone diagnostic purposes. The diagnostic or treatment decisions based on the data provided by Pathpoint® eDerma should be made in consultation with a suitable healthcare professional. The device serves as a supportive tool, enhancing the diagnostic and treatment planning process under the expertise of qualified medical practitioners.

Operating Principle

The operating principle of the Pathpoint® eDerma software involves collecting and analysing patients' data on specific health-related aspects or conditions. This is done through systematic data input, processing, and analysis. The software provides a user-friendly interface for patients to input their responses to relevant questions or surveys. The collected data is then processed and analysed using algorithms and statistical methods to generate meaningful insights for healthcare professionals. The software employs industry-standard security measures to ensure the confidentiality and integrity of the collected data.

Design Requirements

The design requirements for Pathpoint® eDerma are defined in the user and software requirements documentation.

Part of the Body / Type of Tissue Interacted With

The device is stand-alone software. It receives input from the user and outputs information. It doesn't come in contact with tissue or bodily fluids.

Variants / Accessories

The device is stand-alone software and does not have an accessory or a variant.

Performance and Technical Specifications

The technical specifications of the Pathpoint® eDerma are specified below.

Android App Requirement in Mobile Phone	6.0
iOS App Requirement in Mobile Phone	iOS 10
Interface	Mobile phones and Computers with internet connection
Operating mode	<ol style="list-style-type: none">1. Professional Mode for Dermatologists, Admins and HCPs2. Patient Mode for Patients
Software Features	<ol style="list-style-type: none">1. User-Friendly Interface2. Professional and Patient Modes3. Customisable Questionnaires4. Real-time Synchronisation5. Cross-Platform Compatibility6. Administrator Tools7. Clinic/Hospital Configuration8. Data Analysis and Visualisation9. Security and Compliance10. Collaborative Features11. Patient Engagement Tools12. Help and Support Resources
PC/Laptop requirement	Intel Core 2 Duo or better with at least 1 GB RAM, No specific requirement of ROM and internet /browser access
Operating System	Windows, iOS, and Linux