# PERISCOPE
# Decision Support Tool

# Instructions for Use

English

LOT Software version: 1.6.0 (also applies to previously issued versions)

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# 1 General information

## 1.1 About these Instructions for Use for PERISCOPE.

These Instructions for Use (IFU) are intended to assist users in the safe and effective use of the PERISCOPE software product (see section 2.3 for the complete description of the intended users of PERISCOPE; this IFU also apply to all previous versions of PERISCOPE). Before attempting to use the software, users must read the IFU thoroughly, paying particular attention to all safety information, including all the WARNINGS it contains.
Additionally, personnel related to the management, maintenance, and operation of hospitals' IT infrastructure are also advised to read these IFU, since some important WARNINGS (see section 3.1, especially the entries 3.1.5 and 3.1.6) are provided regarding the stability and maintenance of the deployment environment, as it may influence the ability of PERISCOPE to perform correctly. Also, section 6 provides useful information concerning technical specifications, maintenance, and support, as well as important recommendations in terms of security and privacy.

The IFU can be viewed and downloaded via a link on the user interface of the tool and all versions are available on the Healthplus.ai website. A paper hard copy is available upon request. To request a hard copy of the IFU, please contact Healthplus.ai (see section 1.6 for contact details). Such a hard copy will be provided at no additional costs and at the latest within 7 calendar days of reception of the request by Healthplus.ai. It is also possible that a hard copy has already been provided to your organisation (e.g at the time of order or installation, if so requested in advance), so you may also confirm internally whether such copy is already available for consultation.

This IFU does not describe the use of the Information Technology (IT) equipment on which the product is installed.

Be aware that a downloaded or hardcopy version of the IFU can become outdated: see section 1.1.1. below.

### 1.1.1 Updates to these IFU

The information in this IFU is subject to change without notice. If a new software version is released, the corresponding version of the IFU will also be updated within the information displayed on PERISCOPE's user interface (i.e. the weblink provided will conduct directly to the corresponding version of the IFU).
Additionally, all previously released versions of PERISCOPE's IFU are available via the Healthplus.ai website (see section 1.6 for details), along with the corresponding software version number and publication date.

### 1.1.2 About this publication

Neither Healthplus.ai nor anyone else involved in the development, production or delivery of the documentation can be held liable for any special, incidental or consequential damages,

whether on the basis of breach of warranty, breach of contract, negligence, strict liability based on unlawful deed, or any other legal basis.

### 1.2 General information about the Device, the Manufacturer and this Publication

| | |
|---|---|
| MD | PERISCOPE 1.6.0 |
| | Healthplus.ai-Operations B.V.<br>Van Diemenstraat 50, 1013 NH, Amsterdam, the Netherlands |
| | 2025-04-14 |
| REF | HP-0001 |
| UDI | 8720929300006 |
| LOT | 1.6.0 |
| CE certificate number | G10 117595 0002 Rev. 00 |
| Translations available: | English (this version)<br>Dutch |
| Document (IFU) version and change history: | 0.2 - First version - Initial conformity assessment.<br>0.3 - A reference to intended users was included in section 1.1, as well as considerations, information, and a warning related to the provision and use of paper-based IFUs; clarification on the (potential) availability of different eIFU versions for different releases of PERISCOPE; the symbols included in section 1.2 were corrected for compliance with harmonised versions; the glossary of symbols in section 1.5 was updated to include all applicable symbols, as well as to organise it based on the wording of ISO 15223-1:2021; Information regarding reporting to local Competent Authorities was added to section 1.6; Sections 2 and 3 were restructured to contain device description, qualification, classification, and risks associated with the use of the device; An indication of when model performance report is shared and that it should be taken as evidence of readiness for safe operation was added to section 4.8; Section 4.9 was added summarising performance characteristics; Suggested activities for verification of effective installation and safety for use were added to section 5 and further detailed in section 5.1; Additional details were included in section 6, providing more information on expected software updates and recalibration, technical specifications and network safety, security, and privacy; Images and screenshots provided were replaced for improved readability.<br>0.4 - Minor correction to the wording of the contraindications and exclusions in section 2.4.<br>0.5 - Minor design change in tile and column interface in sections 5.3 and 5.4; added section 5.5 with additional information on device identification. |

1.0 - Subgroup exclusion limited to exclusion per specialty. Rephrasing of the warning about no prediction available (section 3.1.10.). Updated UI images to latest version. Minor textual improvements.
1.1 - Raised version number of PERISCOPE.
1.2 - Updated version number of PERISCOPE.
1.3 - Updated version number of PERISCOPE.
1.4 - Updated version number of PERISCOPE. Corrected information regarding on-premise and cloud installations in section 6.1 to make it more accurate. Added to section 6.4 information regarding how users may detect and act upon IT security problems, communicate the loss of authentication elements, as well as additional indications on the use of anti-virus and anti-malware software.
1.5 - Updated version number of PERISCOPE. Included additional notes in warning 3.1.11 and in section 4.4 to highlight the fact that undergoing a new procedure will trigger issuing a new prediction for the same patient.
1.6 - Updated version number of PERISCOPE.

**1.3 Compatibility**

Changes and/or additions to the software product should only be carried out by Healthplus.ai. Such changes and/or additions must comply with all applicable laws and regulations which have the force of law within the jurisdictions concerned, and with best engineering practice.

**1.4 Compliance**

This software complies with all applicable EU Regulations and national laws. Information on compliance can be supplied on request (see section 1.6 for contact information).

**1.5 Symbols Glossary**

The following symbols may appear in the IFU and/or in the user interface:

| SYMBOL | SYMBOL TITLE | DESCRIPTION |
|---|---|---|
| MD | Medical device | Indicates that the product is a medical device. |
| | Manufacturer | Indicates the medical device manufacturer. |
| | Date of manufacture | Indicates the date when the medical device was manufactured. (In the specific case of PERISCOPE, it indicates the date of release of the current version.) |
| REF | Catalogue number | Indicates the manufacturer's catalogue number, so that the medical device can be identified. |
| UDI | Unique device identifier | Indicates a carrier that contains unique device identifier information. |

| | | |
|---|---|---|
| LOT | Batch code | Indicates the manufacturer's batch code, so that the batch or lot can be identified. (In the specific case of PERISCOPE, it indicates the number of the current version.) |
| ⚠ | Caution | Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences. |
| | Consult instructions for use or consult electronic instructions for use | Indicates the need for the user to consult the instructions for use. |

**1.6 Contact Information**

PERISCOPE has been developed and produced by:

Healthplus.ai-Operations B.V.
Van Diemenstraat 50
1013 NH Amsterdam
The Netherlands

For further information, please contact Healthplus.ai:
Website: www.healthplus.ai
Email: support@healthplus.ai

In case of obvious or suspected malfunction, or any other issue thought to impact the performance and safety of PERISCOPE, please contact Healthplus.ai's customer support without delay.

Email: support@healthplus.ai

Serious incidents must be reported to the Competent Authority responsible for the geographical area where the reporting user is based. Vigilance contact points for different EEA countries can be consulted through the link below:
https://health.ec.europa.eu/system/files/2023-06/md_vigilance_contact_points.pdf

Additionally, Healthplus.ai's Competent Authority may also be informed of the identified incident:
Ministry of Health, Welfare and Sport Agency, Health Care Inspectorate
Email: meldpunt@igj.nl

# 2 Description, classification, and use

PERISCOPE is a standalone Software as a Medical Device (SaMD) which offers a short-term (up to and including postoperative day 7) and a medium-term (up to and including postoperative day 30) prediction after a surgical procedure of the likelihood of an individual adult patient developing a clinically-relevant bacterial infection.

The prediction is the output of a supervised machine-learning model that has been trained to identify clinically-relevant bacterial infections in postoperative patients, defined by registration of the infection and/or pharmacological and/or interventional infection treatments by a qualified clinician in the Electronic Health Record (EHR). It processes the patient's electronic health data and provides the prediction after the end of surgery via the hospital's EHR system.
Besides the predictions, PERISCOPE does also display additional information from the patient's EHR which is deemed relevant to help healthcare professionals understand the significance of predictions within the global context of each patient.

PERISCOPE is a clinical decision support system and provides additional information for the clinical team responsible for a patient's postoperative care, and may prompt additional monitoring, diagnostic testing and/or another timely intervention aimed at reducing the severity and impact of infection.

PERISCOPE fulfils the criteria of a medical device according to Article 2(1) of ***Regulation (EU) 2017/745*** on Medical Devices ('***MDR***') in that it is intended to be used for the benefit of individual patients for the following medical purpose: the prediction of disease, namely bacterial infection, requiring clinical action related to diagnosis and/or treatment. It is an active, independent device which does not drive or influence the use of a (hardware) medical device. According to the Rule 11 of the classification rules listed in ***MDR*** Annex VIII specifically related to Medical Device Software, PERISCOPE is a Class IIa device.

## 2.1 Intended use

PERISCOPE is an Artificial Intelligence (AI)-based, standalone clinical decision support software which predicts the probability of an individual patient requiring (a) clinical action related to the diagnosis and/or treatment of a postoperative bacterial infection following a surgical procedure in the hospital setting. The aim is to reduce the severity and impact of infection by supporting decision-making.

PERISCOPE offers two simultaneous predictions after surgery: a short-term prediction (valid up to and including postoperative day 7) and a medium-term prediction (valid up to and including postoperative day 30). The software processes the patient's electronic health data and presents the predictions after the end of the surgery.

PERISCOPE is intended only as a clinical decision support system providing an additional source of information to healthcare professionals and shall not replace a healthcare professional's expert knowledge, hospital protocols or any other sources of information pertinent to the care of the patient.

## 2.2 Indications

PERISCOPE is intended for patients aged 18 years and above who undergo an invasive, including minimally invasive, surgical procedure requiring admission to the hospital. Exceptions and contraindications are stated in section 2.4.

## 2.3 Intended users

PERISCOPE is intended for use by healthcare professionals working in a hospital's surgical department who have access to the local EHR and are involved in providing and making decisions regarding a patient's postoperative care.

Healthcare professionals working in departments other than a surgical specialty are NOT the intended users of PERISCOPE. This includes healthcare professionals responsible for patient care in the intensive care unit (ICU), even in cases where a patient is transferred directly from the surgical department to the ICU after their procedure.

## 2.4 Contraindications and exclusions

PERISCOPE does not issue predictions for patients where the main procedure was not a surgical procedure, including cardiological or a radiological intervention, electroshock-, radiation-, or brachytherapy, diagnostic endoscopy or taking of a biopsy.

PERISCOPE does not issue predictions for patients whom the main procedure was to treat an infection.

PERISCOPE does not issue predictions for patients who are registered to be pregnant. This patient group is deemed to be vulnerable and the validation and clinical evaluation processes for its initial release were not particularly focussed on the collection of data regarding this specific group.

PERISCOPE is not aimed at predicting potential viral, fungal, or parasitic infections. Its operation is based on the state-of-the-art knowledge regarding postoperative bacterial infections and, as such, its underlying machine-learning model is not tailored for the prediction of infections caused by other types of organisms. However, PERISCOPE may predict infection situations where such an organism may also be present. PERISCOPE predictions also cannot apply to infections caused by organisms which are previously unknown to the medical field. If an organism is unknown, no information on it nor on its infectious behaviour and prevention or diagnosis patterns could be taken into consideration to issue a valid prediction.

## 2.5 Intended clinical benefits

PERISCOPE offers a prediction which is an objective, measurable, and data-driven parameter for how likely a surgery patient is to require medical action(s) aimed at diagnosing and/or treating infections following the surgical procedure.

PERISCOPE supports medical decisions by enabling healthcare professionals to decide based on valuable, data-driven insights, based on a set of criteria (i.e. predictive features and

infection definition) that enables automated evaluation of how likely a surgery patient is to require medical action(s) aimed at diagnosing and/or treating infections following the surgical procedure.

**2.6 Risks related to the use of the device**

The information provided by PERISCOPE is expected to help healthcare professionals acquire an improved snapshot of a patient's risk situation with regards to postoperative infection and thus to support any subsequent medical decision. Based on this, some important considerations are needed to establish the nature of the hazards, hazardous situations, and harm that could result from the use of a tool such as PERISCOPE:

- PERISCOPE is a standalone software product, which operates based on the patient information that is available from the local EHR system and does not have direct contact with the patient, rather providing information based on which healthcare professionals can make more informed decisions;
- The use of PERISCOPE is not expected to pose any specific harm to healthcare professionals - the intended users - nor to its environment of use. Any potential harm arising from the use of PERISCOPE should be strictly related to the information it provides and how its interpretation and influence on medical decision may affect patients' health status;
- Healthcare professionals are expected to appraise the information provided by PERISCOPE critically, not taking rash decisions nor bypassing established medical protocols and generally acknowledged good-practice;
- Based on the above, any failures from PERISCOPE to present correct and accurate information shall always be subjected to professional medical judgement before it results in actual harm to the patient;
- The hazards and hazardous situations resulting from the use of PERISCOPE are essentially related to the information, its correctness and completeness, the way it is presented, and any potential sources of misinterpretation by healthcare professionals;
- The character of any potential harm resulting from the use of PERISCOPE is essentially indirect, since information is always expected to be appraised by a qualified medical professional (i.e. there is a qualified professional, 'human filter' between the identified hazards and hazardous situations arising from the information displayed and the occurrence of actual harm to the patient).

Based on these considerations, the hazardous situations associated to the use of PERISCOPE could be said to be enclosed in one of the two situations below:

- Wrong information or its wrong interpretation could lead to underestimation of the severity of a patient's status, thus resulting in delayed or absence thereof;
- Wrong information or its wrong interpretation could lead to overestimation of the severity of a patient's status, thus resulting in unnecessary diagnosing and/or treatment actions.

The table below summarises the formal relationship between hazards and hazardous situations associated with the use of PERISCOPE and their potential consequences in terms of actual indirect harm to the patient:

| Hazards | Resulting hazardous situations | Potential harm |
|---|---|---|
| Information: wrong information displayed<br><br>OR<br><br>Information: missing information<br><br>OR<br><br>Information: misinterpretation | Patient is not treated / treatment is delayed | Escalation of existing infection. |
| | Patient receives unnecessary treatment | Unnecessary treatment harming the patient. |
| | Patient is subjected to unnecessary diagnostics | Inconvenience caused by unnecessary diagnostics. |

Please refer to the safety warnings and precautions listed below in section 3.1.1 for information regarding specific situations that could trigger hazardous situations and potential harm to the involved patients. Observing the information provided therein should help to greatly mitigate any residual risks related to the use of PERISCOPE.

# 3 Warnings, precautions, and information for safety

Before using this software, you must have read and understood all instructions to ensure safe and correct use. Be aware of the warnings below and specifications regarding the intended use, as stated throughout section 2.

Negligence with regards to the safeguards found under 3 and 3.1 implies the risk of misuse of PERISCOPE, and thus the risk of incorrect use and wrong interpretation of the results, possibly leading to safety risks for patients.

### 3.1 Important Safety Warnings

**3.1.1** ⚠ **WARNING:** The software product is not intended for use on mobile devices (tablets or mobile phones).

**3.1.2** ⚠ **WARNING:** The software product is not intended for use by healthcare professionals primarily responsible for the care of patients admitted to the ICU directly after their procedure.

**3.1.3** ⚠ **WARNING:** The software tool operates based on the assumption that the information available on EHR systems' databases is correct, complete, and accurate.

**3.1.4** ⚠ **WARNING:** The software tool is a decision-support tool only, and shall not replace a healthcare professional's expert knowledge, local standards, hospital protocols or any other sources of information or process pertinent to the care of the patient.

**3.1.5** ⚠ **WARNING:** PERISCOPE is intended to function based on information available from the local EHR system and the predictions provided displayed in a dedicated dashboard. Suitable, efficient, and secure connection to local databases must be ensured during its deployment. Any changes to the local system architecture after PERISCOPE deployment may compromise its operation. Heathplus.ai advises healthcare facilities to contact its services prior to implementing changes to local architecture and IT resources so that an impact analysis can be conducted and actions implemented to prevent unavailability of service.

**3.1.6** ⚠ **WARNING:** Deployment of PERISCOPE involves site-specific initial and periodic calibration, which will be included as part of Healthplus.ai installation and servicing procedures, and is required to ensure an adequate performance on the data from each hospital. However, each healthcare facility is advised to request from Healthplus.ai documented evidence that calibration has been performed.

**3.1.7** ⚠ **WARNING:** The update/response time for the software tool may be limited. It is important to be aware when available information has been updated for the last time.

**3.1.8** ⚠ **WARNING:** The end user should be aware of situations that may indicate malfunction or need for recalibration (e.g. repeated cases of obvious prediction inaccuracy). These situations, just like potential (critical) incidents, must be reported immediately to support@healthplus.ai and according to the information found under section 1.6 in this document.

**3.1.9** ⚠ **WARNING:** For each patient, PERISCOPE displays to the user a set of predictive parameters that contribute the most for the prediction issued and indicate correlation to the predicted risk only, not causation. The predictive parameters shown have had the highest influence on the prediction for a specific patient, but are displayed with NO specific order. Acting on these parameters will not yield any changes on the prediction.

**3.1.10** ⚠ **WARNING:** The software tool's predictions will appear as not available for surgical specialties where model performance falls below a prespecified threshold, as well as for cases where the use of PERISCOPE is contraindicated (see section 2.4.).

**3.1.11** ⚠ **WARNING:** The predictions are issued ONLY ONCE after the surgery and are NOT updated during the 7- and 30-day period after the surgery, respectively. This also means that actions and decisions taken regarding the patient afterwards will not yield any changes on the prediction. However, a NEW prediction will be displayed if the patient undergoes a new procedure.

# 4 Product Description

### 4.1 Model Introduction

The PERISCOPE software aims to support healthcare professionals in managing postoperative infection risks for individual patients. The software supports two-fold; it gathers and presents relevant data and it calculates the probability (as a percentage) of the patient requiring a clinical action related to the diagnosis and/or treatment of a bacterial infection in the near future (between day 0 - 7 and day 0 - 30 after the procedure). This probability is calculated by a machine learning algorithm. This is a type of algorithm that can learn to recognise patterns in historical EHR datasets and, using these learnings, predict future outcomes. To develop the PERISCOPE algorithm, EHR registrations from the past years have been used. The algorithm has been trained to predict the following outcome:

### 4.2 Definition of outcome

Risk of a clinically relevant bacterial infection where patients will meet at least one of the following criteria:

1. Infection is registered by a surgeon by means of a specific condition (International Classification of Diseases (ICD) code or hospital-specific code) AND the condition onset date is at least one calendar day after the surgery end date and before respectively 7 days and 30 days after surgery.
2. Patients received systemic antibiotic treatment starting between >= 24 hours and <= 7 or 30 days after surgery, with a duration longer than 3 days. BUT NOT extended (beyond 24 hours after surgery) prophylactic, hospital specific regimes.
3. Patient received a surgical intervention related to treatment of infection within 0 days < surgery < 7 or 30 days BUT NOT during initial surgery itself.

Please note that PERISCOPE is not restricted to surgical site infections, but also predicts other postoperative infections such as pneumonia and urinary tract infection.

### 4.3 Predictive parameters

The algorithm makes predictions based on the data that is registered in the EHR before and during the procedure. Based on recent literature, data availability and predictive value we have selected as predictive parameters:

1. Patient demographic characteristics, such as sex and age.
2. Comorbidities, such as body mass index (BMI), hypertension, and diabetes.
3. Medication history such as usage of immunosuppressive medication and cancer medication.
4. Surgical procedure characteristics, such as the surgical specialty and procedure priority.
5. Aggregated vital signs before and during the procedure, such as mean heart rate and respiratory rate.
6. Biomarkers such as alanine aminotransferase (ALT or ALAT), haemoglobin (Hb), and C-reactive protein (CRP).

### 4.4 Predictions

The result of the algorithm is a percentage between 0 and 100. This number represents the likelihood that the predicted outcome (a clinical action related to postoperative infection) will be required. While developing the model, Healthplus.ai has ensured the predicted outcome is correctly calibrated. This means that if the algorithm produces a 30% likelihood that an intervention/clinical action shall be needed, in the past for patients with similar profiles a clinical action was performed for 3 out of 10 of these patients, whereas a clinical action was not performed for 7 of these similar patients.

PERISCOPE produces 2 predictions, one for the risk of the outcome within the first 7 days of the procedure and one for the risk of the outcome within 30 days of the procedure. If multiple procedures have been performed for a single patient, the predictions for the last procedure will be presented (as well as the prediction category and the top-10 predictive parameters - see sections 4.5 and 4.6 below). It is important to note that these predictions are issued ONLY ONCE after the surgery and are NOT updated during the 7- and 30-day period after the surgery, respectively. (Thus actions and decisions taken regarding the patient afterwards will not yield any changes on the prediction.) The predictions apply to all types of bacterial infections and are only valid for the given 7- and 30-day period after the surgery.

### 4.5 Prediction categories

The predictions are categorised into three risk categories to help with their interpretation, namely low, medium or high. The classification is made by comparing the new prediction to the number of historically occurring infections in your hospital's patient population of the same surgical specialty.

If the probability of an infection falls in the bottom third of the population, the risk is qualified as 'low', with the colour green. If the prediction falls in the middle third of the population, the risk is qualified as 'medium', with the colour orange. If the prediction falls in the highest third of the population, the prediction is qualified as 'high' with the colour red.

This risk classification category is only based on the prediction of the algorithm, compared to the average number of infections that the surgical specialty has had in the past. It does not say anything about the health risk for the particular patient, only that the patient, compared to other patients treated by the same specialty, has a lower / equal / higher chance of requiring a clinical action to treat an infection.

### 4.6 Prediction explanation

In addition to the prediction, an explanation for the prediction is presented. As described in paragraph 4.3 'Predictive Parameters', the algorithm uses around 50 different predictive parameters (depending on the availability in the EHR) to calculate the risk. For you, as a healthcare provider, it is important to see which parameters have mainly led to the result that is shown to you. This is why PERISCOPE shows the 10 most contributing parameters with each prediction. You can see the value of the parameter and whether it raised or lowered the risk, but they are displayed in random order. The explanation will differ per patient. It can be that a predictor that increases risk for one patient, might lower risk for another. For instance, an average body temperature of 36.8 might lower risk for a 70 year old male of normal

weight, but it might raise the risk for a 50 year old male classed as overweight, according to their BMI. The given parameters do not have a causal relationship to the outcome.
By showing the 10 most important parameters you might also be able to see the clinical relevance of a prediction. For instance if one of the values was a registration error, or if there is a reason why this predictor for a specific patient does not raise or lower the infection risk according to your professional assessment.

**4.7 Real-time dashboard parameters**

PERISCOPE has a dashboard that shows the algorithm's predictions, and supporting patient information to help you assess the patient's status. As mentioned, the algorithm uses information that was available in the EHR until the end of surgery. After that the prediction is not updated anymore.
To help you assess the current condition of a patient, PERISCOPE shows current information which is taken directly from the EHR. For instance the measurement of blood pressure, saturation, temperature, respiratory rate and heart rate for the past 5 days, whether the patient has been prescribed antibiotics, and whether cultures have been taken.

**4.8 Model performance report**

Before PERISCOPE is ready for use, the algorithm will be recalibrated on the historical registrations in your institute's EHR system. Firstly, the definition of the outcome is validated. This is done by reporting the outcome for randomly selected patients according to the definition in paragraph 4.2 and matching this with information from the EHR for these patients. With the confirmed outcome definition PERISCOPE can be recalibrated. Consequently the performance of the algorithm is evaluated on the most recent year(s). The most important performance metrics evaluated are the C statistic or Area Under the Receiver Operator Curve (AUROC) and the model's calibration characteristics as explained in paragraph 4.4. The AUROC is a measurement for how good the model can distinguish between high and low risk patients. It is a number between 0.5 and 1.0 where 0.5 means no separation and 1.0 means perfect separation and thus perfect predictions. These and other metrics are summarised in a model performance report that is shared with your institute.
Additionally, the performance of PERISCOPE for different subgroups is evaluated and reported. For instance, the performance per surgical specialty, sex, BMI category or procedure priority. If the model underperforms for certain specialties (e.g. if the AUROC is below 0.7) we conclude that the model is not suitable for use for the patient group of this specialty and the predictions will not be shown.

The model performance report is issued by Healthplus.ai after installation and installation verification activities and shared with your institution as evidence that PERISCOPE is properly installed and ready to perform safely. See section 5.1 for additional information on how to confirm PERISCOPE's readiness for operation.

**4.9 Performance characteristics**

As described above in section 4.8, AUROC is the most relevant parameter that demonstrates PERISCOPE's ability to distinguish between patients at high and low risk of requiring clinical action related to postoperative infection scenarios. Although this parameter can vary across

different patient subgroups, depending on the amount and quality of the data available, Healthplus.ai is confident to deliver a performance of at least 0,7 AUROC. (For safety reasons, where this minimal performance cannot be met, PERISCOPE will show no predictions; see section 5.2 for more information on how to identify these cases.) The predictions displayed should be under the form of a percentage (0 - 100%) (see section 4.4), and accompanied by a risk category that refers to the patient's surgical specialty (see section 4.5) and the 10 predictive features with highest influence on the prediction shown (see section 4.6).
Additionally, and for all patients, PERISCOPE's dashboard displays data on other clinical parameters that are deemed important for postoperative infection-related medical decision-making (see sections 4.7 and 5.2).

The table below summarises PERISCOPE's expectable performance for each of these parameters and how they are conveyed to the users.

| PARAMETER | EXPECTED PERFORMANCE | COMMUNICATED THROUGH: |
|---|---|---|
| AUROC | > 0,7 | Model performance report (see section 4.8) |
| Prediction | 0 - 100 % | Dashboard, tile, and column views (see sections 5.2 to 5.4) |
| Prediction category | **LOW** / **MEDIUM** / **HIGH** | Dashboard, tile, and column views (see sections 5.2 to 5.4) |
| Prediction explanation | Top-10 prediction-correlated parameters displayed. | Dashboard view (see section 5.2) |
| Other real-time parameters | As described throughout section 5., and as available per patient. | Dashboard view (see section 5.2) |

# 5 User instructions

Before starting to use PERISCOPE at your institution, we advise you to confirm if the corresponding model performance report has been made available by Healthplus.ai (it should have been verified before the tool has been put into use, but it could be important for you as a healthcare professional to confirm the level of prediction accuracy to be expected for different patient subgroups).

The completeness of installation can be confirmed by checking that intended users (see section 2.3) have access to the PERISCOPE views from within the EHR system by using their regular EHR credentials.
Readiness for safe use can be additionally confirmed by verifying example patients for included and excluded groups (see section 2.4). Verify that patients that underwent invasive surgery for included surgical specialties in the last week do receive a prediction, and verify that no prediction is shown for patients that underwent non-invasive surgery (e.g.

endoscopic procedures) and for patients that are treated by a not included surgical specialty (see the model calibration report).

## 5.1 Access to the tool

The software tool is integrated in the local EHR system and the predictions provided displayed in a dedicated dashboard within the EHR. In order to start using the tool, you first login to the EHR. Although the exact way of navigating to the main PERISCOPE dashboard may vary across different EHR systems, the option to access PERISCOPE should be visible within each individual patient record (dashboard and tile views - see section 5.2 and 5.3), as well as in the overview of the current list of patients (column view - see section 5.4).

Please note that you will only see such an option if you are an authorised PERISCOPE user (see section 2.3), i.e. a surgeon or nurse working at your institution's surgical department. If you should have access to PERISCOPE and you currently do not, please contact Healthplus.ai's support (see section 1.6) or reach to the management or IT services of your organisation.

For any indicated patient (see sections 2.2 and 2.4) who have already undergone their surgery, you should be able to see information in 3 different views, such as exemplified throughout sections 5.2 to 5.4.

## 5.2 PERISCOPE Dashboard

Within an individual patient record, you can access the PERISCOPE Dashboard.

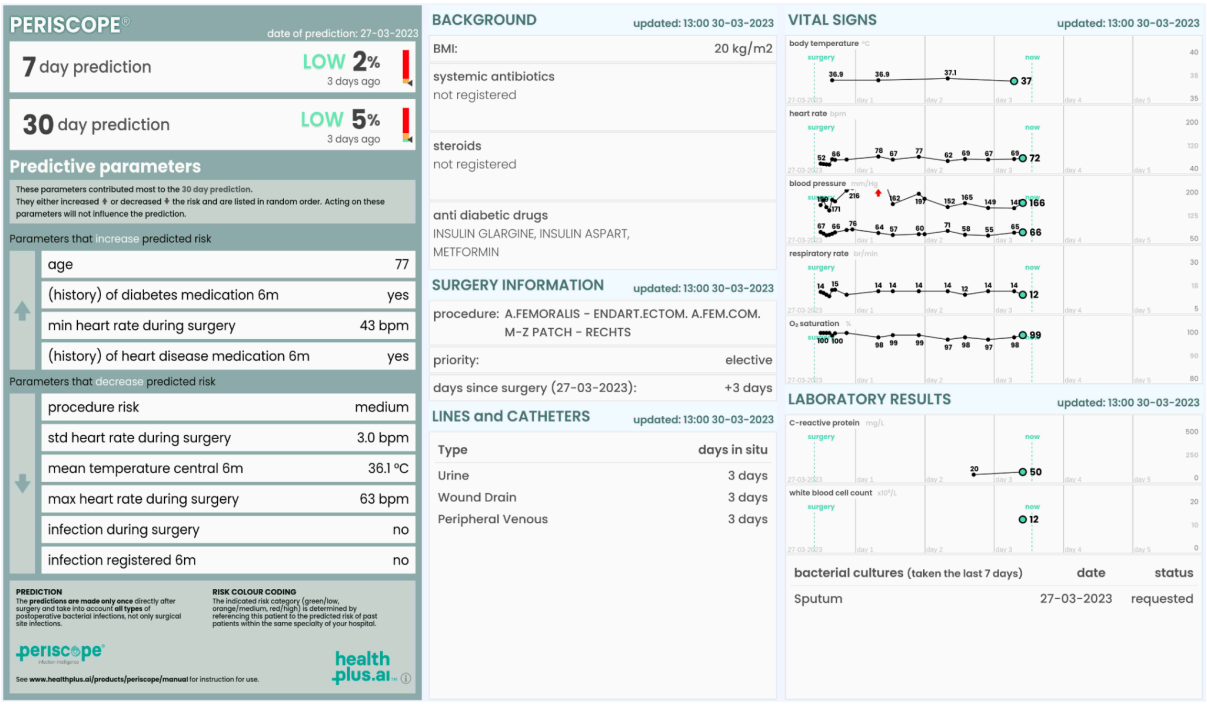


*Figure 1. Example of Dashboard - User Interface showing information for a fictive patient.*

The PERISCOPE dashboard displays the following information (see *Figure 1*, from up to down, from left to right; detailed views of *Figure 1* are also provided below):

**Date of prediction**
The date that the prediction was made is displayed at the top.

**7 day prediction**
This shows the probability (as a percentage) of the patient requiring a clinical action related to the diagnosis and/or treatment of a bacterial infection within 7 days after the surgery, with the day of the procedure classed as day 0. The probability is categorised into either low, medium or high risk.

**30 day prediction**
This shows the probability (as a percentage) of the patient requiring a clinical action related to the diagnosis and/or treatment of a bacterial infection within 30 days after the surgery, with the day of the procedure classed as day 0. The probability is categorised into either low, medium or high risk.

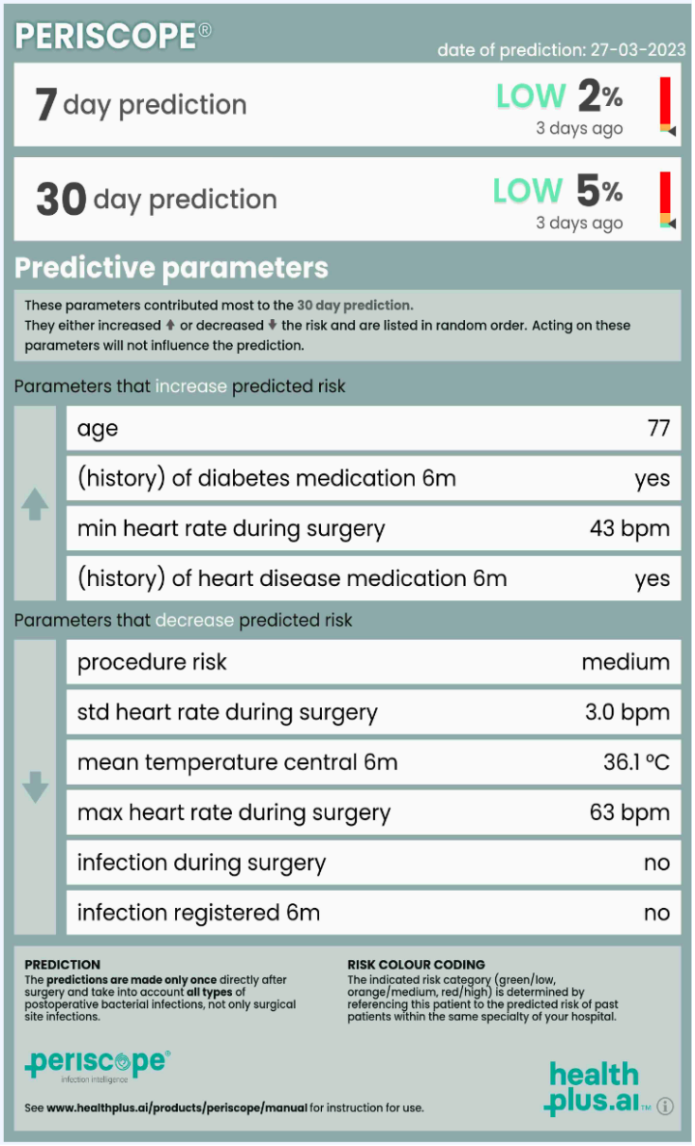


*Figure 2. Left section of Figure 1: Prediction and predictive parameters in the dashboard.*

**Predictive parameters**

The ten most relevant parameters that have the greatest influence on the model's prediction of the probability within **30 days** are listed here. Arrow up or down: the icon indicates whether the parameters increased (arrow up) or decreased (arrow down) the probability. The parameters are displayed and their value and unit of measurement where applicable. Some of these parameters contain abbreviations: *min*: minimal, *max*: maximal, *std*: standard deviation, *24h*: 24 hours, *6m*: 6 months. The parameter 'procedure risk' is calculated based on the number of infections patients developed after the same procedure in the past. The ⅓ of procedures that had the most infections are labelled: 'high risk' and the ⅓ of procedures that had the least amount of infection are labelled 'low risk'. All other procedures are labelled 'medium risk', these are either the ⅓ of procedures in between low and high, or procedures that have not been performed enough to make a risk calculation.

**Warnings**

The following warnings are listed on the User Interface (see *Figure 3* and *Figure 4* below):

⚠ **WARNING:** Predictive parameters: These parameters contributed most to the 30 day prediction. They either increased or decreased the risk and are listed in random order. Acting on these parameters will not influence the prediction.

⚠ **WARNING:** Prediction: The predictions are made only once directly after surgery and take into account all types of postoperative bacterial infections, not only surgical site infections.

⚠ **WARNING:** Risk colour coding: The indicated risk category (green/low, orange/medium, red/high) is determined by referencing this patient to the predicted risk of past patients within the same specialty of your hospital.

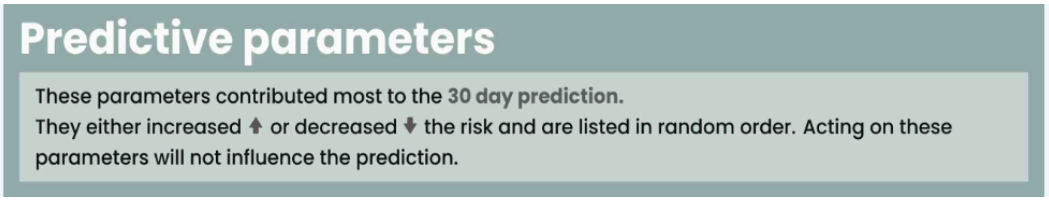


*Figure 3. Detail from Figure 2., enhancing how the warning related to the interpretation of the predictive parameters is displayed.*

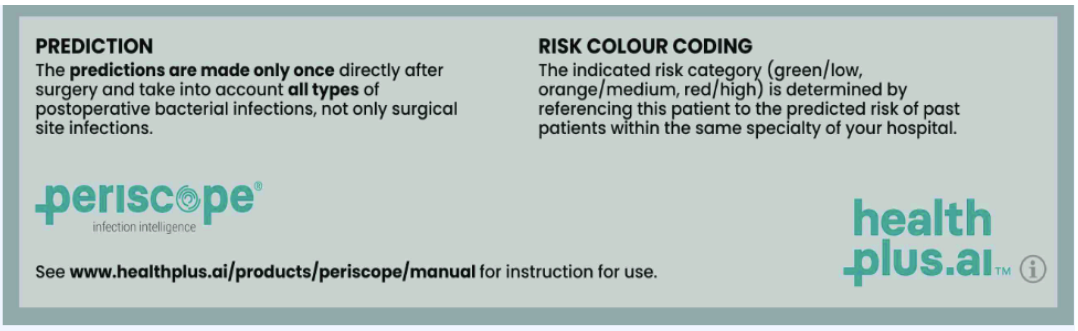


*Figure 4. Detail from Figure 2., enhancing how the warnings related to the interpretation of the prediction and risk colour coding are displayed.*

When model performance for a defined subgroup falls below a prespecified threshold and/or there is insufficient data to provide a representative sample, and/or when there the patient belongs to a contra-indicated patient group (as specified in paragraph 2.3 and 2.4), no prediction will be made. The left column of the dashboard will be grey as displayed below in *Figure 5*:

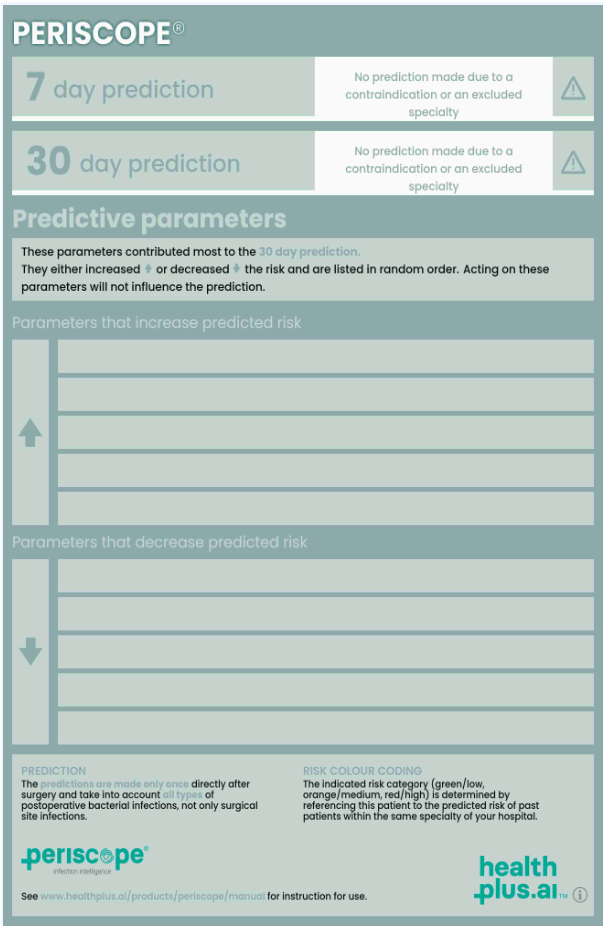


*Figure 5. Prediction could not be made - Greyed-out left column in the dashboard.*

**Updated**

This shows the date and time that the information in this section of the dashboard was issued.

**Body Mass Index (BMI)**

This shows the BMI, quantified in kg/m$^2$.

**Systemic Antibiotics**

This shows the generic name of any systemic antibiotics that the patient is currently taking/has been prescribed, as registered in the EHR (started, ongoing or stopped on the day of the last data update).

**Steroids**

This shows the generic name of any steroids that the patient is currently taking, as registered in the EHR (started, ongoing or stopped on the day of the last data update).

**Anti-diabetic medication**
This shows the generic name of any anti-diabetic medication that the patient is currently taking, as registered in the EHR (started, ongoing or stopped on the day of the last data update).

**Procedure**
This shows the primary surgical procedure that the patient underwent before the prediction was issued.

**Priority**
This shows the level of importance that was assigned to actioning the surgical procedure. The categories are: elective, asap, stat. 'ASAP' means: schedule as soon as possible and the highest priority: 'stat' means immediate surgery.

**Days since surgery**
This shows the number of days which have elapsed since the surgery. The day of the surgical procedure is classed as day 0. Between brackets the date of surgery is shown.

**Lines and catheters**
This shows any indwelling lines and catheters that the patient currently has, as registered in the EHR, with their bodily location and the number of days that they are in situ.

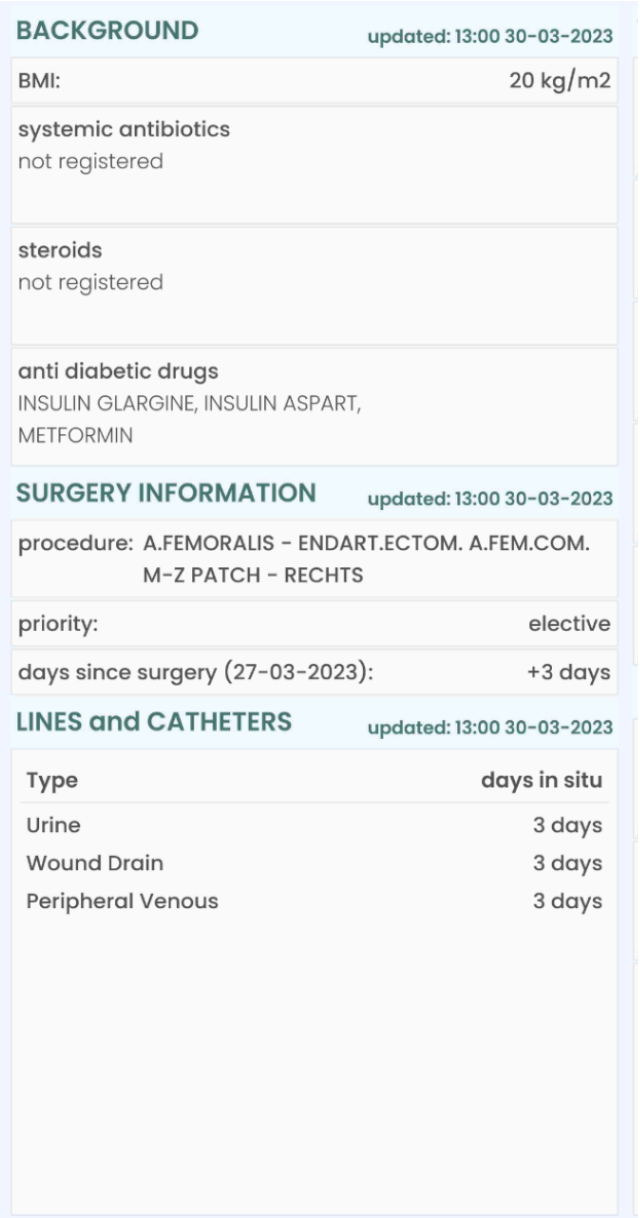


*Figure 6. Background, surgery information and indwelling lines and catheters in the dashboard.*

**Vital signs and laboratory results**

The day of the surgical procedure is classed as day 0 and a line depicts “now”. When a patient is less than 5 days postoperative, the date of surgery is displayed too. When a patient is more than 5 days postoperative, only the last 5 days are shown. A red arrow represents a measurement out of the range of the Y-axis. The mean of all measurements for each hour is depicted, but labels are shown for up to 3 measurements per day: the first measurement, the minimum and maximum value of the day.

**Body temperature**

The patients’ body temperature is displayed here in degrees celsius (°C) . The y-axis ranges from 35 to 40 degrees celsius (°C).

**Heart rate**
The patients' body heart rate is displayed here in beats per minute (bpm).The y-axis ranges from 40 to 200 bpm.

**Blood pressure**
The patients' body blood pressure is displayed here as systolic and diastolic blood pressure (mmHg).The y-axis ranges from 50 to 200 mmHg.

**Respiratory rate**
The patient's respiratory rate is displayed here in breaths per minute. The y-axis ranges from 5 to 30 breaths per minute.
**Oxygen saturation ($O_2$ saturation)**
The patients' blood oxygen saturation level is displayed here (percentage). The y-axis ranges from 80 to 100 %.

**C-Reactive Protein (CRP)**
The patients' blood CRP level is displayed here (mg/dl). The y-axis ranges from 0 to 500 mg/dl.

**White blood cell (WBC) count**
The patients' white blood cell or blood leukocyte count is displayed here in (10^9/L). The y-axis ranges from 0 to 20 x10^9/L.

**Bacterial cultures**
Bacterial cultures taken in the last 7 days are displayed here. The bodily location from where the bacterial culture was taken is specified, as well as the date and status.

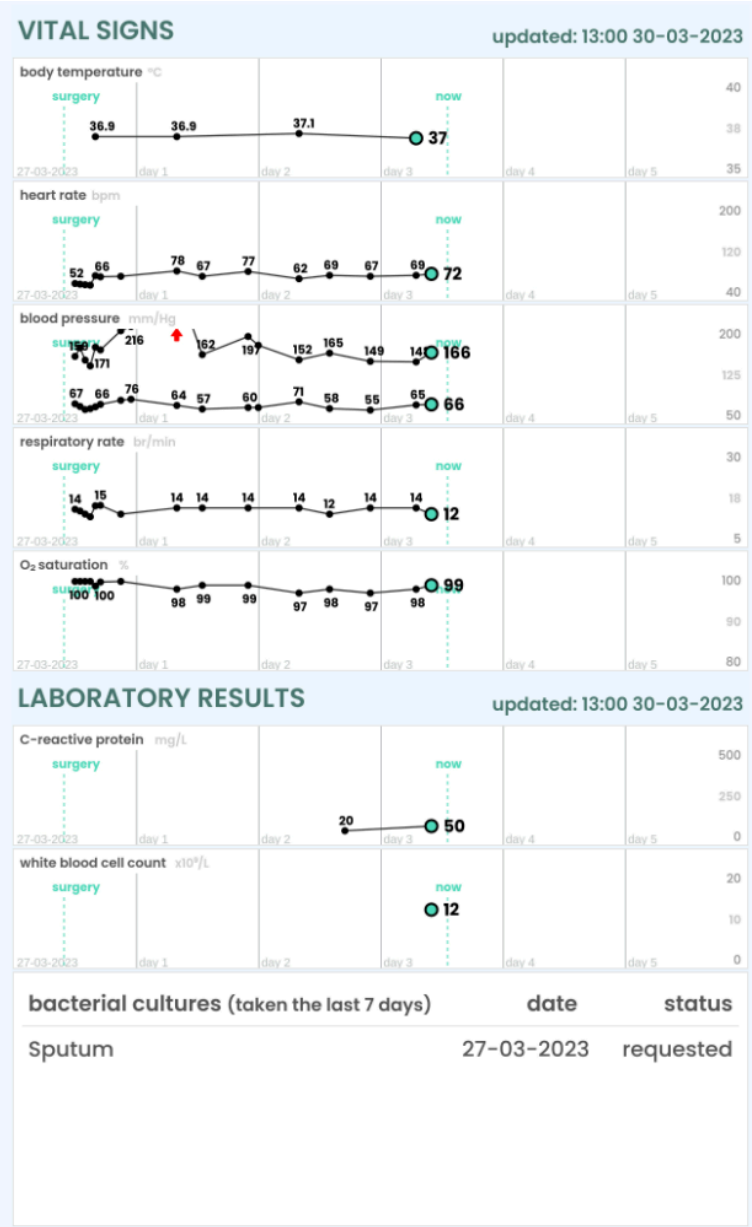


*Figure 7. Vital signs and laboratory results in the dashboard.*

## 5.3 PERISCOPE Tile

PERISCOPE's tile view is displayed as exemplified in *Figure 8* and in the detail of *Figure 9*. This view summarises the information that is included in the left column of the dashboard view.

### 7 day prediction

This shows the probability (as a percentage) of the patient requiring a clinical action related to the diagnosis and/or treatment of a bacterial infection within 7 days after the surgery. The probability is categorised into either low, medium or high risk.

### 30 day prediction

This shows the probability (as a percentage) of the patient requiring a clinical action related to the diagnosis and/or treatment of a bacterial infection within 30 days after the surgery. The probability is categorised into either low, medium or high risk.

### Days since surgery

This shows the number of days which have passed since the surgery. The day of the surgical procedure is classed as day 0. Between brackets the date of surgery is shown.

### Date of prediction

The date that the prediction was issued is displayed.

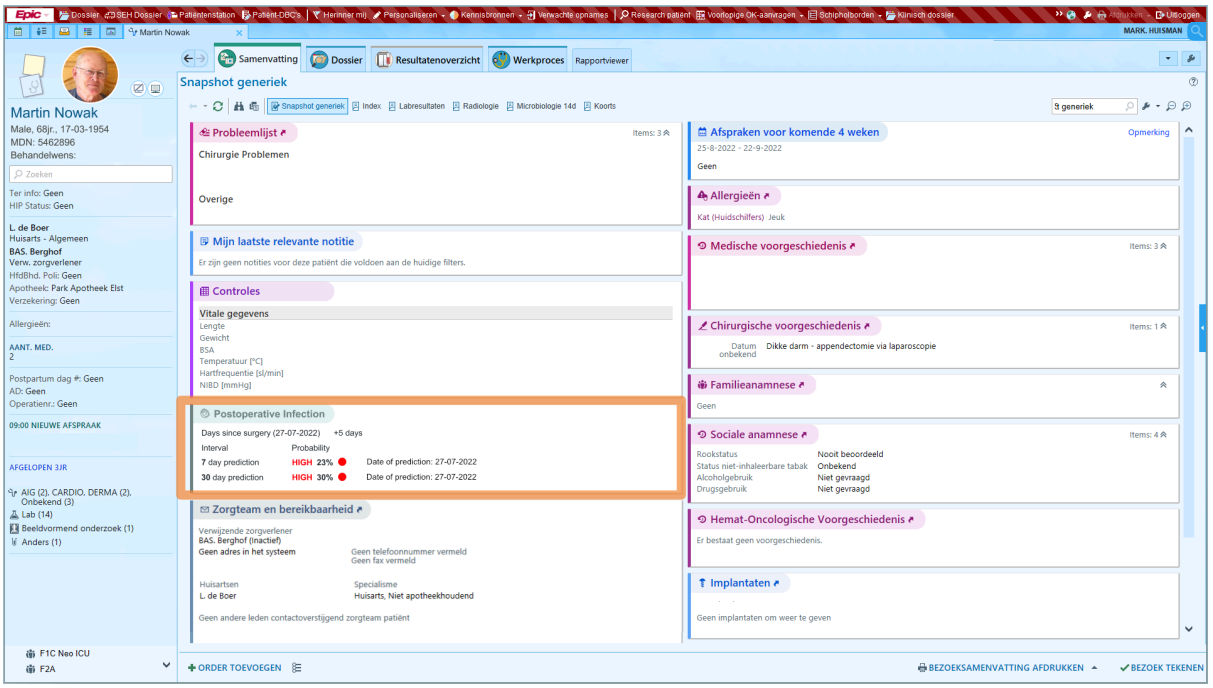


*Figure 8.The PERISCOPE Tile, highlighted in orange, integrated in EPIC environment. See Figure 9 below for a detailed view of the highlighted section.*

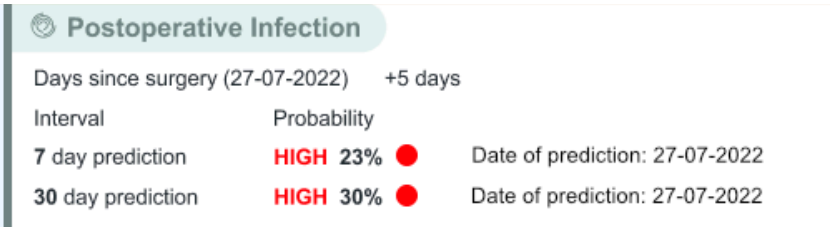


*Figure 9. PERISCOPE's Tile view, magnified from Figure 8.*

## 5.4 PERISCOPE Column in patient overview

The PERISCOPE Column can be added to a patient overview in the EHR. *Figure 10* and *Figure 11* show an example of this view.

### 7 day prediction

This shows the probability (as a percentage) of the patient requiring a clinical action related to the diagnosis and/or treatment of a bacterial infection within 7 days after the surgery. The probability is categorised into either low, medium or high risk.

## Date of prediction

The date that the prediction was issued is displayed.

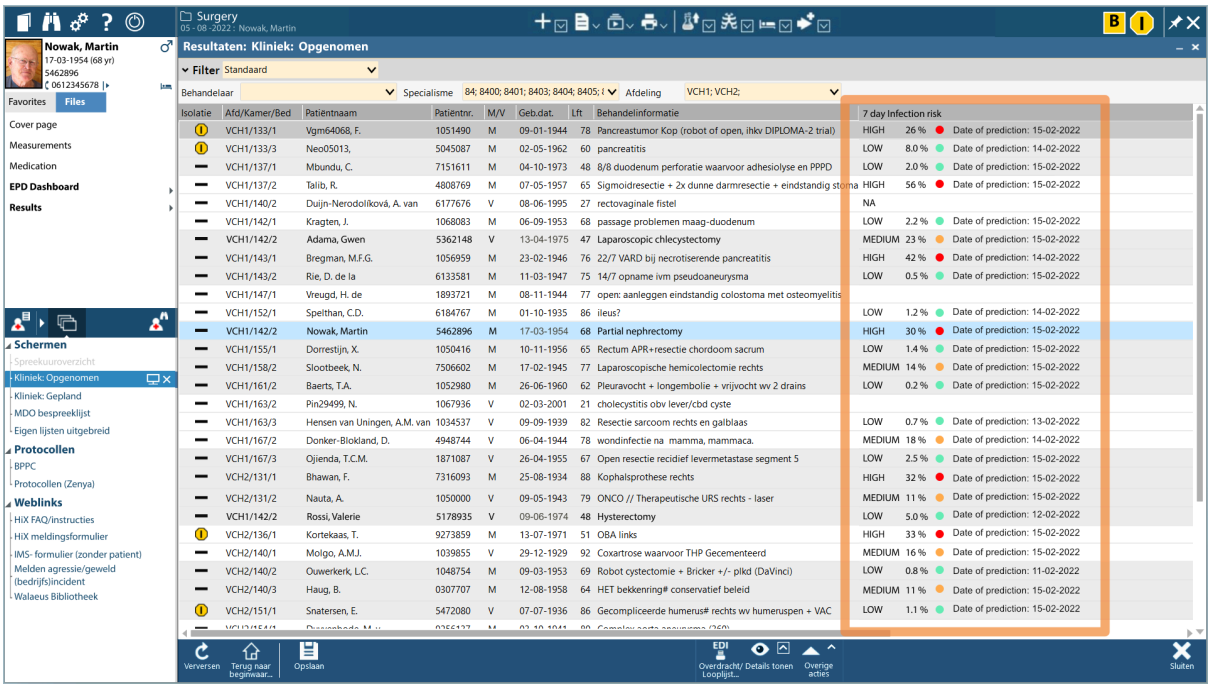


*Figure 10. The PERISCOPE Column in the patient overview (integrated in HIX environment).*

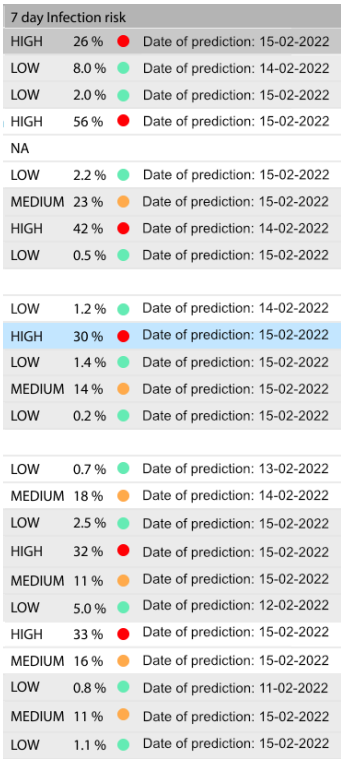


*Figure 11 - PERISCOPE's Column view, magnified from Figure 10.*

### 5.5 Additional information and software identification

The current IFU refers to PERISCOPE, which can be identified by the Unique Device Identifier (UDI) 8720929300006, as well as based on other identification elements provided above in section 1.2.

Additionally, while using this software tool the user can easily check this information by clicking anywhere on the dashboard screen that is described in section 5.2. This action should result in the device label (such as the one illustrated in *Figure 12* below) to be displayed for quick reference to the most relevant product identification information.

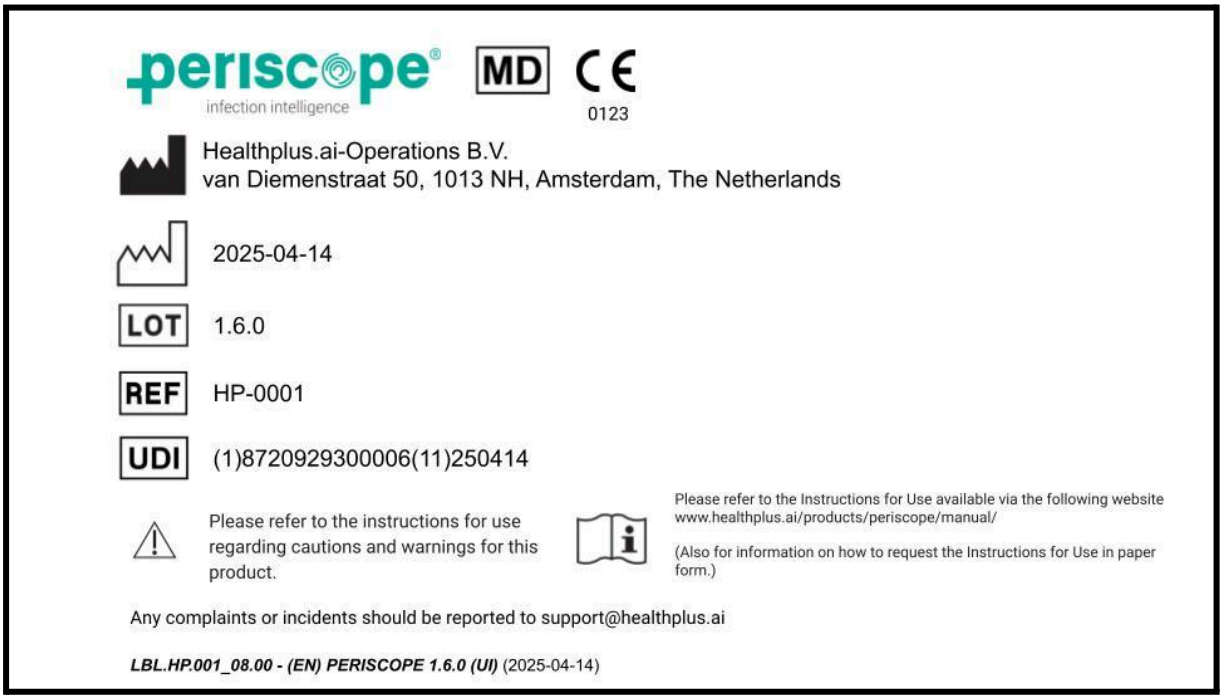


*Figure 12 - Example illustrating the labelling information to be displayed upon clicking on the dashboard screen.*

In case of obvious or suspected malfunction, or any other issue thought to impact the performance and safety of PERISCOPE and/or the health status of involved patients, the information from *Figure 12* should be included in the communication to be established with the manufacturer, as described in section 1.6.

## 6 Technical Specifications, Maintenance and Support

### 6.1 Software Installation and Removal

PERISCOPE is designed to be installed and operated by the PW Consulting runtime engine that is developed on the SAS Viya platform. PERISCOPE can be deployed both on-premise and cloud-based. In both cases, Healthplus.ai will take care of the installation and calibration process. For the integration of PERISCOPE within the existing EHR system and the collection of EHR data, close collaboration is required with both the EHR vendor as well as the technical system administrators and data engineers on site.

## 6.2 Software Updates and recalibration

During the lifetime of PERISCOPE several updates can be made available by Healthplus.ai. These updates can be the result of improvements of the software, updates related to security, additional features or compatibility updates regarding the underlying systems. Healthplus.ai will take care of the installation of these updates, whether running on premise or in the cloud. Besides having the most recent version of PERISCOPE, it is also essential to keep the underlying software, operating system and hardware up-to-date. For cloud installations, Healthplus.ai will ensure the full system is always up to date. For on premise installations a maintenance contract between the customer and hardware/software vendor shall be in place for the hardware and operating systems. Healthplus.ai will ensure that SAS Viya and the PW consulting runtime engine are maintained by their vendors.
The model is updated separately from the PERISCOPE software and has an expected lifetime of 2 years. However, through the regular collection of model performance data an assessment is made of the actual model performance. In case the performance drops below the acceptable value, a recalibration of the model is required. This recalibration will be performed by one of Healthplus.ai's qualified data scientists.

## 6.3 Technical Specifications

The PERISCOPE dashboard is designed to be embedded in the EHR system using the internal browser. It is best viewed with a screen resolution of 1600 x 950 pixels. PERISCOPE has been tested successfully on Internet Explorer 10, Chrome 21-28 and Edge 12-109 however the best experience is achieved with Internet Explorer 11, Chrome 29 and Edge 80.

PERISCOPE also comes with a REST API using OAuth2.0/OpenID authentication. Both interfaces (web and API) require the client to be compatible with TLS version 1.2 or higher. Both interfaces require a valid access token to be added in the 'Authorization' header as 'Bearer' to each request.

## 6.4 Network Safety, Security and Privacy

For our cloud-based solution Healthplus.ai will ensure the underlying systems are equipped with appropriate security measures such as firewalls, virus protection and malware detection. For the on-premise installation it is recommended to install virus protection and apply additional security measures on hardware, operating system and network as required by the customers' policy. No specific anti-virus or anti-malware software has been approved for use with PERISCOPE. Updates to this type of software should observe the instructions provided by the anit-virus/anti-malware manufacturer.

PERISCOPE requires encryption on all connections, including the administration interface, incoming data and outgoing interfaces such as the REST API and web interface.

Remote administration to on-premise installations of PERISCOPE will always be conducted over a Virtual Private Network (VPN) connection. The on-premise installation is not exposed to the public internet but does require outgoing connections to enable monitoring of the software health status. PERISCOPE uses industry standard OAuth 2.0 authentication and encrypted connections to exchange data with the EHR.

Authorised users are assigned access to PERISCOPE on a role-based logic (see also section 2.3 above on intended users) and through the same existing credentials for EHR access. Any issues related to the management of credentials and lost or stolen authentication elements shall be addressed with the designated local system administrator who is responsible for user and access management.

In the case of any security disruption, your local system administrator (or other role responsible for ensuring and/or maintaining IT security) should be immediately notified. Security compromise may originate from several different sources and might not be easy to detect. However, common signs of alert may include:

- Slow network performance or unexpected unavailability of software pages or views.
- The reception of suspicious emails or messages related to the software tool, or displayed web addresses - e.g. PERISCOPE users will never receive an email from PERISCOPE or its manufacturer. Be particularly watchful to suspicious addresses or IPs, such as weblinks containing spelling mistakes or somehow leading to unexpected requests for credentials or other types of private information.
- Suspicious access by users whose job role should not entitle them to it (see section 2.3 above on intended users). Make sure to report such cases immediately.

The raw data to calculate the predictions, the predictions themselves and the eventual actual outcome will be stored on the servers to monitor the performance of PERISCOPE over time.

## APPENDIX I Website statement IFU

URL address: https://www.healthplus.ai/products/periscope/manual/

All users of Healthplus.ai's PERISCOPE have access to an electronic copy of the IFUt. Please note that the IFU are a PDF document: these can typically be viewed with your internet browser, or using specific software like Adobe Acrobat Reader.

If you are unable to access the IFU through your account or require a hard copy, please email support@healthplus.ai from your hospital email address. We will either send you a digital copy via email, or a hard copy if you would desire one. We aim to provide hard copies within 7 calendar days.