Instructions for Use

ENGLISH

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0. Notes on the instructions for use

These instructions for use describe the product's safety equipment, functions, and performance parameters. They describe safe use. Correct use of the product is paramount for safe and successful operation.

Use the following link to download the electronic instructions for use (eIFU) at any time: https://acs-pathfinder.com/ifu/

Carefully read these instructions completely for use prior to using the product.

Representations of safety and warning instructions:

Warning: This is a warning label that warns of hazards where death or serious injury may occur if not avoided.

Caution: This is a warning label that warns of hazards where injury may occur if not avoided

1. Introduction

The ACS Pathfinder is a medical software device based on a machine-learning model, which estimates the individual probability of an acute myocardial infarction (MI) in patients presenting with symptoms indicative of MI. The ACS Pathfinder aims to complement diagnostic assessment and support physicians and other qualified healthcare workers (physicians, nurses, or emergency medical service staff) in their clinical decision-making to ensure safe, efficient and personalized patient management in medical practice, hospital, or emergency medical service environment.

To date, triage of patients with suspected MI is mainly based on troponin only and does not directly include other clinical parameters such as sex, age, ischemic signs in the electrocardiogram (ECG), vital signs or cardiovascular risk factors, which are all known to be strongly linked with MI pretest probability. The ACS Pathfinder considers routinely and immediately available clinical variables beyond troponin concentrations to precisely estimate the individual probability of MI as a percentage ranging from 0-100%. Those defined input variables are listed in Table 1. All required input variables are processed by the ACS Pathfinder machine-learning model to determine the individual probability of MI. In general, MI-probabilities can be estimated by ACS Pathfinder based on a single high-sensitivity cardiac troponin (hs-cTn) measurement or using two, serially measured hs-cTn

concentrations. If two hs-cTn measurements are to be considered, the ACS Pathfinder allows for flexible timing of the second blood sampling. The ACS Pathfinder can be used with a range of established hs-cTn assays from different manufacturers, including point-of-care (POC) assays. The list of the currently applicable hs-cTn assays is displayed in Table 2.

Depending on the availability of one single or two serial hs-cTn measurements, different, but clearly defined variables are used for the estimation of MI probability (Table 1). ACS Pathfinder is intended for reuse on multiple patients. ACS Pathfinder complies with the essential safety and performance requirements laid down in Annex I of Regulation (EU) 2017/745 on Medical Devices, applicable to the product. Legal information for the software such as manufacturer address, date of manufacture, and information pertaining to CE marking and other regulatory markings can be viewed using the "Product Label" information on the lower end of the web-application.

Table 1: Overview on input variables for the ACS Pathfinder.

Number	Variable	Considered by single hs-cTn measurement model	Considered by serial hs-cTn measurement model
1	The hs-cTn concentration at time of presentation	x	x
2	Symptom onset ≥ 3 hours	x	x
3	Age	x	x
4	Sex	x	x
5	Heart rate	x	x
6	Hyperlipoproteinemia	x	x
7	Smoking status	x	
8	Ischemic signs in the 12-lead resting electrocardiogram	x	
9	Family history of coronary arterial disease	x	
10	The hs-cTn concentration after repeated measurement (serial hs-cTn concentration)		x
11	The time between these measurements		x

The time between two hs-cTn measurements is automatically calculated as the difference between the recorded timestamps of the first and second blood sampling for hs-cTn measurement.

Table 2: Overview on hs-cTn assays

High-sensitivity troponin isoform	Manufacturer	Analyzer Platform	Analyzer characteristics
I	Abbott	Architect	Central lab
I	Beckman-Coulter	Access	Central lab
I	Mitsubishi	Pathfast	Point of care
I	Siemens Healthineers	Atellica	Central lab

I	Siemens Healthineers	Atellica VTLi	Point of care
T	Roche	Elecsys Gen 5	Central lab

2. Warnings

The ACS Pathfinder is a medical device and may only be used by trained medical professionals. The ACS Pathfinder calculates a probability estimate for acute myocardial infarction in patients with corresponding symptoms based on the input parameters entered or provided by the user. The ACS Pathfinder is intended for orientation as part of a comprehensive medical diagnosis. The probability estimate must be evaluated and confirmed by the responsible healthcare professional in the context of the overall available clinical data and diagnostics performed, considering the applicable guidelines. This medical device is explicitly not intended as a sole source of information to establish a diagnosis or to make a clinical decision. The medical device should only be considered as an aid in the diagnosis. The final medical decision rests with the treating healthcare professionals.

The diagnosis of MI is per definition based on the presence of an elevated biomarker indicating myocardial injury (e.g., cardiac troponin) and the presence of evidence for myocardial necrosis (this can include chest pain symptoms, ischemic signs on the ECG or other imaging). Therefore, the definite diagnosis of an MI will always be performed by a physician based on multiple information and is not replaced by the ACS Pathfinder (“human oversight” or “human in-the-loop”).

Importantly, the device does not provide an exact value, but a probability estimation. This estimation can be interpreted as its own error margin, in the following sense: If a patient has a low probability of MI, say, p = 0.4% and is treated as not having a MI, then the probability of making a mistake is p = 0.4%. Consequently, the provided probability must always be interpreted in the clinical context, also considering other clinical, laboratory or imaging information.

The clinical validity of the risk estimation depends strictly on the accuracy of the input data. Users are responsible for ensuring that all entered values match the patient’s source medical records (e.g., laboratory reports). To ensure patient safety and auditability, every generated report and archive entry explicitly documents the input values used for that specific calculation. Calculations based on data that deviates from the patient's actual medical status constitute a misuse of the device and invalidate the diagnostic support provided.

The use of the ACS Pathfinder is not allowed for:

- patients with suspected ST-elevation myocardial infarction on the electrocardiogram
- patients aged < 18 years und > 98 years
- hemodynamically instable patients
- patients with a heart rate < 34/min or > 184/min

3. ⚠ Cautions

The ACS Pathfinder always requires a permanent internet connection to communicate with the server-based backend.

Please ensure, that you are logged in to the web-application before using the ACS Pathfinder.

The user is advised that any wrong manually entered input variable may result in over- or underestimation of the MI probability. It is imperative to ensure that the data is entered correctly. Incorrect or false data will result in an incorrect calculation of the probability of an MI, with the aforementioned consequences.

4. Hardware Requirements

ACS Pathfinder is a web application accessible via internet browsers on desktop computers, tablets, and smartphones. The following technical requirements are necessary to use ACS Pathfinder:

Compatibility Disclaimer: The ACS Pathfinder has been validated with the browser and operating system versions listed below. Security updates and minor version patches within these major releases (e.g., Chrome 144.x) are supported and recommended. Users should ensure their systems remain up to date with security patches to maintain a secure operating environment. While the software is designed to be compatible with future major versions, ART-EMIS Hamburg GmbH cannot guarantee full functionality on versions not explicitly listed. ART-EMIS Hamburg GmbH has tested the operating systems listed below, but cannot guarantee full functionality for new versions that are not explicitly listed. We recommend verifying critical functions after major system updates.

Desktop Computer

- **Operating Systems:** Microsoft Windows 11 (64-bit), macOS 15 (Sequoia) or macOS 26 (Tahoe)
- **Browsers:** Google Chrome 144, Mozilla Firefox 147, Microsoft Edge 144, Apple Safari 26
- **Hardware:** Minimum 4GB RAM, Modern CPU (Intel Core i3 / AMD Ryzen 3 equivalent or better)
- **Screen Resolution:** Minimum 1280 x 720 pixels

Mobile Devices

- **iOS Devices:** iOS 26, Apple Safari (Version matching iOS 26), Devices must be capable of running iOS 26 (e.g., iPhone 11 or newer).
- **Android Devices:** Android 16, Google Chrome 144, Smartphones with at least 4GB of RAM
- **Screen Size:** Minimum 4.7 inches

Network Requirements

- ACS Pathfinder requires a permanent internet connection.
- Minimum connection speed: 1 Mbps (broadband or 3G mobile connection or better)
- The software may only be operated in secured networks.
- Appropriate security mechanisms must be installed on the computer systems (e.g., antivirus programs), and the hardware may only be operated within an operator's environment that complies with the currently valid IT guidelines and corresponds to the current state of the art. The operator is responsible for the security and integrity of the software and network infrastructure, such as end devices, network, identity/access management, and their configuration.
- The consequences of attacks on the network cannot be predicted.
- In case of a short network interruption, it is recommended to retry again after a few minutes.

- The operator must take appropriate measures to ensure that only authorized users can access the computers on which the software is used (e.g., by locking the computer).
- Analysis, evaluation, and if necessary, risk management measures by the user/operator are recommended. These must be updated any time changes are made to the network or data connections.

Important Notes

- Users must regularly update their device operating systems and browsers to maintain optimal security and performance.
- If older software is used, users may only be able to use the services to a limited extent or not at all. The minimum requirements are described above.
- ACS Pathfinder is optimized for the latest versions of supported browsers and operating systems.
- For best performance, use a wired Ethernet (LAN), Wi-Fi, 4G or 5G connection rather than 3G.

The ACS Pathfinder application adapts automatically to different screen sizes and orientations. No installation is required as the application runs entirely in your web browser.

5. Intended Purpose

The ACS Pathfinder estimates the probability of a myocardial infarction in patients with clinically suspected acute non-ST-elevation myocardial infarction. The ACS Pathfinder can be used as an aid in the diagnosis of non-ST-elevation myocardial infarction, and as an aid to identify patients who may qualify for outpatient management. The probability estimate must be evaluated and confirmed by the responsible healthcare professional in the context of the overall available clinical data and diagnostics performed, considering the applicable guidelines.

6. Indications for Use

The ACS Pathfinder may be used in patients with a clinical suspicion of an acute non-ST-elevation myocardial infarction.

7. Intended Users

The ACS Pathfinder is only intended to be used by qualified healthcare professionals (i.e. physicians, nurses, or emergency medical service staff), who underwent a product specific training.

The clinical decisions are made by the healthcare professionals (not by ACS Pathfinder) and are ultimately the responsibility of the professionals based on his or her knowledge and experience. These decisions should follow accepted evidence based clinical guidelines within the user's local practice environment and should always be based on a desire to meet the patient's needs and desires.

8. Operator responsibilities and obligations

- Ensure that the operating staff have read and understood the instructions for use.
- Familiarize yourself with the user settings of the software.
- Assume that the technical requirements described are met.
- Use the software for the intended purpose and as described only.
- The software must only be used by trained health-care personnel. Liability claims will be rendered void if the product is used by untrained personnel, and damage is incurred.
- The product must not be modified. If you make changes to the product that are not described in these instructions for use, you are considered the responsible manufacturer of the device according to national guidelines. Furthermore, this may result in a loss of possible warranty and guarantee claims.
- Please observe the statutory stipulations on accident prevention as well as occupational health and safety applicable in the corresponding country.

Ensure that all residual risks, including all foreseeable, adverse events or side effects in connection with the use of the medical device, are explained to the patient. Note the following: Contraindications, safety information, warnings, limitations.

9. Patient Population

Patients ≥ 18 years and < 98 years with clinically suspected non-ST-elevation myocardial infarction.

10.Intended Use Environment

The ACS Pathfinder can be used in any location, where patients with suspected non-ST-elevation MI can be evaluated. The requirements to diagnose or to rule-out MI include measurement of hs-cTn, documentation of an ECG, as well as assessment of clinical variables including the monitoring of vital parameters.

11. Contraindications

The use of the ACS Pathfinder is contraindicated in patients:

- with suspected ST-elevation myocardial infarction in the ECG
- aged < 18 years or > 98 years
- with a heart rate < 34/min or > 184/min
- with hemodynamic instability

12. Undesirable Side Effects

No side effects are known.

13.Input Data Requirements

The following table specifies the valid ranges and formats for all input variables:

Input Variable	Valid Range	Format	Handling of Invalid Values
Age	18–98 years	Integer	Values outside range are rejected; entry is blocked
Heart rate	34–184 bpm	Integer	Values outside range are rejected; entry is blocked
Troponin concentration (first measurement)	Any value above LOD*	Numeric	Values lower than the assay-specific LOD* set in the settings rejected
	For values below LOD*	Categorical	LOD* button for values below reporting limit
Troponin concentration (second measurement)	Any value above LOD*	Numeric	Values lower than the assay-specific LOD* set in the settings rejected
	For values below LOD*	Categorical	LOD* button for values below reporting limit
Time of blood sampling for troponin measurement	HH:MM (24-hour format)	Time	Invalid format rejected; second blood sample must be collected 30–210 min after first blood sample used for troponin measurement

Input Variable	Valid Range	Format	Handling of Invalid Values
Sex	Male / Female	Selection	Required field
Symptom onset ≥ 3 hours	Yes / No	Selection	Required field
Smoking status	Yes / No	Selection	Required field
Hyperlipidemia	Yes / No	Selection	Required field
Family history of CAD	Yes / No	Selection	Required field
Ischemic signs in ECG	Yes / No	Selection	Required field

***Limit of Detection (LOD):** The LOD varies by troponin assay. If your laboratory reports a value as "below LOD" or uses a "<" symbol, use the "Troponin value < x" button instead of entering a numeric value. Consult your laboratory for the exact LOD of your assay.

Missing Values: All input fields are required. The system will not calculate a probability if any required field is missing.

14. Data Protection

- The user and/or person responsible for IT must ensure compliance with national laws and regulations on data protection.
- Operators of IT systems and IT networks are responsible for establishing the necessary security standards, i.e., for creating the necessary technical and organizational framework conditions.
- Misuse is defined as instances in which protected personal data are collected, processed, or otherwise used without proper authorization.
- Violations of data protection (according to the EU General Data Protection Regulation) must be reported to the person responsible for company data security or the responsible supervisory authority.
- Suitable measures must be taken to ensure that only authorized users can access the computers on which the software is installed (e.g. by locking the computer). For this reason, the software must be operated in protected networks only. The operator is responsible for the security of the network.

Note the following definitions:

Personal data: All information regarding personal or factual circumstances of a particular or identifiable person. All data (e.g., name, age, gender, etc.) that can be directly assigned to a person (patient, employee, customer, supplier) must be protected.

Data processing: The storage, transfer (transmission to third parties outside of the organization), modification (including anonymization and pseudonymization), deletion, and blocking (marking to limit further processing or use) of data

Use: The use of data (e.g., transfer within the hospital, doctor's office, etc.)

Recipients: Persons or entities that receive data

Third parties: Persons or entities that are not part of the entity responsible (legal entity). The transmission of data to third parties is considered as data transfer.

Data Collection and Storage: The ACS Pathfinder collects users' email addresses and stores all patient-related data (demographic and clinical) in a pseudonymized manner. All data is stored and processed on a cloud server instance located in Germany, with encryption applied to data at rest to ensure security.

Data Access: Users can only access their own data and measurements. In institutional settings, all users within the institution can access the measurements of all institution members. System Administrators have access to all data, ensuring necessary oversight and support.

Data Transmission: All data transmitted between the frontend and backend systems is secured using HTTPS encryption, safeguarding data during transmission over the internet.

Data Privacy: The ACS Pathfinder complies with relevant data protection regulations, including GDPR. Patient data is pseudonymized to enhance privacy, and access controls are strictly enforced to ensure only authorized personnel can view or handle sensitive information.

Data Integrity: The accuracy and integrity of the data are continuously monitored by an automated external service, which tests the machine learning model's accuracy. This ensures that the ACS Pathfinder provides reliable and accurate diagnostic support.

Data Retention and Deletion: Users can request data deletion at any time. However, data will generally be retained to comply with legal requirements and to address any potential complaints. Secure deletion procedures ensure that data is irreversibly removed when requested.

Third-Party Services: All data storage, processing, and transmission are self-hosted on a server at Hetzner in Germany. No third-party services are used, ensuring complete control over data security and compliance with stringent data protection standards.

15. Algorithm and Model Description

The ACS Pathfinder uses a super-learner ensemble that combines multiple machine-learning models to estimate the probability of acute non-ST-elevation myocardial infarction. The ensemble includes:

- **Gradient boosting models** (LightGBM)
- **Regularized logistic regression** (Elastic Net)
- **Logistic regression with restricted cubic splines**
- **Multivariate adaptive regression splines** (MARS)

How it works: Each model independently estimates the individual acute non-ST-elevation myocardial infarction probability based on the input variables. The final prediction is a weighted average of all model outputs.

Single vs. Serial Measurements: The algorithm uses different model configurations depending on whether one or two troponin measurements are provided.

Calibration: The model output is calibrated to the local myocardial infarction prevalence setting. This ensures the predicted probabilities reflect the actual likelihood of myocardial infarction in the respective patient population.

System Versioning: The model is locked at a specific version for regulatory compliance. Updates are only released after validation and regulatory review. The current system version is displayed in the application footer.

Prediction Integrity Monitor (PIM): An automated monitoring system continuously validates that the prediction algorithm is functioning correctly. If anomalies are detected, the system displays a banner and temporarily disables new predictions until the issue is resolved. A new version will be issued afterwards.

Robustness against Attacks: The ACS Pathfinder is designed to be resilient against standard adversarial attacks. Unlike high-dimensional models (e.g., image recognition), the ensemble model structure (using tree-based algorithms and regression splines) creates discrete decision boundaries that are inherently robust against marginal noise or adversarial perturbations. Furthermore, strict input validation ensures that only physiologically plausible data is processed, maintaining model stability even in the presence of atypical inputs. The integrity of the model itself is secured by the PIM, which ensures the software has not been tampered with.

16. Training and Validation Data

The ACS Pathfinder model was developed and validated using the following datasets:

Dataset	Patients	Participating countries	Assays	MI Prevalence
Development cohort	2,575	Germany	hs-cTnT Gen 5, hs-cTnI (multiple)	11.7%
External validation cohorts	>25,000	Europe: Germany, Scotland, Sweden.	hs-cTnT Gen 5, hs-cTnI (multiple)	
		North America: Canada, United States of America.		4-17%
		Oceania: Australia, New Zealand.		
		Asia: Japan, Taiwan.		

Patient Population: Adults (≥18 years and < 98 years) presenting to emergency departments with symptoms suggestive of MI, without ST-elevation on ECG.

Representativeness: The validation cohorts included diverse patient populations across multiple centers and countries. Nevertheless, performance may vary in populations that differ significantly from these cohorts (e.g., different ethnic composition, healthcare settings).

Data Governance: Training and validation data were collected under appropriate ethical approvals and data protection agreements. Patient data used for model development was fully anonymized.

17. Performance Metrics and Benefits

The following performance metrics were obtained from clinical validation studies published previously *(Neumann JT, Twerenbold R, et al. Personalized diagnosis in suspected myocardial infarction. Clin Res Cardiol. 2023 Sep;112(9):1288-1301. doi: 10.1007/s00392-023-02206-3 and Toprak B, Solleder H, et al. Diagnostic accuracy of a machine learning algorithm using point-of-care high-sensitivity cardiac troponin I for rapid rule-out of myocardial infarction: Lancet Digit Health. 2024 Oct;6(10):e729-e738. doi: 10.1016/S2589-*

7500(24)00191-2). Overall, the use of ACS Pathfinder showed an excellent diagnostic accuracy and safety compared to the current standard of care, while substantially improving the proportion of patients eligible for rapid rule-out of MI.

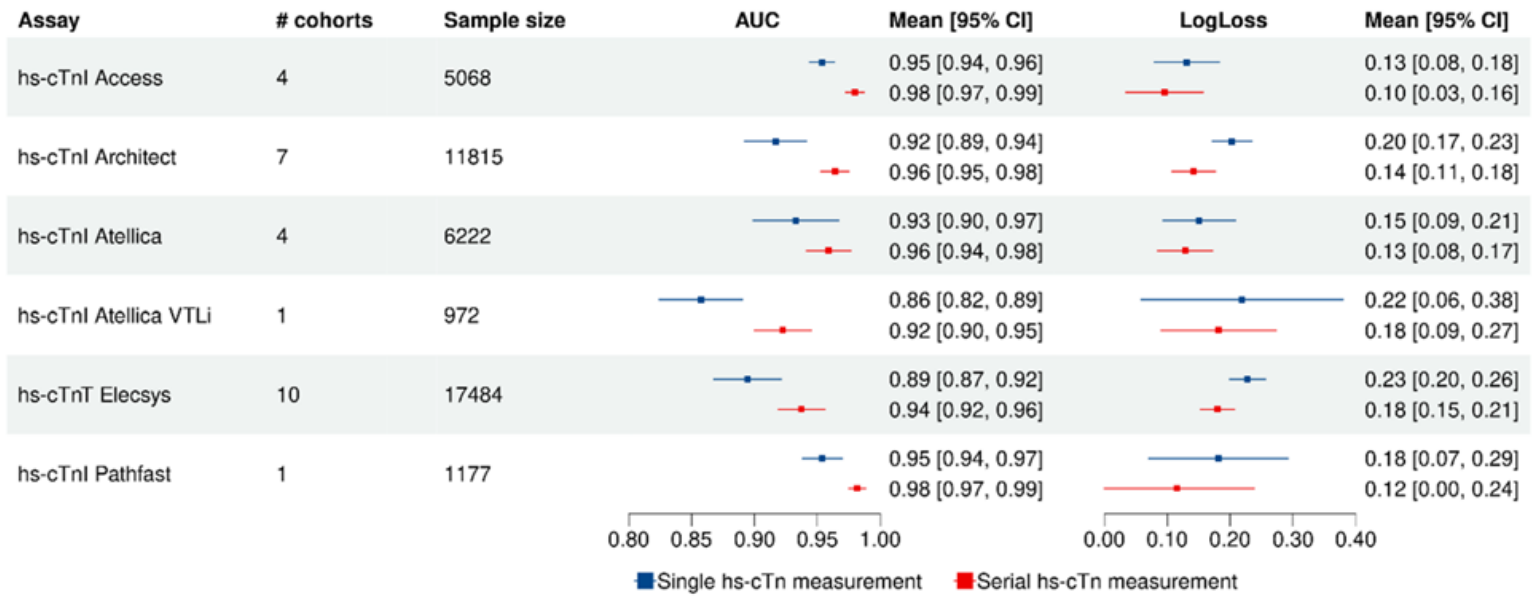


Figure from doi: 10.1007/s00392-023-02206-3

AUC is the area under the Receiver Operating Characteristic curve. An AUC of 0.5 equals random guessing while an AUC of 1.0 represents a perfect model. Higher AUC means better ability to distinguish between cases and non-cases. LogLoss measures the accuracy of predicted probabilities. The lower the LogLoss, the more accurate the predictions. These metrics were derived from multi-centre validation cohorts. Performance may vary in populations that differ significantly from the validation cohorts (see Factors Influencing Performance).

18. Factors Influencing Performance

The following factors may negatively affect the accuracy of predictions:

Factor	Impact	Mitigation
Incorrect troponin assay selection	Significant: may cause under- or over-estimation of MI probability	Verify assay selection with your laboratory; consult laboratory management if uncertain

Factor	Impact	Mitigation
Incorrect unit selection	Significant: may cause under- or over-estimation of MI probability	Double-check if unit selected matches your laboratory reports
Inaccurate MI prevalence setting	Moderate: affects calibration of predictions	Set prevalence based on your patient population; typical emergency department prevalence is 10–20%
Data entry errors	Variable: depends on which variable is affected	Double-check all entries before calculating; use LOD button when appropriate
Pre-analytical issues	Moderate: hemolysis, delayed sample processing	Follow standard laboratory procedures for troponin sampling
Connectivity loss during calculation	Calculation fails	Ensure stable internet connection; retry when connection restored

19. Residual Risks and Limitations

To identify potential risks associated with the software, a risk assessment has been carried out. The potential risks were assessed and minimized as much as possible, to ensure the safety and operability of the software. The following list of identified potential risks serves as an overview for the user:

Clinical Limitations:

- The ACS Pathfinder provides a probability estimate, not a diagnosis. Clinical judgment must always be applied by healthcare professionals.
- The model cannot detect conditions that mimic MI (e.g., myocarditis, pulmonary embolism) or distinguish Type 1 from Type 2 MI.

Technical Limitations:

- Requires continuous internet connectivity; offline use is not supported.
- Predictions depend on correct settings (assay, units, prevalence) defined and entered by the user; misconfiguration leads to inaccurate results.
- Temporary service unavailability may occur during maintenance or if the monitoring system detects anomalies.

Foreseeable Misuse:

- Using predictions as the sole basis for diagnosis or discharge decisions without considering the clinical presentation and other diagnostic tools (e.g. ECG).
- Applying the tool to patient populations outside the intended use (e.g., STEMI patients, pediatric patients).
- Ignoring contraindications or system warnings.

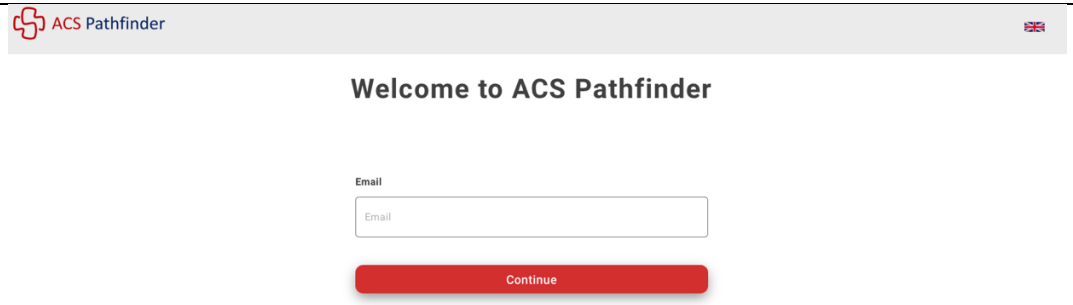
Mitigation:

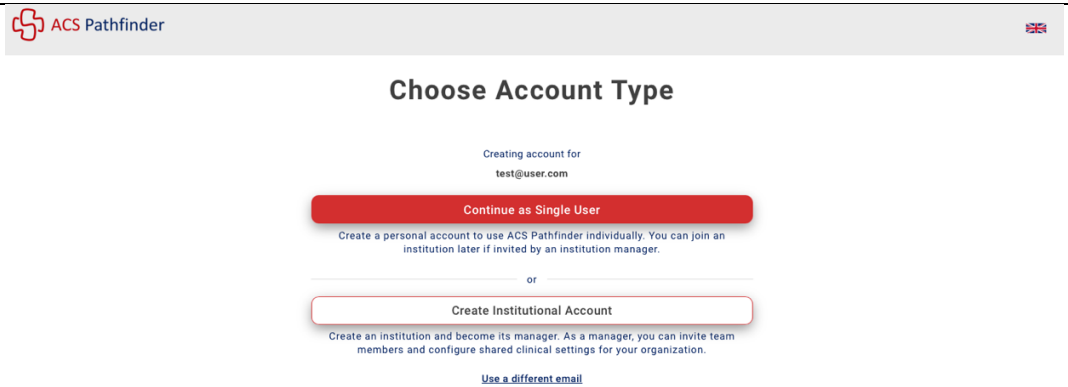
Always integrate ACS Pathfinder results with clinical assessment, ECG findings, and other diagnostic information. The tool is an aid, not a replacement for clinical judgment.

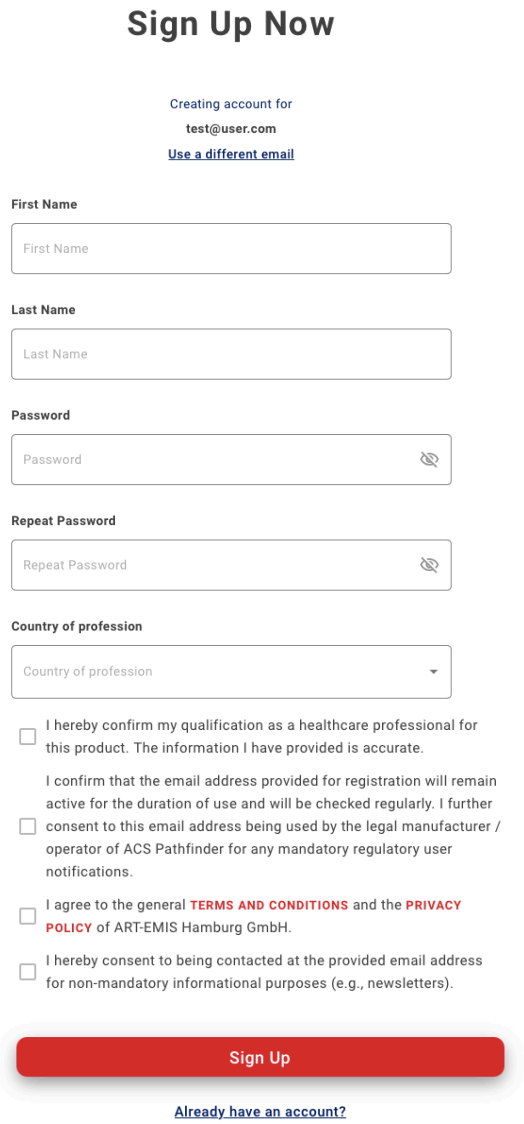
20. How to use the ACS Pathfinder

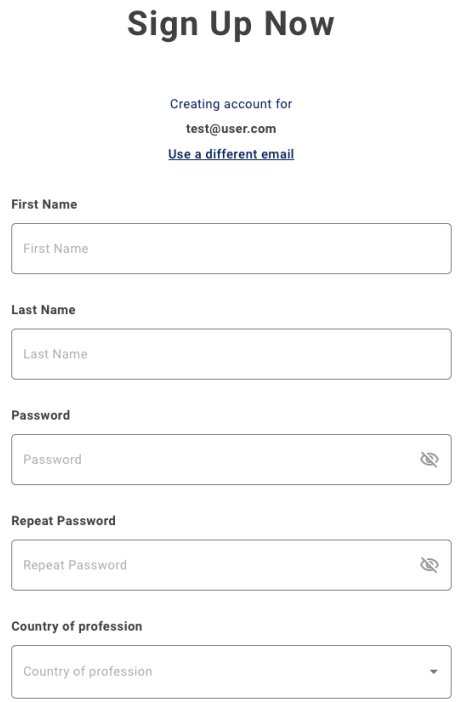
The following steps describe the registration, tutorial, and clinical application of the ACS Pathfinder. Reading the instructions for use and completing the tutorial are required to qualify for using the ACS Pathfinder.

20.1. Registration

Step	Print screen	Details
1. Login-screen		Please enter the following address to your web browser to access the product: app.acs-pathfinder.com On the start screen you are required to provide your email address and click on “continue”.

2. Choose Account Type		At the first login, the product will recognize you as a new user and will give two options – either registration as a “single user” or “create an institutional account”. **Note:** A single user account permits the creation of an individual, personal profile, whereas an institutional account is intended to support concurrent, collaborative use of ACS Pathfinder by providing a unified dashboard accessible to multiple users within the same institution. The first person to register an institutional account automatically becomes the institutional manager for ACS Pathfinder. The associated functions are described under section 20.5.

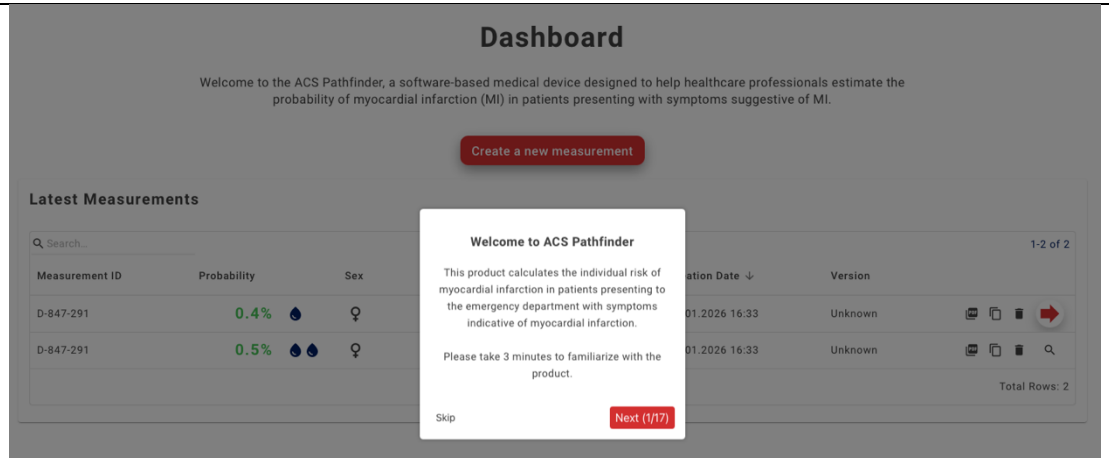
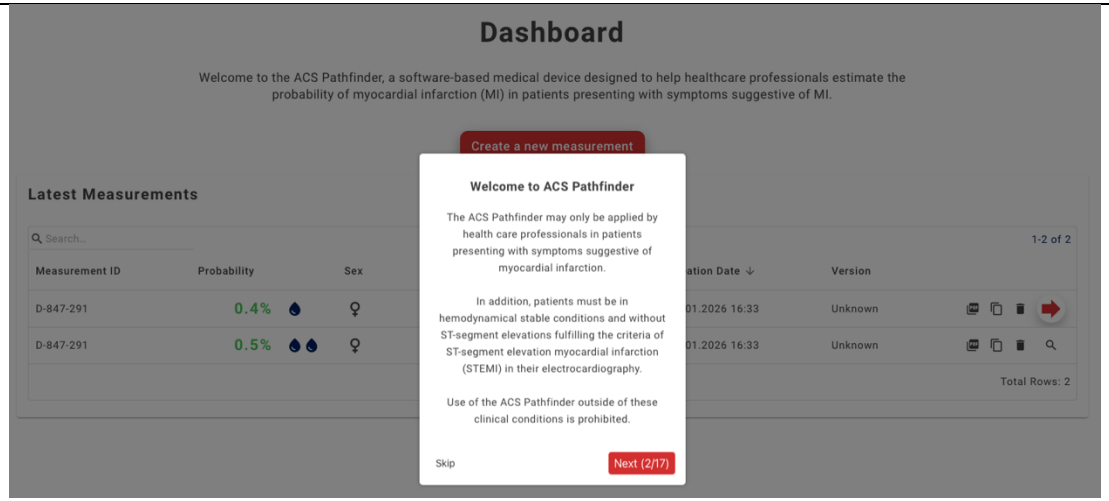
3. Register as single user		To register as a single user, provide the required information and press “sign up”. You will receive an email to activate your account.

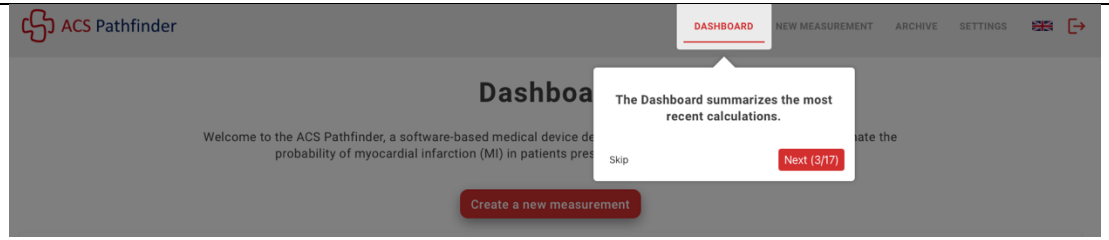
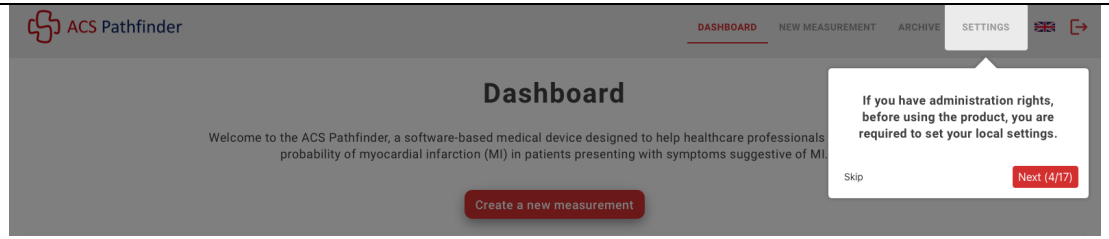
4. Register as institution		To register as an institution please provide the required information and press “sign up”. You will receive an email to activate your account.

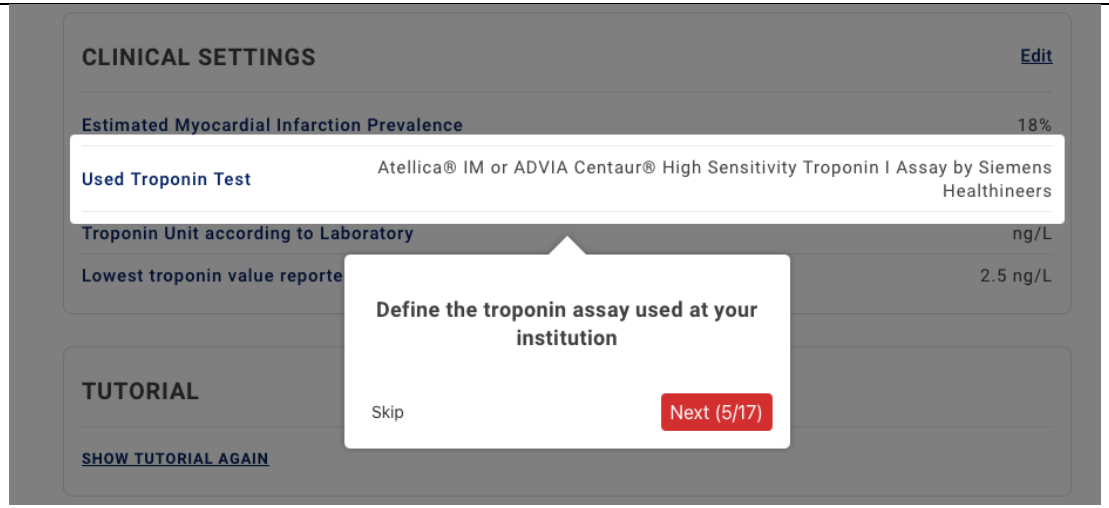
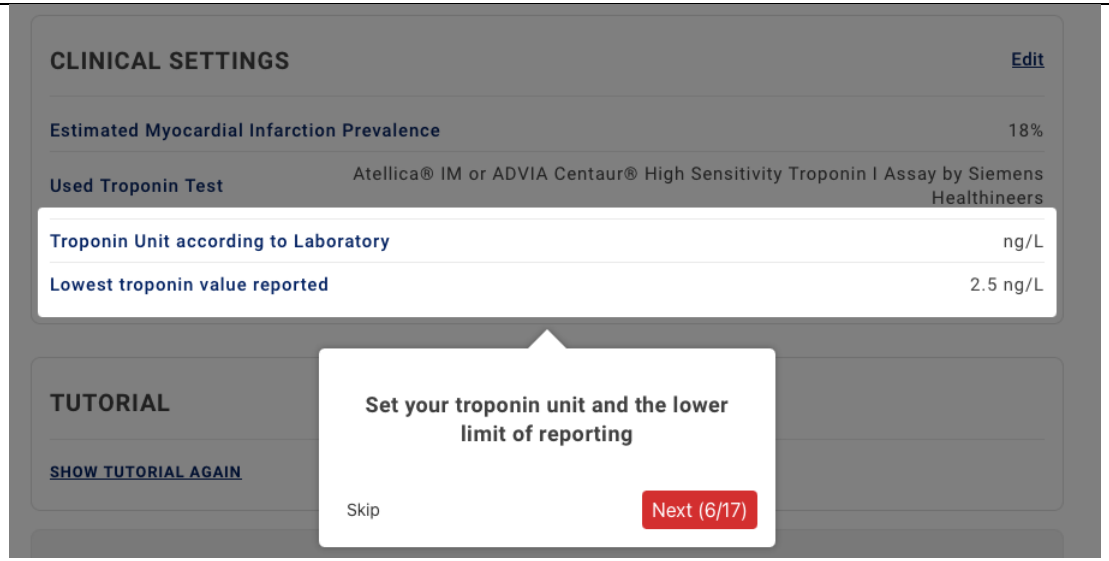
	☐ I hereby confirm my qualification as a healthcare professional for this product. The information I have provided is accurate. ☐ I confirm that the email address provided for registration will remain active for the duration of use and will be checked regularly. I further consent to this email address being used by the legal manufacturer / operator of ACS Pathfinder for any mandatory regulatory user notifications. ☐ I agree to the general **TERMS AND CONDITIONS** and the **PRIVACY POLICY** of ART-EMIS Hamburg GmbH. ☐ I hereby consent to being contacted at the provided email address for non-mandatory informational purposes (e.g., newsletters). As an institution manager, you can invite team members and configure shared clinical settings. **Institution Name** Institution Name **Type** ○ Hospital ○ Medical Office ○ Emergency Service The following fields are optional.	

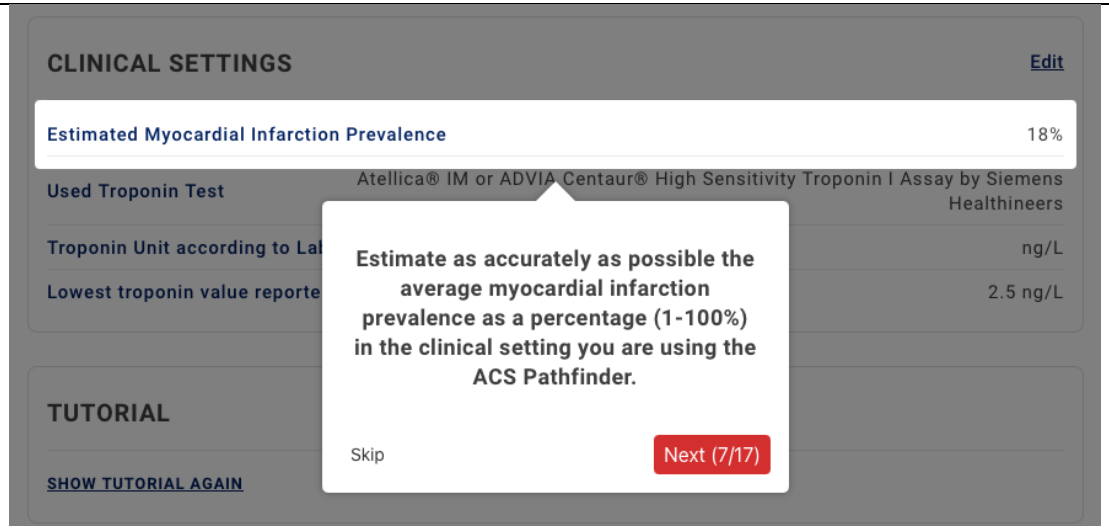
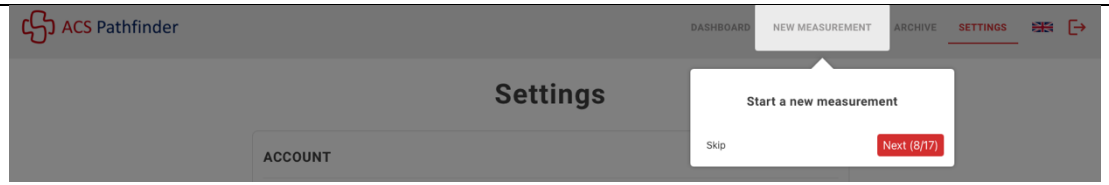
	Street House Number Street House Number Postal Code City Postal Code City Institution Contact Email Institution Contact Email Institution Contact Phone Institution Contact Phone Tax ID Tax ID Sign Up Already have an account?	

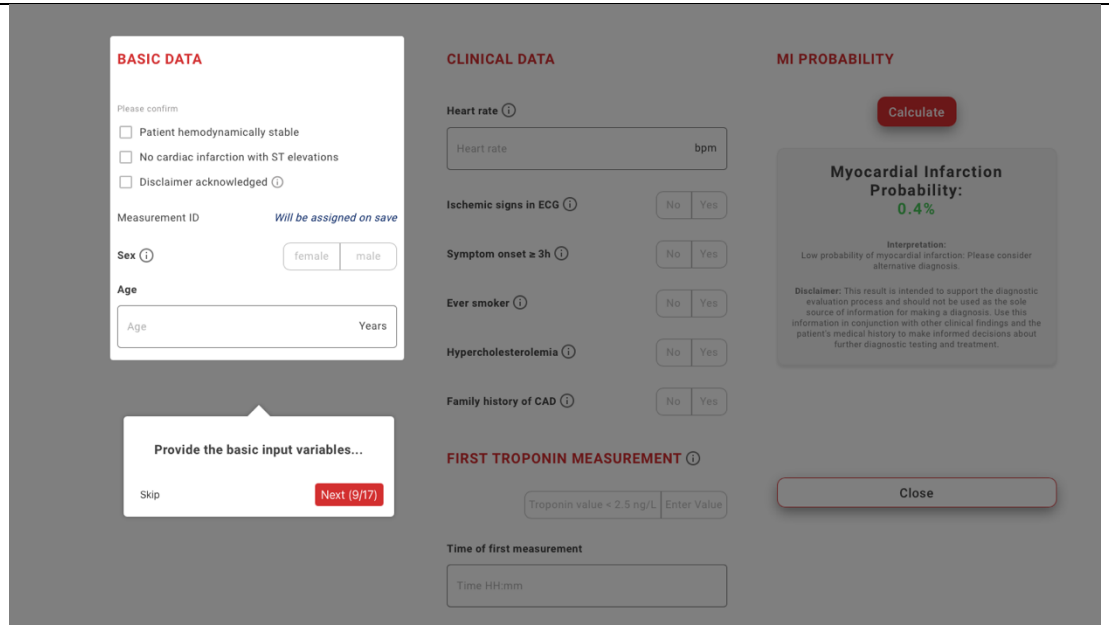
20.2. Tutorial

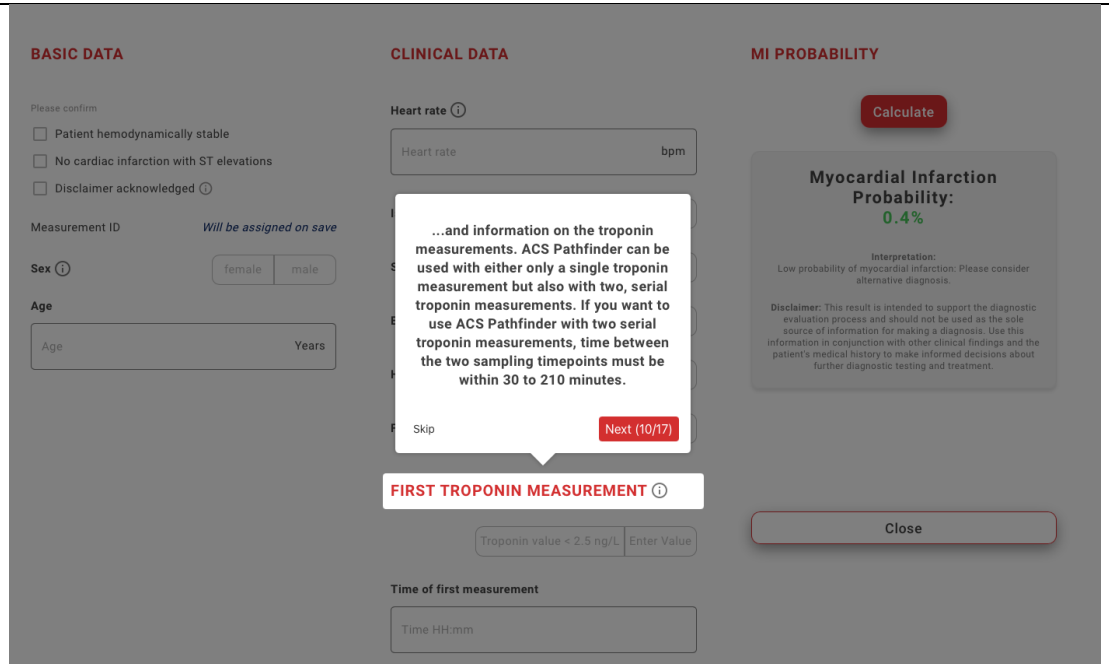
Step	Print screen	Details
1. Tutorial start		This tutorial represents an important training on the indication and actual use of the ACS Pathfinder and is a prerequisite to use the product. After the first login you are required to complete the tutorial to familiarize yourself with the ACS Pathfinder.
2. Indication		Familiarize yourself with the indication and restrictions of using the ACS Pathfinder.

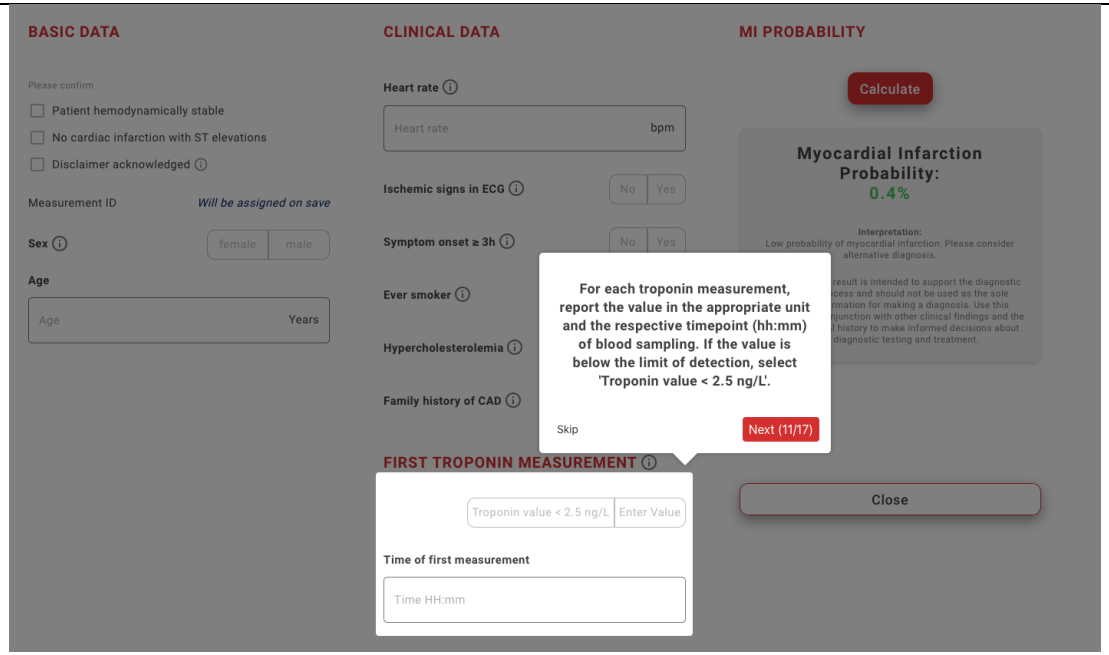
3. Dashboard		The dashboard provides an overview on the most recent calculations and your settings.
4. Settings		Before the first use, you are required to set the local settings. For more detailed information, please consult the chapter on “Settings” below in this document.

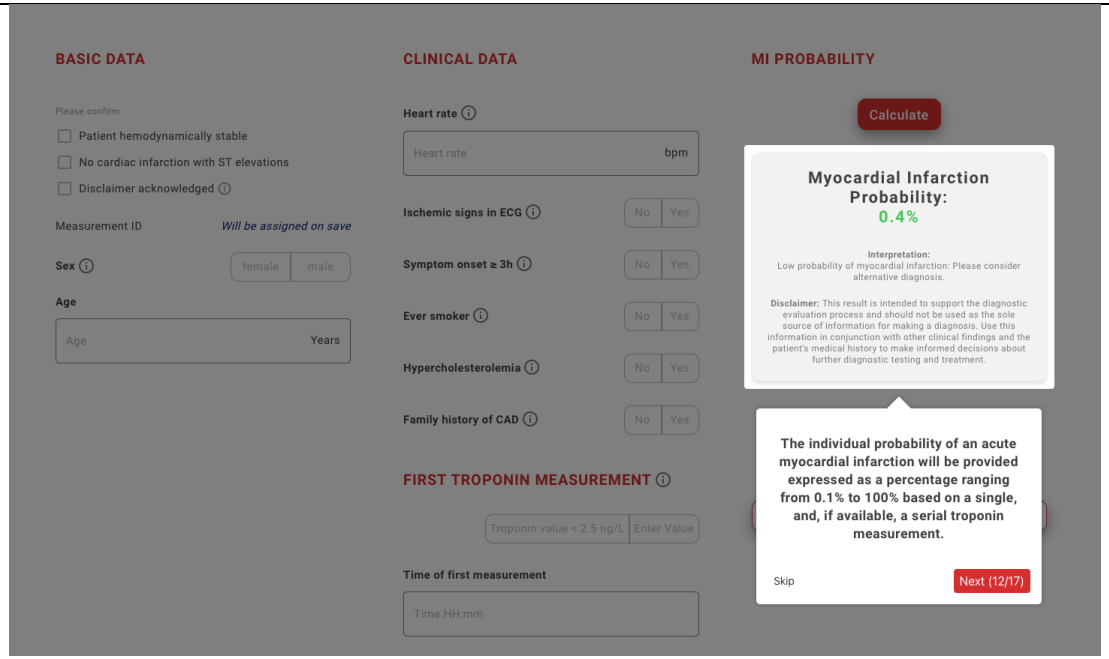
5. Settings Assay		Choose the troponin assay which is locally used. The correct selection of the troponin assay is crucial for accurate calculation of MI probability. If you are unsure which specific troponin assay you are using, please consult your laboratory management. In case your local assay is not precisely displayed in this list, you cannot use the ACS Pathfinder.
6. Settings Unit		Select the unit, in which your laboratory reports the troponin concentrations and provide the information on the lowest troponin concentration, which is reported by the laboratory (limit of reporting).

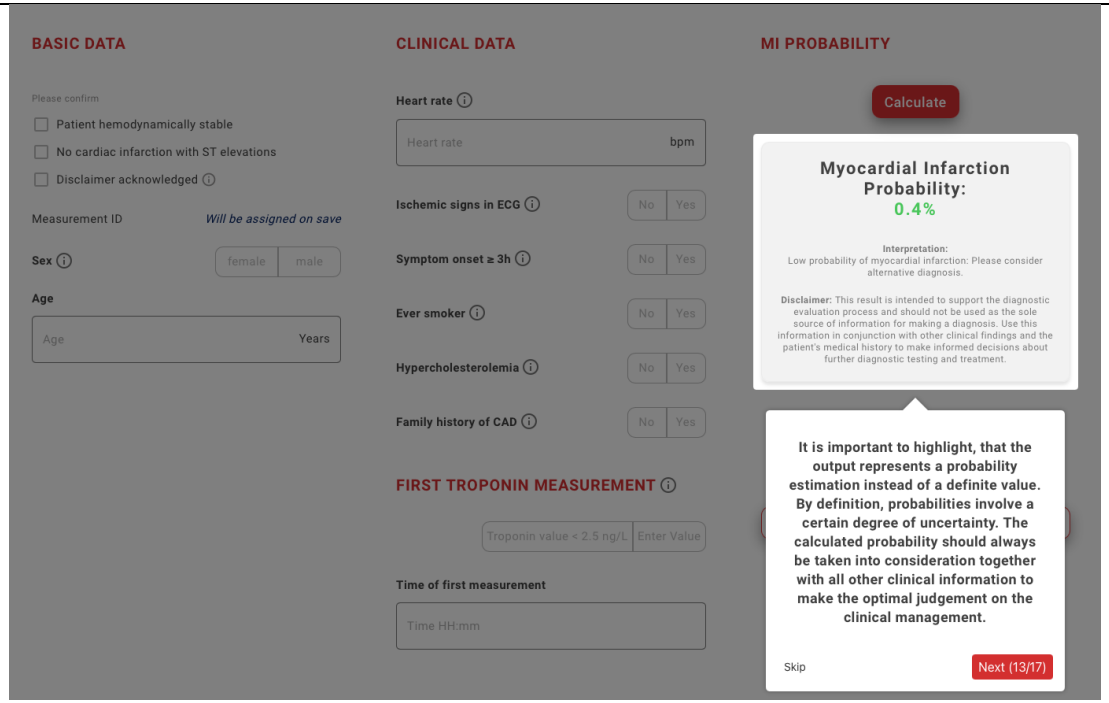
7. Settings MI prevalence		Indicate the estimated prevalence of myocardial infarction in the population to which you will apply the ACS Pathfinder. The prevalence must be a percentage, ranging from 1.0% to 100%. In the example, the prevalence of MI among all patients presenting with symptoms indicative of MI is 18%. This information is used to calibrate the risk estimation.
8. New Measurement		Here you can start a new measurement.

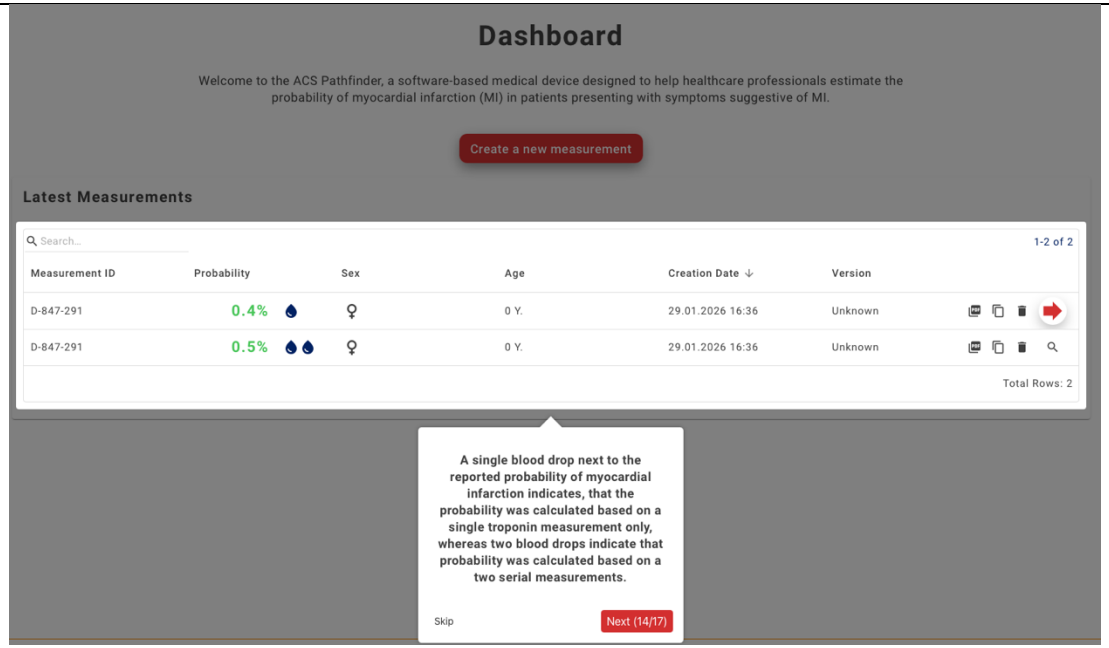
9. Data entry		Please confirm the inclusion criteria, acknowledge the disclaimer, and provide information on all requested basic and clinical data. The measurement ID will automatically be assigned.

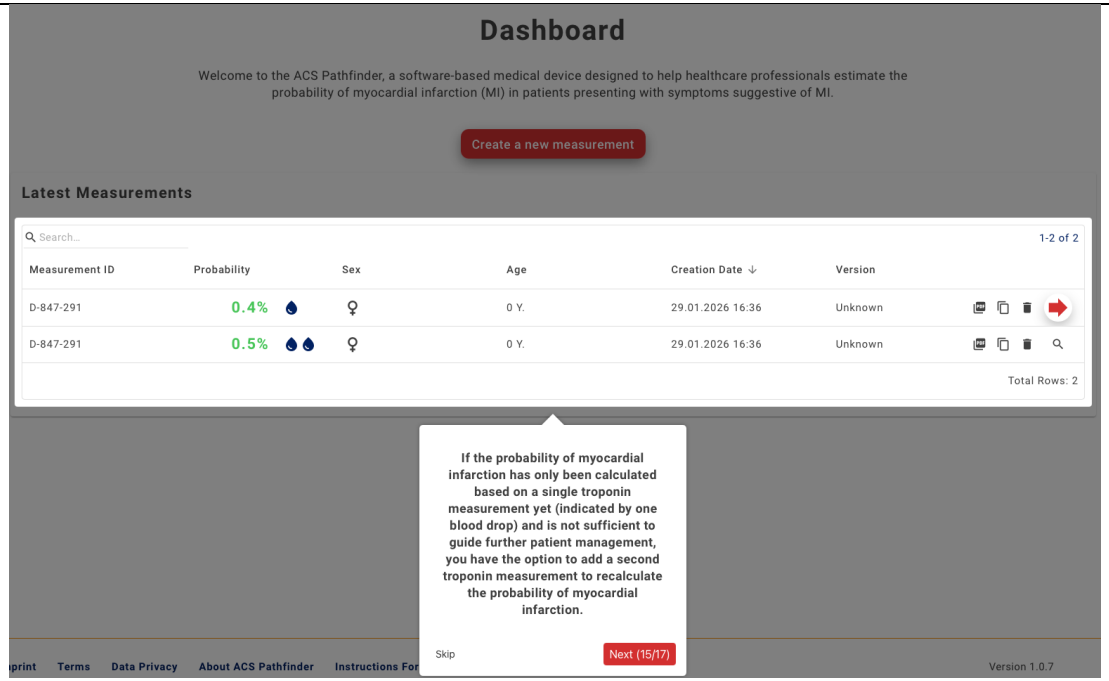
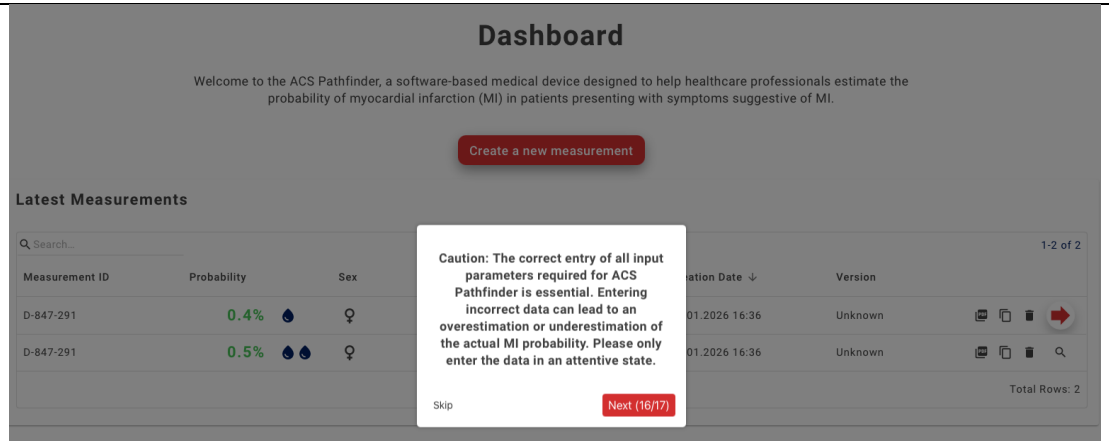
10. Data entry		Add the information on the troponin measurement including the concentrations and the time of blood sampling (hh:mm, in a 24h format).

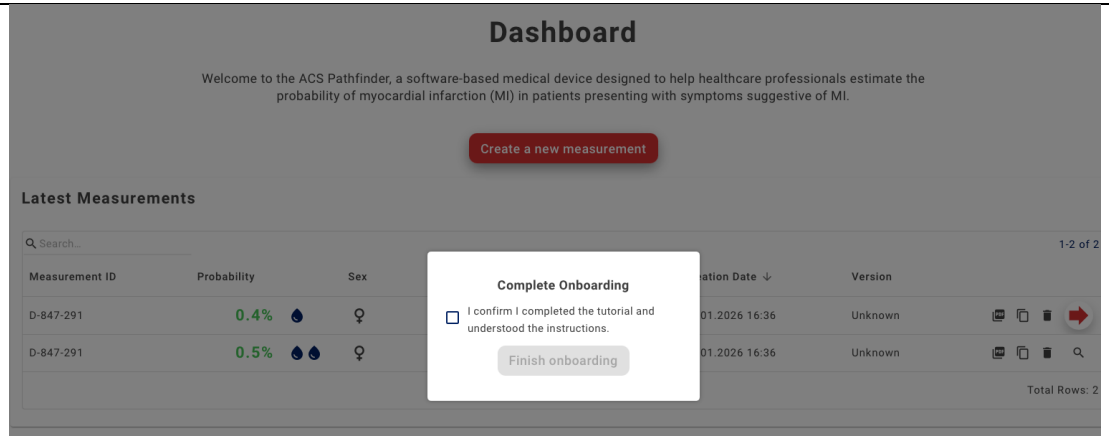
11. Data entry		For all measurable troponin concentrations, please exactly enter the respective concentration as a numerical value. Alternatively, if the troponin concentration is below the limit of reporting, please click on the respective button. Please also enter the time of blood sampling for the respective troponin concentration (HH:MM, in 24h format).

12. Results		After completing the data entry and pushing the “Calculate” button, the individual probability of having acute myocardial infarction will be provided as a probability ranging from 0.1 to 100%. The probability estimation will be accompanied by a disclaimer.

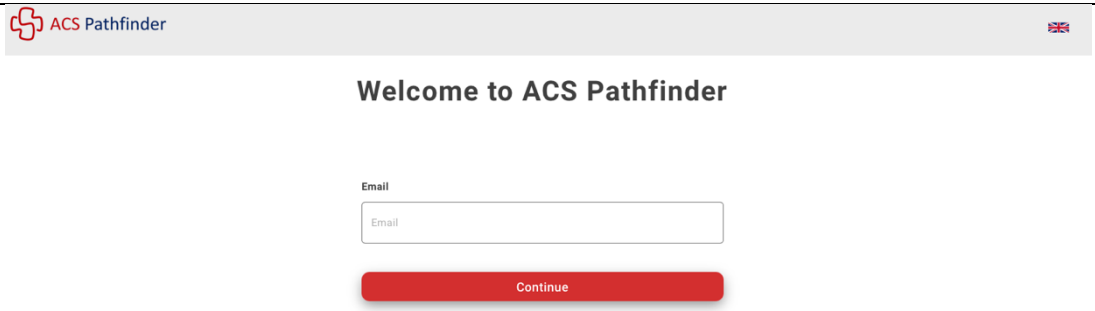
13.		It is important to highlight, that the output represents a probability estimation instead of a definite value. This probability should then be taken into consideration together with all other clinical information to make the judgement on the clinical management.

14.		In the dashboard or the archive, you see your most recent calculations. One blood drop indicates that the calculation was based on a single troponin measurement, while two blood drops indicate that the calculation was based on two troponin measurements.

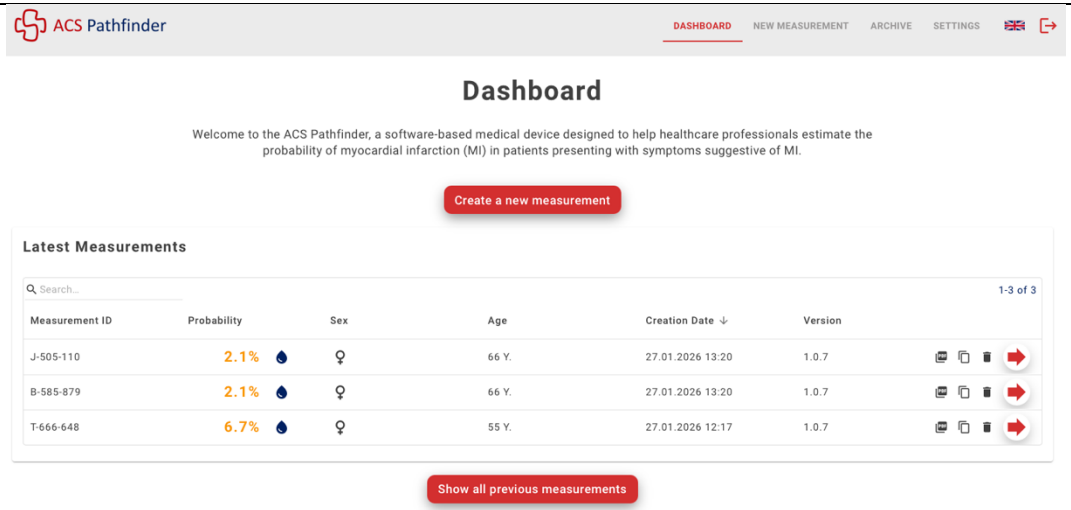
15.		In cases with one blood drop you can use the red arrow to add a second troponin measurement and recalculate the MI probability using also the information obtained from the second troponin measurement.
16.		Caution: The correct entry of al input parameters required for ACS Pathfinder is essential. Entering incorrect data can lead to an overestimation or underestimation of the actual Mi probability. Please only enter the data in an attentive state.

17.		Finally, the user is required to confirm that he fully understood the training content and the intended use of ACS Pathfinder. Without this confirmation, use of the device is not possible.

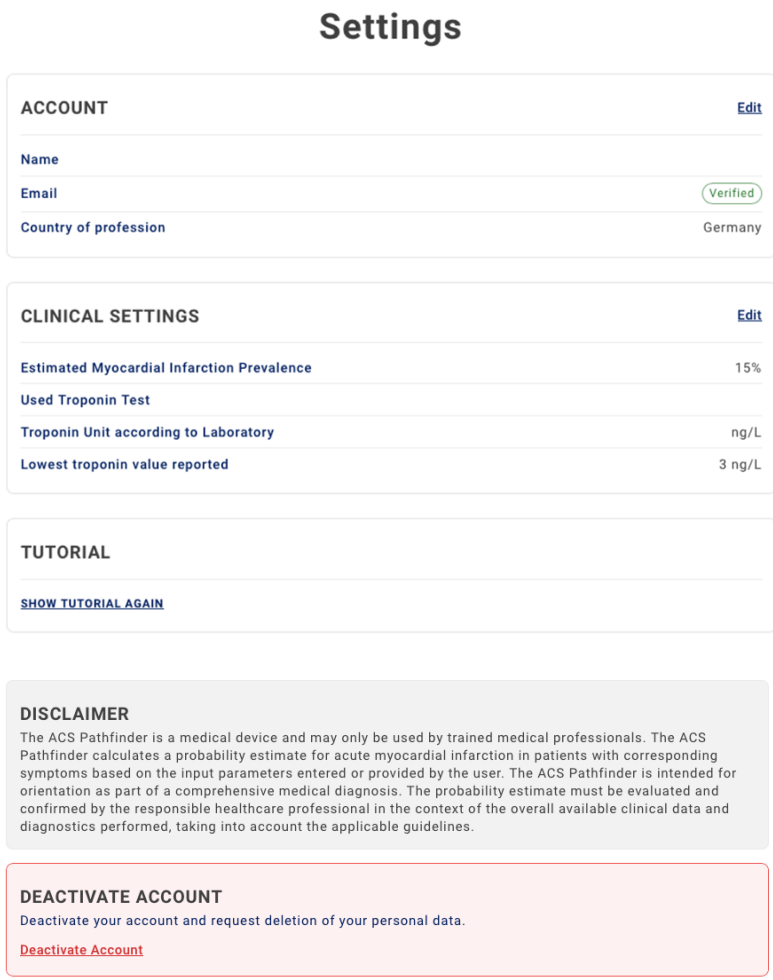
20.3. Login

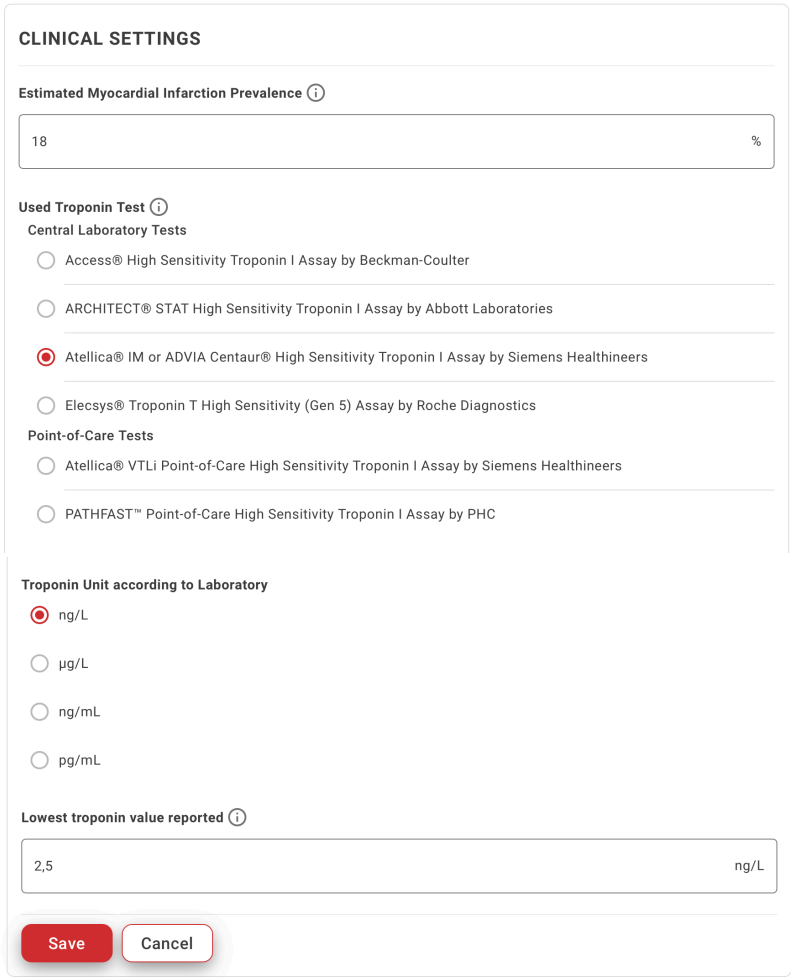
Step	Print screen	Details
1. Login-screen		Please enter the following address to your web browser to access the product: app.acs-pathfinder.com Please provide your login details to access the ACS Pathfinder.

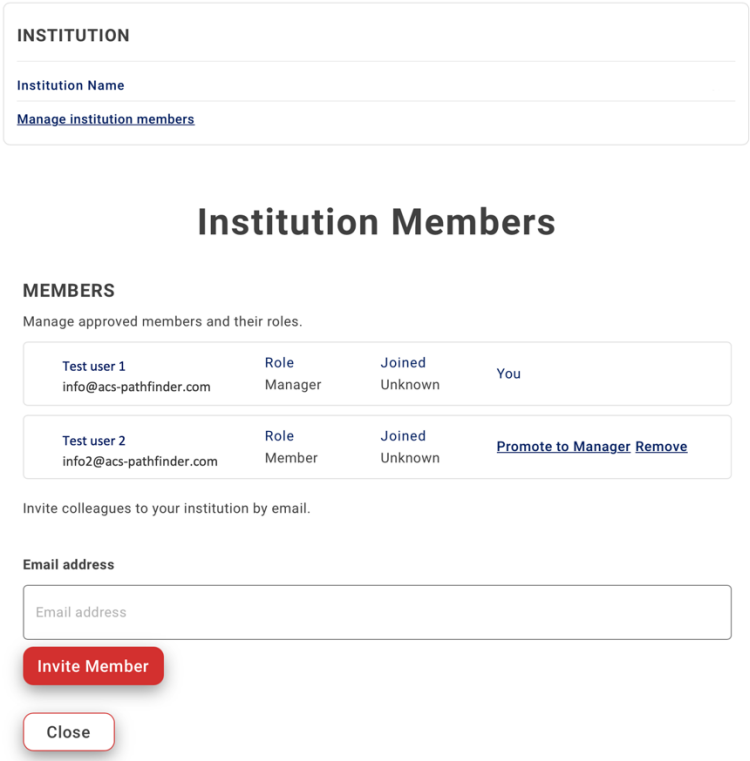
20.4. Dashboard

Step	Print screen	Details
1. Dashboard		The dashboard provides an overview on the most recent calculations and your settings. You can use the menu bar on the top to navigate to “New measurement”, “Archive”, “Settings”, select your language and log-out.

20.5. Settings

Step	Print screen	Details
1. Settings		In the settings you can modify your account information (name and password), and you are required to provide four different information (see 20.5.2 for details): 1. Provide the estimated prevalence of myocardial. 2. Choose the troponin assay which you use locally in your institution. 3. Select the unit, in which your laboratory reports the troponin concentrations. 4. Provide the information on the lowest troponin concentration, which is reported by the laboratory (limit of reporting). The Settings must be done before the initial use and in case of changes, e.g. used troponin tests. You can also use this page to re-visit the tutorial and deactivate your account.

2. Clinical Settings		1. Provide the estimated prevalence of myocardial infarction in the population, in which you will use the ACS Pathfinder. This information is used to calibrate the risk estimation. 2. Choose the troponin assay which you use locally in your institution. The correct selection of the troponin assay is crucial for accurate calculation of MI probability. If you are unsure which specific troponin assay you are using, please consult your laboratory management. In case your local assay is not displayed in this list, you cannot use the ACS Pathfinder. 3. Select the unit, in which your laboratory reports the troponin concentrations. 4. Provide the information on the lowest troponin concentration, which is reported by the laboratory (limit of reporting).

3. Institutional management		Here you can click on “Manage institution members” to open the management section. Now, you can invite new members to the institution, you can remove individuals and promote them to the manager function.

20.6. New measurement

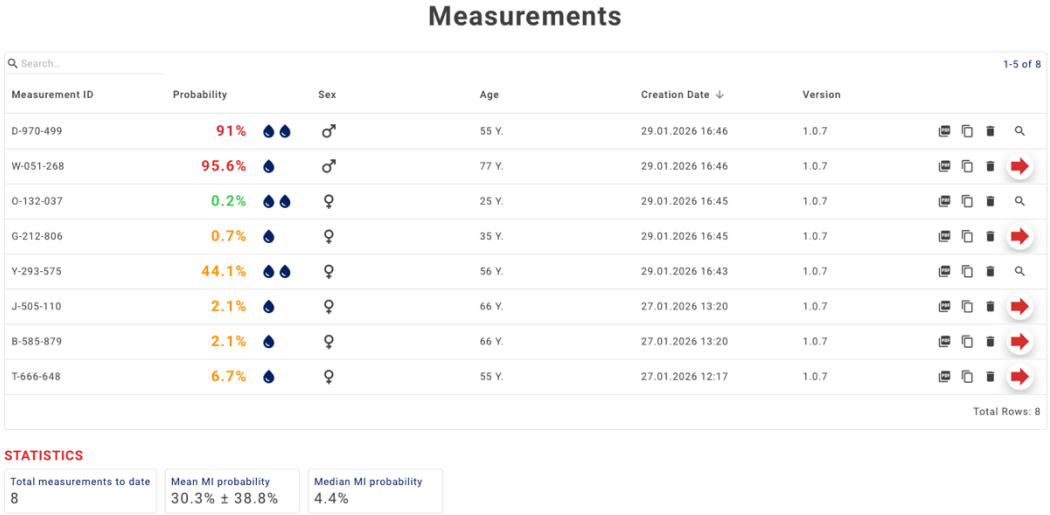
Step	Print screen	Details
1. Data entry	BASIC DATA Please confirm ☐ Patient hemodynamically stable ☐ No cardiac infarction with ST elevations ☐ Disclaimer acknowledged Measurement ID *Will be assigned on save* Sex: female / male Age: Age Years CLINICAL DATA Heart rate: Heart rate bpm Ischemic signs in ECG: No / Yes Symptom onset ≥ 3h: No / Yes Ever smoker: No / Yes Hypercholesterolemia: No / Yes Family history of CAD: No / Yes FIRST TROPONIN MEASUREMENT Troponin value < 3 ng/L / Enter Value Time of first measurement: Time HH:mm MI PROBABILITY Calculate Please enter the missing values and click on calculate Close	To start a new measurement first confirm that the patient is hemodynamically stable, does not have ST-elevation myocardial infarction and acknowledge the disclaimer. Next provide all basic and clinical information required. Add the information on the troponin measurement, which includes the troponin concentration and the time of blood sampling. To report the troponin concentration, you have two options depending on the measured concentration: • For concentrations below your institutional limit of reporting, click on the “Troponin value < x” button, whereas “x” corresponds to your institutional limit of reporting and unit. • For concentrations above the limit of reporting, please provide the actual measured, numerical value in the respective text field. After completing the data entry, push the “Calculate” button for MI-probability.

2. Results using a single troponin measurement	**BASIC DATA** Date 29.01.2026 16:43 Measurement ID Y-293-575 Sex female ♀ Age 56 Years **BASIC SETTINGS** Used Troponin Test PATHFAST™ Point-of-Care High Sensitivity Troponin I Assay by PHC Estimated Myocardial Infarction Prevalence 15% Lowest troponin value reported 3 ng/L **CLINICAL DATA** Heart rate 55 bpm Ischemic signs in ECG No **Yes** Symptom onset ≥ 3h No **Yes** Ever smoker **No** Yes Hypercholesterolemia No **Yes** Family history of CAD **No** Yes **FIRST TROPONIN MEASUREMENT** Value 44 ng/L Time of first measurement 13:05 **MI PROBABILITY** Continue with second measurement Myocardial Infarction Probability: 30.3% Interpretation: Intermediate probability of myocardial infarction: Consider further diagnostic evaluation. Disclaimer: This result is intended to support the diagnostic evaluation process and should not be used as the sole source of information for making a diagnosis. Use this information in conjunction with other clinical findings and the patient's medical history to make informed decisions about further diagnostic testing and treatment. Copy to clipboard Export as PDF Close	In this screen the individual probability of having an acute myocardial infarction is provided as a percentage ranging from 0.1% to 99% together with a disclaimer based on a single troponin measurement. Please note, the ACS Pathfinder calculates the individual probability of type 1 (caused by coronary artery stenosis) and type 2 (caused by myocardial oxygen demand–supply mismatch) myocardial infarction.
3. Adding a second troponin measurement.	**BASIC DATA** Date 29.01.2026 16:43 Measurement ID Y-293-575 Sex female ♀ Age 56 Years **BASIC SETTINGS** Used Troponin Test PATHFAST™ Point-of-Care High Sensitivity Troponin I Assay by PHC Estimated Myocardial Infarction Prevalence 15% Lowest troponin value reported 3 ng/L **CLINICAL DATA** Heart rate 55 bpm Ischemic signs in ECG No **Yes** Symptom onset ≥ 3h No **Yes** Ever smoker **No** Yes Hypercholesterolemia No **Yes** Family history of CAD **No** Yes **FIRST TROPONIN MEASUREMENT** Value 44 ng/L Time of first measurement 13:05 **SECOND TROPONIN MEASUREMENT** Troponin value < 3 ng/L | Enter Value Time of second measurement Time HH:mm **MI PROBABILITY** Calculate Myocardial Infarction Probability: 30.3% Interpretation: Intermediate probability of myocardial infarction: Consider further diagnostic evaluation. Disclaimer: This result is intended to support the diagnostic evaluation process and should not be used as the sole source of information for making a diagnosis. Use this information in conjunction with other clinical findings and the patient's medical history to make informed decisions about further diagnostic testing and treatment. Copy to clipboard Export as PDF Close	Next, if desired by the treating physician and/or if the probability of myocardial infarction based on a single troponin measurement is not sufficient to make a clinical management decision, you can add the information of a second troponin measurement and sampling timepoint (HH:MM) by clicking on the “Continue with second measurement” button. The second sampling timepoint must be between 30 and 210 minutes after the first blood sampling timepoint. After completing the data entry, push the “Calculate” button again.

4. Results using two troponin measurements.	**BASIC DATA** Date 29.01.2026 16:43 Measurement ID Y-293-575 Sex female ♀ Age 56 Years **BASIC SETTINGS** Used Troponin Test PATHFAST™ Point-of-Care High Sensitivity Troponin I Assay by PHC Estimated Myocardial Infarction Prevalence 15% Lowest troponin value reported 3 ng/L **CLINICAL DATA** Heart rate 55 bpm Ischemic signs in ECG No **Yes** Symptom onset ≥ 3h No **Yes** Ever smoker **No** Yes Hypercholesterolemia No **Yes** Family history of CAD **No** Yes **FIRST TROPONIN MEASUREMENT** Value 44 ng/L Time of first measurement 13:05 **SECOND TROPONIN MEASUREMENT** Value 77 ng/L Time of second measurement 15:55 **MI PROBABILITY** Myocardial Infarction Probability: 44.1% Interpretation: Intermediate probability of myocardial infarction: Consider further diagnostic evaluation. Disclaimer: This result is intended to support the diagnostic evaluation process and should not be used as the sole source of information for making a diagnosis. Use this information in conjunction with other clinical findings and the patient's medical history to make informed decisions about further diagnostic testing and treatment. Copy to clipboard Export as PDF Close	Now the individual probability of having an acute myocardial infarction is provided as a percentage ranging from 0.1% to 99% based on two troponin measurements together with a disclaimer.
5. Low MI probability	**MI PROBABILITY** Myocardial Infarction Probability: 0.2% Interpretation: Low probability of myocardial infarction: Please consider alternative diagnosis. Disclaimer: This result is intended to support the diagnostic evaluation process and should not be used as the sole source of information for making a diagnosis. Use this information in conjunction with other clinical findings and the patient's medical history to make informed decisions about further diagnostic testing and treatment.	Any myocardial infarction probability below 0.5% (single troponin measurement) or 1.0% (two troponin measurements) will be considered as low probability of having an acute myocardial infarction.

6. Intermediate MI probability	**MI PROBABILITY** **Myocardial Infarction Probability:** **44.1%** **Interpretation:** Intermediate probability of myocardial infarction: Consider further diagnostic evaluation. **Disclaimer:** This result is intended to support the diagnostic evaluation process and should not be used as the sole source of information for making a diagnosis. Use this information in conjunction with other clinical findings and the patient's medical history to make informed decisions about further diagnostic testing and treatment.	Any myocardial infarction probability between 0.5% and 50% (single troponin measurement) or 1.0% and 50% (two troponin measurements) will be considered as intermediate probability of having acute myocardial infarction.
7. High MI probability	**MI PROBABILITY** **Myocardial Infarction Probability:** **91%** **Interpretation:** High probability of myocardial infarction: Please refer to a cardiologist. **Disclaimer:** This result is intended to support the diagnostic evaluation process and should not be used as the sole source of information for making a diagnosis. Use this information in conjunction with other clinical findings and the patient's medical history to make informed decisions about further diagnostic testing and treatment.	Any myocardial infarction probability above 50% will be considered as high probability of having acute myocardial infarction.

20.7. Archive

Step	Print screen	Details
1. Archive		In the archive you see all your measurements. For each measurement you have the options to a) create a PDF file of the measurement including all input parameters used for the calculation to ensure traceability(while clicking on the symbol) b) copy all details of the measurement into the cache while clicking on the symbol, c) delete the measurement while clicking on the symbol, d) view the measurement (magnifier) or continue with a second measurement (red arrow) . Furthermore, you can reorder the measurements by measurement ID, probability, sex, age, creation date, or version number. Finally, you can use the search field to search the list of measurement by the case ID. At the bottom you see statistics of your current measurements.

21.Accessing the UDI and IFU

Step	Print screen	Details
1. About ACS Pathfinder	**Imprint** **Terms** **Data Privacy** **About ACS Pathfinder** **Instructions For Use** **Product Label**	At the lower end of the website, besides “Imprint”, “Terms” and “Data Privacy”, you can find a link named “About ACS Pathfinder”, “Instructions for use” and “Product label”. “Imprint”: Displays legally responsible for the site, provide contact and company details, and ensure transparency and legal accountability for users.

		"Data Privacy": Displays information on how personal data is collected, used, shared, and protected. "Instructions for use": While clicking on this, the instruction for use will be displayed. "Product Label": While clicking on this, the regulatory required labeling will be displayed.

22.Troubleshooting

Contact ART-EMIS Hamburg GmbH service via info@acs-pathfinder.com, if error messages appear that cannot be solved with the following information.

Error Handling and System Availability:

Situation	System Behavior	User Action
Connectivity loss	Error message displayed; calculation not completed	Check internet connection and retry
Server unavailable	Maintenance banner displayed	Wait for service restoration; do not rely on cached data
Prediction integrity alert	Maintenance banner; new predictions disabled	Use clinical judgment without tool support until service restored
Invalid input	Field-specific error message	Correct the input and retry

23.Reporting

If there is a serious incident in connection with this medical device, which affects the user / operator or another person, the user / operator (or responsible person) must report this serious incident to the manufacturer of the medical device. In the European Union, the user / operator must also report this serious incident to the competent authority in the respective country. In all other countries, the respective country-specific requirements must be followed.

Please contact the manufacturer via: info@acs-pathfinder.com in case of a suspected incident.

24. Software Updates and Maintenance

Automatic Updates: The ACS Pathfinder is a web application; updates are deployed centrally and automatically available when you access the application. No installation or manual update action is required.

Version Information: The current software version is displayed in the application footer. After updates, verify the version number matches any communicated release notes.

Scheduled Maintenance: Planned maintenance windows are announced in advance via email and in-app notifications. During maintenance, a banner is displayed and new predictions may be temporarily unavailable.

Audit Log Access: Measurement history is available in the Archive section.

Service life, maintenance and version support (SaaS): The expected service life for the ACS Pathfinder is four years starting on the date of first activation for clinical use (go-live) at the customer site, if no new version is released. During this period, the manufacturer provides maintenance for the Current Production Release only, including corrective, preventive, and cybersecurity updates necessary to maintain safety and performance. Updates are deployed centrally by the manufacturer as part of the SaaS operation; users do not install updates locally, and earlier releases are retired and not accessible.

At the end of the expected service life, the manufacturer will cease routine maintenance and customer support and may discontinue access to the SaaS service. The manufacturer will provide timely notice to affected users and instructions for safe transition and/or decommissioning, as applicable.

25. Licensing and Intellectual Property

Copyright: © 2026 ART-EMIS Hamburg GmbH. All rights reserved.

Software License: The ACS Pathfinder software is proprietary. Use is permitted only under the terms of the subscription agreement with ART-EMIS Hamburg GmbH.

Open-Source Components: The ACS Pathfinder incorporates open-source software components. A complete list of third-party libraries and their licenses is available upon request from the manufacturer.

Trademarks: ACS Pathfinder is a trademark of ART-EMIS Hamburg GmbH.

26. Ethical Considerations

Bias and Fairness: The ACS Pathfinder model was developed and validated using diverse patient cohorts. Performance is monitored to detect potential disparities across patient subgroups. Any identified biases are addressed through model updates following regulatory review.

Transparency: This IFU provides information about the model's inputs, outputs, performance metrics, and limitations to support informed clinical use. Additional technical documentation is available to regulatory authorities upon request.

Human Oversight: The ACS Pathfinder is designed to augment, not replace, clinical decision-making. Predictions must always be interpreted by qualified healthcare professionals who retain full responsibility for patient care decisions.

Patient Communication: Healthcare providers should inform patients that a clinical decision support tool is being used as part of their diagnostic evaluation and explain how the tool contributes to their care plan.

Non-use of Forbidden Practices as Defined by the AI Act: Data collected within the use of the medical device is not used for any forbidden practices (harmful manipulation and deception, exploitation of vulnerabilities, social evaluation, prediction of crimes, facial image analysis, emotion recognition, biometric characterization and remote identification for law enforcement purposes), as listed in Article 5, section 1 of the EU AI Act.

27.Meaning of symbols

	Manufacturer
DE	Date of manufacture and country of manufacture
CE 0197	CE-designation and notified body number The product complies with the general safety and performance requirements laid down in Annex I of Regulation (EU) 2017/745 on Medical Devices.
	Warnings
	Refer to instruction manual/booklet To signify that the instruction manual/booklet must be read
MD	Medical Device
REF	Reference number

28.Information

Name of the medical device	ACS Pathfinder
Manufacturer of the medical device	ART-EMIS Hamburg GmbH info@acs-pathfinder.com Am Klaassol 1, 21224 Rosengarten, Germany www.acs-pathfinder.com
Version of the instruction for use	3.0
Corresponding Serial Number (version) of the medical device	1.0.7
Date of publication of the instructions for use	29.01.2026
CE Mark	CE 0197
Contact manufacturer	www.acs-pathfinder.com info@acs-pathfinder.com