

ANNEX – POLICY PROTOTYPES

INSTRUCTIONS FOR
USE & DISCLAIMERS

CONTENTS

- 1. Instructions For Use 1**
- 2. Instructions For Use 2**
- 3. Instructions For Use 3**
- 4. Disclaimer 1**
- 5. Disclaimer 2**

INSTRUCTIONS FOR USE 1

Use Case : AI software for detection of eye pathologies based on eye retina images

INSTRUCTIONS FOR USE 1

Contents

1.	Introduction	1
2.	Who we are	1
3.	Product description, intended purpose, intended users	1
4.	Clinical benefits for patients	2
5.	Characteristics, capabilities, and limitations	2
5.1.	Characteristics and capabilities	2
5.1.1.	Specifications for input data & information on ...	2
5.1.2.	Expected output	2
5.1.3.	Accuracy, robustness and performance	3
5.1.4.	Installation and use	3
5.1.5.	Image Capture Protocol	4
5.1.6.	Uploading and Analysis	4
5.1.7.	Interpretation of results and related actions	4
5.1.8.	Retention periods	4
5.1.9.	Cybersecurity, safety and best-practice tips	5
5.2.	Limitations/ Risks to health and safety	5
6.	Human oversight: Organizational and technical measures	5
6.1.	Organizational Measures	5
6.2.	Technical Measures	6
7.	Maintenance and care instructions	6
7.1.	Expected lifetime	6
7.2.	Maintenance and care measures	7
8.	Troubleshooting	7
9.	Logs	7
10.	Reference to other legal instruments	8
10.1.	Other relevant policies and documents	8
10.2.	ISO Standards and Best Practices for Medical Devices	8
11.	Support and contact details	8

1. Introduction

These Instructions For Use (hereinafter "IFU") aim to provide users with information and guidance about our product –including its capabilities, benefits and limitations, as well as a comprehensive explanation of usage, maintenance and oversight instructions.

2. Who we are

- Provider: [Company X]
- Product: [Retina] AI Software
- Address: Rue X, Brussels 1000, Belgium
- Email: contact@company.com
- Phone: +32 XXX.XX.XX.XX

3. Product description, intended purpose, intended users

Product description: [Retina] AI Software is a cutting-edge software tool developed by [Company X] which incorporates AI-based algorithms to evaluate and analyze eye retina images in order to assist and support ophthalmologists and healthcare teams in early detection of specific diseases, such as diabetes-related eye pathologies. Images are captured via retina cameras in hospitals and private practices. These images are uploaded to the web portal/platform (SAAS) where the analysis is performed. The outcome is then sent to and can be reviewed by the ophthalmologists, healthcare providers and respective healthcare teams.

Intended purpose: The AI-based evaluation and analysis of retina images by our software assists ophthalmologists, healthcare providers and respective healthcare teams in early detection of specific diseases, such as diabetes-related eye pathologies. The [Retina] AI Software results help the healthcare provider decide whether to refer for further screening and treatment. It is intended to be used in a medical setting by responsible professionals who are aware of these instructions for use.

Intended users and beneficiaries:

- Ophthalmologists: primary users, end responsible for using and interpreting the AI-supported analysis of retina images when conducting medical diagnosis.
- Healthcare providers (incl. nurses): secondary users, responsible for assistance in the capture, upload and (preliminary) review of retina images analysis results and (possibly) taking a decision whether to refer the patient to ophthalmologists for further screening.
- Adult) patients: The beneficiaries of accurate and timely AI-enabled diagnostics (e.g. detection of diabetes-related eye pathologies), also responsible for consent provision for retina image analysis.

4. Clinical benefits for patients

[Retina] AI Software enables a quick, affordable and early detection of diseases, such as diabetes-related eye pathologies. For people with diabetes, autonomous AI systems used by the healthcare provider have the potential to improve earlier detection of diabetes-related eye pathologies, and to immediately refer the patients to an ophthalmologist for further diagnosis and treatment and thereby lessen the suffering caused by blindness and vision loss.

5. Characteristics, capabilities, and limitations

5.1. Characteristics and capabilities

5.1.1. Specifications for input data & information on training data

Input data from the user

- Original high-resolution retina images in JPEG, PNG, or TIFF formats. It is required to use [Retina] AI Software with high quality, in-focus, unmodified retinal color images (45 degree), which include both the macula and optic disc, and were captured by a non-mydratic color retinal camera. Unmodified means: original exports of the camera, no screenshots or annotated images. One image per eye is sufficient. [Retina] AI Software is not intended to give results with other images of the retina, other tissue, or random objects. See part Error! Reference source not found. and following parts for the full operation instructions.
- The wearing of contact lenses, spectacles or other vision-correcting devices by the person under examination during image acquisition will negatively impact device performance or may even inhibit device operation at all.

Data source: Adult diabetes patient

Training data: our software was trained on training data (i.e. retinal images) which features data labels regarding ethnicity, age, gender and other special categories of data.

Data source: Commercially available data, where the source warrants both the presence of required consents and effective de-identification measures to safeguard individual privacy.

5.1.2. Expected output

A suggestion regarding the presence of certain diabetes-related eye pathologies with an associated confidence score.

[Retina] AI Software is only designed to detect certain diabetes-related eye pathologies. It is not intended to detect any other ophthalmic diseases or any other systemic diseases. Patients should not rely on [Retina] AI Software for detection of any other disease.

Therefore, the existence of diseases not screened by [Retina] AI Software cannot be ruled out by screening. In case the results of [Retina] AI Software are unclear, patients should be referred to an ophthalmologist.

5.1.3. Accuracy, robustness and performance

Accuracy: [Retina] AI Software has artificial Intelligence diagnostic accuracy with a sensitivity of >85% and specificity of >82,5%. The use of these metrics (and their reported levels) are in line with standard market practice and have been checked against fairness metrics.

Robustness: in order to ensure a robust functioning of our software, we have implemented measures that can mitigate or deal with foreseeable risks connected to the limitations of the system (including backups) as well as against malicious actions that may compromise the security of our AI system.

Performance: the [Retina] AI Software was specifically tested against the following parameters: [ethnicity, age, gender]. No statistical relevant outliers were detected. Not respecting these instructions for use will have an impact on the specified levels for accuracy, robustness and performance. Further information can be found in parts 5.1.1, 5.1.4- 5.1.6.

5.1.4. Installation and use

System requirements

In order to guarantee optimal performance, the user should ensure that the server on which the software is being installed, meets or exceeds the following minimum system requirements:

- Operating System: supporting docker
- RAM: 16GB minimum
- Hard Drive: 100GB free space
- Internet Connection: broadband

For ophthalmologists, healthcare providers or technical personnel:

- Use the web portal via the official website.
- Follow the manual or on-screen instructions to complete the image analysis/screening.
- Register the software using the license key provided.
- Access the platform via the recommended and compatible browsers: Chrome, Firefox, Safari, Edge (latest versions)
- Register on our web portal using the credentials provided by your institution.
- Retina Camera: consult the list of compatible devices on our website.

For patients:

- No software installation is required for patients.
- Create your account in order to access the results of retina images.
- Access the result of retina images via the platform by using your credentials.

5.1.5. Image Capture Protocol

For ophthalmologists, healthcare providers, nurses:

- Verify if the set-up is used in a sufficiently dark/dimly lit room without any environmental interferences (such as flashing lights, strong vibrations or sudden changes in temperature)
- Ensure the retina camera lens is clean.
- Adjust the patient's eye to the camera's focus point.
- Capture a high-resolution image.
- Save images in recommended formats: JPEG, PNG, TIFF.

5.1.6. Uploading and Analysis

For ophthalmologists, healthcare providers, nurses:

- Login to the web platform.
- Click "Start screening"
- Select the saved retina images from your system.
- Submit the images. The user is responsible for ensuring that the images submitted (input) to [Retina] AI Software for a patient are correct and correspond to that patient in order to avoid mistaken identity with respect to [Retina] AI Software results.
- The platform will automatically begin the analysis.
- Await results – typically available within seconds.

5.1.7. Interpretation of results and related actions

For ophthalmologists, healthcare providers, nurses:

- The results page will indicate potential presence of diseases.
- A confidence percentage accompanies each diagnosis.
- Results are suggestions; clinical verification (from an ophthalmologist) is required.
- Patients who are subject of a verified result indicating referable diabetes-related eye pathologies should be immediately referred to an ophthalmologist for further diagnosis and treatment.
- Patients who are subject of a verified result indicating non-referable diabetes-related eye pathologies should be strongly encouraged to test again in a time period according to the guidelines applicable in his/her respective country

5.1.8. Retention periods

Uploaded retina images and related analyses are retained for a period of [5 years after which the data is archived for 30 years to meet medical liability retention requirements], after which they are automatically deleted from our servers. Data that is not being used is being immediately deleted in a secure manner only by the ophthalmologists after assessment.

5.1.9. Cybersecurity, safety and best-practice tips

Our system offers an appropriate level of cybersecurity in line with market practices. To help sustain this level as a user, consider the following measures or circumstances when using our product:

- Always prioritize patient's safety and data protection.
- Always keep software updated for optimal results and to take advantage of the latest cybersecurity updates.
- Use only for its intended purpose and within the scope of your medical expertise.
- To prevent unauthorized access to the patient data on [Retina] AI Software (data input and results), it is strongly recommended that the computer/server on which [Retina] AI Software is used/installed is password-protected (using a strong password); free of viruses and malware; with anti-virus software and firewall installed and activated; and updated with the latest security patches.
- All patient data and images are encrypted (in transit and in rest) and stored securely.
- Implement pseudonymisation or anonymisation measures for retina images prior upload.

5.2. Limitations/ Risks to health and safety

[Retina] AI Software is not intended to be used on images from:

- patients with prosthetic eyes.
- patients not diagnosed with diabetes.
- patients with a history of retinal laser treatment or injections in either eye, or history of retinal surgery.
- patients contraindicated for imaging with the fundus imaging system used to obtain retinal images.

6. Human oversight: Organizational and technical measures

Our system is not solely reliant on AI. Human oversight is crucial:

6.1. Organizational Measures

- If the patient reports sight problems, a negative screening result should not be the basis for not referring the patient to a qualified physician.
- Patients should be advised to immediately report to an ophthalmologist if he/she experiences vision loss, blurred vision, floaters or any other symptom as these symptoms require the immediate attention of an ophthalmologist.

- [Retina] AI Software has limitations that the user should be aware of [Retina] AI Software performs computerized interpretation of retinal images therefore [Retina] AI Software will miss diabetes-related eye pathologies in some cases (false negatives), and erroneously flag diabetes-related eye pathologies in others where there is none (false positives).
- Analysis results generated by our software are suggestions and need to be examined and confirmed by an ophthalmologist. Ophthalmologists and healthcare professionals are required to use professional judgment and conventional diagnostic methods.
- Ophthalmologists and healthcare professionals using our system are expected to undergo further professional training and education.
- In case any serious incident occurs in relation to [Retina] AI Software, this should be reported to your [Retina] AI Software representative (or info@company.com) and the competent authority of your country.

6.2. Technical Measures

- Each diagnostic suggestion features an associated confidence score. This confidence score can be an indication for the user of how much caution must be applied in regard to the output. If the system is unable to generate an output with a confidence score above 50%, it will provide a signal to the user and refrain from providing a diagnostic suggestion. It will then provide suggestions regarding how to improve the confidence score (e.g. verifying whether the instructions listed in parts 5.1.4 - 5.1.6 are applied correctly)
- If [Retina] AI Software is not able to generate a result on a patient due to the poor quality of the images, the patient may be retested immediately after pharmacologic dilation. If dilation is not possible or if [Retina] AI Software still does not generate a result, the patient should be referred to an ophthalmologist for evaluation since the patient may have vision threatening diabetic retinopathy, or other abnormalities including cataract.
- If a user considers to overrule the result generated by [Retina] AI Software, we advise to follow our overruling policy which lists various factors that may be considered when making a decision on overruling or subsequent actions. This overruling policy can be found on your online account.

7. Maintenance and care instructions

7.1. Expected lifetime

As our software is not integrated into a physical product, we do not foresee a determinate lifetime but intend to maintain our software as long as possible and commercially feasible.

7.2. Maintenance and care measures

In order to maintain our system, ophthalmologists, healthcare providers, nurses shall ensure that:

- the retina cameras are calibrated and cleaned regularly in order to enable accurate image capture.
- the web portal is accessed using updated browsers for optimal performance.
- the tool is updated to the latest platform version to for improved accuracy and additional features.

We shall ensure:

- to update this IFU in accordance with new developments and releases or added functionalities
- to perform regular performance tests
- to provide regular back-ups and software updates to fix any bugs.
- [...]

8. Troubleshooting

- **Software Not Responding:** Restart your computer and relaunch the application.
- **Integration Issues:** Ensure that your system is compatible and updated.
- **Uploading Issues:** Check your internet connection and file format.
- **Analysis Errors:** Ensure the image is of high quality and properly centred.
- **Platform Issues:** Clear browser cache or try a different browser.
- **Error Messages:** Refer to our online knowledge base or contact our support team.

9. Logs

All activities, such as uploads, analysis requests, and result retrievals, are logged for security and improvement purposes. These logs are retained on our platform as long as required by the applicable limitation period and only for the purposes indicated in this IFU.

You can access these logs by visiting the 'log history' tab in your profile on our web platform. There you can also find guidance on how to read and interpret the logs.

10. Reference to other legal instruments

10.1. Other relevant policies and documents

- Privacy policy (incl. data subject rights). Please take into account that patients have the following rights under data protection legislation: obtain information, access, rectification, erasure, restriction or objection of processing of their data, data portability, object to automated individual decision-making, including profiling. If they wish to exercise these rights, contact our Data Protection Officer at dpo@company.com.
- Corporate Code of conduct
- [...]

10.2. ISO Standards and Best Practices for Medical Devices

Our software complies with the following standards

- ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 14971, Medical devices – Application of risk management to medical devices
- IEC/TR 80002-1, Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software
- IEC 62304/AMD1, Medical device software – Software life cycle processes
- IEC 82304-1, Health software – Part 1: General requirements for product safety
- WHO/ITU: Good practices for health applications of machine learning: Considerations for manufacturers and regulators

11. Support and contact details

For any queries, issues, or support:

- Customer Support: +32 XXX.XX.XX.XX
- Email Assistance: support@company.com
- Online Portal: www.company.com/support

INSTRUCTIONS FOR USE 2

Use Case : Medical device for cardiac arrhythmias prediction

INSTRUCTIONS FOR USE 2

Contents

1.	Identity & contact details	1
2.	Product Description: intended purposes & intended use	1
	2.1. Intended purpose	1
	2.2. Intended use	1
	2.3. Accuracy & performance specifications	1
3.	Operating instructions	3
	3.1. Installation and setup	3
	3.2. Interpretation of results	4
4.	Compatibility	5
5.	Usage	5
	5.1. Limitations	5
	5.2. Target population	6
	5.3. Overruling procedure	6
	5.4. Recommendations	6
6.	Human oversight	6
	6.1. Purpose	6
	6.2. Feedback collection	6
	6.3. Interpretation of the results	6
	6.4. Emergency procedures	7
7.	Security measures	7
	7.1. Warnings	7
	7.2. Organisational measures	7
8.	Expected lifetime & Foreseeable changes	8
	8.1. Expected lifetime	8
	8.2. Technical measures	8
	8.3. Maintenance	8
9.	Logs	8
10.	Support and supplier information	9
11.	Design of the prototype	10

1. Identity & contact details

- Provider:
- Product:
- Address:
- Email address:
- Phone:

2. Product Description: intended purposes & intended use

2.1. Intended purpose

- **Intended purpose:** The [Name Tool] solution predicts the onset of atrial fibrillation before it manifests and this up to one year upfront. The output is a probability score of atrial fibrillation manifestation for the coming year. A threshold is placed on the output to give a recommendation to the medical practitioner. Algorithms are applied to an ECG measurement.
- **Benefits for user:** Using [Name Tool], atrial fibrillation can be predicted upfront. This enables to detection of high-risk patients more accurately and objectively. This way, monitoring can be done efficiently on the better-identified high-risk group.

2.2. Intended use

- The intended use is for adults with known or suspected heart conditions, adults feeling symptoms, adults undergoing a standard ECG examination before surgery, adults referred by their GP or cardiologist, and athletes performing intensive physical exertion. Output results of [Name Tool] are to be interpreted by a general practitioner or cardiologist.
- Patients at increased risk of atrial fibrillation (VKF) (based on symptoms & EKG) so that a higher risk of atrial fibrillation can be detected so they can be monitored (by cardiologists)

2.3. Accuracy & performance specifications (characteristics, capabilities, limitations)

- **Accuracy:** [Name Tool] has undergone rigorous evaluation to ensure its accuracy and reliability. The following performance metrics are derived from an independent test set comprising x adults, and they highlight the application's effectiveness.
 - Performance metrics:
 - Area Under the Curve (AUC):
 - [Name Tool] achieved an AUC of 0.9678, indicating its exceptional ability to discriminate between health conditions.
 - Confidence Interval: 95% CI [0.9545; 0.9712]

- Overall Accuracy:
 - The application demonstrated an accuracy rate of 99.56%, reflecting its proficiency in correctly identifying health-related information.
 - Confidence Interval: 95% CI [98.76; 99.86]
- Age and Gender Inclusivity: [Name Tool] was tested on a diverse population, including individuals across various age groups and genders. Please refer to Table X for specific age range and gender distribution details, highlighting our commitment to serving a broad demographic.
- Threshold-Based Analysis: When applying the recommended threshold of 0.76 to [Name Tool]'s output, the following results were observed:
 - Sensitivity:
 - Sensitivity measures the application's ability to detect true positive cases.
 - [Name Tool] achieved a sensitivity rate of 95.56%, ensuring effective identification of individuals with health concerns.
 - Confidence Interval: 95% CI [94.87; 96.89]
 - Specificity:
 - Specificity assesses the application's capacity to correctly identify true negative cases.
 - [Name Tool] demonstrated a specificity rate of 84.56%, indicating its ability to distinguish individuals without health issues.
 - Confidence Interval: 95% CI [83.45; 86.54]
- Patient Characteristics: For a comprehensive understanding of the evaluation, please consult Table X for details regarding the characteristics of patients in both the test set and the development data set.
- Dataset Characteristics:
 - The test dataset predominantly represents individuals of Caucasian ethnicity and middle age.
 - ECG measures were meticulously collected using two ECG devices, namely X and X, to ensure comprehensive data coverage.
 - The prevalence of atrial fibrillation within the test set was XX%, reflecting the real-world distribution of this health condition.
 - Data collection took place across multiple reputable hospitals, including XXXX, ensuring a wide geographic and medical context.
- Error Rate and Performance Metrics: [Name Tool]'s performance metrics, including threshold-based error rates and sensitivity, were meticulously determined on the test dataset, accounting for the diverse characteristics mentioned above.
 - Threshold: The threshold value used for health assessment is optimized to ensure precision and reliability. Please refer to the [Name Tool] User Manual for specific threshold details.

- Sensitivity: Sensitivity measures [Name Tool]'s capacity to detect true positive cases within the test dataset. Our application achieved remarkable sensitivity, indicative of its ability to identify individuals with health concerns accurately.
 - Specificity: Specificity assesses [Name Tool]'s capability to correctly identify true negative cases. Our application demonstrated strong specificity, ensuring accurate identification of individuals without health issues.
- Comprehensive Dataset Overview: For a detailed understanding of the dataset characteristics, including ethnicity, prevalence of atrial fibrillation, age distribution, and ECG device usage, please refer to the provided dataset documentation.
- **Robustness:**
 - Reproducibility tested by repeated measurements on the same patient and different ECG devices
 - The reproducibility of the prediction algorithms was tested using a test-retest setup in three independent hospitals that are geographically distributed. Variations in the ECG measurement device were also measured. Test-retest reliability measured was XXX.
- **Cybersecurity:** [Name Tool] uses industry-standard encryption protocols to secure all products and data in transfer and at rest. FibrCheck uses industry best practices. Detailed measurement data is only stored on secure, encrypted servers and not on the device of the user. These databases contain encrypted user data when at rest or in transit. A continuous backup system is used to make sure all data is secure.
- Be aware that results from [Name Tool] may differ depending on the ECG measurement device, whether sports were executed before ECG examination, etc.

3. Operating instructions

3.1. Installation and setup

- **System Requirements:**
 - Before you begin, make sure your system meets the following requirements:
 - Operating System: Windows 10, macOS, or Linux
 - Processor: Dual-core processor or higher
 - RAM: 4GB or more
 - Storage: 500MB of free disk space
 - Internet Connection: Required for initial setup and updates

- **Installation steps:**
 - Download the Application:
 - Visit our official website (www.[Name Tool].com) and navigate to the “Downloads” section. Choose the version of the application that corresponds to your operating system (Windows, macOS, or Linux) and click the “Download” button.
 - Install the Application:
 - Once the download is complete, locate the installation file (e.g., “Heart_Felt_App.exe” for Windows) and double-click it to start the installation process. Follow the on-screen instructions to install the application.
 - Launch the Application:
 - After installation, you can find the Heart Felt Application in your system’s applications or programs folder. Double-click the application icon to launch it.
 - Create or Log in to Your Account:
 - Upon launching the application for the first time, you will be prompted to create a new account or log in with your existing credentials if you already have an account. This account will allow you to manage patient data and access predictions.
 - Connect External Devices:
 - Ensure your ECG machine is connected to the computer and configured according to their respective manuals. The Heart Felt Application requires access to these devices for accurate predictions.
 - Patient Data Input:
 - Follow FibriCheck instructions to connect and retrieve the data.
 - Data Processing:
 - The application will process the entered patient data and the ECG data from the FibriCheck application. It will then generate a prediction regarding the likelihood of atrial fibrillation.
 - Save and Export Data:
 - The application allows you to save patient profiles, predictions, and associated data for future reference. You can also export this data in various formats (CSV, PDF, etc.) for integration into your clinic’s electronic health records system.
 - Support and Updates:
 - For technical support, bug reports, or feature requests, please contact our support team at support@[Name Tool].com. We periodically release updates to improve the application’s performance and accuracy. Ensure you keep the application up to date by checking for updates in the “Settings” section.

3.2. Interpretation of results

Results are presented in the form of a probability score, categorized into high, moderate, and low-risk, to assist medical practitioners in making informed decisions.

- **Understanding Risk Categories:**
 - High-Risk: A high-risk prediction indicates a significant likelihood of atrial fibrillation manifestation. This category is essential for identifying patients who may require immediate attention and intensive monitoring.
 - Moderate-Risk: A moderate-risk prediction suggests a moderate probability of atrial fibrillation development. While not as urgent as the high-risk category, patients in this group may still benefit from regular monitoring and further evaluation.
 - Low-Risk: A low-risk prediction signifies a minimal likelihood of atrial fibrillation occurrence in the near future. Patients falling into this category generally have a lower priority for immediate intervention, but routine check-ups are advisable for ongoing assessment.

4. Compatibility

The Heart Felt application is compatible with the following ECG device models

- GE Healthcare:
 - GE MAC 5500 HD
 - GE MAC 800
 - GE CASE 6.7
- Philips Healthcare:
 - Philips PageWriter TC70/TC50/TC30
 - Philips Efficia DFM100
 - Philips Cardiograph 12

5. Usage

5.1. Limitations

- [Name Tool] is only intended for cardiologists or another medical practitioner working in a cardiology department.
- The accuracy of the AFib prediction heavily relies on the quality and accuracy of the input data, the ECG data. If the ECG data is noisy, improperly calibrated, or affected by artefacts, it can lead to inaccurate predictions.

5.2. Target population: Caucasian, middle-aged, not already diagnosed with atrial fibrillation before.

5.3. Overruling procedure

In certain situations, the predictions made by the AI application may need to be overruled based on clinical judgment, patient condition, or other relevant factors. While the AI algorithm is designed to provide valuable insights, healthcare professionals must retain the ultimate authority in decision-making.

5.4. Recommendations

- Always ensure the safety and well-being of your patients while using the AI application.
- Use the AI application in accordance with your clinical expertise and within the scope of your medical knowledge. While the AI provides predictions, always rely on your professional judgment and conventional diagnostic methods to make informed decisions about patient care.
- In order to ensure that patient data and results are not accessed by unauthorized individuals, it is highly advisable to secure the computer or device used to access the AI application with a robust password. It's essential to confirm that the system is devoid of viruses and malware and that it's fortified with up-to-date anti-virus software and an active firewall. Regularly updating the system with the latest security patches is also strongly recommended.

6. Human oversight

6.1. Purpose

Human oversight within the [Name Tool] AI application plays a pivotal role in ensuring the highest standards of safety, accuracy, and reliability. It is integral to various aspects of the system, including monitoring and evaluation, quality control, error handling, and emergency procedures.

6.2. Feedback collection

The medical practitioner can provide feedback on the presented results by

- Rating the results
- Open text field to provide suggestions

6.3. Interpretation of the results

An ECG risk score is used to determine the risk of AF. There are three possible outcomes:

1. 0–2: Low probability of AF.
2. 3–4: Intermediate probability of AF.
3. 5–6: High probability of AF.

The score is comprised of three P-wave variables: morphology in inferior leads, voltage in lead I, and P-wave duration (MVP). The variables and point allocation of the MVP ECG risk score are based on a critical appraisal of the existing literature and the prevalence and predictive value of ECG indices for AF (Alexander, MacHaalany, et al., 2017; Alexander et al., 2016; O’Neal, Zhang, et al., 2016; Tse et al., 2017). Table 1 illustrates the MVP ECG risk score variables and the assigned weighting.

Variable	Value	Score
Morphology in inferior leads	Nonbiphasic (<120 ms)	0
	Nonbiphasic (≥120 ms)	1
	Biphasic	2
Voltage in lead I	>0.20 mV	0
	0.10–0.20 mV	1
	<0.10 mV	2
P-wave duration	<120 ms	0
	120–140 ms	1
	>140 ms	2

6.4. Emergency procedures

Healthcare professionals are equipped to take immediate action when necessary, including bypassing AI recommendations for urgent interventions.

7. Security measures

7.1. Warnings

- Utilize solely for its designated purpose and within the scope of your medical proficiency

7.2. Organisational measures

- **Continuous training and education:** Healthcare professionals utilizing our AI application must undergo regular training and education to stay updated on the latest advancements in arrhythmia prediction and the utilization of the AI algorithm.
- **Algorithm performance monitoring:** The [Name Tool] algorithm will be regularly monitored to detect deviations or inaccuracies. Protocols have been developed for tracking outcomes over time to identify areas for improvement and recalibration.
- **Data security and privacy:** rigorous measures are in place to protect patient data. This includes adhering to data protection regulations, anonymizing patient information, and ensuring secure storage and transmission of sensitive patient data.

- **Reporting incidents and feedback:** Any significant adverse events or incidents linked to the AI application's predictions must be promptly reported to both the AI application provider (support@[Name Tool].com) and the appropriate regulatory authorities in your country.

8. Expected lifetime & Foreseeable changes

8.1. Expected lifetime

[Name Tool] has been designed to provide valuable functionality and assistance for a defined period of time. Understanding the expected lifespan of the system is crucial for optimal utilization and performance.

- **Expected Lifetime Duration:** The expected lifetime of [Name Tool] is estimated to be X, starting from the date of initial activation or installation. This estimate is based on factors such as technological advancements, software updates and the evolving nature of AI technology

8.2. Technical measures

- The AI undergoes routine updates and adjustments, taking into account input from users
- Data is consistently backed up on a regular basis.
- Unused data is promptly and securely removed.

8.3. Maintenance

- Healthcare professionals using the AI have to:
 - Perform routine system checks to verify that their devices and network connections are functioning correctly. This includes assessing internet connectivity, hardware performance, and any potential technical issues that might impact the accuracy of the AI predictions.
 - Access the AI application using up-to-date and supported web browsers to ensure optimal performance and security.
 - Keep the AI algorithm up-to-date with the latest version provided by the application provider. Updates are essential for improving prediction accuracy, incorporating new medical insights, and adding additional features that enhance the diagnostic capabilities of the algorithm.

9. Logs

Our AI application may generate logs that capture certain activities and interactions for the purpose of security, improving user experience, troubleshooting issues, and enhancing the performance of the application. These logs may include:

- User Interactions: Details of user input and interactions with the AI application, such as queries, commands, and preferences.
- Technical Information: Information related to the device, operating system, browser, and network used to access the application.

- Errors and Exceptions: Records of errors, crashes, and exceptions encountered during the use of the application.
- Performance Metrics: Metrics regarding the application's responsiveness, processing times, and resource utilization.
- These logs are primarily used for internal analysis and diagnostic purposes. We take your privacy and data security seriously, and the information collected is handled in accordance with our Privacy Policy (add link). Personal or sensitive information is not intentionally collected or stored within these logs.

How We Use Logs:

- Improvement: Analyzing logs helps us identify areas for improvement and refine the AI algorithms to enhance overall performance.
- Bug Resolution: Logs assist our technical team in diagnosing and resolving any issues that may arise during the use of the application.
- Security: Logs aid in detecting and responding to potential security threats and anomalies.

We do not share individual log data with third parties, except as required by law or as outlined in our Privacy Policy.

If you have concerns about the data captured in logs, you can contact our Support Team for more information.

10. Support and supplier information

If you have any questions, or concerns, or need assistance while using our AI application, our dedicated support team is here to help. We are committed to ensuring a seamless experience for our users, and we encourage you to reach out to us with any inquiries you may have.

Contact Information:

- Email: support@[Name Tool].com
- Phone: +32-XXX-XXXXXXX
- Live Chat: Available on our website during business hours.

Our support team is available from 9:00 AM to 6:00 PM (CMT) Monday through Friday. We strive to respond to all inquiries within 24 hours.

For general information, updates, and announcements, you can also follow us on social media:

- LinkedIn: @[Name Tool]

We value your feedback and suggestions as they help us improve our product to meet your needs better. Thank you for choosing [Name Tool], and we look forward to assisting you.

Sincerely, The [Name Tool] Support Team

11. Design of the prototype

Description of the design of Instructions for Use for the [Name Tool] application:

Feedback Loop: Our digital Instructions for Use (IFU) incorporate a dynamic feedback loop, e.g. using a permanent chat window similar to a chatbot allowing users to provide instant feedback on the content's clarity and usefulness. This real-time input ensures continuous improvement.

Heat Map Methods: We have integrated heat map methods to visualize user interactions. Through intuitive color-coded heat maps, we identify which sections users engage with the most. This data-driven approach guides content optimization, ensuring that the most crucial information is readily accessible and easy to comprehend.

Placeholder for Technical Details: To accommodate the evolving nature of technology, we have incorporated placeholders within the document. These placeholders are designated sections where the data science team can seamlessly integrate technical details. This flexibility ensures that the IFU always reflects the latest advancements and accurate technical specifications.

Drop-Down Menu & Linking: A user-friendly drop-down menu simplifies navigation. Users can effortlessly access specific sections of interest. Additionally, strategic linking within the document enables seamless transitions between related topics. This interconnected structure provides a cohesive user experience, allowing users to explore relevant content effortlessly.

Concise Language Use: We employ concise language throughout the document, ensuring clarity and brevity. Complex technical concepts are explained in simple terms, enhancing user understanding. By eliminating jargon and unnecessary details, the IFU communicates information effectively, catering to users with varying levels of expertise.

Referencing and Cross-Linking: The digital IFU includes references and cross-links to external documents, providing users with additional resources for in-depth exploration. Proper citation and linking enhance the credibility of the content, allowing users to validate information and delve deeper into specific topics if desired.

This design ensures that the digital Instructions for Use of the AI application are not only comprehensive and informative but also user-friendly and adaptable to ongoing technological developments.

INSTRUCTIONS FOR USE 3

Use Case : HR talent matching tool

INSTRUCTIONS FOR USE 3

Contents

1.	Who + Contact Details	1
2.	Intended Purpose for the User / Human Role	1
3.	Data Transparency	1
4.	Time period of data being used to develop the AI system	2
5.	Accuracy/robustness/cybersecurity	3
6.	Oversight + Logs keeping for users	4
7.	Performance	5
8.	Worst Case Scenario + Solution	5
9.	Evolution and Expected life time of AI System / ...	7
10.	FAQ	8

1. Who + Contact Details

- COMPANY

2. Intended Purpose for the User / Human Role

Our primary objective is to facilitate a seamless and highly effective job matching process by employing cutting-edge AI technologies. Specifically, our platform is designed to empower users by intelligently connecting candidates to job offers in the most relevant and personalized manner possible.

- **Geographical scope:** The geographical setting stipulates that the [Name API Tool] is designated for the purpose of matching candidates with job offers within the jurisdiction of the Belgian job market.
- **Age Scope:** The matching functionality is anticipated to perform effectively for applicants satisfying the minimum legal age of work on the Belgian job Market.
- **Ethnicity scope:** The [Name API Tool] is deemed secure for utilization in matching applicants of any ethnicity.
- **Gender Inclusivity:** The [Name API Tool] is designed to be safely employed for matching applicants of any gender.

3. Data Transparency

- **Data used: format, attributes, origin:** The information employed is procured directly from the client, who submits data to the API. Our artificial intelligence model incorporates diverse parameters to facilitate the efficient matching of candidates to job offers, encompassing:

- **For Vacancies:**
 - Job Title
 - Employer Address
 - Job Description
 - Expected Skills
 - Required Job Experience
 - ...

- **For Candidates:**
 - Approximate Address
 - Reported Skills
 - Job Experience derived from Curriculum Vitae
 - Self-Declared Interests

Collectively, these parameters serve to augment the precision of our matching algorithms, thereby guaranteeing a comprehensive and accurate correlation between candidate profiles and job opportunities.

- **Data not used:** Attributes that might potentially give rise to discriminatory practices in the job market, including gender, age, or ethnicity, are intentionally excluded from consideration in the process of matching applicants with job opportunities. Nevertheless, a robust testing regimen has been implemented to thoroughly evaluate and address potential biases specifically related to gender and age within the overall job-applicant matching process. It is noteworthy to mention that ethnicity data is not directly accessible, even to clients.
- **Data pre-processing (bias reduction measures, handling incomplete data, handling obvious bad data; e.g. spelling corrections):** Prior to employing the matching model, a series of pre-processing tasks are systematically conducted. These tasks are delineated as follows:
 - **For Candidate Data:** Extraction of standardized titles and skills from the Curriculum Vitae (CV), ensuring a uniform representation of candidate attributes.
 - **For Job Data:** Extraction of skills from the job description, establishing a comprehensive understanding of the requisite qualifications and competencies.
 - **For Both Candidate and Job Data:** Geolocation based on addresses is performed, a critical factor in calculating the distance between the candidate's residence and the job location, thereby enhancing the contextual relevance of the match.

Semantic embedding of titles and skills mentioned in both the job offer and candidate CV is undertaken. This process involves encoding these textual elements into a meaningful numerical representation, contributing to a more nuanced analysis and facilitating a sophisticated matching process.

4. Time period of data being used to develop the AI system

The temporal scope of data utilized for the development of the AI system spans from [start date] to [end date].

- **Data size and representativity**
 - The system's training dataset comprises a set of [number] job offers and [number] candidate CVs, meticulously curated to encompass dimensions frequently implicated in discriminatory contexts, including gender, age, and origin. This comprehensive approach ensures a representative dataset that reflects diverse attributes.
 - The data is strategically employed in the following ways:
 - Utilization of skills mentioned in CVs as a crucial factor in the matching process.

- Incorporation of [specific aspect] in CVs for a more nuanced understanding.
- The matching process involves the consideration of four dimensions, namely [dimension 1], [dimension 2], [dimension 3], and [dimension 4], ensuring a multifaceted analysis for optimal outcomes.
- **Common definitions**
 - To enhance clarity and consistency, common definitions are established to provide clear interpretations of technical terms and jargon used within the system:

5. Accuracy/robustness/cybersecurity

- **Accuracy:**
 - [Name API Tool] functions by providing job recommendations to applicants based on their demonstrated interest, inferred from their engagement with posted jobs. The accuracy and recall metrics are subsequently assessed by examining the extent to which our recommendations align with the applicants' actual selections. Additionally, scrutiny is applied to clicks made by recruiters and employers on applicant profiles.
 - Accuracy is gauged within the context of the first-N recommended jobs.
- **Robustness:**
 - The robustness of our model is rigorously assessed through various examinations. For instance, the skill/title embedder undergoes meticulous checks for resilience against spelling variations, diverse language usage, and instances such as "nurse" or "male nurse," demonstrating our commitment to accommodating nuanced differences.
- **Security:**
 - Security measures are integral to [Name API Tool]'s deployment on a secure cloud platform. Access to critical cloud resources, including client databases and the source code, is meticulously controlled and limited solely to designated members of the [Name API Tool] technical team.
 - The external-facing components consist of the API itself and a singular Bastion host, exclusively accepting SSH connections from authorized [Name API Tool] developers.
 - Access to the API is facilitated through a robust system of authentication and authorization, anchored in client-specific usernames and passwords, ensuring a controlled and secure environment wherein each client possesses both admin and regular user identities.

6. Oversight + Logs keeping for users

- **Technical Measures to Enhance User Comprehension:**
 - **Job Match Explanation:** Our system provides a detailed breakdown of the job match, elucidating the specific criteria that led to the recommendation. This encompasses a thorough explanation of how the candidate's attributes align with the job requirements.
 - **Matching on Title:** When the system matches based on job titles, users receive a clear explanation detailing the relevance of the title to the job opportunity. For instance, if a job seeks a "Project Manager," the user is informed that the match is made due to the alignment of the candidate's title with the job requirements.
 - **Skills Matching Explanation:** For skills-based matches, a detailed account is provided, outlining the specific skills the job demands and the corresponding skills present in the candidate's profile. This ensures transparency and enables users to comprehend the basis for the match.
 - **Expertise Level Clarification:** When expertise level is a contributing factor, the system articulates the proficiency level required by the job and explains how the candidate's demonstrated expertise meets or exceeds those expectations. This empowers users to gauge the suitability of the match with a nuanced understanding of expertise levels.

Example Scenario:

Consider a job that necessitates expertise with a forklift.

The system would explicitly convey to the user that the match is primarily attributed to the candidate's experience with a forklift, providing a tangible example of how specific attributes contribute significantly to the job recommendations.

[Example Airbnb](#)

These measures collectively enhance the transparency of our system, enabling users to not only receive job recommendations but also comprehend the rationale behind each recommendation, fostering a more informed and empowered user experience.

- **Identifying Anomalies:**
 - Imagine our system as a diligent assistant always working to connect you with the most fitting job opportunities. To make sure everything runs smoothly, we've set up ways to spot any unexpected or irregular situations—those are what we call "anomalies." In simple terms, anomalies are like red flags that tell us if something unusual or not quite right is happening in the job matching process. When you see something that doesn't seem to match your expectations, it could be one of these anomalies, and we'll be on top of it to make things right.

- **Human-Machine Interaction (Premarket):**
 - Before our system goes into action and starts suggesting jobs to you, we've put in place a way for humans and machines to work together, sort of like a team preparing for a big game. This happens before everything gets out into the public, in what we call the "premarket" phase. During this time, we set up the rules and strategies to ensure the best possible job matches. While we're not actively taking feedback from users during this phase, we've carefully considered how the system should operate based on what we know about your needs. So, just like a team getting ready for a game, we've done the preparation work to make sure that when our system starts suggesting jobs to you, it's well-prepared and ready to provide the most relevant and beneficial recommendations.

7. Performance

- **Expectations for Lower Performance:**
 - Consider our [Name API Tool] as your personal job matching advisor. While it usually does a fantastic job, there are certain situations where its performance might not be as accurate. For instance, if a CV is on the shorter side or uses specific words that the system finds challenging to connect, it might lead to slightly less accurate recommendations.
- **Specific Scenario:**
 - We've observed that our system might offer lower-quality recommendations for applicants falling under a specific situation, described as follows: <...>
- **Human Oversight and Final Decision:**
 - In such situations, it's crucial to emphasize that our system is here to assist and enhance the job matching process, but the ultimate decision lies with you, the user. Human oversight is key, and we encourage users to carefully review recommendations, especially in cases where the system might have challenges, such as ethnicity-related considerations. Your judgment and insights are invaluable, and we believe that your final decision should align with your preferences and expectations.

8. Worst Case Scenario + Solution

Worst Case Scenario 1: Job Has No Matching Applicant

In a rare scenario, our [Name API Tool] might encounter a challenge where it fails to find suitable matches for a particular job, leaving the user with no potential candidates. This could be due to various factors, such as a highly specialized job role or specific criteria that are uncommon in the candidate pool.

- **Tackling the Problem:**
 - **User Notification:** Our system will promptly notify the user that no matching candidates were found for the given job. This transparency is crucial in keeping users informed about the outcome.
 - **Analysis of Criteria:** Our technical team will conduct an in-depth analysis of the job requirements to understand the specific criteria that led to the absence of matches. This involves assessing whether the criteria are too niche or if adjustments can be made for better alignment.
 - **User Consultation:** A consultation with the user, especially if they are experts like public employment service recruiters, will be initiated to gather additional insights. Understanding the intricacies of the job and its requirements from the user's perspective is invaluable in refining the matching process.
 - **System Optimization:** Based on user feedback and technical analysis, the system will undergo optimizations. This may involve fine-tuning algorithms, revisiting pre-processing tasks, or adjusting parameters to ensure a more effective matching process in the future.
 - **Continuous Improvement:** The incident will be treated as a learning opportunity, and measures will be implemented to prevent a recurrence. Our commitment to continuous improvement ensures that the system evolves to handle a diverse range of job scenarios effectively.
 - **User Empowerment:** In line with our philosophy of user empowerment, the final decision always rests with the user. Even in situations where the system encounters challenges, we believe that the user's expertise and judgment are paramount. Users are encouraged to actively engage with the system, provide feedback, and make informed decisions based on their unique insights and requirements. This user-centric approach ensures that our system not only meets but exceeds user expectations over time.

Worst Case Scenario 2: Applicant has No Matching Jobs

In rare instances, our [Name API Tool] may encounter a scenario where it fails to provide suitable job recommendations for a specific applicant. While this occurrence is infrequent, we want to be transparent about the possibilities.

Typically, our system strives to present job suggestions tailored to individual profiles. However, there are situations where we might not find an ideal match. In such cases, we undertake an additional step by pruning jobs that fall below a certain match quality threshold. This is part of our commitment to offering recommendations that align closely with your qualifications and preferences.

If, despite our efforts, you find yourself in a situation where no matching jobs are presented, the most common solution is for you to enhance your profile by providing additional details. By filling in more information about your skills, experiences, and preferences, you increase the chances of our system making more accurate and personalized recommendations.

However, if after profile enhancement the situation persists, it may be indicative of a genuine lack of available jobs in our database that precisely match your unique combination of skills and experiences. In these cases, we recommend keeping your profile updated and checking back periodically, as the job market evolves, and new opportunities may arise over time.

We understand the importance of this process in your job search journey, and your insights play a pivotal role. The final decision always rests with you, the user. Our system aims to assist and enhance, but your judgment, preferences, and expectations are paramount. Should you encounter challenges, we encourage you to carefully review recommendations and make decisions aligned with your needs and aspirations.

9. Evolution and Expected life time of AI System/ Maintenance and Care

Our commitment to excellence extends beyond the initial deployment of the [Name API Tool]. We recognize the dynamic nature of technology and the evolving landscape of job markets. Therefore, we have implemented strategies for the continuous evolution and upkeep of our AI system.

- **Evolution:** The [Name API Tool] is designed to adapt and evolve in response to changing user needs, technological advancements, and shifts in the employment landscape. Our development team is dedicated to staying at the forefront of AI innovations, regularly updating algorithms, and integrating new features to enhance the overall user experience. These updates are aimed at improving job matching accuracy, expanding capabilities, and ensuring that our users benefit from the latest advancements in artificial intelligence.
- **Expected Lifetime:** While predicting the exact lifetime of an AI system can be challenging due to the rapidly evolving nature of technology, we are committed to providing long-term support for the [Name API Tool]. Our goal is to ensure its relevance and effectiveness over an extended period. Regular assessments and updates are scheduled to align with industry trends and user feedback, ensuring that the system remains a valuable tool for job seekers and recruiters alike.
- **Maintenance and Care:** Maintenance is a critical aspect of ensuring the continued reliability and security of the [Name API Tool]. Our technical team conducts routine maintenance checks to address any potential issues, update security protocols, and optimize system performance. These measures are implemented to guarantee a seamless and secure user experience.

In addition to technical maintenance, we are attentive to user feedback and actively seek insights from our community. Your input is invaluable in identifying areas for improvement, addressing concerns, and shaping the future development of the [Name API Tool]. We encourage users to share their experiences, challenges, and suggestions to contribute to the ongoing refinement of our system.

As we embark on this journey together, rest assured that the [Name API Tool] is not a static solution. It is a dynamic tool that evolves with the ever-changing dynamics of the job market and the technological landscape, with a commitment to serving your needs effectively and efficiently.

10. FAQ

****1. Q: What is the purpose of the [Name API Tool]?****

- A: The primary objective of the [Name API Tool] is to facilitate a seamless and highly effective job matching process by employing cutting-edge AI technologies. It intelligently connects candidates to job offers in a relevant and personalized manner within the Belgian job market.

****2. Q: How is the geographical scope of the [Name API Tool] defined?***

- A: The [Name API Tool] is specifically designed for matching candidates with job offers within the jurisdiction of the Belgian job market.

****3. Q: Is there an age restriction for using the [Name API Tool]?****

- A: The matching functionality is anticipated to perform effectively for applicants satisfying the minimum legal age of work on the Belgian job market.

****4. Q: Can the [Name API Tool] match applicants of any ethnicity?***

- A: Yes, the [Name API Tool] is deemed secure for utilization in matching applicants of any ethnicity.

****5. Q: Is the [Name API Tool] gender-inclusive?***

- A: Absolutely. The [Name API Tool] is designed to be safely employed for matching applicants of any gender.

****6. Q: What data is used in the matching process?***

- A: The information used includes parameters such as job title, employer address, job description, expected skills, required job experience for vacancies, and approximate address, reported skills, job experience from CV, and self-declared interests for candidates.

****7. Q: Are attributes like gender, age, or ethnicity used for matching applicants with jobs?***

- A: No, attributes that could potentially contribute to discrimination, such as gender, age, or ethnicity, are intentionally excluded from consideration in the matching process. Rigorous testing has been conducted to address biases related to gender and age.

****8. Q: How is incomplete or potentially biased data handled in the system?***

- A: Before using the matching model, pre-processing tasks are performed, including the extraction of standardized titles and skills, geolocation based on addresses, and semantic embedding of titles and skills. These measures help in handling incomplete or biased data.

****9. Q: What is the expected lifetime of the [Name API Tool], and how often is it updated?***

- A: While predicting an exact lifetime is challenging, we are committed to long-term support and regular updates to adapt to technological advancements, user needs, and changes in the job market.

****10. Q: How can users provide feedback or report anomalies in the system?***

- A: Users can contribute to the evolution of the system by providing feedback through our platform. If anomalies are identified, we encourage users to report them, and our team will promptly address and rectify any issues to ensure a seamless user experience.

****11. Q: What kind of information does the [Name API Tool] use to match candidates with job offers?***

- A: The [Name API Tool] utilizes a variety of parameters, including job titles, employer addresses, job descriptions, expected skills, required job experience for vacancies, and candidate data such as approximate addresses, reported skills, job experience from CVs, and self-declared interests.

****12. Q: Can the [Name API Tool] be used by recruiters from the public employment services?***

- A: Yes, the [Name API Tool] is designed to cater to users with varying levels of expertise and skills/needs, including public employment service recruiters.

****13. Q: How is user data processed to reduce biases in the system?***

- A: Our system undergoes pre-processing tasks, including the extraction of standardized titles and skills, geolocation based on addresses, and semantic embedding of titles and skills. These measures contribute to bias reduction and enhance the fairness of the matching process.

****14. Q: Is the [Name API Tool] accessible to users outside of Belgium?***

- A: Currently, the [Name API Tool] is designated for matching candidates with job offers within the Belgian job market, limiting its accessibility to users outside this geographical scope.

****15. Q: What dimensions are considered for matching candidates and job offers?***

- A: The matching process involves the consideration of four dimensions: gender, age, origin, and [specific aspect], ensuring a multifaceted analysis for optimal outcomes.

****16. Q: Can users influence the evolution of the [Name API Tool]?***

- A: Yes, user feedback is highly valuable in shaping the future development of the [Name API Tool]. Users are encouraged to share their experiences, challenges, and suggestions to contribute to ongoing improvements.

****17. Q: How is the [Name API Tool]'s accuracy measured?***

- A: The accuracy of the [Name API Tool] is assessed by analyzing how well its recommendations align with users' actual selections, clicks made by recruiters and employers on applicant profiles, and the relevance of the first-N recommended jobs.

****18. Q: What happens if I don't receive matching job recommendations?***

- A: In the rare case that you don't receive matching job recommendations, we recommend enhancing your profile by providing additional details. If the situation persists, it may indicate a lack of jobs in our database that precisely match your unique combination of skills and experiences.

****19. Q: How is data security ensured in the [Name API Tool]?***

- A: The [Name API Tool] is deployed on a secure cloud platform, and access to critical resources is strictly controlled and limited to authorized technical team members. Security measures, including authentication and authorization, are in place to create a controlled and secure environment.

****20. Q: What kind of oversight is implemented in the [Name API Tool]?***

- A: Oversight includes ongoing monitoring and logs keeping for users. Technical measures are in place to enhance user comprehension, explaining each aspect of the system, such as job match, title and skills matching, and expertise levels, to make the output understandable for users.

DISCLAIMER 1

Use Case: HR Chatbot

DISCLAIMER 1

Use Case Description – background information

This use case concerns a human resources (HR) AI chatbot intended primarily to communicate with employees (white collar, blue collar) and other people involved with a particular company (i.e. managers, outsourced staff) in relation to HR-related queries. Based on a prioritization of ideas and solutions, the Group developed a scheme/decision tree and disclaimer that could be relied upon (cf. avatar, interface,...) to implement Article 52 of the Proposal.

Contents

1.	Background information regarding article 52 of the proposal	1
2.	Prototype User Journey (incl. disclaimer)	3
3.	Prototype decision process	4

1. Background information regarding article 52 of the proposal

According to the explanatory memorandum and recitals of the Proposal, per Article 52 of the Proposal, in essence, (i) natural persons should be notified that they are interacting with an AI system, unless this is obvious from the circumstances and the context of use. Also, (ii) natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system. Such information and notifications should be provided in accessible formats for persons with disabilities. Finally, (iii) users, who use an AI system to generate or manipulate image, audio or video content that appreciably resembles existing persons, places or events and would falsely appear to a person to be authentic, should disclose that the content has been artificially created or manipulated by labelling the artificial intelligence output accordingly and disclosing its artificial origin.

Thus, Article 52 of the Proposal is directed to both providers (situation (i)) and users (situations (ii) and (iii))¹.

The focus of the Group has been on the situation (i) – transparency obligations for providers of a chatbot, with the main goal of developing disclaimers in accordance with Article 52 of the Proposal and a related process that allows to decide whether or not to apply the disclaimer.

In such situation, content of Article 52 of the Proposal can be described as it follows:

- ADDRESSEE: providers
- PROTECTED SUBJECTS: natural persons
- TYPE OF AI SYSTEM: AI system intended to interact with natural persons (chatbots)
- RULE - REQUIRED ACTION: inform users that they are interacting with an AI system
- EXECUTION OF ACTION: information must be provided to a natural person in a clear and distinguishable manner at the latest in the time of the first interaction of exposure
- GENERAL EXCEPTION FROM THE RULE: interaction between AI system and users is obvious from the point of view of a natural person who is reasonably well-informed, observant and circumspect, taking into account the circumstances and the context of the use
- SPECIFIC EXEMPTION FROM THE RULE: AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties (exception from exception: unless those systems are available for the public to report a criminal offence).

Thus, Article 52 of the Proposal applies to AI systems intended to communicate with natural persons. The rationale of this provision is to ensure that that natural persons are informed that they are interacting with an AI system, with the exception of AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties.

¹ Surely, in some cases, the roles of a provider and a user can be identified.

The general rule stemming from Article 52 of the Proposal is that providers must ensure that the information is delivered to a natural person interacting with their AI system. In cases where interaction from the AI system is obvious from the point of view of a natural person who is reasonably well-informed, observant and circumspect, taking into account the circumstances and the context of the use, the provider of an AI system is not required to conduct any specific actions with regards to informing the natural person. In the context of the AI Act, natural person who is reasonably well-informed, observant and circumspect is a standard that is not explained in the explanatory memorandum or recitals of the Proposal, but will have to be clarified through future practice and soft law.

From the wording of Article 52 Paragraph 1 of the Proposal, it is reasonable to interpret the obligation of a provider to ensure an interface of the AI system from which it will in a clear and distinguishable manner obvious to a natural person who is reasonably well-informed, observant and circumspect that he/she is interacting with an AI system, thereat taking into consideration particular circumstances and the context of the use. Otherwise, it seems evident that the provider must explicitly deliver the information to a natural person that he/she is communicating with an AI system, also, in a clear and distinguishable manner at the latest in the time of the first interaction of exposure.

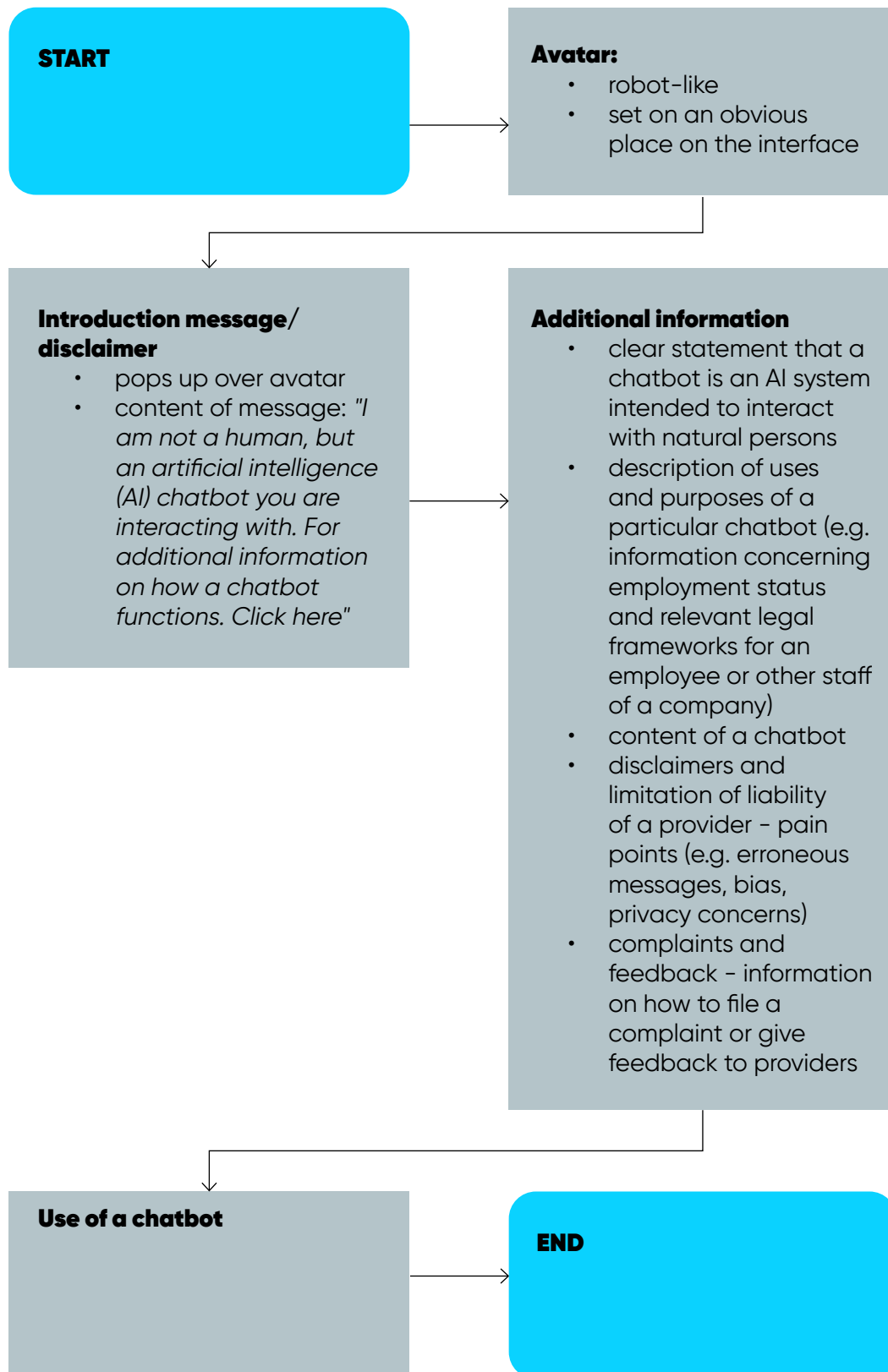
Having all things considered, for AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, subject to appropriate safeguards for the rights and freedoms of third parties, there is no special obligations for providers of AI system to inform natural persons, unless those systems are available for the public to report a criminal offence².

For all other AI systems intended to interact with natural persons, to comply with Article 52 of the Proposal, providers must ensure interface from which the fact that a natural person is interacting with an AI system would be obvious and/or explicitly provide such an information. Good practice is most likely to provide such information to a natural person in writing or through a voice recording in a clear and distinguishable manner at the latest in the time of the first interaction of exposure.

Taking everything in consideration the Group provided a visualisation of an example of requirements/user journey and good practice to satisfy transparency obligation stemming from Article 52 of the Proposal, focusing on a case study of a human resources AI chatbot intended primarily to communicate with employees (white collar, blue collar) and other people involved with a particular company (i.e. managers, outsourced staff) (hereinafter: "the transparency model"). During the development of the transparency model, the Group identified and considered several needs, fears, and obstacles that these (and other) stakeholders may have around the use case (privacy concerns, incorrect information, automation bias, accessibility, presentation). The transparency model combines use of avatar, graphic representation and text and sound on interface to ensure that the information on communication with an AI system is delivered to a natural person using the AI system.

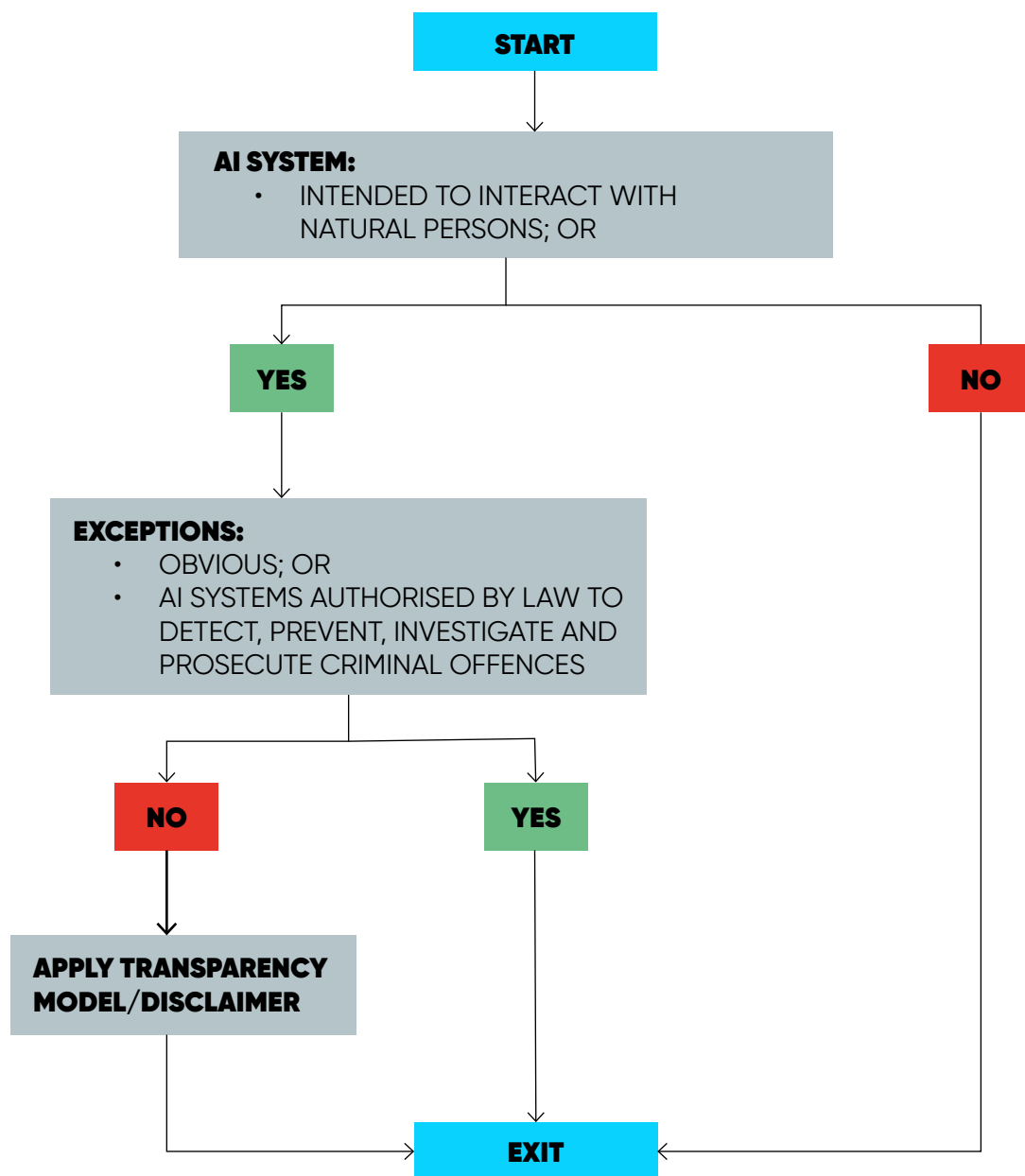
² In the latter case, such AI system is treated as any other AI system intended to interact with natural persons

2. Prototype User Journey (incl. disclaimer)



3. Prototype decision process – Decision tree based on art. 52 AI Act

Further on, the Group also provided a general decision tree for decision-making process on the need for implementing a transparency model to comply with Article 52, §1 of the Proposal:



DISCLAIMER 2

Use Case: Deep fakes in documentaries

DISCLAIMER 2

Use Case Description – background information

- **Type:** Documentary – testimonial of a victim of domestic violence meant for television or online streaming (larger audience).
- **Purpose:** Awareness – raising, inspiring story, prevention, opportunity to educate (pedagogical tool)
- **Legal principles:**
 - In order to preserve anonymity (privacy), the person will be replaced by an AI generated character (deepfake).
 - The purpose of our prototype is to respect the EU AI act requirements related to transparency and keep the authenticity of the message as well as the identification process of the audience which is necessary for awareness – raising and prevention of domestic abuse and violence.
- **Audience:** a large adult audience will watch a program on national TV and the needs of vulnerable viewers are taken into account through trauma – trained professionals, consideration for visually impaired, deaf/hard of hearing audience or viewers with low literacy, ...
- **Permanent watermark:** the transparency requirement and icon needs to be accessible by all audiences at all times.

Contents

1.	Prototype decision process	1
2.	Prototype: Icon (AI-generated)	1
3.	Prototype: Information Notices	2
4.	Prototype: Deep Fake Information Policy	3

1. Prototype decision process: Triple A Matrix (AAA) for decision-making

Based on the audience, the privacy protection of the person and the clear understanding of the transparency requirements of the EU AI ACT, we created a Triple A Matrix (AAA) with scoring as a tool to select the best characteristics for our prototype.

The AAA Matrix consists of two sets of elements. On the one hand (vertical axis), there are tools that can be used to achieve transparency regarding the use of deep fakes (i.e. an icon, an information policy, an oral warning by a presenter, a QR-code, a trigger warning and a permanent disclaimer). On the other hand (horizontal axis), there are three features/characteristics (accessibility, anonymity and apprehension) that these tools can have which will determine their suitability in particular use cases. By awarding scores (between 0 and 3) for each feature/characteristic per tool and by adding up these scores, you can determine which type of tool is most suited to facilitate transparency in your use case.

AAA Matrix	Accessibility <i>Clear and distinguishable manner</i>	Anonymity <i>Safeguard rights and freedoms of third parties</i>	Apprehension <i>Information about the disclaimer shall be provided in a clear manner</i>	Total Scores
Icon	2	2	2	6
Information Policy	2	2	2	6
Audio Presenter	2	2	2	6
QR code	1	2	1	4
Trigger warning ¹	0	0	1	1
Permanent disclaimer	1	2	1	4

Matrix (scores): 0 not relevant, 1 Somewhat relevant, 2 Very Relevant

RESULT: As the Icon, Information Policy and an Oral warning by a Presenter have gathered the highest score, we decided to further elaborate these tools.

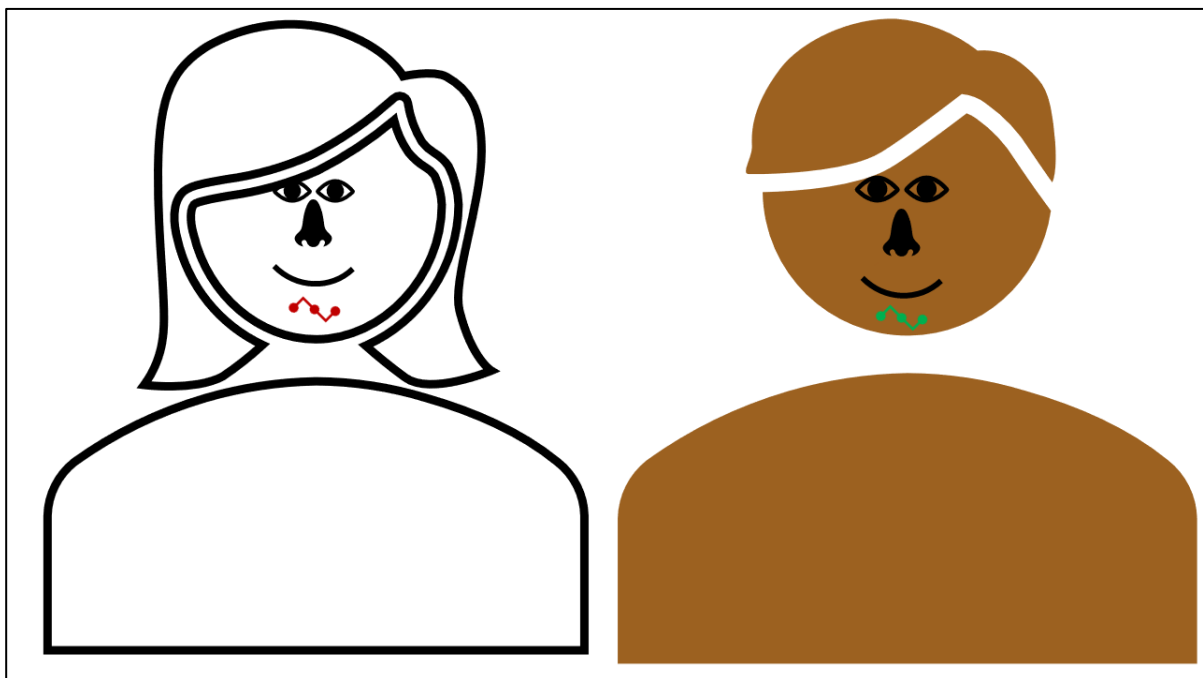
2. Prototype: Icon (AI-generated)

Requirements for the watermark icon prototype for deep fakes

- Part of immutable infrastructure
 - The idea is to add a visual icon to the deep fake character itself, to make sure it is always visible, even when e.g. the format changes, pieces are cut off or the screen is not wholly visible. In any circumstance where the audience sees (part of) the deep fake character, the audience should also be able to see the visual icon.

- Respectful design
- No political connotation
- Standard template ready for implementation
- Adaptable on all skin types, types of faces (beards...)
- [Color contrasts](#) where needed (conformity with accessibility legislations and standards)²
- Same position, easy to find
- Recommend to standardise icon (e.g. ISO graphical symbols³).

Illustrative example: the icon (the coloured line with dots) could be placed on the face/ chin of the deep fake, using colour contrasts to make the icon visible on any background/ face



3. Prototype: Information Notices

[to be made available in the language(s) of the audience]

1. **Oral warning by the presenter prior to each deep fake testimony**

- Before we proceed, please be advised: the testimony you're about to witness uses a computer-generated representation, not an actual person but a so-called 'deep fake'. Any resemblance to real individuals is purely coincidental and unintended. Sensitive viewers, especially those who might recognize similarities with someone they know or who have lived similar experiences, should exercise caution. Please visit the link in the credits or scan the QR code to read more about our use of deep fakes.

² [European Accessibility Act](#) and [Web Content Accessibility Guidelines \(WCAG\)](#)

³ [ISO Graphical symbols](#)

- 2. Short warning to be shown next to the deep fake during the testimonial**
 - This is a visual representation, not the actual witness. For more info, visit [WebsiteURL.com/DeepfakePolicy]. [or QR code]

- 3. Notice in the credits**
 - Some individuals shown in this documentary are visual deepfake representations to protect their identities. You can recognize such deep fake presentations by the icon [ICON] attached to the image. Any resemblance to real individuals is purely coincidental and unintended. Learn more at [WebsiteURL.com/DeepfakePolicy].

4. Prototype: Deep Fake Information Policy

[to be made available in the language(s) of the audience]

Note: the policy is to be drafted in multiple layers – only text marked as layer 1 is visible at first – the text expands upon clicking the title

We use deep fakes to protect the identity and the privacy of the persons testifying in our program. Any resemblance to real individuals is purely coincidental and unintended. [layer 1]

Here's everything you need to know about our use of deep fake technology. [layer 1]

We Use Deep Fakes to Protect Vulnerable Witnesses [layer 1]

- To keep the identities of some witnesses confidential, we apply deepfake technology. This strategy allows us to showcase authentic testimonies without revealing the real faces of those narrating their experiences.

Deep Fakes are entirely computer generated and do not resemble the actual witness [layer 1]

- Deep fakes are computer-generated visuals that mimic human appearances and expressions. While they can serve various purposes, our exclusive intention is protective and truth-preserving.
- Our deep fakes are crafted not to resemble the actual witnesses, ensuring complete discretion.

Deep Fakes are clearly recognizable [layer 1]

1. Visual Indication: [icon] [layer 1]

- The icon / watermark above accompanies each deep fake representation [in this documentary], helping viewers discern between actual individuals and computer-simulated ones.
- For more information about the use of these watermarks, please see here [/link].

2. Narrative Acknowledgement [layer 1]

- Before a deep fake representation appears, our presenter provides an oral warning.

3. Disclaimer [layer 1]

- Our deep fakes are always accompanied by a short disclaimer.

Our Deep Fakes are ethically generated by [Company/Product] [layer 1]

- We have utilized [technology X] to produce the deep fakes presented in this documentary. [Technology X] has undergone rigorous scrutiny to ensure there are no privacy infringements and that its application aligns with ethical standards.
- For a comprehensive overview of [Technology X], the generation of deep fakes and its commitment to privacy, please visit [TechnologyXPrivacyURL.com].

No separate use or modification of our deep fakes

The deep fakes in this documentary are integrated with a specific icon to ensure clarity and transparency. While technology has its limits, we strictly prohibit any alterations or removal of these markers. We urge audiences and platforms to respect the authenticity of our content and not engage in unauthorised modifications or misuse.

Reference List

- [European Accessibility Act](#) and [Web Content Accessibility Guidelines \(WCAG\)](#)
- [Accessibility statements generator](#)
- [A Meta-Analysis of the Effects of Trigger Warnings, Content Warnings, and Content Notes](#)
- [Latest version of the EU AI Act to date -reference for this policy prototype](#)
- [ISO Graphical symbols](#)