# INSTRUCTIONS FOR USE

# Dynamic Anamnesis Module

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Consult Instructions for Use

bsi ISO/IEC 27001 2022 Information Security Management CERTIFIED

Dynamic Anamnesis Module is in compliance with MDR 2017/745.

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# 1. Intended purpose

The Dynamic Anamnesis Module by Bingli is designed to integrate with other Bingli modules. It collaborates with the patient-facing portal to generate relevant questions for patients and interfaces with the HCP dashboard to present differential diagnoses and calculated scores.

Importantly, this module serves a supportive role, aiding HCP by providing preliminary differential diagnoses that help frame further clinical assessment. It is crucial to note that the diagnoses provided by this module are not final and must be considered by HCPs within the broader context of a patient's clinical evaluation and additional diagnostic testing.

## 1.1 Indication for use

The Bingli Dynamic Anamnesis Module is designed to support healthcare professionals during their patient assessment, by providing a list of potential diagnoses based on information supplied by patients, as well as the information itself.

The Bingli Dynamic Anamnesis Module is indicated for patients where a survey-based anamnesis can be appropriately and safely utilized. The patient population is any type of patient who falls within the specified dataset and that is scheduled or non-scheduled for a medical consultation or requiring medical/surgical intervention, screening or follow-up.

Patients who are unable to complete the survey independently, due to physical, cognitive, or technological challenges, can still use the device when they receive the necessary assistance. If assistance is not available, the survey cannot be completed, and the patient should be assessed through traditional consultation methods as if the software were not utilized.

## 1.2 Contra-indications

The use of the Bingli Dynamic Anamnesis Module is not indicated for urgent medical conditions requiring immediate clinical intervention or for patients with physical, cognitive, or technological challenges that do not have any assistance.

## 1.3 Patient target group

The intended patient population is any type of patient who falls within the specified dataset (see above) and that is scheduled or non-scheduled for a medical consultation or requiring medical/surgical intervention, screening or follow-up.

Patients who are unable to complete the survey independently, due to physical, cognitive, or technological challenges, can still use the device when they receive the necessary assistance. If assistance is not available, the survey cannot be completed, and the patient should be assessed through traditional consultation methods as if the software were not utilized. There are no specific restrictions on age, gender or ethnicity.

The Bingli Dynamic Anamnesis module is designed for patients where a survey-based anamnesis can be appropriately and safely utilized. It is important to note that this device is not suitable for urgent or emergent medical conditions that require immediate clinical intervention or diagnostics, as the survey process inherently involves a time delay that could

be detrimental in acute scenarios. However, should the device be used in urgent conditions—whether due to error or necessity—it is designed to still function and provide diagnostic support for HCP's.

### 1.4 Intended users

Bingli's software is designed for healthcare professionals, including but not limited to general practitioners, specialists, and other healthcare providers in hospital settings, who will interpret the data provided by patients and utilize it for clinical decision-making.

While the complete software is intended for direct use by healthcare providers to support patient care, the Dynamic Anamnesis Module specifically functions within the Bingli software ecosystem. It is primarily utilized by other modules to generate dynamic content and support the broader diagnostic and therapeutic functionalities offered by the Bingli system.

### 1.5 Limitations

Patients who are unable to complete the survey independently, due to physical, cognitive, or technological challenges, can still use the device when they receive the necessary assistance. If assistance is not available, the survey cannot be completed, and the patient should be assessed through traditional consultation methods as if the software were not utilized. There are no specific restrictions on age, gender or ethnicity

The module is a medical device software designed to operate independently of the environmental conditions in which it is used. Its functionality remains unaffected whether the patient is at home or in the waiting room of a healthcare facility. The patient adapts to various platforms, allowing patients to comfortably respond to questions using their preferred device, such as smartphones, tablets, or computers. However, a working internet connection and up-to-date browser (see Section 5 on Minimum Requirements) are necessary.

## 2. Warnings and precautions

The Bingli Dynamic Anamnesis Module is designed as a support for the healthcare professional and is no substitute for the clinical evaluation a medical expert conducts. It always provides a list of potential diagnoses (differential diagnosis) with its likelihood and does not provide a final medical diagnosis. Its assessment is based on the information that is provided by the patient, so inaccurate or false answers can lead to an incomplete or incorrect differential diagnosis. The healthcare professional is responsible for integrating the hypothesis.

The module is a medical device software designed to operate independently of the environmental conditions in which it is used. Its functionality remains unaffected whether the patient is at home or in the waiting room of a healthcare facility. The patient facing portal module adapts to various platforms, allowing patients to comfortably respond to questions using their preferred device, such as smartphones, tablets, or computers. However, a working internet connection and up-to-date browser (see Section 5 on Minimum Requirements) are necessary.

It is important to note that this device is not suitable for urgent or emergent medical conditions that require immediate clinical intervention or diagnostics, as the survey process inherently involves a time delay that could be detrimental in acute scenarios. It is also not intended as a diagnostic tool.

# 3. Specification of the clinical benefits to be expected

The Bingli Dynamic Anamnesis Module was conceived as a tool to assist HCPs with the diagnostic process, both in primary and secondary care. Displaying a list of potential diagnoses together with the current health complaint can help physicians generate more diagnostic hypotheses. Such a design might mitigate the tendency to fixate on a narrow set of diagnoses early in the clinical encounter, broaden the spectrum of hypotheses, and serve as a reminder for physicians to consider other possibilities Mitigating diagnostic uncertainty is integral to addressing both the clinical needs of patients and their anxieties over their condition.

# 4. Performance characteristics

The Bingli Dynamic Anamnesis Module demonstrates high accuracy (of at least 90%) in generating differential diagnoses.

It is proven to be able to reliably and robustly generate questions and differential diagnoses based on input of symptom information as indicated by the verification and validation testing related to the technical performance of the system. Use of the device in routine clinical setting will aid in gathering data to support and confirm the effectiveness of generating differential diagnoses and to further improve the technical performance of the system. Bingli will continue to gather data through post market surveillance and post-market follow up activities as planned to also assess the impact of the technical performance with the clinical relevance and clinical safety and performance of the device. The Bingli Dynamic Anamnesis Module complies with current knowledge and technological standards, is suitable for its intended purpose and users, and offers substantial clinical benefits, outweighing potential adverse effects. The Bingli Dynamic Anamnesis Module does not compromise the clinical condition or safety and health of the patients and/or users when used as intended and as described in this document.

# 5. Minimum requirements

## 5.1 Software

As a web-based application, no specific software requirements are necessary. However, the latest browser versions should be used to guarantee the best experience. The 2 most recent versions of the following browsers will be supported throughout the lifetime of the device:

- Chrome
- Edge
- Firefox
- Safari

The patient facing portal module adapts to various platforms, allowing patients to comfortably respond to questions using their preferred device, such as smartphones, tablets, or computers.

### 5.2 IT network characteristics

The user only requires access to a stable internet connection to use the web application. There are no specific internal network bandwidth or configuration requirements.

Users are responsible for maintaining the confidentiality and security of their login credentials. The use of multifactor authentication (MFA) is recommended to enhance security when accessing the platform.

## 6. Residual risks and undesirable side-effects

When considering the security-related risks, no residual risks related to the Dynamic Anamnesis Module were identified, which is why the top level risks will be taken into account. After implementation of mitigation measures, 2 top level risks remain at medium severity level:

- Cybercrime: information theft (sensitive personal information is stolen)
- Rogue staff intellectual property (IP) theft (key staff member leaves the company and steals IP)

However, no sensitive information can be accessed via the Dynamic Anamnesis Module because it is isolated and functions via API with other modules, so no patient or personal information is stored. This also means no information is compromised if IP theft is committed, as this would only affect the company and not jeopardize any patient data.

After verification of implementation of risk control measures, 4 medium-level residual risks remain:

- Information is parsed wrongly from input (potential incorrect or incomplete diagnosis)
- Incorrect or incomplete differential diagnosis (HCP is misguided because of proposed differential diagnosis)
- Irrelevant questions for actual symptoms (incomplete information for HCP)
- Engine can only analyze 1 disease, may lead to incorrect or incomplete diagnosis when patient has multiple complaints (HCP is misguided because of proposed differential diagnosis)

This underlines the importance of an independent evaluation of the provided information by the healthcare provider, using their clinical expertise to formulate a final diagnosis. The Bingli Dynamic Anamnesis Module is designed as a support for the healthcare professional and is no substitute for the clinical evaluation a medical expert conducts. It always provides a list of potential diagnoses (differential diagnosis) with its likelihood and does not provide a final medical diagnosis. Its assessment is based on the information that is provided by the patient,

so inaccurate or false answers can lead to an incomplete or incorrect differential diagnosis. The healthcare professional is responsible for integrating the hypothesis.

## 7. Requirements on training and qualifications of the user and/ or other persons

No formal training or qualifications are necessary. Bingli personnel will provide an onboarding training to healthcare professionals that will use the Bingli software. The instructions for use and user manual should be read before use of the software and can be used as a reference.

## 8. Information on installation and updates

The software does not require any installation as it is web-based. The device will be updated automatically via the web. The latest version will be made accessible in the browser of the user by browsing in the software.

## 9. Consult a healthcare professional

Lay person users should consult a healthcare professional in case they have any questions regarding the use of the Bingli software in the standard care pathway. There are no specific difficulties expected with the use of the Bingli Dynamic Anamnesis Module because it only shows questions to lay persons and never a differential diagnosis or advice. In urgent or emergent medical conditions that require immediate clinical intervention or diagnostics or rapidly deteriorating situations, a healthcare professional should be contacted immediately.

## 10. List of symbols

| | |
|---|---|
|  | Manufacturer |
|  | Date of manufacture |
|   | Medical device |
|   | Unique device identifier |
|  | Conformité Européenne - 2797 (BSI number) |
|  | Consult instructions for use |
|  | Translated version |

## 11. User manual

The user manual can be publicly accessed via https://www.bingli.eu/

## 12. Notice

Any serious incident that has occurred in relation to the device should be reported to Bingli at info@mybingli.com and the competent authority of the Member State in which the user/ and or patient is established.

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These instructions for use are written by Bingli. Any comments or questions can be communicated to Bingli via email to info@mybingli.com.

The original instructions for use are written in English. The translated versions are accompanied by the symbol on the first page.

A paper version of the instructions for use can be requested via email info@mybingli.com. Within 7 calendar days of receiving the request, the paper format will be sent (by regular mail).

Website of the manufacturer: https://www.bingli.eu/

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