



INSTRUCTIONS FOR USE

Dynamic Anamnesis Module



Bingli NV
Lange Gasthuisstraat 29
2000 Antwerpen, Belgium



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Table of Contents

1. Intended purpose	3
1.1 Indications	3
1.2 Contra-indications	3
1.3 Patient target group	3
1.4 Intended users.....	4
2. Warnings and precautions	4
3. Specification of the clinical benefits to be expected	4
4. Performance characteristics	5
5. Minimum requirements	5
5.1 Software	5
5.2 IT networks characteristics.....	5
6. Residual risks and undesirable side-effects.....	5
7. Requirements on training and qualifications of the user and/ or other persons	6
8. Information on installation and updates	6
9. Consult a healthcare professional	6
10. List of symbols	6
11. User manual.....	7
12. Notice	7

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 Indications

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.

The Bingli Dynamic Anamnesis is designed for patients where a survey-based anamnesis can be appropriately and safely 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 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.

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 following clinical benefits can be expected from the Bingli Dynamic Anamnesis module:

- **Personalized Question Generation:** The Bingli Dynamic Anamnesis module dynamically generates anamnestic questions tailored to the patient's specific medical history and presenting symptoms, in the patient's own language. This personalized approach ensures that relevant information is captured, leading to more comprehensive assessments, with patients being able to better express their medical issue, making them better prepared for their consultation with the HCP.
- **Efficient Clinical Decision-Making:** By generating differential diagnoses and automating the calculation of scores based on anamnestic data, the Bingli Dynamic

Anamnesis module helps to streamline the diagnostic process, allowing healthcare providers to make better-informed decisions, ultimately improving patient outcomes.

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 network should have an internal connection of at least 3Mbps, no specific security measures are required from the user other than keeping the login data secure (e.g., by using multifactor authentication).

6. Residual risks and undesirable side-effects

No residual security risks related to the Dynamic Anamnesis Module were identified, with several mitigation measures in place to minimize top level cyber security risks. Because the Dynamic Anamnesis Module is isolated from other modules in the Bingli system, no personal

or medical information can be extracted from the module. Other residual risks range from input being parsed wrongly from input, over irrelevant questions being asked for current symptoms to an incomplete 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.

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
	Consult instructions for use



Translated version



Weblink

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.

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 delivered.



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

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