

Medication monitoring module — Instructions for Use

Publication note

The MDR certification application is in progress. No MDR certificate has yet been issued for this module. The CE 2797 entry in the source symbol table does not confirm certificate issuance.

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This note describes the publication status; the instructions follow on the next page.

Instructions for Use: Bricks Huisarts Medication Monitoring Module

Product information	Details
Product	Bricks Huisarts Medication Monitoring Module
Software version	v.1.0
UDI	(01)08720892556301 (11)260912 (8012)v.1.0
Date of manufacture	12 September 2026
Manufacturer	Tetra B.V., Begijnekade 13, 3512 VV Utrecht, the Netherlands
Intended users	General practitioners using Bricks Huisarts in Dutch primary care
Language	English. A Dutch version (Gebruiksaanwijzing) with the same content is available.
Document identifier	MDR-REC-09-01-02-REC_IFUS-R1-1EB6248D
IFU revision and issue date	Revision 2, issued [date of release]. The IFU revision is the same for the Dutch and the English version and is distinct from the software version.

This product is a medical device. Read these instructions before using the medication monitoring module. Interface labels are quoted in Dutch, as displayed in Bricks Huisarts.

These instructions apply to module version v.1.0. If in doubt, ask Tetra Support to confirm the module version installed for your practice and the corresponding instructions for use. The module version and UDI are not available in a separate identification screen in the software.

1. Intended purpose and conditions of use

1.1 Intended purpose

The Bricks Huisarts Medication Monitoring Module analyses prescribed medications in conjunction with patient-specific health information within primary care. The module utilizes up-to-date data from the G-Standard to identify and alert on potential risks such as allergic reactions, drug interactions, and dose-related risks covered by applicable MFB rules. This system is designed to enhance the safety and efficacy of pharmacological treatments by presenting relevant alerts and recommendations directly to the general practitioner during the prescribing process.

1.2 Intended users

General practitioners. The module is used by the prescriber who takes the prescribing decision. No training beyond the general practitioner's professional qualification is required;

Tetra Support provides instruction on request (section 9).

1.3 Intended patient population and patient selection

Patients undergoing pharmacological treatment with their general practitioner, regardless of their specific conditions. The module is intended for patients (i) receiving pharmacological treatments from (ii) the GP, regardless of the nature of their medical conditions and (iii) for whom detailed patient data exist, such as medication history and known health problems.

1.4 Medical conditions and indications

Conditions and indications that can be treated by a general practitioner with medication in a primary care setting. These include, but are not limited to, acute illnesses such as colds, flu and mild infections; chronic conditions such as hypertension, diabetes and asthma; mental health issues such as anxiety and depression; and minor injuries such as sprains and small cuts.

1.5 Use environment

General practices, for prescribing medication in an out-of-hospital care setting, within the Bricks Huisarts GP information system.

1.6 Contraindications

- The module is not suitable for use in acute or inpatient care settings, where the setting and requirements differ significantly from general practice.
- The module is not optimised for emergency situations requiring immediate medical decisions without comprehensive medication monitoring. Do not delay necessary emergency care for the software.

2. How the module works

The module combines the prescription you are writing with the patient information recorded in Bricks Huisarts and applies the medication monitoring content of the G-Standaard. It covers allergies, contraindications, age, dose-dependent MFB checks, duplicate medication and interactions, and shows special characteristics of a medicine where these are registered in the G-Standaard for that medicine.

Division of responsibility. The clinical content of the checks, including the medical-pharmaceutical decision rules (MFBs), the warning texts and the advice, is determined by Z-Index in the G-Standaard. Your practice uses the G-Standaard under its own licence with Z-Index. Tetra implements this content in Bricks Huisarts, supplies it with the patient and prescription data, and determines how the resulting warnings are presented to you and in what order. Tetra does not author or change the clinical content of the rules.

The module covers the medication monitoring functions within Bricks Huisarts. It is not a description of all functions of the GP information system.

3. Expected clinical benefit and performance characteristics

3.1 Expected clinical benefit

The module supports you in identifying registered interactions, contraindications and other medication risks covered by the implemented G-Standaard checks, at the moment you assess a prescription. This benefit depends on the patient's medication and clinical information being complete and current in the record. The warning supports your decision; it does not choose the treatment for you, and the module is not a guarantee against medication-related harm.

3.2 Performance characteristics

Characteristic	Description
Content source	The medication monitoring content of the G-Standaard of Z-Index, as installed in your Bricks environment.
Checks performed	Allergies (coded registrations), contraindications, age, dose-dependent MFB checks, duplicate medication, interactions and special characteristics, as far as the G-Standaard contains rules for them.
Moment of the check	The check runs on every change to the prescription draft. The prescription cannot be completed with Recept afhandelen while the check is running, or before a warning that requires release has been released with Vrijgeven .
Correctness of implementation	The implementation of the MFB rules is verified against the test cases that Z-Index publishes for the G-Standaard. The expected result for each applicable test case is the outcome specified by Z-Index.
Content updates	Z-Index publishes G-Standaard updates periodically. Tetra builds each update into the Bricks environment and rolls it out to the practices. Tetra Support can tell you which G-Standaard release is installed in your practice.
Dose monitoring	Only where the applicable MFB rules contain dose-related checks. There is no general check of every entered dose against normal or maximum doses (section 6).
Expected lifetime	One year per software version. Within that period Tetra makes a new version available, which must be installed to keep the security and the medication monitoring content current.

4. Before prescribing

1. Check that you have selected the correct patient. The patient's name is shown in the title of the prescription dialog; an individual warning line does not repeat it.
2. Review the medication the patient actually uses, including medicines prescribed elsewhere and as-needed use. Check the recorded prescriptions and their end dates; a chronic label or a visible profile entry alone does not establish that the medicine is included in every check (section 7.1).
3. Check the relevant recorded allergies, diagnoses, age and other patient information. Allergies must be registered in coded form to be checked (section 7.2). Where a rule

depends on renal function or another laboratory value, check that the value is available, current and recorded as a number (section 7.3).

4. Enter the intended medicine, dose, frequency and quantity accurately. Select a reason for prescribing where the interface asks for it. Such information may determine which rule or advice applies.
5. Check any information that is missing, inconsistent or uncertain. The module cannot compensate for unrecorded medication use or incomplete clinical information.

5. Read and handle the warnings

5.1 Review the warning list

After entering or changing a prescription draft, review the **Waarschuwingen** list. Read every line. More than one warning can apply to the same prescription; acknowledging one does not demonstrate that you have reviewed the others.

Presentation in the prescribing interface	Meaning for your interaction
Red warning requiring Vrijgeven	Review the warning before choosing whether to change the prescription or release the draft to continue.
Orange message: interaction leaflet, expired vasthouden tot (hold-until) date or ASTMA/COPD splitting	Read the message and consider its information. This line does not require its own release.
Black warning, such as Pseudo dubbelmedicatie	Read the warning even though it has no mandatory release. Black text does not mean that the information is irrelevant. A pseudo-duplicate warning is not the same as a Dubbelmedicatie warning; do not stop an intended therapy on that basis alone.

All MFB warnings are shown in red with the same priority, whatever their clinical weight. The red colour tells you that release is required. It does not tell you how serious the risk is for this patient. Read the message rather than relying on colour or position in the list.

A prescription without a warning that requires release is completed automatically when you close the consultation. Orange and black warnings therefore do not stop the workflow. Read them before you close the consultation.

In a prescription with several lines, the list does not show which line raised a warning. Identical warnings are shown once, and one release applies to all lines. Use the substance names in the warning to identify the line it concerns before you change or release anything.

If no warnings apply, the Waarschuwingen section is not shown. The screen then looks the same as when a check has not run. The absence of the section is not a confirmation that the prescription was checked or that it is safe. If an error message appeared, if the system responded unusually, or if you expected a warning that is absent, treat the check as unconfirmed (section 8).

There is no practice-level setting to disable alerts or protocols. Automatic rules nevertheless apply for protocol replacement and the G-Standaard show flag. Withdrawn protocol 251 is skipped and identical alert texts are merged.

5.2 Open the available details

Open the details of every red warning before you release it. The detail view provides the full message, advice and protocol information.

The short title is limited to 80 characters and can be cut off mid-word. Some characters are shown as a question mark, for example **?-Blokkers**. The full text in the detail view is complete; read it rather than the title.

Some warning types have no additional handling advice, and a detail view may add no information to the line. That does not cancel the warning. If you cannot interpret the message or suspect missing or incorrect information, use the relevant clinical reference and contact Tetra Support.

5.3 Decide and complete

- If the prescription needs to change, amend or remove the relevant line and review the warnings for the changed draft.
- If you choose to continue with a draft that requires release, select **Vrijgeven** after reviewing the warnings and making your prescribing decision. Then use **Recept afhandelen** to complete the prescription.
- Release allows the workflow to continue. It does not certify that the treatment is safe, correct the patient record, or perform an advised treatment change for you.
- When a draft is changed, review the current warnings again. Do not rely on an earlier review or a release state carried from an existing prescription as proof that the edited prescription has been clinically checked.
- For a repeat prescription, the check runs again with the patient data at that moment. Assess the warning again; do not apply a decision made on an earlier occasion without checking whether renal function, comedication or diagnoses have changed.
- Record clinically relevant decisions and follow-up in the patient's record using the normal clinical workflow. A release is not a substitute for that record.

5.4 Warnings are assessed by the prescriber

Warnings are to be assessed and released by the prescriber who takes the prescribing decision. Do not let a practice assistant or another person release warnings on your behalf, including when a repeat prescription is prepared for you. Bricks Huisarts records the account that was logged in when a warning was answered; it cannot distinguish who was at the screen. Do not share your account and do not leave a session open for others to use.

6. Understand what is checked about the dose

Dose monitoring is performed where the applicable G-Standaard MFB rules include dose-related checks. These rules may use daily or weekly dose in relation to patient or medication context, such as renal function, age or an interaction.

The module does not perform a general check of every entered dose against normal or maximum doses. Where an applicable MFB produces a message with dose advice, read that advice and its conditions.

The status messages **geldige dosering**, **ongeldige dosering** and **dosering wordt gecontroleerd** concern the entered dosage notation. They do not mean that the dose is clinically appropriate for this patient or that it has passed a general overdose or underdose check.

Check the intended dose, unit, frequency, duration and relevant patient factors yourself using appropriate clinical information. **The absence of a warning does not confirm that the prescribed dose is appropriate.**

7. Limitations, warnings and residual risks

The following limitations remain relevant even when the software is functioning as designed.

7.1 A visible medicine is not necessarily included in every check

For MFB checks using the current-medication selection, including the interaction selection in function 19, the implementation uses the prescription end date. Eligible prescriptions are included through that date; prescriptions whose end date is before today are excluded from that selection. The date is derived from the prescription and the estimated supply or use duration, not from a separately verified end of therapeutic use.

Actual use can continue after the recorded end date, particularly with as-needed use or gaps between repeat prescriptions. A **chronisch** label, a profile row or its colour does not by itself show whether a medicine is included in an MFB check. Prescriptions without a G-Standaard medicine code are also outside that MFB selection.

Duplicate-medication checking uses a different selection, including a margin in the documented implementation. Therefore, a duplicate-medication warning does not prove that the same medicine was included in the MFB interaction check.

Confirm actual medication use and correct inaccurate information through the normal medication record and prescribing workflow. Do not create an artificial prescription or alter dates solely to force a warning. Where actual use is not represented by the monitored selection, assess the relevant interaction using an appropriate clinical reference. Contact Tetra Support when the record or its displayed status is unclear.

A later prescription may trigger a warning when the relevant medicines are then included. This does not protect the preceding interval. Do not assume that another care provider's check will necessarily identify a missing interaction.

7.2 Only coded allergy registrations are checked

Allergy checking uses allergies registered in coded form, linked to a G-Standaard product, substance or group. An allergy or intolerance written as free text elsewhere in the record, for example in the journal, an episode text or a memo, is not checked. Allergies recorded before

coded registration was required, or received by conversion from another information system, may not be registered in coded form and are then not checked. Register known allergies in coded form, check older and converted allergy entries, and check free-text information yourself when you prescribe.

7.3 Laboratory values

- Rules that depend on a laboratory value, such as renal function, use the most recent value recorded as a number. A result recorded only as text is not used as a value by the rules.
- When no usable value is recorded, the renal function rules of the G-Standaard produce a warning that asks for the value. Record or look up the value and assess the dose yourself; do not release such a warning as if the dose had been checked.
- Some rules accept a value only up to a maximum age defined in the G-Standaard; other rules use the most recent value regardless of its age. Check that the value is recent enough for your decision.
- The date of the result used is not shown in the alert. You can inspect the MFB decision rule and its applicable recency condition; consult the measurements screen for the result date and further details.
- For a recency question, the module calculates age from the measurement date relative to today. An over-age result or a result without a date is treated as not recent. The applicable G-Standaard protocol then determines the next step, commonly advice to obtain a new measurement. The time limit varies by rule.

7.4 Scope of the G-Standaard

The module warns only about risks that the G-Standaard describes. A risk that is not described in the G-Standaard, or that depends on information not recorded in the patient record, produces no warning. The module does not replace your own assessment of the prescription.

7.5 Other limitations and residual risks

- Missing, outdated or incorrectly coded patient and medication information can cause relevant warnings to be absent or inappropriate warnings to appear.
- An error in the G-Standaard content itself results in an incorrect or missing warning. Report a suspected content error to Tetra Support; Tetra forwards questions about the clinical content to Z-Index.
- Several simultaneous or repeated warnings can be overlooked or acknowledged without being understood. Review their content individually.
- A brief title may not contain the complete warning or an important exception. Read the available detail text.
- A successful input format check, a completed prescription or a released warning is not a clinical safety conclusion.
- The module is decision support, not a replacement for your professional judgement or a guarantee against medication-related harm.

8. If monitoring is unavailable or appears incorrect

If a check fails, does not complete, or appears inconsistent with the recorded medication and clinical data, treat the affected check as unconfirmed. Do not interpret an empty or unchanged warning list, or the absence of the Waarschuwingen section, as evidence that the prescription is safe. Apply the practice's clinical continuity procedure and use appropriate clinical information while the issue is investigated. Do not delay necessary emergency care while waiting for the software.

A red warning starting with **Niet uitgevoerd!** means that a rule could not be completed. The warning requires release like any other red warning, but the check it names has not been performed.

If **Fout bij uitvoeren** appears, the check of the current draft has not completed and technical error information is sent to Tetra Support. If you added or changed a line, or opened a stored prescription for editing, the prescription cannot be submitted until every line has been checked successfully. If you only removed a line, the remaining lines that were checked earlier can still be completed; their earlier warnings and release status still apply. Check the complete prescription again once the module works normally. Until then, follow the practice continuity procedure. Assessment using another clinical reference does not remove the block in Bricks.

Messages and errors

Message	Meaning	What to do
Niet uitgevoerd!	A rule could not be completed, for example because the weight, body surface area, unit or a dose conversion it needs is not available.	Treat that check as not performed; check the medication and the dose yourself before you release the warning.
Fout bij uitvoeren	The check did not complete because of an error.	Treat the check as unconfirmed; check again later or use a clinical reference; contact Tetra Support if it recurs.
ongeldige dosering	The dosage notation entered cannot be interpreted.	Correct the notation.
geldige dosering	The dosage notation can be interpreted.	This is not a clinical assessment of the dose (section 6).
dosering wordt gecontroleerd	The dosage notation is being processed.	Wait for the result before continuing.
Pseudo dubbelmedicatie	A possible overlap between medicines, shown separately from and with lower priority than a Dubbelmedicatie warning.	Read the warning and decide; do not stop an intended therapy on this basis alone.

Contact **Tetra Support** with the software version, if known, the time, the affected function, the expected and observed behaviour, and any error message. Use the agreed secure

support route if patient information is needed; do not send patient-identifying information by ordinary email.

9. Installation, access and maintenance

The module is integrated into Bricks Huisarts and has no separate end-user installer or calibration procedure. Use the Bricks installation and configuration supplied for your practice. Tetra manages the software and the G-Standaard data updates through its delivery process. Opening a patient record is not a guarantee of a live connection to the latest external G-Standaard release.

Use an authorised account, protect access to the workstation and follow the practice's security requirements. Log out or lock the workstation when leaving it unattended. Do not disable security controls or open network access without the practice administrator's instructions.

Technical requirements

The minimum system requirements are a dual-core processor, 4 GB RAM and a 10 Mbps connection. A stable connection and a correctly configured Bricks environment are required. A screen resolution of 1920 × 1080 or higher is recommended. The module is used through Bricks Huisarts in a web browser. Use a current version of a common web browser, such as Microsoft Edge, Google Chrome, Mozilla Firefox or Safari, on an operating system version that is still supported by its supplier, and install their security updates. Do not use browser extensions that modify web pages, such as ad blockers or translation tools, during a Bricks session; they can prevent warnings from being displayed correctly. The required platform and network configuration must match the Bricks deployment supplied by Tetra; see the [Bricks support information](#).

Before first use and after relevant installation or configuration changes, check login, access to the intended patient record and availability of the prescribing and warning functions. If a check fails or warning details cannot be displayed, contact Support before relying on that function. Ask Support for instruction if you are unfamiliar with reviewing and releasing warnings.

Updates

The available clinical knowledge depends on the installed G-Standaard data and the implemented rules. Do not postpone a software or G-Standaard update that Tetra makes available, and do not install external rule updates yourself. Follow Tetra's update instructions and confirm that the system is available again after an update. Report suspected outdated or incorrect information to Tetra Support.

10. Symbols on the label

Symbol	Meaning
Factory symbol	Manufacturer
Factory symbol, outline	Date of manufacture
UDI	Unique device identifier
MD	Medical device
Warning triangle	Caution: read the warnings and precautions
Book with "i"	Consult the instructions for use
CE 2797	CE marking with the identification number of the notified body

11. Manufacturer, support and incident reporting

Contact	Details
Manufacturer	Tetra B.V., Begijnkade 13, 3512 VV Utrecht, the Netherlands
General information	info@tetra.nl , +31 (0)43 358 82 15
Technical support	support@tetra.nl , +31 (0)43 358 82 15
Website	Tetra

Report any serious incident that occurs in relation to this device to Tetra and to the competent authority of the Member State in which you or the patient are established. In the Netherlands, this is the Health and Youth Care Inspectorate (IGJ). Provide the device and software identification, the date and a description of the event, its consequences and the actions taken. Contact Tetra for the secure route for any supporting patient information.

12. Access to these instructions

Product instructions are provided through the [Bricks Huisarts documentation portal](#), in Dutch and in English. Check the document revision and issue information for the copy you use. The software version and device identification must correspond to the installed product; an IFU revision number is not the software version.

To read an electronic copy, use a web browser able to display the documentation and, for a downloaded PDF, a PDF reader. You need a display that allows the text to be read clearly and a connection for online access. Contact Tetra if you cannot access a readable copy.

A paper copy is available free of charge within seven calendar days of your request. Send your name, postal address and the IFU title, language and revision to info@tetra.nl.

The current revision and all previous revisions of these instructions issued in electronic form are available on the documentation portal, each with its date of publication. A paper copy of a previous revision is also available free of charge on request.

13. Ending use and protecting information

Save your work and check the completion of intended prescription transmissions before logging out. Do not interrupt an update or data transfer.

When a practice stops using the product, arrange export, retention and removal of patient information with Tetra through the agreed service process. Preserve records required for continuity of care and the applicable retention duties. Verify the transfer before authorising removal, and revoke access when it is no longer required. Do not delete the practice database or remove software independently as a way of ending use.

The module processes patient information as part of Bricks Huisarts. Follow the practice's confidentiality and access procedures. Further information is available in [Tetra's privacy statement](#).