IBEX Bone Health v1.5.0
Instructions For Use
Service Manual

Document Revision 1

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Overview

Instructions for use of the IBEX Bone Health software are separated by topics relevant to the user.

The end users manual (IBX_PRD_SOP_002) provides an overview of the intended use as well as information on the indications for use, contraindications, suggested use cases, and limited troubleshooting advice. All of the information needed by the end user for safe and effective use of the product, including background on the technical basis and clinical validation of the product is provided in this manual.

The service manual (IBX_PRD_SOP_003) provides guidance to the engineer on how to configure the product for use. The instructions include details on licensing, system calibration, settings optimisation, and troubleshooting. Engineers should familiarise themselves with the contents of the end users manual so they have a good understanding of how the product will be used.

The integration manual (IBX_PRD_SOP_004) is intended for developers integrating IBEX BH into OEM systems. Guidance on hardware requirements, API use, and system optimisation is provided. Integrators should familiarise themselves with both the service manual and the end users manual for a complete understanding of the product and its use.

Revision History

Starting from IBEX BH v1.5.0 the instructions for use will be split into three manuals; one each for end users, service engineers, and integrators. To ensure consistency across all versions of the product, vendor-specific IFUs have been merged into a single set of documents describing the configuration and use of IBEX BH. For traceability purposes, the revision histories for previous versions of the manuals are shown below.

Revision	Date	Comment	Initials
1	2024/01/26	First release IFU for IBEX Bone Health v1.1	BL
2	2024/03/08	IFU for IBEX Bone Health v1.2 including customer feedback and error corrections from the first version; clarification of user responsibilities and activities; additional information on errors and warnings; additional information on system configuration including output configuration and licensing; removing the kV offset setting; adding information on deep learning components.	DJ
3	2024/05/22	IFU for IBEX Bone Health v1.3 including calibration workflow simplification; updated default aBMD normative data; new APIs for flushing pipeline and deleting records; new settings for licensing configuration, report configuration, and HTTP request size limit; minor additions to the licensing status API; updated screenshots to the latest interface.	DJ, CS
v1.3rev2	2024/05/29	Corrected information in [Production and Service Engineers] Section 2.2.6.4 on the management of the "calibration QA mode" setting.	CS
v1.3rev3	2024/06/13	Added instructions for native integrations. Added documentation for new settings on report configuration (rotation and clip). Added recommendations on password storage and sharing. Clarify that passwords may only contain ASCII characters.	CS
v1.4rev1	2024/12/11	Added documentation for new settings on report configuration (scaling and version label). Added description of new error code E210. Added details on the training and testing of deep learning elements of the product, and other minor edits.	CS, DJ

Table 1: Instructions for Use IBEX Bone Health, `AGF_01_PRD_SOP_004` (DISCONTINUED)

Revision	Date	Comment	Initials
0.1	2024/02/14	First release IFU for IBEX Bone Health v1.1	BL
v1.3rev1	2024/06/13	IFU for IBEX Bone Health v1.3 including customer feedback and error corrections from the first version; clarification of user responsibilities and activities; additional information on errors and warnings; additional information on system configuration including output configuration and licensing; removing the kV offset setting; adding information on deep learning components. Also including calibration workflow simplification; updated default aBMD normative data; new APIs for flushing pipeline and deleting records; new settings for licensing configuration, report configuration, and HTTP request size limit; minor additions to the licensing status API; updated screenshots to the latest interface. Corrected information in [Production and Service Engineers] Section 2.2.6.4 on the management of the "calibration QA mode" setting. Added instructions for native integrations. Added documentation for new settings on report configuration (rotation and clip). Added recommendations on password storage and sharing. Clarify that passwords may only contain ASCII characters.	DJ, CS
v1.3rev2	2024/05/29	Corrected information in [Production and Service Engineers] Section 2.2.6.4 on the management of the "calibration QA mode" setting.	CS
v1.3rev3	2024/06/13	Added instructions for native integrations. Added documentation for new settings on report configuration (rotation and clip). Added recommendations on password storage and sharing. Clarify that passwords may only contain ASCII characters.	CS
v1.4rev1	2024/11/15	Added documentation for new settings on report configuration (scaling and version label). Added details on use of IBEX BH in a mammography setting, details on the training and testing of deep learning elements of the product, and other minor edits.	CS, DJ
v1.4rev2	2024/12/11	Added documentation for new settings on report configuration (bone edges scaling). Added description of new error code E210.	CS

Table 2: Instructions for Use IBEX Bone Health, `MET_01_PRD_SOP_001` (DISCONTINUED)

Revision	Date	Comment	Initials
v1.5rev1	2025/03/03	IFU for IBEX Bone Health split into three documents (end users manual, service manual, and integration manual). Document links updated. Cover the use case of adding a new detector to an existing system in Section 1.1. Added information about user accounts in Section 2.1 (new in v1.5.0). Describe additional settings (new in v1.5.0) in Sections 2.3.5 and 2.3.6: series description and number, default script, watermark settings, format tags, and dataset retention. Added information on QA sets and validation history to Sections 2.6.2 and 2.6.4 (new in v1.5.0). Added Sections 3.1 and 3.2. Added error/warning codes (new in v1.5.0) to Table 5: W211, E503, E601, E602, E603, E604, and removed end-user actions (now in the end user IFU).	CS, DJ, BL

Table 3: Instructions for Use IBEX Bone Health, IBX_PRD_SOP_003

Terms and Definitions

Term	Definition
Central Osteoporosis	An individual with a measured T-score ≤ -2.5 at the femoral neck or lumbar spine is defined as having central osteoporosis.
Customer/End User	Clinical end user or medical physicist — responsible person.
Fingerprint	The set of images used to produce calibration files by IBEX.
Fingerprinting	The process of collecting the set of images used to produce calibration files by IBEX.
IBEX	Engineer or other appropriate personnel appointed by IBEX.
Integrator	Production, service, or other appropriate personnel appointed by the system manufacturer.
T-score	Score created by comparing the patient's bone density to the average bone density of a healthy population of the same sex between 20 and 30 years of age. A score of 0 indicates normal bone health, and a score of -1 indicates bone health lower than the norm by one standard deviation. Osteoporosis is typically indicated by a score lower than -2.5 at the neck of femur.
Working hours	Core working hours are Monday through Friday from 10am - 5pm CET. Response times outside of these hours cannot be guaranteed but special arrangements for out of hours support can be made by prior arrangement if necessary.

Abbreviations

Abbreviation	Meaning
AET	Application Entity Title
AP	Anterior Posterior
API	Application Programming Interface
aBMD	areal Bone Mineral Density
CPU	Central Processing Unit
DICOM	Digital Imaging and Communications in Medicine
DP	Dorsi-Palmar
DR	Digital Radiograph
DXA	Dual-energy X-ray Absorptiometry
FRAX	Fracture Risk Assessment Tool
GPU	Graphics Processing Unit
HTML	HyperText Markup Language
HTTP	HyperText Transfer Protocol
IBEX BH	IBEX Bone Health
IP	Internet Protocol
JSON	JavaScript Object Notation
NHS	National Health Service
NICE	National Institute for Healthcare and Excellence
NoF	Neck of Femur
OEM	Original Equipment Manufacturer
PA	Posterior Anterior
PACS	Picture Archiving and Communication System
PMMA	Polymethyl Methacrylate
QA	Quality Assurance
RAM	Random Access Memory
ROI	Region Of Interest
SCP	Service Class Provider
SCU	Service Class User
SDK	Software Development Kit
SID	Source-to-Image Receptor Distance
SOP	Service Object Pair
TD	Distal-third
UD	Ultra-distal
UDI	Unique Device Identifier
UK	United Kingdom
WHO	World Health Organisation
WSL2	Windows Subsystem for Linux version 2

This manual describes the use of the IBEX BH device from the perspective of secondary users (e.g. production and service engineers) who are responsible for configuring and maintaining the device and ensuring it meets the needs of the end users. These guidelines and instructions assume the device has already been installed on the X-ray system and is set to the standard configuration defined by the integrator. For detailed guidance on software integration please see the integration manual (`IBX_PRD_SOP_004`).

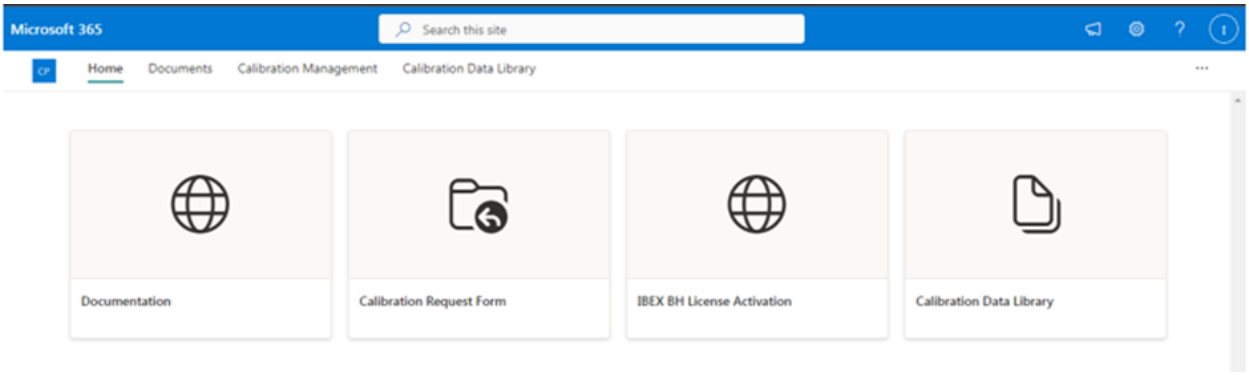


Figure 1: Calibration portal home page

1 Order to Commissioning Process

This section outlines the main steps in the process of ordering and configuring IBEX BH before release to the end user.

- Placing a works order — Communication by the integrator of the intended system configuration and any specific customer requirements (see Section 1.1).
- Calibration — Communication by IBEX of the system calibration plan based on the ordered configuration. Actions will range from i) uploading a pre-existing calibration file for a known configuration (see Section 1.2) to ii) full fingerprinting procedure for a new configuration (see Section 2.5).
- Configuration — Setting up the IBEX BH software by the integrator ensuring all specific customer requirements are met (Section 1.4).
- Commissioning and release — Final tests and training of the customer by the integrator (see Section 1.5).

1.1 Placing a Works Order

A works order can be placed via the IBEX support portal at `https://support.ibexinnovations.co.uk`, see Figure 1.

Detailed instructions can be found in `AGF_01_PRD_SOP_005` - Calibration Portal Instructions for Use. Through this form the user can upload system details including health check and calibration datasets. Project specific upload and download links will be created and the user will be informed by email when a system calibration package is available for use.

Note that the most important characteristic defining a suitable calibration is the detector type. A system-specific calibration package can generally be created if there is a fingerprint dataset on file for the detector type and there is a suitable short form health check data set available (see Section 1.2). For DR applications more than one detector can be supported in a calibration package, for example, if a system is configured with two or more portable panels. The requirement should be highlighted at the start of the project and a short form health check dataset should be provided for each detector. Similarly, if a new detector is being added to an existing installation, all required detectors should be highlighted and suitable datasets provided so a complete configuration file can be generated.

Information to be included in the order form or email:

- Project lead contact details — A key point of contact for all communications on the order. This is likely to be the Original Equipment Manufacturer (OEM) production or service engineer responsible for installing and configuring IBEX BH on an X-ray system.

- Customer information — A unique customer reference used in all communications about this installation. The reference can be an OEM-defined project number, a customer name and system ID or other identifier useful for tracking the system through its lifecycle, including system troubleshooting or field upgrades.
- System information — Primary data used to define the appropriate calibration file structure and license requirements:
  - system type,
  - all detectors to be supported on the system,
  - application,
- Key dates — Helpful in the planning process (with advance notice, it may be possible to support quicker turnaround of calibration files):
  - target factory or field installation date,
  - target shipping date and
  - target release to customer.
- Special customer requirements:
  - Selected configuration options.
  - End user preferred output options can be configured as outlined in Section 2.3.5. These options include risk assessment thresholds, text formatting, and specific wording for some of the output fields.

1.2 Calibration Overview

The system calibration procedures will be defined by IBEX based on a review of the customer requirements. Advice on the most appropriate calibration path will be provided by IBEX to the engineer, if necessary, within 4 working hours of the order.

There are two options for system calibration depending on whether a suitable calibration file already exists for the detector type. Figure 2 shows a flowchart indicating the different process flows through the two options. An overview of pre-configured and supported detector types is provided in the web interface. Detailed test and calibration instructions are provided in associated Standard Operating Procedures.

- **Known system type** — A system calibration file should be returned to the engineer within four working hours of receiving the system health check data, assuming performance checks are successfully completed.
  - Step 1: System health check data collection as described in Section 2.6.4.
  - Step 2: Data upload to IBEX by the engineer.
  - Step 3: Calibration file preparation and release by IBEX.
  - Step 4: Notification of release to the engineer.
- **New system type** — Assumes that there are no previous calibrations available for detectors of this type. The target is to return a calibration file to the engineer within two working days, assuming fingerprinting data are available and performance checks are successfully completed.
  - Step 1: System fingerprinting and baseline checks as described in Section 2.5.
  - Step 2: Data upload to IBEX by the engineer.
  - Step 3: Calibration file generation, testing and release by IBEX.
  - Step 4: Notification of release to the engineer.

The engineer should inform IBEX when the calibration file upload is complete and the QA check has passed so the project can be closed in the calibration portal.

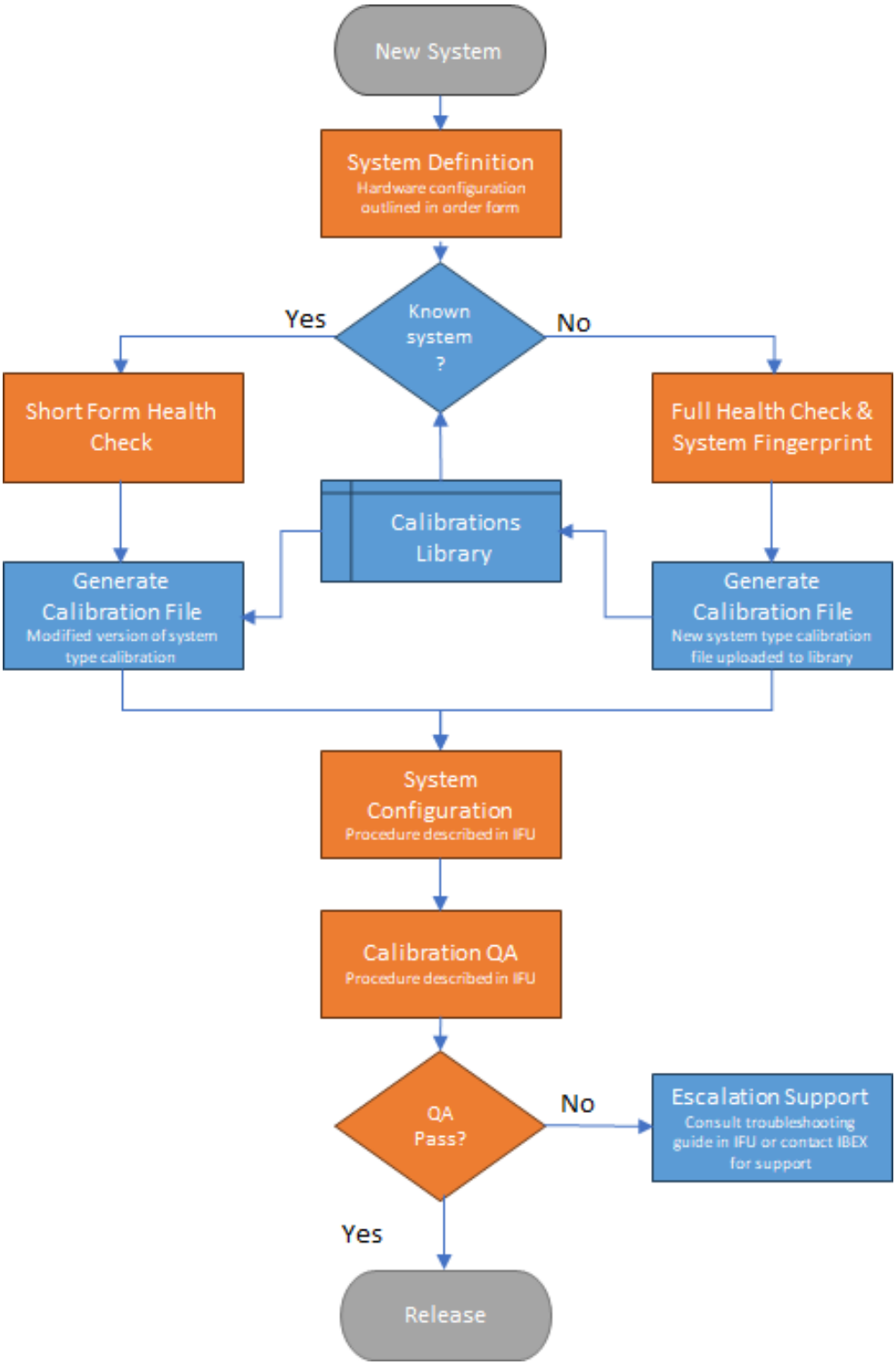


Figure 2: Overview of the system configuration process flow. Activities in orange are primarily performed by the engineer. Activities in blue are primarily performed by IBEX.

1.3 Calibration Phantom

A proprietary phantom designed by IBEX is used for QA purposes. It is a polymethyl methacrylate (PMMA) block, 200 mm wide by 200 mm high and 50 mm thick, with eight aluminium cylinders of varying thickness encased inside.

For a DR QA exposure, the phantom should be located centrally on the detector, with the edges of the phantom parallel to the edges of the detector, and with all aluminium cylinders fully visible, if possible. See Figure 3 for a top-down view of the phantom in its correct position.

For a mammography QA exposure the procedure is similar but the phantom should be placed on the bucky with the side of the phantom at the chest wall edge.

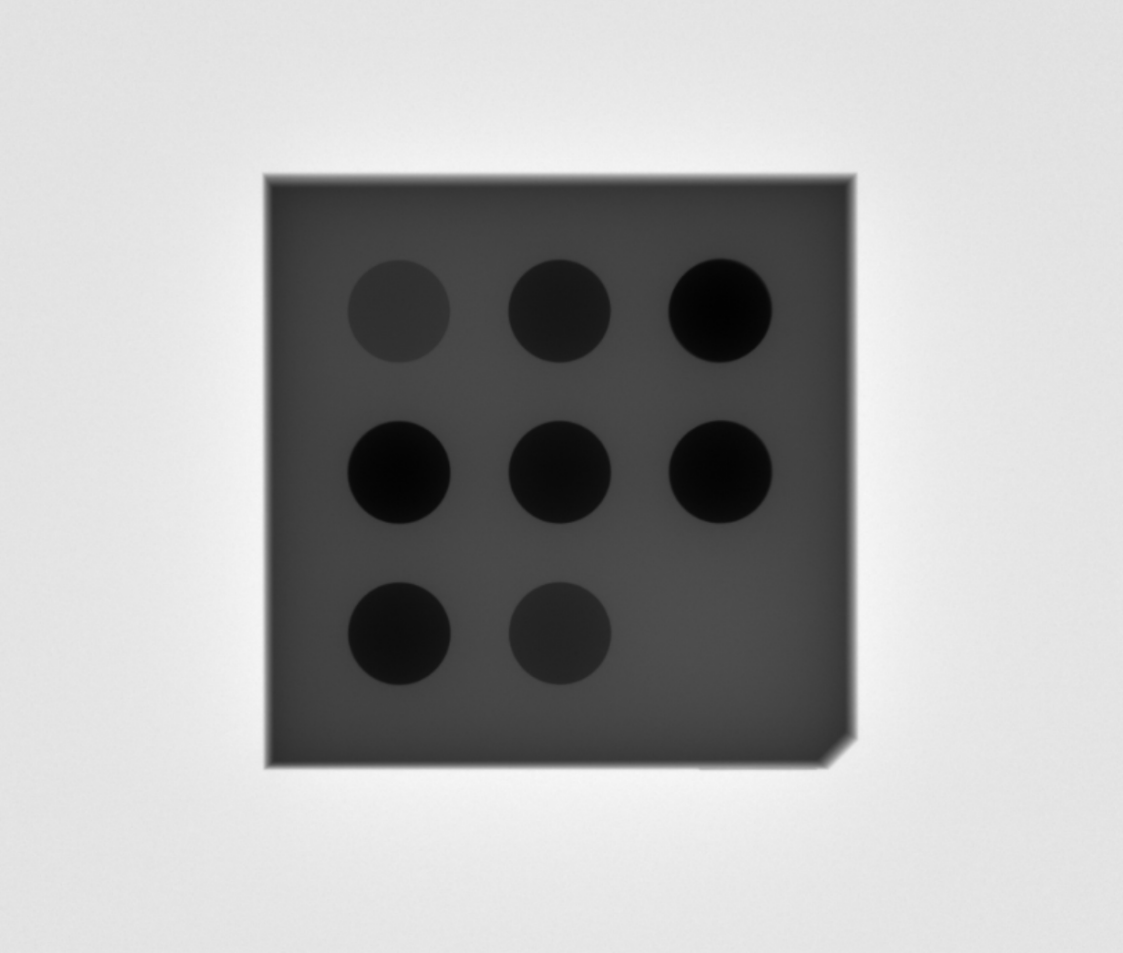


Figure 3: Example DR exposure of the calibration phantom.

1.4 Configuration of IBEX BH

The generic version of IBEX BH should be installed on a system before it is configured to meet the customer needs. It is expected that this generic version is installed identically for all systems, so that generic installation can be automated. The configuration of the generic version is therefore described in the integration manual (`IBX_PRD_SOP_004`). This includes in particular:

- Installing the Trueview Server software, which provides access to the IBEX BH capabilities.
- For sandboxed installations only (with Docker), installing the License Agent utility, which enables

product licensing.

- Configuring IP addresses and other system integration settings, as well as changing default settings if required to suit OEM preferences.

Assuming the generic setup has already been completed, the rest of the setup consists of customer- and system-specific updates to the generic system configuration. This includes in particular:

- Product licensing (Section 2.4)
- Installing calibration data (Section 2.6.2)
- Customer-specific system configuration (if required, see Section 2.3.5):
  - Bone Health risk thresholds
  - Output formatting options

All of these activities can be performed using the engineering web interface, see Section 2.

1.5 Commissioning and Release

A series of checks should be performed before the system is released to the customer:

- QA testing (Section 2.6.4) – One standard phantom image is processed through IBEX BH for each supported detector to confirm the installation is complete and configured correctly. The resulting output DICOMs can be checked to confirm the data flow and output options meet end user expectations.
- Operational run through — The customer is guided through a typical imaging process and confirms that the final configuration matches the requirements set out in the order. The run-through should include a cross-check of the main settings including clinical thresholds and customer-preferred text options.
- Customer training should be provided by an OEM representative. IBEX recommends that training literature should be based on the product description in the end users manual (`IBX_PRD_SOP_002`). IBEX will make reasonable efforts to provide the necessary training materials. Please refer to your distribution agreement in cases where more extensive training is required.
- System sign-off and registration procedures should be defined by the system vendor.

2 The Engineering Interface

The engineering interface is a configuration and debugging tool to be used primarily by production and service engineers when configuring the device for use. More detailed integration and installation instructions can be found in the integration manual (IBX_PRD_SOP_004).

This interface consists of a series of web pages, accessible from a web browser running on the modality where the software is installed. It is expected that integrators will instruct engineers on how to access this interface; e.g., this could include providing shortcuts. In this section, the placeholders <ip> refers to the IP address or host name of the computer hosting the software, and <port> refers to the server outer HyperText Transfer Protocol (HTTP) port as configured during generic installation by the integrator.

2.1 Authentication and Security

Any connection must be established using the http:// protocol, and not the https:// protocol. Therefore, the connections to the configuration interface are not secure, and must not be established over an untrusted network. In practice, this means the interface should only be accessed from the modality.

The interface is password-protected using basic HTTP authentication. The default admin username and password are:

- Username: TrueviewConfig
- Password: (set on installation)

The admin username can be changed, either on installation or at any time thereafter with the configuration Application Programming Interface (API; see the integration manual IBX_PRD_SOP_004). The default password is initialised when the software is installed. It can be changed at any time using the HTTP configuration API.

The admin user has full access to all components of the configuration interface. If necessary, additional users can be created with more limited access rights, using the HTTP configuration API.

2.2 Dashboard

The dashboard is the main page, and can be accessed at the following address (or using the “Dashboard” menu link, if already browsing another page):

http://<ip>:<port>/

Figure 4: Dashboard web page, showing received data sets and the status of the processing pipeline.

This web page includes real-time (and continuously refreshed) information about the Trueview Server pipeline. In what follows, a "data set" means a single X-ray exposure, its corresponding DICOM files, any accumulated errors and warnings, and processing outcome. As shown in Figure 4, the information displayed on this page includes:

- Summary statistics about the current status of the pipeline as a graph (top-left). This includes the number of data sets currently located in each step of the pipeline.
- Summary statistics about the outcome of each data set that has gone through the pipeline (top-right). This includes the number of data sets that have failed in each step the pipeline, and the number of data sets for which the output was successfully sent.
- Detailed information about each data set that has been received by the software (bottom). This includes the location and status of the data set in the pipeline, the date at which it was received, as well as the list of errors and warnings that have been triggered for this data set. A button is also available to download associated files, see Section 2.3.6 for more information on how to use this feature.

The displayed data can be filtered to specific time ranges using the control at the top of the page. The "Live Pipeline" graph is only displayed for the "Live/Today" time range. Data is retained only up to a configurable duration, see Section 2.3.

This page also includes controls:

- "Flush". This can be used to flush the pipeline, i.e., cancel all data sets queued or being processed. This cannot be undone. Cancelled data sets need to be resent.
- "Clear selection". Delete records for the currently selected date range. This cannot be undone; deleted records are permanently lost. Note: data sets queued or being processed will not be cleared by this

command; they must be flushed first.

- "Clear all". As above, but delete all records regardless of the date.

2.3 Using the HTML Configuration Page

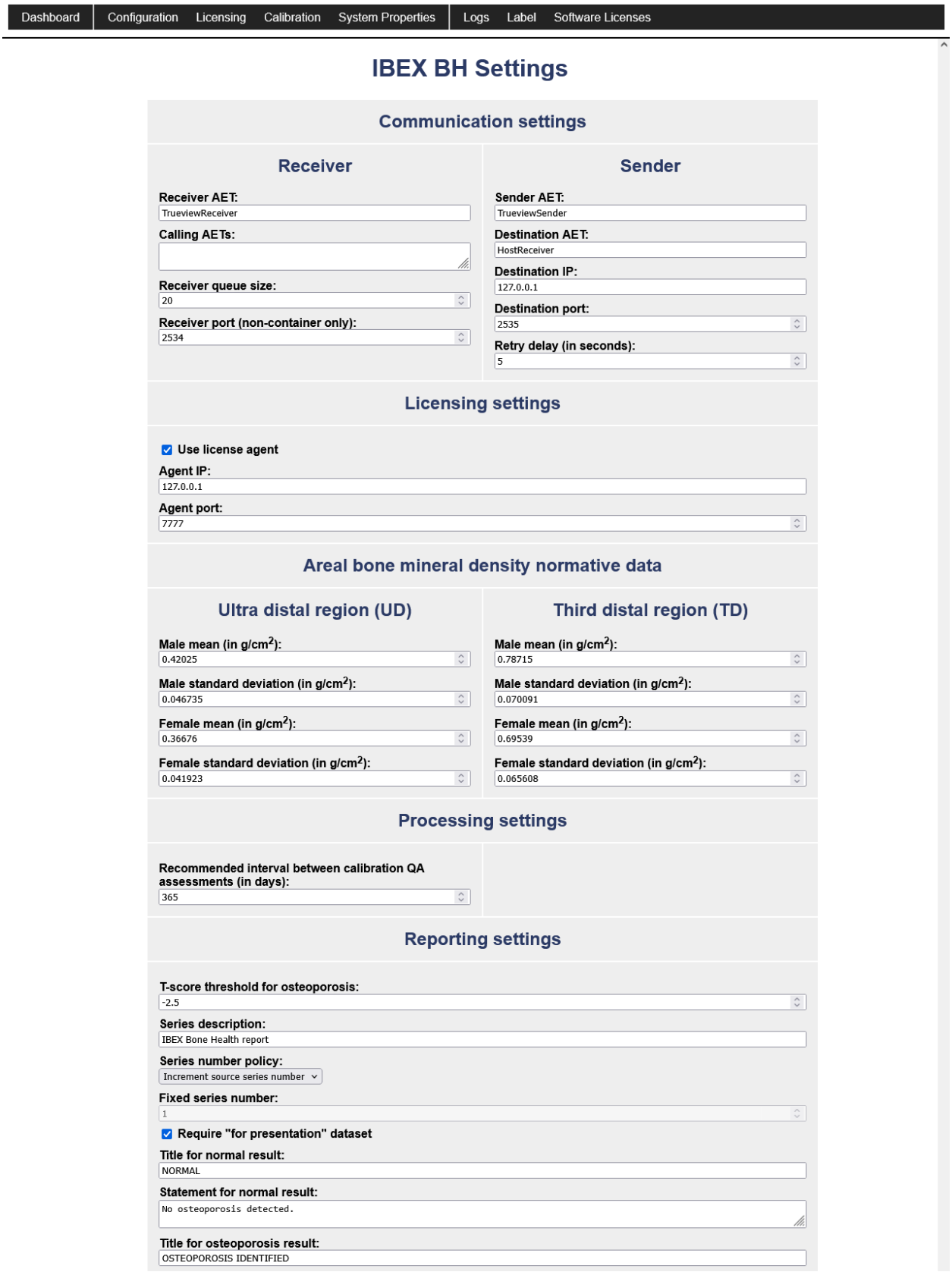
The HTML configuration page (shown in Figure 5) is accessible with a web browser at the following HTTP address (or using the "Configuration" menu link, if already browsing another page):

```
http://<ip>:<port>/conf
```

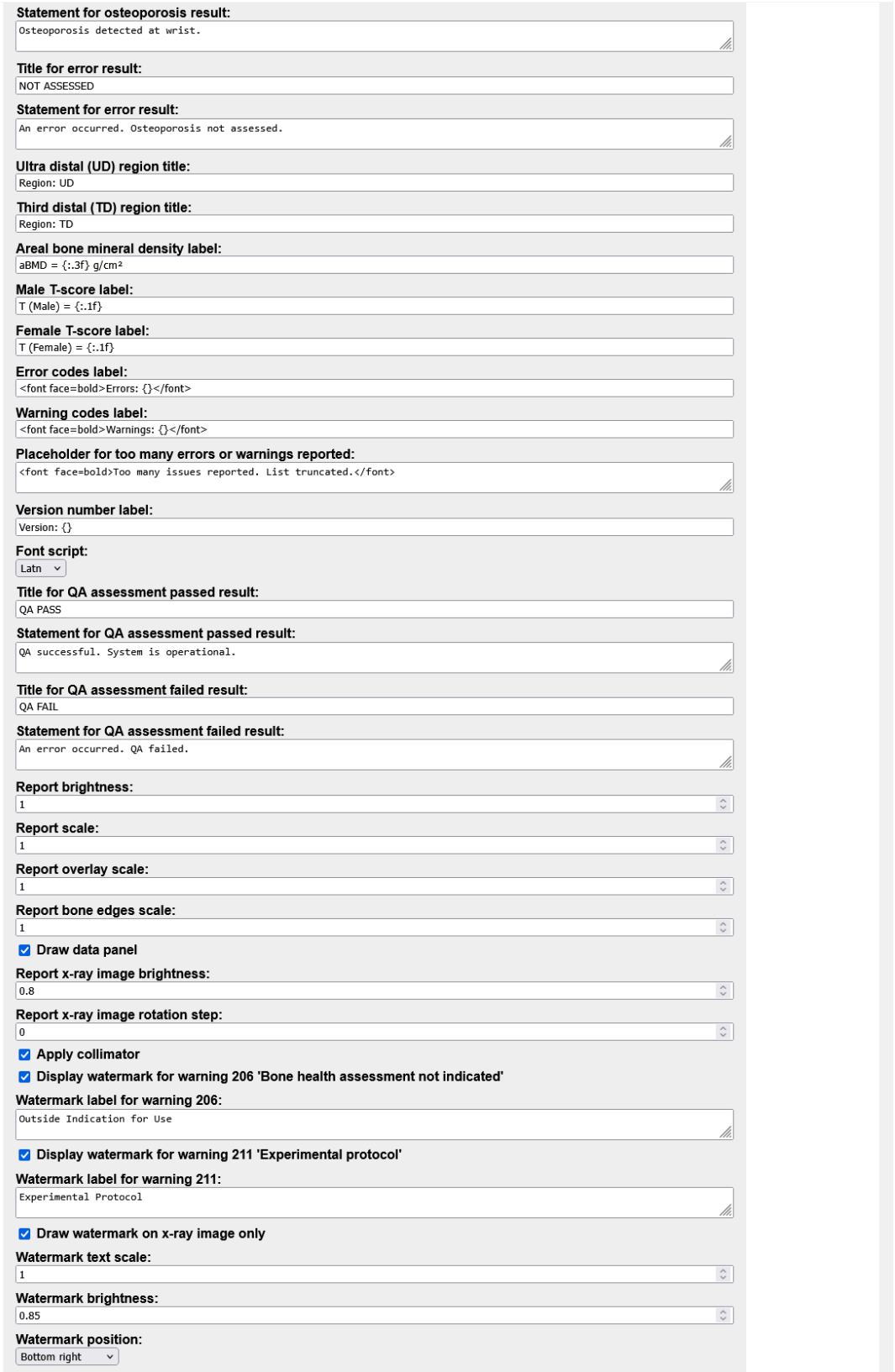
The IBEX BH module will be pre-configured with standard settings, but some fields can be changed to suit system- or customer-specific requirements. The fields most commonly adjusted are Input, Reporting, and System settings. Press the "Update" button at the bottom of the page to upload any changes. Updates can take several seconds to apply, and will trigger an internal server restart. Therefore the server will become unresponsive for a short period of time after applying new settings (at most a few seconds, unless there are data sets in the queue, see below).

If data sets are being processed while settings are updated, these data sets will be discarded (displayed as "cancelled" on the dashboard, see Section 2.2). If a data set is being processed, the server will have to wait for processing to abort, which can take up to a few seconds. Therefore, it is best to avoid changing the configuration while data sets are being processed.

The following sub-sections describe the most common settings and their purpose.



Configuration web page (continued on next page).



Configuration web page (continued on next page).

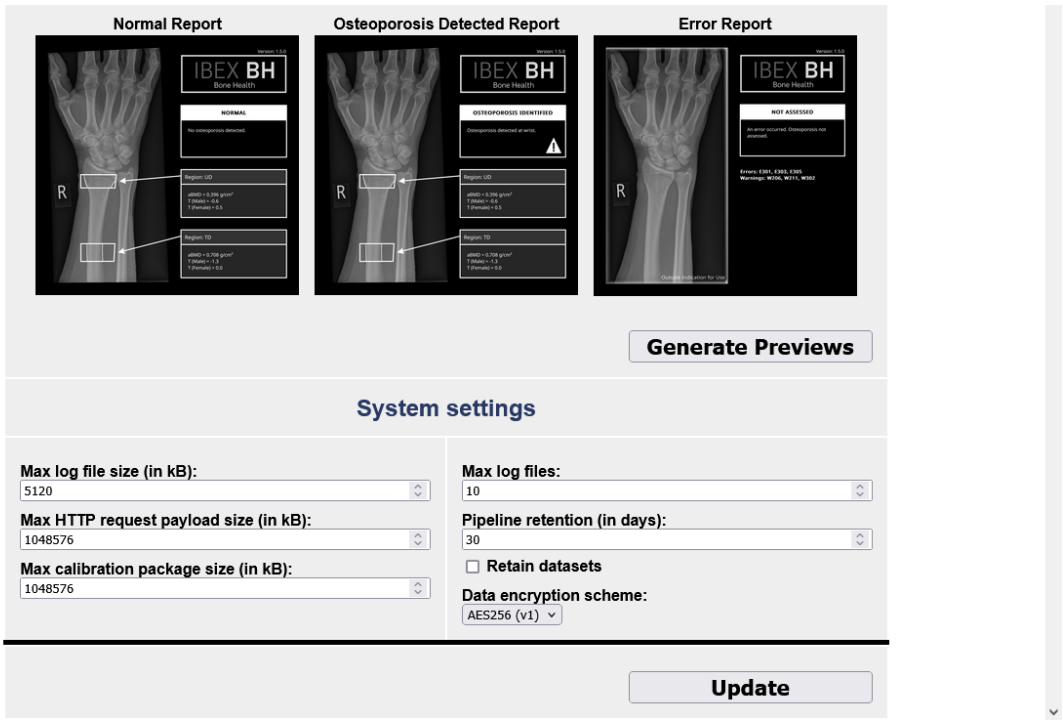


Figure 5: Configuration web page (continued), showing all configurable settings, their current values, a series of image previews (generated on demand), a button to update the image previews with the entered settings, and a button to update the server settings.

2.3.1 Communication Settings

Communication settings will typically be configured by the integrator. Details of the purpose and configuration for each field are described in the integration manual (`IBX_PRD_SOP_004`).

2.3.2 Licensing

Licensing settings will typically be configured by the integrator at the factory. Details of the purpose and configuration for each field are described in the integration manual (`IBX_PRD_SOP_004`).

2.3.3 aBMD Normative Data

Normative data will typically be configured by the integrator at the factory, or using default values. Details of the purpose and configuration for each field are described in the integration manual (`IBX_PRD_SOP_004`). The purpose of the normative data is to match the IBEX calculated Bone Health indicators to a typical healthy population. A more detailed description can be found in the end users manual (`IBX_PRD_SOP_002`).

2.3.4 Input Settings

There is currently no setting to configure in this section.

2.3.5 Reporting Settings

Output reports and indications for follow-on actions can be configured to meet local requirements and preferences. Default values are shown in Figure 5.

When these settings are changed, a preview of the corresponding output can be generated by pressing the "Generate Preview" button. This will generate three images, each corresponding to a different type of output (normal, osteoporosis detected, and error). Each image can be clicked to display a full-screen version. The preview is not automatically updated, and is only generated on demand. It uses the value of the settings as they are entered on the page, instead of the settings currently updated on the server, so the preview can be used to test different settings before updating them on the server.

Please note that generating a preview does *not* update the settings on the server; if the preview is satisfactory, make sure to press the "Update" button to commit the settings to the server.

- T-score threshold for osteoporosis: Influences the number of patients identified as being potentially at risk of osteoporosis. Setting this threshold to higher values (i.e. greater than the default of -2.5) will tend to flag more patients as being at risk and may increase the workload in the clinical pathway. Setting this threshold to lower values (i.e. less than the default of -2.5) will tend to reduce demand on the care pathway but may miss patients who are at risk of osteoporosis. Further background information can be found in the end users manual (`IBX_PRD_SOP_002`).
- Series description: The name of the DICOM series in which the IBEX BH output will be created. This value may affect display and sorting of the results on PACS; please consult with local PACS manager for guidance.
- Series number policy: The method used for generating the series number. This value may affect display and sorting of the results on PACS; please consult with local PACS manager for guidance. Possible options are:
  - Increment source series number. This generates the series number by adding 1 to the series number of the input DICOM.
  - Fixed value. This sets the series number to the value specified in the "Fixed series number" setting.
- Title for normal result: Text displayed in the heading of the DICOM output report for patients with T-score larger the configured threshold for osteoporosis, i.e., being identified as healthy.
- Statement for normal result: Text field returned in the event of a normal result. The default is a simple statement that "No osteoporosis is detected", but it could be changed to prompt follow-on actions meeting local requirements.
- Title for osteoporosis result: Text displayed in the heading of the DICOM output report for patients with T-score lower than the configured threshold for osteoporosis, i.e., those being identified as at risk of osteoporosis.
- Statement for osteoporosis result: Text field returned in the event of an indication of osteoporosis risk. The default is a simple statement that "Osteoporosis is detected at wrist", but it could be changed to reference local guidelines and recommendations for follow-up.
- Title for error result: Text displayed in the heading of the DICOM output report if the process errors. Errors can be flagged for several reasons, including a mismatch between the image protocol and the calibrated range, or failure to identify a suitable ROI for bone health measurement. In the event of an error the image is not processed and no bone health outputs are reported.
- Statement for error result: Text field returned in the event of an error. The default is a simple statement that "An error occurred. Osteoporosis is not assessed." Further guidance on appropriate follow-up could be included to meet local preferences.

- Ultra distal (UD) region title: The header text for the UD region of the wrist can be adjusted to meet local preferences.
- Third distal (TD) region title: The header text for the TD region of the forearm can be adjusted to meet local preferences.
- Areal bone mineral density label: Format and label text content for the aBMD results. Coding options for the number formatting are described below.
- Male T-score label: Format and label text content for the male T-score results. Coding options for the number formatting are described below.
- Female T-score label: Format and label text content for the female T-score results. Coding options for the number formatting are described below.
- Error codes label: Format and label text content for the errors field.
- Warning codes label: Format and label text content for the warnings field.
- Placeholder for too many errors or warnings reported: Text returned in the DICOM output report if there are too many errors to display in the errors or warnings fields.
- Version label: Label text content for the product version.
- Font script: Default font script to use when rendering characters on the DICOM output report. The script influence the choice of font file and exact appearance of characters, and should be set appropriately for the target language.
- Report brightness: Maximum white intensity level (0: black, 1: white) to use when drawing text, logos, and boxes on the output report.
- Report scale: Scale factor of the report elements, such as text boxes and logos (e.g., 1: standard size, 2: twice standard, 0.5: half standard).
- Report overlay scale: Scale factor of overlay elements, such as arrows and ROI borders (e.g., 1: standard size, 2: twice standard, 0.5: half standard).
- Report bone edges scale: Scale factor of bone edges drawn inside ROIs (e.g., 1: standard size, 2: twice standard, 0.5: half standard).
- Report XRay image brightness: Maximum white intensity level (0: black, 1: white) to use when drawing the background x-ray image on the output report.
- Draw data panel: Whether to display the data panel on the right of the X-ray image. The data panel contains the text boxes with measured T-score and aBMD values. This can be turned off to only show the X-ray image and the regions of interest. It is only advisable to turn this off if the reported values are displayed in another part of the integrated user interface.
- Report XRay image rotation step: The step size for the automatic X-ray image rotation, in degrees (a step size of 0 allows all rotations, while a step size of 90 degrees will only rotate the image by multiples of 90 degrees; a step size of 360 effectively disables automatic rotation).
- Apply collimator: Whether to automatically clip the X-ray image to the detected collimated area or not.
- Watermark settings: These settings control whether and how the software generates a watermark for a selected set of important warnings that can be raised (see Section 3.3 for the full description of these warnings).
  - Display watermark for warning X: Whether a watermark will be displayed or not for this specific warning. It is not recommended to adjust this setting unless otherwise instructed.
  - Watermark label for warning X: Text to display on the watermark when this specific warning is raised.

  - Draw watermark on x-ray image only: Whether the watermark is displayed only over the x-ray image, or over of the full output image.
  - Watermark text scale: Scale factor of watermark text (e.g., 1: standard size, 2: twice standard, 0.5: half standard).
  - Watermark brightness: Maximum white intensity level (0: black, 1: white) to use when drawing the watermark on the output report.
  - Watermark position: Location of the watermark on the output report.

For text fields including numerical values, formatting can be customised using format placeholders. These fields can be identified as containing a placeholder of the form `{...}`. This placeholder will be replaced by the actual numerical value output by the software. The full specification for these format placeholders can be found at the following address: `https://fmt.dev/10.1.0/syntax.html`. As a short summary:

- The format placeholder must start with `{:`, and end with `}`.
- Placeholders for floating-point numbers (such as aBMD, T-scores, ...) must end with either `f`, `e`, or `E` characters (e.g., `{:.4f}`).
- If using the `f` format, the number will be displayed with "fixed point" formatting, i.e., it will always display the same number of digits to the right of the decimal point. This number of digits can be configured using the `a.b` syntax, where `a` configures the total width of the displayed number (including padding with whitespace if necessary), and `b` configures the number of digits to the right of the decimal point. The total width can be omitted, which will result in no padding. For example, using `{:.6f}` could result in a number like `13.141500`.
- If using the `e` or `E` formats, the number will be displayed using "scientific notation". This works similarly to the fixed-point formatting, except that exponential notation is used. For example, using `{:.6e}` could result in a number like `1.314150e01`.
- Placeholders for textual values (such as software version, list of errors, ...) must only be of the form `{:}` or `{}` (which are equivalent).

In addition, all settings controlling text displayed on the output image can make use of format tags (e.g., `<font face=bold>...</font>`. The full specification for these format tags can be found the technical specification (`IBX_SWD_PRS_006`). As a short summary:

- Format tags are of the form `<tag attribute=value>text</tag>`, where `tag` is the name of the format tag, `attribute` is the name of an attribute to modify, `value` is the value to give to that attribute, and `text` is the text that will be affected by the specified format.
- The `<font>` tag can be used to modify the appearance of characters drawn for the enclosed text. Allowed attributes:
  - `size`: Font size in pixels (integer).
  - `script`: Font script as an ISO 15924 script code.
  - `colour`: HTML hexadecimal Red Green Blue Alpha (RGBA) colour code. Note: the secondary capture is a greyscale image, so colours are always converted to grey levels before rendering. The Alpha component controls transparency.
  - `face`: Comma-separated list of font face values, possible values: `bold`, `italic`.
- A single tag can contain any number of attributes.
- Tags can be nested if necessary.

2.3.6 System Settings

System settings will typically be configured by the integrator at the factory. Details of the purpose and configuration for each field are described in the system integrators.

One setting in this category may be useful for troubleshooting:

- Retain datasets: When this option is enabled, any DICOM file received or produced by the software is retained for a fixed period of time, and can be downloaded from the dashboard page (see Section 2.2) by clicking on the icon illustrated in Figure 6. The corresponding files are automatically deleted from the system after the duration configured in the "Pipeline retention (in days)" setting (default 30 days), or when the "Retain datasets" option is turned off. Enabling this option only retains files received or produced *after* the option was turned on. When this option is disabled, files may still be downloaded for a brief moment (typically, while the corresponding data set is queued).

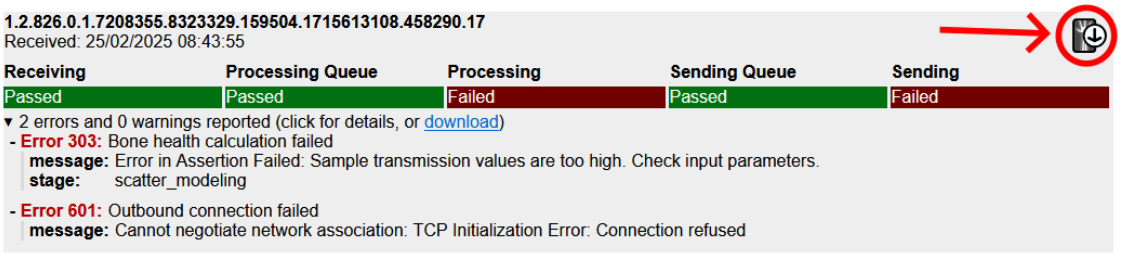


Figure 6: Example of dashboard entry when dataset files are available for download, and can be obtained by clicking the icon highlighted with a red circle and arrow.

2.4 Licensing

The software requires a valid license of IBEX BH to run an image. A detailed description of the licensing system setup is provided in the integration manual (`IBX_PRD_SOP_004`). Instructions for configuring and checking license status on a system are provided below. It is assumed that any required external application (e.g., license agent) is already installed and running on the host system as part of the generic software setup by the integrator. Note that all setup and configuration features are available without a valid license.

2.4.1 License Configuration and Usage Restrictions

The license comes with a set of usage restrictions, which are split into two groups: "base" and "additional".

"Base" restrictions are configured by IBEX when the license is created, and can be tailored to the specific use case. This includes a limited set of supported products (e.g., IBEX BH vs other IBEX products), as well as a base expiry date. The base expiry date is set as a fixed number of days since the license is activated or last renewed on the modality, e.g., 365 days for a license that needs renewing yearly. Perpetual licenses are also an option. A license can also be configured to limit the number of installations. If the same license is used for multiple installations, each installation will have its own expiry date.

"Additional" usage restrictions can be configured locally on the Trueview Server, e.g., to limit the maximum number of uses of the license before it needs to be renewed, or to set up a flexible expiry date based on the time of first use (rather than the time of license activation). License codes are obtained as described in Section 2.4.3 and are configured by the integrator or field service engineer, at the time of activation/renewal of the license (see Section 2.4.3).

2.4.2 Obtaining a License

The license is identified by its "key" and "token". These are provided by IBEX during commissioning based on the requested licensing requirements (see Section 1). The following sections assume that the license key and token are available.

The same license key and token can be used for multiple installations, if allowed by the license terms. Otherwise, a different key and token must be requested for each installation. This is determined during commissioning.

2.4.3 Setting Up or Renewing the IBEX BH License

Initially, the software does not have a valid license set up. This must be done before the software can process data. To do so, use a web browser to access the configuration interface (shown in Figure 8) at the following address:

```
http://<ip>:<port>/licensing
```

Figure 7: Example of the licensing web page status interface.

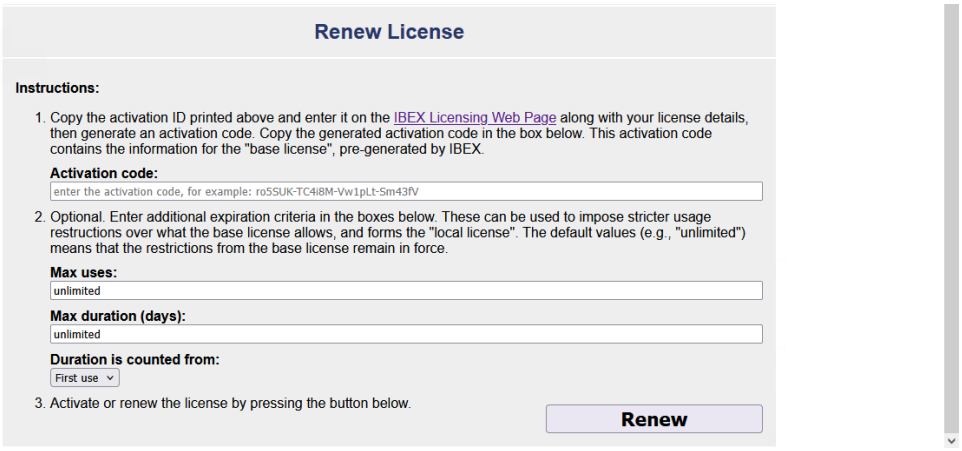


Figure 8: Example of the licensing web page renewal interface. The interface is similar for the initial activation, with only the wording being slightly altered.

Figure 9: The public IBEX licensing web page at `https://licensing.ibexinnovations.co.uk`. Please note: this is a live service, and the page may be updated from time to time, hence the exact look of the page may be different from the one pictured above.

Follow the instructions displayed on the web page, using the license details provided. These instructions are repeated here in more detail.

The first step is to generate a new activation code. This requires a connection to the internet (either on the same browser, or using another device and another browser). The steps are as follows:

1. Read the "activation ID" of the license agent, as displayed at the top of the page (see Figure 7).
2. Open the IBEX licensing web page by following the link on the page, or browsing directly to: `https://licensing.ibexinnovations.co.uk` (see Figure 9).
3. Copy the "activation ID" of the agent (read in step 1) onto this new page, as well as the license key and token.
4. Which button to press depends on the situation:
   - If this device has not yet been activated, press "Activate license".
   - If the device needs renewing, press "Renew license".

- If unsure, press "Show license status": this will display the current status of the license for this device.
  - If the status is "ACTIVE", the device is already activated and its license has not yet expired; it can renewed early if necessary using "Renew license".
  - If the status is "EXPIRED", the device must be renewed using "Renew license".
  - Finally, if the status is "NOT ACTIVATED" (or "License request failed"), the device is not yet activated; press "Activate license".

5. Read the generated "activation code".
6. Go back to the server licensing web page, and enter the activation code.
7. Additional usage restrictions can be configured at this point, or set to "unlimited" to rely only on the base restrictions from the license. The list of additional restrictions includes:
   - Max uses. This can be used to introduce a limit on the maximum number of data sets that can be processed before the license needs renewing. A use of the license is deducted whenever a data set is successfully processed by the software (i.e., when an osteoporosis assessment is provided, regardless of whether osteoporosis is detected or not).
   - Max duration. This can be used to introduce a more stringent expiry date on top of the base expiry; e.g., if the base expiry is set to 1.5 years from activation (i.e., when the license is first installed), the max duration setting can be set to 1 year from the point of first use (i.e., when the end user first processes a data set). The actual expiry date will be the earliest of the base expiry date and the local expiry date.
8. Press the "Activate" (or, for renewal, "Renew") button once the configuration is entered to install the license on the system.

Once the license is set up, no further action is necessary until the point where the license needs to be renewed. This web page displays the expiry date, so the next renewal can be planned (see Section 2.4.4 for querying the license status).

Renewal follows the same process as initial activation.

2.4.4 Querying the Status of the License

The license status can be accessed on the licensing web page (shown in Figure 7):

```
http://<ip>:<port>/licensing
```

The meaning of each entry is as follows (see Section 2.4.3 for more details):

- The agent activation ID denotes the license agent. Necessary only for renewals or first activation.
- Dates and times relate to the current time as measured on the Trueview Server.
- Uses Remaining will be "Unlimited" if there is no limit on the number of uses before the license expires (note: a use of the license is deducted whenever a data set is successfully processed by the software).

2.5 Fingerprinting Procedure

A system calibration is required to maintain a link between the IBEX BH algorithm performance and the system performance. The calibration procedure relies on a fingerprint of the system outputs. This represents the detected X-ray intensity over the specified operating range for energy and the supported range of hardware

configurations. This process is **not necessary** if a valid fingerprint is already available in the calibration library, and should only be performed if advised by IBEX.

If there is no suitable calibration file available in the library, a new calibration is required. The calibration procedure is described in `AGF_01_PRD_SOP_001`. The current standard method takes the following steps:

- Documentation of the system configuration and key components.
- Baseline performance checks using standard phantoms and open beam measurements to assess system performance over a range of operating conditions.
- Exposures over a range of kVp and mAs settings for a set of PMMA and aluminium sheets with different thicknesses at the target protocol(s).

The complete dataset is delivered to IBEX for processing and validation. If the new calibration file meets the acceptance criteria, the file is uploaded to the Calibrations Library and is forwarded to the engineer for installation on the system. The turnaround time for producing a new calibration is 2 working days although, given prior notice, faster turnaround can be achieved. Note that it is not essential for the calibration files to be uploaded in the factory; they can be installed on site.

2.6 Using the Calibration Interface

IBEX BH processing requires a valid calibration on each deployed X-ray system. This section provides instructions for managing the calibration data and system properties. The workflow goes as follows:

1. Obtain a calibration package for the X-ray system (Section 1.2).
2. Upload the calibration package to the software (Section 2.6.2).
3. Configure the software with any required system properties (Section 2.6.3).
4. Validate the uploaded data using the calibration QA procedure (Section 2.6.4).

These activities are expected to be performed by a trained engineer, either at the factory where the system is assembled, or on site when the system is first deployed. The following sub-sections describe each of these activities in more detail.

2.6.1 Obtaining a Calibration Package for the X-ray System

The procedure for obtaining a calibration package is outlined in Section 1.2.

2.6.2 Uploading a New Calibration Package

Use a web browser to access the configuration interface at the following address:

```
http://<ip>:<port>/calibration
```

This web page (shown in Figure 10) provides the list of available calibrations (initially this list is empty), and an upload form. Use the form to select the ZIP archive for the calibration package to upload and press the “Upload” button. Upload can take up to a few minutes if the calibration file is large; please make sure to wait until the web page reports that the calibration has been installed successfully. If the package passes internal validation, it replaces any existing calibration on the server. The list of available calibrations is then updated to reflect the newly available calibrations.

Note that, when first uploaded, all calibrations are flagged as “awaiting QA”, and cannot be used for processing until the QA procedure has been followed. Depending on the exact system setup, calibrations may be grouped in one or more “QA set”. Typically, this will happen for systems that can be used with

more than one panel, in which case each panel will have a corresponding QA set. The QA procedure will need to be followed for each QA set.

If data sets are being processed when a new calibration is uploaded, these data sets will be discarded (displayed as "cancelled" on the dashboard, see Section 2.2).

Key information available on this page (this is updated live and does not require a page refresh):

- Package version: This indicates the version of the current calibration package, which must be supported by the software. Please communicate this information to IBEX during troubleshooting.
- Package assembly date: This contains the date at which the calibration package was assembled by IBEX, for traceability. Please communicate this information to IBEX during troubleshooting.
- Package unique identifier: This is a unique identified generated from the package content. Please communicate this information to IBEX during troubleshooting.
- Most recent calibration QA process result: This contains the status of the last QA check ("Passed" or "Failed"), for each QA set. If "Failed", the calibration is likely not suitable for this system; please contact IBEX. If "Passed", the system is suitably configured to process clinical exposures.
- Date of last QA result: This contains the date of the last QA check (whether it passed or failed), for each QA set. If the last check was too old, this can be used to decide that a new QA check is required, e.g., to check for system drift. It can also be used to determine if some of the system components were repaired or replaced since the last QA check, and whether a new QA check is required to validate the updated system.
- Validation history: This contains the records of all phantom exposures received as part of the QA procedure, including date, time, QA set, processing result, and any generated errors or warnings. These records are retained for the configured data set retention period (default 30 days, see Section 2.3.6).
- Current protocols supported: This contains the list of all supported protocols, including all supported combinations of kVp, detector, tube, etc. This can be used to check that all expected protocols are included (e.g., that the calibration covers the expected range of kVp, the expected detectors, ...). Each protocol also has its own "QA passed" tickbox, which must be ticked for this protocol to be usable for clinical exposures (this will be done by the automated QA procedure; see Section 2.6.4 for more information).

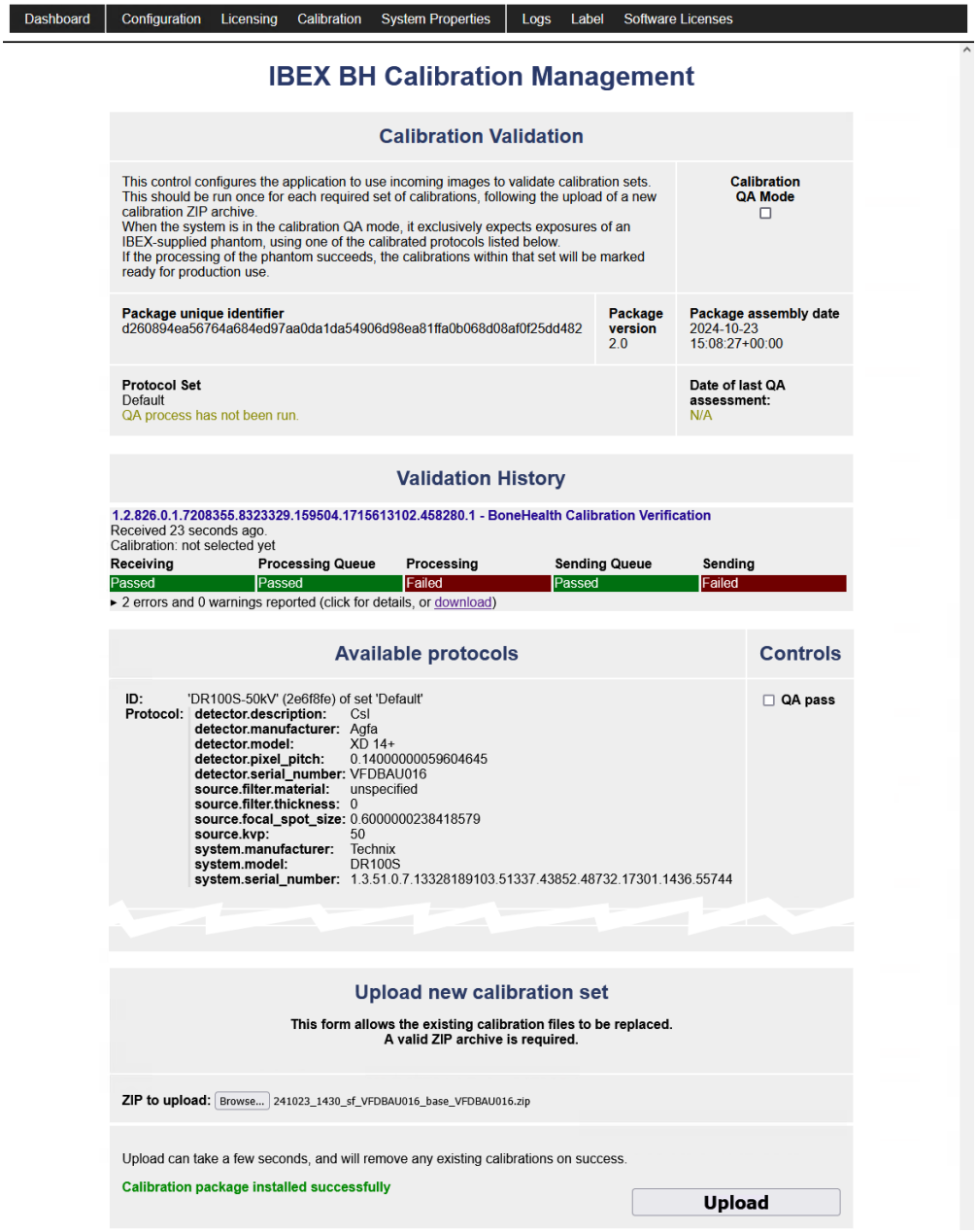


Figure 10: Example of an uploaded calibration on the calibration web page. Key details of the calibration file contents are provided in text format to support troubleshooting activities. The meaning and use of all the fields displayed on this page is described in Section 2.6.2.

2.6.3 Selecting System Properties

Use a web browser to access the configuration interface at the following address:

`http://<ip>:<port>/system-props`

The software will automatically select the appropriate calibration for each input image (or reject the input

if no suitable calibration is available). This is achieved by reading values of standard DICOM attributes in the input DICOM files sent for processing. Since standard DICOM attributes are not always sufficient to unambiguously identify the system configuration, extra inputs may be needed to select the appropriate calibration (for example if there is more than one X-ray tube available on the system). These inputs are called "system properties". They are set globally for the system and are assumed to apply equally to all input images sent to the software.

This web page provides the list of currently configured system properties, as a list of keys and values. The list is built automatically from the uploaded calibrations. If the calibrations do not require any system property to be configured (or if no calibration has been uploaded yet), this page will be empty, and no action is necessary.

Otherwise, follow the instructions provided with the calibration package to select the appropriate properties and their values (or "unspecified" if not known or not relevant), then press the "Update" button. For example, if the calibrations required a "source type" property to be configured, the page would appear as displayed in Figure 11.

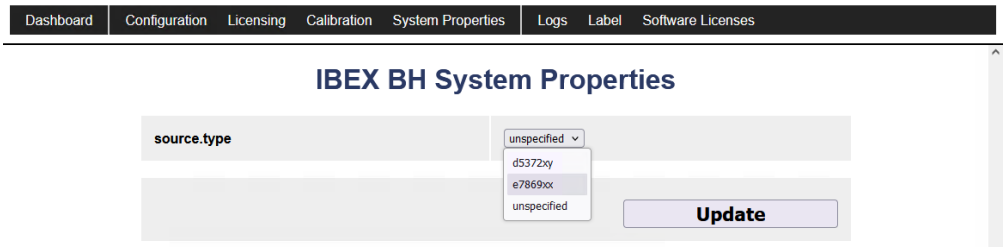


Figure 11: Example system properties on the system properties web page.

2.6.4 Calibration QA Procedure

After upload, the calibration data set needs validating for QA. Until this QA procedure is followed, the calibration data cannot be used for processing. This procedure must be repeated whenever:

- A new calibration package is uploaded.
- A critical setting is modified (see the list of critical settings below).
- The X-ray system undergoes a significant change such as a tube replacement, detector replacement, or other changes affecting the X-ray beam (e.g. a new collimator assembly or suspected system drift).

This procedure must be repeated for each of the "QA set" included in the calibration package (see Section 2.6.1), e.g., typically for each panel. The QA procedure proceeds as follows:

1. An exposure of an IBEX-supplied phantom (see Section 1.3) is taken and sent to the software. This exposure must be taken using one of the protocols for which a calibration has been uploaded on the server (see Section 2.6.2). The software will automatically detect the corresponding "QA set".
2. If the exposure is sent with the DICOM tag `Quality Control Subject` set to `YES`, the software will automatically start the QA pipeline. Otherwise, the "calibration QA mode" setting must be explicitly turned on before the exposure is sent. A control is available on the calibration web page to toggle this mode on and off (see Figure 10), otherwise it can be accessed programmatically using the configuration interface (see the integration manual `IBX_PRD_SOP_004`).
3. Upon receiving the exposure, the software executes an automated QA pipeline. This pipeline may take up to 3 or 4 minutes to complete.
4. If the pipeline is successful, all uploaded calibrations in the corresponding "QA set" are marked as "QA pass". If the "calibration QA mode" setting was explicitly turned on, it must be turned off before

the software can be used for processing clinical data. If the pipeline is not successful, please contact IBEX. Common failure modes are listed in Section 3.2.

The critical settings that will require a QA procedure whenever a change is made are:

- There is currently no setting in this list.

Note: A toggle is provided alongside each calibrated protocol to manually pass/fail the QA procedure. This toggle should only be used as a fallback in case automated QA has failed, after escalating the problem, and only if instructed to do so.

2.7 Using the HTML Logs Page

The Trueview Server displays the content of its logs at the following address (requires authentication; see Section 2 for more information on accessing the engineering interface):

```
http://<ip>:<port>/logs
```

These logs can be used for deeper debugging of issues, when the errors and warnings displayed on the dashboard are not sufficient to understand a problem. Note that the logs are periodically rotated, such that the oldest log entries are eventually deleted to make room for newer entries. This rotation is configurable, see Section 2.3.6.

3 Troubleshooting

Table 4 shows a list of common setup errors, the likely impact and how these can be avoided. The description of error and warning codes can be found in Section 3.3.

When communicating and resolving a troubleshooting issue the following information will be useful:

- A description of the system configuration and activities underway when the problem occurred.
- IBEX BH log files (see Section 2.7).
- Calibration package information (unique identifier, see Section 2.6.2).
- The input DICOM file (raw data provided to IBEX BH) and the output DICOM file (see Section 2.3.6 for instructions on how these can be accessed).

Table 4: Troubleshooting guide.

Issue	Likely Cause	Required Action	Likely Impact
Input DICOMs fail to be received into the software	The C-Store SCU AET does not match the configured calling AET.	Either change the AET of the C-Store SCU that is sending the DICOMs, or update the "Calling AET" setting to match the SCU AET, or delete the "Calling AET" setting (leave empty).	No output can be produced. No error code is raised.
	The C-Store SCU sending the DICOMs is expecting a different AET.	Either change the destination AET used by the C-Store SCU, or update the "Receiver AET" setting to match the AET expected by the SCU.	No output can be produced. No error code is raised.
	Firewall is blocking the connection.	Open the 2534 port in the firewall of the host running the software (note: the port may have been remapped by the integrator, please check with them).	No output can be produced. No error code is raised.
Output DICOMs fail to be sent from the software.	IP or port of the destination C-Store SCP has not been changed from the default (IP: 127.0.0.1, port: 2535).	Edit the "Destination IP" and "Destination port" to a suitable IP address and port. The defaults are placeholders.	No output can be produced. Sending is marked as failed in the dashboard, no error code is raised.
	IP or port of the destination C-Store SCP is incorrect.	Check and update the "Destination IP" and "Destination port" settings then try again.	No output can be produced. Sending is marked as failed in the dashboard, no error code is raised.
	Destination AET is incorrect.	Check and update the "Destination AET" setting then try again.	No output can be produced. Sending is marked as failed on the dashboard, no error code is raised.
	Destination is configured to only accept associations from a limited set of AETs.	Either include the current "Sender AET" (default "TrueviewSender") to the list of accepted AETs for the C-Store SCP, or change the "Sender AET" setting to a value that will be accepted.	No output can be produced. Sending is marked as failed on the dashboard, no error code is raised.

Continued on next page

Table 4: Troubleshooting guide. (Continued)

Issue	Likely Cause	Required Action	Likely Impact
	Firewall is blocking the connection.	Open the relevant port in the firewall of the host running the SCP.	No output can be produced. Sending is marked as failed on the dashboard, no error code is raised.
The license agent cannot be reached.	Agent IP has not been changed from the default (127.0.0.1).	Edit the "Agent IP" settings to a suitable IP address. The default is a placeholder.	No output can be produced. Error code 401 may be raised.
	Agent IP or port is incorrect.	Check and update the "Agent IP" and "Agent port" settings then try again.	No output can be produced. Error code 401 may be raised.
	License agent is not running.	Start the license agent.	No output can be produced. Error code 401 may be raised.
	Firewall is blocking the connection.	Open the relevant port in the firewall of the host running the license agent.	No output can be produced. Error code 401 may be raised.
License agent is running but has no valid license.	No license currently configured.	Follow the licensing procedure.	No output can be produced. Error code 401 may be raised.

3.1 Image and Protocol Compatibility Issues

The IBEX BH software internally validates the image tags, input image and the output result and may produce an error or warning if this validation has not been passed. This is a process called I/O Validation. The risk of processing an incompatible image is mitigated as follows:

- I/O Validation selects images tagged as PA, AP, or DP. It rejects images labelled as Lateral or Oblique. However, image labelling is inconsistent from hospital to hospital and even from user to user so this test is insufficient on its own.
- An image similarity check rejects anything that is obviously not a wrist or hand image. It does this by looking at geometric features as well as outputs such as total thickness and aBMD and checking that they are within the clinical validation data range. For example, if someone input a knee labelled as a wrist, it would be much thicker and more dense than a wrist and would fail.
- Incompatible images are more likely to fail internal checks and be rejected. For instance, if a lateral image is passed as PA, the radius and ulna bones will overlap and the ROI algorithm would most likely fail.
- Output validation checks reject anything falling outside of an acceptable threshold range. For example, if there were a metal implant in the region of interest, the T-score would be unreasonably high and would most likely fail.
- The final check is clinical validation where the reporting physician reviews and rejects results from any image not within the supported range of protocols as described in the End Users Manual (`IBX_PRD_SOP_002`).

Errors captured by I/O Validation include E201, E203, E210, and E301. Warnings raised by I/O Validation include W202, W204, W205, W206, and W302.

The end user perspective on these issues and guidance on recovery is described in the End Users Manual (`IBX_PRD_SOP_002`).

3.2 QA Failure Cases

If the QA procedure in Section 2.6.4 is unsuccessful, it could have been due to one of the following known failure cases:

- The edges of the phantom were not parallel to the edges of the detector. Rotations of up to 8 degrees are permitted.
- There was a $> 5\%$ difference in kVp between the calibration exposures and the QA phantom exposure.
- There was a > 20 cm difference in SID between the calibration exposures and the QA phantom exposure.
- There was a source or detector rotation between the calibration exposures and the QA phantom exposure.
- A different phantom to the one described in Section 1.3 was used.

If these cases have been ruled out, please contact IBEX for further support.

3.3 Warnings and Errors

Warning and error messages are automatically generated by IBEX BH in the event of image presentation, data processing, or other software issues. The more clinically relevant messages are displayed in the Secondary Capture DICOM output image, either as a list of warning and error codes, or as a watermark for the most important messages. The system integrator may also choose to display messages on the user interface. All messages are saved and available to view within a private tag in the DICOM output.

A list of error and warning codes is provided in Table 5. Some warnings are for information purposes only and others should be taken into consideration when interpreting the results. The ability to resolve errors will

depend on your user level - end user, engineer, or integrator. See the appropriate troubleshooting section for further guidance.

Table 5: Error and warning codes

Code	Meaning	Cause	Action
E101	Required DICOM tag unavailable	A required DICOM tag is missing from the input.	Please contact the integrator.
W102	Optional DICOM tag unavailable	An optional DICOM tag is missing from the input.	Review the ID of the tag and check this is expected and that the assumed fallback value is appropriate. If not, please contact the integrator.
E201	DICOM tag value unsupported or out-of-range	Wrong protocol selected.	Please make sure that only protocols that are meant for bone health assessment are configured to run IBEX BH.
		A DICOM tag is set incorrectly.	Please contact the integrator.
W202	Similarity check failed	Incorrect body part or positioning.	Please ensure the wrist is positioned as expected.
		Patient falls under one of the contraindication and limitations of the software.	Output should not be used.
		Incorrect tagging of input data.	Please correct the selected protocol, or contact the integrator.
		Calibration is not suitable for this system or protocol.	Please follow the QA procedure for this protocol.
E203	Protocol out of calibrated range	Wrong protocol selected.	Please make sure that only protocols that are meant for bone health assessment are configured to run IBEX BH.
		No calibration available for the selected protocol.	Please follow the relevant procedure to request a calibration.
W204	Protocol out of explicitly calibrated range	Calibration chosen for the selected protocol was not an exact match.	Please review the difference of exposure parameters between the selected protocol and the protocol used for calibration and ensure the difference is acceptable, ignore the warning if so. Otherwise, please follow the relevant procedure to request a more appropriate calibration.
W205	Calibration out-of-date	Calibration is too old.	Re-run the QA procedure. If the QA procedure fails, request an updated calibration.

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Table 5: Error and warning codes (Continued)

Code	Meaning	Cause	Action
W206	Bone health assessment not indicated	Patient is too young.	Product intended and tested for use on patients over 50 years of age. Discretion advised if used on younger patients.
E207	Ambiguous protocol calibration	More than one calibration matches the selected protocol.	Please contact IBEX to request a corrected calibration package.
W208	Unused system property	Incorrectly configured calibration package.	Please contact IBEX to request a corrected calibration package.
E209	Calibration awaiting QA	The selected protocol has not gone through the QA procedure.	Please follow the QA procedure and try again.
		The QA exposure was missing tags for automatic QA detection, and the manual QA mode was not turned on.	Please turn on manual QA mode on the calibration interface.
E210	Invalid input property	Wrong protocol selected.	Please make sure that only protocols that are meant for bone health assessment are configured to run IBEX BH.
W211	Experimental protocol	Software configured to accept non-standard protocol (e.g., non-standard body part or non-standard view) and exposure from such protocol is received.	Exercise caution when interpreting the results.
E301	Required ROI was not detected	Incorrect body part in image.	Please only send images of wrists or hands containing the ultra distal radius region.
		Field of view too narrow.	Ensure the field of view covers relevant parts of the wrist and ultra distal radius.
W302	Optional ROI was not detected	Field of view too narrow, does not include third distal radius region.	Ensure the field of view covers the third distal radius region, or ignore the warning.
E303	Bone health calculation failed	Error in software pipeline.	Please contact IBEX.
E304	Exhausted resource	The computer running the software has run out of resource.	Please free up resources and try again, or contact the integrator.

Continued on next page

Table 5: Error and warning codes (Continued)

Code	Meaning	Cause	Action
E305	Unexpected internal error	Unexpected error.	Please contact IBEX.
E306	Processing cancelled	The server was restarted during processing.	Avoid restarting the server while data is being processed.
		The server configuration or calibration was changed during processing.	Avoid changing the server configuration while data is being processed.
E307	Calibration QA failed	Wrong calibration package uploaded.	Upload the calibration package suitable for this system.
		Calibration is not suitable for this system	Please contact IBEX.
		Clinical exposure included tags that automatically flagged the exposure for QA.	Please use an appropriate clinical protocol, and ensure that clinical exposures do not have QA-specific tags set.
E401	Invalid license	No license is installed.	Please follow the licensing procedure.
		License has expired.	Please follow the license renewal procedure.
		Software has been updated and license agent is incompatible.	Please contact the integrator.
		Software aborted unexpectedly and license is still considered in use.	Please wait for the license to time out, or restart the system.
E402	No calibration data available	No calibration data installed.	Please upload a calibration package or follow the calibration procedure if no calibration is available.
E403	Corrupted calibration data	Corrupted calibration package.	Please re-upload the calibration package, and if the error persists contact IBEX for a replacement calibration package.
E404	No normative population data available	Population data not configured.	Please configure normative data.
E405	Calibration is invalid	The available or uploaded calibration has an incorrect version.	Please contact IBEX to upgrade the calibration package.

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Table 5: Error and warning codes (Continued)

Code	Meaning	Cause	Action
E501	Request refused	Too many exposures were sent in a short time, and the software input queue is full.	Please increase the size of the input queue, or request that integrators implement a retry mechanism when sending data to the software.
E502	Invalid request	The input DICOM data is missing one or more required data sets.	Please ensure all required DICOM data sets are sent within a single association.
		The input DICOM data contained unexpected data sets.	Please ensure only the required DICOM data sets are sent within a given association.
E503	Inbound connection aborted	The network connection is no longer available.	Please ensure the device running the software is reliably connected to the appropriate network.
		The source application has crashed while sending input data.	Please check the status of the software sending input DICOMs.
E601	Output connection failed	No network connection is available.	Please ensure the device running the software is connected to the appropriate network.
		The configured hostname and/or port for the output DICOM destination is incorrect.	Please check the configured hostname and port for the output DICOM destination in the IBEX BH configuration interface.
		The configured output DICOM destination is not currently reachable.	Please check that the device configured as output DICOM destination is powered on and connected to the network.
		No suitable DICOM association could be negotiated with the configured output DICOM destination.	Please review the settings and capabilities of the destination device.
E602	Output connection aborted	The network connection is no longer available.	Please ensure the device running the software is reliably connected to the appropriate network.
		The output DICOM destination application has crashed while receiving the output data.	Please check the status of the software receiving output DICOMs.
E603	Invalid outbound request	The configured output DICOM destination is not correct.	Please check that the configured output DICOM destination is the intended device.

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Table 5: Error and warning codes (Continued)

Code	Meaning	Cause	Action
		The configured output DICOM destination does not support storage requests.	Please check the configuration of the destination device.
		IBEX BH produced a malformed storage request.	Please context IBEX.
E604	Outbound request refused	The configured output DICOM destination is out of storage space.	Please free up space on the destination device and try again.
		The output data sent by IBEX BH is of a type that is not accepted by the configured destination.	Please review the settings of the output DICOM destination device.
		IBEX BH is not authorized to perform store requests on the configured output DICOM destination.	Please review the settings of the destination device.

4 Appendix

4.1 Medical Device Label

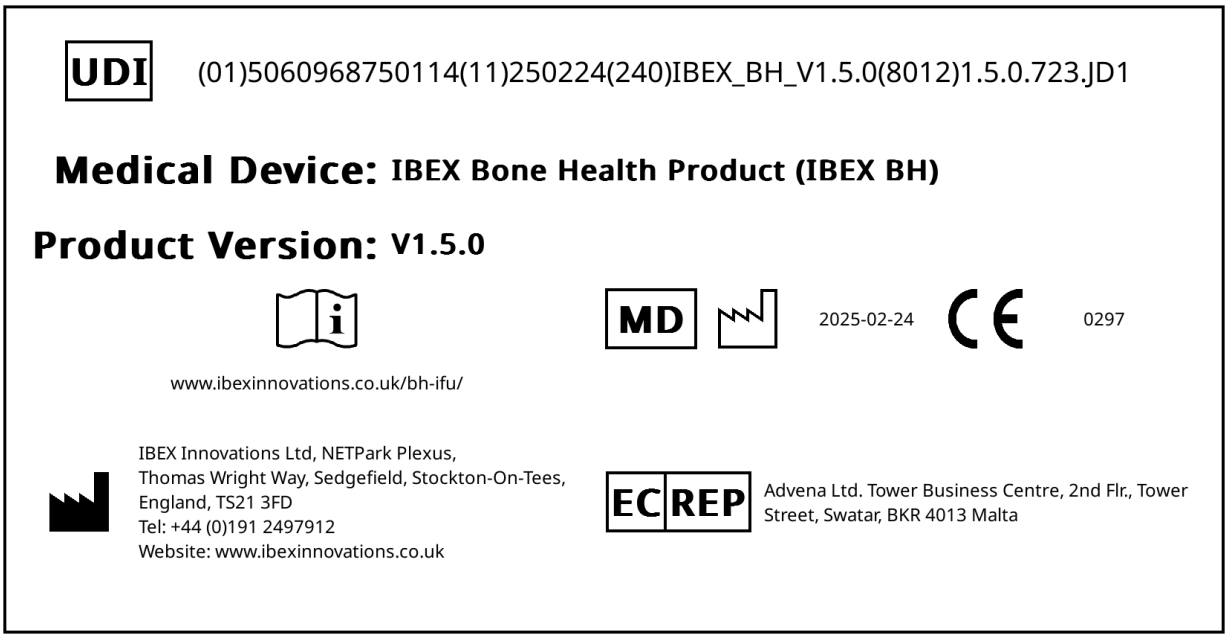

Figure 12: Product label for integration on Nvidia Jetson Xavier NX (Docker, Linux).

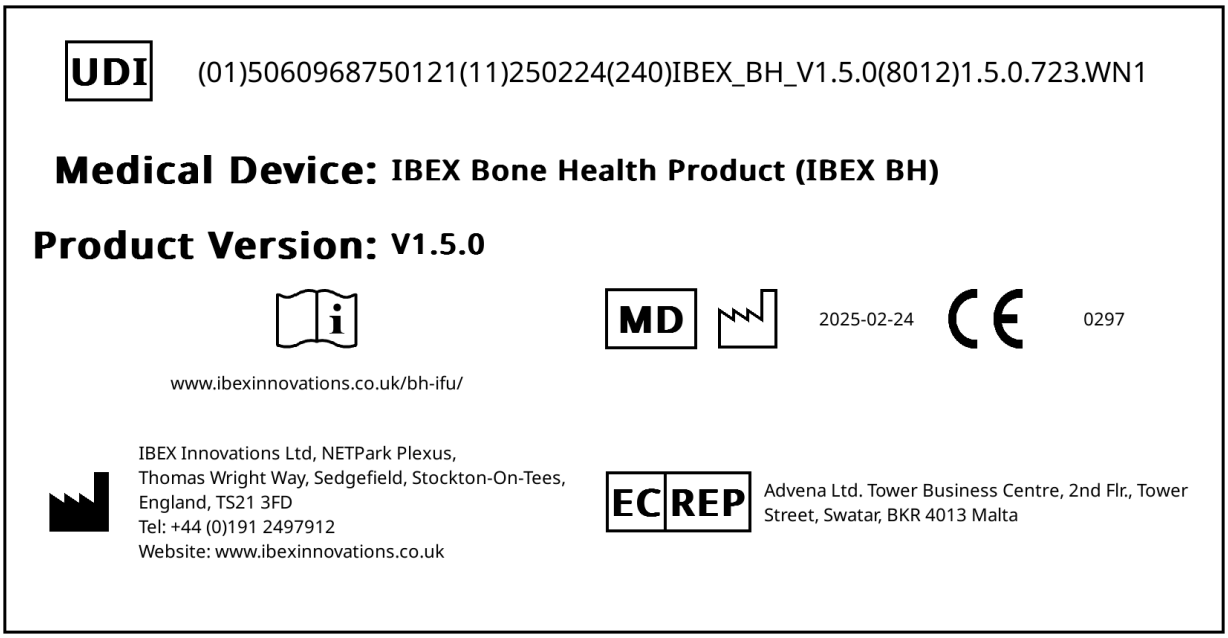

Figure 13: Product label for integration on generic desktop PC (Native, Windows).

4.2 Regulatory Clearance

IBEX BH is a CE marked class IIa according to Regulation (EU) 2017/745 (EU MDR) and approved for use in applicable jurisdictions.

- 2017/745 — Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.
- EN ISO 13485:2016+A11:2021 — Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes.
- EN ISO 14971:2019+A11:2021 — Medical Devices — Application of Risk Management to Medical Devices.
- EN ISO 15223-1:2021 — Medical devices. Symbols to be used with information to be supplied by the manufacturer — General requirements.
- EN ISO 20417:2021 — Medical devices. Information to be supplied by the manufacturer.

4.3 Patents

The IBEX BH software is protected by following patents: JP6598087, US10588592, GB2576772, GB2608900, GB2611231, GB2589643, GB2563115, US 10820878 (Japan, South Korea Pending, EU, China Pending).

Instructions For Use - Service Manual - IBEX BH v1.5.0

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