Instructions for Use

XVIVO Insights™ V2.2- Website

XVIVO

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Please refer to ‘Help’ section 4.13 for terms and conditions of XVIVO Insights.

1 Product description

XVIVO Insights™ (www.xvivoinsights.com) is a website and mobile application used to monitor XVIVO's hardware perfusion devices. The web and mobile application makes it possible to remotely view perfusion data, see GPS data of the hardware device location.

The perfusion run data is accessible through a dedicated website requiring a username and password login. The data for a specific run can be temporarily shared with XVIVO personnel to allow for remote troubleshooting.

1.1 Warnings and precautions

XVIVO Insights is not a substitute for the interface of the perfusion device. Never leave the perfusion device unattended.

Do not use XVIVO Insights to determine organ quality. That should be judged by the transplant surgeon.

Data displayed in XVIVO Insights is intended for monitoring purposes only and must not replace the official accompanying organ records or documentation.

1.2 Intended purpose

XVIVO Insights is a website and mobile application intended for complementary remote monitoring of status and functioning of XVIVO's perfusion devices.

1.3 Intended user profile

XVIVO Insights is intended for use by trained professionals in a professional healthcare environment. Users receive training on XVIVO perfusion devices before using the XVIVO Insights software.

1.4 Intended clinical benefit

XVIVO Insights is not a medical device and has no clinical benefit.

1.5 Intended medical indication

XVIVO Insights is not classified as a medical device and does not have an intended medical indication.

2 Recommended browsers

For optimal performance, it is recommended to access XVIVO Insights using Google Chrome, Microsoft Edge, or Safari browsers. These browsers provide the best compatibility and user experience for navigating the functionalities.

3 Roles and definitions

A device is:

the physical perfusion device. Each device is in turn owned by or connected to an individual clinic/hub/OPO account. Parameters visible on the device are stored internally on the device until maximum storage is achieved or

data is removed either by the user or XVIVO service personnel. If XVIVO Insights is enabled, data is also continuously uploaded into a cloud-based storage system.

A System Manager - Has full administrative privileges within the company:

- Add and remove System Managers and System Users of a device registered to the company (clinic/hub/OPO)
- Add and remove Viewers or XVIVO to a specific perfusion run
- View all ongoing or finished perfusion related to the devices registered to the company
- Add or edit text field data related to an individual perfusion run
- Approve request for deletion of perfusion runs
- Request restoration of deleted runs
- Export run data in PDF or Excel format

A System User - Operational role with access to perfusion data:

- Add or remove Viewers and XVIVO for individual runs
- View all ongoing/completed perfusions related to the devices registered to the company
- Add or edit text field data related to an individual perfusion run
- Submit run deletion requests (approved by System Manager)
- Export run data in PDF or Excel format

A Viewer Premium - View + export:

- View runs explicitly shared by System Manager or System User
- Export PDF or Excel reports for permitted runs

A Viewer – Basic access:

- View shared perfusion runs only

XVIVO Admin - Reserved for internal XVIVO use:

- Create new companies and register a new device to that account
- Create all user profiles including XVIVO Admin, XVIVO Technical Support, System Manager, System User, Viewer Premium, and Viewer

XVIVO Technical Support – Troubleshooting role:

- Access and download run reports when permission is granted by System Manager or System User

4 Operating instructions

The top menu consists of four tabs:

- Home – Overview of devices and their last connection status.
- Manage – Interface to manage user roles, assign viewers, and handle delete requests. (Accessible only to XVIVO Admin and System Manager profiles)
- Run data – View data from previous or ongoing perfusion runs.
- Help – Provides details about Insights, IFU, FAQs, Troubleshooting and Contact Support.

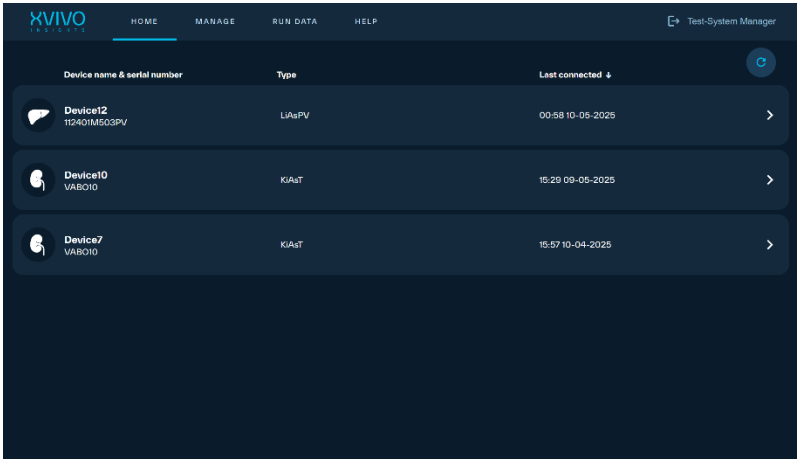

Figure 1 - Overview of Insights

The user's login name appears in the top-right corner of the interface, alongside a logout button.

4.1 Login

1. Go to www.xvivoinsights.com
2. Enter the assigned username and password
3. Click the 'Login' button

The password must be at least 6 characters long and contain at least:

- 1 digit
- 1 lowercase letter
- 1 uppercase letter
- 1 special character

If the password is forgotten, click the 'Forgot password' button to receive a reset link to the registered email.

Ensure that firewall or security settings on the device allow access to XVIVO Insights.

For security reasons, do not leave XVIVO Insights open in a web or mobile browser when unattended. Always log out or close the browser tab after use.

Figure 2 - Login page

4.2 Edit a device name

To personalize or more easily identify devices within a clinic or organization, the default device name in XVIVO Insights can be updated by the System Manager and System User. Follow these steps:

1. Click on the ‘Home’ tab in the top menu.
2. In the device list, hover over the desired device name.
3. An edit icon will appear next to the name.
4. Click the edit icon to enable editing.
5. Enter the new device name.
6. Click the check mark to save the changes.

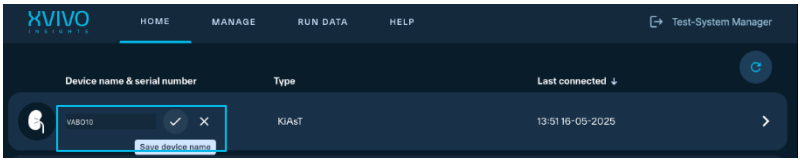

Figure 3 - Edit device name

4.3 Sort devices

In the Home tab, all devices registered to the clinic/hub/OPO are listed along with their type and last connection status.

To manually sort the list:

1. Click on the ‘Home’ tab in the top menu.

2. Click on the ‘Last Connected’ column header to sort devices in ascending or descending order (↑ indicates ascending order and ↓ indicates descending order) Clicking the header again toggles the sort order.

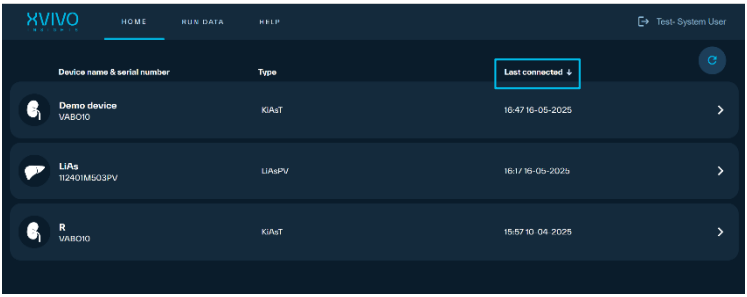

Figure 4 - Sort devices

4.4 Add/edit users

Managing users in XVIVO Insights is a role-based function that ensures the right access levels are granted based on operational needs. This section outlines how to add different types of users. To perform any of the following actions, go to the ‘Manage’ tab and select the ‘Users’ sub-tab.

4.4.1 Add XVIVO Admin/ XVIVO Technical Support

1. Navigate to ‘Manage’ > ‘Users’.
2. Click ‘Add New User’.
3. Enter user details (name, email).
4. Select role: ‘XVIVO Admin’ or ‘XVIVO Technical Support’.
5. Assign the user to a specific company.
6. Click ‘Save’. The user will receive an activation email invitation.

These roles have elevated privileges to manage companies, register devices, and access run data when permitted by company users.

Note: Accessible to XVIVO Admin only

4.4.2 Add System Manager

1. In ‘Manage’ > ‘Users’, click ‘Add New User’.
2. Enter user details (name, email).
3. Select role: ‘System Manager’.
4. Assign the user to a specific company (accessible to XVIVO Admin only). A System Manager can create another System Manager only within the same company.
5. Click ‘Save’. The user will receive an activation email invitation.

System Managers have full control over device and run data for their organization and can manage other users.

Note: Accessible to XVIVO Admin and System Manager only

4.4.3 Add System User

1. Navigate to ‘Manage’ > ‘Users’.
2. Click ‘Add New User’.
3. Enter user details (name, email).
4. Select role: ‘System User’.
5. Assign the user to a specific company (accessible to XVIVO Admin only). A System Manager can create a System User only within the same company.
6. Click ‘Save’. The user will receive an activation email invitation.

System Users can access and edit perfusion data but cannot delete runs or manage other users.

Note: Accessible to System Manager only

4.4.4 Add Viewer Premium/Viewer

1. Select a specific perfusion run in the Run Data tab.
2. Click the Manage Viewers button.
3. Choose an existing user from the list or click Add New Viewer.
4. Enter email and assign either Viewer or Viewer Premium.

Viewers can only access shared runs, while Viewer Premiums can also export data from those shared runs. This access can be revoked at any time.

4.5 Search for a perfusion run

Both ongoing and completed runs can be viewed. There are two ways to locate a specific perfusion run within XVIVO Insights:

Option 1: Using the ‘Run Data’ tab

1. Click on the ‘Run Data’ tab in the top menu.
2. Use the available filters to refine the search. Filtering options include:
    - Session Start date range (Session start from / to)
    - Device name or serial number
    - Organ ID
3. As filters are applied, the list of matching runs will be displayed. Results can be sorted by time & date, Organ ID, device name or Serial number.
4. Select a run from the list to open its detailed view.

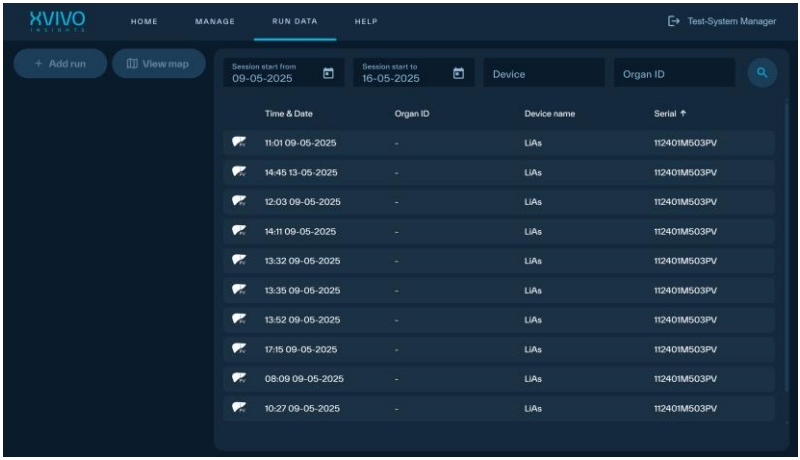

Figure 5 - Search Run Data

Option 2: Using the ‘Home’ tab

1. On the ‘Home’ tab, find and select the desired device from the device list.
2. A list of recent perfusion runs associated with the selected device will be displayed.
3. Select the specific run to view its details.
4. This view automatically applies a filter to show runs from the last 7 days.

Only perfusion runs associated with devices linked to your user account and access level will be displayed.

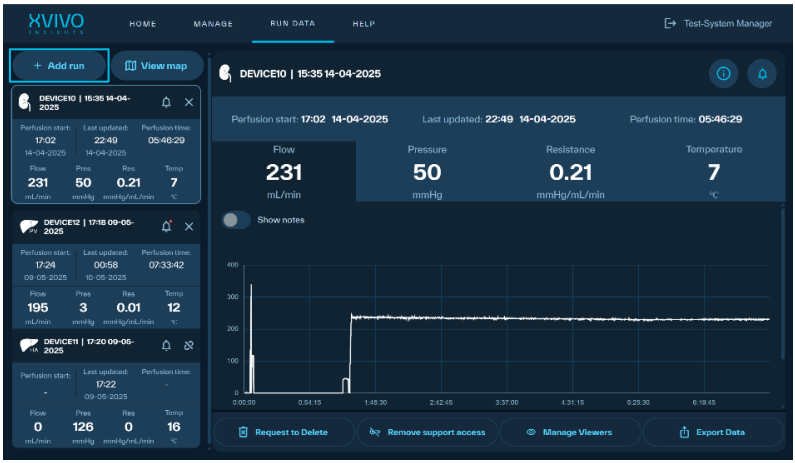

Figure 6 - Perfusion data page

An overview of multiple perfusion runs can be viewed simultaneously. Simply add a new run by clicking on the blue '+ Add run' icon and follow the same steps without closing the existing bookmarked run. To close a run, click on the 'X' icon in the top right of the perfusion run bookmark.

4.5.1 Link/Unlink a HA run to a PV run

For Liver Assist devices, perfusion data is recorded separately from two units: the Portal Vein (PV) and the Hepatic Artery (HA). XVIVO Insights allows users to manually link these separate runs into a single combined view, which is useful for reviewing the entire liver perfusion session.

To link an HA run to a PV run:

1. Go to the 'Run Data' tab.
2. Identify and select the PV run from the list on the left-hand side.
3. Click the 'Add HA' button.
4. On the right, click the search icon. A list of HA runs from the same device will appear.
5. Select the appropriate HA run that corresponds to the PV run.

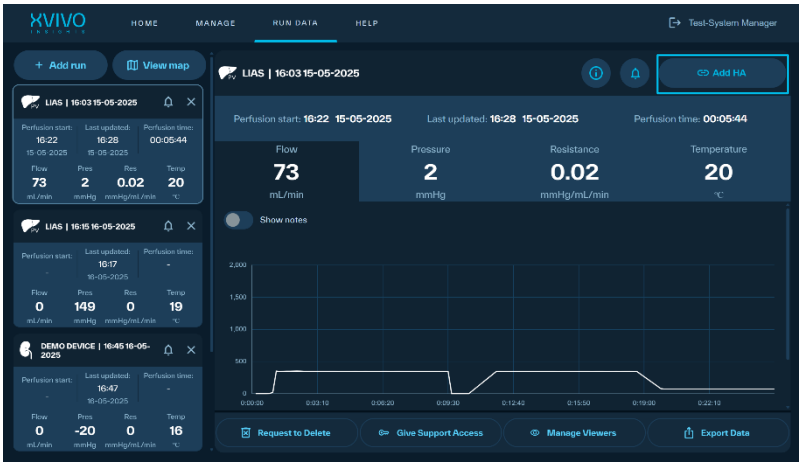

Figure 7 - Link PV run to a HA run

Once linked:

- The PV and HA runs are displayed together on the same perfusion data graph.
- Linked runs can be exported as a single combined report (PDF or Excel).
- Notes and media added to either run remain visible separately.

Each PV run can be linked to only one HA run. In exports and dashboard views, linked runs are displayed under the PV serial number. Only users with the roles of System User or System Manager are permitted to link/unlink runs.

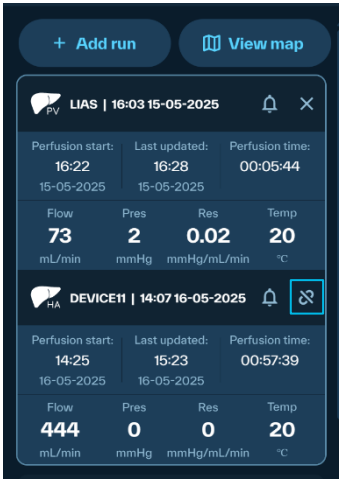

Figure 8 - Unlink PV and HA run

To unlink a HA run from a PV run, select the PV run from the left-hand bookmark in the 'Run Data' tab. Then, navigate to the HA tab in the run view and click on the Unlink icon. This will remove the association between the two runs, restoring the PV as an independent session in the system.

Note: Applicable for Liver Assist devices only

4.6 Notifications

⚠ XVIVO Insights is not a substitute for the interface of the perfusion device. Never leave the perfusion device unattended.

⚠ Data displayed in XVIVO Insights is intended for monitoring purposes only and must not replace the official accompanying organ records or documentation.

4.6.1 View notifications from a device

Notifications include errors, warnings, and informational messages generated by the device during perfusion. To view them:

1. Navigate to the 'Run Data' tab.
2. Select the desired perfusion run.
3. Click on the bell icon in the run window.
4. A red dot next to the bell icon indicates there are unread notifications.
5. Scroll through the list of notifications. The latest notification appears at the top.
6. Each message includes a timestamp and severity level (error or warning).

Notifications can also be downloaded as part of the Excel report for offline analysis.

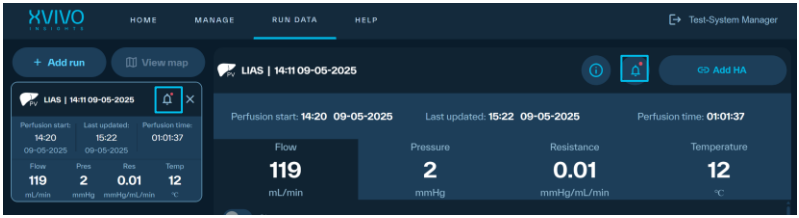

Figure 9 - View notifications

4.6.2 User defined notifications

In addition to notifications generated by the device, XVIVO Insights allows users to configure their own notification thresholds for selected perfusion parameters. This function enables closer monitoring of values that are critical to the user's workflow.

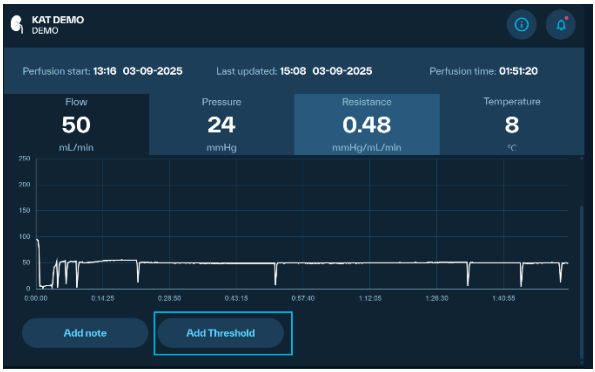

Figure 10 - User defined notifications

Note: This feature is intended solely for user convenience and workflow support. It must not be used to assess or determine organ quality. Notifications are generated within XVIVO Insights based on parameter values transmitted from the device. They are not generated by the device itself.

To configure a user-defined notification:

1. Navigate to the 'Run Data' tab and select the desired perfusion run.
2. Choose the parameter to monitor (Flow, Pressure, Resistance, or Temperature).
3. Scroll down and click "Add Threshold."
4. Enter a minimum and maximum threshold value.
5. Click Save.

4.7 Add/view a perfusion note

Perfusion notes allow comments to be added for specific events that occurred during a perfusion run. Each note is linked to a precise time point on the run graph.

1. Click on the ‘Run Data’ tab
2. Select the desired perfusion run from the left-hand panel.
3. Click the ‘Add note’ button below the graph.
4. A note input panel will appear below the graph with two fields:
   - Time: Enter the time (hh:mm:ss)
   - Note: Enter your comment
5. Click ‘Save note’ to store the entry, or ‘Cancel’ to discard it.
6. Once saved, notes appear as small blue markers on the perfusion graph.
7. Click ‘Show notes’ to view all added notes on the graph and ‘Hide notes’ to hide them

Figure 11 - Add note to the graph

4.8 Access location data

The location of a Kidney Assist Transport perfusion run can be viewed within XVIVO Insights. To access the location data:

1. Click on the ‘Run Data’ tab and select the perfusion run.
2. In the top-left corner above the run list, click the ‘View map’ button.
3. A map view will open, displaying the most recent known location of the selected device.
4. GPS data is also included in the PDF and Excel reports for each perfusion run.
5. Click on ‘Close map’ to return to the overview.

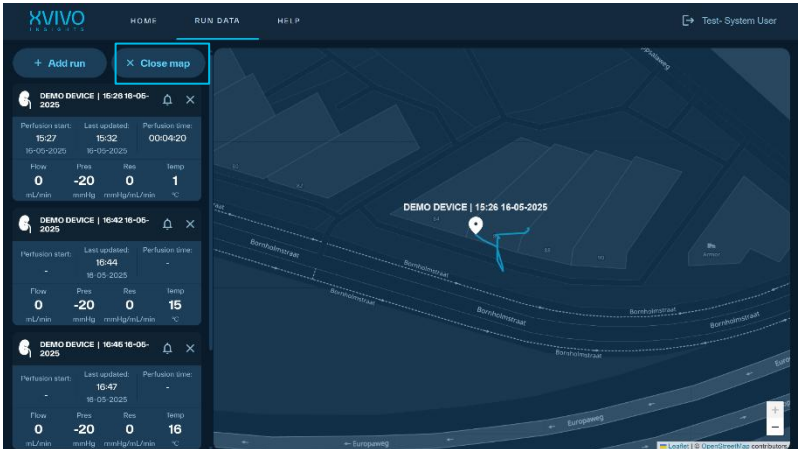

Figure 12 - View map

Note: Applicable for Kidney Assist Transport devices only

4.9 Edit perfusion information

1. In ‘Run Data’, select the perfusion run.
2. Click the ‘i’ information icon to view more details for each run.
3. To edit, click ‘Edit Info’. The available options will vary depending on the device type.
4. A pop-up window will appear with:
    - Information: Editable data fields.
    - Media: Upload images or video associated with the procedure. **Do not upload Personally Identifiable Information (PII) or sensitive data** (such as images or files that can identify a person) to XVIVO Insights.
    - Click ‘Save’ to apply changes

4.10 Delete a perfusion run

Old perfusion runs can be deleted if they are no longer needed. System Users may initiate a deletion request, which must then be reviewed and approved by a System Manager.

1. Select the run in ‘Run Data’.
2. Click the ‘Request to Delete’ button at the bottom of the selected perfusion run.
3. A request is sent to the System manager for approval.

4.10.1 Approve a deletion request

1. Go to the ‘Manage’ tab.
2. Under ‘Delete requests’, find the requested run.
3. Review details and click ‘Delete’.

Note: Accessible to System Managers only

4.10.2 Restore a deleted perfusion run

1. Go to the ‘Manage’ tab.
2. Under ‘Delete requests’, find the run to be restored.
3. Review details and click ‘Restore’.
4. A request is sent to the XVIVO Admin for approval.

Note: Accessible to System Managers only

4.11 Give XVIVO Technical Support access

To temporarily allow XVIVO support to review a perfusion:

1. Select the run in ‘Run Data’.
2. Click ‘Give Support Access’.
3. The technician from XVIVO will receive access to view and export data.

This is useful for troubleshooting or support purposes. This access can be revoked at any time by clicking ‘Remove support access’.

4.12 Download a PDF/Excel report

Reports are downloadable for individual runs. To export:

1. Go to ‘Run Data’ and select a run.
2. Click ‘Export Data’.
3. Choose format: PDF or Excel (xlsx).
4. Choose data resolution (e.g., 10s, 1min, 5min or 30min).
5. Click Download.

For a linked PV and HA run, there is an option to download all connected data. This includes PV and HA runs that have an overlap in time from the same device, allowing for a combined report that presents a full picture of the liver perfusion

session. PDFs include charts and notes; Excel reports include summary of device and perfusion run information, perfusion data, notifications, and changelogs.

> ⚠ Do not use XVIVO Insights to determine organ quality. That should be judged by the transplant surgeon.

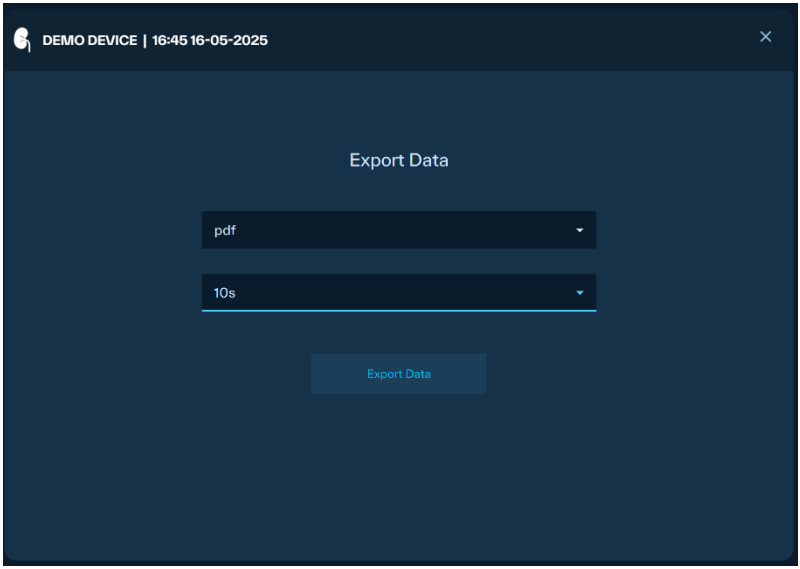

Figure 13 - Download perfusion data

4.13 Help section

The Help tab provides access to support materials:

- About us
- Getting started
- Quick guides
- FAQs
- Troubleshooting guides
- Contact and support information

For any technical issues or questions, consult this section or contact your local XVIVO representative. To view the terms and conditions for XVIVO Insights, please refer to the ‘About us’ page.

XVIVO B.V.

Bornholmstraat 84
9723 AZ Groningen
The Netherlands

+31(0)50-313 19 05
www.xvivogroup.com
getinsights@xvivogroup.com

Document ID: IFU XVIVO Insights Website en
Revision: 06
Article number: 55.602
Date: 20-08-2026