

Instructions for Use

XVIVO Insights™ V2.1- Mobile App

XVIVO

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

1 Product description

XVIVO Insights™ is a website (www.xvivoinights.com) and mobile application used to monitor XVIVO's hardware perfusion devices. The website 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 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 Supported operating systems

The XVIVO Insights app is available for devices running **iOS** and **Android** operating systems. These platforms provide the best compatibility and user experience for accessing the app's 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

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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 bottom navigation bar consists of five 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)
- Data – View data from previous or ongoing perfusion runs.
- Search – Search for perfusion runs
- Help – Provides details about Insights, IFU, FAQs, Troubleshooting and Contact Support.

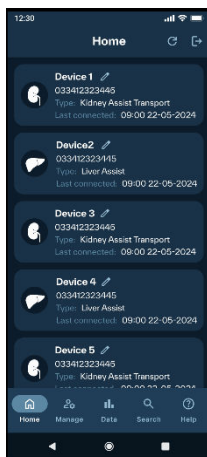


Figure 1 - Overview of Insights

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

4.1 Login

1. Open the XVIVO Insights mobile application on your iOS or Android device.
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 the device has an active internet connection and that app permissions allow network access.

For security reasons, do not leave XVIVO Insights open when unattended. Always log out or close the app after use.

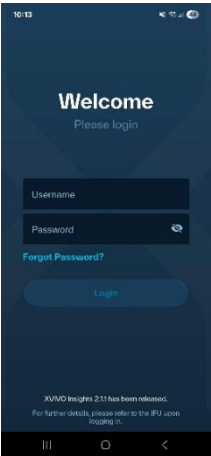


Figure 2 - Login page

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. Select the Home tab in the bottom navigation bar.
2. In the device list, select the edit icon next to the device name to be updated.
3. Enter the new device name.
4. Select Save to confirm the changes.

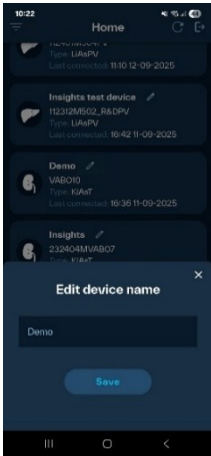


Figure 3 - Edit device name

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4.3 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.

4.3.1 Add XVIVO Admin/ XVIVO Technical Support

(Accessible to XVIVO Admin only)

1. Navigate to 'Manage' > 'Users'.
2. Click 'Add 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 'Add'. 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.

4.3.2 Add System Manager

(Accessible to XVIVO Admin and System Manager only)

1. In 'Manage' > 'Users', click 'Add User'.
2. Fill in required user information.
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 'Add'. 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.

4.3.3 Add System User

(Accessible to System Manager only)

1. Navigate to 'Manage' > 'Users'.
2. Click 'Add 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 'Add'. The user will receive an activation email invitation.

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

4.3.4 Add Viewer Premium/Viewer

1. In the bottom navigation bar, select the Data tab.

2. Select '+', then choose Search and select a perfusion run from the list.
3. Click the three dots next to the logout icon and select Manage Viewers → Add New Viewer.
4. Select Add.
5. Enter the email address and assign the role of 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.

4.4 Search for a perfusion run

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

Option 1: Using the 'Data' tab

1. Click on the 'Data' tab in the bottom navigation bar.
2. Select '+' and 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.
4. Select a run from the list to open its detailed view.

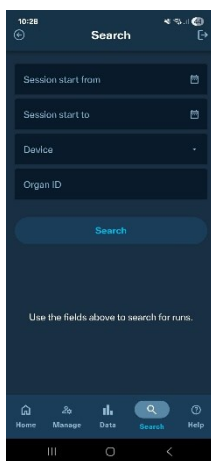


Figure 4 - Search Run Data

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.

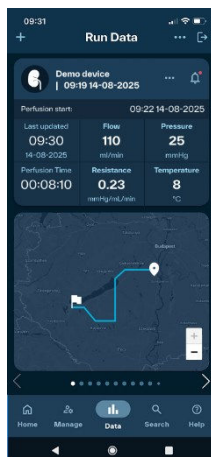


Figure 5 - Perfusion data page

Option 3: Using the 'Search' tab

1. Click on the 'Search' tab in the bottom navigation bar.
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.
4. Select a run from the list to open its detailed view.

Multiple perfusion runs can be opened and viewed. Swipe left or right to switch between open runs. To add another run, click on the blue '+' icon and follow the same steps as in option 1 without closing the existing bookmarked run. To close a run, click on the three dots next to the bell icon in the top right corner of the perfusion run bookmark and select **'Remove run'**.

4.4.1 Link/Unlink a HA run to a PV run (Liver Assist devices only)

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 'Data' tab.
2. Open the desired PV run.
3. Click 'Add HA'.
4. A list of unlinked HA runs from the same device will appear.

5. Select the HA run that corresponds to the PV run.

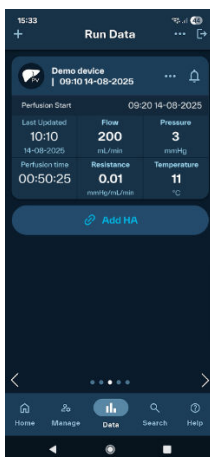


Figure 6 - Link PV run to a HA run

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.

Only users with the roles of System User or System Manager are permitted to link runs. 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.

To unlink an HA run from a PV run, go to the 'Data' tab and select the PV run. In the HA section, click the three dots next to the bell icon, and then select 'Unlink paired run'. This will remove the association between the two runs, restoring the PV as an independent session in the system.

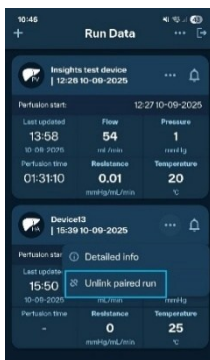


Figure 7 - Unlink PV and HA run

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4.5 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 'Data' tab.
2. Select the desired perfusion run.
3. Click on the bell icon.
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.

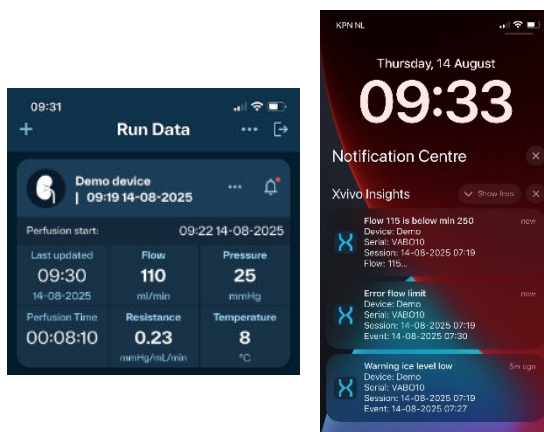


Figure 8 - View notifications

If enabled in your device settings, push notifications are sent directly to your mobile. The account must be logged in and the corresponding perfusion run must be open in the app to receive push notifications. The sound and vibration of push notifications follow your mobile device's notification settings. These alerts appear as standard system notifications and provide a summary of the event (e.g., "Error flow limit"). Tapping the notification opens the app and directs you to the relevant perfusion run for details.

4.6 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 9 - 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 'Data' tab and select the desired perfusion run.
2. Choose the parameter to monitor (Flow, Pressure, Resistance, or Temperature).
3. Click 'Add Threshold' below the graph.
4. Enter a minimum and maximum threshold value.
5. Click 'Save Threshold'.

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.

To add a perfusion note:

1. Click on the 'Data' tab
2. Select the desired perfusion run.
3. Select a perfusion parameter (flow, pressure, resistance or temperature) and 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.

- Click 'Show notes' to view all added notes on the graph and 'Hide notes' to hide them



Figure 10 - Add note to the graph

4.8 Access location data (Kidney Assist Transport devices only)

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

- Click on the 'Data' tab and select the perfusion run.
- A map view will open along with the overview of the perfusion parameters, displaying the most recent known location of the selected device.
- GPS data is also included in the Excel reports for each perfusion run.

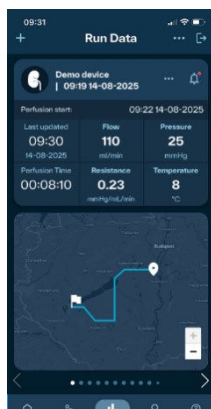


Figure 11 - View map

4.9 Edit perfusion information

1. In 'Data', select the perfusion run.
2. Click on three dots next to the notification icon and select 'Detailed info'.
3. To edit, click 'Edit information'. 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



Figure 12 - Edit perfusion information

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.

To request deletion:

1. Select the run in 'Data'.
2. Click on the three dots next to the notification icon and select 'Request Run Delete'.
3. A request is sent to the System manager for approval.

4.10.1 Approve a deletion request

(Accessible only to System Managers)

1. Go to the 'Manage' tab.
2. Under 'Delete requests', find the requested run.

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3. Review details and click 'Delete'.

4.10.2 **Restore a deleted perfusion run** (Accessible only to System Managers)

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.

4.11 **Give XVIVO Technical Support access**

To temporarily allow XVIVO support to review a perfusion:

1. Select the run in 'Data'.
2. Click on three dots next to the logout icon and select '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 'Data' and select a run.
2. Click on the three dots next to the logout icon and select '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.

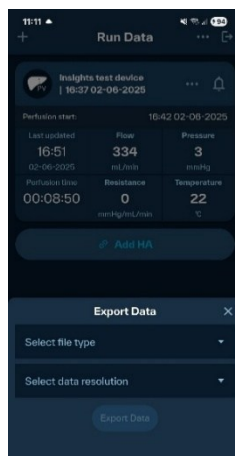


Figure 13 - Export perfusion run data

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.

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