Dormotech Every sleep study, one platform.

DormoVision X™ In-Lab PSG Manual

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1. Purpose

The purpose of this document is to provide comprehensive instructions for the setup, operation, and completion of DormoVision X™ In-Lab PSG studies. It describes the procedures for tablet and camera configuration, system preparation, patient setup, study initiation, live monitoring, study completion, data review, and the cleaning and disinfection of reusable components between patients in accordance with the system's Instructions for Use.

2. Scope

This document applies to the DormoVision X™ In-Lab PSG and the In-Lab Vision application used in attended clinical sleep studies. It includes:

- Tablet configuration and application setup
- Reolink camera configuration and connection to the laboratory network
- Network, protocol, bandwidth, and port requirements
- DormoVision X™ In-Lab PSG kit component identification and preparation
- Pairing and selection of the head, chest, abdomen, leg, and ECG units, as applicable
- Patient preparation, EEG extension setup, and electrode placement
- Application of the head, chest, abdomen, leg, and ECG units
- Impedance testing and physiological signal verification
- Study initiation, live waveform and video monitoring, live event scoring, and physiological signal monitoring
- Titration and Split-Night studies
- Study completion, upload confirmation, equipment removal, cleaning, disinfection, inspection, charging, and preparation for the next patient.

This document is intended to support the safe and consistent operation of the DormoVision X™ In-Lab PSG. It does not replace the official Instructions for Use (IFU), device labeling, or other applicable regulatory documentation for the system. Users should always follow their institution's policies and procedures, applicable regulations, and the current DormoVision X™ Instructions for Use. Do not operate the system until all users have read and understood the warnings, precautions, and operating instructions provided in this document and the official Instructions for Use.

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3. Warnings, Precautions, and Safety Information

Read this section in its entirety before operating the system or performing cleaning and disinfection of reusable components. Failure to follow the instructions, warnings, and precautions in this document and the official Instructions for Use may result in inaccurate study data, equipment damage, or injury to the patient or operator.

3.1. General Warnings

- For use only by trained healthcare professionals qualified to perform polysomnography and familiar with the DormoVision X™ In-Lab PSG and its Instructions for Use.
- Do not use any system component that is visibly damaged, cracked, or shows signs of electrical or mechanical damage or excessive wear.
- Do not reuse single-use or disposable components. Discard these components after each study in accordance with the Instructions for Use and your institution's policies and procedures.
- This system acquires, transmits, and stores patient physiological data and, where configured, synchronized video. Handle patient information, network credentials, and system access in accordance with your institution's privacy, cybersecurity, and information security policies, as well as applicable regulations (e.g., HIPAA in the United States).

3.2. Reprocessing Precautions

- Use only the cleaning and disinfecting agents identified in Section 12 or otherwise specified in the DormoVision X™ In-Lab PSG Instructions for Use. Use of unapproved cleaning or disinfecting agents may damage system components or adversely affect device performance.
- Always follow the disinfectant manufacturer's Instructions for Use, including the specified concentration (if applicable), contact time, and required personal protective equipment (PPE), in addition to the instructions provided in this manual.
- Allow all cleaned and disinfected reusable components to dry completely before reassembly, storage, or use on another patient.
- Do not immerse the recording units, tablet, camera, charging accessories, or other electrical components in liquids unless specifically identified as immersible in the Instructions for Use.

3.3. Network and Data Security

- Configure the laboratory network, tablet, and camera in accordance with the instructions provided in Section 7. Incorrect network configuration may affect system communication, interrupt video transmission, or prevent normal system operation.
- Configure firewall settings to allow only the outbound connections identified in Section 7.8 that are required for normal system operation. Consult your institution's IT or network administrator to verify network and firewall configuration before initial system use.

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4. Intended Use

The Dormotech In-Lab PSG (DormoVision X™) is intended to be used in a clinical sleep laboratory setting to acquire, display, and record physiological signals together with synchronized patient video, in order to support in-lab overnight polysomnographic sleep studies performed under the supervision of a qualified sleep physician or technologist. This manual describes the configuration and use of the system as shipped. It does not itself constitute a regulatory Indications for Use statement. Refer to the device labeling, package insert, and applicable FDA clearance (e.g., 510(k)) documentation for the complete, legally binding indications, contraindications, and limitations of use.

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5. Kit components



In the Case

- Head unit
- Chest unit
- Abdomen unit
- Combined Leg unit
- ECG unit

Peripherals

- Leg strap
- Leg extension electrodes
- Charger and cables
- EEG disposable electrodes
- Textile cover
- EEG cap
- Device QR card

Provided separately

- Tablet
- Reolink Camera
- EEG Paste

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6. Network Setup

6.1. Tablet and IP Camera Configuration

This section describes the one-time configuration of the Samsung tablet and IP camera for use with the In-Lab Vision application.

Each patient room is equipped with an IP camera connected to the laboratory network and integrated with the In-Lab Vision application. During a study, the camera provides synchronized video for live viewing on the tablet and securely uploads recorded video for access through the web application.

Complete the following procedures to configure the Samsung tablet and IP camera before placing the system into clinical use. Unless the tablet, camera, or network configuration changes, this setup is required only once for each device.

6.1.1. Unboxing And Powering On

1. Carefully remove the Samsung tablet and its accessories from the packaging.
2. Connect the tablet to a power source using the supplied USB Type-C charging cable.
3. Press and hold the Power button located on the upper-right side of the tablet until the device powers on.
4. When the Welcome screen appears, tap **Start**.

6.1.2. Initial Agreements and Device Setup

1. **For your review:** Select **Agree to all** and tap **Agree** to accept the Samsung terms and privacy policy.
2. **Easy Setup with another device:** To ensure a clean clinical configuration, select **Set up manually** at the bottom of the screen.

Note: Manual setup is required to configure the tablet for operation with the DormoVision X™ In-Lab PSG.

6.1.3. Network Configuration

1. **Choose Wi-Fi Network:** Select the **designated laboratory Wi-Fi network** from the list.
2. **Enter Password:** Type in the lab's Wi-Fi password and tap **Connect**. The tablet will then proceed to the "Getting your tablet ready" screen.
3. When prompted to copy apps and data, select **Don't copy**, then select Next.

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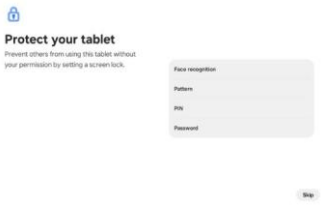
6.1.4. Google Account Configuration



1. On the **Google sign-in screen,** tap **Create account.**
2. Select **For work or my business,** then click **Next.**
3. Enter the lab information (e.g., First Name: **Lab Name**, Last Name: **Rm 4**) and click **Next**.
4. Enter the required account information, including a date of birth and gender, then select **Next.**
5. Select or create a clear email address that includes the Lab Name and Room Number (e.g., **LabNameRm4@gmail.com**) and click **Next**.
6. **Agreement:** Review the terms and tap **I agree** to finalize the Google account.

6.1.5. Security Configuration

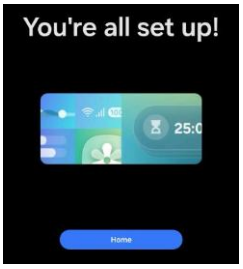


1. **Protect Your Tablet:** Select **PIN** as the preferred screen lock method.
2. **Set PIN:** Enter a **6-digit code**, then click **Continue**.
3. **Confirm PIN:** Re-enter the same 6-digit code and click **OK**.

6.1.6. Google Service Preferences & Assistant Setup

1. **Google Services:** Review the available Google services (e.g., Backup, Location, etc.), then tap **Accept**.
2. **Hey Google:** Tap **Skip** when prompted to set up voice activation.
3. **Assistant access:** On the "Access your Assistant without unlocking your device" screen, tap **Skip**.

6.1.7. Samsung Account and Services



1. **Samsung account:** When prompted, select **Sign in with Google** and sign in using the account configured during tablet setup.
2. **Terms and conditions:** Select **All** and tap **Agree**.
3. **Review** the Samsung services presented during setup (e.g., Auto Blocker and Customization) and **configure** them in accordance with your organization's policies and the system requirements.
4. **Two-step security:** If prompted, complete the required two-step verification process.
5. **Personalization:** Choose between Light or Dark mode.
6. Once the "**You're all set up!**" message appears, tap Home to access the tablet's main interface.

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6.2. Tablet System Optimization

This phase ensures the tablet environment is optimized for clinical monitoring, preventing sleep disruptions and ensuring the screen remains active longer during studies.

System Configuration

1. **Access Settings:** From the tablet's home screen, locate and tap the settings (gear) icon.

2. **Mute System Sounds**:
   - Tap the **search icon** (magnifying glass) in the Settings menu and type **"System Sound."**
   - In the right-hand column, select **Mute**.
   - *Goal:* This allows the tablet to receive necessary notifications without audible alerts interrupting the patient's sleep.

3. **Adjust Screen timeout:**
   - Return to the search window and type **"Screen Timeout."**
   - Tap the result to open the display settings.
   - Change the setting from the default **30 seconds** to **30 minutes**.
   - *Goal:* This ensures the technician can monitor the study without the screen repeatedly locking or turning off.

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6.3. Installing Essential Applications

After the tablet has been configured, install the required applications from the Google Play Store to complete the DormoVision X™ In-Lab PSG setup.

6.3.1. Accessing The Google Play Store

Locate and tap the Play Store icon on your tablet's home screen.

- If this is your first time opening it, a "Terms of Service" window will appear. Tap **Accept**.
- On the "Welcome to Google Play" screen, tap the blue Get started button.

6.3.2. Installing The Reolink App

1. Tap the Search icon (the magnifying glass) located on the left-hand sidebar or the search bar at the top of the screen.
2. Type **"Reolink"** into the search bar.
3. Select the **Reolink** app from the results (it is published by *Reolink Innovation Limited*), then tap **Install.**
4. Once the installation is complete, the button will change to **Open**, indicating the app is ready for use.

6.3.3. Installing The In-Lab Vision App

1. Go back to the search bar at the top and type **"In-Lab Vision"**.
2. Look for the app named **In Lab Vision** by *Dormotech Medical*, then tap **Install.**
3. Once the installation is complete, the button will change to **Open**, indicating the app is ready for use.
4. A window labeled **"Complete account setup"** may pop up to finish your Google Play profile. Tap **Continue**.
5. **Important:** On the screen asking to "Add a payment option," you do **not** need to add a card for these apps. Tap **Skip** at the bottom left of the window to proceed.



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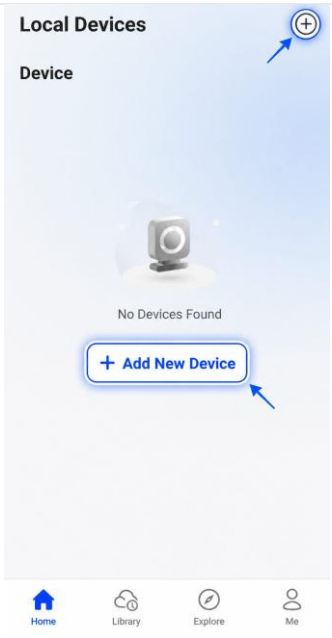
6.4. Camera Installation

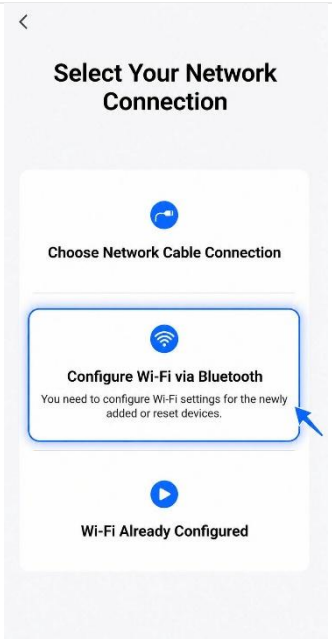
Open The **Reolink** app you just installed and follow steps below to connect your IP camera to the laboratory network:



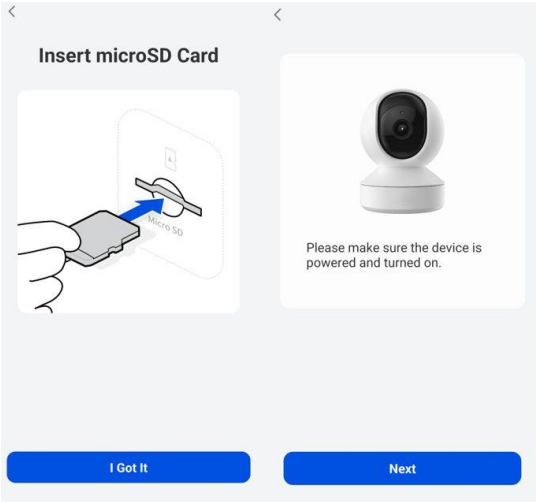
1. Select the **+** icon in the upper-right corner of the screen, or select **Add New Device**, to begin camera setup.



2. Connect the camera to a power source in the patient room and Scan the **QR code** on the back / side of the camera.



3. Choose Connection Method: Select **Configure Wi-Fi via Bluetooth**, then select **Next**.



4. On the "**Insert micro-SD Card**" screen, click "I got it" (no need to insert SD card) and confirm the camera is powered on, then tap Next.

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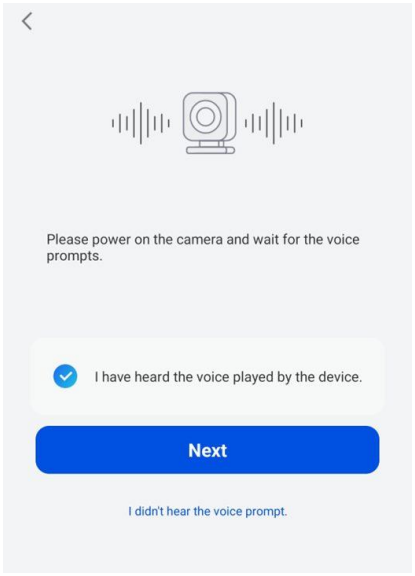
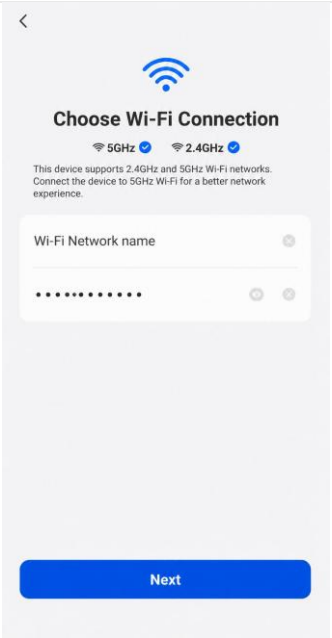


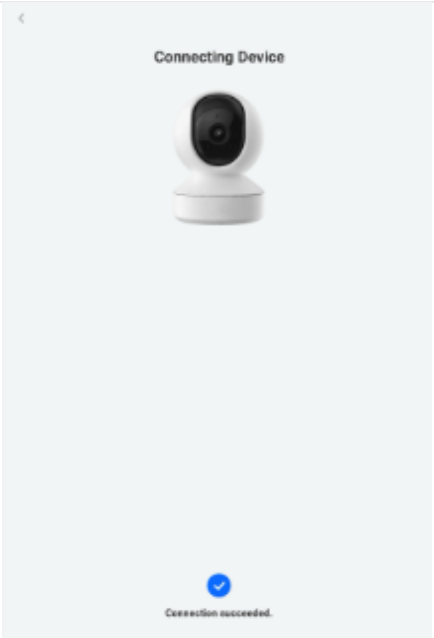
5. Voice Prompts: Ensure the camera is powered on and wait for the voice prompts. Check the box for "**I have heard the voice played by the device**" and tap **Next**.



6. Location Permission: When the tablet prompts you for location access, select **While using the app**.
Nearby Devices Permission: select **Allow**.



7. Enter the laboratory Wi-Fi network name (SSID) and password, then select Next. ***It is essential that both the tablet and the camera operate on the same laboratory Wi-Fi network to communicate properly.***



8. Establishing Connection: The app will display a "Connecting Device" message while it establishes the link.

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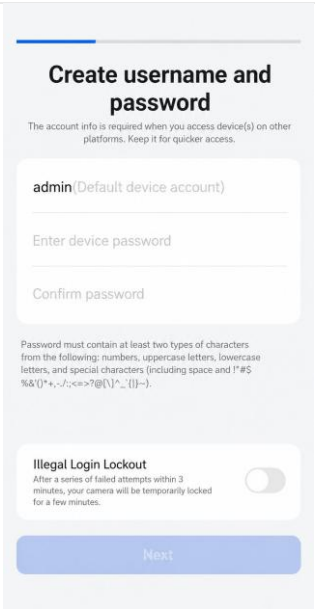
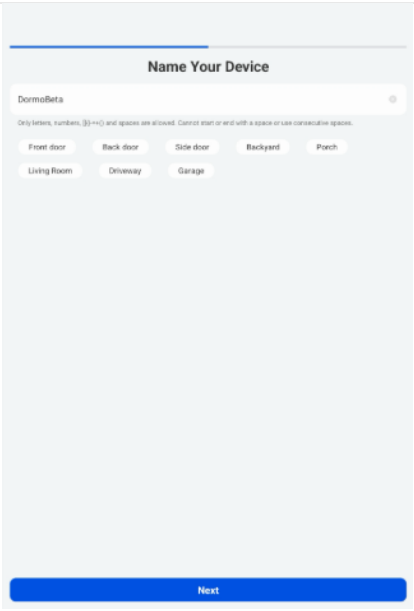


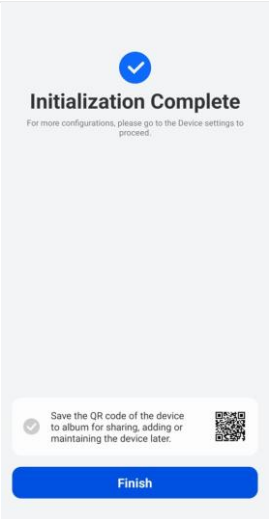
9. After the connection is successful, you will be prompted to set up the camera's login credentials. **Keep "admin" in the username field** and create a secure password according to the listed specifications.



10. **Naming the Device:** Once the "Connection succeeded" message appears, tap Next to reach the "Name Your Device" screen. Enter a specific name (e.g. patient room number) and tap Next



11. Skip Promotional Offers: You may be asked to claim an offer or extend a warranty. Tap the "X" in the top-right corner or select the option to Skip this screen.



12. Finalizing Setup: After the initialization process is complete, an **Initialization Complete** window will appear. Click **Finish** to proceed. A final screen displaying a live video image from the camera will then appear. Verify that the video is visible, and then click **Done** to complete the initial setup wizard

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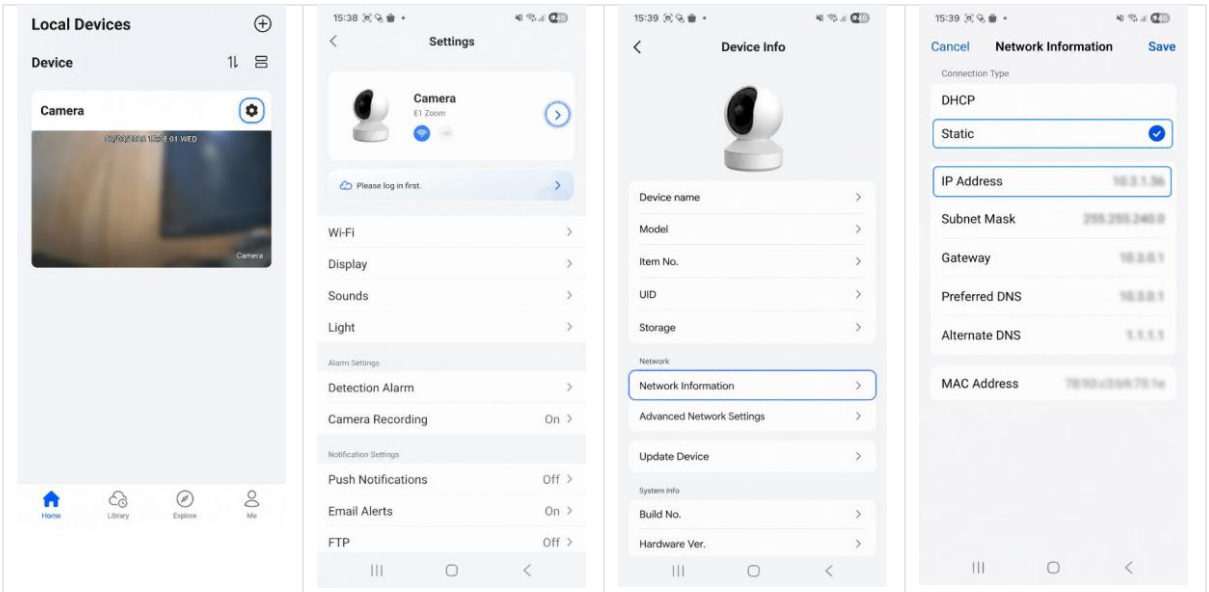
Note: Record the administrator username and password. These credentials are required when configuring the camera in the In-Lab Vision application.

If no voice prompt or audible tone is heard during Step 5, press and hold the Reset button located on the rear of the camera (below the lens) for several seconds, then repeat the configuration procedure.

6.5. Camera Network Configuration

Use the Reolink app to retrieve the camera's IP address and enable the required streaming protocols.

6.5.1. Retrieve The Camera IP Address



1. From the Reolink Home screen, tap the Settings (gear) icon.	2. Under Settings, select the arrow next to the camera name.	3. Under Device Info, select **Network Information.**	4. Change the Connection Type to **Static** and click **Save.**

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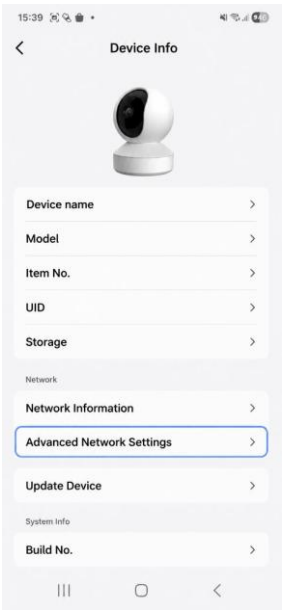
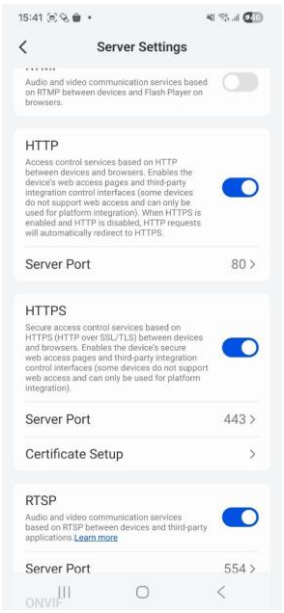
6.5.2. Enable Required Streaming Protocols

Configure the camera to enable the streaming protocols required for operation with the DormoVision X™ In-Lab PSG.



1. Return to Device Info and select **Advanced Network Settings.**



2. From the **Server Settings**, Enable the RTSP, HTTP, and HTTPS .

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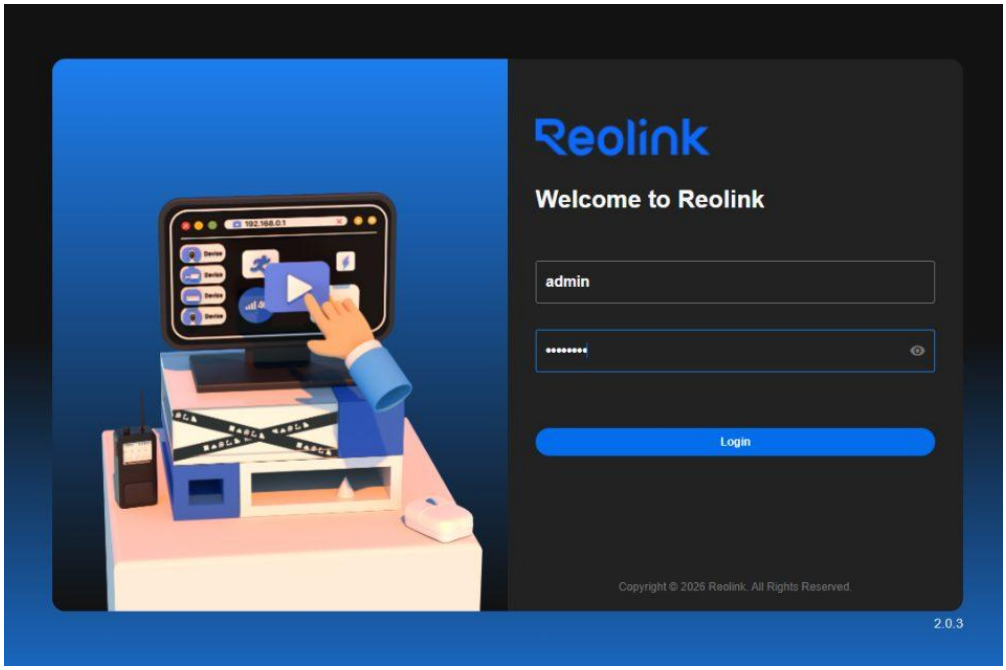
6.6. Configure the Camera Using a Web Browser

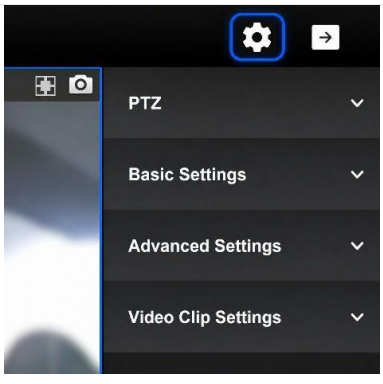
Use a computer to access the camera's web interface and configure the network and streaming settings required for operation with the DormoVision X™ In-Lab PSG.

6.6.1. Log In to the Reolink Camera

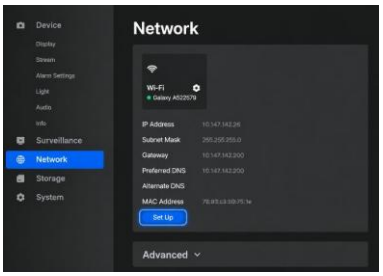


1. Open a supported web browser and enter the camera's IP address in the address bar.
2. Sign in using the camera admin username and password and select “I have read and understand” to continue.

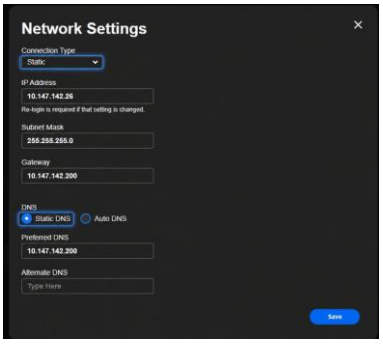
6.6.2. Configure The Network Settings



1. From the Live View screen, select the **settings** (gear) icon in the upper-right corner



2. In the left navigation pane, select **Network**, then tap **Set up**.



3. Set the following:
- Set Connection Type to **Static**.
- Set DNS to **Static DNS**.

Select Save to apply the settings.

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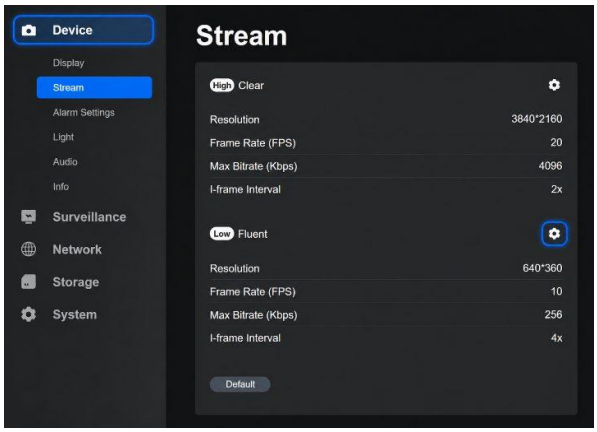
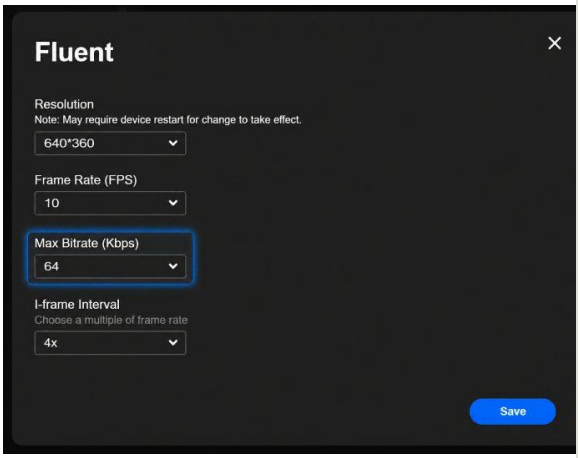
3. Configure The Video Stream



1. In the camera's Settings menu, select **Streaming** from the left-hand navigation pane. Next, click the Settings gear icon located next to **Fluent**.



2. Set the Max Bitrate (Kbps) to **64**, then click **Save** to apply the changes.

This completes the camera configuration. You may now proceed with the In-Lab Vision application for the next phase of setup.

Note: If network performance requirements differ from the recommended configuration, consult your institution's IT or network administrator before modifying the bitrate setting.

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6.7. In-Lab Vision Application Configuration

This phase ensures the In-Lab Vision application is properly linked to your configured IP camera so you can begin patient studies.

1. **Launch the App:** From the tablet's home screen, tap the **In-Lab Vision** icon to open the application.
2. Select Next and grant the required application permissions when prompted.
3. When you reach the **Start Test** window, tap Open Camera, then tap Camera Settings.
4. Enter the camera username (“admin”) and password created during camera configuration, along with the camera's static IP address.
5. Tap on **“Advanced settings”** and ensure the following default settings:
    - **RTSP Port:** set to 554
    - **Channel:** set to Preview_01_sub
6. Click **Save**. The application will display a notification that it is searching for the device
7. **Confirm Connection:** Once the connection is established, the application should display the status **“Ready,”** indicating successful communication.
8. **Begin Study:** You are now ready to proceed. Tap **Start Test** to begin the recording. Within a few seconds of starting, the status will automatically transition to **“Recording,”** confirming the study is active.

Note: Camera configuration is a one-time setup procedure for each camera unless the camera credentials or network configuration are changed.

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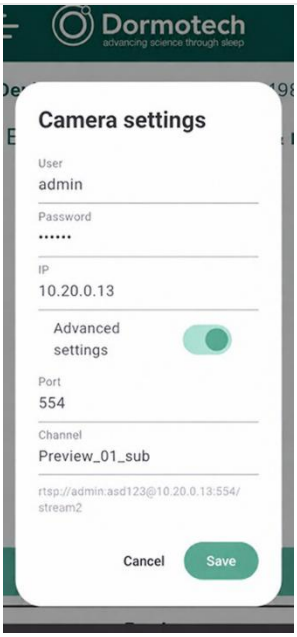
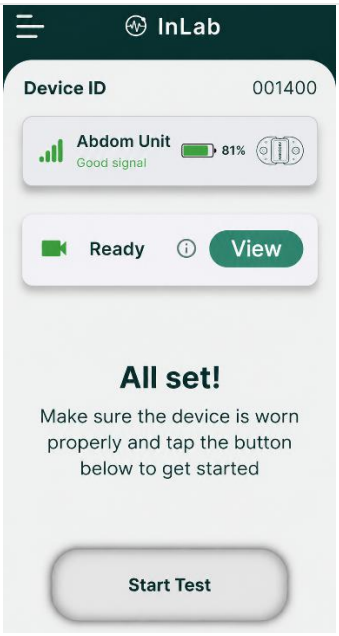
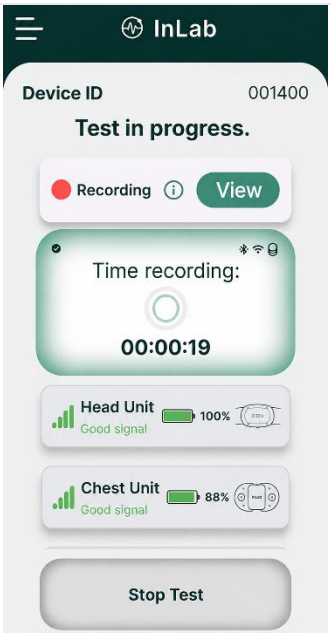


Camera settings



Start the Test



Test in Progress

Troubleshooting: Camera Status Does Not Display "Camera Ready"

If the camera status does not display **"Camera Ready,"** verify the following:

- Confirm that the camera IP address, admin username, and password entered in the In-Lab Vision application match the values configured in the Reolink application.
- Verify that the **RTSP** port is set to **554,** and **Channel** is set to Preview_01_sub
- Confirm that both the Samsung tablet and the Reolink camera are connected to the same laboratory Wi-Fi network.
- Verify that the camera is powered on and connected to the network.
- If the issue persists, repeat the camera configuration procedure or contact Dormotech Technical Support.

Viewing Live Video

After the study is initiated and the camera connection is established, the camera status changes to "Camera Recording," indicating that video recording is active.

To view the live video in the In-Lab Vision application, select **View** next to the camera status.

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6.8. Network Requirements

Local Network (LAN / VLAN)

The following network requirements apply to the DormoVision X™ In-Lab PSG to support communication between the Samsung tablet, Reolink camera, and the In-Lab Vision application.

Local Network (LAN/VLAN)

The Samsung tablet and Reolink camera must be connected to the same local area network (LAN) or virtual local area network (VLAN) to enable communication.

Recommendation:

- Dedicated Wi-Fi SSID for DormoVision X™ In-Lab PSG devices
- Static IP assignment for Reolink cameras
- DHCP reservation for Samsung tablets (optional)

Network Bandwidth (RTSP)

Per camera:

- **2–8 Mbps** typical RTSP stream
- Additional bandwidth may be required depending on the configured video resolution and frame rate.

Recommendation Network Capacity: Minimum of 50 Mbps of available Wi-Fi bandwidth per patient room.

Services, Protocols & Ports

The following outbound network connections must be permitted to support normal operation of the DormoVision X™ In-Lab PSG.

Destination	Protocol	Port
Backend API	HTTPS	443
MQTT Broker	TCP (TLS)	8883
DNS Servers	UDP/TCP	53
NTP Servers	UDP	123
Reolink Camera	RTSP	554
AWS CloudFront	HTTPS	443
AWS S3	HTTPS	443

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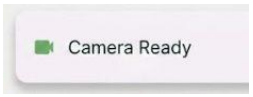
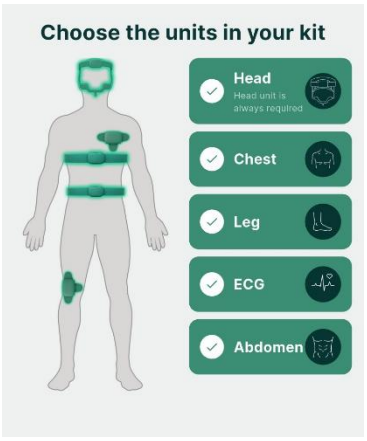
7. Pre-Study Preparations

7.1. Tablet Workflow

1. Verify that the Dormotech In-Lab Vision application is installed on the Samsung tablet and that the camera has been configured. Confirm that the camera status displays **Ready**.
2. Scan the QR code provided with the DormoVision X™ In-Lab PSG kit.
3. Select the recording units required for the planned study (Head, Chest, Abdomen, Leg, and/or ECG), as applicable.
4. Power on each recording unit by connecting it to the magnetic charging cable and disconnecting the cable after the unit powers on. Begin with the Head unit. Verify that the blue LED illuminates and that the unit is recognized by the In-Lab Vision application.
5. Repeat Step 4 for each remaining recording unit required for the study. Verify that all selected units are connected before proceeding.



Camera pairing in the app



Unit selection in the app



Magnetic charger

Status Indicator

A steady blue LED indicates that the recording unit has powered on successfully. Verify that the unit is displayed as connected in the In-Lab Vision application before proceeding to the next unit.

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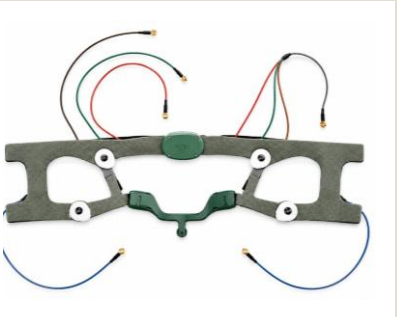
7.2. In-Lab EEG Extension Electrode Setup

The head mask includes 12 numbered connection points. Complete the following procedure to install the EEG extension electrodes and prepare the head mask for patient application.



Head mask · 12 connection points



Fully assembled

Apply the EEG extension electrodes

1. Remove the gray textile cover from the head mask.
2. Connect the 3-to-1 EEG extension electrode to connection points 7, 8, and 9.
3. Connect the five 1-to-1 EEG extension electrodes to connection points 1, 2, 3, 5, and 11.
4. Reinstall the gray textile cover over the installed EEG extension electrodes.
5. Connect the disposable EEG electrodes to connection points 4, 6, 10, and 12.

Preparing the Electrode Sites

Before applying the disposable EEG electrodes:

- Clean each electrode site with an alcohol wipe to remove oils and debris.
- Prepare the skin using an approved skin preparation gel or abrasive preparation material in accordance with your laboratory protocol to help achieve acceptable electrode impedance and signal quality.

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7.3. Head Mask Application and Electrode Positioning

7.3.1. Apply the Head Mask

1. Remove the protective liners from the disposable electrodes.
2. Position the head mask on the patient's head.
3. Secure the upper strap, ensuring the EOG electrodes are positioned in full contact with the skin.
4. Secure the lower strap, ensuring the EMG electrodes are positioned in full contact with the skin.
5. If necessary, adjust the height of the nose support using the side adjustment straps to position the nose section comfortably between the nose and mouth.
6. Apply conductive paste to each gold cup electrode before positioning the electrodes on the patient.

Gold cup electrode placement



Left Side



Right Side

Electrode	Location	Procedure
Reference (grey)	**Right mastoid (M2)** Bony area behind the ear	Place the reference gold cup electrode over the right mastoid (M2), on the bony prominence behind the right ear.
Ext. 5 (blue)	**Right mastoid (M2)** Contralateral	Place electrode 5 at the right mastoid (M2) electrode site, over the bony prominence behind the right ear.
Ext. 11 (blue)	**Left mastoid (M1)** Contralateral	Place electrode 11 at the left mastoid (M1) electrode site, over the bony prominence behind the left ear.
Secure the mastoid electrodes with medical-grade adhesive tape (two behind the right ear and one behind the left ear). Next, position the EEG head cap over the head mask before positioning extension electrodes 1–3.		
Ext. 1 (red)	**Left Frontal - F3**	Place extension electrodes 1, 2, and 3 at the left frontal (F3, red), central (C3, green), and occipital (O1, brown) electrode sites. Use the head cap to verify proper electrode positioning and secure each extension electrode with medical-grade adhesive tape.
Ext. 2 (green)	**Left Central - C3**	
Ext. 3 (brown)	**Left Occipital O1**	

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7.4. Wearing the body units

7.4.1. ECG Unit Application

1. Connect 3 disposable electrodes to ECG unit
2. Remove the protective liners from the disposable electrodes.
3. Position the ECG unit on the left side of the chest, as shown. Ensure all electrodes are in full contact with the skin. Apply gentle pressure to secure the unit and verify that it is positioned comfortably and remains stable throughout the study.



ECG unit placement

7.4.2. Chest & Abdomen Unit Application

1. Position the **chest unit** over the center of the chest, with the sensor centered over the sternum and the Dormotech logo facing forward. Attach one end of the chest strap to the snap connector, wrap the strap around the chest, and secure it to achieve a snug, comfortable fit.

2. Position the **abdomen unit** over the patient's navel with the Dormotech logo facing forward. Attach the strap to the snap connector, wrap it around the waist, and secure it to achieve a snug, comfortable fit.



Respiratory effort monitoring

Unit Orientation

Always position the chest and abdomen units with the Dormotech logo facing forward and the magnetic charging connector oriented upward.



Chest unit · front



Chest Strap

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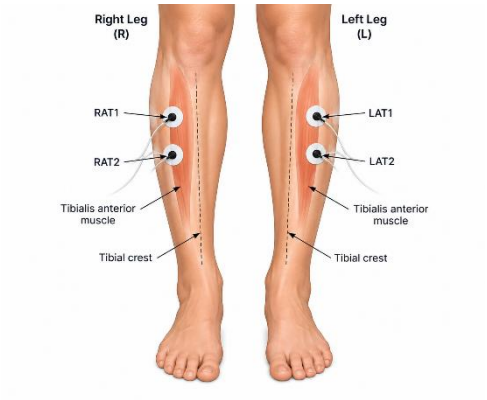
7.4.3. Leg Unit Application

Combined channel from both legs:

Recommended Electrode Placement: For optimal Leg EMG signal acquisition, the recommended electrode placement is over the left and right tibialis anterior muscles. Position the electrodes over the muscle belly of the tibialis anterior on each lower leg, as illustrated.



1. Attach three disposable electrodes to the three inner attachment points of the Leg Unit (points 1, 2, and 3).
2. Connect the two Leg Extension Cable connectors to the two outer attachment points of the Leg Unit (points 4 and 5). Ensure that both connectors are fully connected and securely attached.



3. Before electrode application, ensure that the skin at the electrode sites is clean and dry to support good electrode-to-skin contact and signal quality.
4. Remove the clear protective covers from the three disposable electrodes attached to the Leg Unit.
5. Position the Leg Unit on the inner side of the lower leg, over the intended muscle location. Press gently to ensure full and secure electrode-to-skin contact.
6. Wrap the leg strap around the leg and secure it comfortably to keep the Leg Unit in place throughout the study.
7. Attach one disposable electrode to the free end of each Leg Extension Cable, then remove the clear protective covers.

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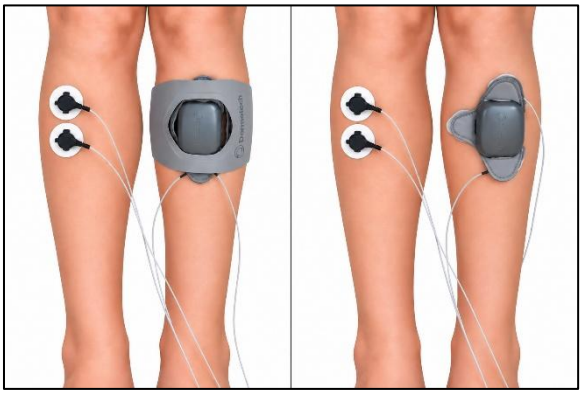
8. Place the two extension-cable electrodes on the **contralateral lower leg, preferably over the tibialis anterior muscle, in accordance with the recommended electrode placement described above**. Position the electrodes **1–2 cm apart**. Secure with medical tape if needed.



For patient comfort and safety, we recommend instructing patients to wear shorts or loose-fitting clothing during the study and avoid tight clothing that may interfere with the sensors, leads, or movement. Route the leads downward along each leg and avoid crossing, twisting, or bunching them. Position the leads comfortably with sufficient slack to allow movement in bed without pulling on the sensors, while avoiding excessive tension on the wires. Neatly bundle and secure any excess wire to minimize the risk of tangling or tripping. Before the patient goes to sleep, ask them to stand and walk a few steps to confirm that the leads remain comfortably positioned, do not pull on the sensors, and do not create an entanglement hazard.

Important: When the Leg Extension Cables are used, EMG activity from both legs is recorded and displayed in a single combined Leg EMG channel. The system does not provide separate right- and left-leg EMG channels; therefore, activity observed in the combined channel cannot be attributed to a specific leg based on the signal trace alone.

7.4.4. Leg Unit Application

One leg EMG channel:

1. Connect 3 disposable electrodes to leg unit.
2. Remove the protective liners from the disposable electrodes.
3. Position the leg unit over the muscle on either lower leg, as shown. Wrap the securing strap around the leg and adjust it to hold the unit firmly in place while maintaining full electrode contact with the skin.



Leg Securing strap



Leg unit placement

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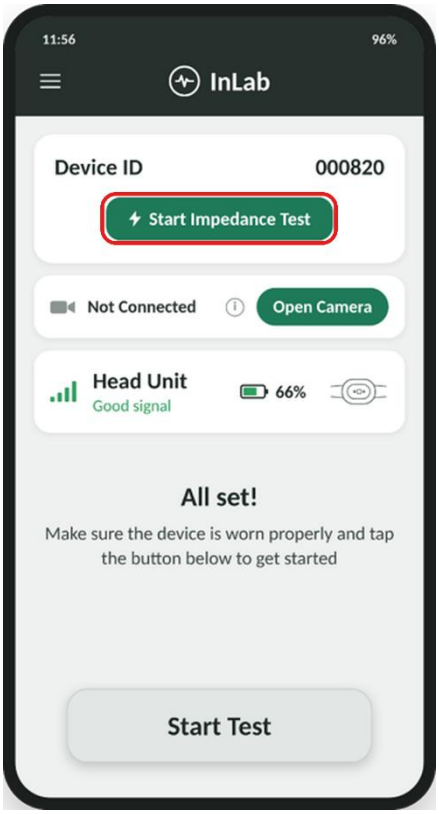
8. Starting the test

8.1. Pre-Study Check: Impedance Test

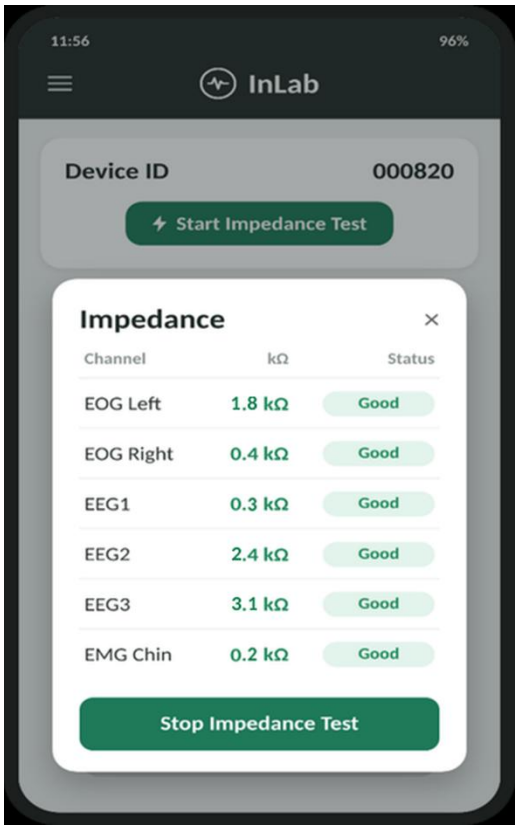
Once the patient is set with the device, a pre-recording impedance assessment is recommended to evaluate electrode-skin contact. The recommended target is "**Good**" status across all applicable channels.

1. Select **Start Impedance Test** below the Device ID
2. Review the channel values and status indicators in the **Impedance** window (Figure 5).
3. For channels rated **Moderate** or **Poor**, consider adjusting the electrodes to improve skin contact, then repeat the assessment to verify improvement (see Troubleshooting).
4. Select **Stop Impedance Test** to close the window, followed by **Start Test** to initiate the recording.

As illustrated in Figure 5, the **Impedance** window presents three columns: channel name, measured impedance in kΩ, and status. The listed channels are EOG Left, EOG Right, EEG1, EEG2, EEG3, and EMG Chin. Status indicators are color-coded **green** for **Good**, **orange** for **Moderate**, and **red** for **Poor**.



In-Lab Vision screen with the Head Unit connected. Select Start Impedance Test before starting the study.



Impedance test results in the In-Lab Vision app, with all channels showing "Good" status.

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8.1.1. Impedance Interpretation

Electrode-skin impedance is an indicator of electrical contact quality and supports the assessment of signal quality. Lower impedance indicates better electrode-skin contact, supporting stable signal acquisition with reduced susceptibility to electrical noise. Impedance thresholds differ by channel type: for EEG and EOG channels, values below 5 kΩ indicate good contact, while for EMG channels, values below 10 kΩ indicate good contact (Table 2).

Higher impedance may indicate inadequate contact and compromise signal quality. Proper skin preparation, electrode placement, and secure attachment are therefore essential for reliable recordings with the DormoVision X™ In-Lab head unit.

Impedance (kΩ)	Status	Action
EEG, EOG: <5 EMG: <10	kΩ Status 0.3 kΩ Good	Proceed with the study
EEG, EOG: 5-10 EMG: 10-20	kΩ Status 6.2 kΩ Moderate	Consider re-adjusting the electrodes before proceeding.
EEG, EOG: >10 EMG: >20	kΩ Status 11.4 kΩ Poor	Readjust the electrodes to improve skin contact.

9.1.1 Troubleshooting: Improving Electrode-Skin Contact

For channels displaying Moderate or Poor status, the following steps are recommended to improve contact and verify impedance before proceeding:

1. **Check electrode connections.** Check that each electrode is securely connected to the mask and rests firmly against the skin.
2. **Move hair aside.** Clear hair from beneath the electrodes to improve direct skin contact.
3. **Prepare the skin.** Use NuPrep skin preparation gel according to its instructions to remove oils and gently exfoliate the electrode site.
4. **Apply conductive paste.** Apply conductive paste (e.g., Ten20) as appropriate and reposition the electrode at the designated recording site.
5. **Secure the electrodes.** Consider using the electrode cap or suitable medical adhesive tape to maintain stable contact.
6. **Repeat impedance testing.** Repeat the test to confirm improved impedance.

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8.2. Starting the study in the app

After completing the pre-study checks, navigate to the final screen in the In-Lab Vision application and select **Start Test** to begin recording.

Once recording has started:

- Verify that the study is actively recording.
- Do not close the In-Lab Vision application or select **Stop Test** until the study is complete.
- Keep the Samsung tablet in the patient room for the duration of the study to maintain communication with the recording system.

8.3. Physiological signal calibration

Verify that all physiological signals are displayed correctly, are free from excessive noise, and respond appropriately to patient actions before starting the study.

Confirm the following:

- EEG, EOG, and EMG channels display physiologically appropriate responses during standard bio-calibration maneuvers (e.g., eye movements and jaw clenching).
- Respiratory effort, airflow, ECG, and SpO_2 signals are present and stable.
- The camera is positioned correctly and provides a clear view of the patient.
- All displayed waveforms are free of excessive noise, saturation, signal dropout, or flat-line signals.

Correct any disconnected, noisy, saturated, or absent signals before proceeding with the study.

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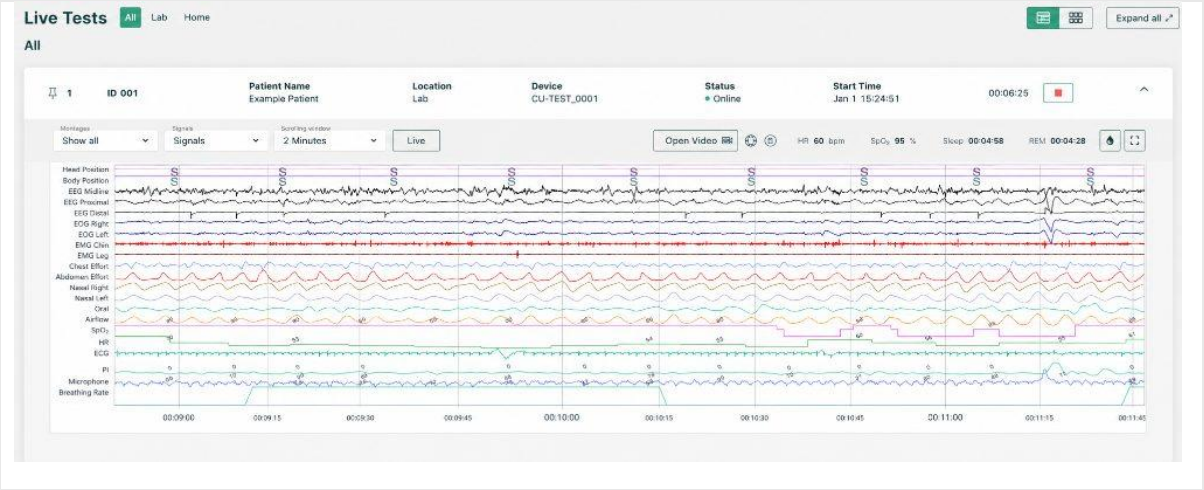
8.4. Live study monitoring

Once recording is live, the Dormotech Platform displays the acquired physiological signals and synchronized video to support real-time study monitoring and documentation.



Live Test View

- **Open the live video:** Tap **Open Video** from the dashboard toolbar to display the synchronized camera feed alongside the physiological signals. Verify that the patient remains visible throughout the study.

  Note: The live video may have a delay of up to 5 seconds. When viewing the completed study offline, the video is automatically synchronized with the physiological signals and displayed without delay.

- **Real-time scoring:** Choose a Montage and score sleep stages, arousals or respiratory events live. Sleep and REM latency indicators will update according to your scoring.

- **Monitor HR & SpO_2:** The header strip surfaces live heart rate (HR) and Oxygen desaturation alongside signal stability and battery percentage from the different device units.

Dashboard controls

1. **Montages –** select the channel groups displayed (e.g., All Channels, EEG, Respiratory).
2. **Signals** - show or hide individual channels within the selected montage.
3. **Scrolling window** - adjust the displayed recording duration (e.g., 30 seconds, 1 minute, or 2 minutes).
4. **Live** - return to the current point in the recording after reviewing previously acquired data.

Automatic Session Timeout

For security purposes, the application automatically signs out inactive users after 15 minutes. Re-enter your password to resume access. Study acquisition continues during sign-out, and previously documented events remain saved.

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9. Study Completion

At the conclusion of the sleep study:

1. Select **Stop Test** in the In-Lab Vision application or the Dormotech Platform to end the recording.
2. Wait until the upload confirmation message is displayed, confirming that the study and synchronized video have been uploaded successfully before closing the application.
3. Carefully remove all body units from the patient- head mask, chest, abdomen, leg and ECG units.
4. Follow the cleaning and disinfection protocol (Section 12)
5. Place each unit back on its magnetic charger to be fully charged for the next patient.

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10. Titration and Split-Night Study

PAP titration studies are performed to determine the appropriate positive airway pressure settings required to effectively treat sleep-disordered breathing while maintaining patient comfort and adequate sleep quality.

The DormoVision X™ platform supports attended PAP titration studies by allowing the sleep technologist to monitor physiological signals and PAP therapy parameters in real time throughout the study. The platform enables integration of PAP data with recorded sleep signals, allowing pressure changes, respiratory events, oxygen saturation, sleep stages, and other relevant parameters to be reviewed within the same study environment.

This section provides an end-to-end workflow for conducting a PAP titration study using the Dormotech system, from equipment preparation and PAP device connection through signal verification, live monitoring, titration, and study completion.

10.1. Supported Devices

The Dormotech platform currently integrates with the **ResMed AirCurve 11** for attended PAP titration studies, enabling PAP therapy parameters to be monitored alongside the physiological signals recorded during the study.

10.2. Required Equipment

- **Dormovision X™ Device** 3-to-5-unit setup
- Disposable electrodes
- Tablet running In Lab Vision app
- **ResMed AirCurve 11**
- **ResMed TxLink 2-** communication unit
- Ethernet Cable
- Optional: **Reolink camera** for live video monitoring.

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10.3. Study Preparations

10.3.1. Creating a Titration/Split-Night Study in the Dormotech Web Platform

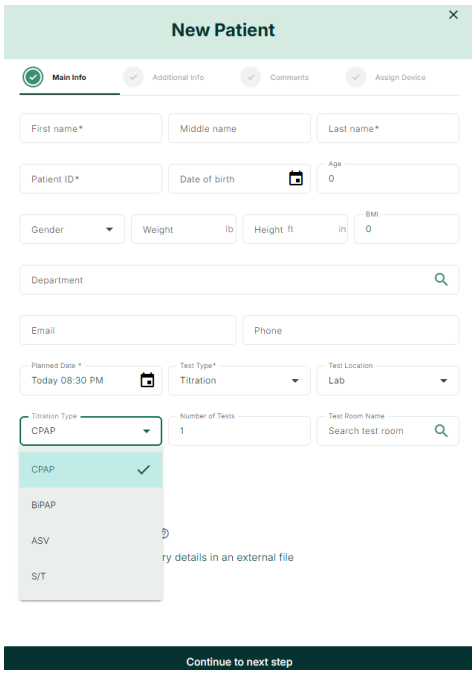
1. From the upper-right menu, click **+ New Patient** to create a test for a new patient.
   To create a test for an existing patient, search for and select the patient from the patient list.



2. Enter the required patient details
3. In the **Test Type** Field, select **Titration** or **Split-Night**.
4. Once **Titration** or **Split-Night** is selected, the **Titration Type** field will appear. Select the titration modality that will be used for the study: **CPAP, BiPAP, ASV, or ST**.

   The selected titration type determines the study title displayed in the final report. If the titration modality changes during the study, the titration type can be updated later from the dashboard or report.

5. Any additional or optional patient and study information, then select the DormoVision X™ device that will be used for the study and click **Save**.
6. Confirm that the newly created test appears on the dashboard under **Scheduled Tests**.



Creating Titration Study for new patient

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10.3.2. Preparing the DormoVision X™ In-Lab Device

Titration Study: Before starting the study, gently pull the nasal piece upward to remove it from the DormoVision X™ head unit. The nasal piece does not need to be replaced. During PAP titration, airflow will be measured through the PAP device rather than the DormoVision X™ nasal piece.

Split-Night Study: During the diagnostic phase, follow the standard DormoVision X™ setup procedure, including nasal piece placement. Before transitioning to the treatment phase, gently pull the nasal piece upward to remove it from the head unit. Airflow during PAP therapy will be measured through the PAP device.

10.3.3. ResMed Device Setup

Prepare and configure the ResMed AirCurve 11 according to the instructions provided in the applicable **ResMed User Guide.**

Once the ResMed device is prepared for use:

1. Connect an **Ethernet cable** to the laboratory's network router or an available Ethernet wall outlet.
2. Connect the other end of the Ethernet cable to the **ResMed TxLink 2 communication unit**.
3. Ensure that the ResMed device and TxLink 2 are connected to their respective power supplies and powered on.
4. Verify that the following three indicators on the TxLink 2 are illuminated:
    - **Power**
    - **PAP Device**
    - **Ethernet**

    The **Error** indicator should remain off.



ResMed TxLink 2 light indicators

All other device preparation, patient circuit setup, mask fitting, and therapy configuration should be performed according to the ResMed instructions for use.

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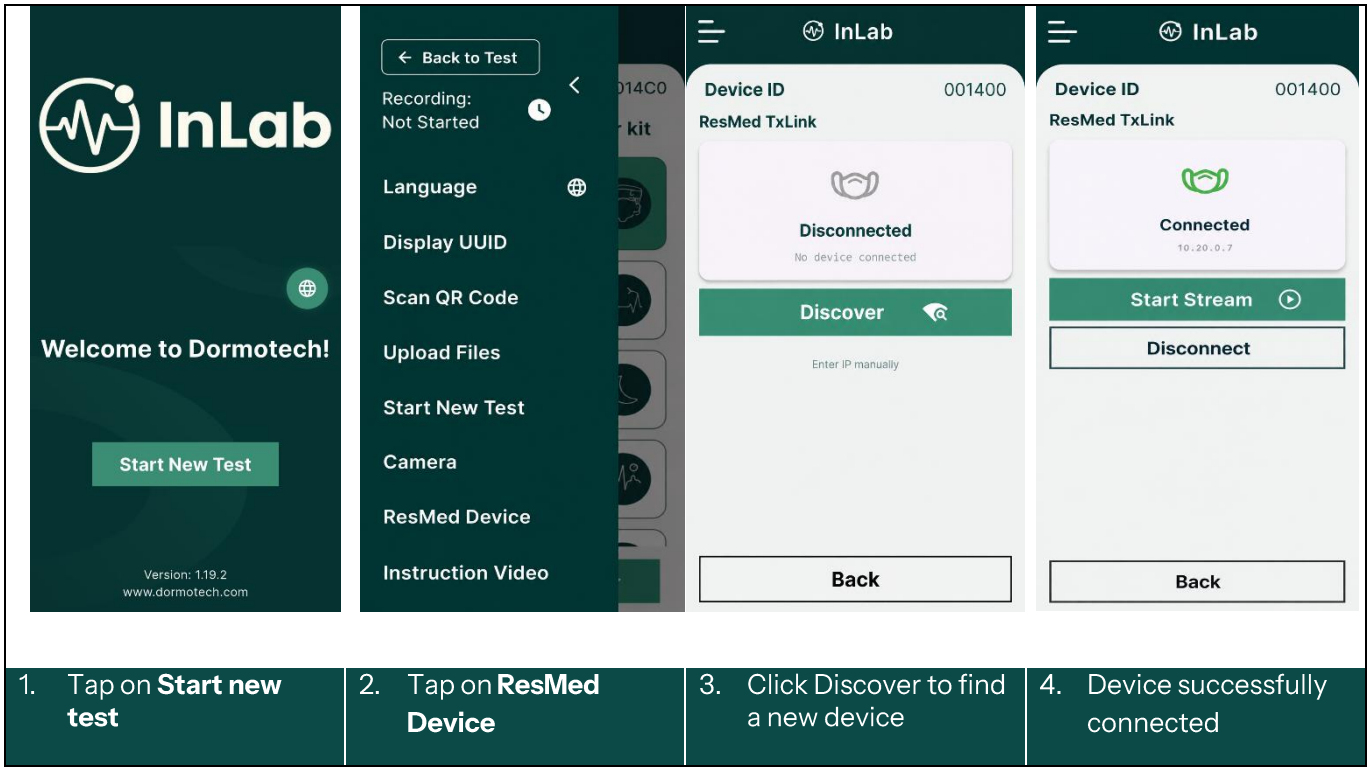
10.3.4. Connecting the ResMed device to the app

1. Open the Dormotech In-Lab Vision app in the clinic's Tablet. Tap on **Start new test**.
2. Tap the menu icon in the upper-left corner and select **ResMed Device**.
3. Ensure that the ResMed device and the tablet are connected to the same local network, then tap **Discover**.
4. The app will search for the ResMed device and establish a connection automatically. Once connected, the status will change to **Connected**.



1. Tap on **Start new test**	2. Tap on **ResMed Device**	3. Click Discover to find a new device	4. Device successfully connected

Connecting the ResMed device to the In-Lab Vision app

TROUBLESHOOTING

If the app fails to connect to the ResMed device, follow these steps:

1. Verify that the ResMed device and the phone or tablet are connected to the **same local network**.
2. Check the **Ethernet indicator** on the TxLink 2 and ensure that the blue LED is illuminated, indicating an active network connection.
3. If the connection issue persists, contact your clinic's **IT or network administrator** to verify that the network configuration meets Dormotech's connectivity requirements.

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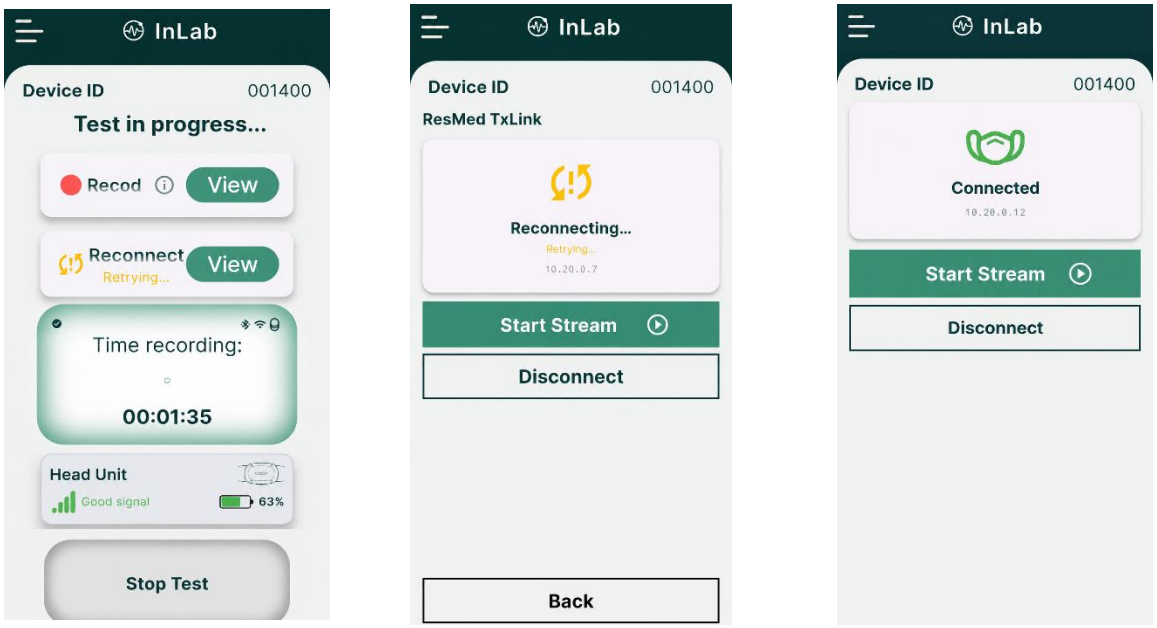
10.4. Starting the Titration Study

1. Connect all DormoVision X™ units to the app as described in section 8.
2. Once the setup is complete, verify again that the ResMed device status is displayed as **Connected**.
3. Tap **Start Test** to begin the recording.
4. Verify that the ResMed device status changes to Streaming, indicating that data is being successfully transmitted from the ResMed device to the app.

10.4.1. Connection status and Troubleshooting

- **Device Does Not Start Streaming:** If the ResMed device status does not change to **Streaming** after starting the test:
    1. Tap **View** next to the CPAP icon to open the ResMed device controls.
    2. Tap **Start Stream** to manually initiate data streaming.
    3. Verify that the device status changes to **Streaming**.

- **Network Disconnection During the Test:** If the network connection to the ResMed device is interrupted, the device status will change to **Reconnecting**. Once the network connection is restored, data streaming will resume automatically. Verify that the status returns to **Streaming** to confirm successful reconnection.



"Reconnecting" and "Start Stream" indicators in the In-Lab Vision app

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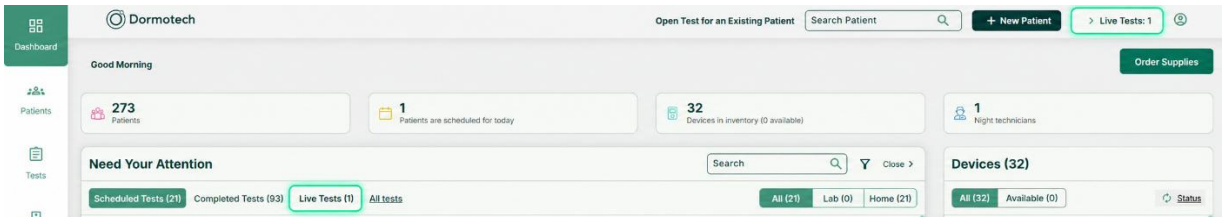
10.5. During the Live Study

10.5.1. Live Test View

To access the live recording, open the Dormotech Web Platform and select **Live Tests** from the dashboard.

The **Live Test View** allows technicians to monitor physiological signals and PAP therapy data in real time throughout the study. During titration, the platform displays the signals recorded by DormoVision X™ alongside data received from the connected ResMed device.



Live Tests access from the Dashboard

10.5.2. Upper Toolbar

The upper toolbar provides access to display settings, monitoring tools, and real-time study information.

Montages: The Montage is automatically set to Titration, displaying the relevant physiological and PAP therapy signals. To customize the display, select a different montage from the dropdown or use the Signals dropdown to choose individual signals.

PAP Parameters: The toolbar displays real-time PAP parameters, including IPAP, EPAP, Pressure, and Leak, received automatically from the connected ResMed device.



Upper toolbar during live Titration/Split-Night studies

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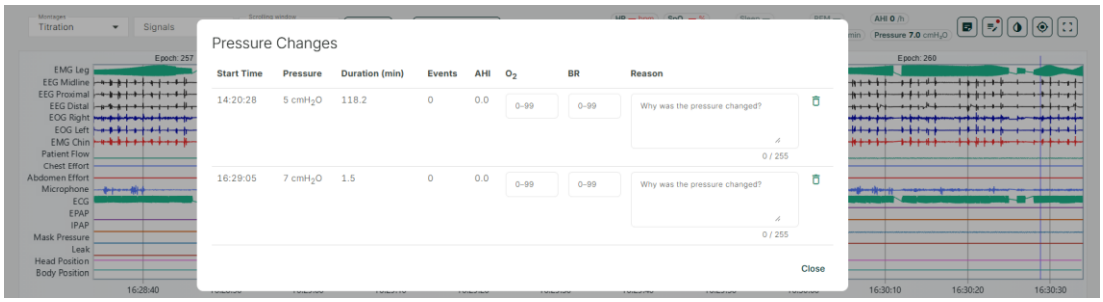
10.5.3. Pressure Table

Click the Pressure Table icon in the upper toolbar to open the table.

The Pressure Table automatically records PAP pressure changes and summarizes the respiratory events and AHI associated with each pressure setting.

- **Automatic pressure tracking:** A new row is added whenever a pressure change is detected.
- **Time and duration:** The start time and duration of each pressure setting are calculated automatically.
- **Respiratory events and AHI:** The table displays the number of manually scored respiratory events and the corresponding AHI for each pressure setting. During the live recording, the AHI is continuously updated as the duration at each pressure setting increases.
- **Additional parameters:** Technicians can manually enter the **backup respiratory rate (BR)** and **supplemental oxygen (O_2)** settings, if applicable.
- **Pressure-specific notes:** Notes can be added to individual pressure settings and will be included in the final study report.



Pressure Changes table during the live study

Technician Notes: To document general observations or comments related to the overall study, click the **Tech Notes** icon in the upper right toolbar. These notes are separate from the pressure-specific notes entered in the Pressure table and are editable via the report section.



Tech Notes during the live study

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10.5.4. Live Scoring

The **Live Test View** allows technicians to manually score sleep stages and respiratory events in real time during the recording, in the same way done after the test is done. Live scoring helps technicians monitor the patient's response to PAP therapy and evaluate respiratory events at each pressure setting.

Scoring Sleep Stages

1. In the **Live Test View**, set the display window to **30 seconds**.
2. Navigate between epochs using the mouse scroll wheel or keyboard arrow keys.
3. Assign the appropriate sleep stage using the corresponding **keyboard shortcut (number key)**, or right-click on the signal view and select the sleep stage from the menu.
4. To mark **Lights On** or **Lights Off**, right-click anywhere in the signal view and select the corresponding option.

Note: Live sleep staging is optional. Manually scored respiratory events are included in the live event counts regardless of whether sleep stages have been assigned.

Scoring Respiratory Events

1. Review the relevant signals, including Patient Flow, respiratory effort, and SpO_2, to identify respiratory events.
2. Select the event's start and end points on the waveform to mark its duration.
3. Assign the appropriate event type (e.g., Obstructive Apnea, Central Apnea, Mixed Apnea, Hypopnea, or RERA) using the corresponding keyboard shortcut, or right-click and select the event type from the menu.
4. Continue scoring respiratory events throughout the recording. Scored events are automatically reflected in the live event counts and Pressure Table.

Note: Accurate live scoring is essential for evaluating the patient's response to PAP therapy. Review and verify all scored events and sleep stages before finalizing the study.

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10.5.5. Transitioning from Diagnostic to Treatment Phase (Split-Night Studies)

During a split-night study, the diagnostic phase is performed without PAP therapy, followed by the treatment phase once PAP titration is initiated according to the facility's clinical protocol.

To transition to the treatment phase:

1. Confirm that the diagnostic phase is complete and that the patient is ready to begin PAP therapy.
2. Document the transition time and any relevant observations in the Technician Notes.
3. Gently remove the nasal piece from the DormoVision X™ head unit, as described in Section 11.3.2.
4. Fit the PAP mask and initiate therapy according to the facility's clinical protocol and ResMed instructions for use.
5. Verify that the ResMed device is connected and streaming PAP data to the Dormotech platform.
6. Confirm that Patient Flow, Mask Pressure, Leak, and the applicable PAP pressure channels are displayed correctly.
7. Continue monitoring and documenting pressure changes and respiratory events throughout the treatment phase.

Note: Ensure that the transition between the diagnostic and treatment phases is correctly reflected in the study data and final report.

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10.6. Ending the Titration Study

10.6.1. Ending the Recording

At the conclusion of the sleep study, follow these steps:

1. Select **Stop Test** in the DormoVision X™ **In-Lab Vision app** or **DormoVision X™ Platform** to end the recording.
2. Wait for the upload confirmation message before closing the application. This confirms that the study data and synchronized video (if recorded) have been uploaded successfully.
3. End PAP therapy and disconnect the ResMed equipment according to the applicable ResMed Instructions for Use (IFU).
4. Carefully remove the DormoVision X™ units and PAP mask from the patient.
5. Clean and disinfect the equipment according to **Cleaning and Disinfection protocol (section 11)** and the applicable ResMed cleaning instructions.
6. Place each DormoVision X™ unit on its magnetic charger to ensure it is fully charged and ready for the next study.

10.6.2. Post- Study Scoring and Review

Once the recording is complete, the platform automatically runs the scoring algorithm for any signal group that was not manually scored during the live study. For example, if sleep stages were not scored during the recording, the automated sleep staging algorithm will run after the study ends. Signal groups that were manually scored during the live recording will retain their existing scoring.

Note: If even one event in a scoring group was scored manually during the live study, automatic scoring does not run for that group. For example, if a technician scored a single N1 epoch, automatic scoring will not run for sleep staging, but will still run for respiratory events.

Re-running Automated Scoring

To rerun automated scoring for a specific signal group:

1. Open the working area.
2. Click on **Auto scoring** and select the desired signal group (e.g., **Respiratory Events**).
3. Click **Auto Scoring** to rerun the algorithm for the selected group.
4. Review the automatically generated results and make any necessary manual adjustments.

Important: Rerunning autoscoring will overwrite existing manual scoring within the selected signal group

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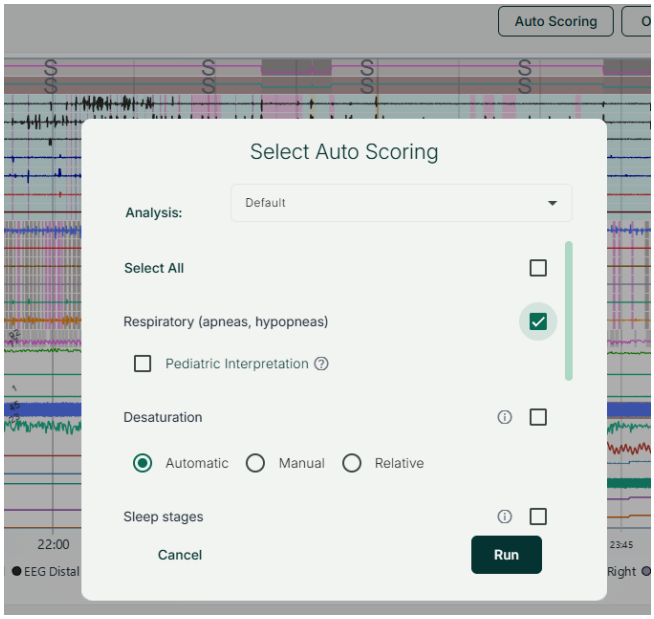
Before finalizing the study, review the scored sleep stages, respiratory events, and PAP therapy data to ensure accuracy and completeness. Technician and scorer notes can also be reviewed and edited after the study is completed in the working area or as described in Section 11.7 - Report.



Re-running the Auto Scoring for respiratory events

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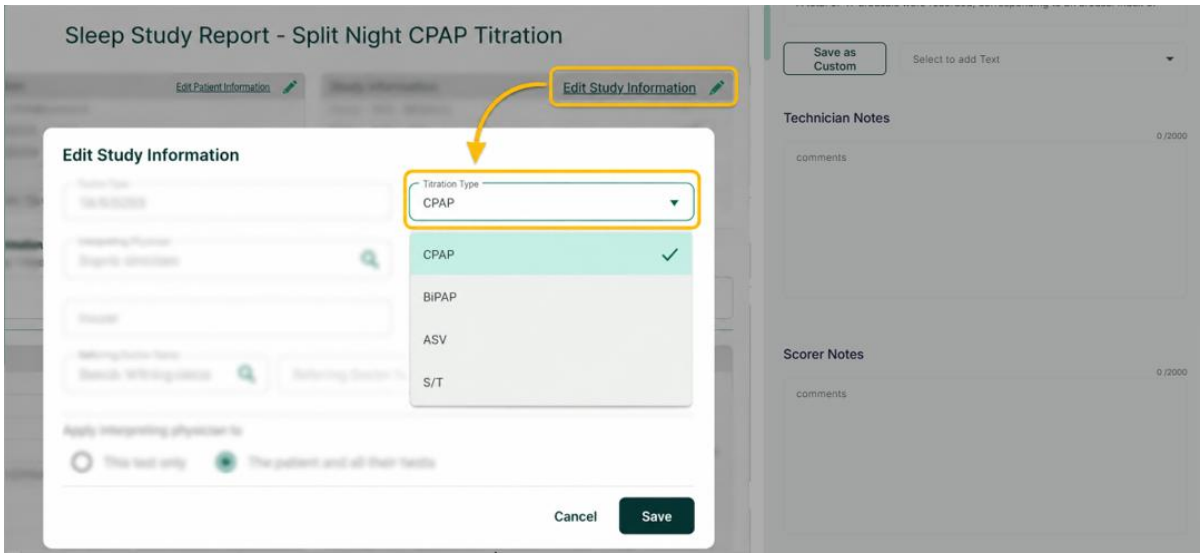
10.7. Titration Report

10.7.1. Report Overview

- The appropriate report template is automatically selected based on the study type (**Titration** or **Split-Night**).
- To change the PAP modality displayed in the report, click **Edit Study Information** and select the desired **Titration Type**.
- Technician Notes and Scorer Notes can be viewed and edited directly from the left sidebar of the report.



Changing Titration Type

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10.7.2. Titration Treatment Table

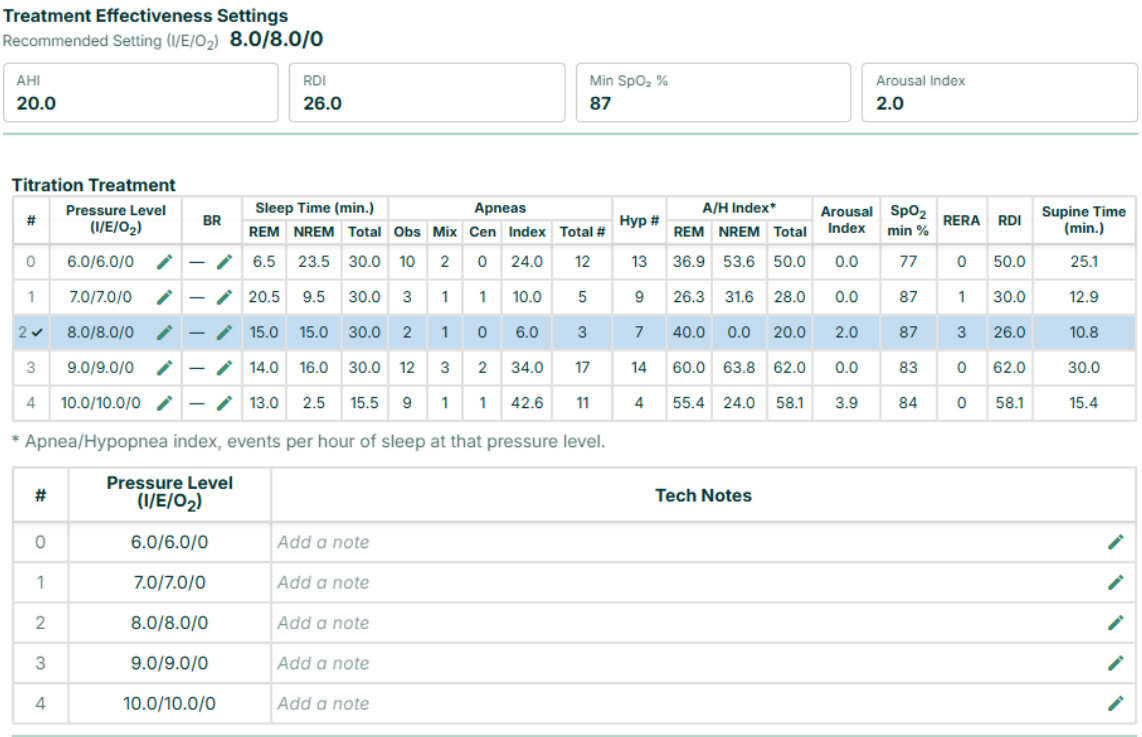
The **Titration Treatment Table** displays all PAP pressure settings recorded during the study, as shown in the Live Test View, along with additional respiratory and sleep-related indices calculated for each setting.

A separate table below displays the corresponding **Technician Notes** entered for each pressure setting during the live recording. These notes can also be edited directly in the report as explained in section 11.7.1.

The **Recommended Treatment Settings** are automatically selected based on the pressure setting associated with the lowest AHI. To manually change the recommended settings:

1. Locate the desired pressure setting in the Titration Treatment Table.
2. Click the corresponding row to select it.
3. The selected row will be highlighted, and the Recommended Treatment Settings will update automatically to reflect the selected pressure.

Note: The automatically selected setting is a suggested value and should be reviewed by the interpreting clinician before finalizing the report.



Treatment Effectiveness Settings

Recommended Setting (I/E/O_2) **8.0/8.0/0**

AHI	RDI	Min SpO_2 %	Arousal Index
20.0	26.0	87	2.0

Titration Treatment

#	Pressure Level (I/E/O_2)	BR	Sleep Time (min.)			Apneas					Hyp #	A/H Index*			Arousal Index	SpO_2 min %	RERA	RDI	Supine Time (min.)
			REM	NREM	Total	Obs	Mix	Cen	Index	Total #		REM	NREM	Total					
0	6.0/6.0/0	—	6.5	23.5	30.0	10	2	0	24.0	12	13	36.9	53.6	50.0	0.0	77	0	50.0	25.1
1	7.0/7.0/0	—	20.5	9.5	30.0	3	1	1	10.0	5	9	26.3	31.6	28.0	0.0	87	1	30.0	12.9
2 ✓	8.0/8.0/0	—	15.0	15.0	30.0	2	1	0	6.0	3	7	40.0	0.0	20.0	2.0	87	3	26.0	10.8
3	9.0/9.0/0	—	14.0	16.0	30.0	12	3	2	34.0	17	14	60.0	63.8	62.0	0.0	83	0	62.0	30.0
4	10.0/10.0/0	—	13.0	2.5	15.5	9	1	1	42.6	11	4	55.4	24.0	58.1	3.9	84	0	58.1	15.4

* Apnea/Hypopnea index, events per hour of sleep at that pressure level.

#	Pressure Level (I/E/O_2)	Tech Notes
0	6.0/6.0/0	*Add a note*
1	7.0/7.0/0	*Add a note*
2	8.0/8.0/0	*Add a note*
3	9.0/9.0/0	*Add a note*
4	10.0/10.0/0	*Add a note*

Titration Tables in the report

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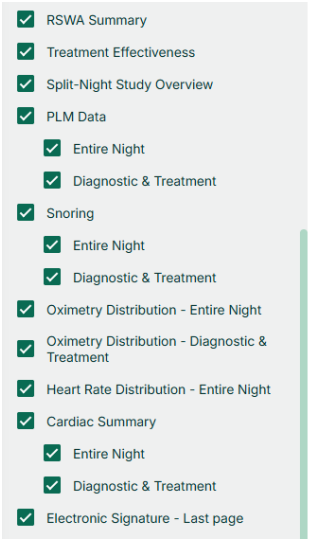
10.7.3. Split-Night report

For Split-Night studies, the report presents the recorded data in three sections:

- **Entire Night:** Data collected throughout the complete study.
- **Diagnostic**: Data collected during the diagnostic phase, before PAP therapy is initiated.
- **Treatment:** Data collected during the PAP therapy phase.

Each section can be included or excluded from the report by selecting or deselecting the corresponding checkbox in the right sidebar.

This allows users to customize the report and display only the relevant study sections.



PLM Data

Event	Entire Night		Diagnostic		Treatment	
	Count	Index	Count	Index	Count	Index
PLM	24	5.2	0	0.0	24	10.6
PLM Arousal	0	0.0	0	0.0	0	0.0

Arousal Summary

	Entire Night			Diagnostic			Treatment		
	NREM	REM	Total	NREM	REM	Total	NREM	REM	Total
Respiratory-related (number)	9	3	12	6	1	7	3	1	4
Spontaneous (number)	30	5	35	33	6	39	0	0	0
Total (number)	39	8	47	39	7	46	0	1	1
Index (#/hour)	12.1	5.7	10.1	18.3	28.0	19.4	0	0.9	0.4

Snoring

	Entire Night					Diagnostic					Treatment				
	Supine	Prone	Left	Right	All	Supine	Prone	Left	Right	All	Supine	Prone	Left	Right	All
Highest Snoring Level (dB)	94.6	0.0	0.0	92.0	94.6	92.0	0.0	0.0	91.3	92.0	94.6	0.0	0.0	92.0	94.6
Snore (Index)	17.7	0.0	0.0	90.7	31.3	5.2	0.0	0.0	0.0	4.8	35.5	0.0	0.0	118.8	60.0
Absolute Snore (min)	220.8	0.0	0.0	34.5	255.2	131.5	0.0	0.0	0.0	131.5	89.8	0.0	0.0	35.1	124.9
Snore Episodic (min)	88.2	0.0	0.0	3.9	92.1	0.0	0.0	0.0	0.0	0.0	126.8	0.0	0.0	4.0	130.8
Snore (% TST)	93.0	0.0	0.0	64.0	91.8	96.0	0.0	0.0	0.0	92.2	90.0	0.0	0.0	85.0	92.2

Split-Night report: entire night, diagnostic and treatment sections

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11. Cleaning and Disinfection

11.1. Remove and discard disposable components

Before cleaning and disinfecting the reusable components, remove and discard all single-use components. Removing disposable components provides access to reusable surfaces and helps reduce the risk of cross-contamination.

1. **Disposable electrodes:** Remove and discard all disposable electrodes from the headgear, leg and ECG units.

2. **Head Unit:** Remove and discard the following single-use components:
   - Inner textile liner
   - Forehead optic sticker
   - Nasal unit

3. **Leg Strap:** Remove and discard the disposable inner textile liner from the leg unit strap.



Head Unit



Leg unit



Head Unit Textile Liner



Leg Unit Textile Liner

Before you continue

Discard all single-use components in accordance with your institution's waste disposal procedures and applicable regulations. Do not begin cleaning and disinfection until all disposable components have been removed.

IMPORTANT: FDA Compliance Note

Perform the cleaning and disinfection procedure exactly as described in the DormoVision X™ In-Lab PSG Instructions for Use. Use only the approved cleaning and disinfecting agents identified in this manual or the IFU. Use of unapproved products or failure to follow the validated cleaning procedure may damage system components or adversely affect device performance.

If you have questions regarding the compatibility of a cleaning or disinfecting agent, contact Dormotech Technical Support before use.

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11.2. Clean and Disinfect Reusable Components

After all disposable components have been removed, clean and disinfect the reusable components using one of the validated cleaning and disinfection agents listed below.

Cleaning Procedure

1. Select a validated cleaning and disinfection agent from the table below.
2. Thoroughly wipe all reusable components, ensuring all patient-contact surfaces and frequently handled areas are cleaned and disinfected.
3. Follow the disinfectant manufacturer's Instructions for Use, including the required contact (dwell) time, application method, and any applicable personal protective equipment (PPE) requirements.
4. Allow all components to dry completely before inspection, storage, or reuse.

Validated Cleaning and Disinfection Agents

Commercial Name	Manufacturer
Sani-Cloth – HB	PDI
Sani-Cloth – Plus	PDI
Sani-Cloth – Bleach	PDI
Sani-Cloth – AF3	PDI
Sani-Cloth – Prime	PDI
Universal Wipes	Clinell
CaviWipes	Metrex

IMPORTANT: Use approved agents only

Use only the validated cleaning and disinfection agents listed above. If compatibility of a cleaning or disinfecting product with the DormoVision X™ In-Lab PSG is uncertain, contact Dormotech Technical Support before use.

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11.3. Gold Cup Electrode Cleaning

Perform the following after each patient:

1. Wipe the gold cup electrodes and electrode cables using a clean, lint-free cloth lightly moistened with water or an approved cleaning solution
2. Ensure all electrode surfaces and exposed cable areas are thoroughly wiped.
3. Remove any residual gel or debris from the electrode surface and cable.
4. Wipe the electrodes with clean, dry cloth and allow all components to air dry completely in a cool, dry environment before storage or reuse.

WARNING:

Do not immerse the reusable gold cup electrodes or electrode cables in liquid. Immersion may damage the electrodes or internal wiring and may adversely affect device performance.

Disinfection- AFTER EACH PATIENT

1. Wipe the electrode cups and cable with a clean sponge or soft cloth dampened with 70% ethanol or 70% isopropyl alcohol.
2. Ensure that all electrode surfaces and exposed cable areas are thoroughly wiped.
3. After disinfection, wipe the electrodes with a clean dry cloth and allow them to air dry completely in a cool, shaded environment.

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11.4. Inspection and Quality Control

After cleaning and disinfection, all components should be visually inspected to ensure that no visible contamination remains. During the inspection, confirm the following:

✓ No adhesive residue from electrodes, dressings, or conductive paste remains

✓ No hair or other biological material is present.

✓ No dust, debris, or other foreign material is present.

✓ The reusable EEG cup electrodes and electrode cables are free from cracks, damage, excessive wear, or other visible defects.

Acceptance Criteria

Before reuse, all reusable components must:

- Be visually clean and free of contamination.
- Be completely dry.
- Be free from visible damage or excessive wear.
- Be suitable for clinical use.

Do not return any component to service if it does not meet these acceptance criteria.

11.4.1. Preparing For the Next Study

Once all reusable components have passed inspection:

- Reassemble the DormoVision X™ In-Lab PSG kit.
- Place each recording unit on its magnetic charger, if applicable.

Store the system in accordance with your institution's procedures until the next study.

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12. Revision History

Version	Date	Author	Change Description	Approval
V1.0	07/20/2026	Noa Scheinowitz	New Document	N.S
V2.0	09/20/2026	Ofir Avivi	Leg extension	O.A
V3.0	10/25/2026	Ofir Avivi	Titration and Impedance	O.A

13. Approval

Name	Role	Signature	Date
Noa Scheinowitz	Clinical Product Specialist	N.S	07/20/2026

DormoVision X™ is the commercial platform utilizing the FDA-cleared Dormotech NLab™ and Vlab™ physiological data recording systems (510(k) K242290 and 510(k) K230148). The platform is indicated for prescription use by or on the order of a licensed physician for the acquisition and display of comprehensive physiological sleep parameters in both supervised (clinical/laboratory) and unsupervised (home) environments for patients 6 years of age and older. Automated scoring and analytical features function strictly as data visualization aids and do not supersede manual review or clinical interpretation by a qualified sleep technologist or physician.

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