

SynX™

User Guide



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Stereotaxis Companion Systems

System	Part Number
<i>Odyssey Vision</i>	001-007010-2



WARNING: No modification of this equipment is allowed. No user-serviceable parts are inside *SynX*. The user should not attempt to disassemble any portion of *SynX*.



WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains that have a protective earth ground.

Disposal

This product should be recycled and not disposed of as general waste (subject to WEEE annex IV resp. EN 50419).

Waste and Recycling

A contractor is responsible for the disposal and recycling of scrap metals and electronics found in *SynX*.

Suggested Contractor: Walch Recycling & Eldelmentalle



Notice to the User and/or Patient

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Cover art

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1. Overview

Introduction

SynX™ is an optional add-on product and provides the following functionality:

- View procedure video in real time-
 - From your hospital or at a remote site.
 - Using a mobile device or PC with *SynX* system or app.
- Video chat with host and other users-
 - Collaborate with other physicians during live procedures.
 - Enable fellows to view live procedures remotely for training purposes.

About This User Guide

The purpose of this user guide is to provide the *SynX* user with instructions for operating it. The *SynX* User Guide describes how to operate the *SynX* system. It describes how to operate the *SynX* application for use in the interventional lab. It does not describe how to operate any other devices it might be working with.

Intended Use

SynX enables connectivity between an interventional lab and physicians allowing them to provide remote support and collaboration through shared lab video streams and person to person calling. There are no known indications or contraindications.

Intended Users

SynX system should be used only by qualified medical professionals who have been thoroughly trained in its use.

Clinical Benefits for the Physician and Staff

SynX provides the ability to share real time procedure displays with multiple users for broadcasts, peer to peer collaboration and a clinical or technical support.

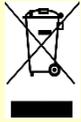
Graphics and Symbols

Warnings and Cautions precede the text and any procedure involving a clear risk to the operator(s), the patient, or the equipment. General warnings are listed in the Warnings and Precautions summary, which can be found in the *Safety* section. Pay close attention to the instructions that accompany the warnings, notes, and symbols. The following graphics and symbols are used in this User Guide:

WARNING		WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION		CAUTION indicates a potentially hazardous situation which, if not avoided, could result in injury to patient or operator or damage to the equipment.
Note		Note identifies information that could affect the outcome or results of the procedure.

The following graphical symbols are used in this document and/or on system components:

Symbol	Name	Description
REF	Catalogue Number	Part number
	Caution	Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot be presented on the medical device.
	Consult Instructions	See the Operating Instructions for additional information or instruction.
	Date of Manufacture	The date when the medical device was manufactured.
	European Representative	Name and address of the authorized representative in the European Community.
	Importer	Name and address of the entity importing the medical device into the locale.
	Manufacturer	Name and address of the manufacturer of the product.
	Medical Device	Indicates the item is a medical device.

Symbol	Name	Description
	Recycle: Electronic Equipment	Product that is subject to the European Union’s Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC/EU Directive for recycling of electronic equipment.
	Refer to Instruction Manual/Booklet	The instruction manual or booklet must be read.
SN	Serial Number	The manufacturer’s serial number so a specific medical device can be identified.
UKRP	UK Responsible Person	A person established in the United Kingdom (UK) who acts on the behalf of a non-UK established manufacturer in relation to the manufacturer’s obligations under UK regulations.

Glossary

Term	Description
<i>SynX</i>	A global video streaming platform that is accessible from PC browsers and mobile devices.
<i>Lab Host</i>	User in charge of a group video conference call that contains the live lab video feed.
<i>Hosted Session</i>	A group video conference call that contains the live lab video feed.
<i>Lab Participant</i>	User that is part of a group video conference call that contains the live lab video feed.

Safety

Warnings / Precautions

-  **WARNING:** *SynX* should be used only by qualified medical professionals who have been thoroughly trained in its use.
-  **WARNING:** Video content viewed using *SynX* is intended for support and collaboration only.

2. Basic Information

Installing *SynX*

1. Users can install the software *SynX* onto their device.
2. The *SynX* app can be downloaded or used from the following locations:
 - a. [Apple App Store](#)
 - i. System required to be iOS device at version 12.0 or later.
 - ii. Check the app store for availability with the intended device first.
 - b. [Google Play Store](#)
 - i. System required to be Android – 5.0 Lollipop (API level 21) or higher.
 - ii. Check the app store for availability with the intended device first.
 - c. [Direct URL to SynX for Desktop or Laptop](#)
 - i. The browser required for the computer is Google Chrome version 100 or higher.
 - ii. Check browser version and update if required for the intended computer.

1. Navigate to **SynX Sign Up** on the main SynX webpage.
2. Verify your email address.
 - a. The verification code will be sent to the provided email address, check your spam folder if you don't see it in your inbox.



Note: This code will not begin with an S-.

3. Fill in the required information to create an account.
4. Choose the **Use Invitation Code** button (as seen in **Figure 1**) on the **Validate Your Identity** page.

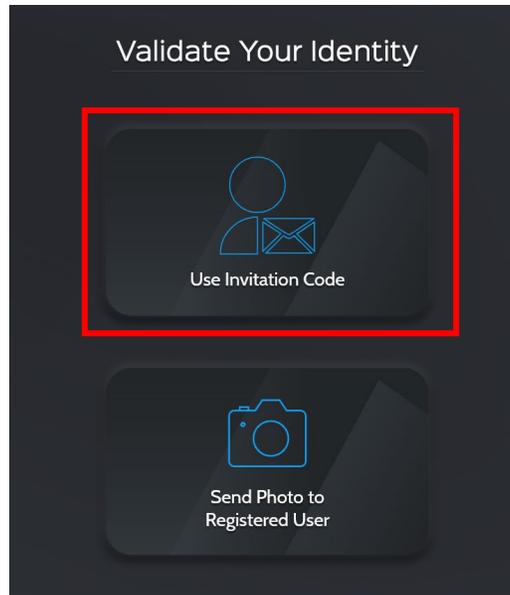


Figure 1. Validate Your Identity Choices

5. Enter the 8-digit invitation code sent to you by a *SynX* Site Manager.

 **Note:** This code will begin with an S-.

6. Welcome to *SynX*.

Send a Photo to a Registered User

 **Note:** Please be on a device that has access to a camera.

1. Navigate to **SynX Sign Up** on the main *SynX* webpage.
2. Verify your email address.
 - a. The verification code will be sent to the provided email address, check your spam folder if you don't see it in your inbox.

 **Note:** This code will not begin with an S-.

3. Fill in the required information to create an account.
4. Choose the **Send Photo to Registered User** button (shown below in **Figure 2**) on the **Validate Your Identity** page.

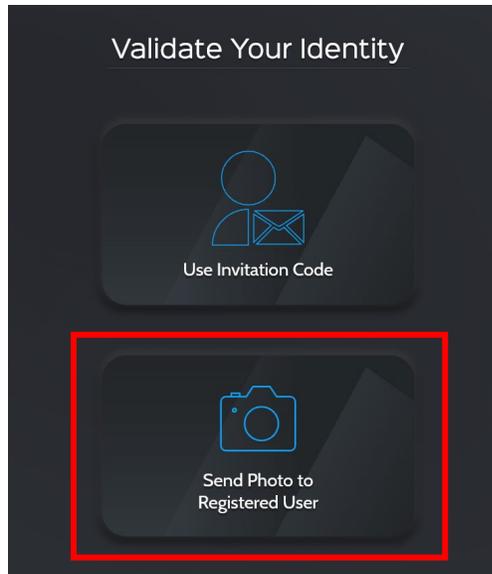


Figure 2. Validate Your Identity Choices

5. Enter the names of up to 3 people that you already know in the *SynX* system. One of these people will validate your identity.
6. Take a photo of yourself to send to your selected contacts.
7. Confirm and send your photo.
8. As an un-validated user, you will have limited access to the application (which **Figure 3** depicts).



Note: You can only edit your phone number and password with limited access.

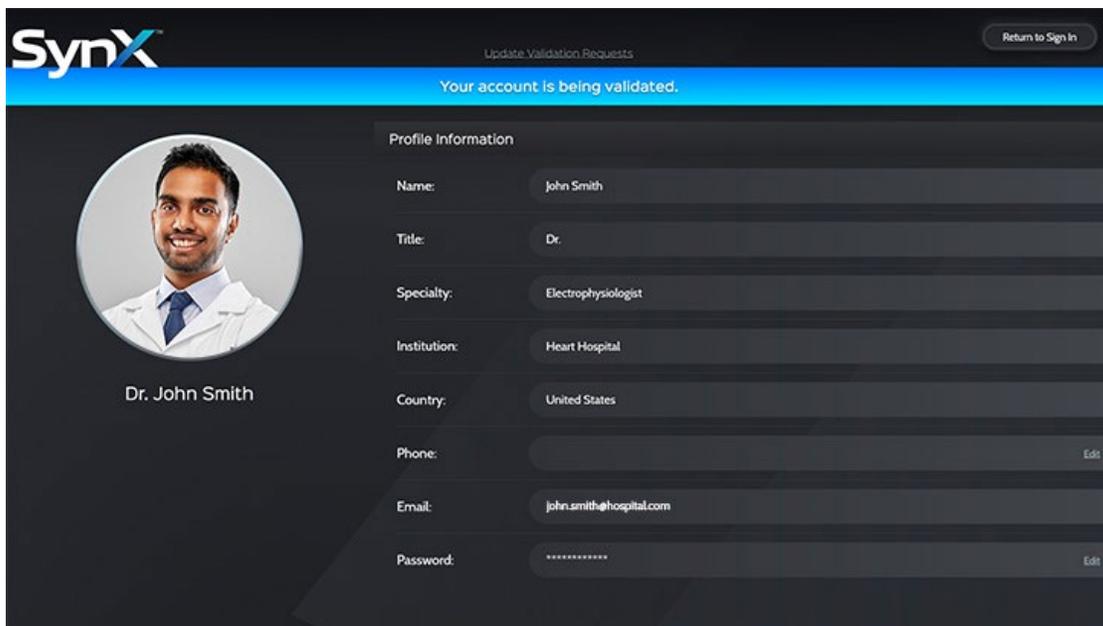


Figure 3. Restricted Access View

9. When validated by one of your chosen contacts, you will have full access to the application, like as shown in **Figure 4**.

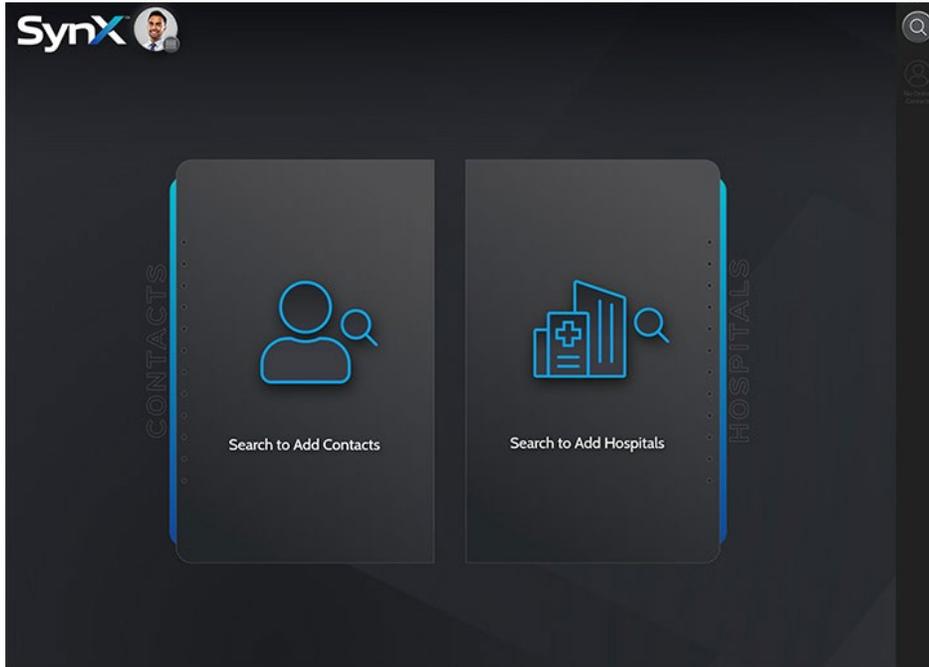


Figure 4. Full Access View

Editing Contacts that were Sent Validation Requests

1. Click the **Update Validation Requests** link at the top of the page.
2. To remove possible validators:
 - a. Click the X next to their name.
3. To add a validator:
 - a. Enter the names of up to 3 people to send a new validation request to.

What Happens If My Account Validation Fails?

If your account validation fails, you have the option to update and send new validation requests to other people in the *SynX* system. Click the **Send New Validation Requests** link at the top of the page.

3. Hosting, Joining, and Viewing Labs

Host a Lab



Note: Anyone with access to the lab manager tablet in a lab can host from their account.

Host Using QR Code

1. Sign into *SynX* on a secondary mobile device with a camera.
2. Go to the main menu by clicking your avatar in the top left corner.
3. Click the **Host a Lab** button at the top of the menu.
4. Unlock the lab manager tablet.
5. Scan the QR code on the lab manager tablet with the other device's camera.
6. Once scanned, a hosted session will begin under the account you signed into on your secondary device.

Host Using Numeric Passcode

1. Sign into *SynX* on a secondary device.
2. Go to the main menu by clicking your avatar in the top left corner.
3. Click the **Host a Lab** button at the top of the menu.
4. Unlock the lab manager tablet.
5. Type the numeric code you see on the lab manager into the indicated field.
6. Click **Check-In**.
7. A hosted session will begin under the account you signed into on your secondary device.

Host Using Local Sign-In

If you have never hosted this lab before:

1. Unlock the lab manager tablet.
2. Click the **Sign In** link at the bottom right corner of the colored square on the right side of the screen.
3. Enter your username and password.

If you have hosted this lab before:

1. Unlock the lab manager tablet.
2. Click on the tile with your name and avatar.
3. Enter your password.

Host Settings

SynX allows hosts to control how their session will be run with several session specific settings.

Changing Settings on the Lab Manager Device

Click the "..." **button** (shown in Figure 5) for the in-call controls.



Figure 5. "... Button from In-Call Controls

1. Incoming Calls can be set to:
 - a. Ask Host (icon shown in **Figure 6**) – The host is prompted for each person that wishes to enter the session.

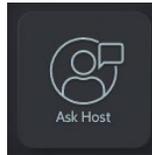


Figure 6. Ask Host Button

- b. Auto Reject (icon shown in **Figure 7**) – All further people trying to call into the hosted session will be denied access.



Figure 7. Auto Reject Button

- c. Auto Accept (icon shown in **Figure 8**) – All further people trying to call in the hosted session will be allowed access.

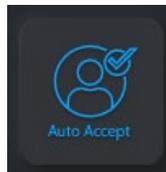


Figure 8. Auto Accept Button

2. Click the **Mute All** button to mute all participants in the session.
3. Click the **Dismiss All** button to remove all participants from the session but keep the session running. (**Mute All** and **Dismiss All** buttons both shown below in **Figure 9**.)

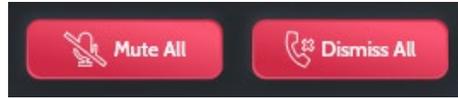


Figure 9. Mute All and Dismiss All Buttons

What Do My Other Devices Look Like While I'm Hosting?

When hosting, any other device that you are signed in on, other than the lab manager, will act as a satellite device, allowing you to adjust settings, add callers, and end the session.

View a Lab

From Home Screen

1. Navigate to your site list on the main app screen.
2. If labs are not visible, click the site tile to expand the lab list.
3. Select the lab you'd like to view.
4. On the lab's info screen, click **View Lab**.

From Search

1. Click the search icon at the top right of the screen.
2. Search for the site whose lab you'd like to view.
3. If labs are not visible, click the site tile to expand the lab list.
4. Select the lab you'd like to view.
5. On the lab's info screen, click **View Lab**.

Calling

Outgoing Call – From Home screen

1. Navigate to your contacts list on the app main screen.
2. Select the contact you'd like to call.
3. On the contact's info screen, click **Begin Call**.
4. While ringing, you will see a video preview and be able to adjust your in-call settings.

Outgoing Call – From Search

1. Click the search icon at the top right of the screen.
2. Search for the person you'd like to call.
3. If who you have searched for is already a contact, click the blue video icon on their tile.

4. On the contact's info screen, click **Begin Call**.
5. While ringing, you will see a video preview and be able to adjust your in-call settings.

Add a Contact to an Active Call



Note: You can make multiple outgoing calls while using this calling method.

1. From the in-call controls, click the blue **Add Contact to Call** button.
2. Click the contact's tile to initiate a call.
3. While ringing, a blue animation and end button will appear on the contact's tile.
4. If accepted, the contact will be added to the call and removed from the list.
5. The list may be closed by clicking on the blue **Add Contact to Call** button or by tapping on the blank space to the right of the contact list.

Join a Hosted Session – From Contact List

1. Navigate to your contacts list on the app main screen.
2. Select the contact who is hosting the lab you'd like to join.
3. On the contact's info screen, click **Join Call**; this step is shown in **Figure 10**.

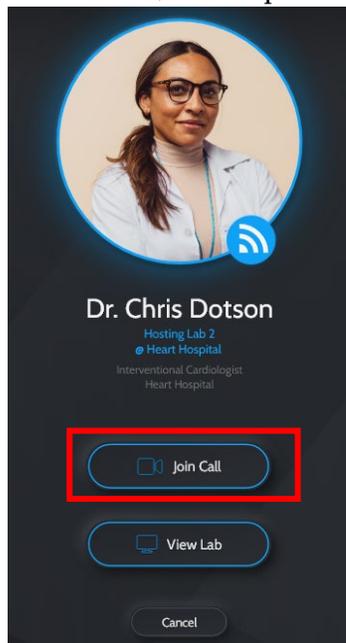


Figure 10. Contact Info Screen

4. While ringing, you will see a video preview and be able to adjust your in-call settings.

Join a Hosted Session – From Site List

1. Navigate to your site list on the app main screen.
2. Select the lab you'd like to join.

3. On the lab's info screen, click **Join Hosted Call**; this step is shown in **Figure 11**.

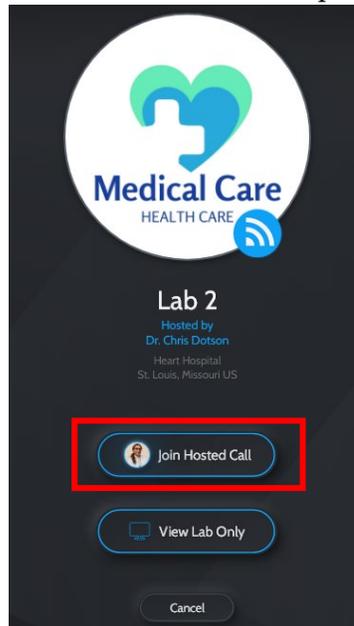


Figure 11. Lab Info Screen

4. While ringing, you will see a video preview and be able to adjust your in-call settings.

Join a Hosted Session – From Lab View

1. Navigate to your site list on the main app screen.
2. If labs are not visible, click the site tile to expand the lab list.
3. Select the lab you'd like to join.
4. On the lab's info screen, click **View Lab Only**.



Note: When in “View Lab Only” mode, the stream of the lab will be visible. Interaction with the host or hosted session participants will not be possible until you join the call.

5. Click the **Join** button.
6. While ringing, you will see a video preview and be able to adjust your in-call settings.

Requests

Send a Contact/Site Access Request

1. Click the search icon at the top right of the screen.
2. Search for the person or site you'd like to send a request to.
3. Click the blue **Add Contact** icon to send a request.
4. While the request is pending, a green request sent icon will appear on the tile.

5. To un-send the request, click the **Green Sent** icon.

Respond to a Contact/Validation Request

1. Go to the main menu by clicking your avatar in the top left corner.
2. Click **Requests**.
3. Click the contact tile to expand the request.
4. Confirm or delete the request.

4. Editing Profiles and Settings

Edit Profile

1. Go to the main menu by clicking your avatar in the top left corner.
2. Click **Profile**.

Edit Personal Information



Note: Name changes require approval from a *SynX* Administrator. You may send a name change request from the profile edit page.

1. Click the **Edit** link to the right of the field you'd like to edit.
2. Make any desired changes to your information.
3. Click **Save**.

Edit Profile Picture

1. Click the pencil button atop your profile picture.
2. Choose how you'd like to update your image. The two options are shown in **Figure 12**.
 - a. Take Photo
 - i. Snap your new photo.
 - i. Review your photo.
 - ii. Click **Update Photo**.
 - b. Choose from Library
 - i. Use your file explorer or camera roll to select your new profile image.
 - ii. Review your photo.
 - iii. Click **Update Photo**.

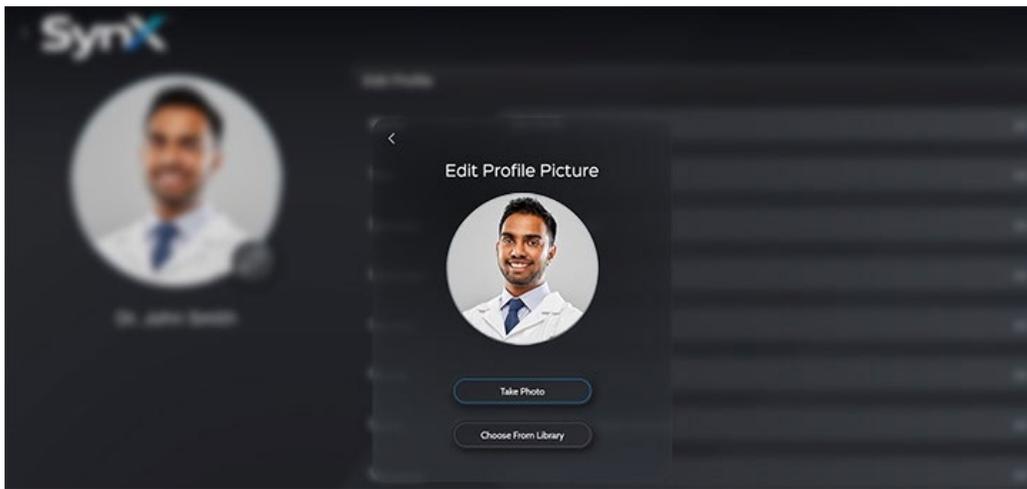


Figure 12. Edit Profile Picture Options

Preferences

1. Go to the main menu by clicking your avatar in the top left corner.
2. Click **Preferences**.

Notification Preferences

1. Click **Notifications**.
2. From here you can manage notification related preferences:
 - a. Missed Calls – Toggles native iOS and Android notifications for missed calls.
 - b. *SynX* Requests – Toggles native iOS and Android notifications for *SynX* requests.
 - c. Validation Requests - Toggles native iOS and Android notifications for validation requests.

Audio & Video Preferences



Note: Can only be accessed from a web browser.

1. Click **Audio & Video**.
2. From here you can manage default audio & video preferences:
 - a. Camera – Use the dropdown to select the default camera for calls.
 - b. Microphone – Use the dropdown to select the default microphone for calls.
 - c. Speaker – Use the dropdown to select the default speaker for calls.

Privacy & Security Preferences



Note: Can only be accessed from a mobile device.

1. Click **Privacy & Security**.
2. From here you can manage privacy and security preferences:
 - a. Biometrics – Toggles whether or not local biometrics is used to sign in.
 - i. When toggled on, your mobile device will use native biometric sign in or your device passcode when the app is opened.
 - ii. When toggled off, you will have to sign in using your username and password when the app is opened.

5. Account Management and Signing Out

Signing Out and Shutting Down *SynX*

1. Go to the main menu by clicking your avatar in the top left corner.
2. Click **Preferences**.
3. Click **Account**.
4. Click **Sign Out**.
5. Close the *SynX* app your device is using to safely shutdown operation of *SynX*.

Delete your Account and Delete *SynX*

1. Go to the main menu by clicking your avatar in the top left corner.
2. Click **Preferences**.
3. Click **Account**.
4. Click the **Delete Account** link in red at the bottom of the page.
5. Enter your password to confirm.
6. Click **Continue**.
7. To safely decommission and dispose of *SynX* system, uninstall and delete the software from your device.

6. Troubleshooting Technical Difficulties

Report an Issue

1. Go to the main menu by clicking your avatar in the top left corner.
2. Click **Help**.
3. Enter a description of the error in the text field.
4. Click **Report Issue**.
 - a. Security breaches can be submitted by users through using **Help** and **Report Issue**.

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