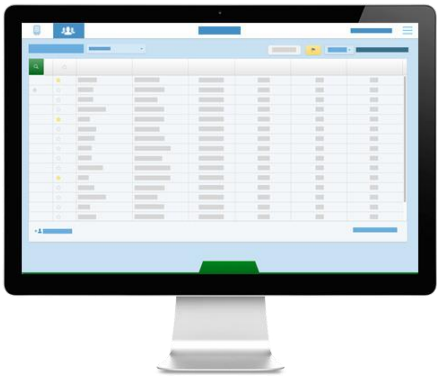
LibreView



Quick Start Guide
for
Professionals

Welcome to LibreView - the all-in-one, web-based data management platform for FreeStyle Libre Pro*, FreeStyle Libre and most major blood glucose meters. Connect your patients' devices to quickly upload patient data into your LibreView account. Your patients' information will be encrypted and secure.

Because LibreView is a web-based platform, you'll be able to access your patient's glucose information from anywhere with an Internet connection, even outside the office. LibreView supports all Abbott devices and other compatible blood glucose meters to create standardised, easy-to-read reports.

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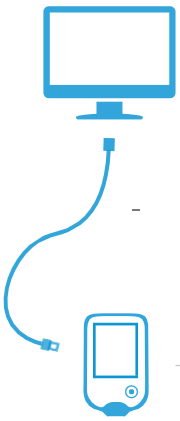
What You Will Need



A computer with a compatible Windows or Mac operating system

The corresponding cable for the device

Compatible Devices

*When using a Mac OS, only FreeStyle Libre and FreeStyle Pro readers are compatible

** Not all devices and reports are available in all regions. Units of measure are for purposes of illustration and will be available as applicable per region.*

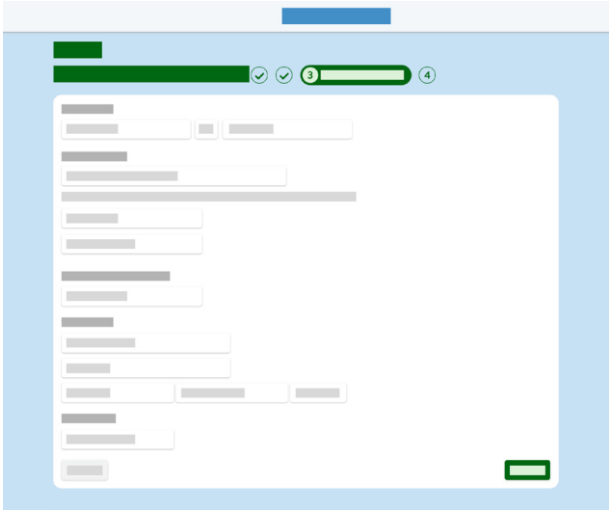
Set Up Your LibreView Account

LibreView

Sign Up For A LibreView Account

You can create a professional account from an email invitation or directly on the LibreView website. To set up your own individual account:

1 - Go to www.libreview.com and click **Sign Up**
2 - Select **Professional Account**
3 - Select your country of residence
4 - Agree to the Terms of Use and Privacy Policy
5 - Fill out your information and select a password
6 - Log in to the email address that you provided and click on the verification email to complete your registration



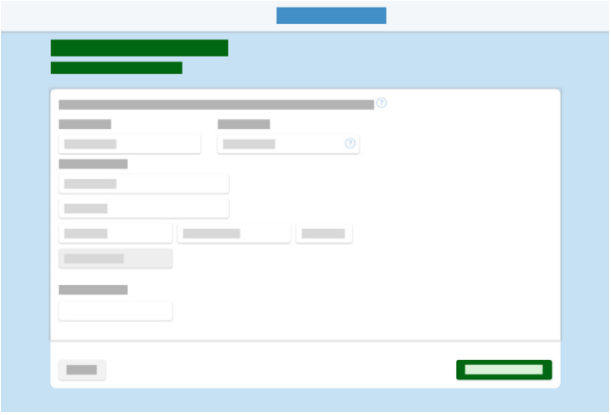
Note: Your email address will be your login username. You can use the same email address to log in to multiple practices.

Setting Up Your Practice

When you first sign up for LibreView, you'll be uploading devices under Private Patients, which means only you can access the information.

Create a LibreView practice in order to add Care Team members, securely share patient information with your staff and easily allow patients to upload remotely.

1 - Click the Settings icon ☰
2 - Select **Create a LibreView Practice**
3 - Follow the instructions to set up your new practice
4 - Once you complete the form, you'll be prompted to click on Switch Practices to upload patients into the practice account



Note: When setting up a new practice, you can customise your practice ID to make it easier for patients to connect to your account.

Set Up Your LibreView Account

LibreView

Downloading Device Drivers

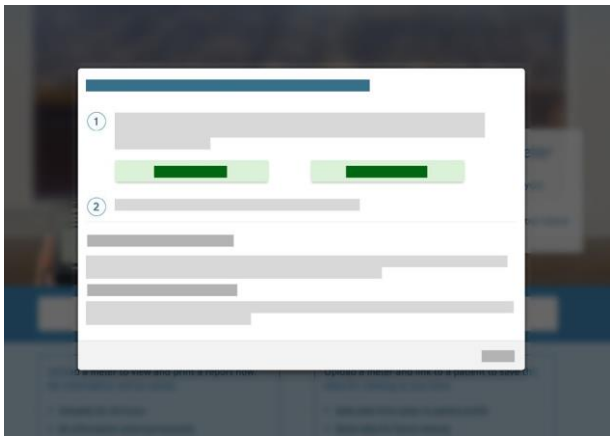
LibreView only requires a one-off download of a device driver file that recognises when your blood glucose device is plugged in. Make sure that you are using the most updated version of your Internet browser when initiating the download.

1 - Click the **Create 1-Time Report** button

2 - In the window that appears, click on the **Download** button specific to your operating system

3 - Open the downloaded file and allow it to run

4 - Follow the prompts on the screen to complete the installation



Note: When setting up the device drivers on a computer for the first time, make sure that you are logged in as a Local Administrator or have your IT team available.

Installation Best Practices

- ✓ Make sure that you are logged in as the Local Admin or have your local administrator's username and password available when you are installing the device drivers
- ✓ If you are part of a larger practice or hospital system, you may need to contact your IT team for assistance
- ✓ Have a compatible blood glucose meter, FreeStyle Libre or FreeStyle Libre Pro reader available after installation to test the drivers by carrying out a one-off report upload

Set Up Your LibreView Account

LibreView

Minimum System Requirements

LibreView can be used just to view data, or to upload data.

The minimum system configuration required to use LibreView as a viewer is:

Windows 7 SP1, Windows 8.1 or Windows 10 Anniversary update (and higher)

- Display resolution of 1024 x 768 pixels or greater.
- Internet Explorer 11, Firefox release 32.0, or Chrome release 37.0
- 1 Ghz processor (dual/multi-core recommended)
- 2 GB RAM
- Internet connection with 0.5 Mbps download speed.

Mac OS X Yosemite (10.10) or higher

- Display resolution of 1024 x 768 pixels or greater
- Safari release 10.1 or Chrome release 37.0 or higher
- 1 Ghz processor (dual/multi-core recommended)
- 2 GB RAM
- Internet connection with 0.5 Mbps download speed.

We recommend using the most up-to-date version of your browser. Please note, at this time, Microsoft Edge is not a supported browser.

Minimum System Requirements *continued*

In order to upload data, you must install the LibreView Device Drivers (LDD), with the following additional specifications required.

There are two version of the Windows LDD for Windows, depending on when you installed the software and if you upgraded when prompted. The newer version offers some enhancements when dealing with similar software installed on the machine.

Windows

LDD 2.1.6

- Windows 7 SP1, Windows 8.1 or Windows 10 Anniversary update (and higher)
- Will install if not present .Net Framework 4.5 and Microsoft Visual C++ 2015 Redistributable (x86)
- 8 GB+ RAM and 200 MB free disk space
- USB 2.0
- Internet connection with 1 Mbps upload speed.
- Local Administrator account

LDD 3.1.0

- Windows 7 SP1, Windows 8.1 or Windows 10 April 2018 update (and higher)
- Will install if not present .Net Framework 4.7.2 and Microsoft Visual C++ 2017 Redistributable (x86)
- 8 GB+ RAM and 200 MB free disk space
- Internet connection with 1 Mbps upload speed.
- Local Administrator account

Mac

LDD 1.1.0

- Mac OS X Yosemite (10.10) or higher
- 8 GB+ RAM and 200 MB free disk space
- Internet connection with 1 Mbps upload speed.

Uploading A Device

Once you have successfully downloaded the device drivers, you can plug in any compatible device to start uploading data. Go to the upload screen and choose one of two options.

For a one-off report:

1 - Select **Create 1-Time Report** to create a temporary report, which is accessible to you for 24 hours, contains no patient identifying information and is not saved in the system permanently.

2 - The reports will automatically load and open

3 - Email, print or save the report as a PDF on your computer

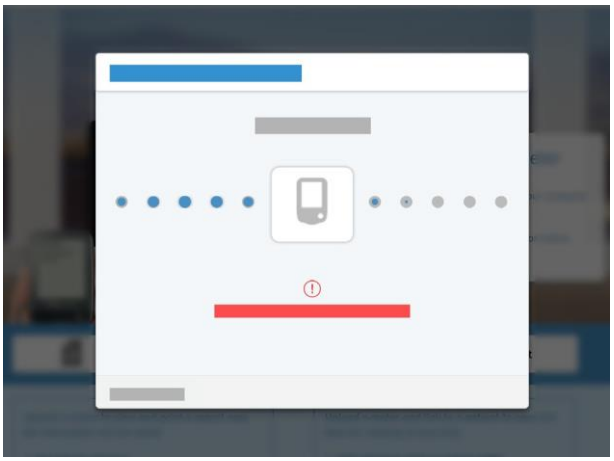
For a saved report:

1 - Select **Create Report Linked to Patient** to save the report to a patient's profile, making it easy to view at any time

2 - For new devices, search for an existing patient or create a new one. Once you choose or attach a patient to the device, the reports will automatically be linked to that patient.

3 - The patient's reports will automatically open under their profile

4 - To access saved reports in the future, from the patient's profile, click on **View Full Reports**



Note: When you're first uploading a device into your LibreView account, you may need to allow your browser to access the device drivers file. Save time by ticking the box to have your browser remember your selection before selecting "Allow" or "Launch application".

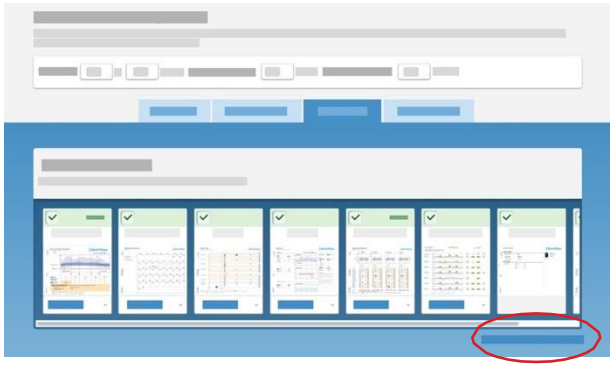
For FreeStyle Libre for FreeStyle Libre Pro AGP reports to populate, the patient needs to have worn the sensor for at least 5 full days.

Changing Report Settings

You can easily customise your report preferences by report, by patient or by Care Team member.

Changing a specific report/patient's settings:

1 - From a report, select the **Report Settings** tab
   a. For BGM reports, change the amount of data to display by selecting the time range under a specific report
   b. For FreeStyle Libre or FreeStyle Libre Pro reports, select Edit to change your preferences
2 - Set the report or patient's target ranges or adjust the thresholds for high or low glucose events
3 - Customise Report End Date if desired
4 - Select "Generate Reports" to update the reports with the new settings



Note: Click on Revert to report default settings in the bottom right if you want to undo any changes you have made.

Changing the default report settings:

1 - Select the Settings icon and go to **Report Preferences**
2 - Change the target ranges and thresholds for all reports uploaded going forward
3 - Toggle between tabs to change the default report settings per device type
4 - Click on "Save Changes" when done

Note: When viewing reports, click on the Available Meters button in the bottom left to toggle between reports for different devices. You can set a primary device you want to automatically load for this patient.

Your Patient Dashboard

LibreView

Accessing Your Patient Dashboard

Now that have you have the basics down for saving reports, you can use your patient dashboard to quickly identify patients and access saved reports. Click on the dashboard icon to see all the patients you have uploaded.

Click on the dashboard icon to access your patient population. At the top of your dashboard, you will see a drop-down list of different filters you can apply to your patient list.

1 - Click on a patient's name

2 - You'll land on a summary of the patient's reports You can edit the patient information, invite them to upload from home, compare date ranges and see recent uploads.

3 - Select from the applicable tabs:

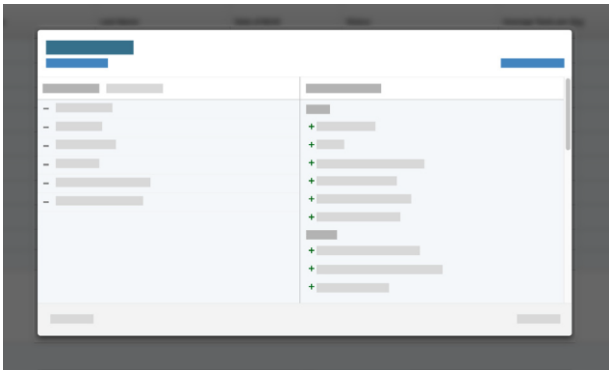
   1 - **Reports** for FreeStyle Libre and blood glucose meter information

   2 - **FreeStyle Libre Pro Reports** if available in your region, you will see a separate tab

   3 - **Patient Notes** to record notes or fill out customised practice fields

Customise Your Dashboard

You can customise your dashboard columns to view additional information on your patients. This will allow you to manage your patient population and identify at-risk patients.



1 - Select **Edit Columns** to add or remove any columns from your dashboard

2 - You'll see a complete list of possible fields that can be created from uploaded device data. Click on "+" to add any columns to your list from **available columns** or select "-" to remove any under **active columns**.

3 - Add customised practice fields as columns by going to **Practice Info** - **Practice Records** and adding new fields that will live in the patient's profile under **Patient Notes**.

4 - Select **Save** when finished

Flagging Patients

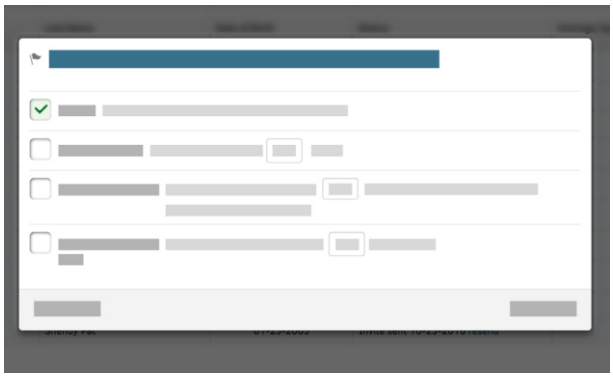
Add flags to locate patients easily whose information fits certain parameters. There are currently four types of column flags in LibreView. Be sure to add the column type to your patient dashboard that corresponds to the selected flag to be able to use this feature.

Usage: Choose to highlight patients who haven't had any uploaded device data within a preferred time span. Column to display flag is "Status".

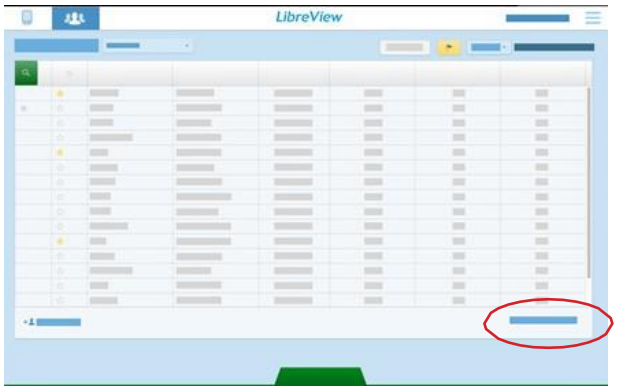
Average Glucose: Patients whose average glucose is above a certain value will have this column flagged once the column is added to the dashboard. This average will be generated from all their devices. Column to display flag is "Average Glucose Reading"

Low Glucose Events: This will highlight patients that have greater than the set number of hypo events. Column to display flag is "Low Glucose Events".

Average Tests per Day: Simply input the number of tests preferred per day. Column to display flag is "Average Tests per Day".



Note: Starring patients will help you narrow down your patient list. Simply select the star next to the patient's name on the patient dashboard and then use the drop-down list next to "My Patients" to only view starred profiles.



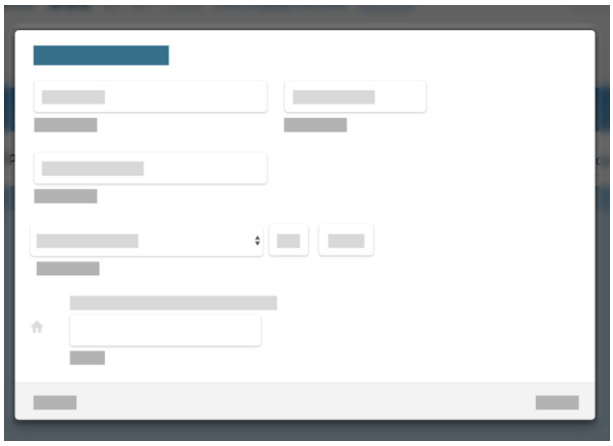
Note: You can export your Patient Dashboard into a CSV file for further analytics by clicking "Export My Patients List" in the bottom-right corner of the dashboard.

Your Patient Dashboard

LibreView

Invite Patients To Remotely Upload

You can invite patients who have their own blood glucose meters or FreeStyle Libre readers to create a LibreView patient account and complete uploads from home prior to their appointments. Data your patients upload remotely is automatically added to their profile, saving you valuable time during office visits.



Inviting a patient:

1 - Go to the patient's profile

2 - Select the "Invite to upload from home" link next to their name

3 - Enter the patient's email

4 - This will send the patient instructions to log in and set up their patient account. You can also give your patients your practice ID - located under your practice's name in the Settings menu - if they already have an existing LibreView patient account.

5 - Use the drop-down menu next to "My Patients" to see patients who have accepted their invite or are still pending.

Note: Patients will need to have their own cables at home to connect their devices. They will also need to complete a one-off installation of the device drivers, similar to the setup process for your account.

They will only be able to see their own history of uploads, their current devices and their connected practices.

If you have not yet uploaded any devices for a patient but want to invite them to upload their glucose devices, go to your Patient Dashboard and click on Invite Patient in the bottom left. Enter in their name and email address to send an invitation.

Inviting Your Care Team

LibreView

Invite Your Care Team

You can include other members of your team as well as the patient's Care Team to access your patient dashboard. Keep in mind that anyone you add as a Care Team member will have access to all of the data in the practice.

You will first be required to set up a LibreView Practice before you can add Care Team members. Refer to the "Setting up a Practice" section above. Make sure you are logged into the correct practice when adding Care Team members.

1 - Go to the Settings section and select **Practice Info**

2 - Select the **Care Team** tab

3 - Add in the user's email address, click Invite and then Save Changes within the green bar in the top-right corner. The new Care Team member will receive an automated email with instructions to log in.

4 - If the user that you added already has an existing LibreView account, they can enter in their login credentials to join and switch between practices.

5 - If the user is new to LibreView, they will need to set up a new account that will then be linked to your practice.

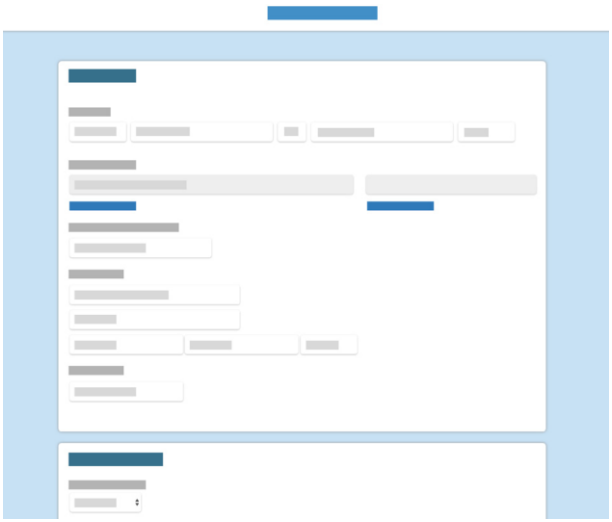
6 - The new user will need to click Accept on the invitation pop up that appears when they finish the login process.

Note: You can make other members administrators. Scroll over the question mark next to "Admin Permissions" to see what this user will able to control. It is recommended to have at least two admins in your account.

If you belong to several practices, you can use the "switch practices" option in the Settings menu to access the other practice's separate Patient Dashboard. You will need to manually switch to a new practice after you accept the new invitation.

Updating Account Information

Change your practice and personal information at any time.



If you are an account administrator, under the Settings menu go to **Practice Info** to change the practice's address/phone number, upload a logo or customise the practice ID. Your practice ID is how your patients can connect their LibreView accounts to yours.

Under **Account Settings**, you can edit your own information, change your email or change your password. If you ever forget your password, you can always select Forgot Password on the login screen to reset it.

Account Information

LibreView

Helpful Resources

LibreView has several resources to help you successfully set up and use your LibreView account for your diabetes population.

[LibreView Support Site]

[List of Compatible Devices]

[System Requirements]

Contact Support

Argentina	+0800-800-6334
Australia	+61 1800 801 478
Austria	+43 0800 222 775
Bahrain	+973 172 41745
Belgium	+32 0800 82106
Brazil	0800 703 0128
Canada	1-800-461-8481
Chile	800 802 226 / 22 3683080
Colombia	01800 5181895
Denmark	80 83 10 42
Finland	+358 0800 772 355
France	+33 800947909
Germany	+49 8006365500
Greece	800-491423863
Hong Kong	+852-5808-4196
Ireland	+353 1800719995
Israel	00 97236900300
Italy	+39 800693000
Jordan	+962 6 51 62 971
Kuwait	2206 7372
Lebanon	+961 1387 815
Luxembourg	+32 0800 82106
Mexico	55244175 / 018007112208
Netherlands	+31 8002424400
Oman	800 74396
Poland	800 388 700
Portugal	800780870
Qatar	00800 100869
Saudi Arabia	92000 3788
Singapore	+65 1800 272 2881
South Africa	0800-222-688
Spain	+34 900800726
Sweden	+46 200439522
Switzerland	+41 0800 10 21 02
United Arab Emirates	800 0178174
United Kingdom	08006123006
United States	1-754-210-8584 ext. 3

Foreword

Safety and efficacy are key cornerstones in the design and support of the LibreView system. Newyu takes its responsibilities as a medical device manufacturer seriously.

The LibreView Data Management Software includes the LibreView website and LibreLinkUp mobile app.

Intended Use

LibreView is intended for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical glucose meter data to support effective diabetes management.

In other words, LibreView is a secondary viewer and is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

This device is not intended to replace self-monitoring practices as advised by a doctor.

Home users should consult a healthcare professional before making any medical interpretation and therapy adjustments from the information in the software.

Healthcare professionals should use information in the software in conjunction with other clinical information available to them.

When using the LibreLinkUp mobile app:
Patients should not rely on caregivers to notify them about low or high glucose.

Any problems with the mobile device, NFC, wireless Internet connection, mobile data connection, LibreLink or FreeStyle LibreLink, LibreLinkUp or LibreView could cause data to not be shared with caregivers, or delay transmission to caregivers.

LibreView (and thus LibreLinkUp) should be used only to give a secondary level of awareness and should not be expected to always communicate and transfer sensor glucose information.

Quality Management

ISO (INTERNATIONAL ORGANIZATION FOR STANDARDIZATION) 13485

LibreView services are considered a medical device in many global countries and regions. Alongside our security program, Newyu has achieved ISO (International Organization for Standardization) 13485 certification for our Quality Management Systems (QMS), covering our medical devices and related activities. ISO 13485 is a globally recognised quality standard that specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Our certification encompasses our product life-cycle, including design and development, production, storage and distribution and support.

21 CODE OF FEDERAL REGULATIONS (CFR) PART 820

The United States maintains one of the world's most robust set of legislation and guidance concerning medical devices. There are similarities to ISO 13485 but also many differences. As a US-based device manufacturer, Newyu maintains compliance with the US Quality System Regulations (QSR) and registers our establishment with the FDA annually.

Global Regulatory Representatives

Newyu maintains our Quality Management System for our global product in support of regional registrations or approvals as required to place the device on the market.

Shown below are in-country representatives for regulatory affairs issues and incident reporting, including Newyu partners, sponsors or representatives where applicable.

If a country is available from the product as a country for registration, but is not listed below, most likely it is not a medical device or does not require registration in that country. Please contact LibreView support with any questions.

LibreView Website

LibreLinkUp Mobile App

Global Regulatory Representatives *continued*

MANUFACTURER

Newyu, Inc., 3452 Lake Lynda Dr. Suite 352, Orlando, FL 32817 USA

ARGENTINA

Class 1 device, Argentina Representative ABBOTT LABORATORIES ARGENTINA

PM number: 39-703

AUSTRALIA

Class 1 device, Australian Sponsor:

EMERGO AUSTRALIA, Level 20, Tower II, Darling Park, 201
Sussex Street, Sydney, NSW 2000, Australia
ARTG ID: 296121

BRAZIL

Class II device, Brazil Importer of Record: Emergo Brazil Import Imp Distr de Prod Méd Hosp Ltda., CNPJ: 04.967.408/0001-98

Av. Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo-SP, CEP – 05001-200
BRAZILVIGILANCE@UL.COM
Resp Téc: Luiz Levy CRF-SP: 42415
ANVISA: 80117580705

COLOMBIA

Class IIa device, Colombia Importer of Record: Impomed S.A.S.

INVIMA registration number: IMVIMA 2018DM-008191

EUROPE

Class 1 device, EU Authorized Representative:

EMERGO EUROPE, Prinsessegracht 20, 2514 AP
The Hague, The Netherlands

ISRAEL

Class 1 device, Israeli Registration Holder:

I.L.Emergo Israel Ltd., 9 Andrei Sakharov St., Matam, P.O.B. 15401, Haifa 3190501, Tel: 02-6731634
AMAR registration number: 24820088

Global Regulatory Representatives *continued*

NEW ZEALAND

Class 1 device, New Zealand Sponsor: CLINICAL & REGULATORY SERVICES LIMITED (CARSL)
WAND Reference: 171216-WAND-6PFS9Z

SAUDI ARABIA

Class 1 device, Saudi Authorized Representative:

MEDICAL SUPPLIES & SERVICE CO. LTD MEDISERV

SINGAPORE

Class A Exempt device, contact Manufacturer as above,

imported by ABBOTT LABORATORIES (SINGAPORE) PRIVATE LIMITED

UNITED STATES

Class 1 Exempt device, contact Manufacturer as above