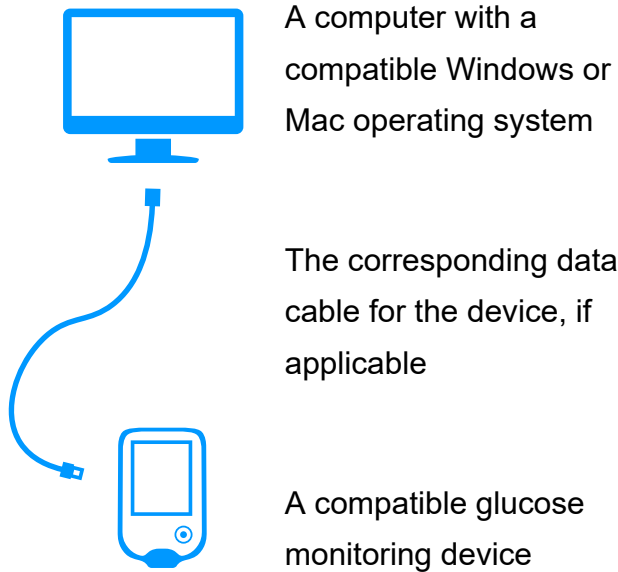




# Quick Start Guide for Patients

## LibreView

To use LibreView you will need:



Using LibreView in partnership with your healthcare professional will give you greater insights into your glucose levels and enable you to more effectively manage your diabetes. Uploading data from a compatible mobile app or reader within the FreeStyle Libre Portfolio\* or FreeStyle brand blood glucose meter directly into LibreView allows you to send results to your healthcare network easily and securely.

\*Not all devices, mobile apps, and reports are available in all regions. Refer to the Compatible Devices article on the LibreView Support site for a list of supported devices. Units of measurement are for purposes of illustration and will be available as applicable per region. Mac computers can only support uploads from compatible devices within the FreeStyle Libre Portfolio.

DOC43869 Rev. H

## 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.

**LibreView includes the LibreView website and LibreLinkUp mobile app.**

## Intended Use

---

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

In addition:

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

LibreView is not intended to be used for immediate clinical decision making, and is not intended to replace self-monitoring practices as advised by a physician.

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:***

LibreLinkUp is not intended to be used by clinicians.

Patients should not rely on caregivers to notify them about low or high glucose.

Dosing decisions should not be made based on this device . The user should follow instructions on the continuous glucose monitoring system.

Any problems with the mobile device, NFC, Bluetooth, wireless internet connection, mobile data connection, 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.



## Minimum System Requirements

LibreView can be used just to view data, or to also upload data. The minimum system configuration required to use LibreView as a data viewer is:

### **Windows 8.1 or Windows 10 Anniversary update (and higher)**

- Display resolution of 1024 x 768 pixels or greater.
- The latest version of Google Chrome and Mozilla Firefox
- 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.

### **Mac OS X Yosemite (10.10) or higher**

- Display resolution of 1024 x 768 pixels or greater
- The latest version of Safari (Mac OS X Yosemite 10.10 or higher) and Google Chrome
- 1 Ghz processor (dual/multi-core recommended)
- 2 GB RAM
- Internet connection with 0.5 Mbps download speed

Uploading data from a compatible reader within the FreeStyle Libre Portfolio or FreeStyle brand blood glucose meter into LibreView requires the installation of the Device Drivers File. The installation requires the following additional system specifications:

**Windows LDD 3.2.0 and higher**

- 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 1.2.0 and higher**

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



## Creating a LibreView Account

You can create an individual account from an email invitation or directly on the LibreView website.

1. Go to [www.libreview.com](http://www.libreview.com) and click **Sign Up**
2. Select **LibreView Patient Account**
3. Select your country / region of residence
4. Agree to the Terms of Use
5. Agree to the Privacy Notice
6. Fill out your information
7. Go to your email inbox, find the verification email from LibreView and click on the **Verify Email** button
8. Complete 2-factor authentication using your SMS enabled phone number or e-mail address, then click the **Verify and Log In** button. Your account registration is complete!

*Note - There may be additional steps during account registration specific to your country / region of residence.*

Your email address will be your username.



## Installing Device Drivers

To upload glucose data into LibreView from a compatible reader within the FreeStyle Libre Portfolio or FreeStyle brand blood glucose meter, you must first complete the one-time download and installation of a device drivers file. The device drivers file makes sure that LibreView that recognizes the glucose monitoring device when it is plugged in to the computer. Make sure that you are using the most up-to-date version of your internet browser before starting the download.

1. From the Upload Device screen, click the **Press to Begin Upload** button under Upload a Device
2. In the window that appears, click on the **Download** button specific to your computer's operating system
3. Wait for the file to download onto your computer
4. Open the downloaded file by clicking on it and allowing it to run
5. Follow the prompts to complete the installation

Note: The downloaded file will appear at the bottom of the screen for Chrome users and the top right of the screen for Firefox and Safari users. If you are not using a personal computer, you may need your IT Administrator to grant permission for the download and installation.

Links to the latest LibreView Device Drivers are also available on the LibreView Support website. Search for the "Install LibreView Device Drivers" topic and follow the instructions to download and install the drivers.



## Uploading from Apps

LibreView Device Drivers are not required to upload data from FreeStyle LibreLink or other compatible mobile apps within the FreeStyle Libre Portfolio into LibreView. Data from a compatible mobile app can automatically upload to LibreView if there is an internet connection.



## Uploading a USB Device

Once the device drivers are downloaded and installed, you can plug in a compatible reader within the FreeStyle Libre Portfolio or FreeStyle brand blood glucose meter using the corresponding cable and start uploading data.

### Things to note before uploading:

- LibreView is compatible with Abbott glucose devices only.
- Make sure the device's battery is charged and the device screen shows "computer mode" when plugged into a USB port.
- Make sure you have the right USB cable for your device. A cable that you use for a different device may not work.

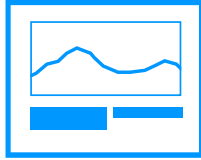
### Uploading a USB Device:

1. Connect your compatible device to a USB port on to your computer using the appropriate cable.
2. Click the **Upload** button
3. Once the data is uploaded, the reports will automatically open
4. Once the data is uploaded, it can be viewed anytime under the My Glucose section by clicking the **Glucose Reports** button.

Note: When you upload a device, you may need to allow your browser to access the Device Drivers file. Save time by ticking the box so your browser will remember your selection before selecting "Allow" or "Launch application".

Note: If your healthcare professional uses LibreView, they will also be able to upload the data from your device during your appointments.





## Viewing Reports

1. From the **My Glucose** screen, click the **Glucose Reports** button to see your reports.
2. Use the menu to navigate between the different available reports

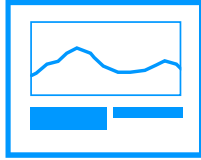
You will see a different set of reports depending on the primary device selected:

- If a compatible FreeStyle brand blood glucose meter is selected, you will see the **Glucose Only reports**: Snapshot,<sup>2</sup> Daily Log, Modal Day
- If the FreeStyle InsuLinx meter is selected, you will see the **FreeStyle InsuLinx reports**: Snapshot, Daily Log, Mealtime Patterns, Modal Day, Weekly Summary, Meter Details.
- If a compatible reader or app within the FreeStyle Libre Portfolio is selected, you will see the **FreeStyle Libre reports**: Snapshot, AGP, Glucose Pattern Insights, Daily Patterns, Daily Log, Weekly Summary, Monthly Summary, Mealtime Patterns, Device Details

Note: Not all devices, mobile apps, or reports are available in all regions.

See the Report Overviews at [pat.libreview.io](https://pat.libreview.io) for more information on specific reports.

Refer to the Compatible Devices article on the LibreView Support site for a list of supported devices.



## Understanding Reports

**IMPORTANT:** Work with your healthcare professional to understand your reports. LibreView provides a standard set of information and graphs relating to your diabetes management and is only one part of understanding your glucose patterns.

---

**Use the report labels and legends to understand your reports. Additional Information is provided below:**

- Glucose Management Indicator (GMI) uses average Sensor glucose data. GMI can provide an indication of the current state of your glucose management when used in conjunction with your entire glucose management program. Your laboratory A1C may be different than your GMI, and should be discussed with your healthcare team.
- In reports other than those with specific fixed standards, the glucose values are labelled as high when higher than 250 mg/dL (13.9 mmol/L) and low when lower than 70 mg/dL (3.9 mmol/L). The target range is set for 70-180 mg/dL (3.9-10.0 mmol/L).
- The target glucose range is displayed on some glucose graphs and is used to calculate Time in Range.
- Sensor data captured is the percentage of possible sensor data the device recorded from your sensor. To maximize this percentage, wear your sensor for the entire duration and follow your sensor user manual instructions.
- If you have gaps in data on your glucose monitoring device, you will also have gaps in data on your LibreView reports. Some information may be missing from reports if:

- You changed the time on the device.
- There was an excess of information to include in the report.



## Changing Report Settings

**IMPORTANT: Work with your healthcare professional to set your report parameters.**

---

While viewing reports you can change the settings you'd like to use.

**When you're viewing reports, use the buttons on the bottom of the screen to adjust your settings.**

1. You can change the report dates by clicking on the blue button that says Change Report End Date. The default setting will show data from the date of the most recent upload. Click **Save** to generate reports using the new settings.
2. You can select or unselect the devices that are used in the report set by clicking the blue button that says Data Sources. The default setting will show data from all devices that have data in the reporting period and can be included in the report set. Click **Save** to generate reports using the new settings.
3. You can select the reports, adjust target ranges, change report parameters and more by clicking the blue Report Settings button. Click **Save** to generate reports using the new settings.

**To set new default report preferences, go to your Settings menu.**

1. Click the Settings Menu icon and go to **Report Preferences**
2. Set your target ranges, glucose thresholds, and report display order for all reports. Not all reports have adjustable target ranges.
3. Deselect any reports you don't need to view
4. Your settings will be saved as you make changes

Note: Click Restore Defaults to return to the default report settings.



## Share with your Healthcare Professional

LibreView allows you to easily share data with your healthcare professional when you connect with their LibreView Practice. When you are connected to their Practice, any data you upload to LibreView will be automatically stored and visible to your LibreView Care Team.

**If you received an email invitation from your healthcare professional, follow the instructions in the email to allow the connection.**

**Otherwise, follow these steps to initiate the connection yourself.**

1. Ask your healthcare professional for their Practice ID. A Practice ID is a unique code associated with each LibreView Practice.
2. In LibreView go to the Settings Menu and select **Account Settings**
3. Click **My Practices**
4. Enter the Practice ID from your healthcare professional and click **Add**. You should now see their information in your Practice list.

Note: To stop sharing data with a Practice, click Remove next to the Practice name in the list. Then confirm you want to proceed with removal.



## Manage Account Information

Click the Settings Menu icon and select Account Settings to change your account information

- **Profile:** Change your name, email, password, 2-factor authentication methods and other account information.
- **My Practices:** Add or remove Practices that you share with
- **My Devices:** See a list of all the devices that are associated with your account. Click Remove next to the device name in the list if you no longer want to display data from that device.

# Helpful Resources

LibreView offers several resources to help you set up and use your LibreView account.

**For Customer Support, contact the Abbott Diabetes Care Customer Support line for your country / region of residence**

**Argentina** +0800-800-6334

**Australia** +61 1800 801 478

**Austria** 0800 222 775

**Bahrain** 800 19722

**Belgium** 0800 82106

**Brazil** 0800 703 0128

**Canada** 1-800-461-8481

**Chile** 800 802 226 / 22 3683080

**Colombia** 01800 5181895

**Czech Republic** 800 143688

**Croatia** 0800 989097

**Denmark** 39 77 01 90

**Finland** +358 0800 772 355

**France** 0800 10 11 56

**Germany** +49 8006365500

**Greece** 211 198 5892 / 00800 123393

**Hong Kong** +852-5808-4196

**Ireland** +353 1800719995

**Israel** +972773645506

**Italy** +39 800693000

**Japan** 0120-37-8055

**Lebanon** [01-426-801] [855-583-3354]

**Luxembourg** 800 72 106

**Mexico** 55244175 / 018007112208

**Netherlands** 0800 242 4400

**New Zealand** 0800 106 100

**Norway** +47 80011706

**Oman** 800 74396

**Philippines** +63 2 8702 8577

**Poland** 800 388 700

**Portugal** 800860207

**Qatar** 00800 100869

**Russia** 8-800-100-88-07

**Saudi Arabia** 8008500863

**Singapore** +65 1800 272 2881

**Slovenia** 0800 82028

**South Africa** 0800-222-688

**Spain** +34 900800726

**Sweden** +46 200439522

**Switzerland** 0800 102 102

**Taiwan** 0800 28 08 28

**Turkey** 0 850 2034323



**Jordan** 64296013

**Korea** 080-014-5757

**Kuwait** 220 62972

**United Arab Emirates** 800 0178174

**United Kingdom** 08006123006

**United States** 855-786-4263

# Intended Use and Regulatory Information

## About

---

LibreView, version 3.10  
(including LibreLinkUp, version 4.3)



(01) 00860000502016  
(10) 3.10 23 AUG 2022



<https://www.libreview.com>  
<https://www.librelinkup.com>

**LibreView  
Website**



**LibreLinkUp Mobile App**



## Quality Management

---

### ISO (INTERNATIONAL ORGANIZATION FOR STANDARDIZATION) 13485

Newyu 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 recognized quality standard that specifies requirements for a quality management system where an organization 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.

### Vigilance

Any serious injury or death 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.

## Global Regulatory Representatives

---

Newyu is a subsidiary of Abbott Laboratories.

Newyu maintains a 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 or region 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.



Medical Device



### MANUFACTURER

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

### ARGENTINA

Argentina Representative ABBOTT LABORATORIES ARGENTINA

PM number: 39-703

### AUSTRALIA

Australian Sponsor:

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

ARTG ID: 343435

### BRAZIL

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**

Colombia Importer of Record: Impomed S.A.S.

INVIMA registration number: INVIMA 2018DM-008191

## **ISRAEL**

Israeli Registration Holder:

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

AMAR registration number: 24820088

## **NEW ZEALAND**

New Zealand Sponsor: CLINICAL & REGULATORY SERVICES LIMITED (CARSL)

WAND Reference: 171216-WAND-6PFS9Z