LibreView

Quick Start Guide

for

Patients





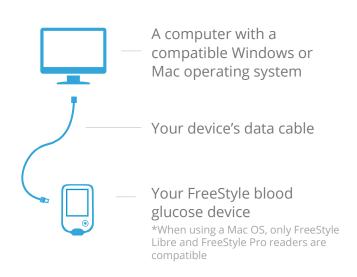
Using LibreView in partnership with your healthcare professional will give you greater insights into how your body is functioning and enable you to more effectively manage your diabetes. Using the FreeStyle LibreLink mobile app* or uploading your compatible FreeStyle glucose devices directly into LibreView allows you to send results to your health care network easily and securely.

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Getting Started

You'll need:



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

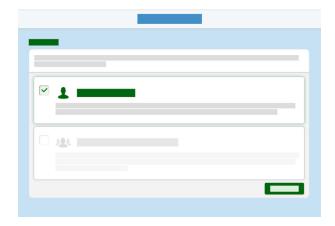


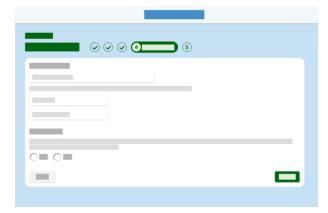
Creating A LibreView Account

To get started, you will need to set up a LibreView patient account. Your healthcare professional might have already enrolled you and sent you an email with an invitation link. In this case, simply open the email and follow the instructions to create your account or, if you have set up your account previously, simply go to www.libreview.com and log in if you have set up your account previously.

If you have not been invited to create a LibreView account, follow these simple steps:

- 1 Go to www.libreview.com and click Sign Up
- 2 Select LibreView Account
- 3 Select your country of residence
- 4 Agree to the Terms of Use and Privacy Policy
- 5 Fill out your information, enter your email as your username and create a password
- 6 Go to your email inbox, find the verification email from LibreView and click on the Verify Email button
- 7 Select **Next** on the original sign up screen window to complete signup





Note: Your email address will be your login username.



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

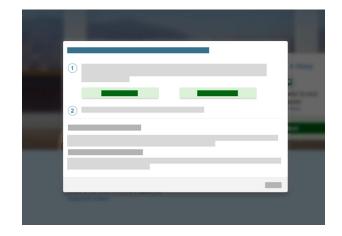
- Mac OS X Yosemite (10.10) or higher
- 8 GB+ RAM and 200 MB free disk space
- Internet connection with 1 Mbps upload speed.



Setting Up Your Account

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 green **Upload** button under **Upload a Meter**
- 2 In the window that appears, click on the Download button specific to your operating system
- 3 Wait for the file to download onto your computer
- 4 Open the downloaded file by clicking on it and allow it to run
- 5 Follow the prompts on the screen to complete the installation



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



Connecting Your Blood Glucose Device

Once you have successfully downloaded the device drivers, you can plug in your blood glucose device using the corresponding cable. A couple of things to keep in mind before you start uploading the data:

Things to note before uploading:

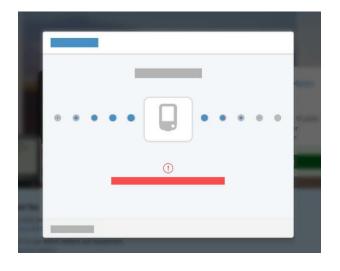
- 1 Make sure that your device's battery is charged and the screen on the device displays computer mode when plugged into a USB port.
- 2 Your blood glucose device must be manufactured by Abbott Diabetes Care, which will include FreeStyle in the name.
- 3 Double-check that you have the correct cable for your device. A cable from a different device may not work.
 - a. To contact Customer Service for your Abbott Diabetes Care device go to https://www.myfreestyle.com/customer-support or refer to the Helpful Resources section in this guide for the customer service phone number.



Uploading Your Device From Home

Connect your compatible device to a USB port on your computer to start uploading. Navigate to the upload screen.

- 1 Click on the green **Upload** button under **Upload a Meter**
- 2 You'll see a message saying that LibreView is searching for the meter Note: If this is your first time uploading a device after
 - downloading the device drivers, you may need to select allow access or launch application to ensure that your account can access the drivers. Make sure that you tick the boxes to remember your choices or untick the boxes to always ask for these permissions. The message will be dependent on which browser you are using.
- 3 Your reports will automatically open and you will see a banner confirming that your upload was successful. Click on the green View Full Reports button to see your latest set of reports



At the doctor's office

If your healthcare provider uses LibreView, they will also be able to upload the data from your device. Simply hand your device to your healthcare provider during your visit and they will do the rest.

Your provider may send you an email before your appointment inviting you to create an account on LibreView, if you have not already done so. This way you will be able to upload your FreeStyle devices at your own convenience prior to your appointment. Once you have uploaded your devices into LibreView, your provider will receive your readings securely in their account.

Note: Make sure that you bring all - Abbott and non-Abbott brand - devices to your appointment.



Viewing your reports

When you upload your data into LibreView, you will be taken directly to the "My Glucose History" screen. You can also click on the blood droplet icon in the top-left corner to access your glucose history. As a default, you will see your most recent uploads from a 14-day period. You can change the timeframe by using the drop-down menu if you would like.

Click on View Full Reports to see the available reports for all of your meters. Use the drop-down menu to choose which report to view and the up/down arrows on the left side to scroll between pages within a report. These are the reports you'll see, depending on your meter:

- Basic reports (for compatible FreeStyle blood glucose devices): Snapshot, Daily Log, Modal Day
- Meal and insulin reports (for FreeStyle Insulinx only): Snapshot, Daily Log, Mealtime Patterns, Modal Day, Weekly Summary, Reader Details
- FreeStyle Libre reports: Snapshot, Glucose
 Pattern Summary, Glucose Pattern Insights, Daily
 Patterns, Daily Log, Weekly Summary, Monthly
 Summary, Mealtime Patterns, Reader Details

Note: Some devices may not be available in your country. Please refer to the Compatible Devices article on the LibreView support site for additional information.





Creating Reports With Multiple Devices

If you use more than one glucose monitoring device to check your glucose, you can create reports that combine data from all your devices. Please note that FreeStyle LibreLink data is not combined with any other data at this time.

- Upload glucose data from each device into your LibreView account
- 2 Go to the My Glucose History screen and select View Full Reports
- 3 Click on the **Report Settings** tab on the bottom
- 4 Click on Available Meters
 - a. Choose one device as your Primary Meter. This will determine which report types you can generate. Data from the other devices will be included where relevant.
 - b. Choose which meters to show and which to hide by clicking on the green eye icon.



Setting Report Preferences

You can customise your reports view to fit the preferences you have set with your healthcare provider.

Changing your report settings:

- 1 Select the Settings icon and go to Report Preferences
- 2 Set your target ranges and thresholds for all reports
- 3 Toggle between tabs to change the default report settings for different devices
- 4 Untick any reports that you don't need to view
- 5 Click on **Save Changes** when finished



Note: You can also do this from the **Report Settings** tab that is visible on the bottom of your full reports view.

Sharing Your Data



Link to Your Healthcare Provider

LibreView lets you easily share your data with your healthcare provider by linking to their LibreView professional accounts. Your provider may have sent you an email invite to link your accounts. Follow the instructions in the email to get connected.

If you did not receive an email from your provider, follow the steps below:

- 1 Ask your doctor for their Practice ID. A practice ID is a code that is unique to each healthcare practice's LibreView account.
- 2 Go to your Settings section and select **Account**Settings
- 3 Click on My Practices
- 4 Enter in your healthcare provider's Practice ID and click Add. You should now see their name or their practice name appear under your practice list.

To stop sharing data with a provider, click on **remove** next to the practice or provider's name under this list. Confirm you want to remove them.



Updating your Account Information



Updating Account Information

Click on the Settings icon and select **Account Settings** to change any information in your account

- Profile: Change your name, email or password
- My Practices: Add or remove practices and providers you are sharing your data with.
- My Meters: Come here to see a complete list of all meters you have uploaded into LibreView.
 Click on Remove next to any devices that you no longer want to display. You can also add nicknames to your devices to help you keep track of which ones you have updated.



Helpful Resources



Helpful Resources

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

<u>LibreView Support Site</u>
<u>List of compatible devices</u>
<u>System Requirements</u>
<u>FAQs</u>



To contact Customer Service for your Abbott
Diabetes Care device go to https://www.myfreestyle.com/customer-support or call the Abbott Diabetes customer service line for your country of residence:

Argentina	+0800-800-6334	Kuwait	2206 7372
Australia	+61 1800 801 478	Lebanon	+961 1387 815
Austria	+43 0800 222 775	Luxembourg	+32 0800 82106
Bahrain	+973 172 41745	Mexico	55244175 / 018007112208
Belgium	+32 0800 82106	Netherlands	+31 8002424400
Brazil	0800 703 0128	Oman	800 74396
Canada	1-800-461-8481	Poland	800 388 700
Chile	800 802 226 / 22 3683080	Portugal	800780870
Colombia	01800 5181895	Qatar	00800 100869
Denmark	80 83 10 42	Saudi Arabia	92000 3788
Finland	+358 0800 772 355	Singapore	+65 1800 272 2881
France	+33 800947909	South Africa	0800-222-688
Germany	+49 8006365500	Spain	+34 900800726
Greece	800-491423863	Sweden	+46 200439522
Hong Kong	+852-5808-4196	Switzerland	+41 0800 10 21 02
Ireland	+353 1800719995	United Arab Emirates	800 0178174
Israel	00 97236900300	United Kingdom	08006123006
Italy	+39 800693000	United States	855-786-4263
Jordan	+962 6 51 62 971		

Regulatory



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 <u>historical</u> glucose meter data to <u>support</u> 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