

 **SynfuGo**™  
Automated Infusion Pump  
Instructions for Use



**CSL Behring**  
Biotherapies for Life™

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# Chapter 1

## Important Safety Information



## 1.1 Important information about your SYNFUOGO

- Read these instructions entirely before you use your SYNFUOGO infusion pump for the first time, to quickly resolve any issues using SYNFUOGO. Keep these instructions in a safe and easily accessible place.
- Before you use your SYNFUOGO for the first time, make sure you have been trained by your doctor or healthcare provider.
- Only trained users shall use SYNFUOGO. If this is your first self-administered infusion with your SYNFUOGO, it should be given under the supervision of a doctor or health care provider. Training will guide you using SYNFUOGO safely.
- You **MUST** have successfully performed manual intravenous infusions on yourself before using this infusion pump. Manual infusions is to be performed in case of malfunction of SYNFUOGO.
- Use only with AFSTYLA or IDELVION medication supplied by your doctor, health care provider, or pharmacy. Using other medications can cause unpredictable risk.
- Use only syringes and butterfly needle supplied along with your medication. Other syringes or butterfly needles may interfere with normal infusion pump operation and may cause incorrect infusion rate or dose.

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- Refer to the instructions for use of your AFSTYLA or IDELVION medication for directions on how to prepare it for use with your SYNFIGO infusion pump.
  - Check expiration dates on medication and accessories before using. Do not use the medication beyond the expiration date printed on the vial labels.
  - Sight or hearing impaired patients should only use SYNFIGO with the help of a caregiver who has been properly trained on how to use it. To safely see and hear information's or alerts from the infusion pump.
  - Keep your SYNFIGO pump and all of its accessories out of reach of children. Cables may present a strangulation risk and risk of suffocation/asphyxiation.
  - Caution: US Federal Law restricts this infusion pump to be for sale by or on order of a physician.
  - DO NOT use the SYNFIGO infusion pump for patients under 2 years of age.



## 1.2 Critical device use

See the prescribing instructions accompanying your AFSTYLA or IDELVION for direction on the reconstitution of your medication.

- DO NOT use your SYNFIGO if it does not operate as described in this instruction manual. If you require further assistance please refer to the contact information in Chapter 6.5.
- DO NOT use your SYNFIGO if you experience a problem and cannot resolve the issue using Chapter 6.2 Troubleshooting.
- DO NOT use your SYNFIGO if your prepared syringe cannot be inserted or removed according to the instructions for use. Perform a manual infusion.
- DO NOT use your SYNFIGO if it has been exposed to extreme vibration, pressure, or shock (such as being dropped or stepped on) as it may have been damaged.
- DO NOT use your SYNFIGO if you observe any worn, damaged, or broken parts, or if you hear any unusual or unexpected sounds during use. Inspect your SYNFIGO regularly for damage and wear.

- DO NOT use your SYNFIGO if you are exposed to environments with excessive noise and/or distractions that may impact your ability to use your SYNFIGO.
- DO NOT use your SYNFIGO in areas with high oxygen levels, such as when supplemental oxygen is in use.
- DO NOT allow your SYNFIGO to become submerged or wet. It is an electronic device and may be damaged if submerged or exposed to excessively wet conditions.
- DO NOT attempt to use your SYNFIGO while it is charging. Your SYNFIGO cannot be used while charging.
- DO NOT attempt to disassemble, tamper with, or repair your SYNFIGO. It contains Lithium Ion batteries which could explode or lead to severe burns and/or electrical shock.
- DO NOT use your SYNFIGO if it has been exposed to extreme temperatures. Keep your SYNFIGO away from heat or fire. Keep your SYNFIGO out of direct sunlight.
- DO NOT attempt to use any charging adapter or charging cables other than those included with your SYNFIGO. Other adapters or cables may create problems and may interfere with normal device operation.

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- DO NOT expose SYNFIGO to any kind of MRI, X-ray, CT, or Ultrasound.
  - DO NOT use your SYNFIGO close to or stacked with other electrical equipment.
  - Portable RF communications equipment, including antennas, can effect medical electrical equipment. Always keep a minimum distance of 12 inches (30 cm) to RF equipment such as mobile phones, WIFI transceivers, etc.
  - The battery in your SYNFIGO is not replaceable. Your SYNFIGO contains a non-replaceable battery. There are no user serviceable parts.
  - Always scan all vials needed for the infusion prior to beginning the infusion.

### 1.3 Intended use

SYNFIGO, is intended for the following use:

1. For use with reconstituted drug (AFSTYLA and IDELVION) in a user filled syringe.
2. To be used in the intravenous administration of reconstituted drug solution through controlled infusion rates.
3. To be used as a portable personal syringe infusion pump in home environment.
4. Re-usable, personal device for one specific patient to be used by the adults, adolcents and children.

## 1.4 Essential performance

### **-Reverse plunger movement of more than 1mL**

SYNFUGO will prevent the plunger being moved more than 1mL backwards to prevent unintended air in the syringe.

*Always check that all air in the syringe is removed, electromagnetic disturbance (e.g. from mobile phones) may result in unintended reverse plunger movement.*

### **-Correct scanning of the vial the dose IU**

SYNFUGO will display the sum of the scanned IU of the vials.

*Electromagnetic disturbance may result in wrong readings, always make sure the scanned IU is correct.*

# Chapter 2

## Getting to Know Your SYNFUGO



## 2.1 Introduction

- Your SYNFIGO is a personal automated infusion pump that allows hands-free infusion with user controlled infusion speed.
- Your SYNFIGO is a home use device with dedicated charging adapter and micro USB cable, for use by patients or caregivers.

Only use your SYNFIGO with AFSTYLA or IDELVION medication as supplied by your doctor, health care provider or pharmacy.

- Only use your SYNFIGO with Becton Dickinson (BD) 5 mL (catalog # 309646) and 10mL (catalog #309604) plastic syringe. Any changes to compatible butterfly needles made after date of publication may be confirmed using CSL Behring SYNFIGO website or by contacting customer service.
- Only use your SYNFIGO with NIPRO brand SafeTouch PSV 25G x 3/4" x 350mm long butterfly needles. Any changes to compatible syringes made after date of publication may be confirmed using CSL Behring SYNFIGO website or by contacting customer service.
- Your SYNFIGO can record and store the patient's infusion information and enables easy patient's access to his/her complete infusion and medication history.

- Optionally, your infusion record can be transferred to mobile or web apps. If you choose, you may also share your infusion history with your healthcare provider- see Chapter 5.
- If connected with the SYNFUGO mobile app, the date and time will automatically be set.(Chapter 5)
- SYNFUGO is for patients greater than 2 years of age and diagnosed with Hemophilia A or B, who are trained in manual infusions.
- For patients greater than 2 and less than 7 years of age, a caregiver must operate SYNFUGO and perform the infusion.
- For patients from 7 to 11 years old a caregiver must be available to supervise or assist (as needed) with the use of SYNFUGO.
- Patients 12 years of age and older, who can independently perform a manual infusion, can self-infuse using SYNFUGO if trained.
- Patients under the age of 2 must not use the SYNFUGO infusion pump.
- Applied parts (part that comes in contact to the skin) is the Butterfly Needle.



## 2.2 What is included in the box

Before starting, check that all items listed are present.

Your SYNFIGO infusion pump kit contains the following items:

- A SYNFIGO infusion pump
- B Charging adapter
- C Charging cable 1m
- D Quick Start Guide
- E Instructions For Use (IFU)
- F Storage case (not shown)

Your medication, syringe(s) and butterfly needle(s) ARE NOT INCLUDED in this kit and will be supplied separately from your Doctor, health care provider, or pharmacy.

Note: The optional software for your SYNFIGO (mobile and web apps) are not included. See Chapter 5 for more information.

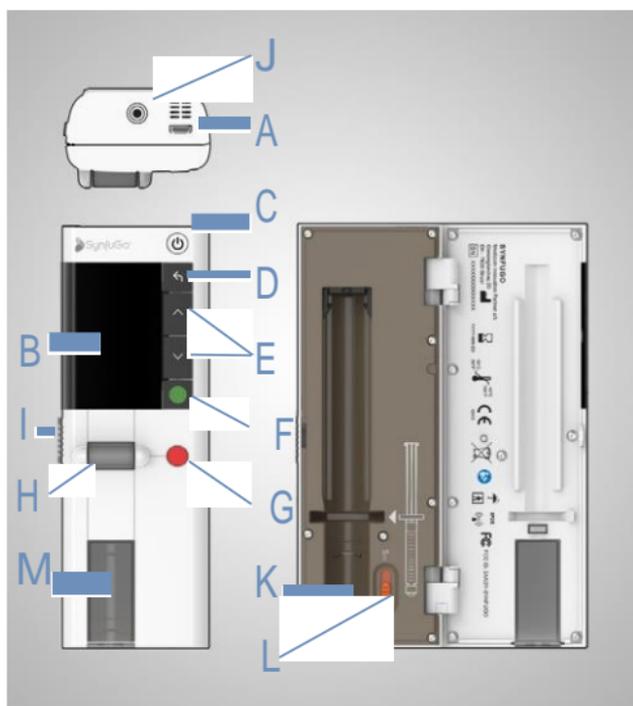


## 2.3 Features of your SYNFIGO

Study the features listed below before attempting to use your SYNFIGO. If you have any questions regarding these features, consult with your doctor, health care provider, or pharmacist first. You may also contact one of our technical specialists for assistance (See Chapter 6.5 for additional information).

- A Charging Port: Receives the Charging Cable.
- B Display: Displays all device settings and information.
- C Power Button  : Press to turn your SYNFIGO's power on and off.
- D Back Button  : Use to step back to previous selection.
- E Navigation Buttons   : Use to navigate up or down through the display menu.
- F Ok/Confirm Button  : Use to confirm a desired input selection.
- G Stop/Emergency Stop Button  : Use to immediately stop an infusion.
- H Grey Tab: Manually move plunger to Remove air or check for blood.
- I Lid Release: Use to unlock and open lid and access syringe.
- J Vial Scanner Target: Use to scan and record vial information.

- K Syringe Cradle: Receives and retains your 5mL or 10mL syringe.
- L Syringe Selector: Use to select a 5mL syringe or 10mL syringe size.
- M Syringe Window: Use to visually monitor the syringe volume.



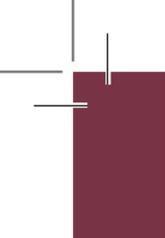


## 2.4 Cleaning and storage

- Always keep your SYNFIGO clean and free of any dirt and debris.
- If medicine or other fluid is spilled or leaked onto your SYNFIGO, be sure to clean it off immediately.
- To clean your SYNFIGO, wipe carefully with a dry or slightly damp cloth and mild detergent.
- Alcohol wipes (70% isopropyl) may be used to clean your device.
- DO NOT place or submerge your SYNFIGO in any liquid, and do not sterilize.
- DO NOT attempt to clean your SYNFIGO in a dishwasher.
- Always store your SYNFIGO with the lid closed and in its storage case to protect it from dust, dirt, or direct sunlight.
- Keep SYNFIGO away from heat, fire, and extreme temperatures.
- Keep your SYNFIGO out of direct sunlight.
- Keep SYNFIGO and all of its accessories out of reach of children. Cables may present a strangulation risk.

## 2.5 Disposing of your SYNFUGO

- Your SYNFUGO contains Lithium Ion batteries. Dispose of this device according to your local environmental laws and guidelines.
- DO NOT dispose of in fire. Your SYNFUGO contains Lithium Ion batteries which could explode when exposed to fire or extreme heat.
- DO NOT attempt to disassemble your SYNFUGO.
- Used butterfly needle and syringe must be disposed of with due consideration to National and Local safety and environmental regulations.
- Always dispose of your empty syringe and used butterfly needle immediately after you completed your infusion into an appropriate sharps container.
- Your used SYNFUGO device, charging adapter and micro USB cable are to be disposed of safely according to WEEE regulation (requirement in Europe).

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- To protect natural resources and to promote material reuse, please separate packaging material from other types of waste and recycle the material through your local recycling system.

# Chapter 3

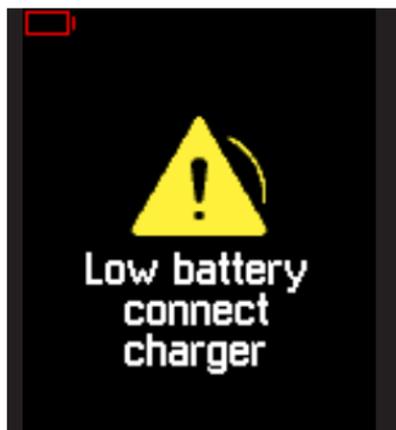
Charging, Initial Setup,  
and Settings

### 3.1 Before turning on your SYNFUOGO for the first time

Before turning on your SYNFUOGO for the first time, you will need to charge it. Refer to Chapter 3.2 for charging instructions.

### 3.2 Charging

Your SYNFUOGO will need to be charged before the first time you use it, or when the low battery warning appears on the screen.



To charge your SYNFUOGO:

- 1 Insert the Charging Cable and Charging Adapter into a 110V AC outlet. Only use supplied cable and adapter.
- 2 Insert the Charging Cable into the Charging Port on the device to begin charging.

Your SYNFUOGO will not work while charging.

Note that the plug only inserts one way, and must be oriented correctly before inserting.



NOTE: If charged, turn on by pressing the power button.

You will know that your SYNFUGO is charging when you see this screen.



When charging is complete, you will see this screen and a full green battery symbol.



A typical charge from a low battery should take no longer than 3 hours.

With typical use, the battery should last for at least 10 infusions before recharging is needed.

At low temperatures, the battery capacity is reduced and the battery may need to be charged more frequently.

To save battery capacity, always turn off SYNFIGO after use. If not used within 20 minutes, SYNFIGO will turn off automatically to save battery capacity.



#### WARNINGS:

- ③ Always make sure your SYNFIGO is adequately charged before performing an infusion.
- ③ If the battery indicator is flashing or red, the battery is low. Your SYNFIGO will need to be charged.
- ③ Your SYNFIGO will not perform an infusion while charging. You must remove the Charging Cable from the Charging Port prior to performing an infusion.
- ③ DO NOT attempt to use any charging adapter or charging cables other than those included with your SYNFIGO. Other adapters or cables may interfere with normal device operation.

### 3.3 Initial setup



#### WARNING:

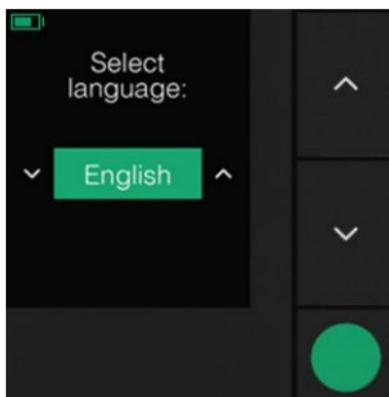
Make sure the date and time is correct before using. If not correct, go to settings and set correct date and time before use.

If you are using the SYNFUGO mobile app, please connect your infusion pump to the mobile app. The mobile app will set the date and time automatically e.g., in case of traveling and daylight savings time changes.

The first time you turn on your SYNFUGO you will be prompted to set the following settings:

#### 1 Select Language

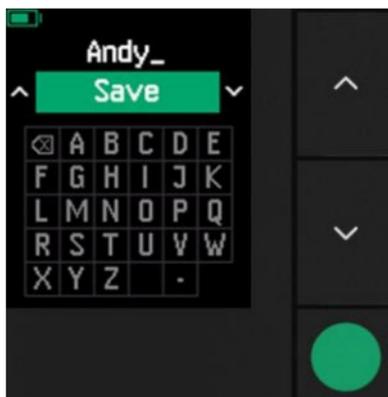
Use Navigation Buttons   to select your preferred language then press Ok/Confirm  to confirm.



## 2 Enter Name

Use Navigation Buttons   to select each letter, then press Ok/Confirm  to confirm the letter. Repeat this process until your name is complete. Note that you can also delete characters or add spaces as desired.

When your name is complete, use Navigation Buttons   to select Save, then press Ok/Confirm  to save.

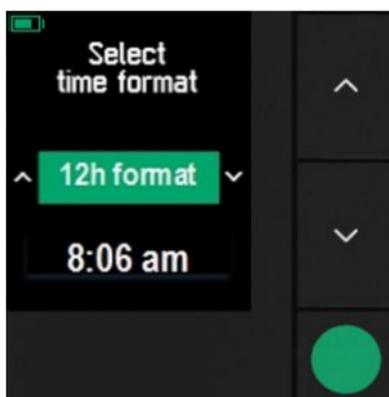


Your name will be shown when turning the device on. Make sure it is your personally named SYNFUGO before using the device.

### 3 Set Time Format

Use Navigation Buttons   to select preferred time format, then press Ok/Confirm  to confirm.

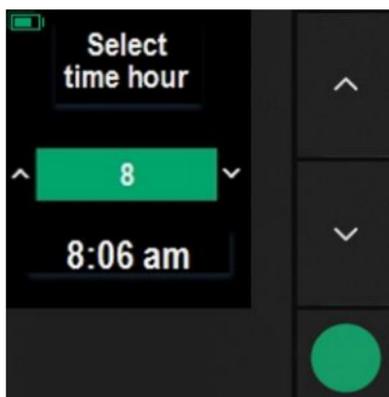
NOTE: The 12 hr format is more common in the USA than the 24 hr format. If you are not familiar with or do not specifically need the 24 hr format, the 12 hr format is recommended. If you have paired your SYNFIGO pump to a mobile device, it will be updated to the time of the mobile device.



NOTE: If you choose to pair your pump with a mobile device, the time on the pump will automatically be updated to the time on the mobile device.

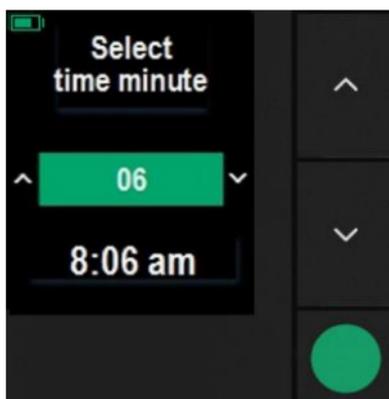
#### 4 Set Hour

Use Navigation Buttons   to select the current hour, then press Ok/Confirm  to confirm.



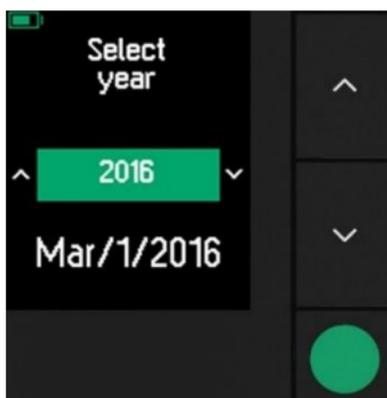
#### 5 Set Minutes

Use Navigation Buttons   to select the current minute, then press Ok/Confirm  to confirm.



## 6 Set Year

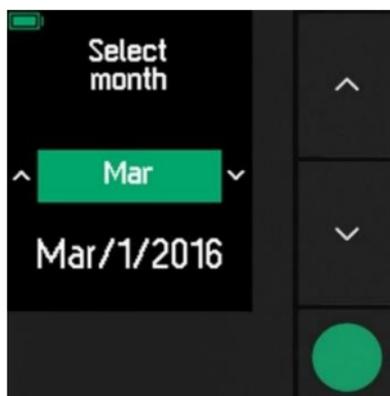
Use Navigation Buttons   to select the current year, then press Ok/Confirm  to confirm.



This concludes the initial setup, your SYNFUOGO should now have returned to the Main Menu.

## 7 Set Month

Use Navigation Buttons   to select the current month, then press Ok/Confirm  to confirm.

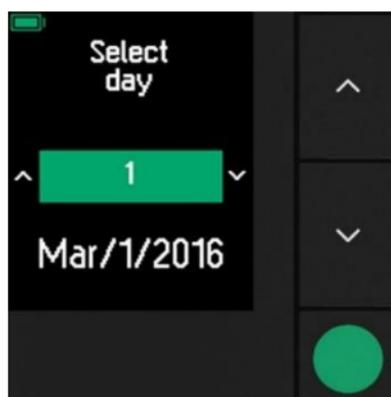






## Set Day

Use Navigation Buttons   to select the current day, then press Ok/Confirm  to confirm.



## 3.4 Main menu

Your SYNFIGO will display the Main Menu after you turn the power on or when an infusion is complete, and when you are finished adjusting settings. The following is a description of the Main Menu items.

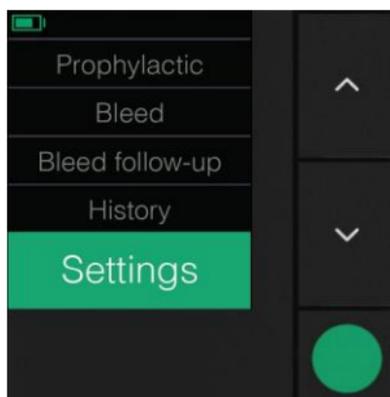
- Prophylactic: Select to perform a prophylactic (or scheduled) infusion.
- Bleed: Select to perform an infusion in response to a bleed event. (or on-demand)
- Bleed Follow-Up: Select to perform a bleed follow-up infusion.
- History: Select to access infusion history.
- Settings: Select to access pump settings.



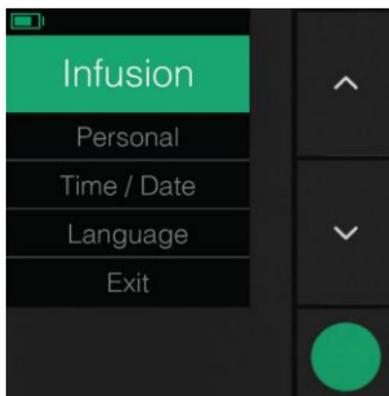
### 3.5 General settings

Using the Settings menu you may change the date, time and default infusion rate settings. You may also set the pump to a RECORD ONLY mode where the pump will scan vials but the infusion may be performed manually.

- 1 Use Navigation Buttons   to select Settings, then press  to confirm.



- 2 Use Navigation Buttons   to select the desired category, then press Ok/Confirm  to confirm.

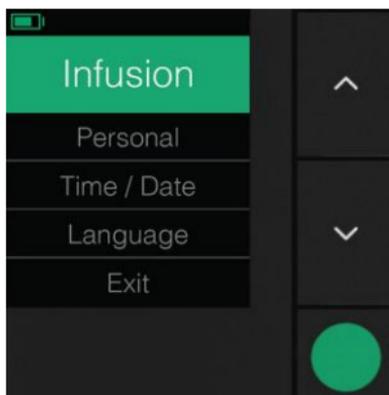


- 3 Follow further prompts to adjust any settings.

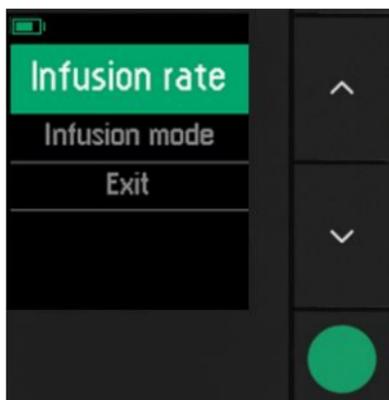
## 3.6 Setting default infusion rate

After selecting and confirming Settings from the Main Menu:

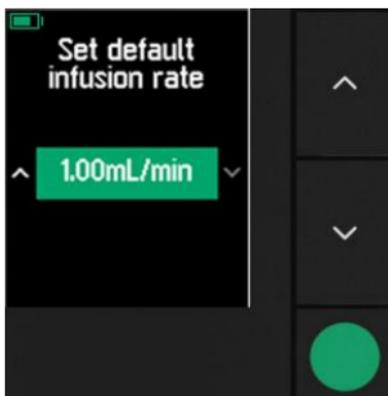
- 1 Use Navigation Buttons   to select Infusion, then press Ok/Confirm  to confirm.



- 2 Use Navigation Buttons   to select Infusion Rate, then press Ok/Confirm  to confirm. The maximum infusion rate for your SYNFUOGO is governed by local regulatory agency approvals (10 mL per minute in U.S.), and is encoded on each drug vial.



- 3 Use Navigation Buttons   to select the default infusion rate, then press Ok/Confirm  to confirm.



**WARNING:**

The maximum infusion rate is determined by the prescribing information for your medication, and is encoded on each vial.

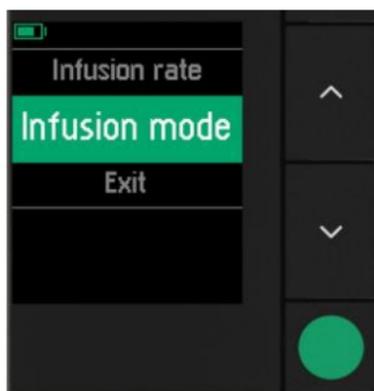
**Set Infusion Mode:** You may also choose to use SYNFIGO to scan and record vial information, but choose to perform infusions manually.

This selection is available to you by selecting INFUSION MODE and then turning the RECORDING ONLY/NO INFUSION selector to ON.

### 3.7 Infusion Mode

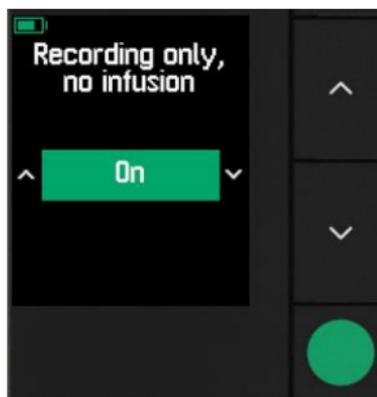
Choose how pump is used. SYNFUOGO may be used to only scan and record the infusions without using the pump function to infuse your medication. In this case, the infusions must be performed manually.

- 1 Use Navigation Buttons   to select Infusion Mode, then press



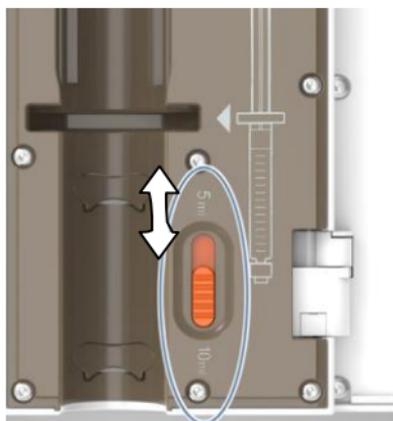
Ok/Confirm  to confirm

To enable recording only select "On". To use SYNFUOGO for automatic infusion select "Off"



### 3.8 Syringe selector

Inside your SYNFUOGO, select the correct setting for the Syringe Selector depending on whether you are using a 5mL or 10mL syringe.



# Chapter 4

## Performing an Infusion



## 4.1 Before you begin

- Prepare the infusion site and work surface as trained by your healthcare provider.
- Make sure your SYNFIGO is sufficiently charged for the infusion. If the battery indicator is red or blinking, device should be recharged.
- If this is an emergency treatment and the device is not sufficiently charged, do not use the device and perform the infusion manually according to the medication instructions.
- Make sure that no debris is present on or inside your SYNFIGO, particularly in the Syringe Cradle.
- Before turning on make sure SYNFIGO is within operating temperature. If stored cold, wait minimum 2 hours before turning SYNFIGO on.
- Your SYNFIGO will perform a self test when turned on. Make sure no alerts or warnings are present when you turn on your SYNFIGO.

## 4.2 Turn on your SYNFIGO and select infusion type

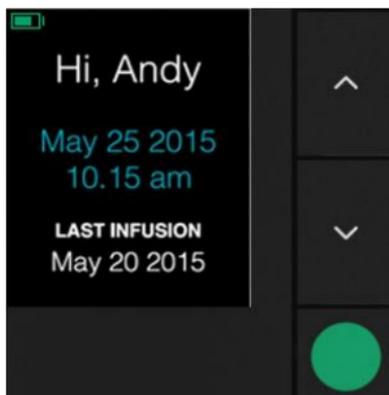


### WARNING:

If not paired to the mobile app: Make sure the date and time is correct, if not go to settings and set correct date and time. If you have paired SYNFIGO to a mobile device, the time will update automatically.

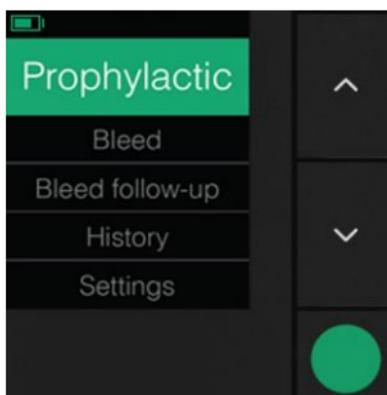
- 1 Press and hold Power  to turn on SYNFIGO.

A welcome screen will now appear. This will disappear after a few seconds and be replaced by the main menu screen.



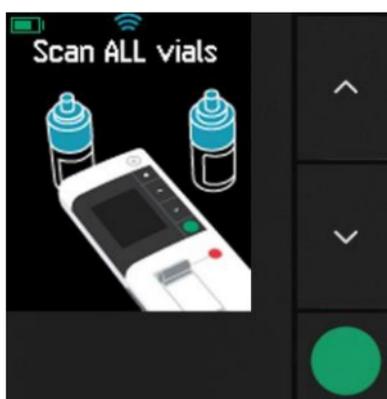
- 2 When the Main Menu appears, use the Navigation Buttons   to select Prophylactic (for a scheduled or preventative infusion), Bleed (for a bleed event), or Bleed Follow-Up.

- 3 Press the Ok/Confirm  to confirm the infusion type.



### 4.3 Scan medication vials

Touch the target on top of your SYNFUOGO to each vial to be scanned.

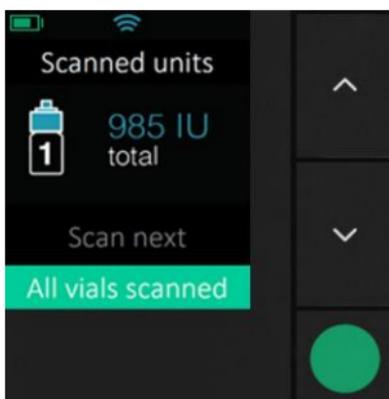


- 1 Scan each vial one at a time. As you scan each vial, you will hear a beep confirming that the vial has been scanned.

NOTE: Scanning the same vial twice will generate an error.



The total IU's (International Units) of all vials scanned will automatically update after each scan.



The maximum number of vials that can be scanned is four. If you have any further issues with scanning vials refer to Chapter 6.2: Troubleshooting.

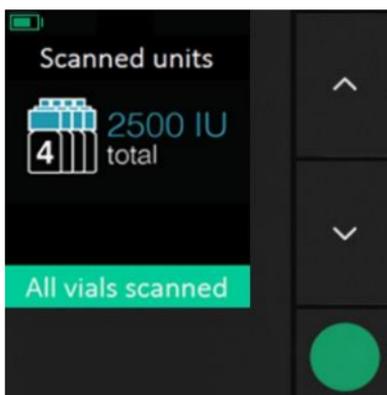
- 2 Confirm that total IU's is correct, then use the down Navigation Button  to select All Vials Scanned.



### WARNING:

If total IU's on the display differs from the IU's indicated on the labels of the medication vial(s), cancel and proceed with manual infusion instead.

- 3 SELECT "ALL VIALS SCANNED" and then Press Ok/Confirm  to confirm scan is complete.



If the total IU's is incorrect select Cancel and proceed with a manual infusion.

NOTE: If your SYNFIGO is set to the Record Only Infusion mode, You will now be returned to the Main Menu.

If you wish to infuse with the SYNFIGO pump (and not RECORD ONLY), you can change this setting in the INFUSION menu. (Chapter 3.7- Infusion Mode)

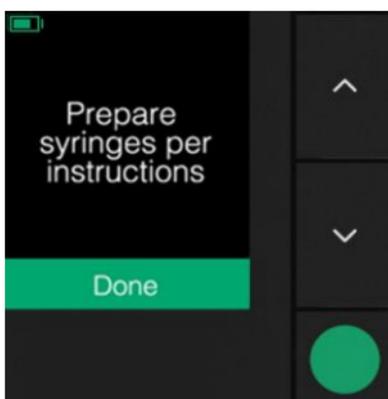


## WARNINGS:

- ③ Always scan all vials needed for the infusion prior to beginning the infusion.
- ③ Do not attempt to scan more than one vial at a time.
- ③ Do not scan empty vials.
- ③ If the scanning function is not working, perform a manual infusion without using your SYNFIGO.
  
- ③ Vial scanning will only work for vials that include this feature- Only vials with an "RFID" logo on the box will work with SYNFIGO.

## 4.4 Prepare medication, syringe, and butterfly needle

- 1 Reconstitute medication and prepare your infusion using the instructions provided with medication. Attach butterfly needle.
- 2 You may either prime (remove air from) the syringe and butterfly needle manually now, OR you may use the SYNFUOGO device in a later step. (Chapter 4.7)

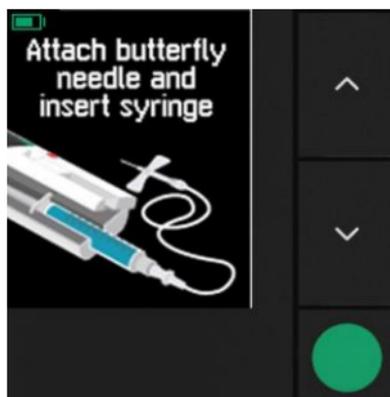


### WARNINGS:

- ③ Only 5mL and 10mL syringes provided with medication are compatible.
- ③ Prime (remove air from) the syringe and butterfly needle.
- ③ Always check for air and never inject an empty syringe.
- ③ Clean needle insertion site on skin per your health care provider's instructions.
- 3 Press Ok/Confirm  to confirm that you have finished preparing medication, syringe, and butterfly needle.

## 4.5 Load syringe

Ensure that butterfly needle is securely attached to syringe.



- 1 Slide the Lock Release to open your SYNFUOGO.





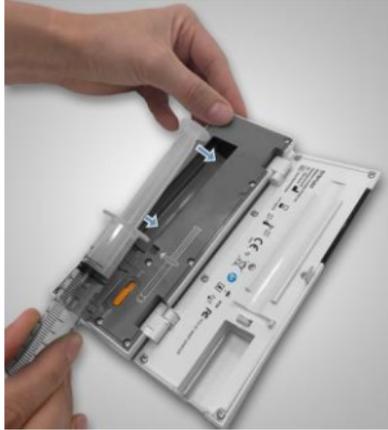
## WARNING

2

Before loading syringe, confirm that the Syringe Selector switch is set to the correct syringe size (5mL or 10mL). See Chapter 3.8 for more details.



- 3 Load syringe and butterfly needle into your SYNFUOGO. Confirm that the syringe is seated properly and that there are no leaks anywhere.



- 4 Close your SYNFUOGO. You will now hear the motor advancing to the start position for the infusion. This is normal.

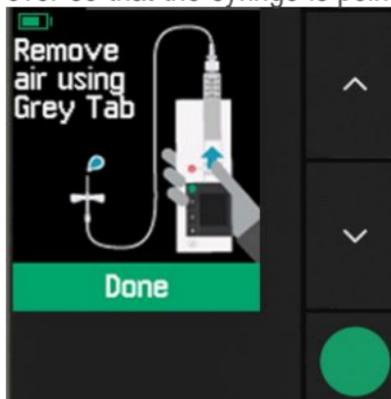
NOTE: If the lid is hard to close, confirm that the syringe selector is set to the proper size for the syringe you are using.



## 4.6 Priming the system (removing air) using your SYNFUOGO

SKIP THIS STEP IF THE SYSTEM HAS ALREADY BEEN PRIMED MANUALLY.

- 1 You will now see this screen. Note that you now need to flip your SYNFUOGO over so that the syringe is pointing up.



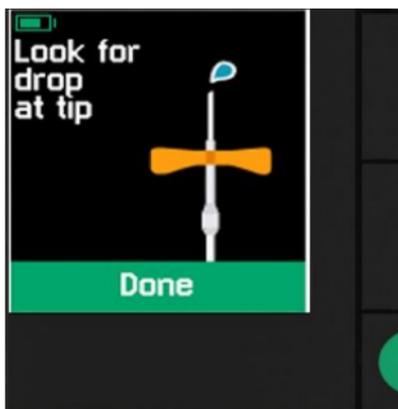
- 2 Push the Grey Tab toward the syringe until you see the air has been removed and a drop of medication exit the needle. Check that all air has been removed.





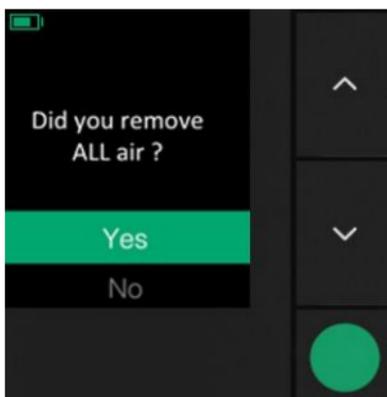
### WARNING:

- ③ Grey Tab is only intended for priming and checking blood and NOT for infusing.
- ③ Butterfly needle and syringe must be primed (air removed) either manually or with the device before infusion.



## 4.7 Confirm that system is primed (air is removed)

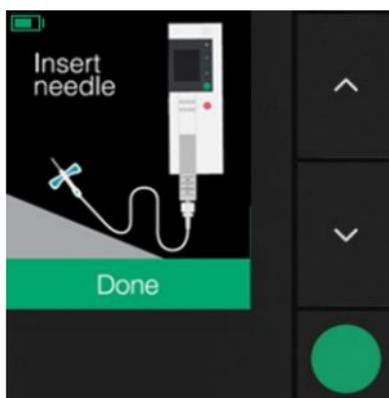
- 1 If all air has been removed from the syringe and butterfly needle, use Navigation Buttons   to select Yes.
- 2 Press Ok/Confirm  to confirm.



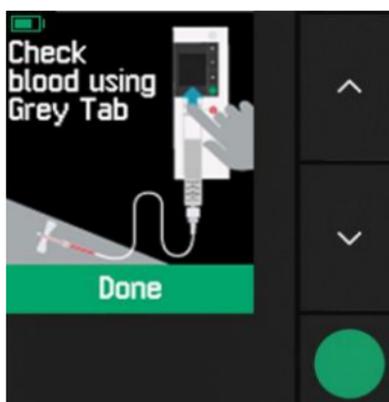
NOTE: Clean skin and insert needle into vein as per your training. Press OK/Confirm .

## 4.8 Insert butterfly needle into vein and check for blood

After following proper technique to clean your skin, insert needle into vein using butterfly as per manual infusion training. Press Ok/Confirm  when done.



#### 4.9 Check for blood



NOTE: Location of needle is only an example, place as per your training.

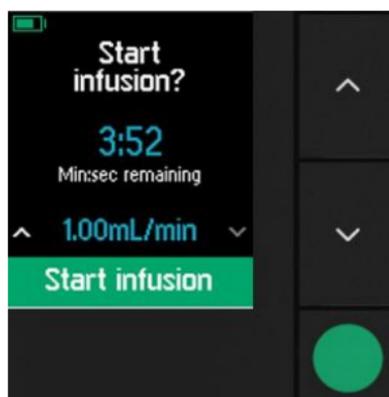


Push the Grey Tab towards the screen until you see a small amount of blood in the butterfly needle just before the butterfly fitting. You will hear a tone when pushing the Grey Tab. If blood is not seen, the needle may not be in the vein. The needle may need to be reinserted.

NOTE: The blood check function can be limited to 1mL on the syringe; there may be a slight delay before you see the plunger retracted.

## 4.10 Start infusion

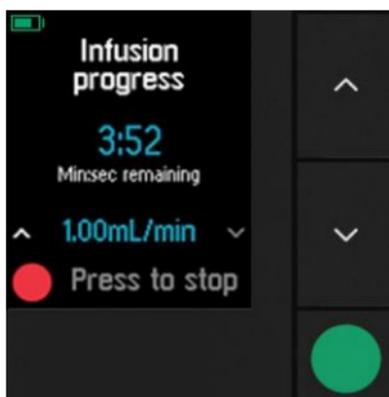
- 1 You will now see this screen. Press Ok/Confirm  to start the infusion. The infusion will start on the default infusion rate. If needed you can use the Navigation Buttons   to adjust the infusion rate.



### WARNINGS

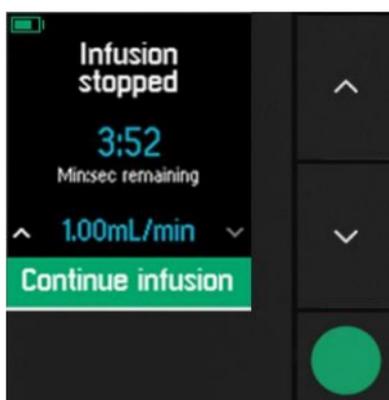
- ③ In case of emergency, press Stop  to halt infusion.
- ③ Monitor for any swelling or medication leakage during infusion. In case of leakage,

stop infusion and proceed with manual infusion without using your SYNFUOGO.



NOTE: When the infusion is stopped, you may also use the Grey Tab to check for blood and ensure the needle is properly placed. See also Chapter 4.9: Check for Blood

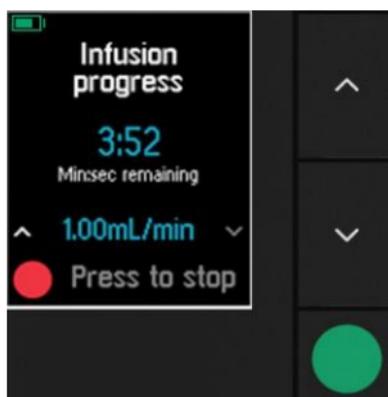
If you have stopped the infusion, you will see this screen. Press Ok/Confirm  to resume.



NOTE: If you want to end the infusion, press the Back Button and select Yes to end the infusion.

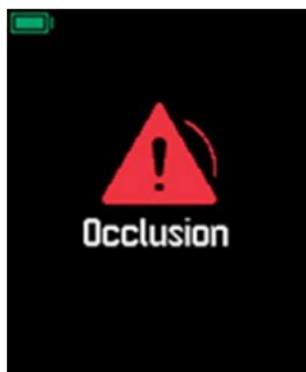
## 4.11 Adjust infusion rate (if necessary)

Use Navigation Buttons   to adjust infusion rate during infusion.



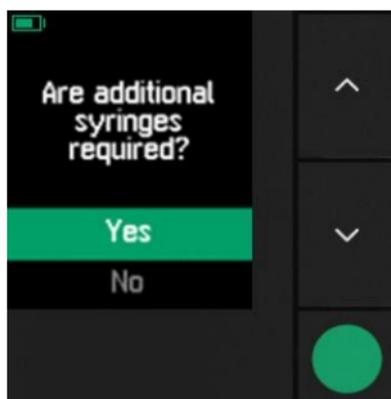
### WARNINGS

- ③ If you see this Occlusion warning screen while performing an infusion, something has occurred to cause the medication to stop flowing through the butterfly needle. Proceed to Chapter 6.3 for further instructions.



## 4.12 Is there a second syringe to infuse?

Wait for infusion of first syringe to finish. If two or more vials have been scanned, you will see this screen:



If there is a second syringe to infuse:

- 1 Use Navigation Buttons   to select Yes, then press Ok/Confirm .
- 2 Continue to Chapter 4.13 for instructions on infusing with a second syringe.

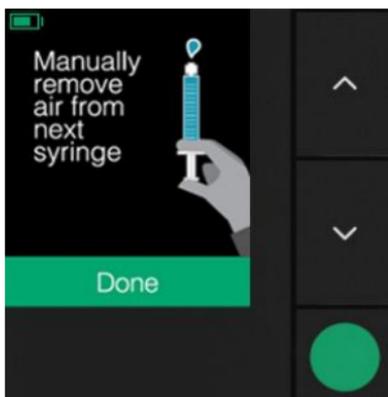
If there is NOT a second syringe to infuse:

- 1 Use Navigation Buttons   to select No, then press Ok/Confirm .
- 2 Continue to Chapter 4.14 for instructions on finishing the infusion.

## 4.13 Infuse with second syringe (if necessary)

NOTE: Do not remove the needle from your vein prior to infusing with the second syringe.

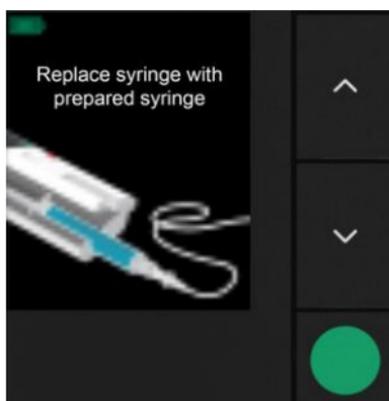
- 1 You will now see this screen:



- 2 Manually prime second syringe (remove all air), then press Ok/Confirm  to confirm that the syringe is primed.

NOTE: The second syringe must be primed manually (by hand) and cannot be primed with your SYNFIGO.

- 3 You will now see this screen:



- 4 Remove the first syringe from your SYNFIGO, then detach the butterfly needle from the first syringe and attach it to the second syringe.

- 5 Load the second syringe into your SYNFIGO and close the lid.

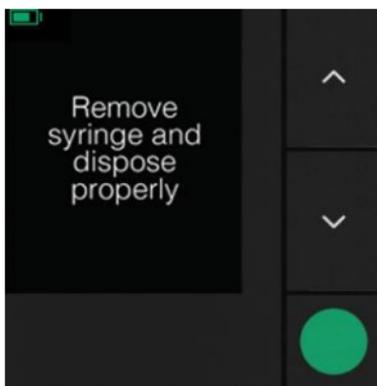
NOTE: If you have already loaded the second syringe, you will need to open and close the lid of your SYNFIGO before you can continue.

- 6 See Chapter 4.10 in order to infuse the second syringe. For help, please refer to earlier sections of this chapter.

#### 4.14 Remove final syringe and remove needle

When you are finished infusing the final syringe, remove the syringe and dispose of properly, as directed in your medication instructions.

Then remove needle from vein and apply bandage as per manual infusion training.



#### WARNING:

Ensure that you have received your full intended medication dose. If the syringe is not fully emptied and you have not received your full medication, remove syringe and complete manually.

#### 4.15 Turn off your SYNFUOGO

Press and hold Power  to turn off your SYNFUOGO.



#### WARNING:

Ensure that all vials, syringes, and butterfly needles are properly disposed of. Consult local directives/ authorities for correct disposal.

# Chapter 5

Using your SYNFIGO with  
Mobile and Web apps

- 
- The SYNFUGO infusion pump records your infusions- both the medication used and the time infused on the SYNFUGO device
  - You have the option to view infusion information and set up reminders with a mobile application. This application is available for Android or iOS devices through the Google Play™ store and the Apple App Store™ respectively.
  - The SYNFUGO mobile app may also be used to scan medication info and provide calendar reminders for your scheduled infusions. The application may be used to store infusion history and schedule using a secure cloud-based Web application. This feature is provided as an extension of your paper journals, and is not intended to replace (or supplement) guidance from your healthcare providers. As always, any questions about your treatment or schedule should be directed to your doctor.
  - Use of the SYNFUGO mobile and web apps is optional- use of your SYNFUGO device is not affected by your choice. Likewise, you choose if and whom you share information with. You may opt to share infusion history with your healthcare provider, a caregiver/family member, or with no one at all. This applies to the SYNFUGO mobile and web apps: You control (and are required to opt into) any data sharing.

- During an infusion with your SYNFIGO, the mobile app cannot be connected to your mobile device.
- If you wish to take advantage of the mobile or web apps, more information may be found at the SYNFIGO information web site here <<holding space for SYNFIGO web site address here>>. Information on software features, functions and limitations may be found there.

NOTE: If you choose to pair to the mobile app, your SYNFIGO will automatically have the time and date updated to the info on the mobile device.

# Chapter 6

FAQ, Troubleshooting, Alerts  
and Errors, Labeling,  
and Contact Info

## 6.1 Frequently asked questions

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### Question

Can any syringe be used with my SYNFUOGO?

### Answer

No, only Becton Dickenson 5mL (cat #309646) and 10mL (cat #309604) syringes provided with your medication can be used with your SYNFUOGO. Any changes to compatible syringes made after date of publication may be confirmed using the CSL Behring SYNFUOGO website or by contacting customer service

### Question

Can other medications be used with my SYNFUOGO?

### Answer

No, use only Afstyl<sup>a</sup> or IDELVION supplied by your Doctor, health care provider, or pharmacy can be used with your SYNFUOGO.

Compatible medication is marked with an RFID tag on the box. Medication without the RFID tag cannot be scanned by SYNFUOGO..

### Question

How do I determine the infusion rate?

### Answer

Default Infusion rate may be changed according to patient comfort by adjusting the infusion rate in Settings (see Chapter 3.6), and is adjustable up to the maximum infusion rate for your medication. The maximum infusion rate is automatically set when your medication is scanned. You may also adjust the rate during an infusion by pressing the [up/down] navigation buttons.

### Question

How do I determine what syringe size to set on my SYNFIGO?

### Answer

Always verify your Syringe Selector setting matches the size specified on the syringe prior to performing an infusion (5mL or 10mL). See Chapter 3.7 for more details.

### Question

What do I do if my SYNFIGO stops working during an infusion?

### Answer

Remove the syringe and butterfly needle from your SYNFIGO and finish the infusion manually.



## Question

Can I just use SYNFUOGO to record the vials I've scanned and infuse manually?

## Answer

Yes, you can- you have the option! In the SETTINGS menu, select INFUSION and then INFUSION MODE. Set "RECORDING ONLY, NO INFUSION" to ON. When using the pump to scan, information for your vial(s) will be recorded and when all vials have been recorded, you'll return to the main menu and you can manually infuse.

If you change your mind, you can turn this feature to OFF and use SYNFUOGO to perform your infusion.

## 6.2 Troubleshooting

NOTE: If you need assistance at any time setting up, using, or maintaining your SYNFIGO infusion device, talk with your doctor, health care provider, or pharmacy first. For Technical questions or concerns call CSL Behring anytime at 1-800-878-XXXX.

### Problem

Unable to turn your SYNFIGO on by pressing Power .

### Cause

Power  was not pressed long enough.

### Solution

Firmly depress the Power .

### Cause

Battery is not charged.

### Solution

Recharge your SYNFIGO until the display shows charging complete. Refer to Chapter 3.2 for more information.

### Problem

Unable to use your SYNFIGO while it is being charged.

### Cause

Your SYNFIGO will not operate while it is being charged.

### Solution

Fully charge your SYNFIGO and remove the charger before using.

### Problem

Unable to scan a medication vial.

### Cause

You attempted to scan the same medication vial more than once.

### Solution

Only scan each medication vial once.

### Cause

You attempted to scan a medication that is not AFSTYLA or IDELVION

### Solution

Only use AFSTYLA or IDELVION with your SYNFIGO.

### Cause

Synfigo does not recognize your medication vial.

### Solution

Only AFSTYLA or IDELVION vials with RFID tags are compatible. Look for the RFID logo on the box. If not present, perform a manual infusion.

### Cause

Label on medication vial is damaged.

### Solution

Proceed with a manual infusion

### Cause

You attempted to scan more than 4 vials.

### Solution

Do not attempt to scan more than 4 medication vials.

### Cause

You are holding your SYNFIGO too far away from the medication vial.

### Solution

Touch the top of SYNFIGO to the medication vial while scanning.

### Cause

Your SYNFIGO is malfunctioning.

### Solution

Perform a manual infusion instead of using your SYNFIGO.

### Problem

Unable to close the door (NOTE: DO NOT force the door closed).

### Cause

The syringe being used doesn't match the setting of the Syringe Selector.

### Solution

Set the Syringe Selector to the correct setting. See Chapter 3.7 for details.

### Cause

The wrong syringe type is used.

### Solution

Your SYNFIGO is only designed for use with the Becton Dickinson 5mL (cat #309646) and 10mL (cat #309604) syringes provided with your medication. If your syringe is a different brand or style, STOP IMMEDIATELY and contact your Doctor, health care provider, or pharmacy.

Any changes to compatible syringes made after date of publication may be confirmed using the CSL Behring SYNFIGO website or by contacting customer service.

### Cause

The syringe is not inserted into the Syringe Cradle correctly.

### Solution

Make sure the flanges of the syringe align correctly with the slots that receive them.

### Cause

There is debris in the door latch area preventing the door from closing.

### Solution

Check the hinges, latch area, and insides of both covers for debris. Remove and clean as necessary.

### Cause

There is debris in the Syringe Cradle preventing the syringe from seating properly.

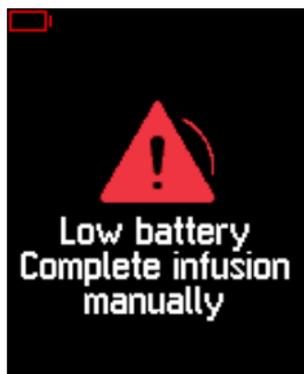
### Solution

Remove debris from the Syringe Cradle.

## 6.3 Alert and error screens

A red warning will blink to indicate an alert or error. To recover, follow the instructions and press the Ok/Confirm Button  to reset the alarm.

### Low Battery, Complete Infusion Manually



#### Reason

The battery charge is too low for your SYNFUOGO to perform an infusion.

#### How to Resolve

- 1 Remove the syringe from your SYNFUOGO and complete the infusion manually.
- 2 Charge your SYNFUOGO using the supplied charger until fully charged.

## Syringe Removed



### Reason

The syringe has been removed during infusion, user is instructed to complete manually.

### How to Resolve

Complete the infusion manually

## Device Expired



### Reason

The lifetime of the SYNFIGO is expired and the device can no longer be used.

### How to Resolve

- 1 Request a new SYNFIGO device
- 2 Complete infusion manually until a new device is received.
- 3 Dispose the old SYNFIGO per local regulation.

## Fatal Error



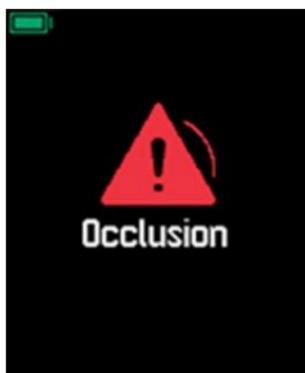
### Reason

A fatal error has occurred.

### How to Resolve

- 1 Remove the syringe from your SYNFIGO and complete the infusion manually.
- 2 Replace your SYNFIGO.
- 3 Note the error code. And contact customer service.

## Occlusion

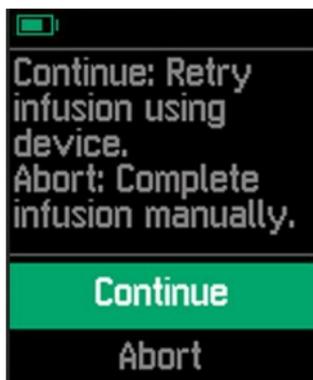


### Reason

The flow of your medication has been blocked, so your SYNFIGO has stopped working.

### How to Resolve

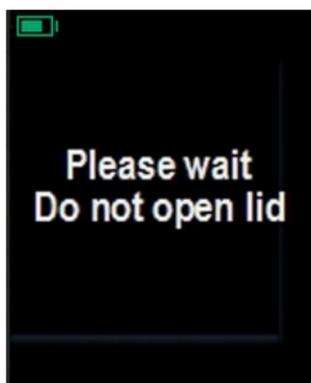
- 1 Press Ok/Confirm . You will now see this screen:



- 2 Try to correct the occlusion by making sure that the tube is not kinked, or by correcting any other .Then select Continue and then press Ok/Confirm ●. You will now be returned to the Infusion Progress screen (Chapter 4.10, Step 1) to continue the infusion.

If you do NOT think that you can correct the occlusion, select Complete (meaning that you intend to complete the infusion manually), then press Ok/Confirm ● and proceed to Step 3.

- 3 You will now see this screen. Wait until the plunger finishes resetting, and you see the screen in Step 4.



Continued on next page

- 4 You will now see this screen. Push any button to return to the Main Menu.



In case of an occlusion, SYNFIGO will automatically release the pressure. Once the occlusion condition is removed, you will need to start SYNFIGO to continue the infusion.

If the occlusion condition cannot be resolved, proceed with manual infusion.

## Disconnect USB Cable



You may also see a yellow warning such as the one above. In this case, follow the instructions on the screen

## 6.4 Labeling

The following table is an explanation of the various labels found on your SYNFUOGO.

Label	Description
	It is important that you read this instruction before you use your SYNFUOGO.
	This symbol is accompanied by an expiry date to indicate that the device should not be used after the end of the indicated year (YYYY), month (MM), and date (DD), printed as YYYY-MM-DD.
	Keep your SYNFUOGO dry.

	<p>Your SYNFUGO contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives/ authorities for disposal of electrical and electronic equipment. When disposing of electrical and electronic equipment by use of the collection systems available in your country, you protect the environment, human health and contribute to the prudent and rational use of natural resources.</p>
	<p>Your SYNFUGO is a type BF device and provides protection against electrical shock and electrical current leakage.</p>
	<p>Manufacturer</p>
	<p>The unique serial number of your SYNFUGO.</p>



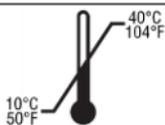
Your SYNFUGO complies with the requirements of The Medical Device Directive (MDD 93/42/EEC), and the RoHS (Restriction of Hazardous Substances) directive (2011/65/EU).



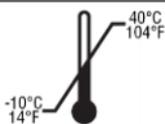
Your SYNFUGO radiates non-ionizing electromagnetic signals.  
FCC ID 2AAGY-SYNFUGO



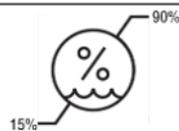
Your SYNFUGO complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.



Your SYNFUGO can be operated at a temperature from 10° to 40°C (50° to 104°F).



Your SYNFUGO can be stored at a temperature from -10° to 40°C (14° to 104 °F).



Your SYNFUGO can be operated at a relative humidity range from 15-90% RH

	<p>Your SYNFUGO can be stored at a relative humidity range from 15-90% RH</p>
<p><b>IP20</b></p>	<p>SYNFUGO is protected against solid foreign objects of 12.5 mm Ø and greater.</p>
<p>5.0V <math>\equiv</math> 1.0A</p>	<p>Only use the charging adapter and USB cable supplied with SYNFIGO which will supply the required 5V DC and 1A charging conditions.</p>



## 6.5 Important contact information

If you experience any problems or malfunctions with your SYNFIGO you may report the issue to the FDA or to CSL Behring.

If you have any technical questions or concerns about your SYNFIGO infusion pump, you may contact one of our technical specialists at the number below:

### CSL Behring

(Distributor)

Phone: 1-800-878-XXXX

Fax: 1-610-878-4009

1020 First Avenue

PO Box 61501

King of Prussia, PA

19406-0901 USA

# Chapter 7

## Technical Specifications

## 7.1 Environmental

- The operating temperature for your SYNFUGO shall be within:  
10–40°C / 50–104°F, 15-90% RH
- SYNFUGO can be charged between  
10–35°C / 50–95°F
- The storage and transportation temperature for your SYNFUGO shall be within:  
-10–40°C / 14–104°F, 15-90%RH
- The operating, storage, and transportation atmospheric pressure conditions for the auto infuser shall be within 700 kPa and 1060 kPa.

## 7.2 Physical

- Product dimensions: 163 x 56 x 38 mm  
(6.4 x 2.2 x 1.5 inch)
- Weight: Approx. 192 g (6.8 oz)
- Expected service life: See expiry date.

## 7.3 Product classification

Class IIa medical device in Europe or class II medical device in the USA.

## 7.4 Electrical

1 rechargeable internal Li-Ion battery, non-replaceable.

**Alert and Error sound pressure:**

**Typical 56 dB(A) @1m**

## 7.5 Radio transmitter

- Bluetooth® v4.0 @2.4GHz, customized encrypted protocol
- RFID @13.56MHZ
- Class B digital device

## 7.6 Infusion flow rates

- Maximum defined by US Regulatory clearance: 10mL/min in the US market for AFSTYLA and IDELVION.
- Selectable from 1mL/min to 10mL/min  $\pm$  15% in steps of 0.25mL/min, default setting 1mL/min
- Maximum infusion pressure: 40 psi
- If maximum pressure is achieved, an occlusion alarm is generated. Occlusion alarm will occur within 60 seconds at minimum flow rate 1mL/min

## 7.7 Scanning RFID

- Reading distance < 0.8inch (2cm)
- A maximum of 4 vials can be scanned for each infusion

## 7.8 Charging Adapter

Aquil Star Precision Industrial

Model ASSA54

Input 100-240Vac 50/60Hz

Output 5V, 1A

## 7.9 Pump identification

Model name: SYNFIGO

Serial Number (SN): Please refer to inside of SYNFIGO marked after 

## EMC compliance levels

SYNFUGO has been tested for electromagnetic disturbances according to international standards for a home healthcare environment. The table below list the compliance levels for SYNFUGO.

<b>Electromagnetic compatibility (EMC) Compliance levels</b>	<b>Basic EMC Standard</b>
<b>EMC – Radiated RF Emission / Conducted RF Emission:</b> RF emissions CISPR 11 : Group 1 RF emissions CISPR 11 : Class B  Radiated Emission: 30 MHz- 1 GHz Conducted emission: 150kHz-30MHz	IEC 60601-1-2:2014 CISPR 11:2019+A1:2010
<b>EMC - RF Field radiated immunity – Electrical field:</b>  10 V/m 80 MHz to 2.7 GHz, 1 kHz 80% AM	IEC 60601-1-2: 2014 IEC 61000-4-3
<b>EMC: Conducted Disturbances Immunity, induced by RF fields:</b>  Conducted immunity disturbance by RF fields 3 Vrms 150 kHz to 80 MHz (6Vrms in ISM and amateur radio bands)	IEC 60601-1-2: 2014 IEC 61000-4-6
<b>EMC - Power Frequency Magnetic Field, Immunity:</b>  30 A/m	IEC 60601-1-2: 2014 IEC 61000-4-8

<p><b>EMC - Fast transients and bursts</b></p> <p><b>Immunity:</b></p> <p>Fast transients and bursts <math>\pm 2</math> kV ac mains</p> <p>Surge <math>\pm 1</math> kV Line-to-Line ac mains</p>	<p>IEC 60601-1-2: 2014</p> <p>IEC 61000-4-4</p> <p>IEC 61000-4-5</p>
<p><b>EMC – Voltage dips and interruptions:</b></p> <p>0% <math>U_T</math>; 250/300 cycle</p> <p>0% <math>U_T</math>; 0,5 cycle, At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°</p> <p>0% <math>U_T</math>; 1 cycle, 70% <math>U_T</math>; 25/30 cycles Single phase: at 0°</p>	<p>IEC 60601-1-2: 2014</p> <p>IEC 61000-4-11</p>
<p><b>EMC - RF Field Immunity to Proximity fields from Wireless communication equipment, Immunity at 0,3m separation:</b></p> <p>a) 27 V/m at 380-390 MHz</p> <p>b) 28 V/m at 430-470 MHz</p> <p>c) 9 V/m at 704-787 MHz</p> <p>d) 28 V/m at 800-960 MHz</p> <p>e) 28 V/m at 1700-1990 MHz</p> <p>f) 28 V/m at 2400-2570 MHz</p> <p>g) 9 V/m at 5100-5800 MHz</p>	<p>IEC 60601-1-2: 2014</p> <p>IEC 61000-4-3</p>
<p><b>ESD Immunity:</b></p> <p><math>\pm 8</math> kV contact</p> <p><math>\pm 2</math> kV, <math>\pm 4</math> kV, <math>\pm 8</math> kV, <math>\pm 15</math> kV air</p>	<p>IEC 60601-1-2: 2014</p> <p>IEC 61000-4-2</p>

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.



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