
digivibe
User Manual &
Instruction Guide
Digivibe by süthe

Thanks for choosing Digivibe

by süthe™

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Digivibe Symbols and Icons


Consult User Manual


Manufacturer


Single person use only


Biohazard after use

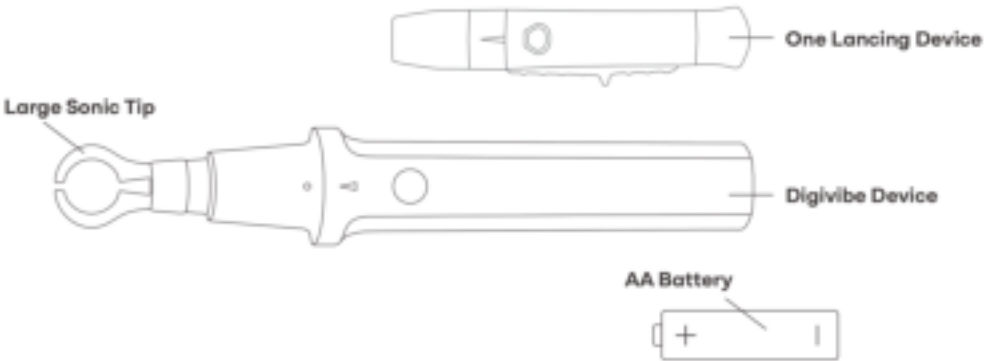

Not waterproof


Warning


Pacemaker/Defibrillator Safe


European Conformity

THE DIGIVIBE INJECTION KIT CONTENTS



Safety Information

Before using the product carefully read the User Manual & Instruction Guide that comes with the Digivibe device

Lancets are for single use only.

Do not share the Digivibe lancing device or used lancet with anyone else, including family members.

Do not use the Digivibe lancing device on multiple patients.

After use and exposure to blood, all parts of this kit are considered bio-hazardous. A used kit may potentially transmit infectious diseases even after you have performed cleaning and disinfection.

Clean and disinfect the Digivibe device before initial use and after each use with warm soapy water and germicidal wipes.

Keep away from young children. Small parts may present a choking hazard.

Do not use in an oxygen-rich or explosive environment.

Do not expose the unit to high temperatures for an extended period of time (Example: Leaving it in a vehicle trunk on a hot day or in a sun-baked space). This may reduce the performance and/or cause a failure of the disposable tip.

For best performance and greatest comfort, if the device is stored at extreme temperatures such as -25°C to +35°C, allow the device to come to room temperature or at least into the normal operational range of +5°C to +40°C before use. This should take about 2 hours when exposed to room temperature.

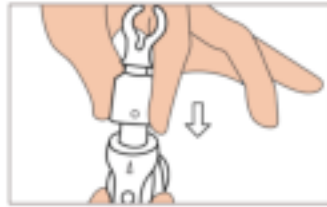
NOTE: Safe with pacemaker/defibrillator when used normally in accordance with proper intended use.

WARNING: Battery can explode or leak and cause burns if installed incorrectly, disembled, or exposed to water, fire, or high temperature. No user-serviceable parts inside. Modification or disassembly not allowed.

Digivibe device setup

Before handling the Sonic Tip wash your hands thoroughly with warm soapy water. Rinse and dry hands completely.

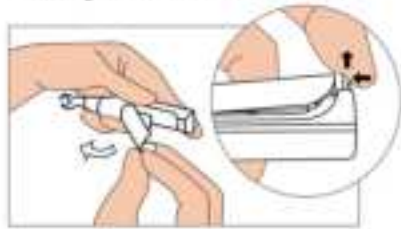
Sonic Tip Installation / Removal



Install the Sonic tip onto the Digivibe device by aligning the dot located at the base of the Sonic tip with the triangle located on the Digivibe handle and push the tip down until you hear a click.

To remove, turn the Sonic tip ¼ turn counterclockwise and lift.

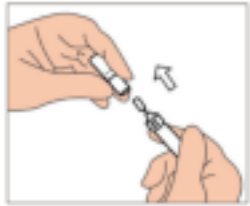
Battery Installation/Removal



Open the battery cover by pressing and lifting the latch located at the bottom rear of the device. After installing or removing the AA battery reinstall the battery cover properly.

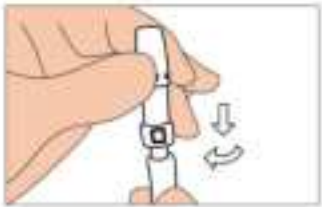
Lancing device setup

Before handling your lancing device, wash your hands thoroughly with warm, soapy water. Rinse and dry hands completely.



1. Remove the lancing device cap by turning it counterclockwise and then pulling it straight up from the device.

2. Insert a sterile lancet into the grooves of the lancet holder. Push the lancet into the device until it is fully seated in the holder. Twist the protective cover until it separates and save it for the removal and disposal of the used lancet.



3. Place the lancing device cap back onto the device; gently turn clockwise to secure the cap.

Do not overtighten.

4. Adjust the depth setting of the lancing device by turning the wheel to the desired depth. Minimum starting from 1 and maximum ending at 5.
A shallower puncture works for children and most adults.

5. Cock the lancing device trigger by sliding the device back until it clicks. If it does not click, it might have already been cocked. The device is now ready to use.

Removing the Used Lancet

1. Remove the cap by turning it counterclockwise and then pulling it straight up from the device.
2. Before removing the lancet, place the lancet protective cover on a hard surface, then push the lancet tip into the cupped side of the cover.
3. After securing the tip of the lancet with its cover, remove the lancet by gently pulling away from the lancet device.
4. Place the cap back onto the device; turn clockwise to secure the cap. Do not over tighten. It is important to use a new lancet each time you obtain a blood sample. This will help prevent infections.
5. Discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used lancets may be considered bio-hazardous waste. Be sure to follow your healthcare professional's recommendations or local regulations for proper disposal. Wash hands thoroughly with warm soapy water after handling the Digivibe device, lancets, lancing device, and cap.

Cleaning your Lancing Device

The lancing device and cap should be disinfected after each use.

First, clean your lancing device and cap with warm soapy water prior to disinfecting.

Use a new germicidal wipe to rub or swab the outside of the lancing device until the surface is damp.

Wipe dry with clean, sterile gauze. Wash your hands thoroughly with warm soapy water after handling the Digivibe and lancing device.

Do not use alcohol or any other solvent.

Do not spray a cleaning solution on the Digivibe and lancing device.

Do not immerse the Digivibe device in any liquid, including water.

Taking a glucose test

(HAND HELD) PATIENT, PARENT

Purpose

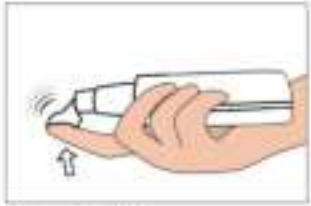
The Digivibe device is designed to reduce the perception of pain during capillary blood sampling (fingerstick) through controlled vibration. This instruction outlines the proper use of the device prior to and during lancing for glucose monitoring.

Materials Needed

- Digivibe Device
- Lancing Device
- Glucose meter and test strip

1. Device Activation

Press the power button on the Digivibe to activate vibration.



2. Finger Positioning

Hold the device securely in one hand. Place the target finger either on top of or beneath the vibrating sonic tip, ensuring firm contact.

3. Pre-Lancing Vibration

Maintain finger contact on the vibrating tip for the recommended duration (see Vibration Chart below) prior to performing the fingerstick.

Vibration Timing Guidelines	
Lancet Gauge	Vibration (Prior to Lancing)
28-30 gauge	15 seconds
23-27 gauge	20 seconds

4. Lancing procedure

While vibration is ongoing and the finger remains in place, apply the lancing device directly over the center of the vibrating tip. Ensure the lancet contacts the intended area of the finger and activate the device to obtain the blood sample.

Safety Notes

- The Digivibe is a non-invasive Class I device.
- The device should not interfere with blood collection or glucose measurement accuracy.
- Do not use the device on broken skin or in the presence of infection.

Taking a glucose test

(HANDS FREE) PATIENT, PARENT

Purpose

The Digivibe device is designed to reduce the perception of pain during capillary blood sampling (fingerstick) through controlled vibration. This hands-free protocol uses the Digivibe stand for stability and ease of use.

Materials Needed

- Digivibe Device
- Digivibe Stand with suction base
- Flat, clean surface (e.g., table or counter)
- Lancing Device
- Glucose meter and test strip

1. Prepare the Surface

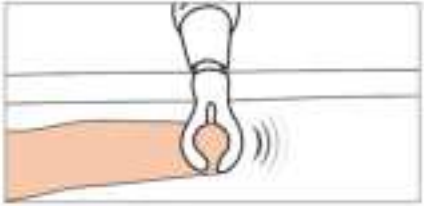
- Select a **flat, clean surface** to place the Digivibe stand.
- **Secure the stand** by pressing the **suction activation button** through the center of the stand using your thumb. Ensure the base is firmly suctioned to the surface.

2. Insert the Digivibe

Place the Digivibe device into the holder on the stand so that the vibrating tip is positioned **horizontally and accessible** for finger placement.

3. Activate the Device

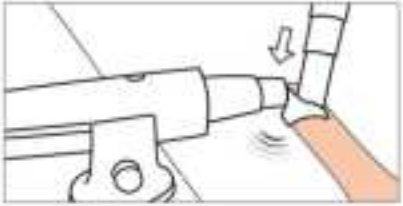
Press the **power button** on the Digivibe to begin vibration.



4. Pre-Lancing Vibration

Place your target finger under the vibrating tip so that it makes firm, stable contact.
Maintain contact for the recommended vibration time based on needle gauge (see chart below).

Vibration Chart	
Lancet Size	Vibration Time
28-30 gauge	15 seconds
23-27 gauge	20 seconds



5. Perform the Fingerstick

While your finger remains in contact with the vibrating tip and vibration is active:

- Align the lancing device with the center of the vibrating tip.
- Apply the lancing device so it presses against the finger through the vibration zone.
- Activate the lancet to perform the fingerstick.

Note: The Digivibe Stand is not included with the Digivibe by SGthe Kit. It can be ordered separately by visiting digivibe.com

6. Post-Use

Remove your finger and wipe any residual blood.

Abdominal Injections with Digivibe

Purpose

The Digivibe device is designed to reduce the perception of pain during subcutaneous abdominal injections through the application of controlled vibration. This instruction outlines the proper use of the device to enhance comfort during self-administered or caregiver-assisted injections, such as insulin administration.

1. Prepare Injection Materials

Prepare your insulin or medication injection according to medical guidance. A 30-32 gauge needle with a length of 6-8 mm is recommended.

2. Clean the Injection Site

Use an alcohol wipe to clean the designated area of the abdomen where the injection will be administered.

3. Device Activation and Placement

Press the power button on the Digivibe to activate vibration. Place the vibrating sonic tip directly on the injection site.

4. Pre-Injection Vibration

Vibrate the injection site for up to 20 seconds prior to inserting the needle.

Vibration Chart	
Needle Gauge	Vibration Time
30-32 gauge	20 seconds

5. Injection Procedure

While maintaining vibration on the injection site, insert the needle through the center area of the vibrating tip into the tissue.

6. Complete the Injection

Continue vibrating the site during the entire injection process until the needle is withdrawn.

Safety Notes

- The Digivibe is a non-invasive Class I device.
- The device should not interfere with medication absorption or injection accuracy.
- Do not use the device on broken skin or in the presence of infection.
- Follow standard hygiene protocols for all injection procedures.

Care & Maintenance

Cleaning your Digivibe device

Clean your Digivibe device by wiping it with a damp cloth and then with a germicidal wipe.

DO NOT wet the Digivibe device.

Use germicidal disinfecting wipes. Clean the Digivibe sonic tip by first removing it from the device and then cleaning it with a mild liquid detergent and rinsing with warm water.

Technical Information

Permissible environmental conditions during normal use.			
	Temperature		
Operating:	+5°C to +40°C	Storage:	-25°C to +55°C

Replacing & Disposal of Battery

Your Digivibe device uses one 1.5v AA lithium battery or one AA alkaline battery. A lithium battery will operate the Digivibe device for approximately 450 uses, assuming each use requires 15 seconds. If the device vibration is weak, replace the battery.

IMPORTANT: The recommended battery to use with this device is a 1.5v AA lithium battery, which will give the greatest performance and life of operation before needing to replace the battery.

Replacing the Battery

Start with the device turned off. Remove the battery cover by sliding it downward and pressing the release latch. Pull up on the battery to lift it out of the compartment. Remove the old battery.

Insert a new AA lithium battery or one AA alkaline battery into the battery compartment. Plus (+) and minus (-) signs will guide you in placing the battery. The battery needs to be the Energizer 1.5v AA L91 or AA alkaline battery.

Disposal of Battery and Device

Dispose of battery and device according to your local environmental regulations.

Troubleshooting / FAQs

Digivibe device stand does not stick to the flat surface.

Detach the stand from the Digivibe device and wash the stand with a mild dishwashing detergent, then dry with a paper towel.

Digivibe device vibration is weak.

Replace the battery with a new lithium battery if the pain reduction effect is not felt. Do not use a rechargeable battery. We recommend a lithium battery. Alkaline batteries are not powerful enough to run the device at full strength.

What if my Digivibe device does not turn on?

Ensure that the battery is installed correctly.

What if my Digivibe device tip is cracked or damaged?

If your Digivibe device tip is cracked or damaged, contact Customer Service at 1-844-403-8423 or order a new Digivibe tip at digivibe.com.

Limited 1-Year Warranty

Bing Innovations, LLC warrants the Digivibe device and its contents to be free of defects in material and workmanship for a period of one year from the date of original purchase. If Digivibe exhibits such a defect, Bing Innovations, LLC will, at its option, repair or replace it without cost for parts or labor. The product must be shipped, prepaid, and insured (recommended) to Bing Innovations, LLC. Proof of date of original purchase is required.

The warranty does not cover damages resulting from accidents, misuse, water, tampering, unreasonable use, failure to provide reasonable and necessary maintenance, services performed or attempted by an unauthorized service agency, use of any tip other than those supplied by Bing Innovations, LLC.

The warranty extends only to the original purchaser and is not transferable.

User Profile

The Digivibe device by sūthe is the latest product innovation from Sting Innovations, LLC. The Digivibe device is designed to alleviate needle pain during injections and finger pricks or both. The user profile varies from a wide range of users who regularly administer or receives injections. The Digivibe device employs vibration technology making needle related procedures more comfortable. The Digivibe device by sūthe is appropriate for use with children younger than 12 years of age but must be operated by an adult for their safety.

IP rating: This device has an IP21 rating, which means that it is resistant to water being sprayed on it from the top only.

Do not service the Digivibe device while equipment is in use.

Radio Frequency Emissions

Class B Group 1

Suitable for use in all establishments, including those directly connected to a public low-voltage power supply network

ELECTROSTATIC DISCHARGE

IEC 61000-4-2

± 8 kV contact
± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air

Radiated RF EM fields

IEC 61000-4-3
Table 9 Proximity Fields from RF Wireless communications Equipment

10 V/m: 80 MHz – 2.7 GHz
80 % AM at 1 kHz

Power Frequency Magnetic Field

EN 61000-4-8

30A/M 50 or 60Hz

EMC

Phenomenon	Basic EMC standard or test method	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields [a]	IEC 61000-4-3	3 V/m [f] 80 MHz – 2.7 GHz [b] 80 % AM at 1 kHz [c]	10 V/m [f] 80 MHz – 2.7 GHz [b] 80 % AM at 1 kHz [c]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10	
Rated power frequency magnetic fields [d]	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Proximity magnetic fields	IEC 61000-4-39	See 8.11	

[a] [illegible]

[b] [illegible]

[c] Testing may be performed at other modulation frequencies identified by the risk management process.

[d] Applies only to ME equipment and ME systems with magnetically sensitive components or circuitry.

[e] [illegible]

[f] [illegible]

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	Home healthcare environment
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges [1] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [1] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [2,3]	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips [4]	IEC 61000-4-11	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	
Voltage interruptions [4]	IEC 61000-4-11	0 % U_T; 250/300 cycle	

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Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields [a]	IEC 61000-4-3	3 V/m [b] 80 MHz – 2,7 GHz [b] 80 % AM at 1 kHz [c]	10 V/m [b] 80 MHz – 2,7 GHz [b] 80 % AM at 1 kHz [c]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10.	
RATED power frequency magnetic fields [d]	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Proximity magnetic fields	IEC 61000-4-39	See 8.11.	

Digivibe by süthe

Bing Innovations, LLC 7606 NW 6th Ave., Boca Raton FL 33487 1-844-303-8423 www.sütheskinmd.com

CE

Digivibe Device:
Model Name: Digivibe by Süthe
Model Number: DigiD01

Lancing Device:
Model Name: Lancing Device
Model Number: LDF

Digivibe Kit:
Model Name: Digivibe Device and Lancing Device Kit
Model Number: DigiKit 001

Version: 20230616 Part: 7600-01, Rev 2

Manufactured in Mexico