

User Manual Pact Sense Muscle Scanner

PLEASE READ ALL INSTRUCTIONS PRIOR TO USE v1.1
Oct 2022

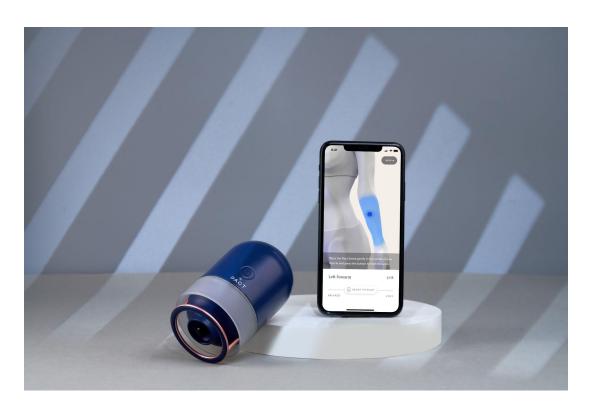




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Important Safety Information

READ ALL INSTRUCTIONS IN THIS MANUAL BEFORE USE SAVE THESE INSTRUCTIONS



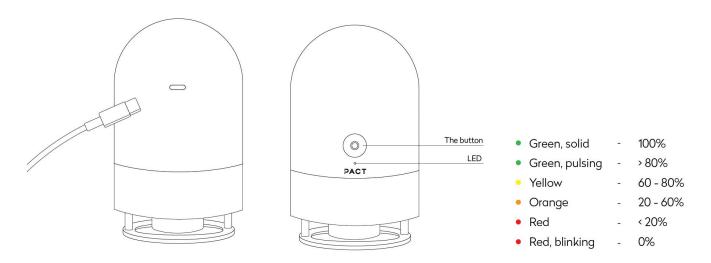
To reduce risk of burns, electric shock, fire, personal injury, and/or property damage, this product must be used in accordance with the following safety instructions:

- 1. This device is not intended for use by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning the use of the device by a person responsible for their safety. Close supervision is necessary when the device is used by, on, or near children, or individuals with certain disabilities.
- 2. Use this device only for its intended use as described in this manual.
- 3. Never operate this device if it is not working properly, if it has been dropped or damaged, or dropped into water. Never operate the charging cord or adapter if either is damaged. Return the device to an authorized service center for examination and repair.
- 4. Do not carry the device by the charging cord or use the cord as a handle.
- 5. Keep the device, charging cord, and charging adapter away from heated surfaces.
- 6. Do not use outdoors.
- 7. Do not drop the device. Dropping the device may cause it to malfunction.
- 8. Do not insert any object into any opening on the device.
- Do not use the device while bathing or in the shower. Do not place or store the device where it can fall or be pulled into a tub or sink. Do not place in or drop into water or other liquid.
- 10. Do not expose the device to water. Keep liquids away from ports, buttons, and other openings.
- 11. Do not remove screws or attempt to disassemble.
- 12. This device is not a toy. Adult supervision required. Children should be supervised to ensure that they do not play with the device
- 13. Use product only according to Instructional Use materials at https://thepact.com.

Quick Start

Charge Pact Sense

A charging cable and wall adapter are provided in the box. Charge the scanner by plugging in the cable into the USB-C charging port located on the back of the device. The light's color will indicate the charge level. A red blinking light indicates that the device must be charged before use.



Setup the Pact Mobile App

Scan the QR Code to install the app. Follow in-app instructions to create your account.



https://thepact.com/getting-started



Unboxing

When unboxing the Pact Sense, please check that the package has not been damaged during the shipping. In case of any damage to the package, please <u>contact Pact customer support</u> Open the package and compare its contents with the list of product items in the documentation. Each package should contain:

- One Pact Sense
- One USB-A to USB-C Charging Cable
- One 7.5W Power Adapter
- One Hard Shell Carry Case
- One Quick Start Guide bearing QR code access to the user manual

If the package does not contain each of the items listed above, contact the Pact customer support team immediately.

Impact Biosystems Inc. 5 Colebrook St Boston, MA 02127

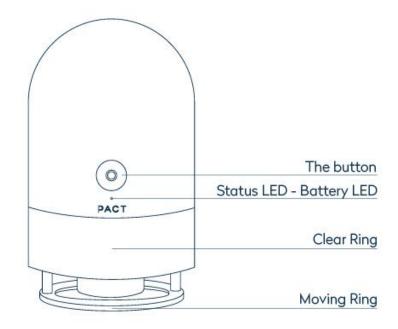
+1 (617) 237-0124 https://www.thepact.com/support support@thepact.com



Operation

SAVE THESE INSTRUCTIONS

This device is not intended to diagnose, treat, cure, or prevent any disease



Performing a Scan

- 1. To **power on**: press and hold button for 2 second until LED turns on
- 2. Enable **Bluetooth** on your mobile device
- 3. Use the **Pact App** to connect to your Sense
 - The Status LED will glow white when it is connected
- 4. Follow the app instructions to prepare your **scanning session**
- 5. Lightly **press** the Pact Sense into the target tissue
 - Follow app guidance for pressure and placement tips
 - Use on soft tissue only
- 6. **Tap the button** to start the measurement
- 7. Receive **results** in the app
- 8. To power off: press and hold button for 2 seconds until LED turns off



Signals are subject to change. Please refer to the online documentation and release notes for the most up-to-date information on device signaling.

Status LED

The Status LED is used to communicate the status of the device during setup, paring, use, and charging

- Off: device is powered down
- Breathing Blue: awaiting Bluetooth connection
- Solid White: connected to the app
- Slow Breathing White: ready to scan
- Fast Breathing White: performing measurement
- Solid Yellow: bootloader mode, waiting for firmware update
- While the device is charging, the LED will indicate charge status:
 - Solid Green: 100%Green, pulsing: > 80%
 - Yellow: 60-80%Orange: 20-60%
 - o Red: < 20%

Audio Signals

Beeps are used to communicate throughout the scanning process

- One beep: the scanner will beep at the end of each muscle group in the scanning flow to indicate that it's time to move on to the next muscle
- Two beeps: the scanner will beep twice if the button is pressed while the scanner is unable to scan. This usually means the app requires attention before you can complete the next scan

CAUTION: Immediately stop using the Pact Sense if you experience any pain or discomfort from using the device. Avoid using the Pact Sense on bruises, contusions, rashes, or irritated or injured areas of the body until they are fully healed.



Limited Warranty

Impact Biosystems, Inc. ("Company" or "we") warrants to the original purchaser or gift recipient only that the Pact Sense Device (the "Product") you purchased from Company shall be free from defects in materials and workmanship under normal use for a period of one (1) year from the date of retail purchase by the original purchaser ("Warranty Period"), as documented by a valid proof of purchase—e.g., receipt (or bank or credit card statement). If you order the Product via our website located at www.thepact.com/sense, the Warranty Period starts on the date of purchase.

A manufacturer's limited warranty is included with your Pact Sense device for one year from the purchase date. To be covered under the warranty, all you need is your receipt. If your device was a gift, just gently twist the gift-giver's arm for proof of purchase (a bank or credit card statement is fine if they can't find a receipt).

- 1. REMEDIES. If a defect in the Product's hardware arises and a valid claim is received by Company within the Warranty Period, Company will, at its option and to the extent permitted by law, either (1) repair the Product at no charge, using new or refurbished replacement parts, or (2) exchange the Product with a new or refurbished Product. If Company, in its sole discretion, determines it is not reasonable to replace the defective Product, Company may refund to you the purchase price paid for the Product. In the event of a defect, to the extent permitted by law, these are your sole and exclusive remedies. You may be responsible for payment of shipping and handling charges for the delivery of a repaired or replacement Product, except where prohibited by applicable law. This Limited Warranty is valid only in the jurisdictions where the Products are sold by Company and is valid to the extent permitted by the applicable laws of such jurisdictions. Any replacement Product will be warranted for the remainder of the original Warranty Period or thirty (30) calendar days, whichever is longer, or for any additional period of time that may be applicable in your jurisdiction.
- 2. HOW TO OBTAIN WARRANTY SERVICE. To obtain warranty service under this Limited Warranty, please contact our Customer Service team at support@thepact.com to begin your claim. You must deliver the Product, in either its original packaging or packaging providing an equal degree of protection, together with proof of purchase, to the address specified by Company. By sending the Product, you hereby acknowledge that ownership of the Product is transferred to Company upon Company's receipt of the defective Product. If the claim is justified based on this Limited Warranty, Company shall bear the cost of shipping the repaired or replacement Product to you. Any Product returned to Company without a valid warranty claim may be rejected and returned at your cost (subject to prepayment). For specific instructions on how to obtain warranty service on your Product, visit the Company website at www.thepact.com/warranty

3. EXCLUSIONS AND LIMITATIONS. This Limited Warranty applies only to Products manufactured by or for Company that can be identified by the Pact trademark, trade name, or logo affixed to it. The Limited Warranty does not apply to, and the term "Product" shall not include, any (a) Company products and services other than the Product, or (b) software, even if packaged or sold with the Product or embedded in the Product (e.g., firmware and/or system software), and including our Pact Mobile Application ("**Company Software**"). Please refer to the applicable licensing agreement that covers such Company Software for details of your rights with respect to its use.

This Limited Warranty does not apply to any damage to the Product caused by: (a) use with non-Company products; (b) accident, abuse, misuse, spillage of food or liquid, mishandling, transport or other external causes; (c) operating the Product outside the permitted or intended uses described by Company; (d) failure to follow the Product's use, storage, or care instructions or use of improper voltage or power supply; or (e) service performed by anyone who is not an authorized service representative of the Company. This Limited Warranty also does not apply to cosmetic damage to the Product, including but not limited to scratches or dents or defects or parts requiring replacement due to ordinary wear and tear, corrosion, rust or stains, scratches, dents on the casing or paintwork of the Product. This Limited Warranty excludes Products where you fail to provide a dated proof of purchase or Products where the serial number has been removed.

Recovery and reinstallation of software programs and user data are not covered under this Limited Warranty. It is your responsibility to backup any data, software, or other materials you may have stored or preserved on the Product. It is likely that such data, software, or other materials will be lost or reformatted during the performance of any warranty service, and Company will not be responsible for any such damage or loss.

Company does not warrant that the operations of the Product will be uninterrupted or error-free.

No Company employee is authorized to make any modification, extension, or addition to this Limited Warranty. If any term of this Limited Warranty is held to be illegal or unenforceable, the legality or enforceability of the remaining terms shall not be affected or impaired.

- 4. IMPLIED WARRANTIES AND CONDITIONS. EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, ALL IMPLIED WARRANTIES AND CONDITIONS (INCLUDING WARRANTIES AND CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) SHALL BE LIMITED IN DURATION TO THE DURATION OF THIS LIMITED WARRANTY. SOME STATES DO NOT ALLOW LIMITATIONS ON THE DURATION OF AN IMPLIED WARRANTY, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS THAT VARY FROM STATE TO STATE.
- 5. LIMITATION OF DAMAGES. EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, COMPANY SHALL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL, OR CONSEQUENTIAL DAMAGES, OR ANY LOSS OF PROFITS, REVENUE OR DATA, RESULTING FROM ANY BREACH OF EXPRESS OR IMPLIED WARRANTY OR CONDITION, OR UNDER ANY OTHER LEGAL THEORY, EVEN IF COMPANY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND REGARDLESS OF THE FORM OF ACTION WHETHER IN CONTRACT,



TORT (INCLUDING NEGLIGENCE) OR ANY OTHER LEGAL OR EQUITABLE THEORY. Some jurisdictions do not allow the exclusion or limitation of special, indirect, incidental, or consequential damages, so the above limitation or exclusion may not apply to you.

- **6. GOVERNING LAW**. This Limited Warranty shall be governed by the laws of the Commonwealth of Massachusetts, USA, without giving effect to any conflict of laws principles that may require the application of the law of another jurisdiction.
- **7. NATIONAL STATUTORY RIGHTS**. Consumers in some jurisdictions may have legal rights under applicable national legislation governing the sale of consumer goods, including, without limitation, national laws implementing EC Directive 99/44. These rights are not affected by the warranties in this Limited Warranty. If you have any questions, please contact the Company at: support@thepact.com.

Please view the full terms and conditions of the limited warranty at:

https://www.thepact.com/warranty





Maintenance

Cleaning the Measurement Probe

The external surfaces of the Pact Sense can be cleaned with a dry soft cloth. Avoid getting water and other liquids inside the device. Alcohol wipes can be used to disinfect surfaces that come in contact with skin, such as the measurement probe and moving ring.

To enter cleaning/test mode:

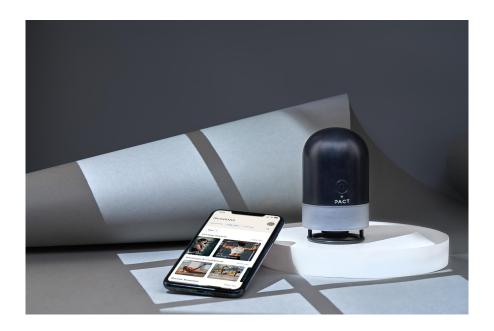
- Power the device on
- Do NOT connect the device the Pact Muscle Recovery app
- Enter cleaning/test mode by triple tapping the button
- Use an alcohol wipe to gently clean probe
- Single tap the button to exit cleaning/test mode

Manufacturer Servicing

Pact Sense has no user-serviceable parts. Damage resulting from user servicing is not covered under the limited warranty. Repairs, battery change, calibration and testing can be performed only by Impact Biosystems. See www.thepact.com/warranty for full details on warranty coverage. Contact support@thepact.com for servicing requests.

Storage

- ullet Store the Pact Sense in a dry location, between 0 $^{\circ}$ C 40 $^{\circ}$ C
- Intended for indoor use only
- Operating temperature: 5 °C 40 °C (40 °F 105 °F)
- Relative air humidity: 0 50% RH
- When not stored in the carry case, the Pact Sense should be placed on a flat surface with the moving ring side facing down (as seen below).



Pact Sense (Carbon color) with Pact Mobile App

Technical Specifications

Pact Sense Device Type and Measurement Method

Classification Category

Monitoring device for non-vital physiological parameters

Type of Device

• In vivo, non-invasive, mechanical measurement device for soft biological tissues

Measurement Sensor

- 2 x digital linear position sensors: 0 10 mm
- 2x Inertial Measurement Unit
- Current sensor

Measurement probe drive

Linear Lorentz force actuator

Measurement probe force/pressure

0 - 5 N / 64 kPa

Measurement method

• The Pact Sense applies a proprietary force waveform to the tissue and measures the underlying tissue response

Measurable parameters

- **Stiffness** [N/m] Amount of force produced by the skin, as a result of the measurement probe depressing into the tissue
- **Stiffness Slope** [N/m²] Relationship between stiffness and depth of the measurement probe when depressed into the tissue
- **Damping** [Ns/m] Degree to which your muscles resist the end-effector's motion.
- **Damping Slope** [Ns/m²] Relationship between damping and depth of the measurement probe when depressed into your soft tissue

System Precision

Coefficient of Variation when measured against Dragon Skin[™] 20A

Stiffness: 0.08%Stiffness Slope: 1%Damping: 0.15%Damping Slope: 5%

Signal Processing

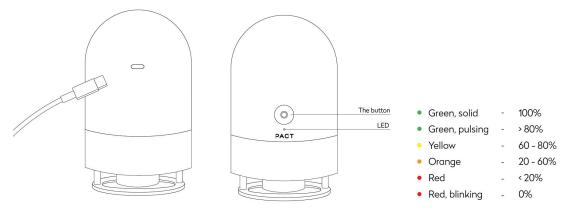
• Proprietary algorithms for waveform generation & parameter extraction

Charging

Battery	 Built-in rechargeable Lithium Polymer Battery 680mAh, 7.4V, 5.03Wh Do not attempt to disassemble the battery 	
Charger	 AC-DC Adapter, Input AC 100-240V 50/60Hz Output DC 5.0V, 1.5A, 7.5Watts, USB type A socket USB-C Port, 5.0V, 500mA 	
Recharge time	60 minutesLED will display solid green for full charge	
Recharge cycles	Min 500 cycles	
Single Charge operation period	Min 1,000 measurements	
Power management	 Automatic shut-down in 10 minutes with Bluetooth connectivity Automatic shut-down in 5 minutes without Bluetooth connectivity 	

Status LED while Charging

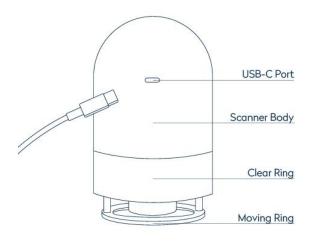
While the device is charging, the LED will indicate charge status:

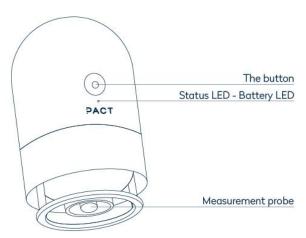


WARNING: For the purposes of recharging the battery, only use the detachable supply unit provided with this appliance.



Dimensions and Weight





Product:

Height	110 mm
Diameter	70 mm
Weight	340 g



Packaging

Height	75 mm
Width	100 mm



Depth	180 mm
Weight (with device and charger)	550 g

Device Firmware

Firmware Upgrades

- 1. Turn the Pact Sense on and connect to it via Bluetooth using the Pact Mobile App.
- 2. Go to Settings by clicking the gear icon
- 3. Click on "Update Firmware"
- 4. Follow the on-screen instructions to complete the update process

See Troubleshooting for help with firmware update issues

Checking Firmware Version and Bluetooth Address

- 1. Turn the Pact Sense on and connect to it via Bluetooth using the Pact Mobile App.
- 2. Go to Settings by clicking the gear icon
- 3. Scroll to the bottom of the Settings page. The Pact Sense's information will be displayed as follows:
 - Scanner Firmware version
 - Scanner UUID (Bluetooth address)



Troubleshooting

Device Not Powering On

- Press and hold the button for 2 seconds
- If device does not turn on, connect the device to the provided charger and connect the wall adapter to a powered wall outlet
- If no LED indication occurs, try removing and reconnecting the USB-C cable
- Triple tap the button to attempt to enter cleaning/test mode
 - o If LED remains off, but measurement probe moves, the LED may be broken
- If LED indication still does not turn on and the device will not enter cleaning/test mode contact support@thepact.com for assistance

Charging

- If LED indication does not turn on after plugging in a USB-C charging cable, ensure that the included 7.5W wall adapter is being used
- Connect the wall adapter to a powered wall outlet
- If no LED indication occurs, try removing and reconnecting the USB-C charging cable
- Triple tap the button to attempt to enter cleaning/test mode
- If LED indication still does not turn on contact support@thepact.com for assistance

Cleaning/Test Mode

- Power the device on
- Do NOT connect the device the Pact Muscle Recovery app
- Enter cleaning/test mode by triple tapping the button
- Use an alcohol wipe to gently clean probe
- Single tap the button to exit cleaning/test mode
- Expected behavior
 - The measurement probe will stick out
 - Changing the position of the moving ring will result in the measurement probe moving as well
 - The LED will cycle through red, green, and blue, as a result of the moving ring position

Bluetooth Pairing

Follow the in-app instructions to connect your phone to the device via Bluetooth



LED Glowing Yellow

- If your scanner was accidentally placed in Firmware Update Mode (the LED is glowing yellow), press and hold the button until the LED glows white. This puts the device in normal operation mode
- If a firmware update started but did not complete successfully, you will need to restart and complete the firmware update before you can use the device again
- Retry the update by going to Settings > Update Firmware within the app

SAVE THESE INSTRUCTIONS

FCC Compliance

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

Change Log

Version	Change
v1.1	 Update warranty information Update figures Formatting updates
v1.0	Initial Release

