

PATIENT GUIDE

How to use
and care for
your Jewel

Jewel



WEARABLE PATCH DEFIBRILLATOR

PATIENT NAME: _____

PHYSICIAN NAME: _____

EMERGENCY CONTACT: _____

JEWEL DEFIBRILLATOR UNIT SERIAL NUMBER(S): _____

CUSTOMER SERVICE

1-800-985-5702

customerservice@elementsci.com

ELEMENT SCIENCE, INC.

301 Chesapeake Dr.

Redwood City, CA 94063

www.elementscience.com/manuals

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1
**ABOUT
THE JEWEL®**

1.1 INTRODUCTION TO THE JEWEL

ABOUT THE JEWEL

The Jewel is a Wearable Patch Defibrillator that is worn outside the body and is attached with adhesive patches.

Much like an implantable cardioverter defibrillator (ICD), the Jewel will continuously monitor your heart and can detect specific life-threatening heart rhythms that can lead to Sudden Cardiac Arrest (SCA). Sudden Cardiac Arrest occurs when the heart’s electrical system stops functioning correctly. This type of heart condition can be treated with an electrical shock, which resets the electrical activity of the heart to restore its function to normal.

When the Jewel detects life-threatening ventricular tachycardia or ventricular fibrillation, it will be able to save your life by delivering an electrical shock. The electrical shock passes between the Upper and Lower Patches, through your chest, and restores your heart’s electrical activity back to normal. The Jewel alarms before an electrical shock is given so that you can cancel the electrical shock if you are conscious.

ABOUT THIS PATIENT GUIDE

Please read this patient guide closely. It describes how to use your Jewel safely and effectively.

- 1. About the Jewel** tells you important safety information about the Jewel. It includes information about activities that could lead to serious injury or death. The indications for use, intended use locations, and symbol definitions are found in this section. This section also introduces you to the components of the Jewel and Placement Accessory as well as the contents of each box. The Jewel Mobile App is also covered in this section.
- 2. Daily Use** tells you about daily living with the Jewel and what activities you should and should not do. This section also includes frequently asked questions.
- 3. Applying Your Jewel** walks you through all the steps to apply the Jewel including: preparing your skin, assembling the Patch Unit and Defibrillator Unit, turning on the Jewel, loading and aligning the Placement Accessory, and applying the Jewel to your body.
- 4. Notifications** tells you about all the notifications you can receive from the Jewel. This section tells you why you received a notification and what actions you should take in response.
- 5. Removing Your Jewel** walks you through all the steps to remove the Jewel including entering Removal Mode, removing the Jewel from the body, cleaning your skin, and disassembling the Patch Unit from the Defibrillator Unit.
- 6. Returning Your Patch Units and Defibrillator Unit** takes you through the steps to return used Patch Units and Defibrillator Unit to Element Science.
- 7. Troubleshooting** helps answer any questions you have about your experience with the Jewel.
- 8. Index** can help you quickly find topics of interest.

WHO SHOULD USE THE JEWEL?

INDICATIONS FOR USE

The Jewel Wearable Cardioverter Defibrillator (WCD) is indicated for patients 18 years of age and older who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator.

WHO SHOULD NOT USE THE JEWEL?


CONTRAINDICATIONS

DO NOT USE the Jewel on patients who have an active Implantable Cardioverter Defibrillator (ICD).

SAFETY INFORMATION

Read and understand the warnings, cautions, and symbols before using the Jewel. This information will help you safely operate the Jewel.

TERMS USED

**WARNING:** A situation which, if not avoided, could result in death or serious injury.

CAUTION: A potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or damage to the equipment or other property.

See following pages for Warnings, Cautions and Important Patient Considerations.

WARNINGS

- Do NOT use the Defibrillator Unit or apply Patch Units if any component is broken or defective.
- Do NOT stress the connection cable. If the cable is stressed, the Jewel may be damaged, potentially leading to an inappropriate electrical shock or no shock delivered when needed.
- Do NOT apply the Patch Unit after the use by date. Applying the Patch Unit after the use by (expiration) date could result in an electrical shock not given when needed and may impact product performance.
- Do NOT apply the Patch Unit if the seal is open. An open pouch seal may allow the Patch Unit electrodes to dry out, resulting in an ineffective electrical shock.
- ALWAYS ensure the Jewel is in the correct location on the body. Always use the Placement Accessory while applying the Jewel. Do NOT skip alignment steps or adjust the settings of the Placement Accessory, which could result in the Jewel being applied in the wrong location. Applying the Jewel in the wrong location could result in an electrical shock not given when needed or in an ineffective shock.
- Do NOT put anything between the Jewel and the skin. Placing anything between the Jewel and the skin could result in an electrical shock not given when needed or in an ineffective electrical shock.
- ALWAYS press both buttons to defer therapy delivery if the patient is conscious when hearing the siren alarm. If the patient does NOT press both buttons, an electrical shock will be delivered.
- ONLY the patient should press the buttons to defer therapy. Anyone other than the patient pressing the buttons during the siren alarm may result in an electrical shock not given when needed.

CAUTIONS

- AVOID unusually high levels of electromagnetic interference. In the event of electromagnetic interference, the Jewel will issue an electromagnetic interference alert. In this situation,the Jewel will return to normal monitoring mode in approximately 30 seconds.
- The Jewel must not be worn during magnetic resonance imaging (MRI), an X-ray, a computed tomography (CT) scan, radiation therapy, diathermy therapy, or a procedure requiring the use of electrocautery.

- The Jewel is suitable in hospital environments except near active HF surgical equipment or the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- Portable RF communications equipment (including mobile phones and peripherals such as antenna cables and external antennas) should NOT be operated closer than 30cm (12 inches) to any part of the Jewel P-WCD, including cables.
- AVOID use of the Jewel adjacent to or stacked with other equipment. This may result in improper operation. If such use is necessary, observe the equipment to verify normal operation.
- No more than one FDA-cleared or FDA-approved, DEFIBRILLATION PROOF device should be used concurrently with the Jewel.
- The Jewel should NOT be used on patients with an implantable pacemaker that produces a pacemaker pulse artifact greater than 0.5mV on any Jewel ECG channel. Artifact may interfere with the system’s ability to detect dangerous heart rhythms and prevent shock delivery.
- The Jewel should NOT be installed on an aircraft as “Airborne Equipment.” The Jewel may be used by the patient while traveling by air.
- When wearing the Jewel do not pass through airport body scanners (backscatter x-ray or millimeter wave technologies).
- The Jewel should NOT be worn on railway systems while traveling internationally (Outside of the United States).
- Do NOT use the Jewel in the presence of flammable agents or in an oxygen enriched atmosphere. This could present an explosion and fire hazard.
- Do NOT use accessories, transducers and cables other than those provided for use with the Jewel. This may result in increased electromagnetic emissions , decreased electromagnetic immunity and/or improper operation.
- Do NOT tamper, alter, drop, or abuse any part of the Jewel system. There are no user-serviceable components in the Jewel. Altering the Jewel could create an electrical safety hazard or malfunction, which may cause an electrical shock.
- The Jewel should NOT be used by patients with known allergies to medical grade adhesives and conductive hydrogels.
- Do NOT apply patches to broken, damaged skin or open wounds. This may result in damage to skin, infection or allergic dermatitis.
- Skin burns may occur due to heating of the device during charging prior to defibrillation.
- Do NOT touch the patient while an electrical shock is being given. Anyone touching the patient during an electrical shock may also receive an electrical shock.

- Do NOT remove the Patch Unit plastic backings until ready to apply the Jewel. Dust and lint may impact the Patch Unit adhesive’s ability to stick to the body. Prolonged sunlight may degrade electrode signal quality and result in early Patch replacement.
- Do NOT place other electrodes or metal items in contact with the Jewel.
- Do NOT submerge the Jewel in water or any liquid. Submerging the Jewel may allow liquid to enter the device and could cause a malfunction.
- Do NOT dispose of or incinerate the Jewel Defibrillator Unit or Patch Units. The batteries contain lithium ion and must be returned to Element Science for proper disposal.
- Do NOT assemble or disassemble the Defibrillator Unit from the Patch Unit while in a wet or humid environment. This may damage the Defibrillator Unit.
- Do NOT touch the battery electrical connections or place anything in the recessed areas on the Patch Unit or Defibrillator Unit. This may result in skin injury or device malfunction.

- In some occupational and hospital environments, unusually high levels of electromagnetic interference may be encountered. In the event of electromagnetic interference, the Jewel will issue an electromagnetic interference alert. In this situation,the Jewel will return to normal monitoring mode in approximately 30 seconds after the patient has moved away from the source of interference. The Jewel is still capable of providing an electrical shock during the electromagnetic interference alert.
- If the plastic housing containing the buttons on your Defibrillator Unit has been damaged or possibly tampered with exposing access to the Defibrilator Unit electronics immediately contact Customer Service at 1-800-985-5702 to replace your Defibrillator Unit.

IMPORTANT CONSIDERATIONS FOR PATIENTS

- Do NOT use the Jewel or the accessories until trained by Element Science certified personnel and thorough review of the Patient Guide. Incorrect use might lead to misunderstanding the information provided by the Jewel.
- ALWAYS wear the Jewel when instructed to do so by a medical professional. If traveling for longer than 24 hours, the patient should bring additional Patch Units, along with all application and removal accessories.
- ALWAYS keep the Jewel in an environment according to the storage and operating parameters (refer to storage and cleaning instructions below). Do NOT attempt to use home appliances such as a hair dryer, microwave, refrigerator, or freezer to heat up or cool down the Jewel or the Patch Unit.
- ALWAYS turn on the Jewel before applying it. Do NOT apply the Jewel if the lights, speaker, or vibration motor are not working. When turning on the device, the patient should feel the device vibrate, see a green light, and hear “Jewel is in Application Mode. Apply Jewel now using Placement Accessory.”
- ALWAYS listen to the Jewel notifications and respond in a timely manner. Failure to follow the instructions provided by the Jewel, such as replacing the Patch Unit, may result in the Jewel not performing as intended.

ELECTROMAGNETIC INTERFERENCE

Many common devices, including motors and electronic equipment, may produce electromagnetic interference that can affect the operation of the Jewel.

The Jewel has been tested with a number of common sources of such electromagnetic interference, including cellular telephones, airport security systems, and anti-theft detection systems.

Anti-theft detection systems, also known as electronic article surveillance systems, are often used in department stores and libraries to prevent theft by electronically sensing a special tag on a piece of merchandise when the tag passes through a detector gate. In the U.S., these detector gates are commonly located near the doorways. In Europe, the detector gates may be near the checkout areas.

To prevent possible interference with the Jewel, follow these simple guidelines when passing through security or anti-theft detection systems:

- Walk through the gate at a normal pace.
- Avoid lingering near or leaning on the gate.
- Once you have walked through the gate, keep a distance of at least 1.5 feet from the gate.
- Remaining near a security gate for an extended period of time may result in alerts from the Jewel.

In some occupational and hospital environments, unusually high levels of electromagnetic interference may be encountered. Examples of possible sources of such interference include: communication equipment such as microwave transmitters, arc welding equipment, high voltage transmission lines, electrocautery systems, and electronic muscle stimulators. These environments should be avoided while wearing the Jewel.

In the unlikely event that the electromagnetic interference causes you to receive an Electromagnetic Interference Alert move away from the source of the interference. The Jewel should return to normal Monitoring Mode approximately 30 seconds after you have moved away from the source of Electromagnetic Interference. Jewel is still capable of providing an electrical shock during the time you hear this Electromagnetic Interference Alert.

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WHERE SHOULD YOU USE THE JEWEL?

INTENDED OPERATOR, USE, AND LOCATIONS



























The Jewel is intended for use by patients prescribed the Jewel by a physician. An Element Science representative fits and trains the patient on proper use and care of the Jewel. The patient will be the primary operator of the Jewel.

The Jewel is designed to be worn continuously and intended for use by the patient during normal daily activities. It is expected to be used in environments common to daily living, including:

- Hospital
- Ambulatory patient center / outpatient
- Home
- Public transportation
- Automobile
- Workplace
- Gyms or physical therapy locations
- Showering
- Commercial Air Travel

See Chapter 2 Daily Use and FAQ’s for guidance when visiting a hospital and traveling with the Jewel.

SYMBOL DEFINITIONS

	Manufacturer		Defibrillation proof Type BF applied part voltage
	Catalog or Model Number	IPN1N2	Degree of Ingress Protection Provided by Enclosure
	Serial Number		Single patient, multiple use
	Batch Code Number		Do not reuse
	Use by		Non sterile
	Follow instructions for use or follow electronic instructions for use.		Do not use if package is damaged and consult instructions for use.
	Consult instructions for use or consult electronic instructions for use.		Recycle: Electronic Equipment
	Caution: Read all warnings and precautions in instructions for use		Medical device
	Storage humidity range		Unique device identifier
	Storage temperature range		Non-ionizing electromagnetic radiation
	Magnetic Resonance (MR) unsafe		Fragile, handle with care
	Keep away from sunlight unsafe		Prescription only
	Keep dry	FCC ID:OH2XXXX	Federal Communication Commission Identifier (FCC ID #)
			Bluetooth® wireless or enabled technology
			Flame

1.2 GETTING TO KNOW YOUR JEWEL

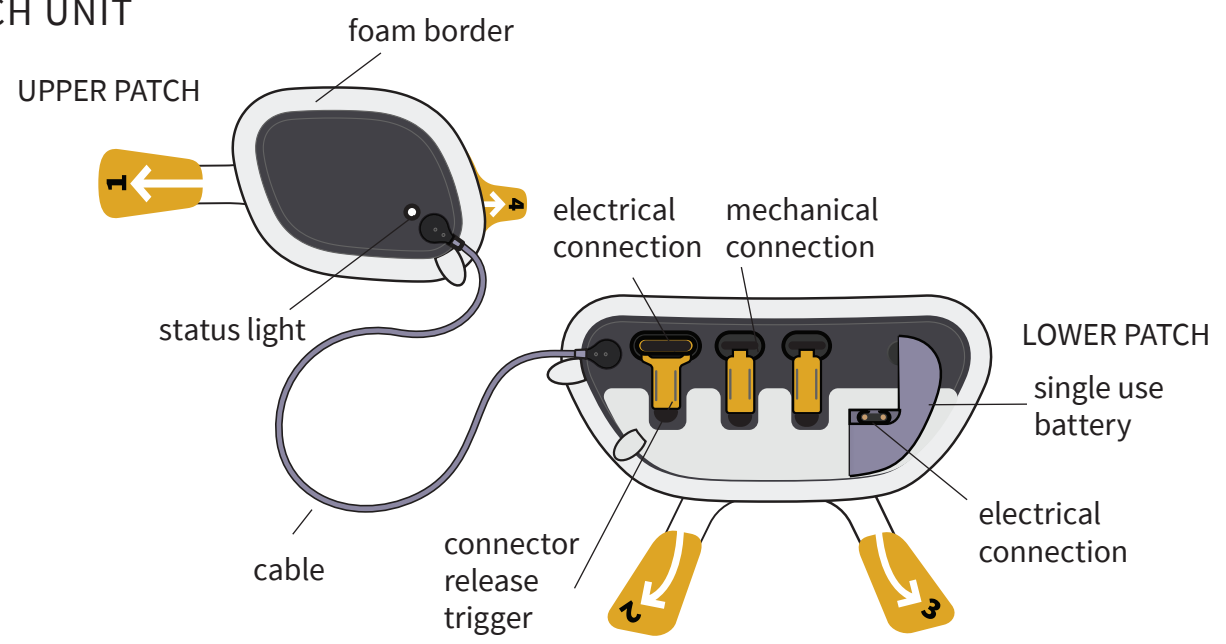
THE JEWEL COMPONENTS

The Jewel is designed to be applied directly to your skin on the upper right chest and lower left torso to continuously monitor your heart.

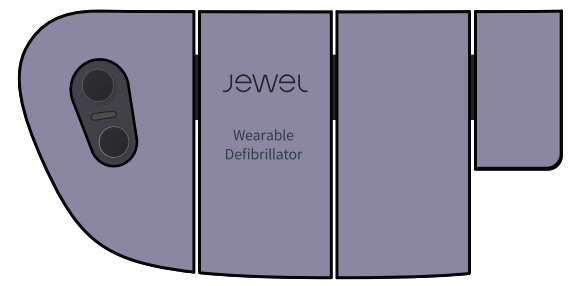
The Jewel consists of an Upper Adhesive Electrode Patch, Connection Cable, Lower Adhesive Electrode Patch and Battery Unit, collectively referred to as the Patch Unit, as well as a reusable Defibrillator Unit. The Jewel is designed to be placed and worn beneath all clothing, including undergarments.

If the Jewel detects specific life-threatening heart rhythms, it delivers an electrical shock to restore normal rhythm. The Jewel can be worn continuously, 24-hours per day for up to 8 days until it is removed and replaced with a new Patch Unit. Once the Jewel has been removed from your body, the used Patch Unit cannot be re-used. The Defibrillator Unit is intended to be reused with multiple Patch Units throughout the duration of a prescription.

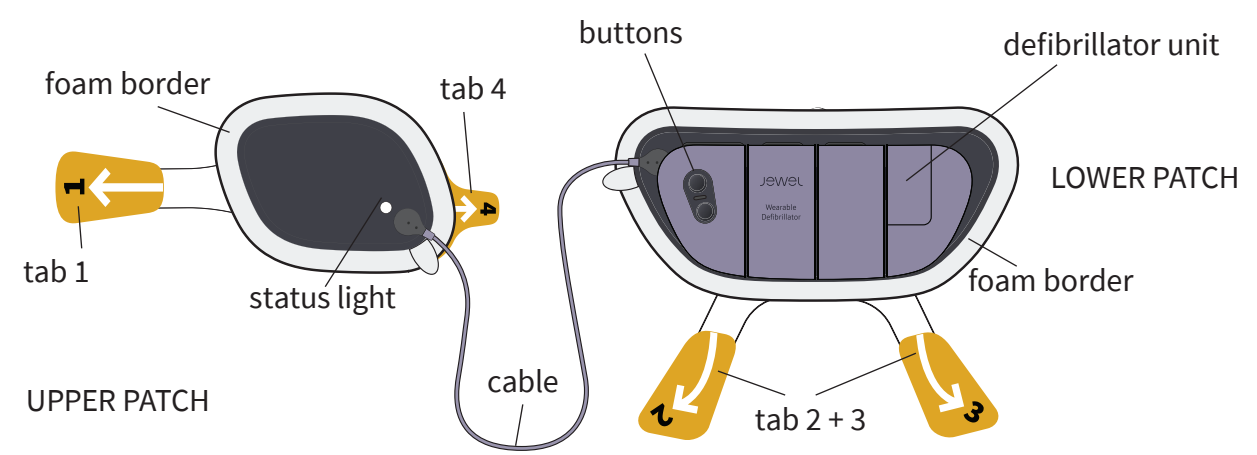
PATCH UNIT



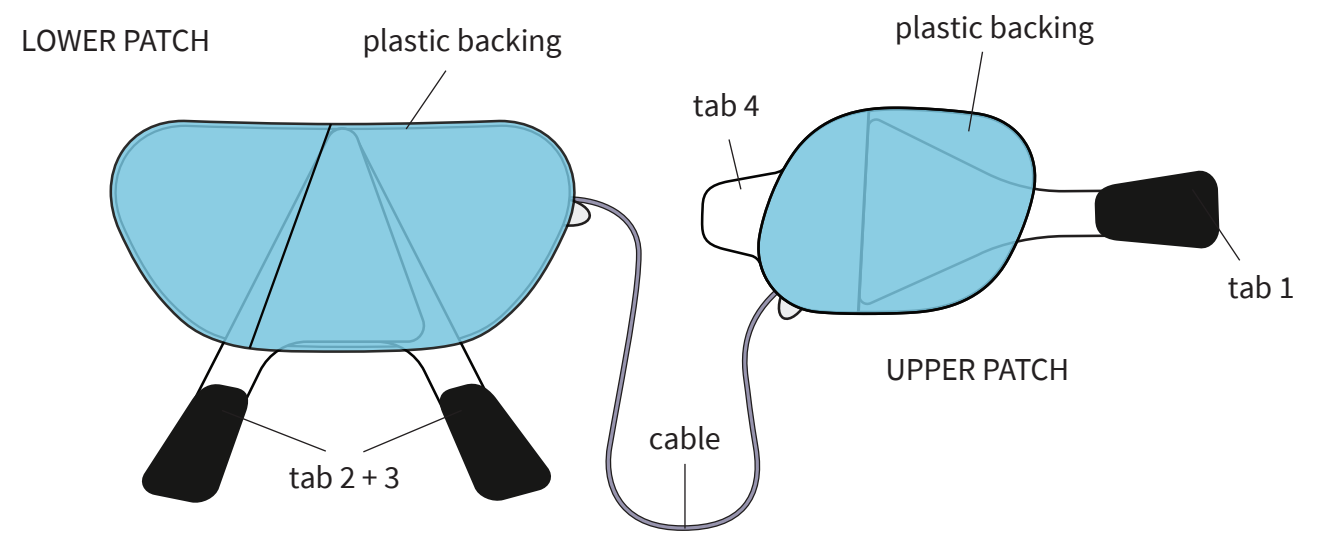
DEFIBRILLATOR UNIT



THE JEWEL OUTER SIDE



THE JEWEL SKIN SIDE



THE JEWEL COMPONENTS CONTINUED

DEFIBRILLATOR UNIT

The Defibrillator Unit of the Jewel is reusable and contains all system electronics. The electronics within the Defibrillator Unit monitor your heart and provide an electrical shock if needed. The Buttons are located on the Defibrillator Unit. The Defibrillator Unit also contains four connection interfaces to connect to the Lower Patch and Battery Unit. The Defibrillator Unit must be properly connected to the Lower Patch and Battery Unit for the Jewel to operate as intended.

UPPER PATCH

The Upper Patch of the Patch Unit is a single-use, conformable adhesive patch containing ECG electrodes and a defibrillation electrode. The adhesive patch is made up of various medical grade adhesives (including hydrogel and hydrocolloid) and contains some of the sensing electrodes and an electrical shock pad. It is approximately 6.8 inches x 5 inches and will be placed on your upper right chest, below the collar bone.

CONNECTION CABLE

The connection cable is a single-use multi-conductor cable assembly permanently connecting the Patch Unit.

LOWER PATCH

The Lower Patch of the Patch Unit is a single-use, conformable adhesive patch containing ECG electrodes, a defibrillation electrode, and batteries for powering the electronics contained in the Defibrillator Unit. The Lower Patch has a permanently attached Battery Unit and also contains four connectors which attach to the interfaces of the Defibrillator Unit. The adhesive patch is made up of various medical grade adhesives (including hydrogel and hydrocolloid) and contains some of the sensing electrodes and an electrical shock pad. The Lower Patch is approximately 5.3 inches x 11.3 inches and will be placed on the lower left torso.

CONNECTORS

The connectors on the Lower Patch are used to mechanically and electrically connect to the Defibrillator Unit. All connections have to be secured for the Jewel to operate as intended.

BUTTONS

The two buttons located on the Defibrillator Unit are used to turn the Jewel on, cancel an electrical shock, check the status of the Jewel and put the Jewel into Removal Mode. To cancel an electrical shock, press and release both buttons.

STATUS LIGHTS

Status lights are located on the Upper Patch and the Lower Patch. During normal monitoring, no lights will be flashing. If the Jewel detects specific life-threatening heart rhythms, the lights on both the Upper and Lower Patch will flash red. The lights on the Upper and Lower Patch will also flash to communicate replacement alerts and other notifications. See voice prompts in *Chapter 4: Notifications*.

PLASTIC BACKINGS

Plastic backings cover the adhesive on the Upper Patch and the Lower Patch. The plastic backings prevent the device from sticking to your body before it is in the correct location. The plastic backings should not be removed until the Jewel is turned on, loaded into the Placement Accessory and the Placement Accessory is in the correct location on your body.

TABS

Each tab is attached to a portion of the plastic backing. Pulling the tab removes the plastic backing from the patch to apply the device to the body. The tabs should not be pulled until the Jewel is turned on and the Placement Accessory is in the correct location. Each tab is meant to be pulled in a specific direction to help apply the Jewel correctly to your body. For more information, see *Chapter 3: Application*.

THE PLACEMENT ACCESSORY

The Placement Accessory is designed to be used to apply the Jewel throughout your entire prescription duration.

The Placement Accessory should be returned to Element Science at the end of the prescription duration. If you are concerned that your Placement Accessory no longer fits, see *Chapter 7: Troubleshooting*.

Store your Placement Accessory in a cool, dry area. Do not set anything on top of it or allow it to become compressed between other items. If your Placement Accessory becomes bent or twisted, it may lead to incorrect alignment and placement of the Jewel in the wrong location. Call Customer Service (1-800-985-5702) if you feel your Placement Accessory may have become warped or damaged.

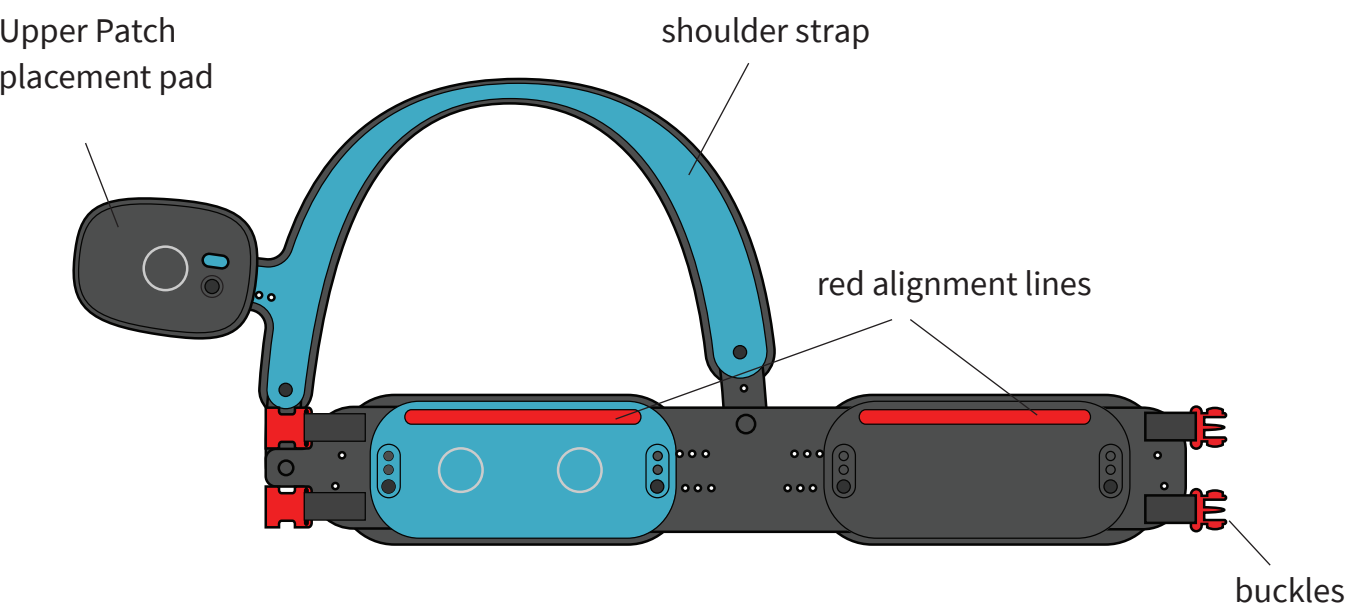
If the Placement Accessory gets dirty, wipe it with a water dampened cloth. Do not use soap. Do not put the Placement Accessory in automatic washer or dryer.

RED BUCKLES AND RED ALIGNMENT LINES

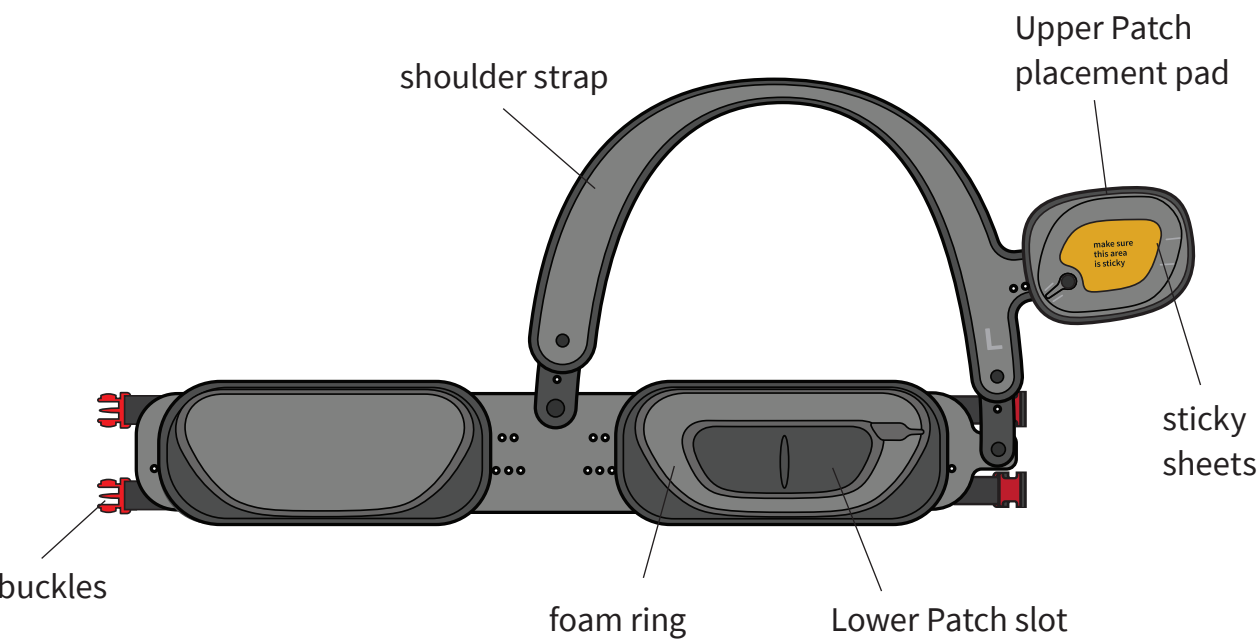
Red Buckles and Red Alignment Lines on the Placement Accessory are used to help you align the Placement Accessory in the correct location before applying the Jewel. See Aligning the Lower Belt, *Chapter 3 Section 3, Application Preparation*.

PLACEMENT ACCESSORY COMPONENTS

PLACEMENT ACCESSORY OUTER SIDE

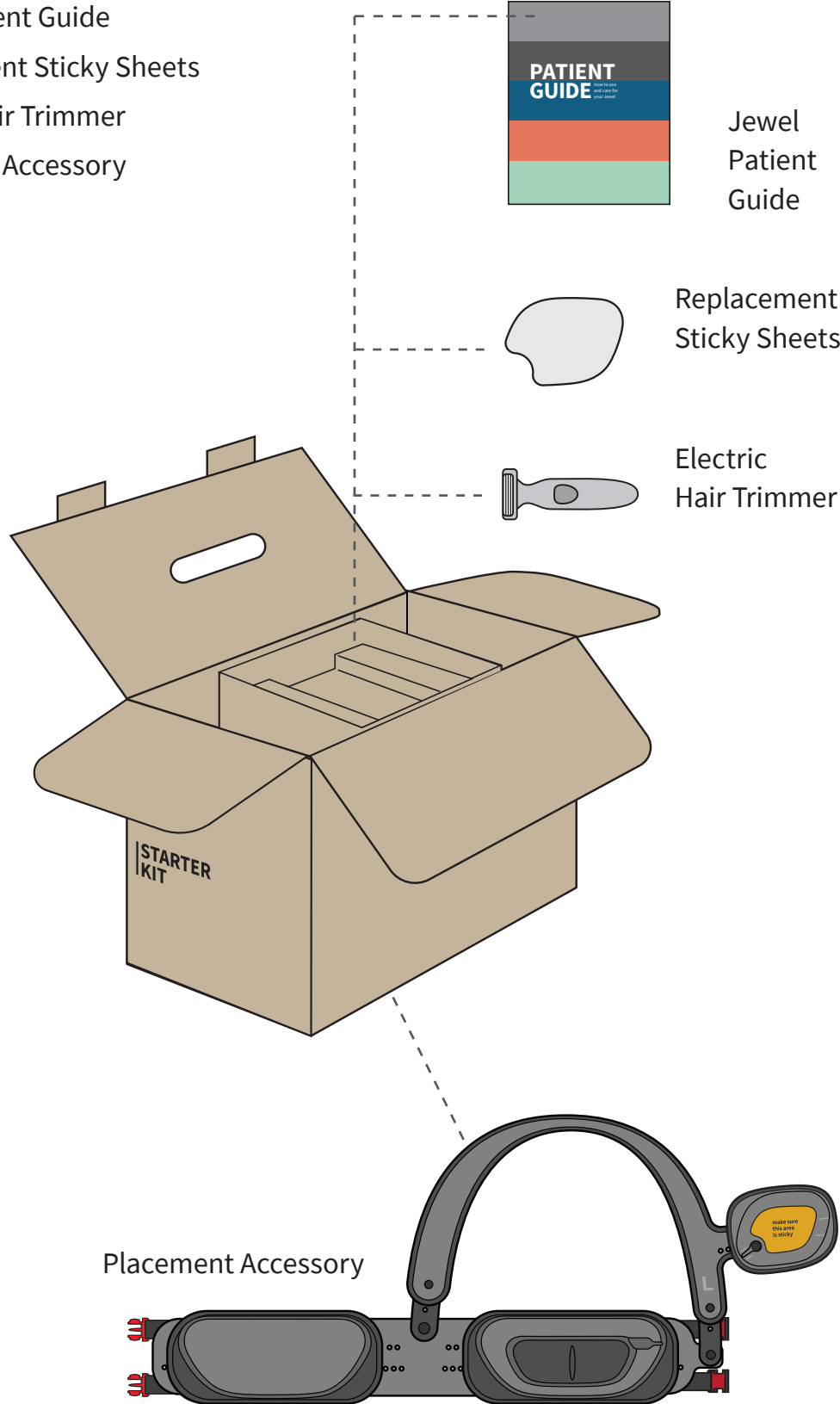


PLACEMENT ACCESSORY SKIN SIDE



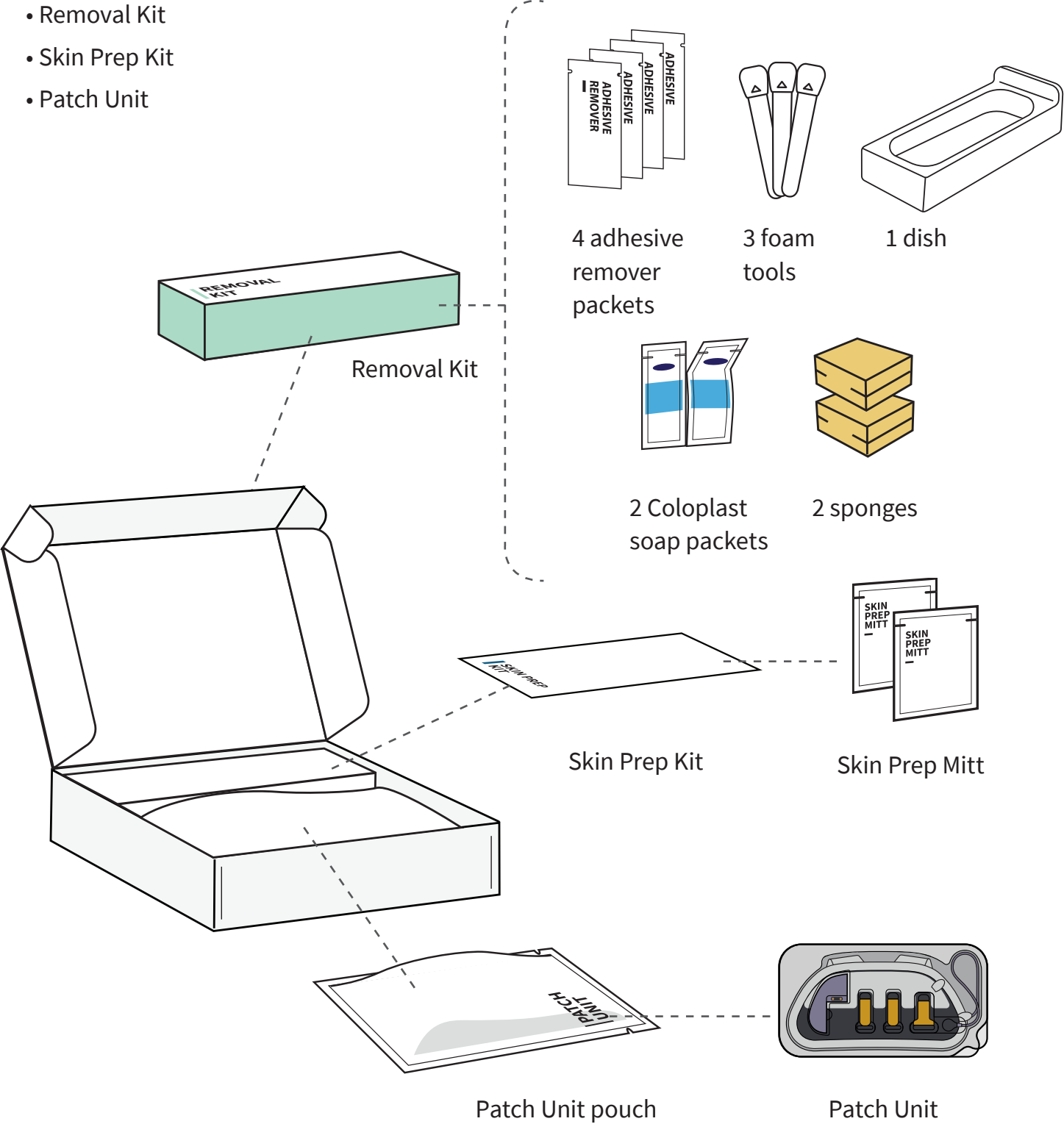
STARTER KIT BOX CONTENTS

- Jewel Patient Guide
- Replacement Sticky Sheets
- Electric Hair Trimmer
- Placement Accessory



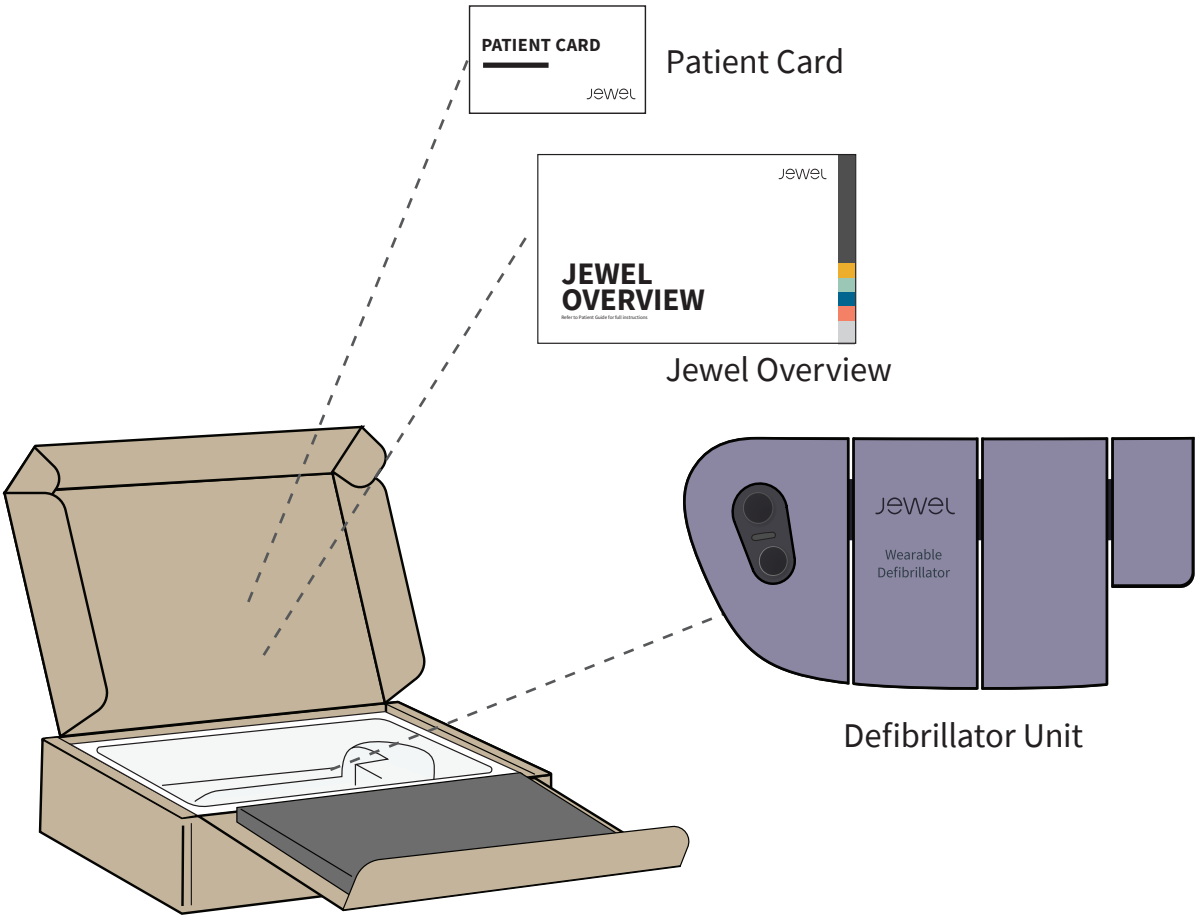
PATCH KIT BOX CONTENTS

- Removal Kit
- Skin Prep Kit
- Patch Unit



DEFIBRILLATOR UNIT BOX CONTENTS

- Patient Card
- Jewel Overview
- Defibrillator Unit



RETURNS

Keep your Patch Unit boxes, Defibrillator Unit box and Starter Kit box in order to ship back to Element Science. See Chapter 6: Returning Your Jewel and Accessories.

PATCH UNIT

You cannot recycle or dispose of Patch Units. After use, you should return Patch Units to Element Science.

DEFIBRILLATOR UNIT

You cannot recycle or dispose of the Defibrillator Unit. After your prescription is complete, you should return the Defibrillator Unit to Element Science.

PLACEMENT ACCESSORY

You cannot recycle or dispose of the Placement Accessory. After your prescription is complete, you should return the Placement Accessory to Element Science.

DISPOSAL

SKIN PREP AND REMOVAL KITS

Contents of the Skin Prep Kit and Removal Kit can be discarded after use. Do not dispose into any sewers, on the ground, or into any body of water. All disposal practices must be in compliance with all Federal, State/Provincial and local laws and regulations (which may vary in different locations).

1.3 ABOUT THE JEWEL APP

THE JEWEL MOBILE APP

The Jewel Mobile App is a mobile application (App) available on the iPhone. The Jewel has the ability to connect with the Jewel Mobile App through Bluetooth to provide status and overview information to you and to report to your doctor in the event of a shock delivered.

The Jewel Mobile App is optional and not required to use the Jewel. The Mobile App is intended for use by the Patient and not family members or caregivers. If used by someone other than the patient, the Mobile App may not have full functionality.

The Jewel Mobile App is NOT a substitute for this Patient Guide. For complete information on how to use the Jewel, please review this Patient Guide in its entirety. The Mobile App can ONLY be downloaded and used on an iPhone mobile device. It cannot be used on an iPad, laptop computer, desktop computer, or non-iPhone mobile devices.

DOWNLOADING AND LOGGING INTO THE JEWEL MOBILE APP

After you undergo your training session and apply your first Jewel, Element Science will send you an e-mail with a link to download the Jewel Mobile App onto your iPhone. Using your iPhone, click on the link from the e-mail to download the Mobile App. The email will also include a temporary password for logging into the Jewel Mobile App. (Your username is your email address.) After initially logging into the Mobile App you will be prompted to create a new password. Once you have created a new password please write it and your username in the space provided below. You may need it to log in again in the future.

USERNAME: _____

PASSWORD: _____

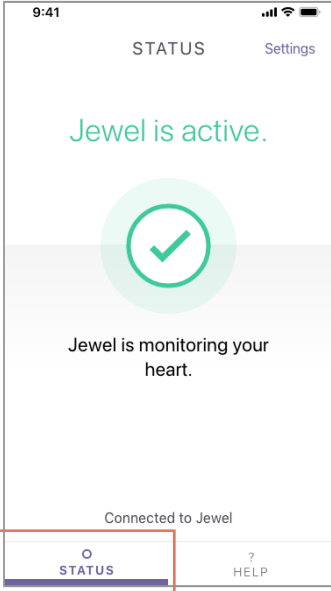
BEFORE USING THE JEWEL MOBILE APP

- Always keep Bluetooth turned on in your iPhone settings. The Mobile App needs Bluetooth enabled to pair with the Jewel and remain connected.
- Allow notifications from the Jewel Mobile App in your iPhone settings. If you turn notifications off, you will not receive updates about the status of the Jewel on your iPhone.
- Stay within 50 feet of your iPhone. If the Jewel you are wearing goes out of range of your iPhone, it will become disconnected and the Status Screen will be unable to update. Walk back in range when you are able and the Jewel and Mobile App will automatically reconnect. Note that even if you are out of range of your iPhone, the Jewel you are wearing will still provide alerts and alarms.
- Make sure you have an internet connection through Wi-Fi or cellular networks. Avoid connecting to Wi-Fi or cellular networks with poor service quality including low signal strength or frequently dropped connections. The Jewel Mobile App and the Jewel remain connected without an internet connection.
- The Jewel Mobile App needs an internet connection with good service quality to send data to Element Science and your doctor in the event that you receive an electrical shock. In case of lack of internet connection, the Jewel Mobile App will resend therapy data received from the Jewel when internet connection is reestablished.
- Although the Jewel Mobile App uses the latest up-to-date encryption to protect data, Element Science recommends that you avoid unsecured networks and connect your mobile phone only to secured Wi-Fi networks while running the Jewel Mobile App.
- After applying the Jewel to your body, you can pair it to the Mobile App by pressing and holding only the top button on the Jewel for 5 seconds. See *page 32* for full instructions.
- The Mobile App does not automatically pair to the Jewel upon first application. You must start pairing for the first time from the Jewel rather than the Mobile App.
- Keep your iPhone with you when you remove the Jewel. This way, the Mobile App will remain in-range and know when you have removed the Jewel.
- Element Science recommends that you enable a passcode, touch ID or face ID to lock your iPhone and provide another layer of protection to your personal information and the Jewel Mobile App. Go to your iPhone Settings > Touch ID & Passcode or Settings > Face ID & Passcode and follow Apple Support instructions for your specific phone to turn it on.
- Make sure you keep your iPhone up to date with respect to security updates. Element Science recommends you turn Download and Install iOS Updates in your iPhone Settings > General > Software Update > Automatic Updates screen.

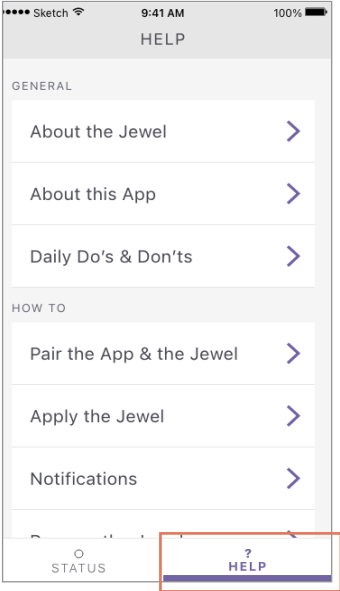
- Element Science will never request your Jewel Mobile App password. If you suspect your password has been stolen, immediately change your password by clicking on “Forgot Password?” on your Jewel Mobile App Login and follow the steps to reset your password or contact Customer Service at 1-800-985-5702 to reset your password.
- Element Science will periodically release new versions of the Jewel Mobile App to add functionality, address issues and provide security updates. Element Science recommends you turn on App Updates in your iPhone Settings > App Store screen to ensure you stay current with security updates for your Jewel Mobile App.
- Element Science will notify you via email in the unlikely event of a cybersecurity incident with the software infrastructure supporting your Jewel App. The communication will include information on the incident such as impact, recovery timeline, and guidance on actions to mitigate the incident.

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THE JEWEL MOBILE APP SECTIONS: STATUS AND HELP

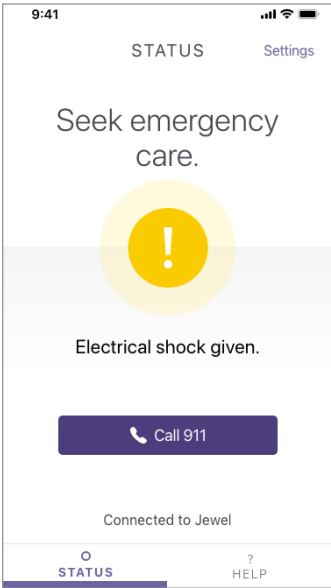


The **Status Section** shows the current state of the Jewel you are wearing.

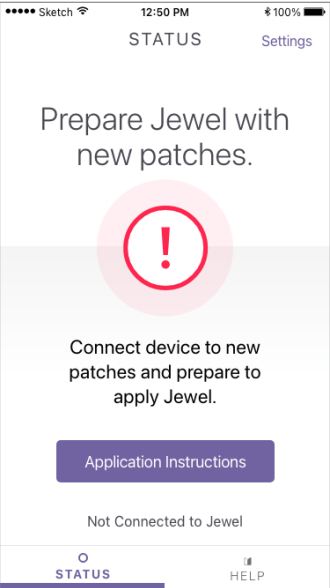


The **Help Section** provides basic information about the Jewel, daily use, application instructions, removal instructions, contact information, and troubleshooting.

The instructional training videos can also be found in this section.

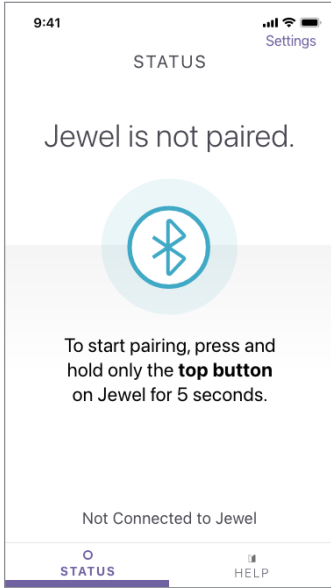


If you have received an electrical shock the Mobile App will show the status “Seek Emergency Care” and tell you to call 911.

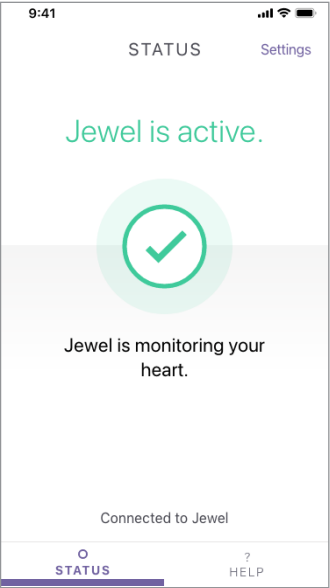


While you are replacing the Patch Unit, the Mobile App will show the Status “Prepare Jewel with new patches” until you apply the new Patch Unit onto your body.

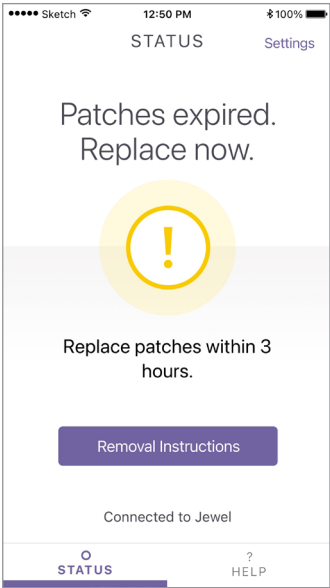
COMMON STATUS SECTION SCREENS:



When the Jewel is not paired with the Mobile App, the Mobile App will show the status “Jewel is not paired.”



If the Jewel has been applied and no action is needed, the Mobile App will show the status “Jewel is active.”



When the Patch Unit needs to be replaced, the Mobile App will show the status “Replace Patches now.”

THE JEWEL MOBILE APP CAN DO THE FOLLOWING:

- The Mobile App displays the current status of the Jewel (except during a siren alarm) when it is connected by Bluetooth.
- If you receive an electrical shock, the Mobile App will transmit the treatment data to your physician. The Mobile App will only transmit data when you have an internet connection.
- The Jewel Mobile App will provide a “Call 911” button. If pressed, 911 is dialed. You will still need to initiate the call.

THE JEWEL MOBILE APP CAN NOT DO THE FOLLOWING:

- The Mobile App will not track information about your location or health. The Mobile App only displays information about your Jewel.
- The Mobile App cannot control the Jewel. The Jewel alerts and alarms cannot be turned off from the Mobile App.
- You cannot cancel an electric shock from the Mobile App. If you are conscious and receive a siren alarm, press both buttons on the Jewel. ONLY the patient wearing the Jewel should press the buttons.

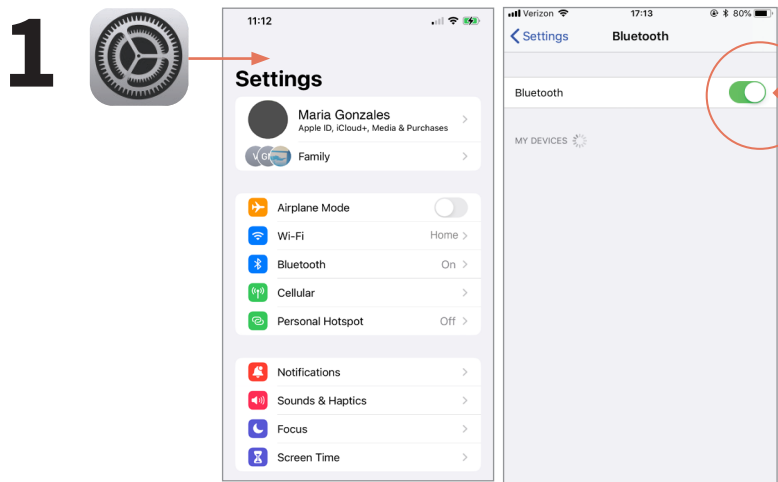
For questions, contact Customer Service at 1-800-985-5702.

PAIRING THE JEWEL

Apply the Jewel to your body and confirm it is active before you try to pair the Jewel and the Mobile App for the first time.

Pairing is not possible if the Jewel has not been applied to your body. You do not have to manually pair each time you replace a Patch Unit. Once the Jewel is paired with your phone, there is no need to pair again unless you need to replace your Defibrillator Unit. Call Customer Service if you have any questions. The Jewel Mobile App will display an alert if it is not connected to the Jewel.

Before you start pairing, complete the following steps on your mobile device:

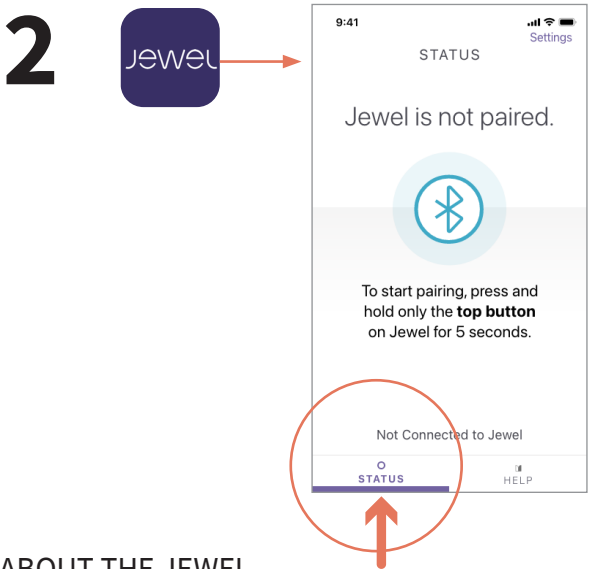


Make sure you have a stable internet or data connection and Bluetooth is turned ON in your iPhone settings.

Open Settings and then select “Bluetooth” to find this option.

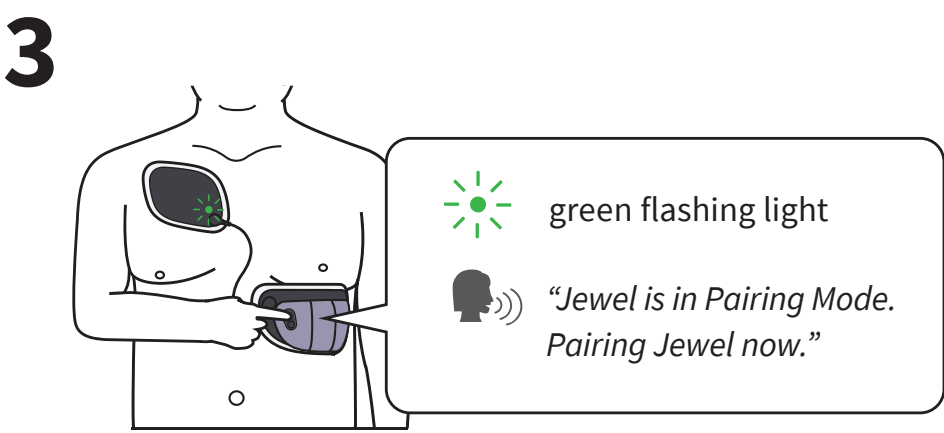
Make sure you have allowed the Jewel App to use Bluetooth and notifications. To check if Bluetooth has been allowed, open Settings, scroll down and select “Jewel”, and confirm that the Bluetooth option is enabled.

Make sure notifications are allowed as well.

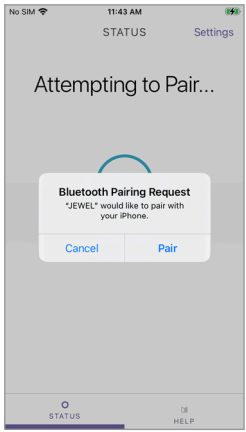


Open the Jewel App.

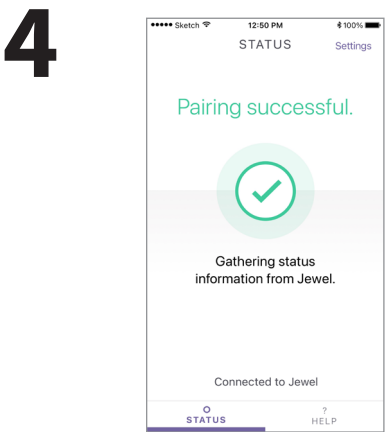
Click on “Status” so that you are viewing the Status section.



Press and hold the **top button** on the Jewel for 5 seconds until you hear “Jewel is in Pairing Mode. Pairing Jewel now.”

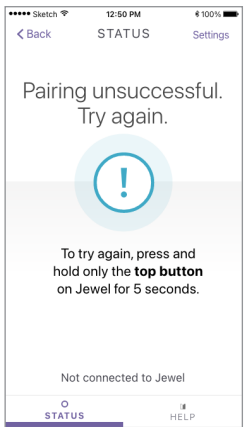


The App should display an ‘Attempting to Pair’ screen and then a pop-up. Tap ‘Pair’ to confirm that you would like to pair with the Jewel.



Check the status section on the Mobile App. As the Jewel and Mobile App communicate you should then see the screen “Pairing Successful.”

Once the Jewel and the Mobile App have successfully paired, the Status screen should show the status of your Jewel.



If the Mobile App does not pair and you receive the “Pairing Unsuccessful” screen, the Mobile App and the Jewel will attempt to re-pair automatically. You do not need to initiate pairing on the Jewel again.

If the Mobile App still will not pair, see Troubleshooting on the next page.

MOBILE APP TROUBLESHOOTING

IF YOU ARE HAVING TROUBLE PAIRING:

- 1. Make sure Bluetooth is turned ON in your phone settings and enabled for your Jewel Mobile App.
- 2. Make sure your mobile device is no more than 5 feet away from the Jewel.
- 3. If you have previously paired your Jewel with your mobile device and are experiencing connection issues, try restarting the application.
- 4. If the Jewel is still unable to connect, try turning Bluetooth off and then back on in your mobile device settings.
- 5. If the issue persists, contact Customer Service: 1-800-985-5702

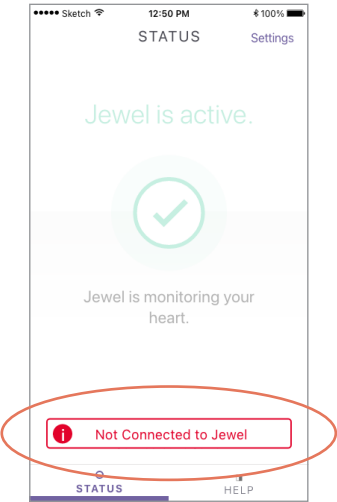
IF YOU ARE PAIRING A REPLACEMENT DEFIBRILLATOR UNIT:

- 1. Go to your Bluetooth settings and find the Jewel within the list of ‘My Devices’. Tap the information icon next to the Jewel and select ‘Forget This Device’.
- 2. Complete pairing steps in previous section ‘Pairing the Jewel’ to pair your replacement Defibrillator Unit.

IF YOU ARE HAVING TROUBLE RECONNECTING:

- 1. If the application displays the alert 'Not connected to Jewel' at the bottom of the screen, do not attempt to re-pair by pressing and holding the top button on the Jewel.

Check that Bluetooth is turned on in your phone settings and Mobile App settings. Make sure your phone is no more than 5 feet away from the Jewel.

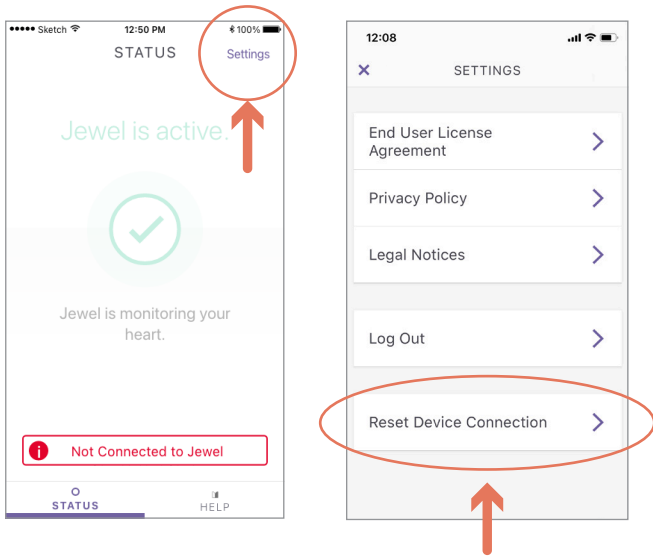


- 2. If the Jewel and Mobile App do not reconnect after completing the previous step, try restarting the Mobile App and turning Bluetooth off and then back on in your phone settings.

- 3. If the Jewel and the Mobile App do not reconnect after completing the previous step you should reset the connection between the Mobile App and the Jewel.

To do this, open the Mobile App settings and select ‘Reset Device Connection’.

Wait for the Mobile App and the Jewel to reconnect. The Mobile App should reconnect and display previous status screen.



- 4. If this issue persists call Customer Service.

2

page intentionally left blank.



2

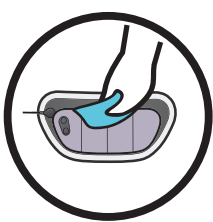
DAILY USE & FAQ

2.1 LIVING WITH YOUR JEWEL

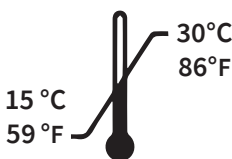
DO'S AND DON'TS



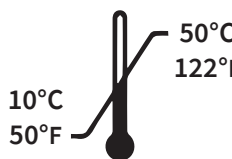
WATER RESISTANT
ONLY SHOWERING
ALLOWED



TO CLEAN:
GENTLY WIPE
WITH DRY CLOTH



STORE DEVICE
BETWEEN
15 °C (59 °F)
AND 30 °C (86 °F)



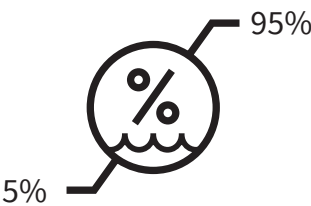
OPERATE DEVICE
BETWEEN 10 °C (50 °F)
AND 50 °C (122 °F)



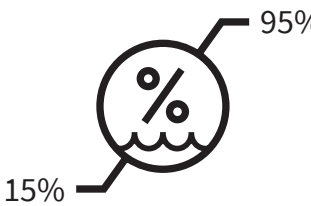
DO NOT SUBMERGE
NO BATHING
NO SWIMMING



MR UNSAFE



STORE DEVICE
BETWEEN 5 - 95%
RELATIVE HUMIDITY



OPERATE DEVICE
BETWEEN 15 - 95%
RELATIVE HUMIDITY



DO NOT APPLY
DIRECT HEAT



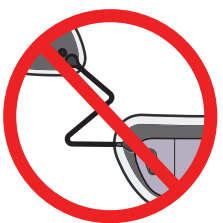
DO NOT TAMPER
WITH DEVICE



DO NOT CLEAN
WITH CHEMICALS



STORE IN A COOL,
DRY PLACE



DO NOT
STRESS CABLE

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FREQUENTLY ASKED QUESTIONS

DAILY ACTIVITIES

How long can I wear my Jewel?

The Defibrillator Unit is intended to be reused with multiple Patch Units throughout a prescription. The Defibrillator Unit has a service life of up to 3 years. The disposable Patch Unit is intended to be replaced after each wear throughout a prescription. Each Patch Unit can last up to 8 days. The Jewel will notify you when the Patch Unit should be replaced. If you receive a replacement alert from the device, the Patch Unit or Defibrillator Unit it should be replaced as soon as possible (additional information on replacement alerts can be found in *Chapter 4: Notifications*). Avoid activities that cause you to sweat as this may result in the Jewel coming off early.

When should I replace my Patch Unit?

To remain protected, it is recommended that you do not replace your Patch Unit until you receive a replacement alert. Replacement alerts usually happen 6-7 days after applying the Jewel. For more information on removal see *Chapter 5: Removal*.

Can I shower wearing my Jewel?

Yes. You may take showers, but try to keep the Jewel out of direct prolonged hot water spray. This will help the Jewel stay on longer. Gently wipe the Jewel after getting wet.

Can I swim wearing my Jewel?

No. The Jewel cannot be submerged in water or any liquid. Do not swim, take a bath, or sit in a hot tub while wearing the Jewel. Submerging the Jewel may result in a device malfunction.

Can I exercise wearing my Jewel?

Yes, light exercise is permitted. Avoid strenuous activity that would cause profuse sweating. Avoid moderate activity for extended periods of time that would cause profuse sweating. Minimize activities that include a lot of stretching, twisting, or excessive sweating as this will reduce the ability of the Jewel to stick to your skin. If the Patch Unit peels off your body, this may cause the electrode signal quality to degrade and can result in needing to replace the Patch Unit early.

Can I sleep wearing my Jewel?

Yes. The Jewel is designed to be worn 24 hours a day. The Jewel will not be damaged even by lying on your side. Do not remove the Jewel while you are sleeping so that you remain protected at all times.

Can I travel wearing my Jewel?

Yes. Bring all necessary supplies to replace the Jewel Patches if needed, including the Placement Accessory, extra Patch Units and Removal Kits. If your travel includes security screening, present your Patient Card to the security agent before going through security gates. The Jewel Defibrillator Unit should not be put into any X-ray machine.

To prevent possible interference with the Jewel, follow these simple guidelines when passing through security or anti-theft detection systems:

- Walk through the gate at a normal pace.
- Avoid lingering near or leaning on the gate.
- Once you have walked through the gate, keep a distance of at least 1.5 feet from the gate.
- Remaining near a security gate for an extended period of time may result in alerts from the Jewel.
- When wearing the Jewel do not pass through airport body scanners (backscatter x-ray or millimeter wave technologies).

Some European railways have been known to use frequencies that may interfere with the Jewel.

What if I need to go to the hospital?

It may be helpful to bring your Patient Card and a Removal Kit in case you have procedures that require you to remove the Jewel. If you need to remove the Jewel during your appointment or stay at the hospital, reapply your Jewel as soon as you can to remain protected continuously.

Do not wear the Jewel during the following procedures:

- X-rays, fluoroscopy, radiation therapy, MRI, CT scans, electrocautery, diathermy therapy
- Consult your doctor prior to undergoing procedures not listed above.

How do I turn the Jewel off?

The Jewel does not have an off button.

- Once the device is in Removal Mode, the Jewel will turn off automatically during removal when it detects that it is no longer attached to your body. (See *Chapter 5: Removal* for Removal Mode details.)
- Pressing both buttons at any time during a Siren Alarm will cancel the electrical shock, but will not turn off the Jewel. The Jewel will automatically continue monitoring your heart. (See *Chapter 4: Notifications* for details.)
- In Application Mode, the Jewel will automatically turn off after 2 hours if it detects it has not been applied to your body. (See *Chapter 3: Application* for details.)

Which voice prompts mean the Jewel is monitoring for specific life-threatening heart rhythms?

If you receive any of the following voice prompts, the device IS monitoring for specific life-threatening heart rhythms:

- “Jewel is Active.”
- “Replace Patches Soon.”
- “Patches expired. Replace patches now.”

If you receive any of the following voice prompts, the Jewel IS monitoring for specific life-threatening heart rhythms but CANNOT provide an electrical shock:

- “Patches expired and no longer working. Replace patches immediately.”

If you receive any of the following voice prompts, the Jewel IS NOT monitoring for specific life-threatening heart rhythms:

- Application Mode: “Jewel is in Application Mode. Apply Jewel now using Placement Accessory.”
- Removal Mode: “Jewel is in Removal Mode. Replace Patches now.”

If you are unsure of the most recent voice prompt, press and release both buttons to perform a status check.

Does the Jewel require time to warm up or cool down prior to use?

The Jewel does not require time to warm up or cool down prior to use.

PATCH UNIT

What should I do if I experience skin irritation or itching under the patches?

Some mild or moderate itching or irritation may occur. Contact your doctor for any skin concerns. NEVER stick any object or material between patches and your skin (such as scratching with your fingers or another object).

Can I move the patches after the device has been applied to my body?

No, the patches cannot be moved or adjusted once they have been applied. Patches that have been applied in the incorrect location must be removed and a new Patch Unit applied (See *Chapter 5: Removal*). If you are concerned you applied the Jewel in the incorrect location, see *Chapter 3: Application* for more information.

Can I use lotion or ointment under or around the patches?

No. Keep the patch area clear of lotions and ointments. Lotions or ointments around the patch may reduce the ability of the Jewel to stick to your skin and result in needing to replace the Patch Unit early.

Can I peel the patches off my skin at any time?

No. Always use the adhesive remover included in the Removal Kit and removal instructions (*Chapter 5: Removal*) to remove the Jewel. The entire patch is made up of strong adhesive and could cause damage to your skin if you do not use the adhesive remover and foam tools provided.

Is the adhesive remover safe on clothing?

Yes, the adhesive remover is safe on clothing. It should not stain most fabrics.

Is it OK if the patches are peeling on the edges?

The patch edges might start to peel off the skin as you wear your Jewel. This is expected. The Jewel will tell you when it needs to be replaced. Removal of the Jewel prior to replacement alerts is not recommended. Refer to *Chapter 4: Notifications* for replacement alerts.

What if one of my Jewel patches comes off unintentionally?

You need to replace the Patch Unit. See *Chapter 5: Removal*. Do not attempt to re-attach a patch that has come off your body. Do not use any adhesive such as tape or band-aids to keep the device secured to you. Do not attempt to dry the area between the patch and your skin if it becomes partially detached. NEVER stick any object or material between patches and your skin (such as scratching with your fingers or another object).

Can I recharge the batteries in the Jewel?

No. The batteries in the Jewel are not rechargeable or user recyclable. The Patch Unit, which includes the battery, must be replaced when prompted.

NOTIFICATIONS: ALERTS AND ALARMS

Will the Jewel vibrate, light up, or make noise?

Yes, the Jewel will give you auditory sounds and voice prompts, vibrations, and lights to get your attention and communicate with you. For more information, see *Chapter 4: Notifications*.

What do I do if I start hearing voice prompts, seeing lights, or feeling vibrations from the Jewel?

Listen and follow the instructions provided by the Jewel. Refer to *Chapter 4: Notifications* if you do not know what an alarm or alert means and how frequently they will repeat. You can also perform a Status Check by pressing both buttons to have the Jewel repeat the last voice prompt. More information on Status Checks can be found in *Chapter 4: Notifications*.

What if I receive a Siren Alarm while I am conscious?

If you ever receive a Siren Alarm while you are conscious, press and hold both buttons to cancel the electrical shock. If you continue to get Siren Alarms but feel fine, something in the environment may be affecting operation of the Jewel. Move away from motors and any electronic equipment. Keep the Jewel on, it is still monitoring your heart unless you hear an alert otherwise. See *Chapter 4: Notifications* for details on Siren Alarms.

ELECTRICAL SHOCKS

What is an electrical shock?

The Jewel is designed to monitor the heart’s signals for specific life-threatening heart rhythms that can lead to Sudden Cardiac Arrest (SCA). Sudden Cardiac Arrest occurs when the heart’s electrical system stops functioning correctly. This type of heart condition can be treated with an electrical shock, which will reset the electrical activity of the heart and restore its function to normal.

The Jewel can automatically detect and treat these specific life-threatening heart rhythms. The electrical shock delivered by the Jewel passes between the Upper and Lower Patches, through the heart, and restores the heart’s electrical activity back to normal.

What should I do if I receive an electrical shock?

If you receive an electrical shock, you should seek emergency care. Keep the Jewel on until you are with trained medical professionals. See *Chapter 4: Notifications* for details.

REPLACEMENTS, RETURNS, AND STORAGE

How do I get a new Defibrillator Unit?

You can call Customer Service (1-800-985-5702) and let them know you need a replacement Defibrillator Unit.

How do I get a new Patch Unit?

You can call Customer Service (1-800-985-5702) and let them know you need additional Patch Units. Additional Patch Units will be sent directly to your home. Make sure you always have one extra Patch Kit on hand.

How do I get new skin preparation or removal kits?

You can call Customer Service (1-800-985-5702) and let them know you need additional skin preparation or removal kits. Additional kits will be sent directly to your home.

How do I get new sticky sheets for the Upper Accessory Pad?

You can call Customer Service (1-800-985-5702) and let them know you need additional sticky sheets for the Upper Accessory Pad. Additional sticky sheets will be sent directly to your home.

How do I return my Jewel?

You can mail the Defibrillator Unit or Patch Unit back using the same box that it was given to you in. A return shipping label will be found inside each return shipper box. See *Chapter 6: Returns* for details.

What should I do if my weight changes and my Placement Accessory no longer fits me?

Fluctuations in weight may affect how tightly the Placement Accessory fits you and could result in an incorrect application. If your Placement Accessory is not fitting the same as when you received it, contact Element Science (1-800-985-5702) to receive a replacement. See *Chapter 7: Troubleshooting* for additional details on checking the fit of your Placement Accessory.

How should I store the Patch Kit box and Placement Accessory?

Store the Jewel Patch Kit box and Placement Accessory in a clean, dry place in ambient temperature. Do not store the Placement Accessory in an area where it could become compressed or crumpled.

How should I clean the Placement Accessory?

If the Placement Accessory becomes dirty, clean it using a water dampened cloth. Do not use soap, harsh chemicals, or cleaners. Do not put the Placement Accessory in an automatic washer or dryer.

How should I clean the Jewel?

If the Jewel becomes dirty, clean it using a dry cloth. Do not use harsh chemicals or cleaners.

3

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3

**APPLYING
YOUR JEWEL**

3.1 SKIN PREPARATION

HAIR TRIMMING

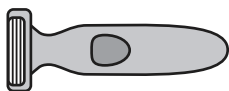
These steps cover trimming hair in the patch areas. If you do not have any hair on your chest or torso, skip to Preparing Skin with Skin Prep Mitts on *page 54*.

TIPS FOR THIS SECTION:

Read over all instructions before applying your Jewel. Use a mirror for hard to see areas. Ask someone to assist you for hard to reach areas.

SUPPLIES NEEDED:

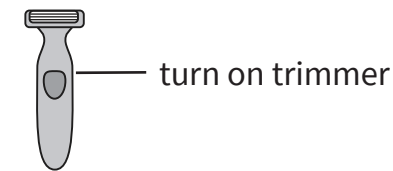
- electric hair trimmer (provided in Starter Kit)



ATTENTION:

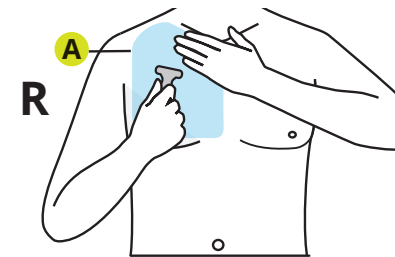
Do NOT shave hair with a razor. Shaving can cause small scratches on the skin. This could result in skin irritation and not being able to wear the Jewel.

1

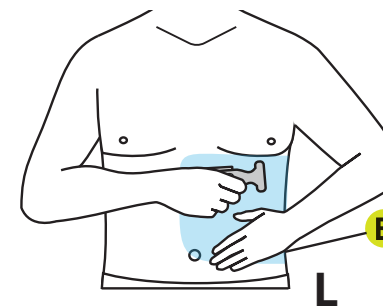


Use electric trimmer to trim hair if you have hair on your chest and torso.

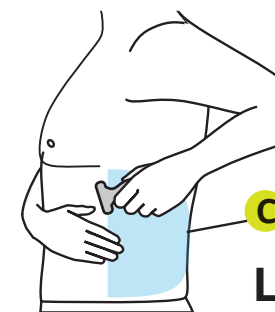
Trim hair close to skin in the following areas:



A. RIGHT CHEST
(Upper Patch area)

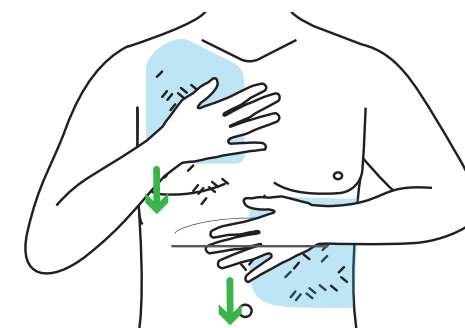


B. LEFT TORSO FRONT
(front of Lower Patch area)

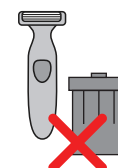


C. LEFT TORSO SIDE/BACK
(back of Lower Patch area)

2



Wipe away trimmed hair.



Do not discard trimmer: You will use it again prior to each Jewel application. Refer to trimmer instructions for cleaning and storage.

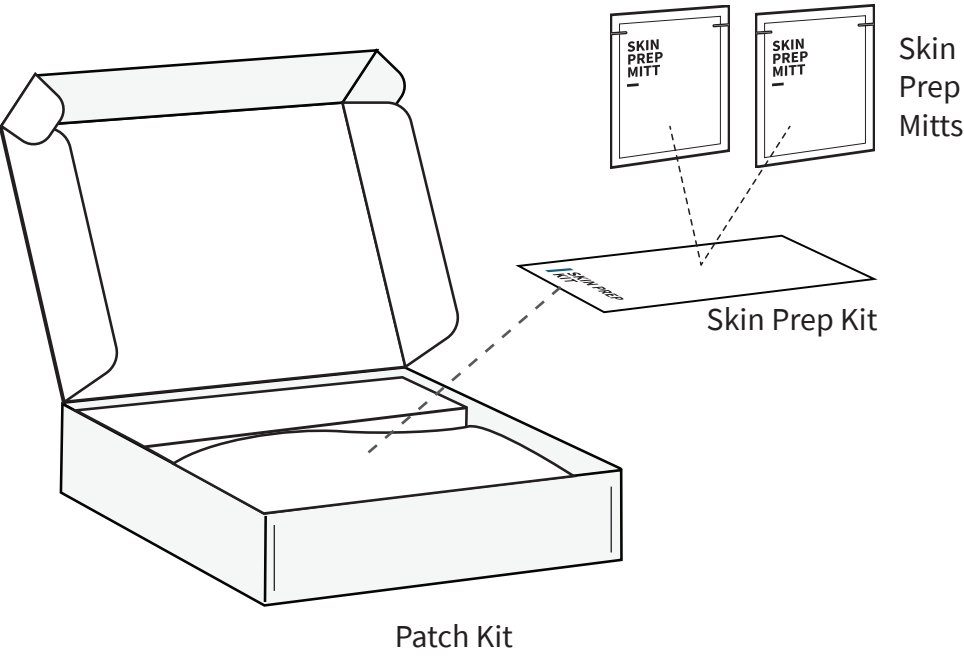
PREPARING SKIN WITH SKIN PREP MITTS

These steps cover preparing skin for application. Follow these steps to prevent skin irritation and early Patch Unit replacement.

TIPS FOR THIS SECTION:

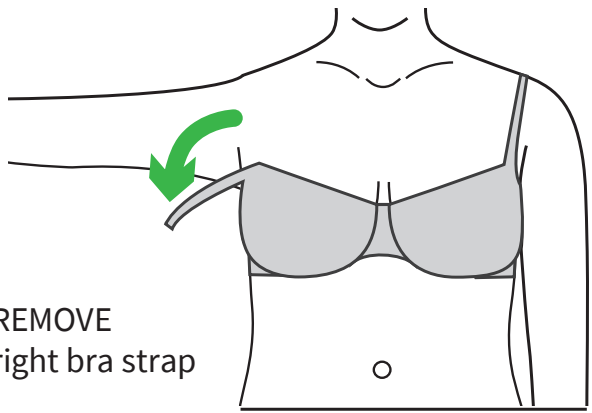
Use a mirror for hard to see areas. Ask someone to assist you for hard to reach areas.

SUPPLIES NEEDED:



timer (not provided)

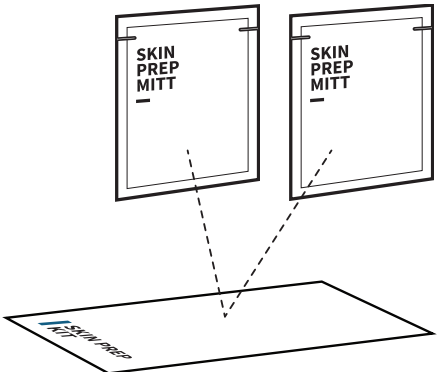
1



Remove all clothing and jewelry from upper body.

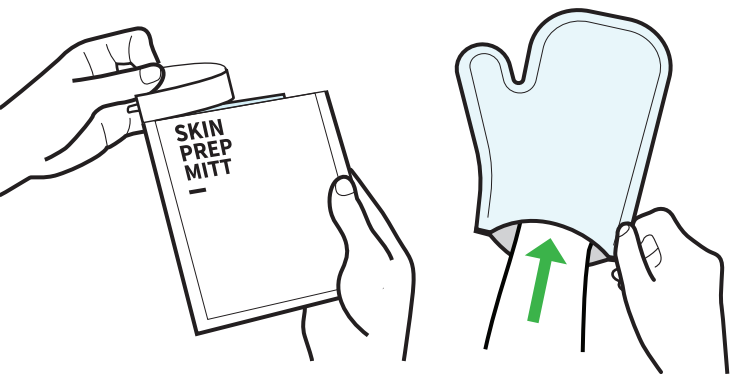
Do NOT wear a bra that cannot be unclasped. Your bra will become trapped under the Jewel when applied.
A bra is not required to be worn for skin prep or your Jewel application.

2



Remove two skin prep mitt packets from the box.

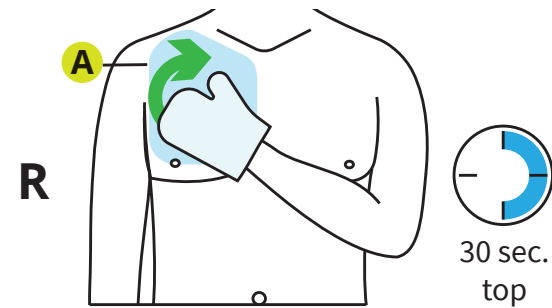
3



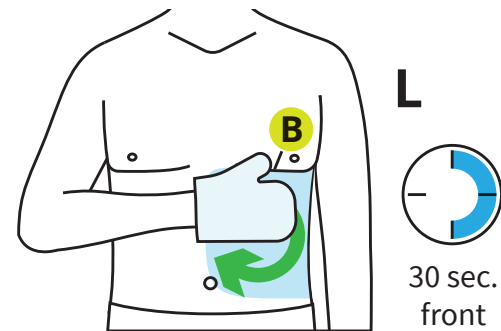
Take one mitt out of packages. Place mitt on your hand.

continue →

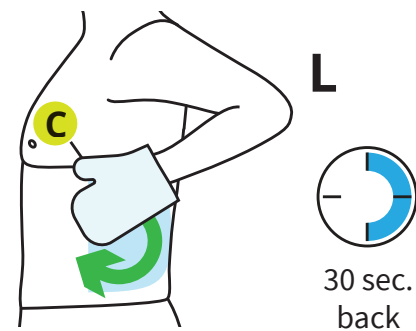
- 4** Only one mitt is opened and used at a time.
One mitt should be used for the Upper Patch, the second mitt should be used for the Lower Patch area. The Lower Patch mitt should be flipped so that the opposite side is used on the back.



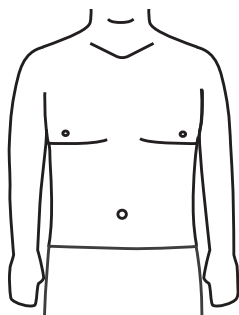
A. RIGHT CHEST
(Upper Patch area)



B. LEFT TORSO FRONT
(front of Lower Patch area)



C. LEFT TORSO SIDE/BACK
(back of Lower Patch area)



Skin preparation is complete when

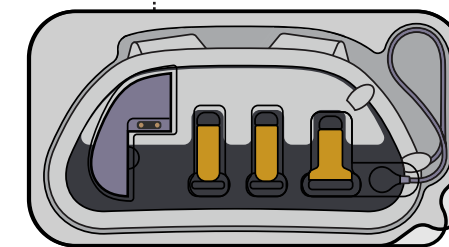
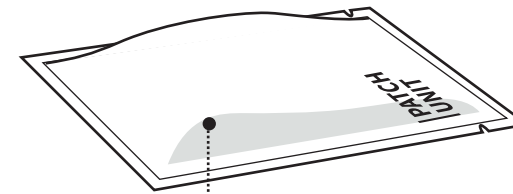
- hair is trimmed
- skin is clean and dry

3.2 JEWEL PREPARATION

SUPPLIES NEEDED:

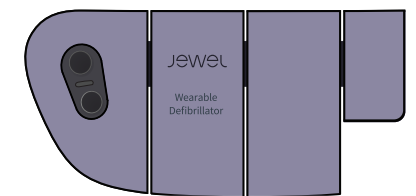
- Patch Unit
- Defibrillator Unit

PATCH UNIT POUCH

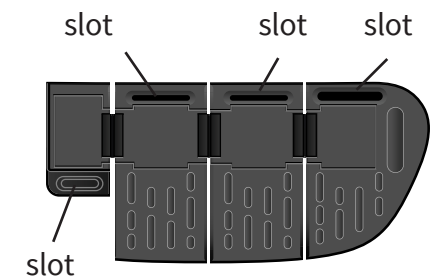


PATCH UNIT IN TRAY

DEFIBRILLATOR UNIT FRONT



DEFIBRILLATOR UNIT BACK



NOTE: To disassemble your Defibrillator Unit from used Patch Unit, refer to instructions in *Chapter 5 Section 3: Disassembling your Jewel*.

WARNING

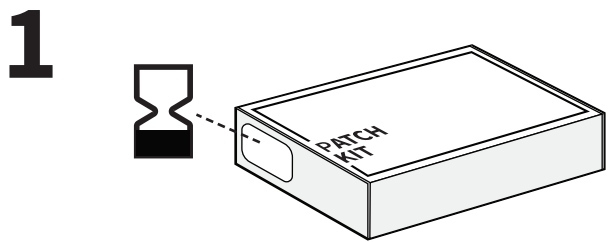
•Do NOT apply the Patch Unit after the use by date. Applying the Patch Unit after the use by (expiration) date could result in an electrical shock not given when needed and may impact product performance.



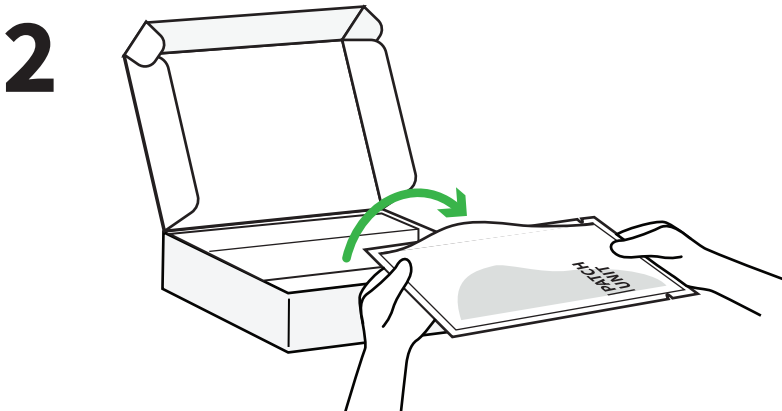
IMPORTANT CONSIDERATION

•ALWAYS turn on the Jewel before applying it. Do NOT apply the Jewel if the lights, speaker, or vibration motor are not working. When turning on the device, the patient should feel the device vibrate, see a green light, and hear “Jewel is in Application Mode. Apply Jewel now using Placement Accessory.”

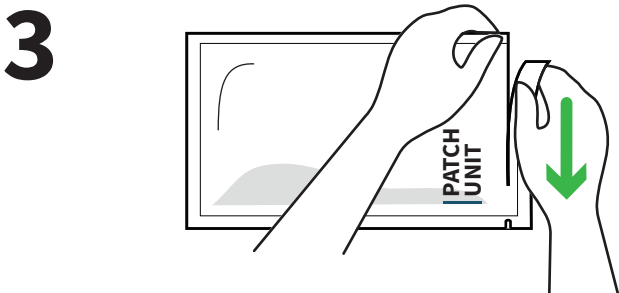
PREPARING TO ASSEMBLE THE JEWEL



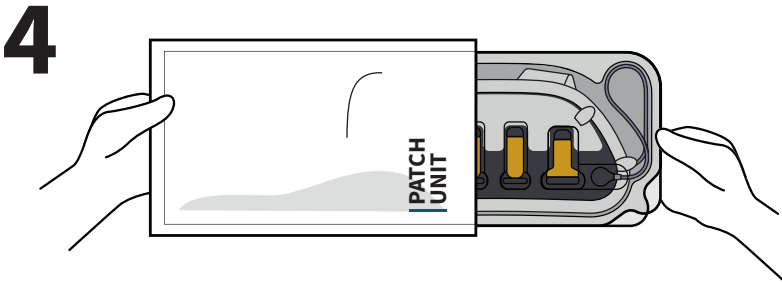
Confirm Use by date on outside of Patch Kit box before opening. Apply the Jewel on or before the Use by date.



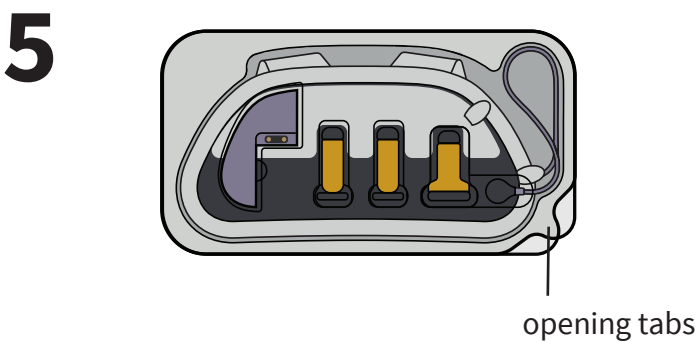
Open Patch Kit box and remove the sealed pouch.



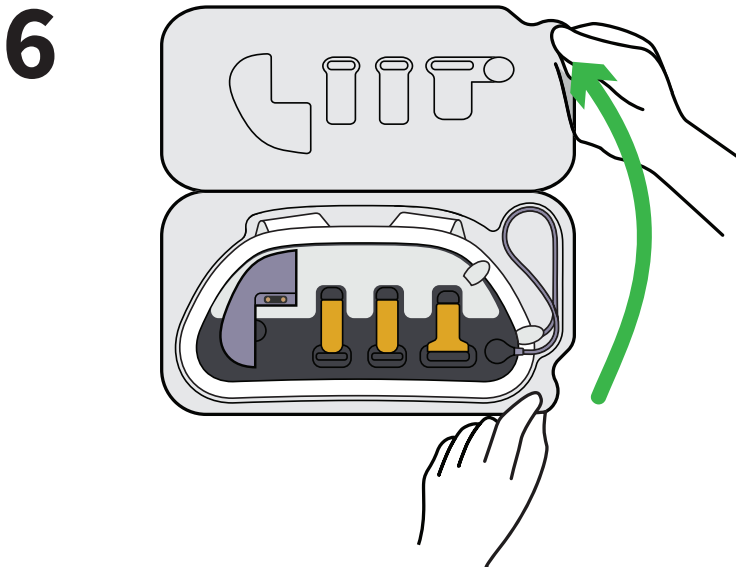
Look for the tear lines on the pouch and open the pouch. If using scissors, make sure to cut straight along edge and not cut into the patch tray inside.



Remove patch tray from the pouch and place in front of you with the opening tabs to the right of you. Make sure the surface you are using is clean.



Position the patch tray so that the opening tabs are on the right side of the tray.



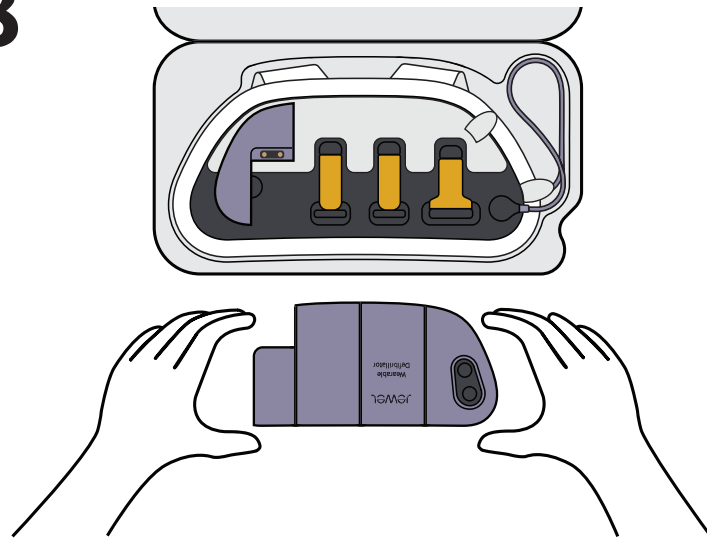
Open the patch tray using the opening tabs with both hands.

ATTENTION: Leave the Patch Unit in the Tray when assembling the Jewel.



Position the Defibrillator Unit so that buttons are on the right side.

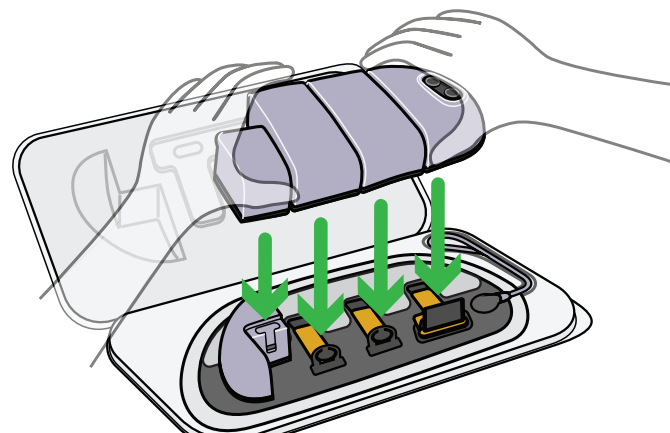
8



Hold the Defibrillator Unit with both hands so that it is positioned as shown. Align the slots on the Defibrillator Unit with the connectors on the Patch Unit.

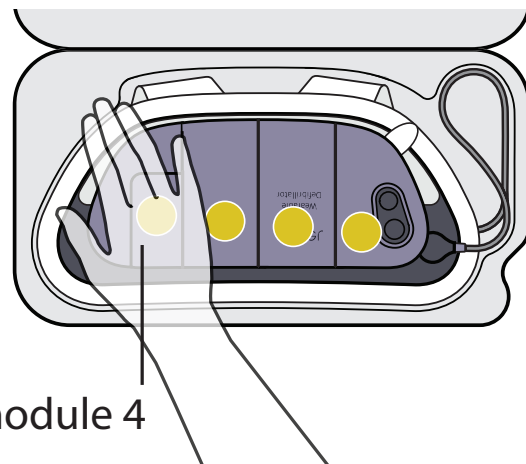
CAUTION: Do NOT assemble or disassemble the Defibrillator Unit from the Patch Unit while in a wet or humid environment. This may damage the Defibrillator Unit. Do NOT touch the battery electrical connections or place anything in the recessed areas on the Patch Unit or Defibrillator Unit. This may result in skin injury or device malfunction.

9



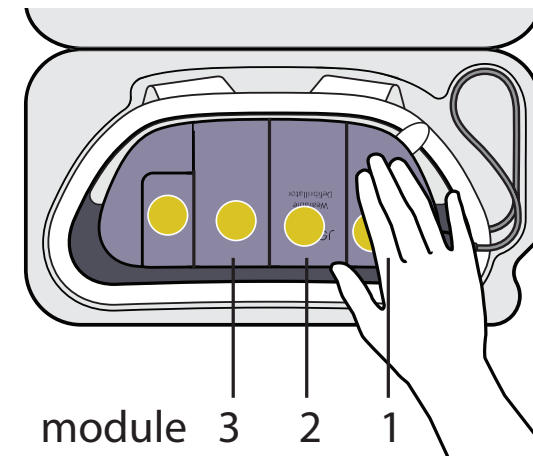
Gently lower the Defibrillator Unit making sure the connectors on the patch are guided into the slots.

10



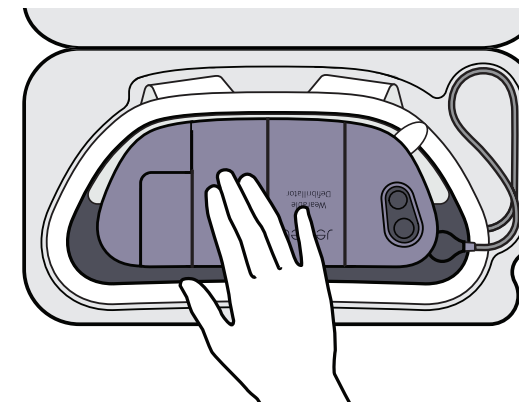
Press down on **module 4** with the palm of your hand until you hear a click.

11



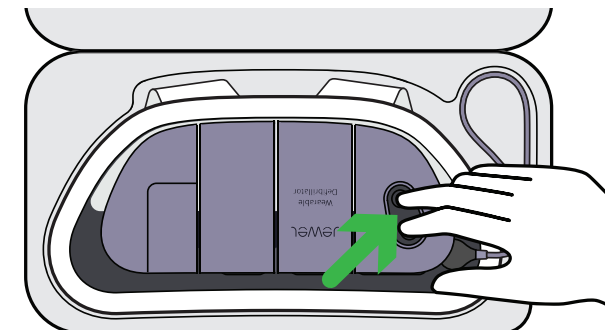
Press down on the remaining **modules 3, 2 and 1** until you hear each module click.

12



Press down on each module individually to confirm they are properly engaged.

13



Turn on the Jewel by pressing and holding both buttons simultaneously until you feel the Jewel vibrate.

ATTENTION: Make sure Jewel has been turned on before proceeding to next page.

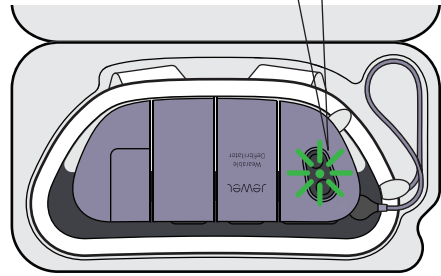
continue →

12



green flashing light

“Jewel is in Application Mode. Apply Jewel now using Placement Accessory.”



✓ JEWEL OK

Proceed with your Jewel application.

Check the Jewel status and proceed to loading the Jewel into Placement Accessory.

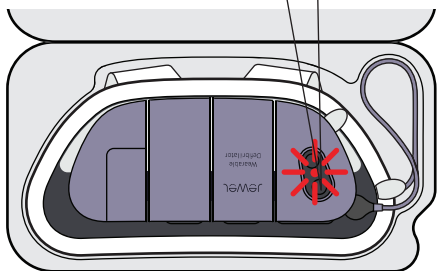
If you see a red flashing light, follow below instruction.

If you see a red flashing light instead of a green flashing light:



red flashing light

No voice prompt



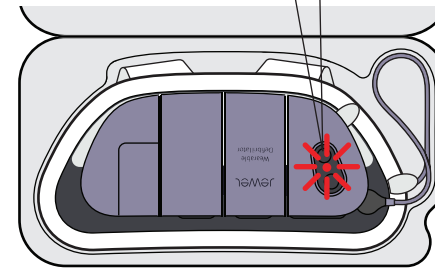
✗ ASSEMBLY INCOMPLETE

If the Defibrillator Unit is not properly engaged with the connectors on the Patch Unit, press on module 1 and 4 to properly connect.



red flashing light

“Device is disconnected from patch and is unable to provide electrical shock. Press on (first or last) module of device.”



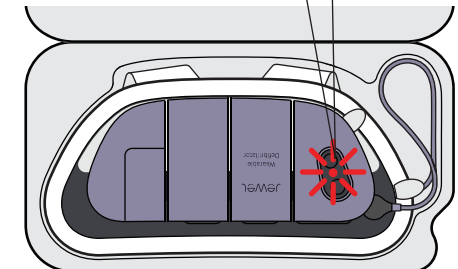
✗ DISCONNECTED

Make sure the Defibrillator Unit is properly connected to the Patch Unit.



red flashing light

“Device is disabled and must be replaced. Call Customer Service immediately” OR “Patches no longer working. Replace patches immediately.”



✗ JEWEL MALFUNCTION

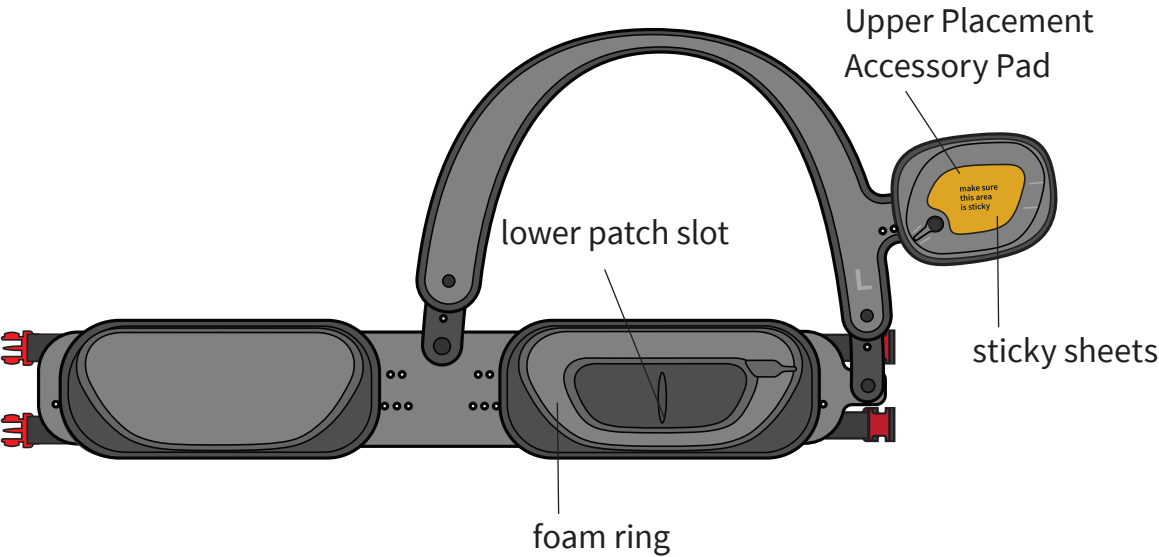
Do not apply the Jewel.

LOADING THE JEWEL INTO THE PLACEMENT ACCESSORY

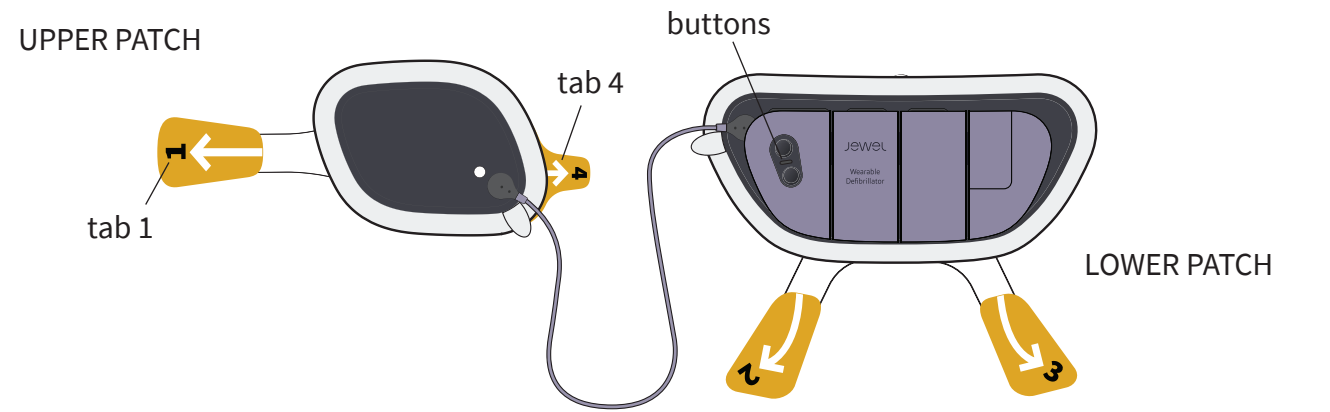
These steps cover loading the Jewel into the Placement Accessory. The Placement Accessory is required to apply the Jewel in the correct location on your body.

SUPPLIES NEEDED:
- The Jewel and the Placement Accessory

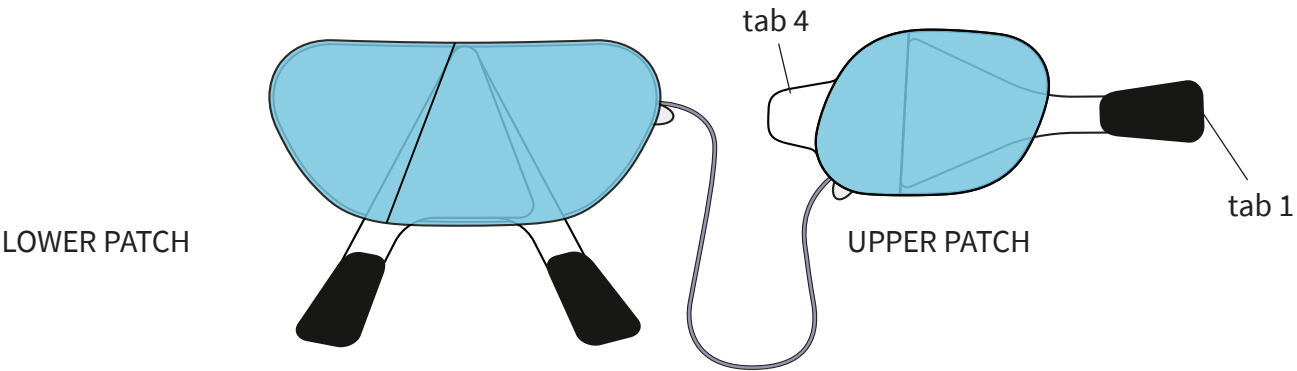
PLACEMENT ACCESSORY COMPONENTS TO KNOW:



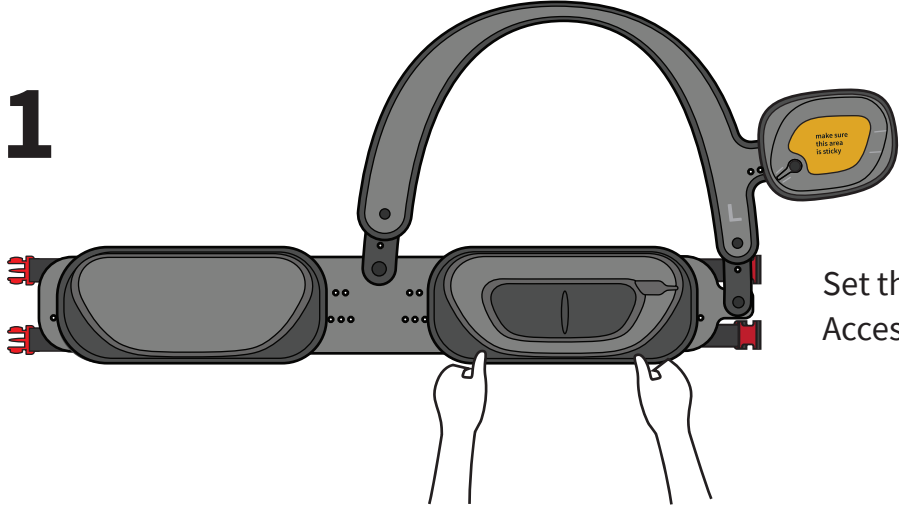
THE JEWEL (OUTER SIDE) COMPONENTS TO KNOW:



THE JEWEL (SKIN SIDE) COMPONENTS TO KNOW:



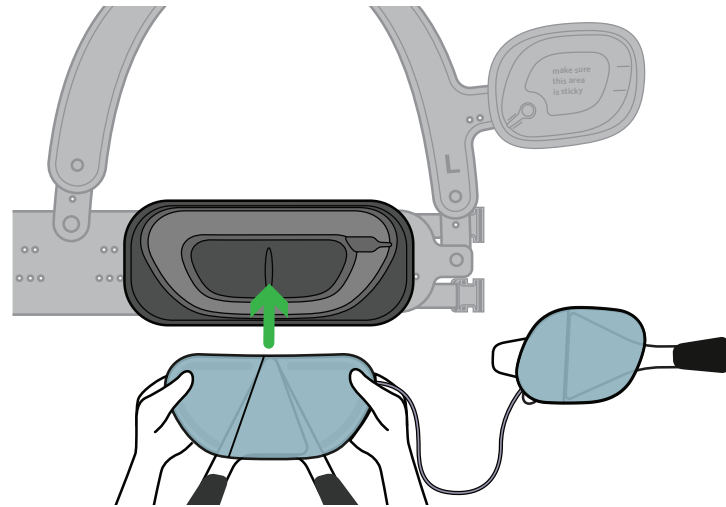
Make sure you have turned the Jewel on BEFORE loading into the Placement Accessory.



Set the unbuckled Placement Accessory on a flat surface.

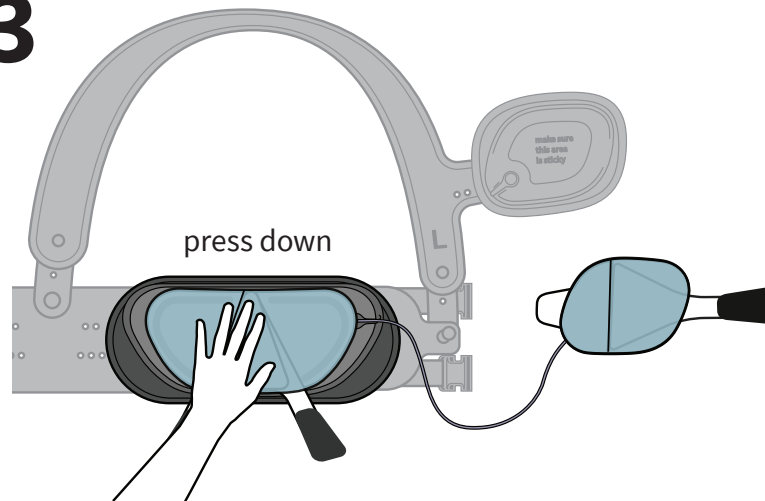
continue →

2



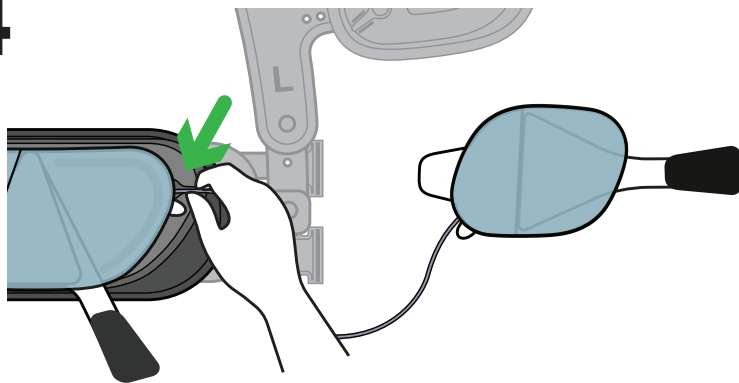
Hold the Lower Patch button side down. Place the Lower Patch into the slot.

3



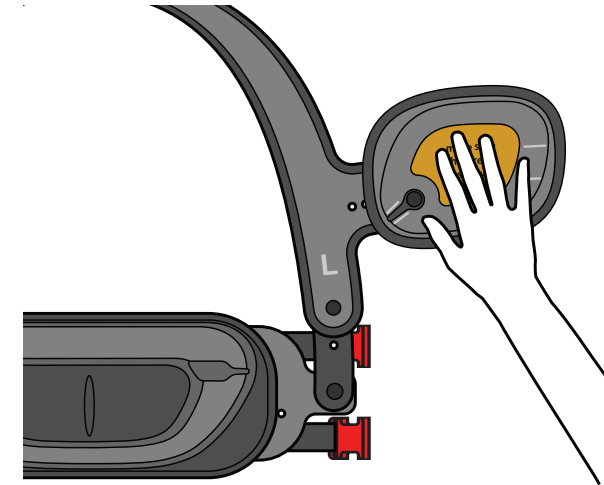
Press the Lower Patch into the slot until the patch is flush with the foam.

4



Check that the cable is resting in the cable slot.

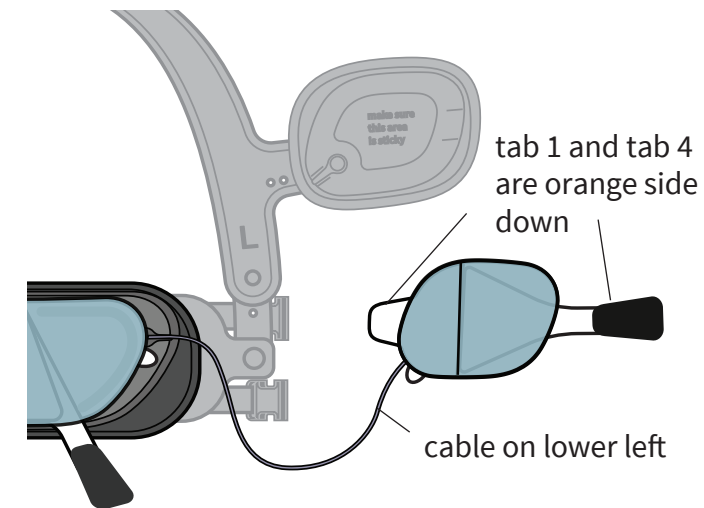
5



Touch orange center of Upper Placement Accessory Pad to check that it is sticky. If it is not sticky, remove one sticky sheet to reveal a new one.

If there are no more sticky sheets, replace with the provided extra sticky sheets. If you need extra sticky sheets contact Customer Service for replacement sticky sheets.

6

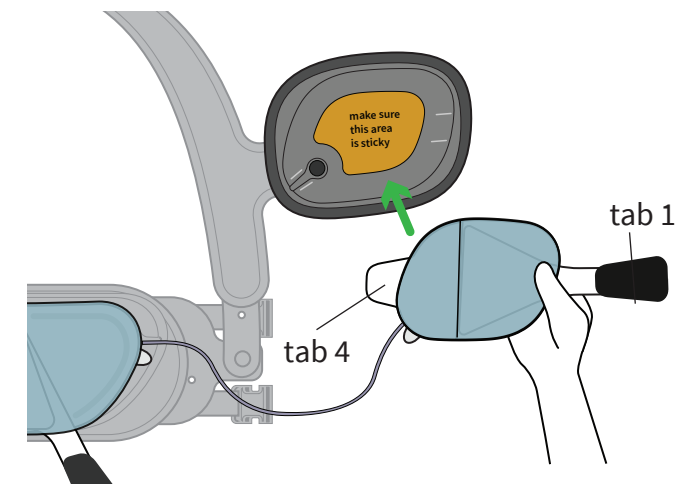


Check that the cable is not twisted before placing Upper Patch on upper pad.

Orient the Upper Patch so that:

- the light blue plastic backing is facing up
- tab 1 and tab 4 are orange side down.
- cable is coming from bottom left of Upper Patch.

7

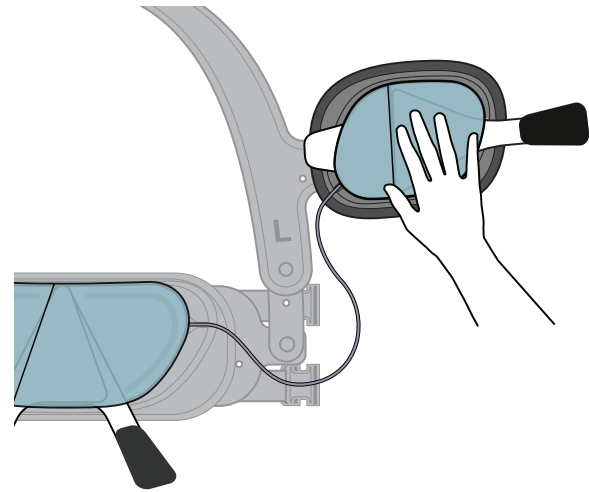


Align the Upper Patch so that:

- cable is in line with cable slot.
- Patch matches the shape of the Upper Placement Accessory pad. (tab 1 will hang off right side of pad and tab 4 hang off left side of pad)

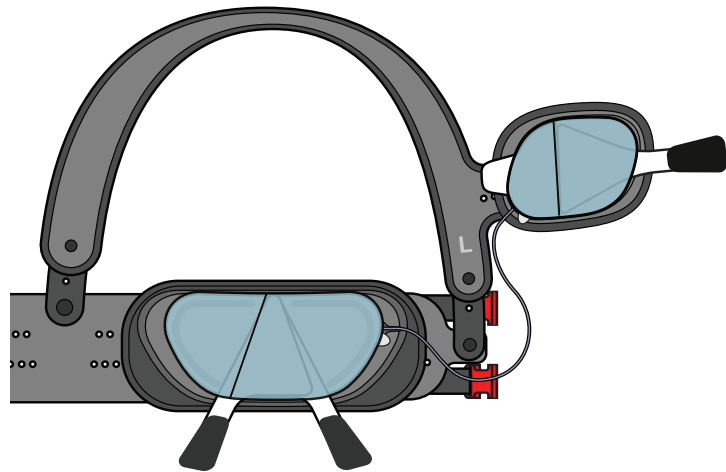
continue →

8



Press the Upper Patch in place.

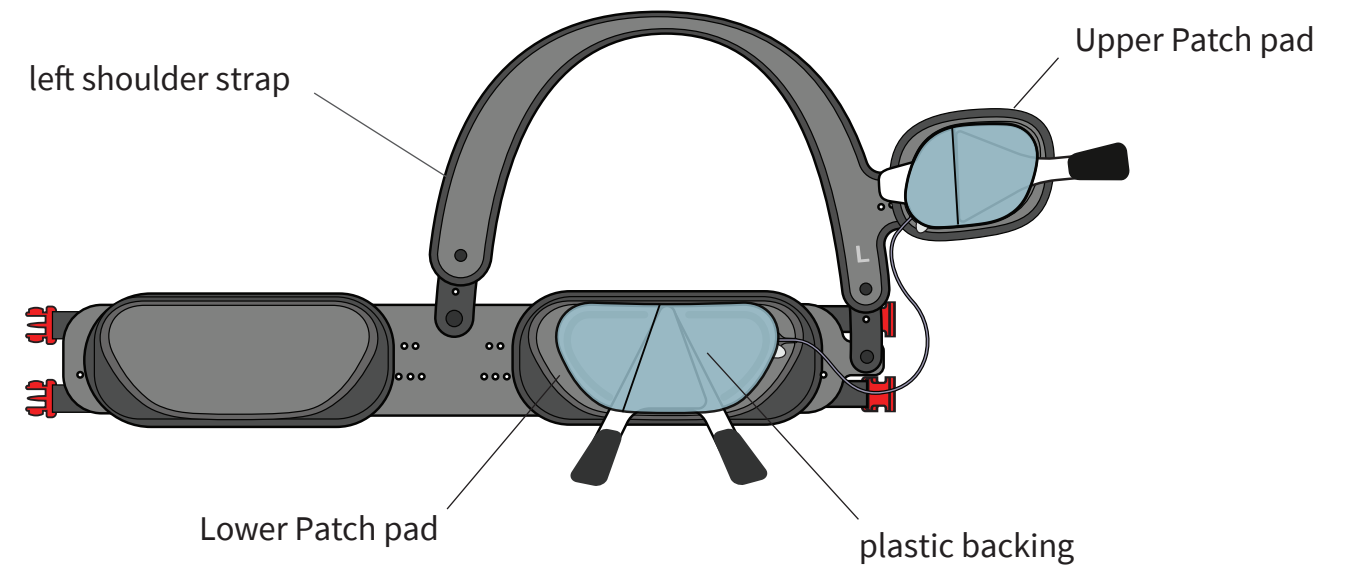
9



The Jewel loading is complete.

3.3 APPLICATION PREPARATION

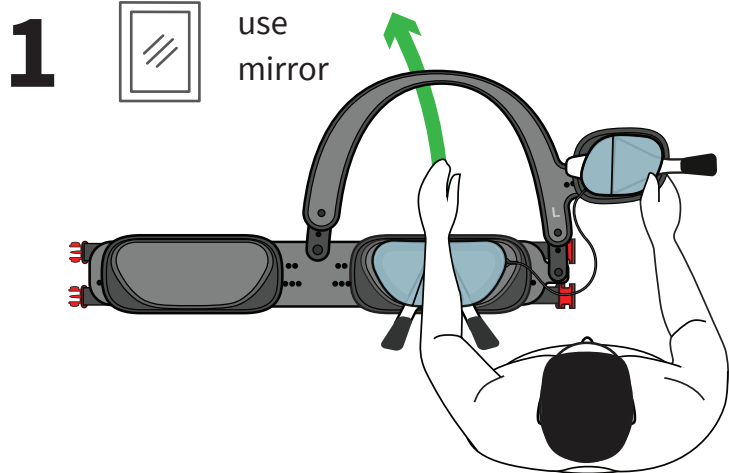
PLACEMENT ACCESSORY COMPONENTS TO KNOW:



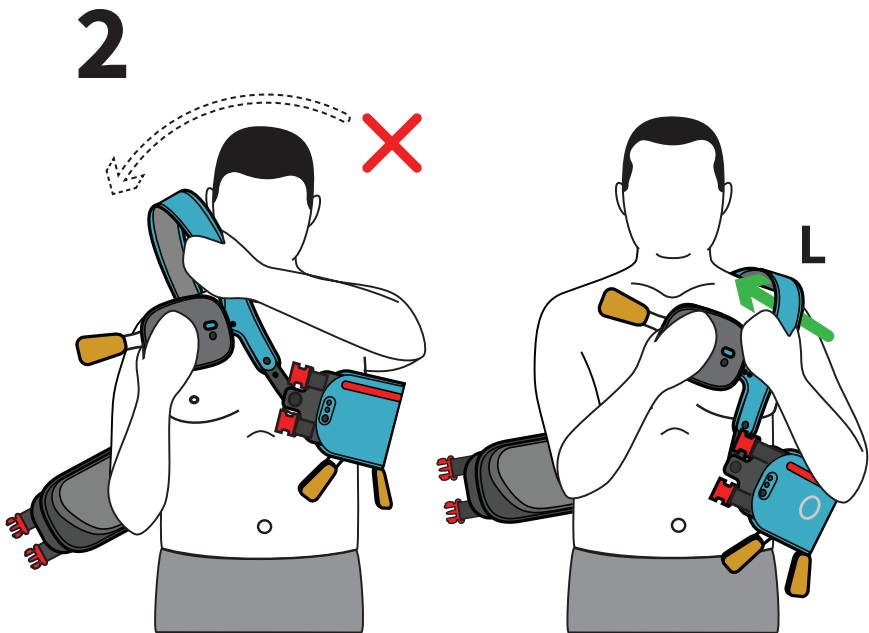
Make sure the plastic backings have not been crumpled and are intact before putting on the Placement Accessory.

PUTTING ON THE PLACEMENT ACCESSORY

These steps cover putting the Placement Accessory on your body. Follow these steps carefully to prevent damaging the Jewel.

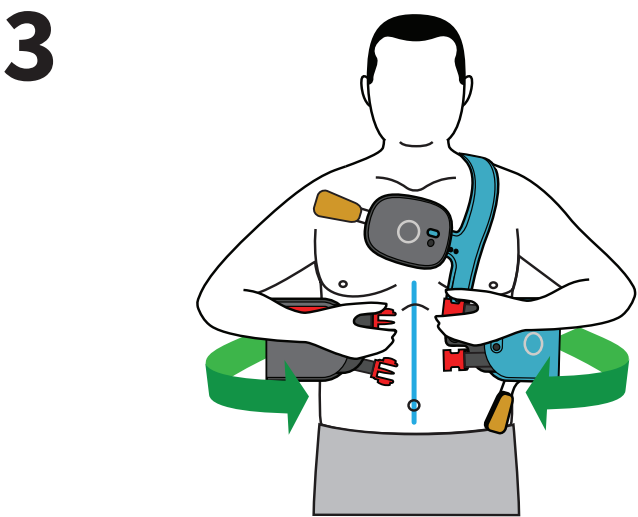


Lean forward.
Pull shoulder strap
onto left shoulder.

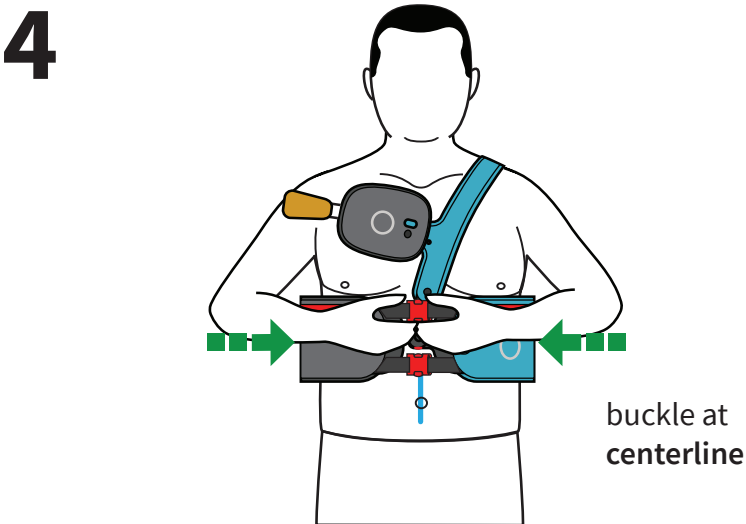


Position Upper Patch Placement
Accessory onto your right chest area.

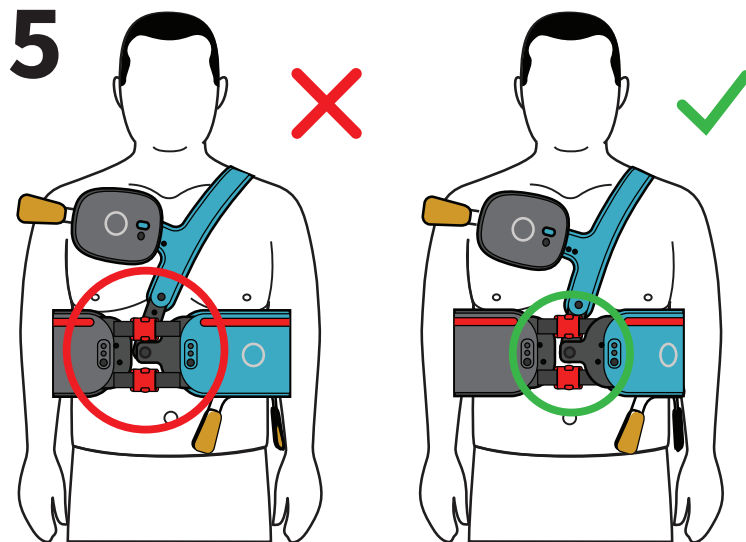
Do NOT put shoulder strap
over your head.



Hold both ends of the buckles.
Align the buckles to the centerline
of your body.



Fasten buckles.



 use mirror

Check again that the buckles are in line
with centerline of your body.

Check that the belt is not twisted in the
back.

ALIGNING THE LOWER BELT

These steps cover aligning the lower belt of the Placement Accessory. Follow these steps so that the Lower Patch is applied in the correct location.

You will also lift away chest/breast tissue from under the belt. You will also remove any clothing under the belt. Follow these steps so that nothing is stuck under the Lower Patch when applied.

TIPS FOR THIS SECTION:
Use a mirror to see red lines while aligning the belt.

WARNING:

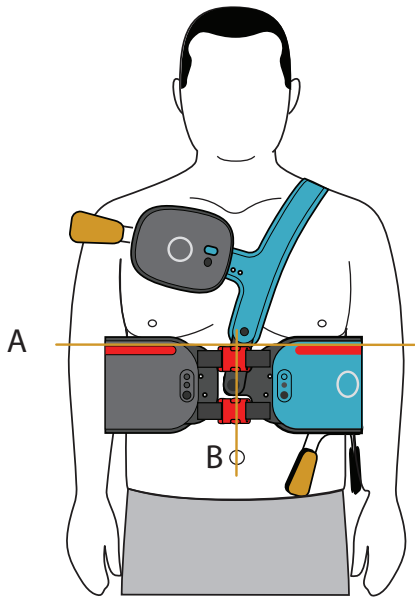


ALWAYS ensure the Jewel is in the correct location on the body. Always use the Placement Accessory while applying the Jewel. Do NOT skip alignment steps or adjust the settings of the Placement Accessory, which could result in the Jewel being applied in the wrong location. Applying the Jewel in the wrong location could result in an electrical shock not given when needed or in an ineffective shock.

1

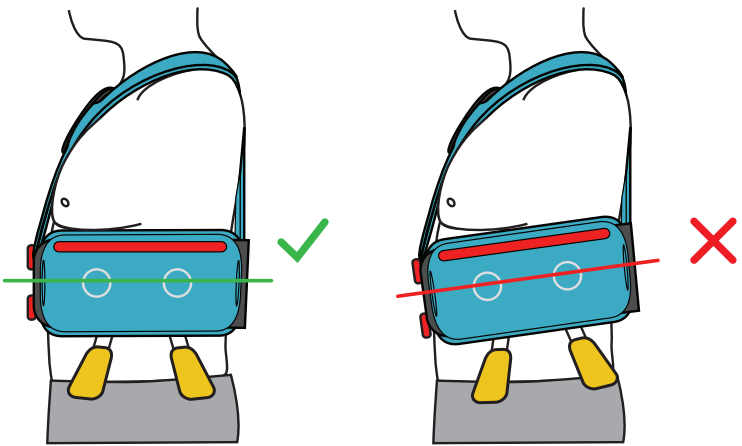


use mirror



- Align belt so that:
- A. Red lines on belt are level and under chest/ breasts.
 - B. Red buckles are on centerline of body.

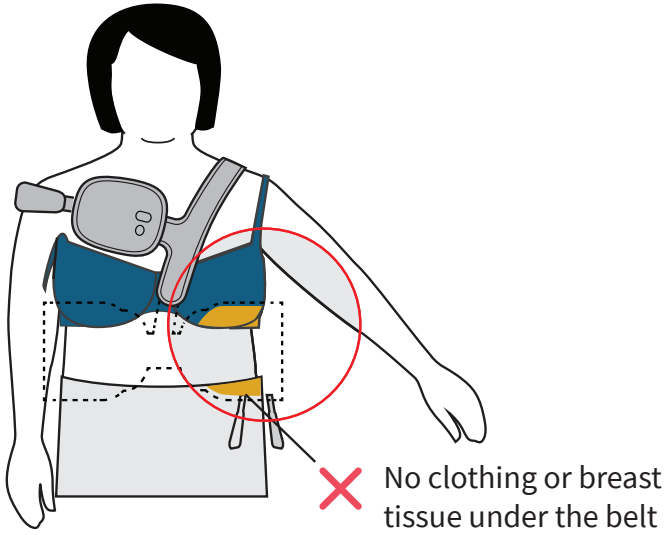
✗ do NOT pull tab 2 or 3



C. Check that the belt is level in front and back.

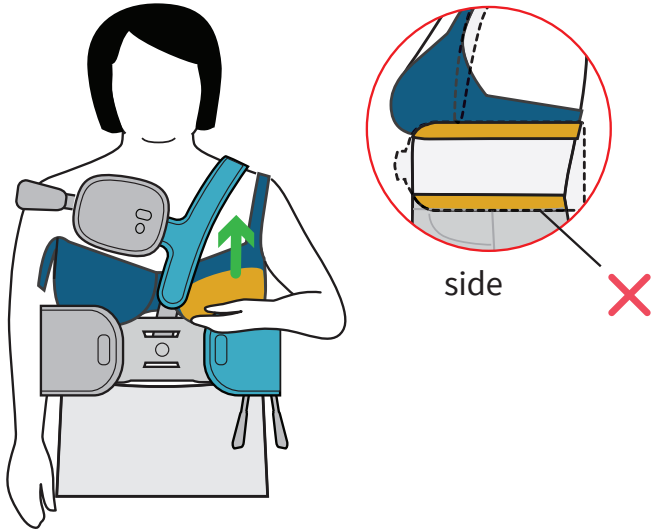
continue →

WOMEN:



ATTENTION: Do not leave any clothing or breast tissue under the belt. Anything under the belt will stick to the device. This may result in discomfort and early device replacement.

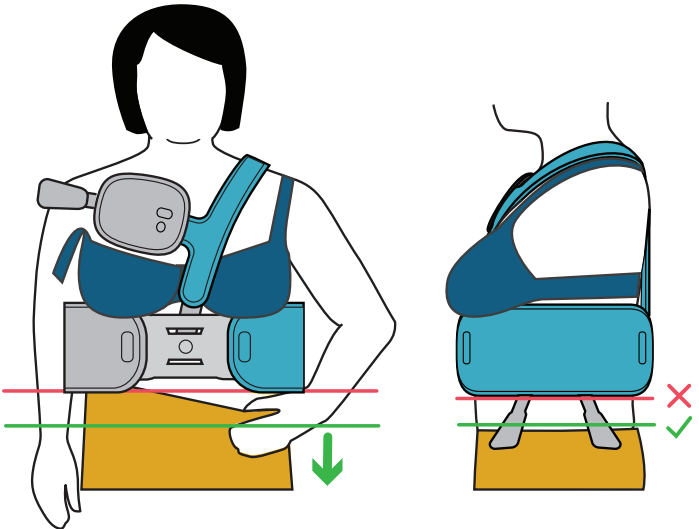
2



Lift any breast tissue under belt.
Pull bra cup at least 1 inch above belt.
Pull bra band at least 1 inch above belt.

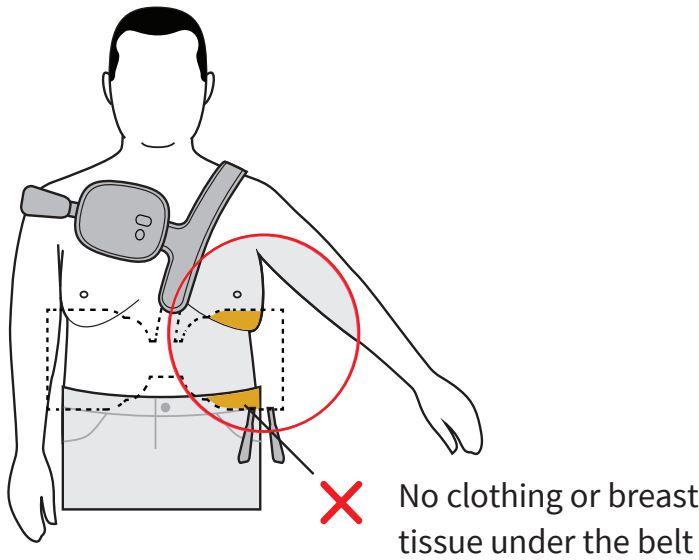
ATTENTION: The foam ring of the lower patch slot must lay flat on skin and not span any skin folds.

3



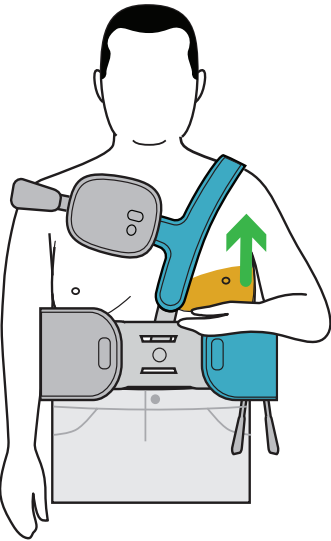
Pull clothing at least 1 inch below belt.

MEN:



ATTENTION: Do not leave any clothing or chest tissue under the belt. Anything under the belt will stick to the device. This may result in discomfort and early device replacement.

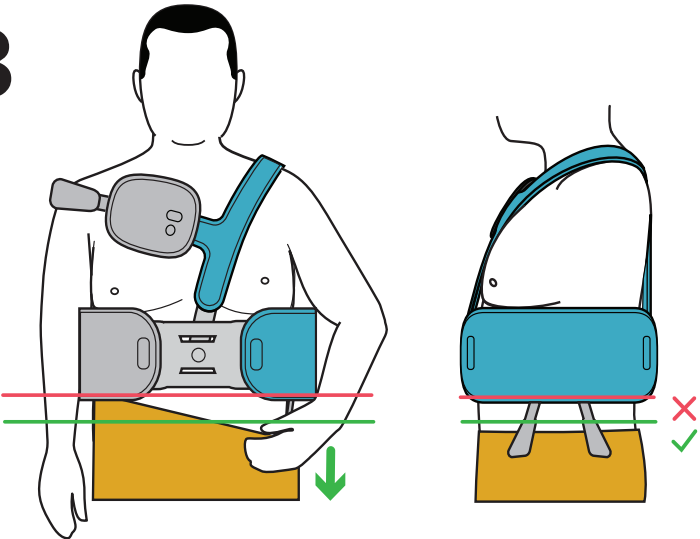
2



Lift any chest tissue from under belt.

ATTENTION: The foam ring of the lower patch slot must lay flat on skin and not span any skin folds.

3



Pull clothing at least 1 inch below belt.

ALIGNING THE UPPER PLACEMENT ACCESSORY

These steps cover aligning the Upper Placement Accessory. Follow these steps so that the Upper Patch is applied in the correct position.

You will also remove any clothing or jewelry from under the Upper Placement Accessory. Follow these steps so that nothing is stuck under the Upper Patch when applied.

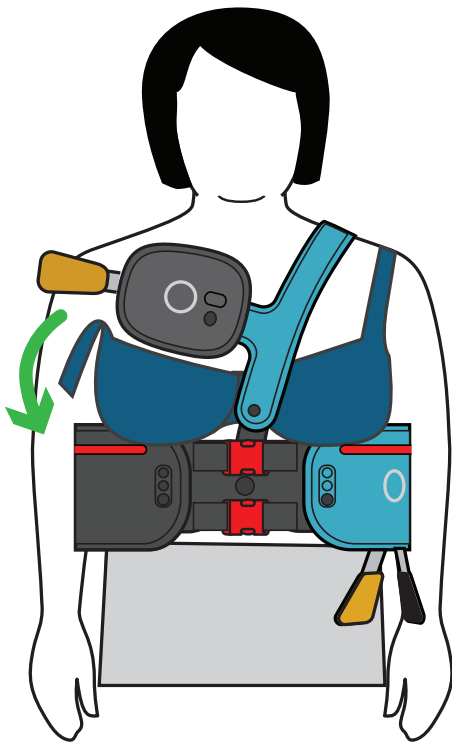
TIPS FOR THIS SECTION:

Use a mirror while aligning the Upper Placement Accessory.

1



use mirror

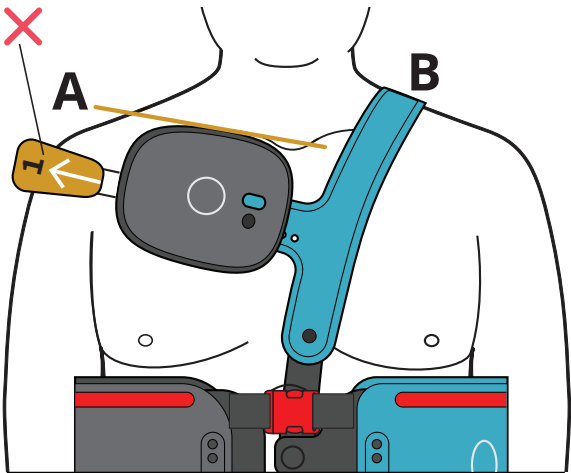


Remove jewelry from under the Upper Placement Accessory.

Women: Remove bra from under the Upper Placement Accessory.

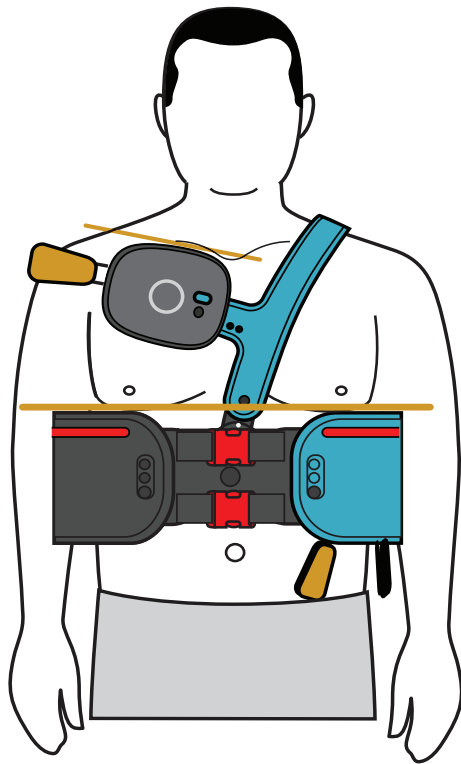
2

do NOT pull tab 1



Align Upper Placement Accessory so that:

- A. Horizontal edge is on top of collar bone
- B. Shoulder strap lays flat on left shoulder.
- C. Rivet is on or to the right of the center of the chest.

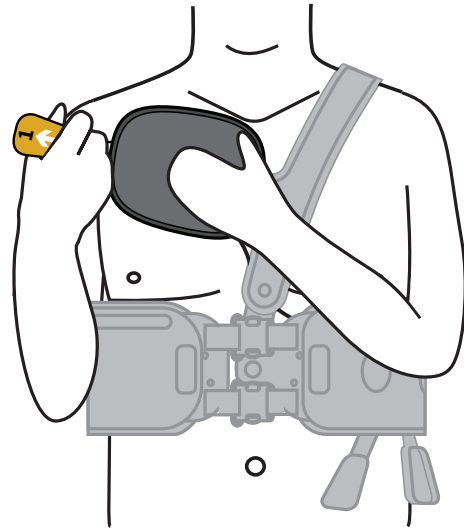


Placement Accessory Alignment complete.

3.4 APPLICATION

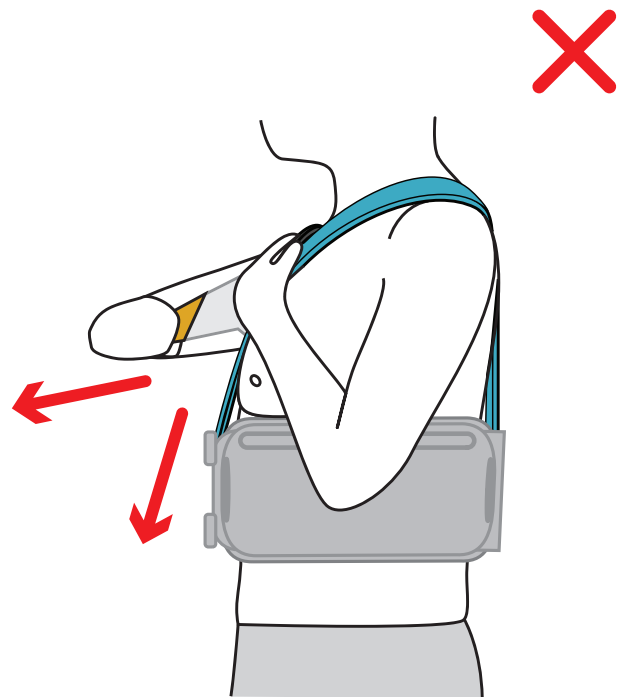
PULLING TAB 1

1



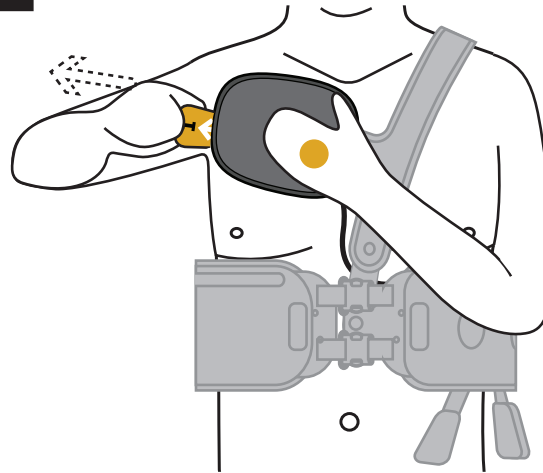
Gently rest hand on upper pad with left palm.

Grip tab 1 with right hand.



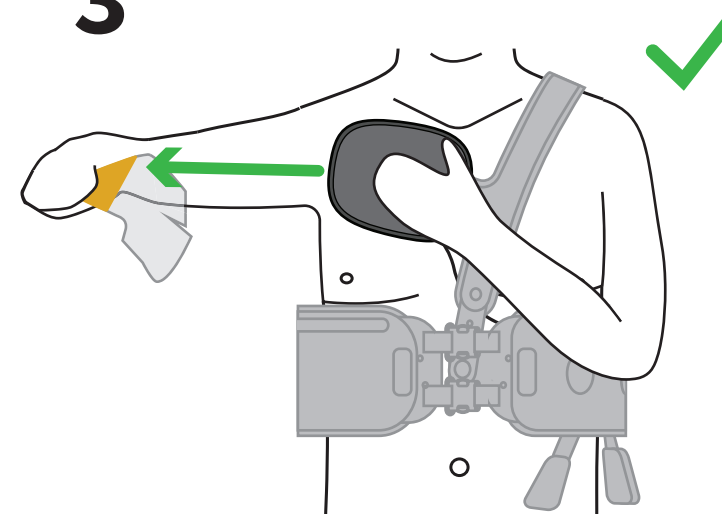
DO NOT pull tab 1 straight down or forward away from the body. (This may result in a poor device application.)

2



Keep pad in place with left palm.

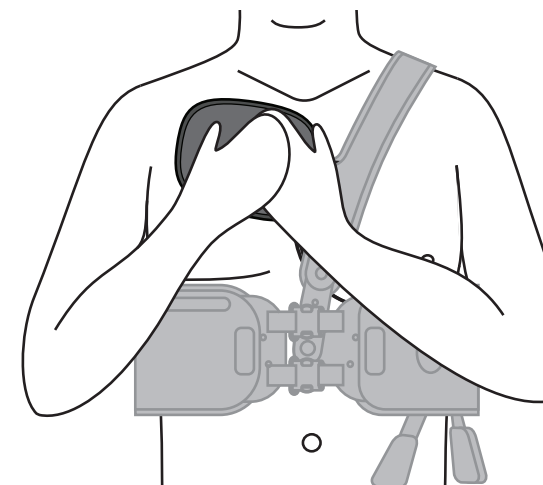
3



Pull tab 1 straight to the side away from your body in a continuous motion until the plastic backing pulls free.

Discard tab 1.

4



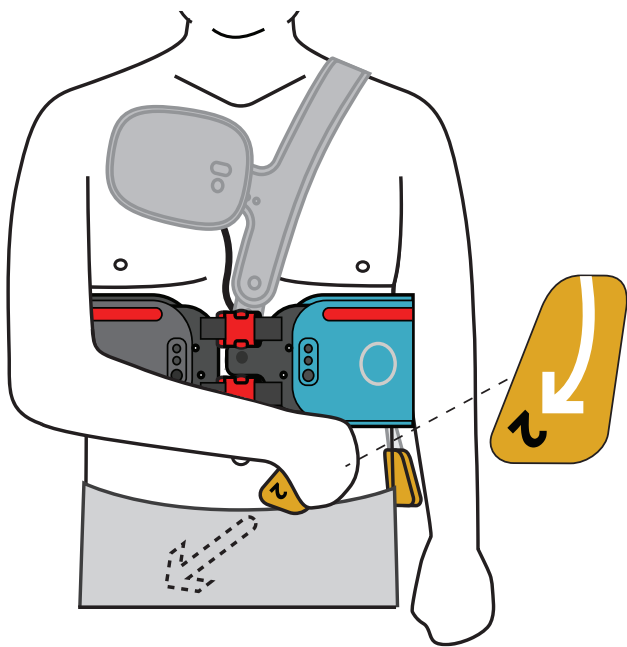
30 sec.

Press down on circle with both hands for 30 seconds to adhere patch to body.

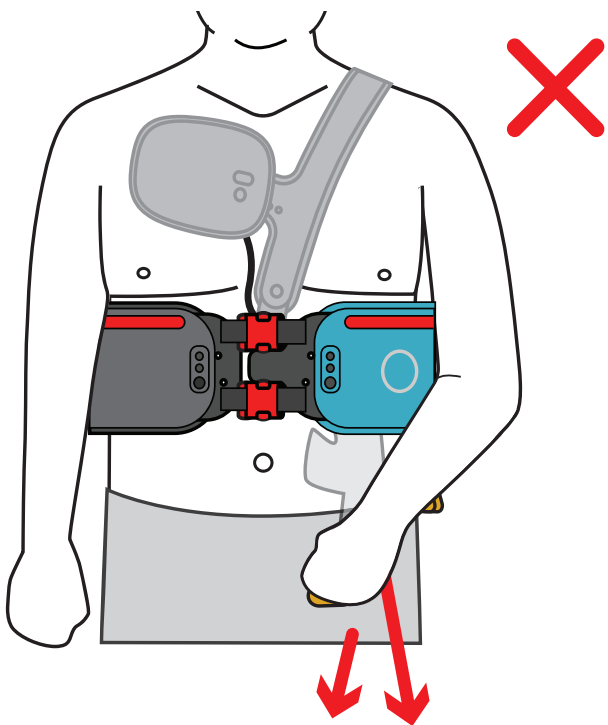
continue →

PULLING TAB 2

1

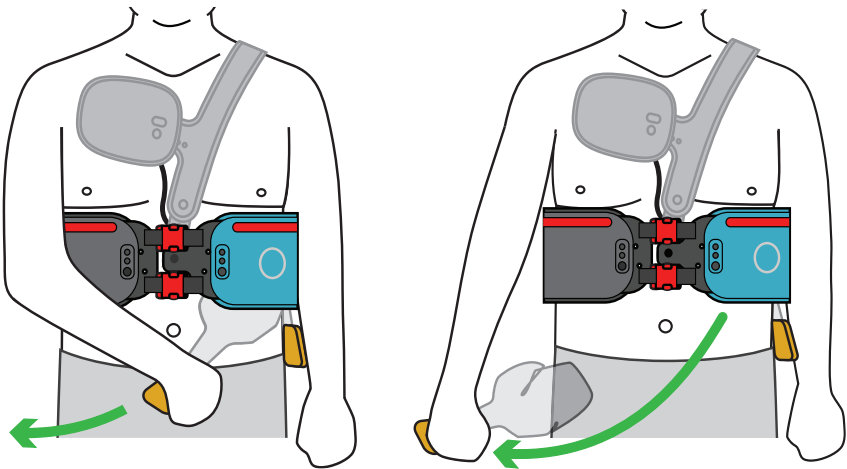


Grip tab 2 with right hand.
Keep left arm straight down.
Do NOT apply pressure on the
belt with your left arm.



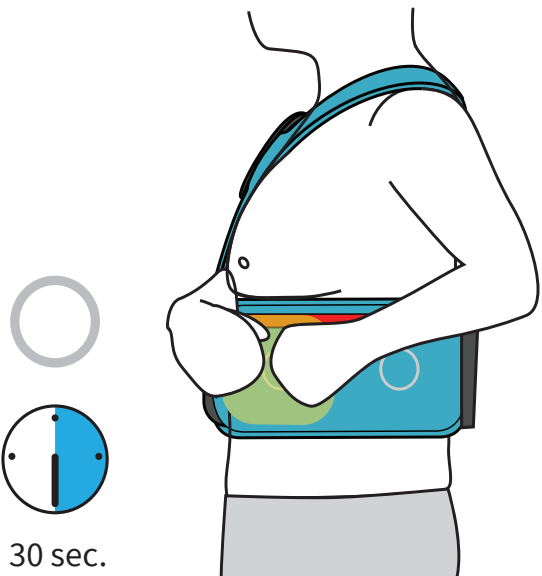
Do NOT pull tab 2 with your left
hand, straight down or forward
away from body.
(This may result in a poor device
application.)

2



Swing arm across the body in a slow
continuous motion until the plastic
backing pulls completely free.
Discard tab 2.

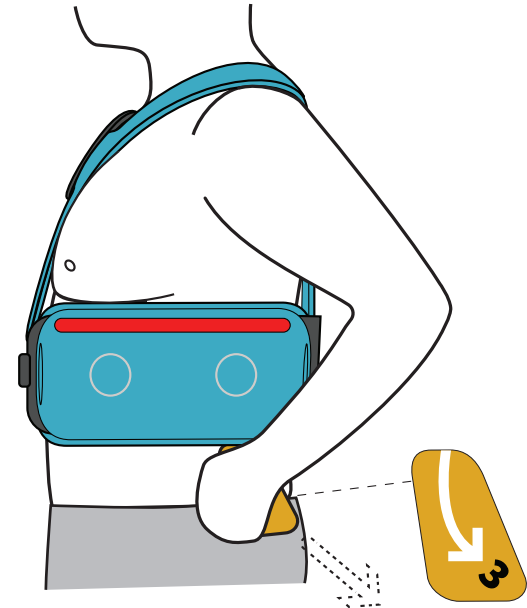
3



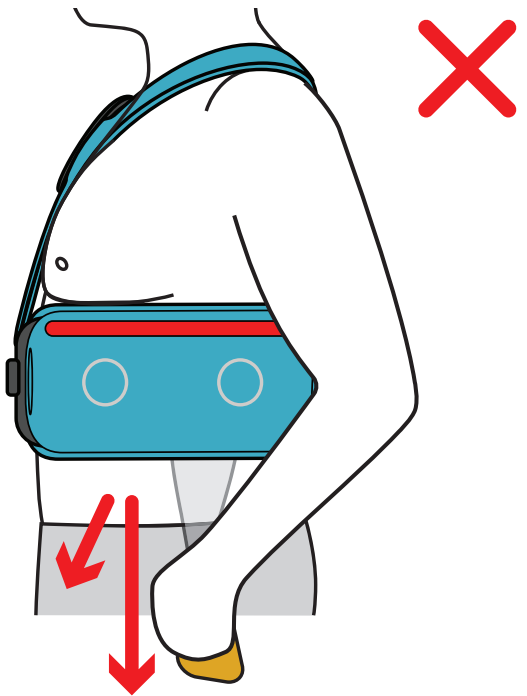
Press down for 30 seconds
on circle (front left) to
adhere patch to body.

PULLING TAB 3

1

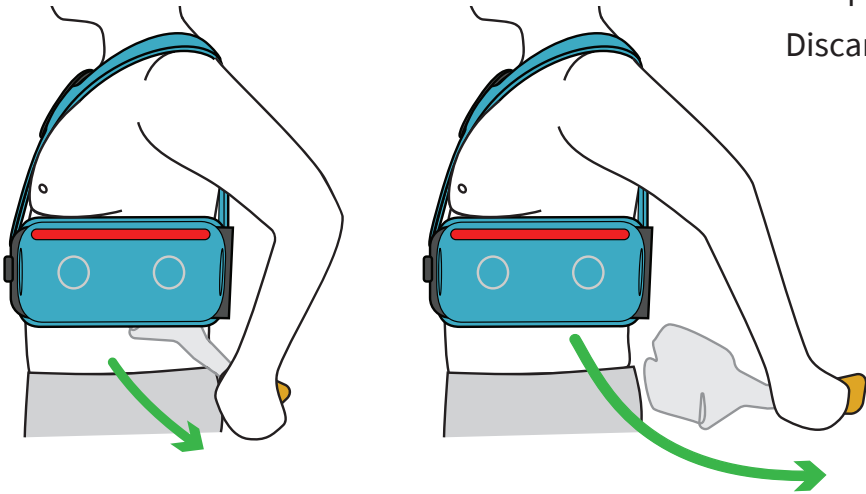


Grip tab 3 with left hand.



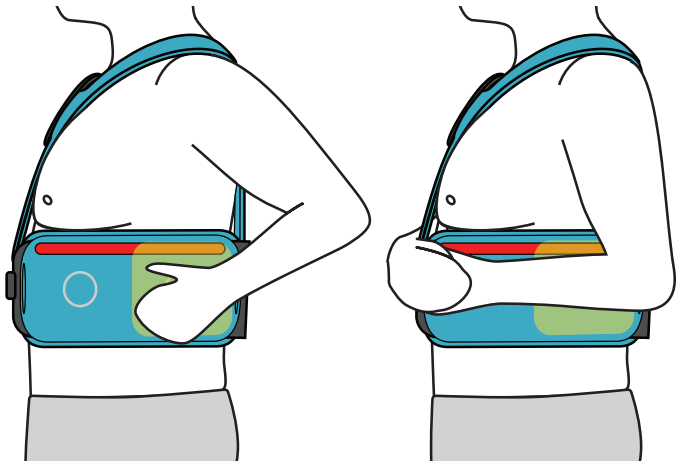
Do NOT pull tab 3 straight down or forward.
(This may result in a poor device application.)

2



Swing arm back in a continuous motion until plastic backing pulls completely free.
Discard tab 3.

3



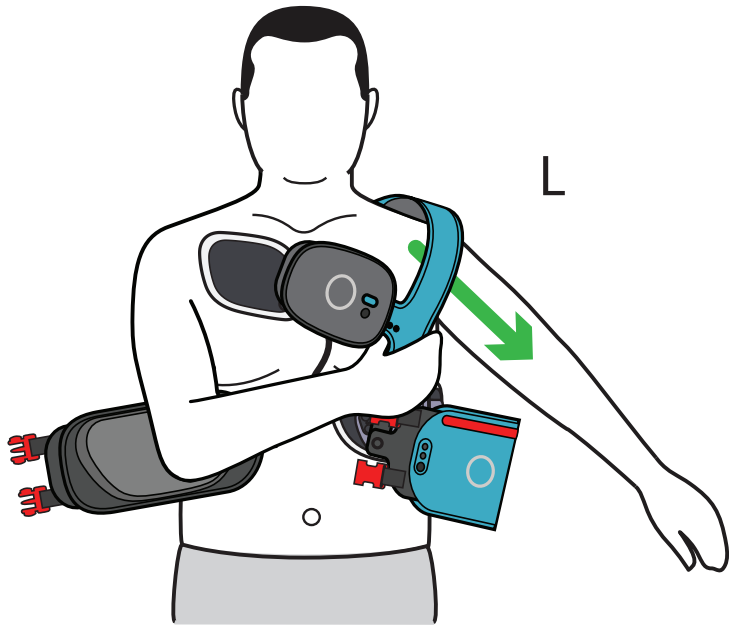
Press down for 30 seconds on circle (back left) to adhere patch to body.



30 sec.
hand or inner arm.

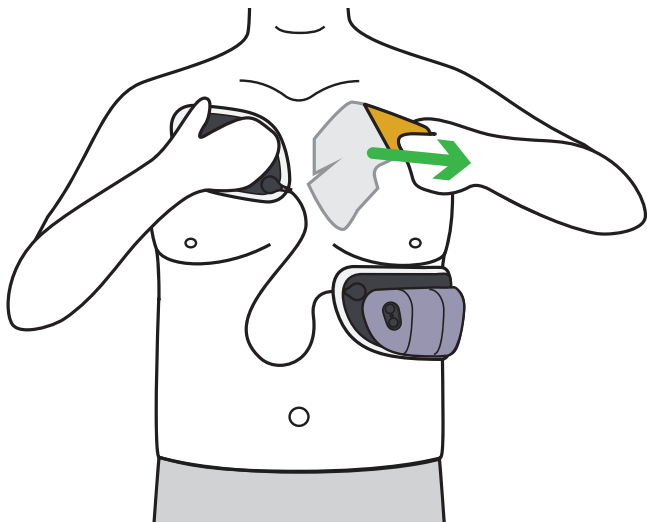
PULLING TAB 4

1



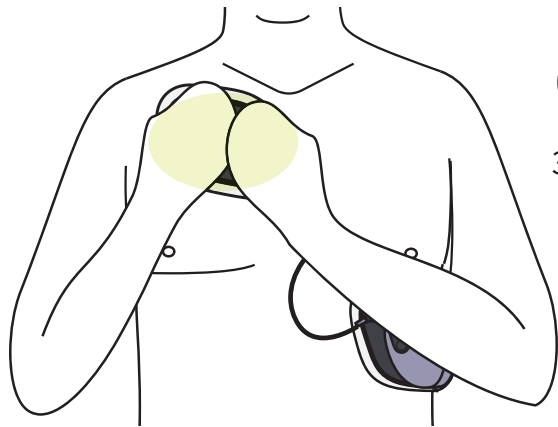
Take off the Placement
Accessory.

2



Pull tab 4 across the body in a
continuous motion until the plastic
backing pulls free.
Discard tab 4.
When the Jewel recognizes it is on
your body and is preparing to monitor
your heart signals, it should beep and
give you a solid green light.

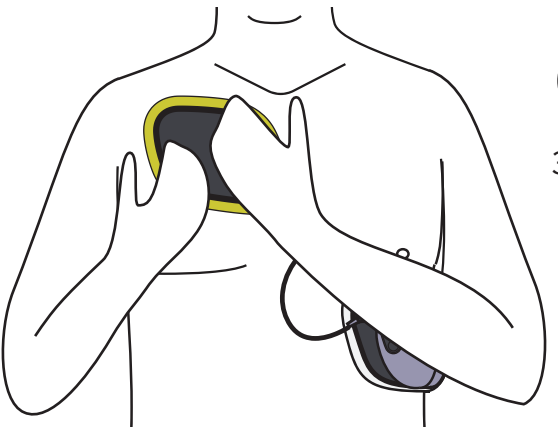
3



30 sec.

Press down on Upper Patch with
both hands for **30 seconds** to
adhere patch to body.

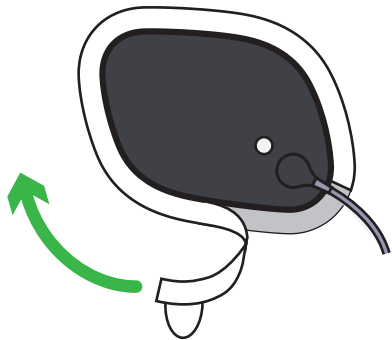
4



30 sec.

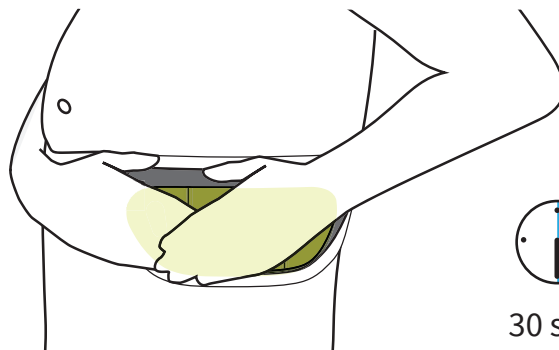
Smooth down patch fabric and
white border for **30 seconds**.

5



Remove white foam border on
edge of Upper Patch

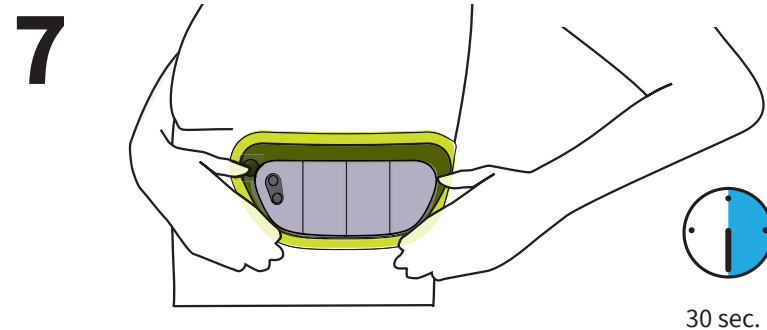
6



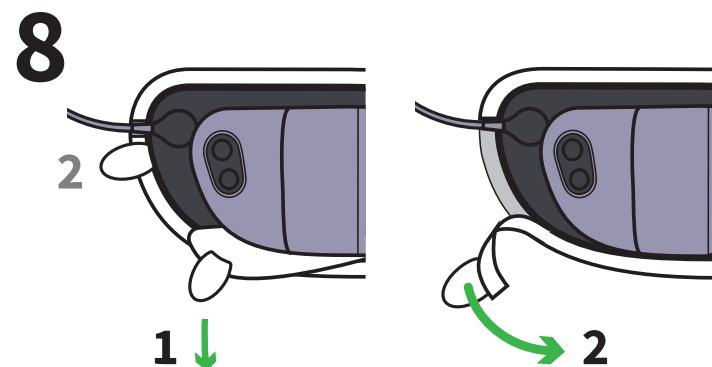
30 sec.

Press down on Defibrillator Unit
for **30 seconds**
to adhere patch to body.

continue →



Smooth down patch fabric and white border for **30 seconds**.



Remove white foam borders on edge of Lower Patch and under Defibrillator Unit.

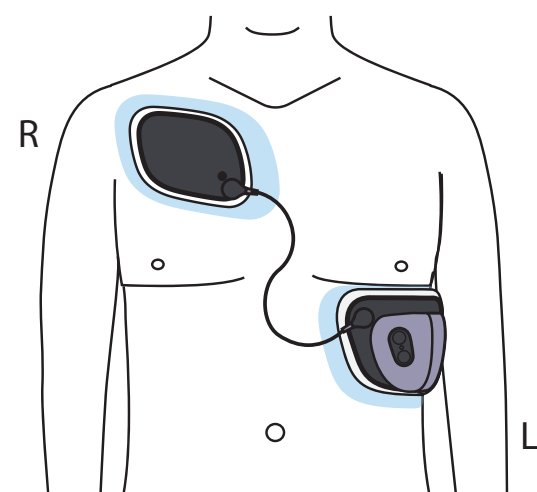
WARNING

Make sure the Jewel is in the correct location on your body.



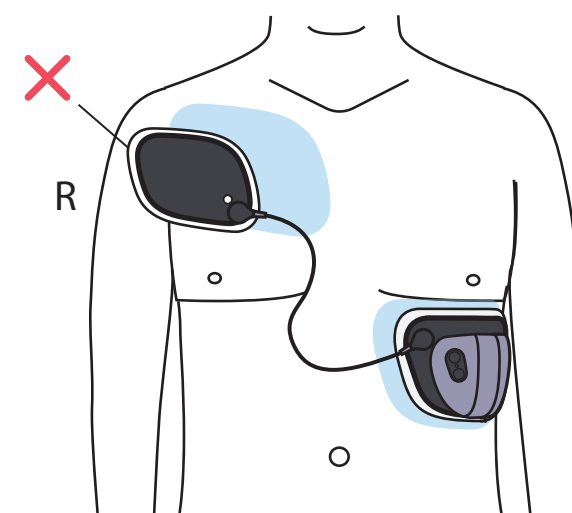
Always use the Placement Accessory while applying the Jewel and do NOT skip alignment steps. If the Placement Accessory is not aligned correctly, the Jewel may be applied in the wrong location. Applying the Jewel in the wrong location could result in an electrical shock not given when needed or in an ineffective shock possibly resulting in serious injury or death.

9 CHECKING PATCH PLACEMENT



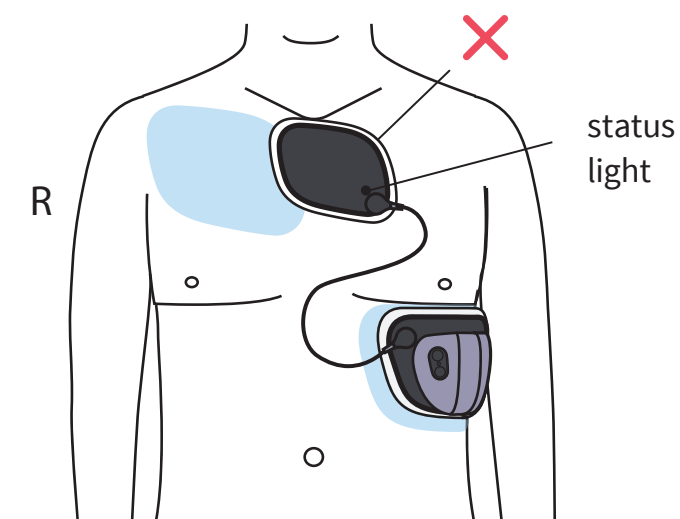
Check that the patches have been applied in the correct locations:

- The Upper Patch should be on your right chest.
- The Lower Patch should be below your breast line on your left side.
- The plastic housings should sit under your left arm.



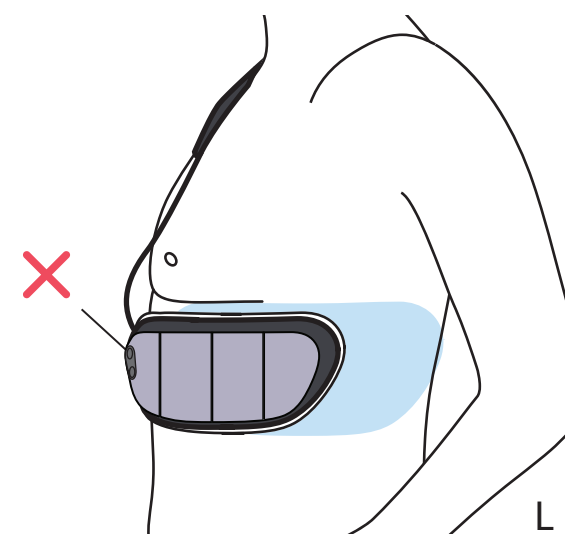
INCORRECT:

More than an inch of the Upper Patch is over your shoulder.



INCORRECT:

Status light on Upper Patch is over your centerline.



INCORRECT:

None of the Lower Patch plastic housings are under your arm.

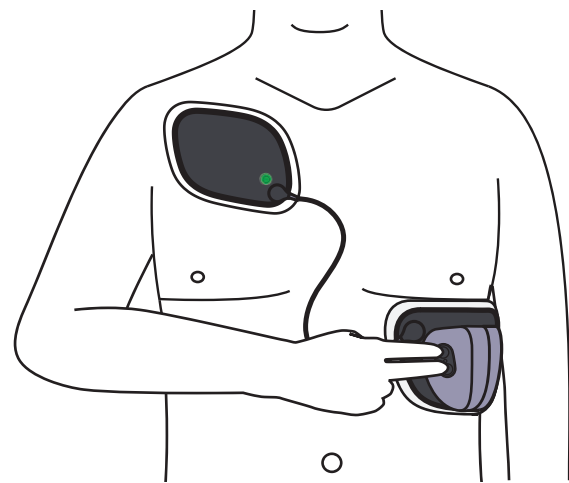
If the Jewel has been applied in an incorrect location you need to remove it and reapply the Jewel with a new Patch Unit.

The Jewel needs to be replaced with a new Patch Unit even if you hear "Jewel is active."

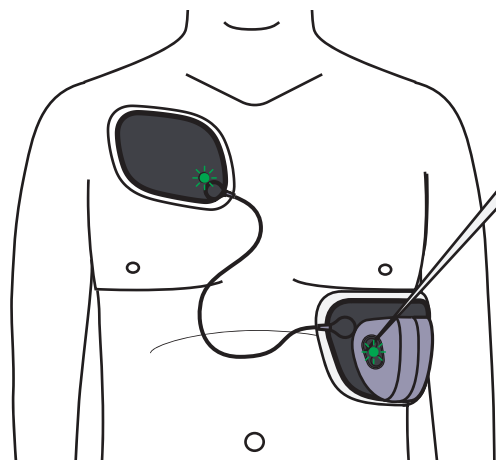
See *Chapter 5: Removal*.



continue →

10





Complete a Status Check to confirm that the Jewel is monitoring: Press both buttons and release after you feel a click.



 Solid green light
 "Jewel is active."

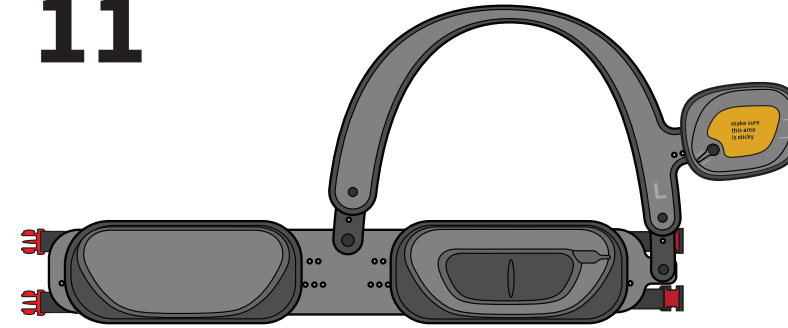
If you do NOT hear "Jewel is active" then see *Chapter 7: Troubleshooting*.

Once applied, you should receive the Jewel is Active alert:

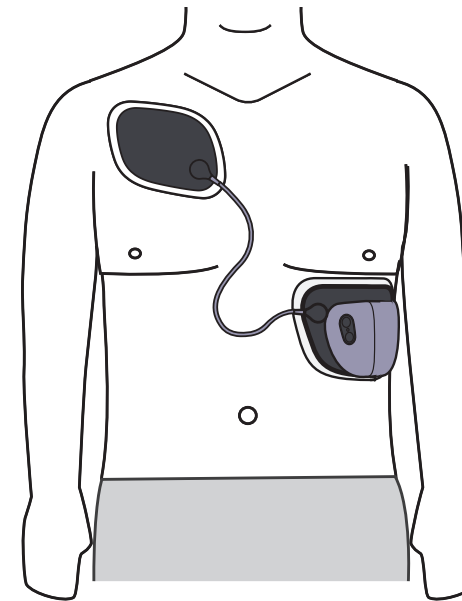
 Solid green light
 "Jewel is active."

The Jewel is now actively monitoring for specific life-threatening heart rhythms.

11



Store Placement Accessory in a clean and dry space for next application.



Application complete.

Note: If you already paired the Mobile App and Jewel, you do not need to pair again. The Mobile App and Jewel will automatically reconnect.

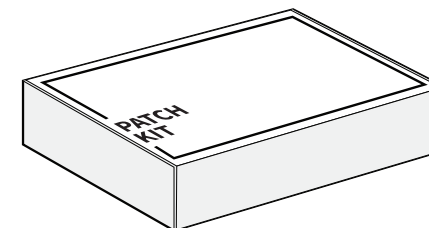
To remove your Jewel, see *Chapter 5: Removal*

To repackage and return your used Patch Unit and Defibrillator Unit, see *Chapter 6: Returns*.

12



DEFIBRILLATOR UNIT BOX



PATCH KIT BOX

Do not discard the Patch Kit box, Defibrillator Unit box, and shipping box as well as the contents inside each box.

Store boxes in a cool, dry location. The contents of the Patch Kit box will be used to remove and return the used Patch Unit.

page intentionally left blank.

4



4

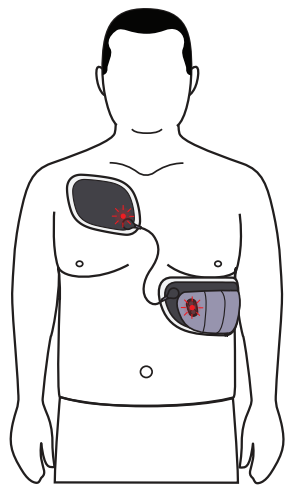
NOTIFICATIONS RESPONDING TO ALERTS AND ALARMS


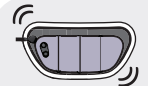
4.1 WHAT ARE THE JEWEL NOTIFICATIONS?

HOW THE JEWEL COMMUNICATES




The Jewel communicates to you through tones, voice prompts, lights, and vibrations. Use this section to know what each alert and alarm means and how to respond.

SYMBOL GUIDE:



-  Tones
-  Voice Prompts
-  Vibration
-  Lights

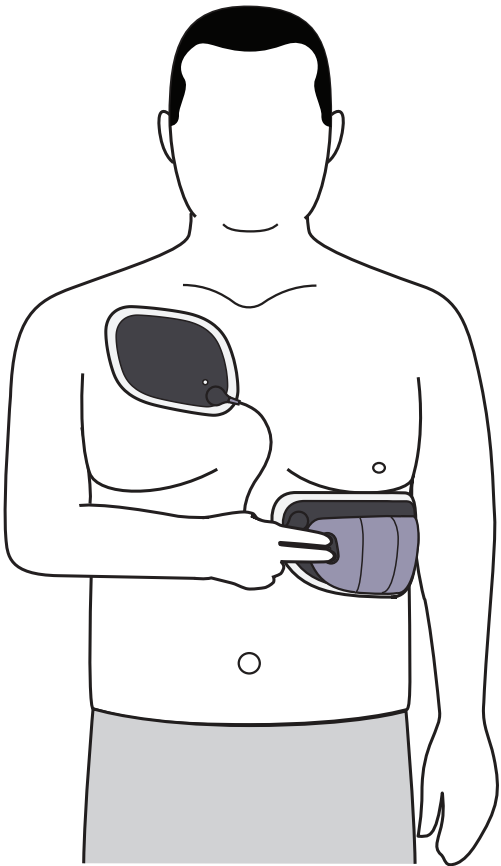
LIGHT COLOR GUIDE:

-  RED LIGHT Immediate Action Required
-  YELLOW LIGHT Action Required
-  GREEN LIGHT No Action Required

STATUS CHECK

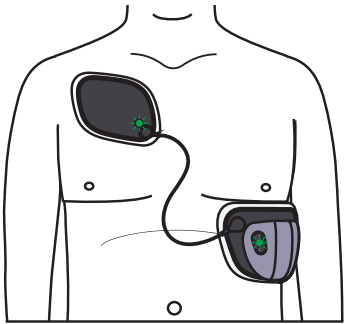
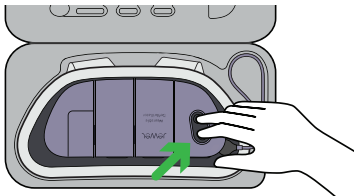
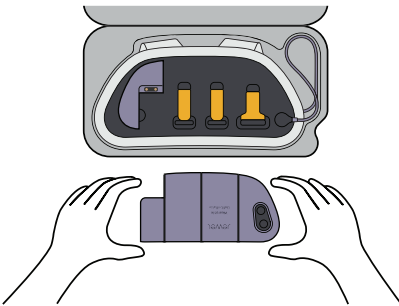
Status check helps you understand the current state of the Jewel. If a voice alert has been delivered, a status check will repeat the last voice alert.








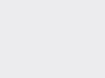


TO COMPLETE A STATUS CHECK:
Press both buttons and release after you feel a click.



WEEKLY JEWEL NOTIFICATIONS

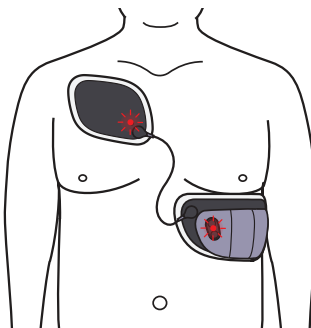
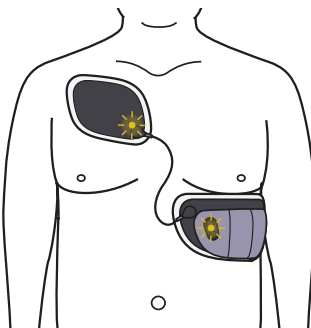
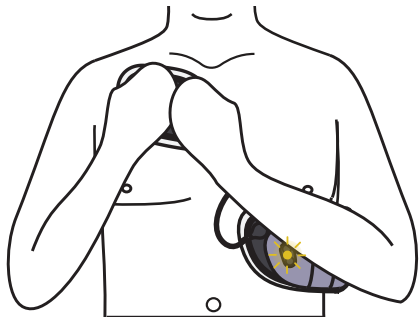
APPLICATION











				
				
<p><i>*no voice prompt or tone*</i></p>	<p><i>"Device is disabled and must be replaced. Call customer service immediately."</i></p>	<p><i>"Jewel is in Application Mode. Apply Jewel now using Placement Accessory."</i></p>	<p><i>*tone*</i></p>	<p><i>"Jewel is active."</i></p>
<p>Defibrillator Unit and Patch Unit are not assembled</p> <p>This means the Defibrillator Unit and Lower Patch are not assembled correctly. Press each module to make sure the Defibrillator Unit and patch are fully connected.</p>	<p>Jewel Turn On: Device Malfunction</p> <p>The Defibrillator Unit is not working and should NOT be applied. Call Customer Service immediately to request a new Defibrillator Unit.</p>	<p>Application Mode</p> <p>The Jewel is in Application Mode and has not yet detected that the Jewel has been applied yet.</p>	<p>Normalization</p> <p>The Jewel has been successfully applied but is not active yet. This beep is the start of a 2 minute warming up stage before becoming active.</p>	<p>Jewel is Active</p> <p>The Jewel has been successfully applied. The Jewel is now actively monitoring for specific life-threatening heart rhythms. If the Jewel continues to play the Application Mode message, it means the Jewel is NOT active yet.</p>

DURING WEAR

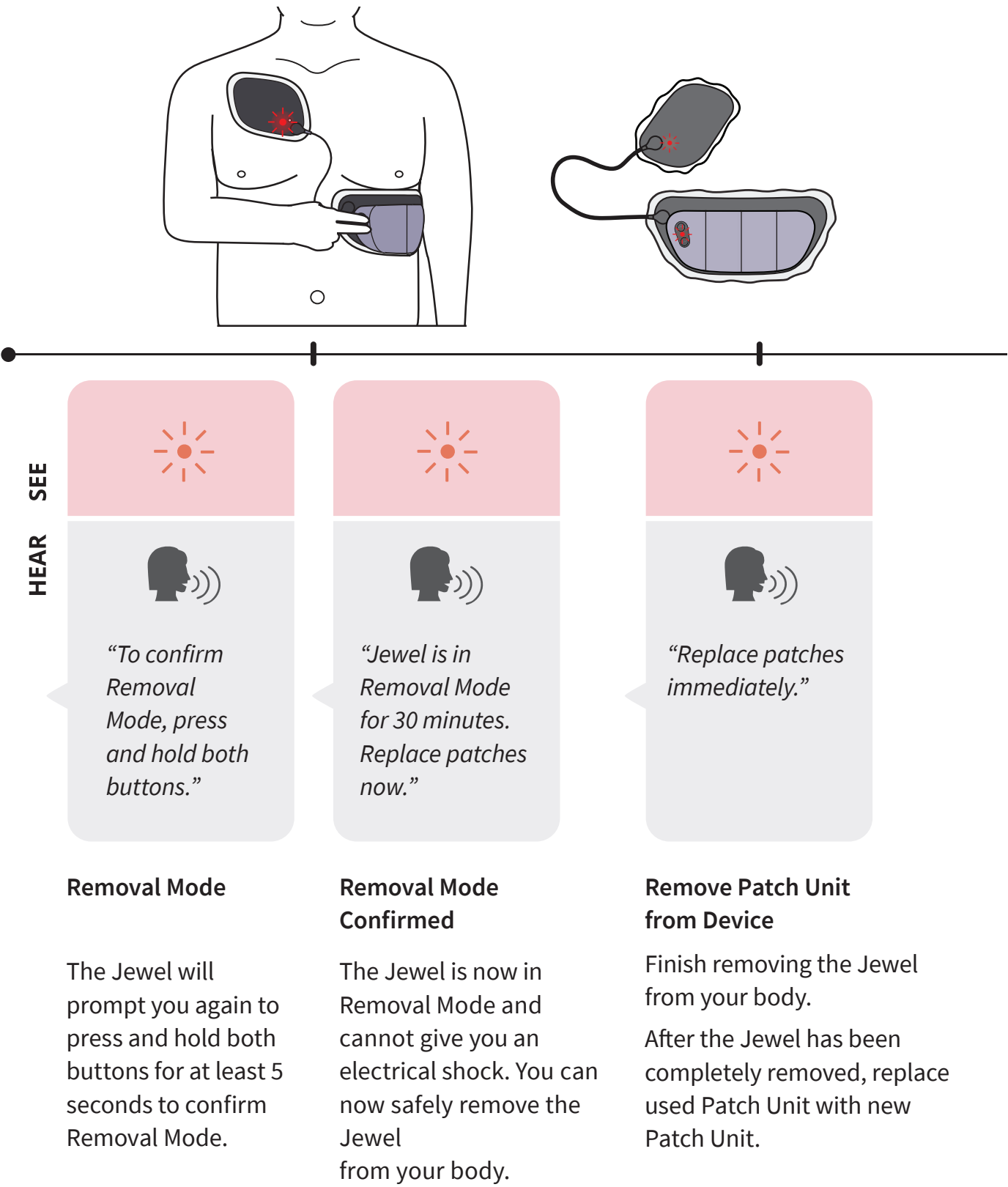
Alerts and alarms cannot be turned off. Only the Siren Alarm can be canceled.



			
			
<p><i>"Patches losing contact with skin. Press and hold both patches."</i></p>	<p><i>"Replace Patches Soon."</i></p>	<p><i>"Patches expired. Replace Patches now."</i></p> <p><i>To start Removal Mode press and hold both buttons."</i></p>	<p><i>"Patches expired and no longer working. Replace patches immediately."</i></p> <p><i>To start Removal Mode press and hold both buttons."</i></p>
<p>Press and Hold Alert</p> <p>The Jewel has detected that the patches may be losing skin contact and need to be pushed back onto your skin.</p>	<p>Replace Patches Soon Alert</p> <p>Patches must be replaced within 24 hours. This alert repeats every 6 hours.</p>	<p>Replace Patches Now Alert</p> <p>Patches must be replaced within three hours. This alert repeats every hour.</p>	<p>Replace Patches Immediately Alert</p> <p>Patches must be replaced immediately. The Jewel will not be able to detect specific life-threatening heart rhythms or deliver an electrical shock if needed. This alert repeats every 20 minutes.</p>

continue →

REMOVAL

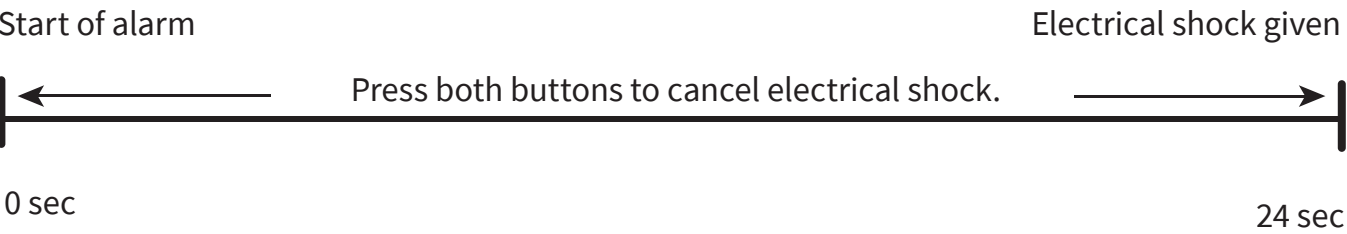


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SIREN ALARM OVERVIEW

The Siren Alarm plays when the Jewel detects specific life-threatening heart rhythms and will deliver an electrical shock in 24 seconds.

You should immediately press both buttons to respond to this alarm. No one else should press the buttons for you. If you do not press both buttons, the Jewel will deliver an electrical shock.



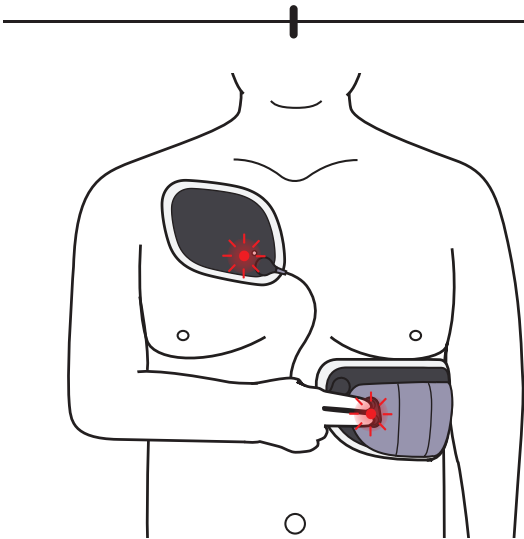
flashing red

vibration

siren

*“Preparing for electrical shock.
To cancel electrical shock, press both buttons.
Do not touch patient.
Bystanders, do not touch patient.”*

IF YOU ARE CONSCIOUS:
Press both buttons immediately.
(See warning on next page.)

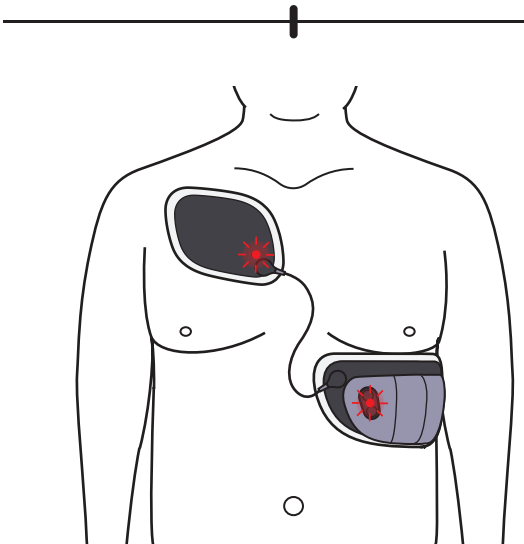


The alarm and shock are cancelled when you hear the Jewel say “Electrical Shock Canceled”. If you do not hear this, press both buttons again.
The Jewel is now actively monitoring for specific life-threatening heart rhythms.

solid green

“Electrical shock canceled. Jewel is active.”

IF YOU ARE UNCONSCIOUS:
You are experiencing specific life-threatening heart rhythms and will receive an electrical shock.
Bystanders should NOT touch you or the Jewel.



Electrical shock was given.
You should keep wearing the Jewel and seek emergency care.

flashing yellow

“Electrical shock given. Seek emergency care.”

WARNING:

•**ALWAYS** press both buttons to defer therapy delivery if the patient is conscious when hearing the siren alarm. If the patient does NOT press both buttons, an electrical shock will be delivered.

•**ONLY** the patient should press the buttons to defer therapy. Anyone other than the patient pressing the buttons during the siren alarm may result in an electrical shock not given when needed.

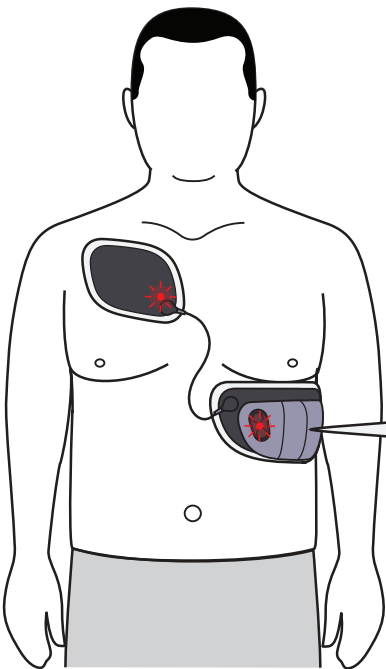


If you keep getting the siren alarm but feel fine, there is something in the environment that may be affecting the Jewel. Continue to cancel the electrical shock by pressing both buttons and change your location.

If you continue to get the siren alarm after you have changed locations, replace the Patch Unit immediately so you do not get an electrical shock when your heart is in a normal rhythm. See removal instructions in *Chapter 5: Removal*.

EMERGENCY SERVICES REQUIRED ALARM

This alarm may occur when the Jewel detects specific life-threatening heart rhythms that it cannot treat OR after the Jewel has delivered all available electrical shocks.



THIS ALARM INCLUDES THE FOLLOWING:



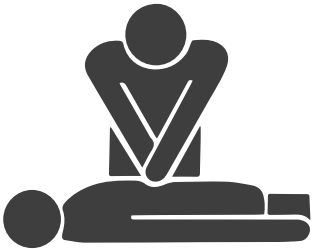
Red Flashing Light



Loud Siren



"If patient is unresponsive, call 911 and start CPR"



IF YOU ARE CONSCIOUS:
Seek emergency care. If available, replace Patch Unit.
See Chapter 5: Removal

IF YOU ARE UNCONSCIOUS:
Bystanders should call 911 and start CPR.

ALERTS AND ALARMS INDEX

This index lists all of the possible voice prompts you might receive while using the Jewel. You may feel a vibration during some of these notifications.

flashing green light

AFTER TURNING ON THE JEWEL:

If you hear: “Jewel is in Application Mode. Apply Jewel now using Placement Accessory.”	What it means: The Jewel is in Application Mode but has not detected that it has been applied. The Jewel cannot give you an electrical shock.	What to do: Insert the Jewel into Placement Accessory and apply the Jewel now. <i>See Chapter 3: Application</i>
---	--	---

AFTER APPLYING THE JEWEL:

If you hear: “Jewel is in pairing mode. Pairing Jewel now.” "Pairing Successful" "Pairing Unsuccessful. Try again."	What it means: The Jewel is in the process of pairing with your iPhone. The Jewel is paired with your iPhone. The Jewel was not able to pair with your iPhone.	What to do: If pairing is successful, there are no additional steps. If pairing is unsuccessful, repeat process until the Jewel and your iPhone are paired. Go to pairing troubleshooting in <i>Chapter 1 Section 3</i> for help.
---	--	--

solid green light

AFTER THE JEWEL APPLICATION:

If you hear: “Jewel is active.”	What it means: The Jewel has been successfully applied. The Jewel is now actively monitoring for specific life-threatening heart rhythms.	What to do: No action is needed. The Jewel is in monitoring mode.
---	--	---

AFTER ELECTRICAL SHOCK CANCELED:

If you hear: “Electrical shock canceled. Jewel is active.”	What it means: You canceled the electrical shock by pressing both buttons. The Jewel did not give you an electrical shock. The Jewel is now actively monitoring for specific life-threatening heart rhythms.	What to do: No action is needed. The Jewel is in monitoring mode.
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flashing yellow light

WHILE WEARING THE JEWEL:

If you hear: “Patches losing contact with skin. Press and hold both patches.”	What it means: The Jewel has detected the patches are losing skin contact.	What to do: Press and hold both patches for 1 minute to improve patch contact with skin.
---	--	--

“Replace patches soon.” This alarm repeats every 6 hours and cannot be turned off.	This is a Replacement Alert. The Jewel may detect the battery has a maximum of 24 hours remaining or patches are losing skin contact and need to be replaced within 24 hours. The Jewel can still detect the specific life-threatening heart rhythms and deliver an electrical shock if needed.	Replace patches within 24 hours. <i>See Chapter 5: Removal</i>
---	--	---

“Patches expired. Replace patches now. To start Removal Mode press and hold both buttons.” This alarm repeats every hour and cannot be turned off.	This a Replacement Alert. The Jewel may detect the battery has a few hours remaining or patches are losing skin contact and need to be replaced within 3 hours. The Jewel can still detect the specific life-threatening heart rhythms and deliver an electrical shock if needed.	Replace patches within 3 hours. <i>See Chapter 5: Removal</i>
---	--	--

“Jewel is detecting magnetic interference. Move away from current location.”	The Jewel is sensing magnetic interference which can negatively affect its operation.	Move at least 3 feet away from your current location in order to refrain from exposure to magnetic interference nearby.
--	---	---

AFTER ELECTRICAL SHOCK:

If you hear: “Electrical shock given. Seek emergency care.”	What it means: The Jewel gave you an electrical shock. An electrical shock was given because the Jewel detected you had specific life-threatening heart rhythms.	What to do: You should keep wearing the Jewel and seek emergency care.
---	--	--

 **flashing red light**

AFTER JEWEL TURN ON:

If you hear: “Device is disabled and must be replaced. Call Customer Service immediately.”	What it means: There is a malfunction with the Defibrillator Unit.	What to do: Do not apply the Jewel. Call Customer Service immediately to request a new Defibrillator Unit.
“Patches no longer working. Replace patches immediately”	There is a malfunction with the Patch Unit.	Do not apply the Jewel. Replace current Patch Unit with a new Patch Unit.
No voice prompts or tones. Only red flashing light.	Defibrillator Unit and Lower Patch are not assembled correctly.	Check to make sure that the Defibrillator Unit and Lower Patch are fully connected.

WHILE WEARING THE JEWEL:

If you hear: “Patches expired and no longer working. Replace patches immediately. To start Removal Mode press and hold both buttons.” This alarm repeats every 20 minutes and cannot be turned off.	What it means: This a Replacement Alert. The Jewel may detect a critically low battery or patches have lost skin contact and need to be replaced immediately. The Jewel will not be able to detect the specific life-threatening heart rhythms or deliver an electrical shock if needed.	What to do: Replace patches immediately. See <i>Chapter 5: Removal</i>
“Preparing for electrical shock. To cancel electrical shock, press and hold both buttons. Do not touch patient. Bystanders, do not touch patient.”	The Jewel senses specific life-threatening heart rhythms and is preparing to give you an electrical shock.	Press and hold both buttons to cancel the alarm. Bystanders: if patient is unconscious, do not touch patient. See <i>Siren Alarm Instructions: Page 100</i>
No voice prompts or tones. Red flashing light and vibration.	There is a malfunction with your Defibrillator Unit	Call Customer Service immediately, because you need a replacement Defibrillator Unit

 **flashing red light**

If you hear: “If patient is unresponsive, call 911 and start CPR”	What it means: The Jewel detects an abnormal heart rhythm but cannot deliver treatment, or electrical shock is not the correct treatment for this type of heart rhythm. This alarm cannot be turned off.	What to do: If you, the patient, are conscious, replace the Patch Unit immediately. If patient is unconscious, bystanders should call 911 and start CPR. See <i>Emergency Services Required Instructions: page 103</i>
“Patches no longer working. Replace patches immediately.”	The Jewel detected that the patches have come off your body and it is waiting to confirm that it is no longer attached. The Jewel may not be able to detect the specific life-threatening heart rhythms or deliver an electrical shock if needed.	If you continue to hear this alert, replace the patches immediately. See <i>Chapter 5: Removal</i>
“Device is disconnected from patch and is unable to provide electrical shock. Press first module of device.”	The first module of the Defibrillator Unit has become disconnected from the patch. The Jewel is no longer working properly.	Press the first module of the Defibrillator Unit to reconnect it with the patch.
“Device is disconnected from patch and is unable to provide electrical shock. Press last module of device.”	The last module of the Defibrillator Unit has become disconnected from the patch. The Jewel is no longer working properly.	Press the last module of the Defibrillator Unit to reconnect it with the patch.

AFTER ELECTRICAL SHOCK:

If you hear: “Electrical Shock Given. Seek Emergency care. Patches expired and no longer working. Replace patches immediately.”	What it means: The Jewel gave you an electrical shock. An electrical shock was given because Jewel detected you had specific life-threatening heart rhythms. The Jewel will not be able to detect or deliver any more additional electrical shocks if needed.	What to do: Seek emergency care. Replace Patch Unit if one is available.
---	--	--

 **flashing red light**

REMOVING THE JEWEL:

If you hear: “To confirm Removal Mode, press and hold both buttons.”	What it means: The Jewel needs you to confirm that you would like to put it into Removal Mode.	What to do: Press and hold both buttons to put the Jewel into Removal Mode. <i>See Chapter 5: Removal</i>
“Removal Mode not confirmed, to confirm Removal Mode press and hold both buttons.”	You have not confirmed that you would like to put the Jewel in Removal Mode.	Press and hold both buttons to confirm that you would like to put the Jewel into Removal Mode. <i>See Chapter 5: Removal</i>
“Jewel is in Removal Mode for 30 minutes. Replace patches now.”	The Jewel is now in Removal Mode and cannot give you an electrical shock. You can now safely remove Jewel from your body.	Remove the Jewel from your body with the removal tools provided. <i>See Chapter 5: Removal</i>
“Patches no longer working. Replace patches immediately.”	The Jewel has detected that the patches have come off your body and it is waiting to confirm that it is still attached. If Jewel was not put in Removal Mode before being removed from your body, this alarm will repeat for 10 minutes.	Make sure you have placed the Jewel in Removal Mode. <i>See Chapter 5: Removal</i>
“Replace patches immediately.”	The Jewel has confirmed that it is off your body. If this voice prompt continues to repeat, put the Jewel into Removal Mode.	Follow the instructions for removing the Jewel from your body. Apply a new Patch Unit to the Defibrillator Unit immediately. Ship the used Patch Unit back to Element Science.

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page intentionally left blank.

5



5

REMOVING & DISASSEMBLING

YOUR JEWEL

5.1 REMOVAL MODE

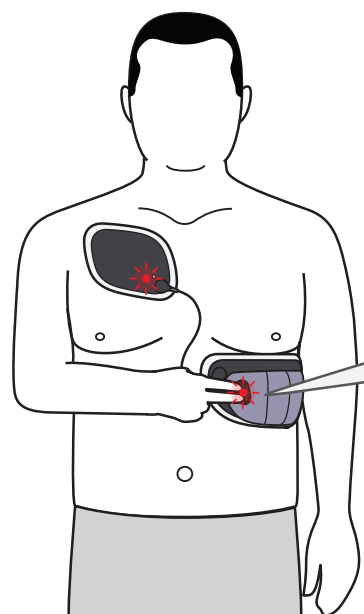
Removal Mode needs to be activated before you start removing the Jewel from your body. Removal Mode ensures you will not receive an electrical shock while removing the Jewel.

You will press and hold both buttons two times to initiate and confirm Removal Mode. The Jewel is NOT monitoring for specific life-threatening heart rhythms in Removal Mode. Remove the Jewel immediately and apply a new Patch Unit.



Put the Jewel in Removal Mode **BEFORE** you remove it.

1 TO START REMOVAL MODE:



Press and hold both buttons for at least 5 seconds until you hear:

"To confirm Removal Mode, press and hold both buttons."

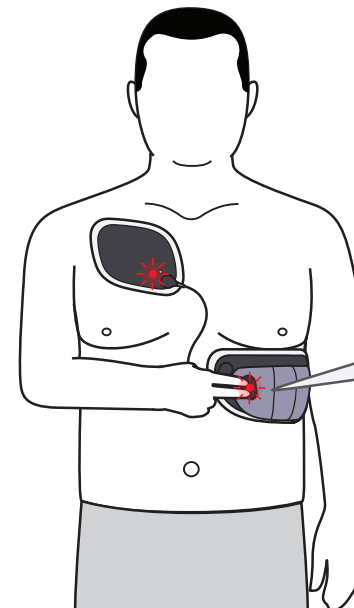


Red Flashing Light

Press and hold both buttons longer if you did not hear the words above.

Removal Mode must be confirmed within 1 minute.

2 TO CONFIRM REMOVAL MODE:



Press and hold both buttons again until you hear:

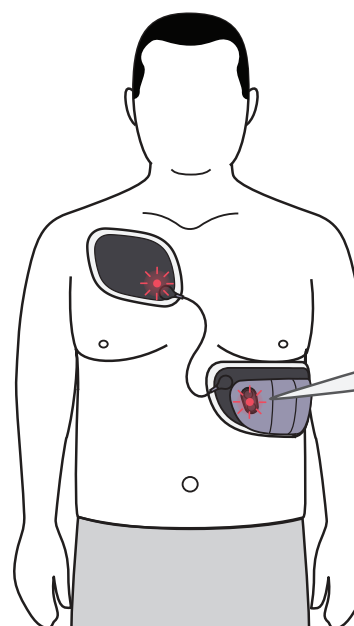
"Jewel in Removal Mode for 30 minutes. Replace patches now."



Red Flashing Light

Press and hold both buttons longer if you did not hear the words above.

The Jewel is in Removal Mode for 30 minutes. Continue to next page for removal instructions.



If Removal Mode is not confirmed within 1 minute you will hear:

"Removal Mode not confirmed."



Red Flashing Light

If you hear this response, repeat steps 1 and 2 to put device in Removal Mode.

If you are unsure if the Jewel is in Removal Mode, press and release both buttons for a status check.

5.2 REMOVING THE JEWEL

This section covers removing the Jewel, removing leftover adhesive, washing, rinsing, and drying your skin.

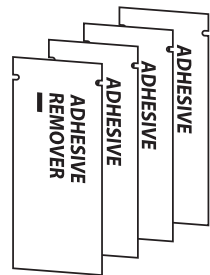
PATCH REMOVAL

These steps cover removing the Jewel.

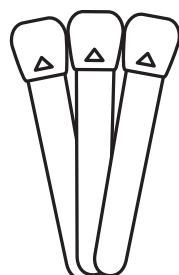
TIPS FOR THIS SECTION:

Read over all instructions before removing your Jewel. **ONLY** use the materials provided for removal. Use a mirror for hard to see areas. Ask someone to assist you for hard to reach areas.

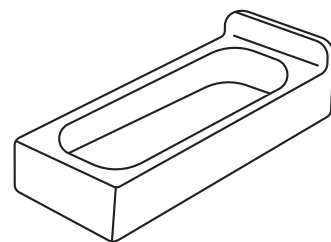
SUPPLIES NEEDED:



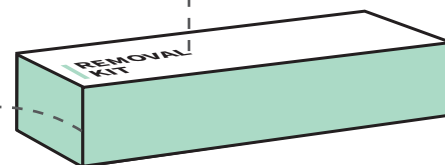
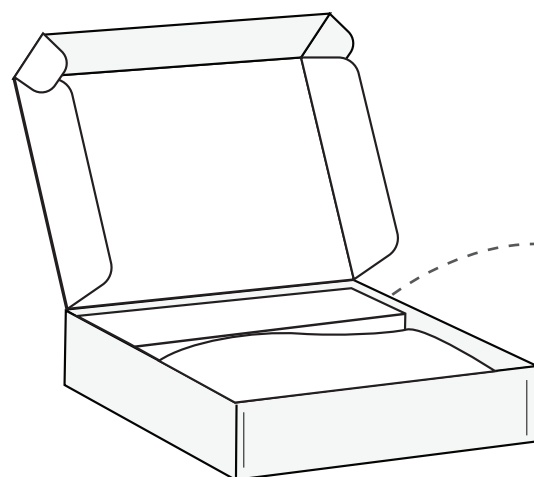
4 adhesive remover packets



3 foam tools



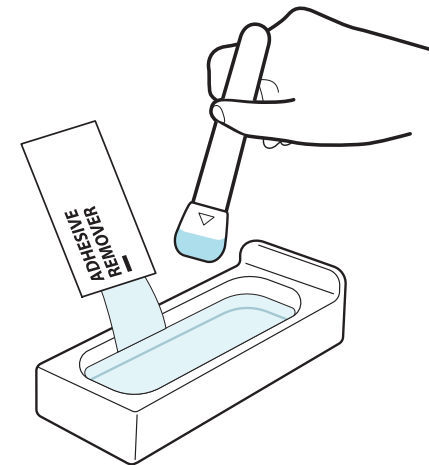
1 dish



Removal Kit (included in the Patch Kit box)

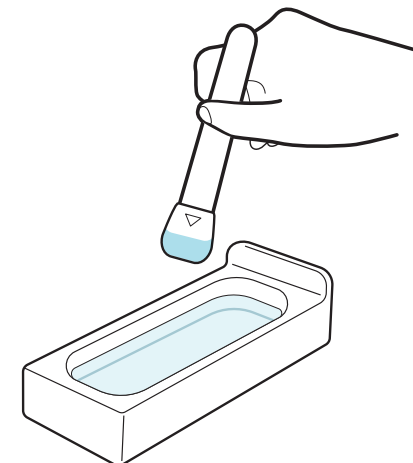
ATTENTION: Do NOT remove patches without adhesive remover. If you do not use adhesive remover, it may cause injury to your skin.

1



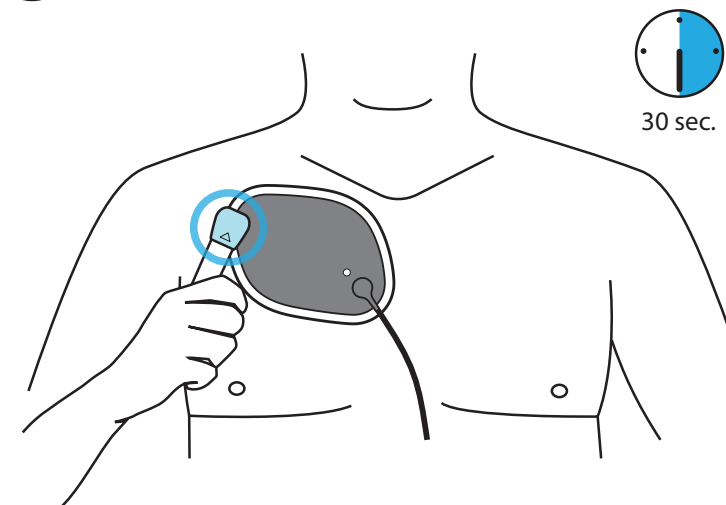
Remove dish from box.
Open two adhesive remover packets.
Pour adhesive remover into dish.

2



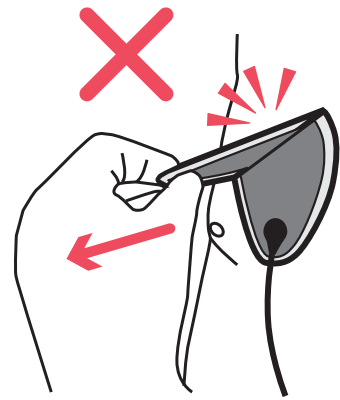
Dip foam tool into adhesive remover.
Repeat as needed.

3



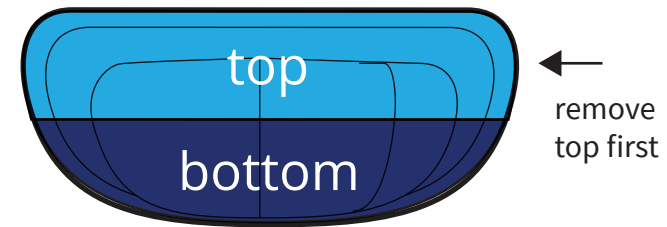
UPPER PATCH REMOVAL:

Rub wet foam tool on one spot for 30 seconds to lift an edge.



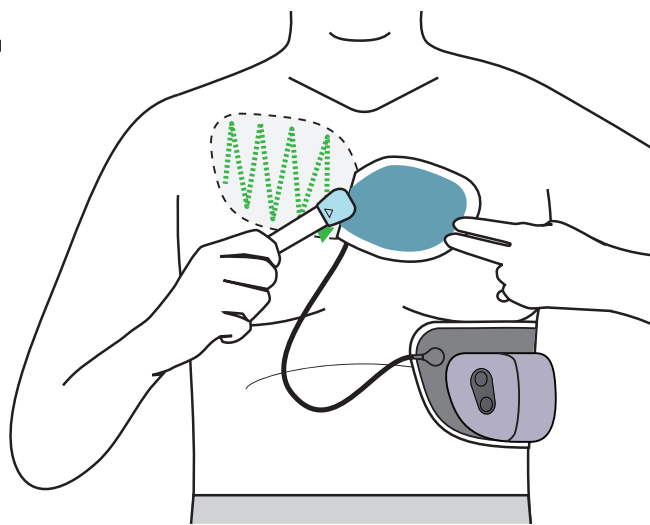
Use adhesive remover and foam tool.
Do NOT rip patch off your skin.

LOWER PATCH REMOVAL:



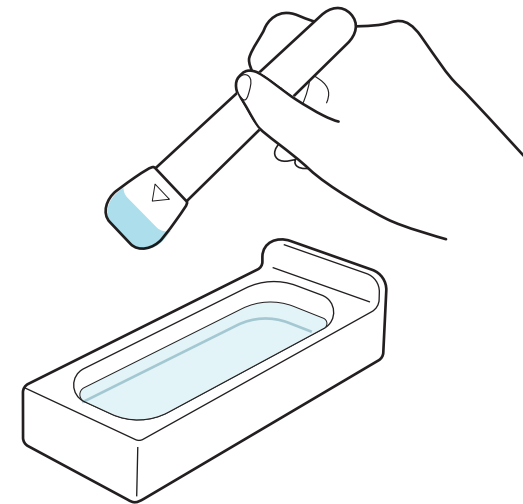
Remove top section of Lower Patch before moving to bottom section.

4



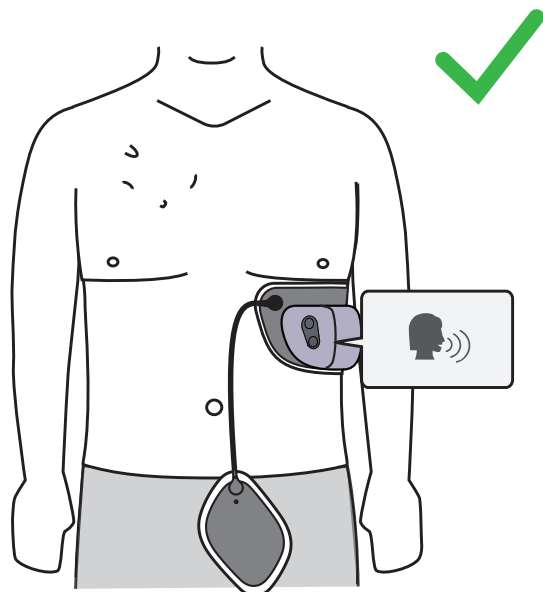
Rub wet foam tool on crease between skin and patch.

6



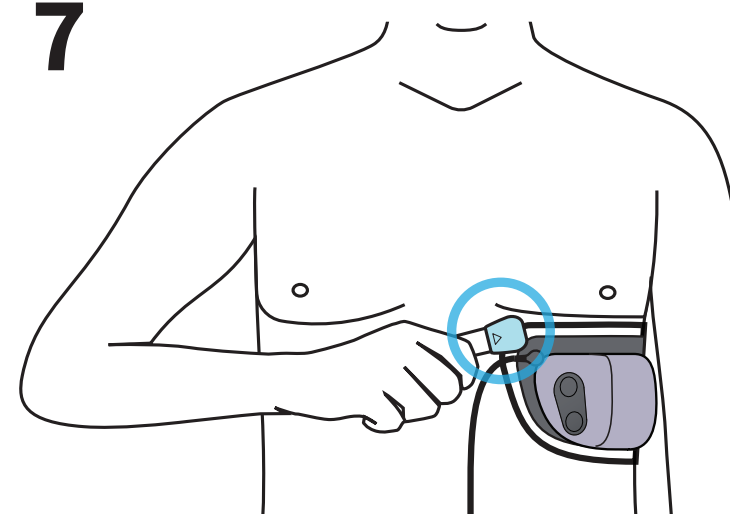
Use adhesive remover and foam tool.
Do NOT rip patch off your skin.

5



Repeat step 4 until the Upper Patch is fully detached from the skin.
Allow Upper Patch to hang when fully removed.
The Jewel may now say "Replace patches immediately."

7



Rub wet foam tool on one spot for 30 seconds to lift an edge.

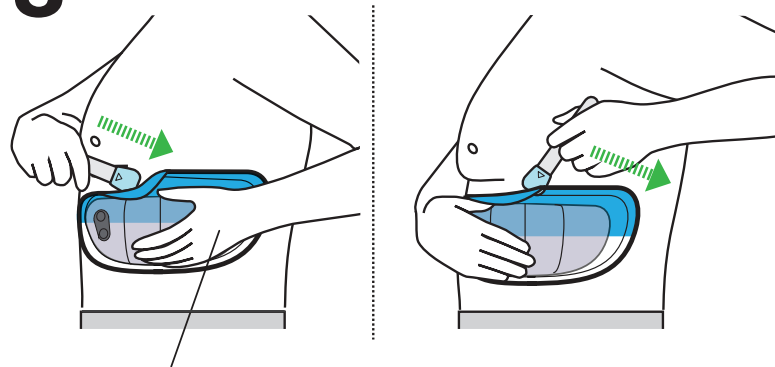


30 sec.

continue →

ATTENTION: Support the Defibrillator Unit with your hand while removing the lower patch. If the Defibrillator Unit is not supported, the weight of the device may rip the patch off your skin. This may injure your skin.

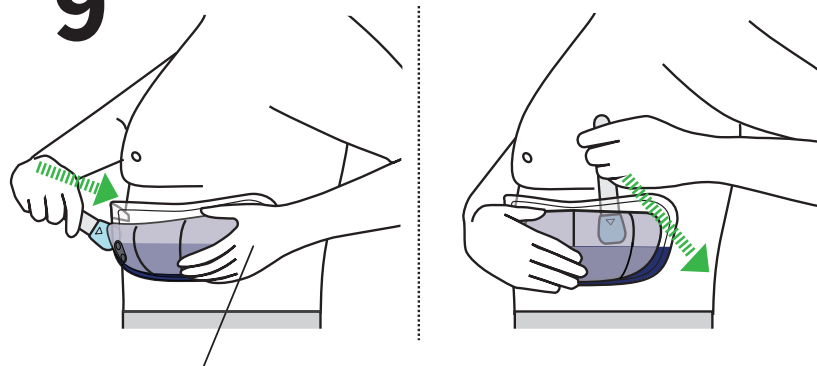
8



support with hand

Start at front and move to back.
Rub wet foam tool on crease
between skin and patch.
Continue until the top section
is fully detached.

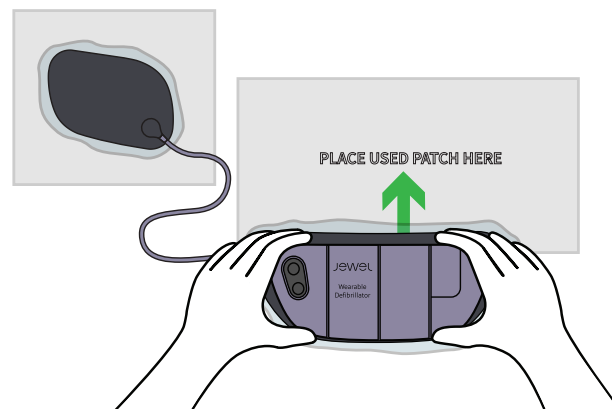
9



support with hand

Repeat step 8 to remove
the bottom section.

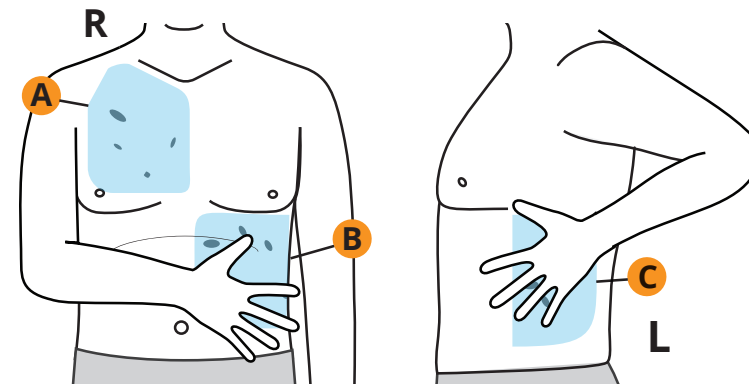
10



Place the Jewel onto two
discard sheets and set aside.

REMOVING LEFTOVER ADHESIVE:

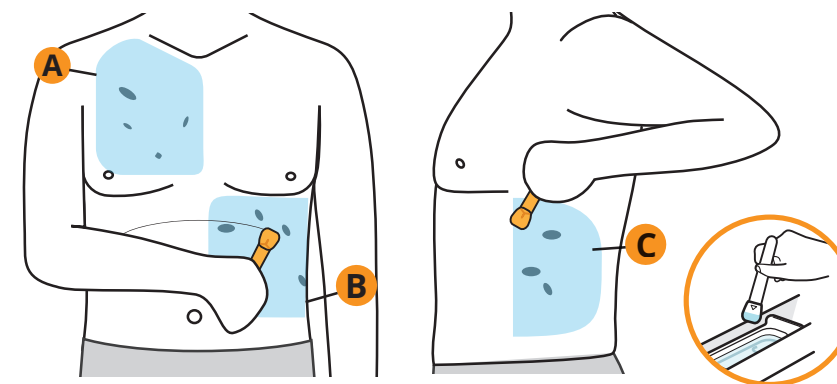
11



Feel for sticky spots of adhesive
in the following areas:

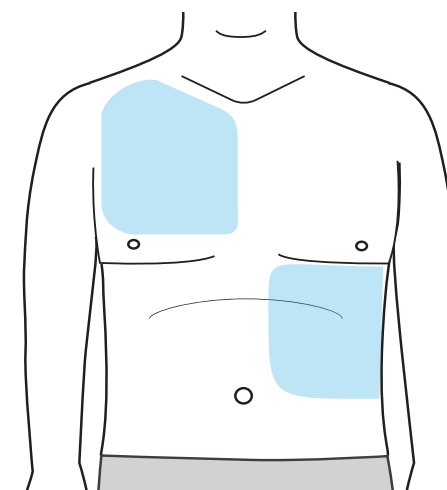
- A. Right chest (upper patch area)
- B. Left torso front (front of lower
patch area)
- C. Left torso side/back (back of
lower patch area)

12



Rub wet foam tool in a circular
motion on skin to remove sticky
spots of adhesive.

13



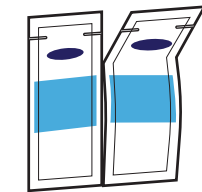
Inspect skin again for remaining
sticky spots of adhesive.
Repeat cleaning until these
areas are no longer sticky.

continue →

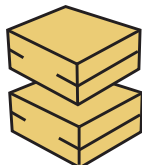
WASHING, RINSING, AND DRYING YOUR SKIN

These steps include washing, rinsing, and drying the skin. Follow these steps so that your next Jewel is applied to clean skin.

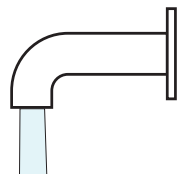
SUPPLIES NEEDED:



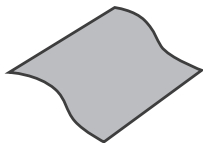
2 soap packets



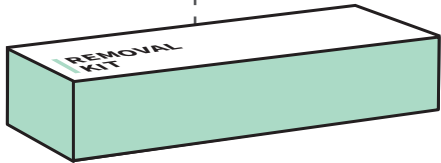
2 sponges



water
(not provided)



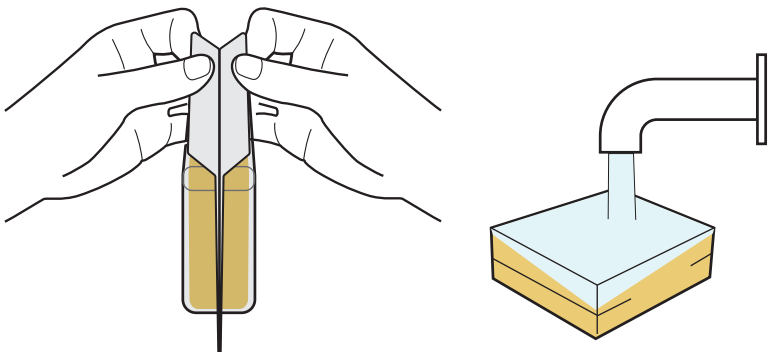
clean and dry towel
(not provided)



Removal Kit Box
(included in the Patch Kit box)

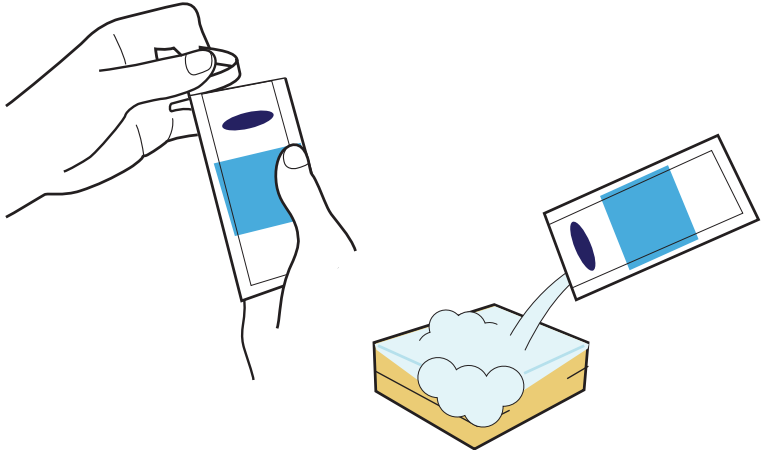
1

WASHING SKIN



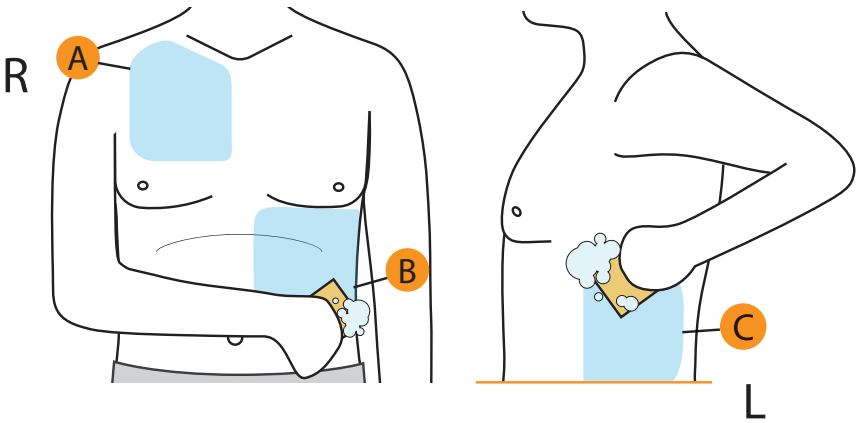
Open sponge packet.
Wet sponge with water.

2



Open soap packet.
Apply soap to sponge.

3

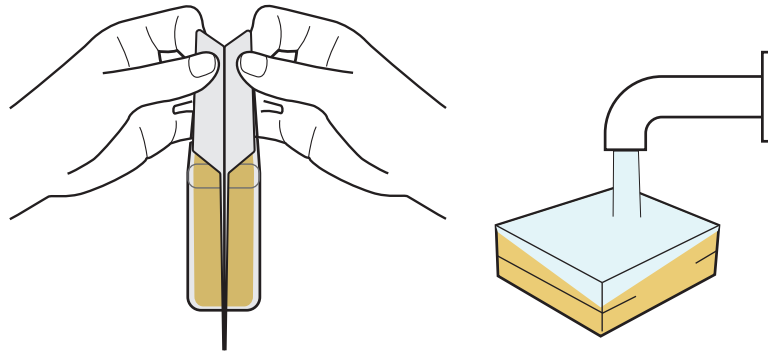


Clean skin with soapy sponge in the following areas:

- A. Right chest (Upper Patch area)
- B. Left torso front (front of Lower Patch area)
- C. Left torso side/back (back of Lower Patch area)

4 RINSING SKIN WITH WATER:

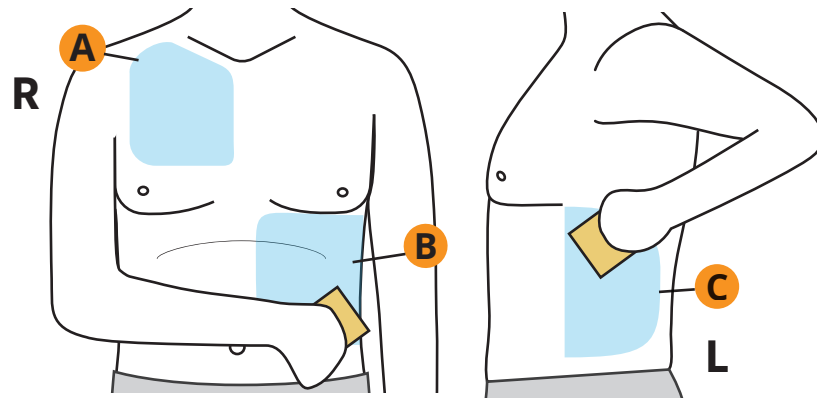
Open new sponge packet.
Wet sponge with water.



5

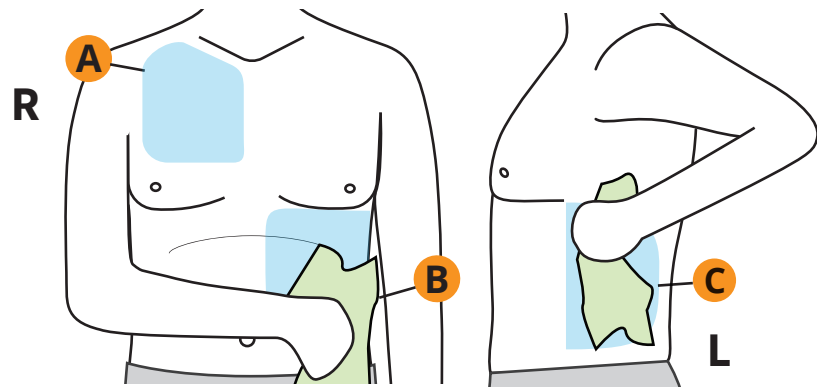
Rinse skin with wet sponge in the following areas:

- A. Right chest (Upper Patch area)
- B. Left torso front (front of Lower Patch area)
- C. Left torso side/back (back of Lower Patch area)



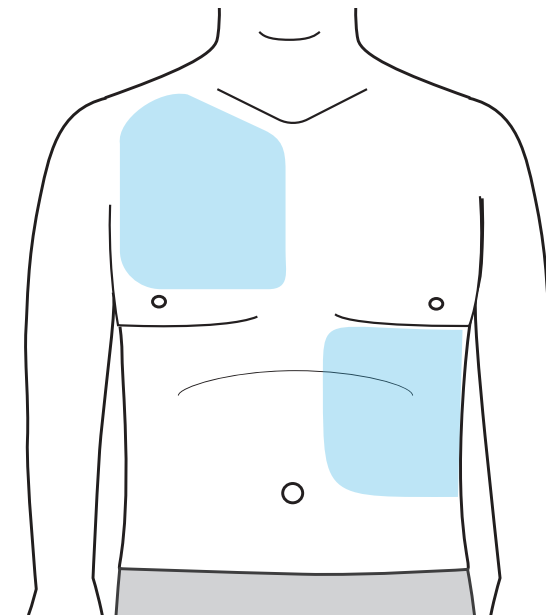
6

Dry skin areas A, B, and C with a clean, dry towel.



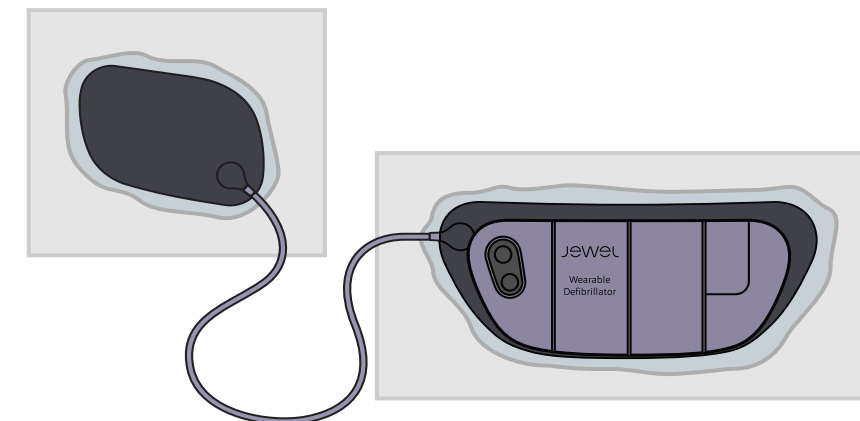
7

Check that skin is dry and no soap or sticky spots can be seen or felt.



8

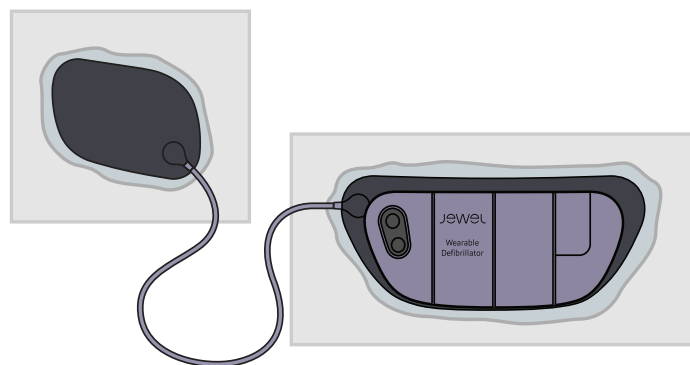
Continue to instructions in the next section to disassemble your Defibrillator Unit from the used Patch Unit.



5.3 DISASSEMBLE YOUR JEWEL

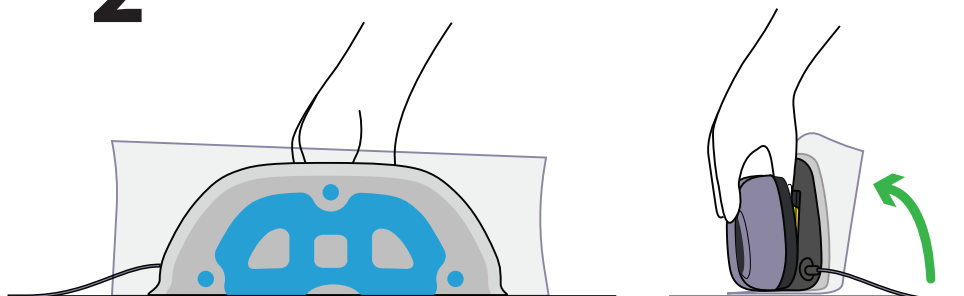
Note: It is important that the Defibrillator Unit remains completely dry and protected during disassembly steps. **Keep the Defibrillator Unit in a dust and lint-free environment when disconnected from the Patch Unit.** Accumulation of lint or dust within the electrical connections of the Defibrillator Unit can affect the performance of the device.

1



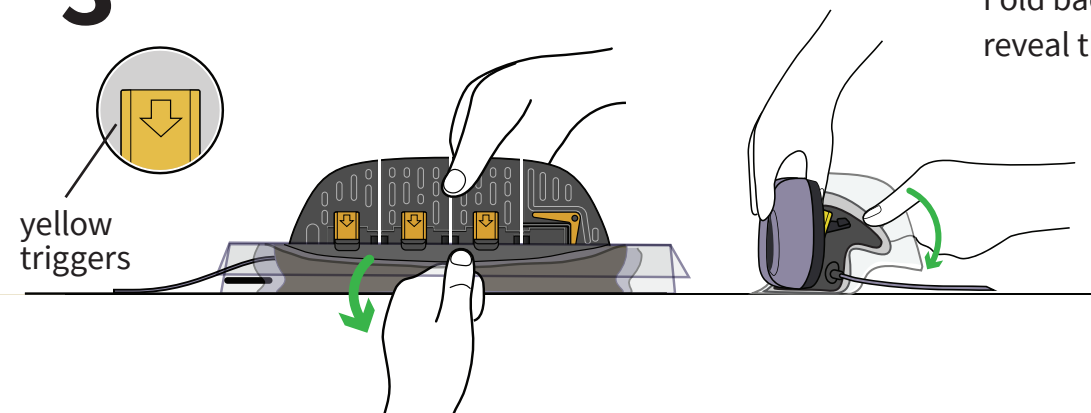
Place the Jewel in front of you with the cable on the left hand side and battery on the right before you start disassembling.

2



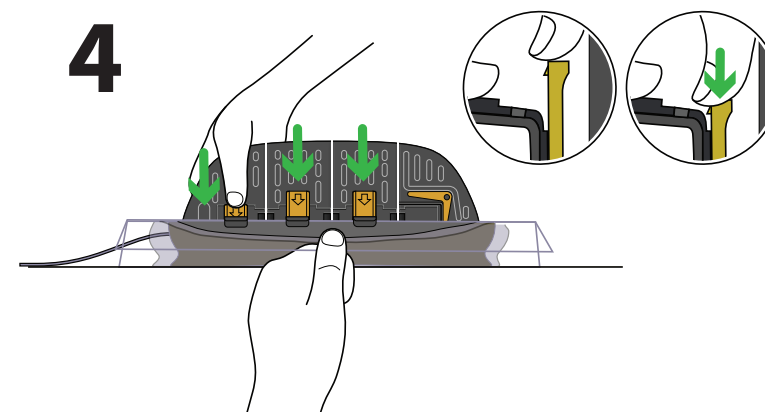
Tilt the Defibrillator Unit so that it is perpendicular to the table.

3



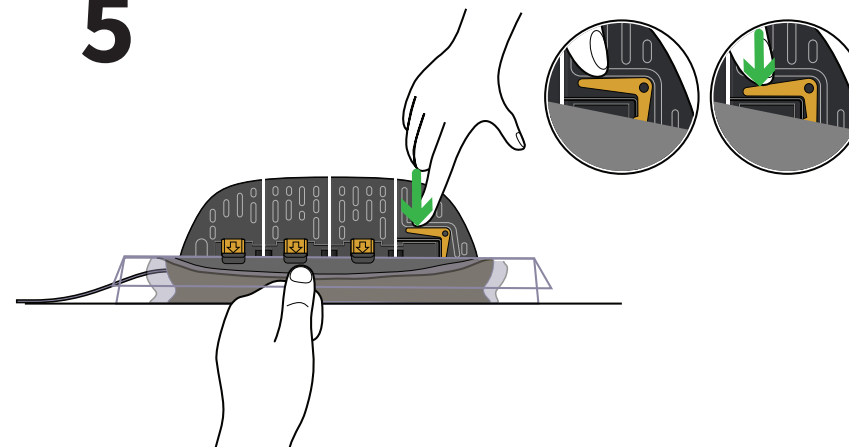
Fold back the Patch Unit to reveal the yellow triggers.

4



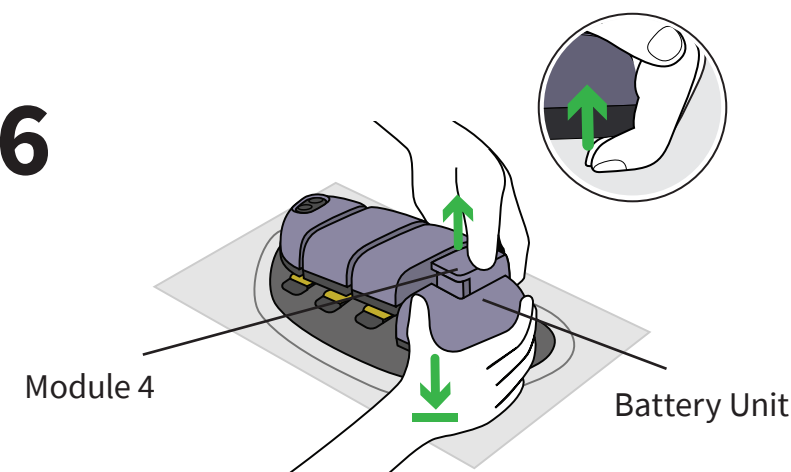
Push each yellow trigger down until you hear a click.
(The trigger should stay in place once pushed down.)

5



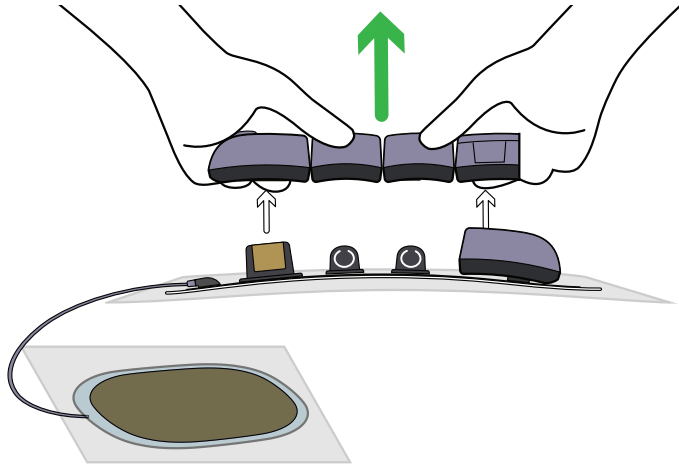
Push down the L shaped lever to unlock battery latch.
(The lever should stay in place once pushed down.)

6



Hold Battery Unit down with one hand. Using the other hand, insert fingers under Module 4 of the Defibrillator Unit. Lift Module 4 directly upwards to disassemble.

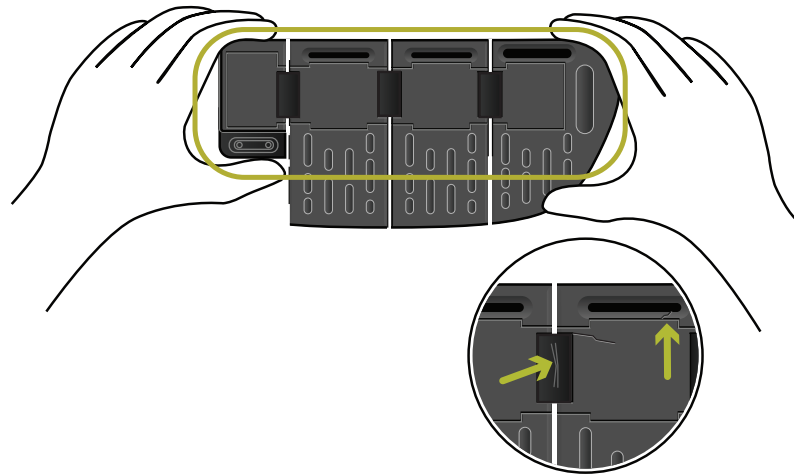
7



With all modules disconnected, carefully lift up the Defibrillator Unit from the used Patch Unit.

CAUTION: To prevent potential damage of the Patch Unit and Defibrillator Unit: Avoid touching and do not allow fluids to come into contact with the Patch Unit connectors. Do not allow fluids to come into contact with the slots on the Defibrillator Unit.

8



Inspect the back of the Defibrillator Unit for any damage such as cracks or breaks. If you notice visible damage, call Customer Service at 1-800-985-5702 as you may need to replace your Defibrillator Unit.

Return used Patch Unit to Element Science. See *Chapter 6: Returns*.

To apply the Jewel with a new Patch Unit, see Chapter 3: Application.

To return the used Patch Unit or Defibrillator Unit to Element Science, see Chapter 6: Returns.

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6

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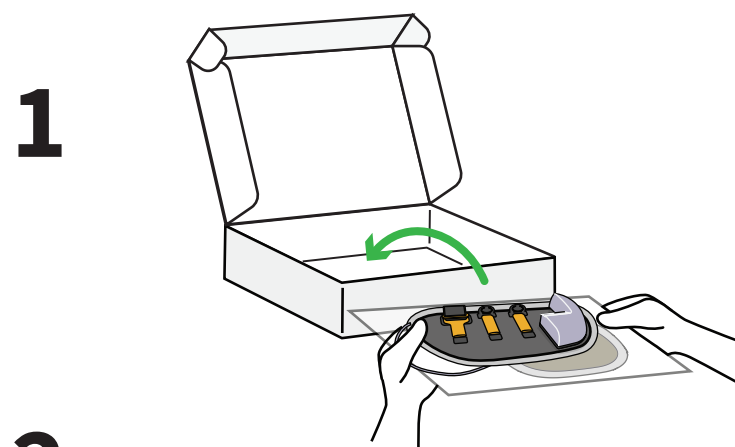
6

RETURNING

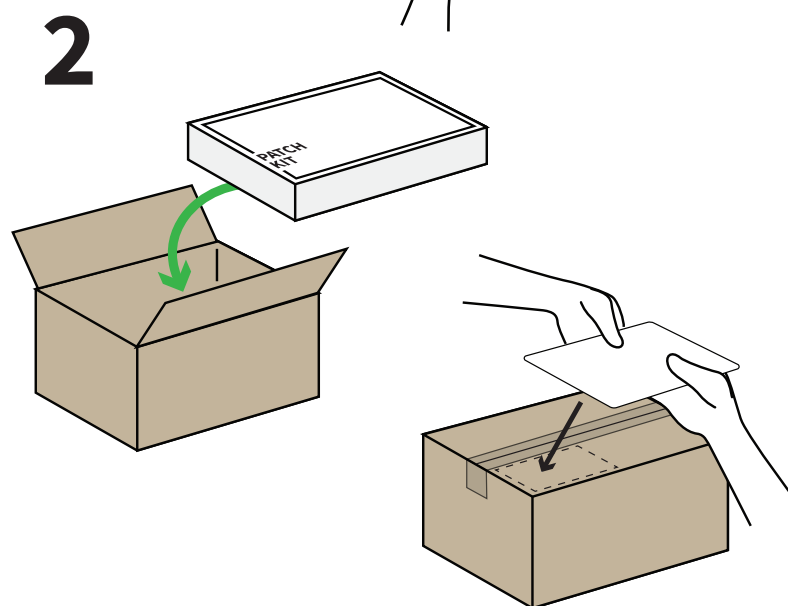
**YOUR JEWEL AND
ACCESSORIES**

6.1 RETURNING USED PATCHES

Note: It is important that the used patches are shipped back to Element Science for processing and proper recycling of the battery.



Place used Patch Unit into the saved Patch Kit Box.

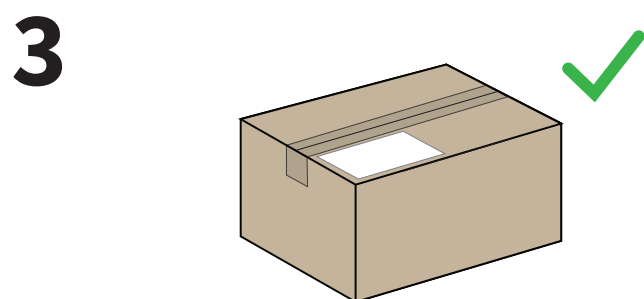


Retrieve the saved shipper box (the box you received your Patch Kits in), and put the used Patch Kit box into the shipper box.

(**NOTE:** The shipper box can fit two used Patch Kit boxes.)

Seal the box closed.

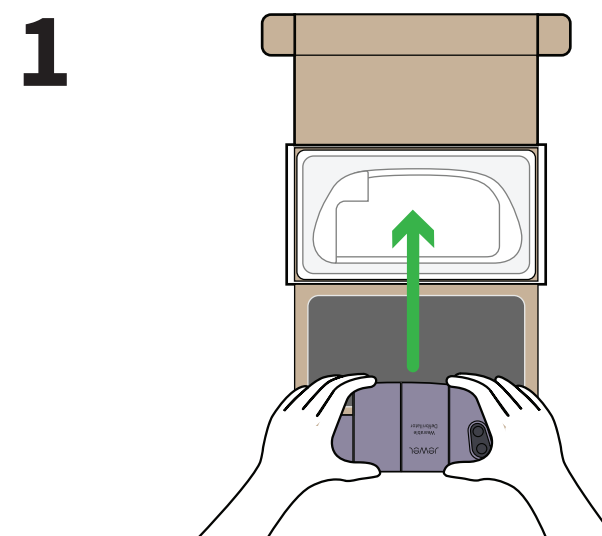
Use the return label enclosed and apply to the box for shipping.



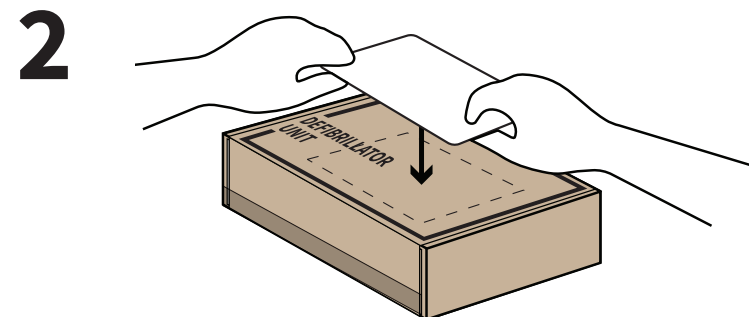
The Patch Unit is ready to be shipped back to Element Science.

6.2 RETURNING DEFIBRILLATOR UNIT

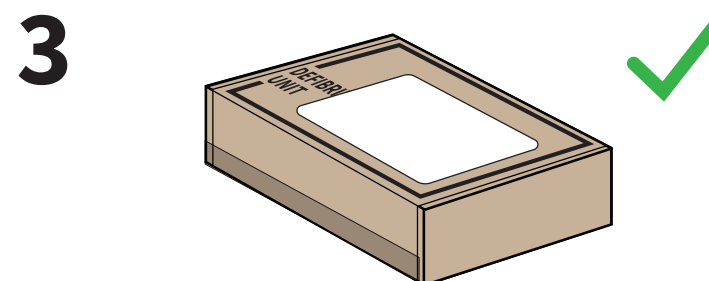
Note: It is important that the Defibrillator Unit is shipped back to Element Science for processing and proper recycling at the end of your prescription or if the Defibrillator Unit is disabled and needs to be replaced.



Retrieve the saved Defibrillator Unit box from the Starter Kit and place the Defibrillator Unit in the box.



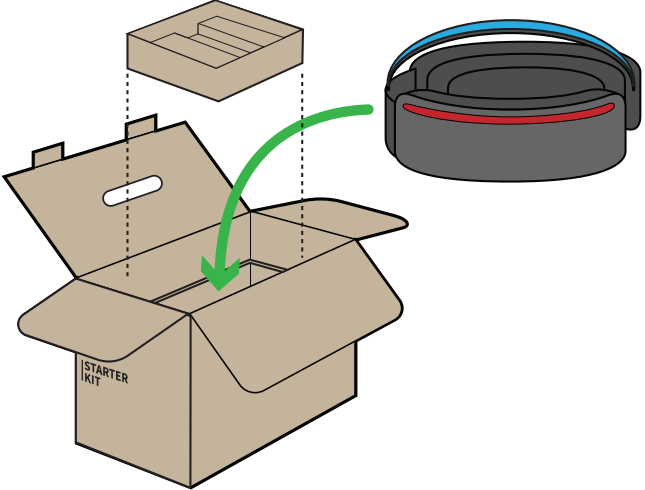
Apply the return label on the top of the box and use tape to seal the box for shipping.



The Defibrillator Unit is ready to be shipped back to Element Science.

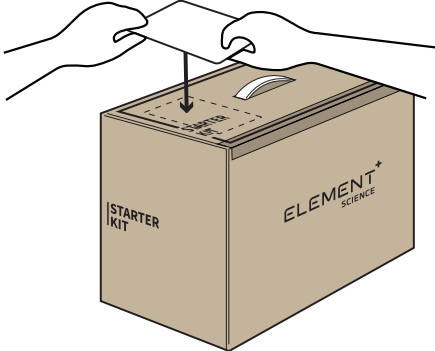
6.3 RETURNING ACCESSORIES AT END OF PRESCRIPTION

Note: The Placement Accessory should be shipped back to Element Science for processing and proper recycling at the end of your prescription.

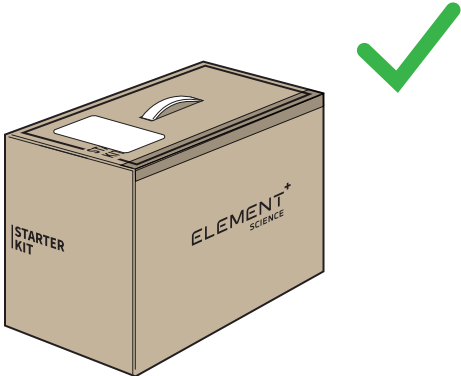
- 

1

Retrieve the saved Starter Kit box and place the Placement Accessory in the box.

Keep storage insert in box to ensure Placement Accessory stays in place during shipping.
- 

2

Apply the return label on the top of the box and use tape to seal the box for shipping.
- 

3

The Placement Accessory is ready to be shipped back to Element Science.

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7

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7

TROUBLE SHOOTING

7.1 TROUBLESHOOTING

PLACEMENT ACCESSORY

I have lost weight and the belt of the Placement Accessory feels loose.

If you have lost more than 1 pant size or 2 inches, the Placement Accessory needs to be refit. Call Customer Service (1-800-985-5702) to arrange for a new Placement Accessory. Do NOT try to adjust the Placement Accessory yourself. See *page 146* for additional details on checking the fit of your Placement Accessory.

I have gained weight and the belt of the Placement Accessory feels tight.

If you have gained more than 1 pant size or 1 inch, the Placement Accessory needs to be refit. Call Customer Service (1-800-985-5702) to arrange for a new Placement Accessory. Do NOT try to adjust the Placement Accessory yourself. See *page 146* for additional details on checking the fit of your Placement Accessory.

JEWEL APPLICATION

I tried to turn on the Jewel but nothing happened.

If you have pressed both buttons for 10 seconds and nothing happened (no lights, no sound, and no vibration), Make sure the Patch Unit and the Jewel are correctly assembled. Carefully check to make sure each patch connector is fully inserted into slots on the Jewel.

After making sure the Jewel and Patch Unit are assembled, turn on the Jewel again. If nothing happens again it means there is a malfunction. Do not apply Jewel. Call 1-800-985-5702 immediately because you need a replacement Defibrillator Unit.

I turned on the Jewel but see a red light.

If you see a red light, make sure the Patch Unit and the Defibrillator Unit are correctly assembled. Carefully check to make sure each patch connector is fully inserted into slots on the Defibrillator Unit. After making sure the Defibrillator Unit and Patch Unit are assembled, turn on the Jewel again. If you see a red light again it means there is a malfunction. Do not apply the Jewel. Call Customer Service (1-800-985-5702) immediately because you need a replacement Defibrillator Unit.

I turned on the Jewel but only see a flashing green light. I do not hear a voice prompt.

Press and release both buttons to perform a status check.

If you do not hear anything, there is a malfunction with the speaker. Do not apply Jewel. Call Customer Service (1-800-985-5702) immediately to order a replacement Defibrillator Unit. Return the Defibrillator Unit and Patch Unit to Element Science.

I turned on the Jewel but only hear a voice prompt. I do not see any light.

Press and release both buttons to perform a status check.

If you hear a voice prompt but no lights turn on, there is a malfunction with the lights. Do not apply the Jewel. Call Customer Service (1-800-985-5702) immediately to order a new Defibrillator Unit. Return the Defibrillator Unit and Patch Unit to Element Science.

I have applied the Jewel to my body but I keep hearing “Jewel is in Application Mode. Apply Jewel now using Placement Accessory”?

The Jewel has not detected it is on your body.

Confirm all 4 tabs have been pulled until the plastic backings are fully removed. If all 4 plastic backings have been removed and you continue to hear the same message, replace the Patches and apply the Jewel again. See removal instructions in *Chapter 5: Removal*.

I have applied the Jewel to my body but I did not hear “Jewel is Active”?

Press and release both buttons to perform a status check. You should see a solid green light and hear the Jewel say “Jewel is active.”

If you see a solid green light and hear a beep, the Jewel is preparing to monitor. Wait a few minutes and then perform another status check.

If the Jewel says “Jewel is in Application Mode. Apply Jewel now using Placement Accessory”, then the Jewel has not detected it is on your body.

Confirm all 4 tabs have been pulled until the plastic backing is fully removed. If all 4 plastic backings have been removed and you continue to hear the same message, replace the Patches and apply the Jewel again. See removal instructions in *Chapter 5: Removal*.

I have applied the Jewel to my body but it is bunched up or folded under in some spots.

- If you hear “Jewel is Active”, you can continue wearing the Jewel but the Jewel may need to be replaced sooner than the Jewel applied with no bunching or folds.
- If you continue to hear “Jewel is in Application Mode. Apply Jewel now using Placement Accessory”, the Jewel has not detected that it is on your body and you need to replace the patches and apply the Jewel again. See removal instructions in *Chapter 5: Removal*.

I have applied the Jewel to my body but I think it is in the wrong location.

See *page 86* for the proper location of the patches. If one or both of the patches are in the wrong location, you must remove the Jewel from your body and then replace Patch Unit with new patches and apply again to your body in the correct location. See removal instructions in *Chapter 5: Removal*.

I ran out of sticky sheets on the Upper Placement Accessory.

Apply the spare sticky sheets that were included in your Starter Kit to the orange area on the Upper Patch Placement Accessory. If you no longer have spares, call Customer Service (1-800-985-5702) to get additional sticky sheets.

WHILE WEARING THE JEWEL

The Jewel is telling me to Replace Patches, but it has been less than 8 days.

The duration of your wear may depend on your activity or environment. To get as long a wear as possible, avoid heat and moisture as much as possible, especially in the first 24 to 36 hours after applying a new patch.

I keep hearing “Device has been disconnected from patch and is unable to provide electrical shock. Press down on first/ last module” after I press on first/last module.

If you keep hearing this after pressing on first/last module repeatedly remove the Jewel and replace with a new Patch Unit. This alarm should stop once you have replaced the Patch Unit. If you keep hearing this alarm after pressing on first/last module it means your Defibrillator Unit is malfunctioning. Call Customer Service for a Defibrillator Unit replacement immediately.

I pressed both buttons and the green, yellow, and red lights appeared at the same time.

This means the Jewel is not monitoring for specific life-threatening heart rhythms and cannot give an electrical shock if it is needed. There is a malfunction with the Jewel, remove the Jewel from your body. Apply the Jewel with a new Patch Unit. The Defibrillator Unit is not monitoring for specific life-threatening heart rhythms and cannot give an electrical shock.

I pressed both buttons and nothing happened (no lights, no sound, no vibration).

Make sure the Jewel is turned on: press and hold both buttons until you feel a vibration.

- **If you have pressed both buttons and the Jewel said “Jewel is Active”,** the Jewel is now monitoring your heart and no further action is required.
- **If you have pressed both buttons for 10 seconds and nothing happened (no lights, no sound, and no vibration),** there is a malfunction with the Defibrillator Unit. Call Customer Service for a Defibrillator Unit replacement immediately. See removal instructions in Chapter 5: Removal.
- **If you have pressed both buttons for 10 seconds and hear “Device disabled and must be**

replaced. Call customer service immediately”, there is a malfunction with the Defibrillator Unit. The Jewel is not monitoring and cannot give an electrical shock. Call 1-800-985-5702 immediately because you need a replacement Defibrillator Unit.

I pressed both buttons and I saw a light but I didn’t hear anything.

- There is a malfunction with the Defibrillator Unit. Call Customer Service Immediately for a Defibrillator Unit replacement immediately.
- The speaker of your Jewel is not working. If the Jewel were to detect a specific life-threatening heart rhythm, you would not hear a siren alarm but the red lights would flash and the Jewel would vibrate. If you were to see red lights and feel vibrations, you should press both buttons to cancel the electrical shock until you can reach your replacement Defibrillator Unit.

I need to check the status of the Jewel or repeat the last voice prompt.

To perform a status check, press and release both buttons. Do not hold the buttons for longer than 5 seconds.

I tried to perform a status check but keep hearing “To confirm Removal Mode, press and hold both buttons”.

Wait 1 minute until the Jewel is no longer seeking confirmation for Removal Mode. Then perform a status check by pressing and releasing both buttons. Do not hold the buttons for longer than 5 seconds.

I accidentally put the Jewel into Removal Mode.

After 30 minutes in Removal Mode, the Jewel will return to monitoring your heart if it has detected that it is still on your body.

During Removal Mode, the Jewel is not monitoring for specific life-threatening heart rhythms and cannot give an electrical shock.

I am not at home, but I received one of the following messages:

“Patches expired and no longer working. Replace patches immediately” + Red Flashing Light

The Jewel is not capable of monitoring for specific life-threatening heart rhythms and cannot give an electrical shock. Get to your replacement Patch Unit as soon as possible.

“Patches expired. Replace patches now” + Yellow Flashing Light

Jewel is still monitoring for specific life-threatening heart rhythms and can give an electrical shock but needs to be replaced. The Jewel may detect a low battery or that the patches are coming off your body. Get to your replacement Patch Unit within the next three hours.

“Replace patches soon.” + Yellow Flashing Light

The Jewel is still monitoring for specific life-threatening heart rhythms and can give an electrical shock but needs to be replaced within the next 24 hours. Get to your replacement Patch Unit when you have time within the next 24 hours.

The Jewel keeps repeating a voice prompt and I cannot turn it off.

Only the siren alarm can be canceled by pressing both buttons. You should pay attention to the voice prompt and take action. For more information on voice prompts, see *Chapter 4: Notifications*.

I keep getting the siren alarm, but I feel fine.

If you keep getting the siren alarm but feel fine, there may be something in the environment that is affecting the Jewel. Continue to cancel the electrical shock by pressing both buttons and change your location. If you continue to get the siren alarm after you have changed locations, replace the Patch Unit immediately so you do not get an electrical shock when your heart is in a normal rhythm. See removal instructions in *Chapter 5: Removal*.

I keep hearing “If patient unresponsive, call 911 and start CPR”, but I feel fine.

If you have gotten this alarm but feel fine, there is something in the environment that may have affected the Jewel. To stop the alarm, put the Jewel into Removal mode and replace the Patch Unit immediately. See removal instructions in *Chapter 5: Removal*.

I submerged the Jewel in water (or any other liquid). What should I do now?

If you have submerged the device in water or any other liquid (such as by taking a bath, swimming in a pool, or getting in a hot tub while wearing the device,) you should remove the Jewel, call Customer Service Immediately for a new Defibrillator Unit. See *Chapter 5: Removal*.

SKIN

My skin itches.

Some mild or moderate itching or irritation may occur. Contact your doctor for any skin concerns. NEVER stick any object or material between patches and your skin (such as scratching with your fingers or another object). Make sure to follow instructions in Removal Chapter and Skin preparation instructions in Application Chapter. Keep your skin clean and dry before applying a new patch.

I took off the Jewel and I see some red bumps on my skin

Some bumps and redness may occur. Contact your doctor for any skin concerns. Make sure to follow instructions in Removal Chapter and Skin Preparation instructions in Application Chapter. Keep your skin clean and dry before applying a new Patch.

REMOVAL

I took off the Jewel and now it keeps saying “Patches no longer working. Replace patches immediately”.

If you hear this prompt it means that Jewel was removed prior to initiating Removal Mode and it has detected it is off your body. To turn off the voice prompt immediately, initiate Removal Mode (See Chapter 5: Removal).

I need to replace my Patches, but I don't have my removal or Skin Prep Materials with me.

It is always recommended to use the provided materials for removal and application. Make sure that you have sufficient materials in advance of Patch replacement. If you need additional materials contact Customer Service.

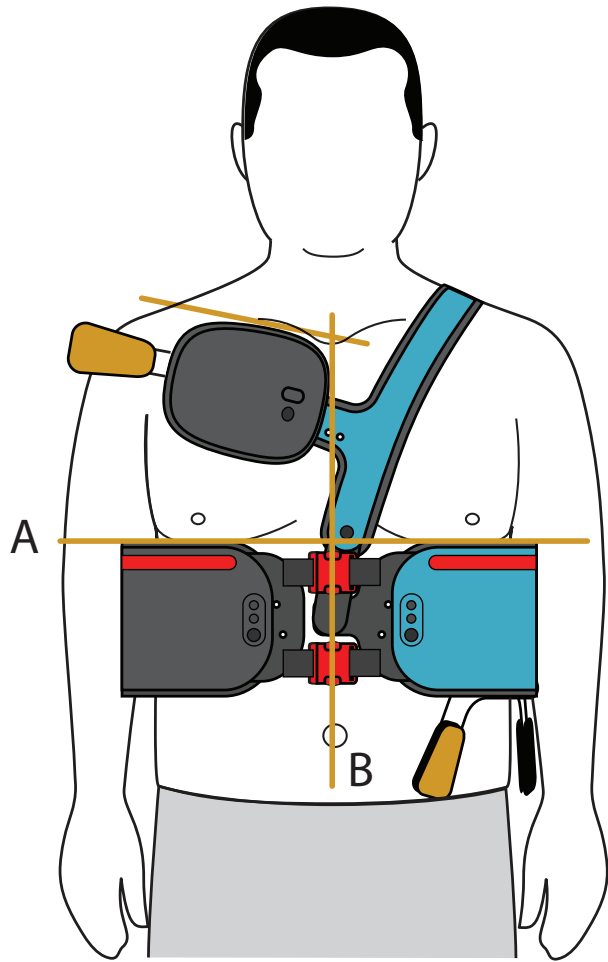
I can't disassemble my Defibrillator Unit from my used Patch Unit

Refer to the Disassembly Instructions in Chapter 5. If you still cannot separate the Defibrillator Unit and Patch, call Customer Service for additional assistance.

IF YOUR WEIGHT CHANGES: CHECKING THE FIT OF THE PLACEMENT ACCESSORY

These steps cover making sure the Placement Accessory fits on your body correctly if you have lost or gained weight. Proper Placement Accessory fit is required to apply the Jewel in the correct location.

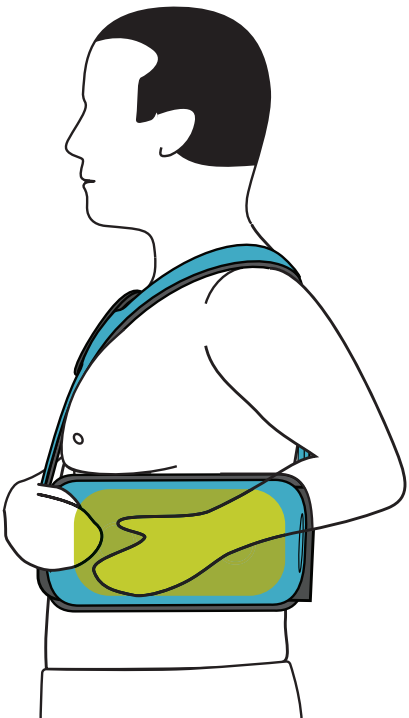
1



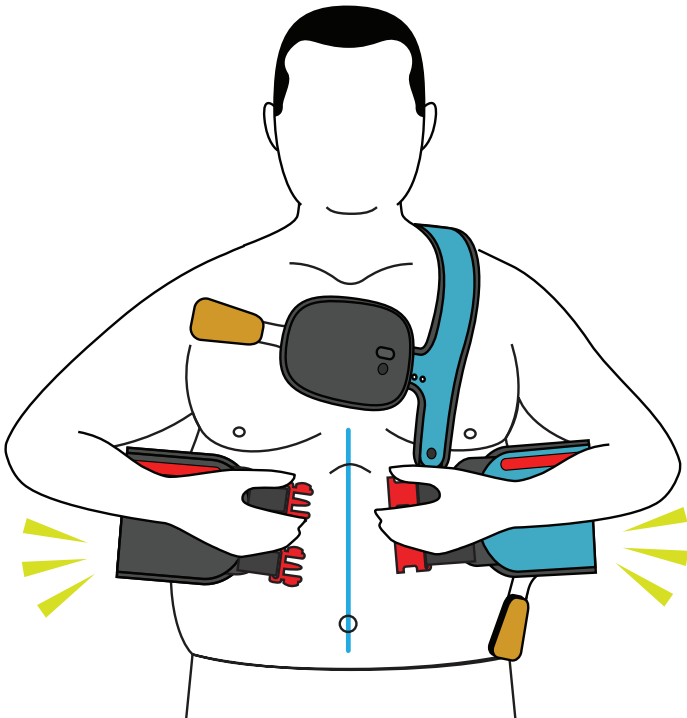
- Put on Placement Accessory and align belt so that:
- A. Red lines on belt are **level** and **under** chest/breasts
 - B. Red buckles are on **centerline** of body

2

If the Placement Accessory fits in any of the following ways it means that your Placement Accessory no longer fits you properly. Call Customer Service (1-800-985-5702) for a new Placement Accessory as soon as possible.



If there is noticeable gap under the left side of the belt in the area highlighted above, this means the Placement Accessory is too big for you. It is likely that you have lost weight.



If it is difficult for you to buckle the belt or if you cannot buckle the belt, this means the Placement Accessory is too small for you. It is likely that you have gained weight.

WARNING



Do NOT adjust the settings of your Placement Accessory. Changing the settings of your Placement Accessory could result in the Jewel being applied in the wrong location. Applying the Jewel in the wrong location could result in an electrical shock not given when needed or in an ineffective shock possibly resulting in serious injury or death. If your Placement Accessory no longer fits you because it is too loose or too tight, is damaged, or is not functioning as intended, contact Element Science for a replacement at 1-800-985-5702.

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