Jewel

Jewel® Patch Wearable Cardioverter Defibrillator (P-WCD)

INSTRUCTIONS FOR USE

ELEMENT SCIENCE

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Rx Only Federal law restricts this device to sale by or on the order of a physician.

IMPORTANT INFORMATION

Trademarks

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INTRODUCTION

The Jewel Patch Wearable Cardioverter Defibrillator (Jewel P-WCD) is a wearable automated external defibrillator that provides continuous, automatic monitoring of cardiac rhythms to support rapid detection of life-threatening arrhythmias. If the Jewel detects life-threatening ventricular tachycardia (VT) or ventricular fibrillation (VF), it can deliver a defibrillation shock to the heart to restore a normal rhythm without further interaction from the patient or bystander.

The Jewel communicates its status to the patient through voice messages, LEDs, audio tones, and vibration. In the event a life-threatening rhythm is detected, the Jewel will issue an alert to notify the patient and bystanders. If the rhythm is consistent with ventricular tachycardia or ventricular fibrillation, the Jewel will indicate that a shock is about to be delivered and give the patient an opportunity to defer therapy if they are conscious. If therapy is not deferred, the Jewel will automatically deliver a defibrillating shock to restore the patient's rhythm without further interaction from the patient or bystander.

The Jewel can deliver up to five shocks during an arrhythmic episode. Information about the patient's heart rhythm is stored on the device. In the event therapy is delivered, a Therapy Report will be generated by the Report Generator and can be reviewed by the patient's healthcare team once the device data has been uploaded.

An *optional* Mobile Application is available for patients, which allows the Jewel to connect to the patient's telephone via Bluetooth. Event data connected through the Mobile Application can be transferred to the Report Generator when an internet connection is active.

The Jewel is designed to function with or without the use of the Mobile Application. In case the Mobile Application is not being used, Element Science will upload the event data upon return of the device and the Therapy Report will be available for review at that time.

1.1 Indications for Use

The Jewel P-WCD is indicated for adult patients 18 years of age and older who are at risk for Sudden Cardiac Arrest, and either are not candidates for or refuse an Implantable Defibrillator.

1.2 Contraindications

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

1.3 Considerations for Prescribers

The Jewel should not be used concurrently with unipolar or antitachycardia pacing configurations, or pacing with pulse artifacts greater than 0.5mV in any ECG lead. This artifact may interfere with the Jewel's ability to detect dangerous heart rhythms and could prevent shock delivery.

1.4 Intended Operator, Use, and Location

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 center / outpatient
- Home
- Public transportation
- Automobile
- Workplace
- Gyms or physical therapy
- Showering
- Commercial air travel

1.5 Safety Information

The following safety labels apply:

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

| **CAUTION:** a potential 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.

1.5.1 WARNINGS

- 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.
- 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 replace the Patch Unit when instructed to do so. The Patch Unit is single-use and is intended to be replaced after each wear.

1.5.2 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. More information can be found in the "Electromagnetic Interference" section of the Patient Guide.
- 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 high-frequency (HF) surgical equipment, or the radio-frequency (RF) shielded room of a medical electrical (ME) system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- Portable radio-frequency (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.
- The Jewel may ONLY be worn with ONE (1) FDA-cleared or FDA-approved, device CONCURRENTLY, which MUST be DEFIBRILLATION PROOF (meaning protected against the effects of defibrillation).
- Devices that are not DEFIBRILLATION PROOF (meaning protected against the effects of defibrillation) should not be worn with the Jewel.
- The Jewel's performance may be impacted if worn in conjunction with an implantable or transcutaneous electrical stimulating device.
- 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 P-WCD was tested to demonstrate compliance to the emissions and immunity requirements of the following standard: RTCA DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 20 (RF immunity) and Section 21 (RF emissions). RTCA DO-160G test results indicate potential susceptibility to electromagnetic disturbances from radio frequency emissions in a narrow frequency band from 400 MHz to 588 MHz. Devices which operate in this band include some meteorological and earth exploration satellites, astronomy radios, and broadcasting radios. In the extremely unlikely event these emissions do interfere with Jewel device performance, alarms will sound indicating this. In the unlikely event that the Jewel alarms indicate abnormal device performance during the landing and takeoff portions of a flight, press both buttons for at least 5-seconds to enter the mode (Removal Mode) to temporarily pause Jewel operation, then follow the audible instructions from the Jewel to confirm. No further action is necessary. The Jewel will automatically return to Monitor Mode after 30-minutes and will continue normal operation. After returning to Monitor Mode, if similar alarms resume, the device can once again be placed into Removal Mode. 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 and damage or break the device.
- 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. The patient should contact their doctor for any skin concerns.
- 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 damage or break the device.
- 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 damage or break the device.
- 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.

1.5.3 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.
- 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 Defibrillator Unit electronics immediately contact Customer Service at 1-800-985-5702 to replace your Defibrillator Unit.
- If you have any skin issues underneath the Patch Unit such as redness, bumps, inflammation, irritation, continue to wear the Jewel and contact your doctor.
- Patients can contact Customer Service if they need assistance, have questions, or require retraining for the Jewel System use. Customer Service is available 24 hours a day, 7 days a week and can be reached by phone at 1-800-985-5702 and email at customerservice@elementsci.com.
- Always handle the Jewel carefully in order to avoid potential damage. When the Defibrillator Unit is not on your body, hold it with both hands and keep it as flat as possible. Do not fold or twist the Defibrillator Unit.

2. SAFETY AND EFFICACY DATA

2.1 Clinical Studies

The following clinical data demonstrates a reasonable assurance of safety and effectiveness of the Jewel P-WCD:

- The Jewel IDE Study evaluated the safety and effectiveness of the Jewel in patients at risk for sudden cardiac arrest (NCT05201495).
- The Jewel EP Lap Study evaluated the conversion effectiveness of the Jewel defibrillation waveform (NCT05490459).

2.1.1 THE JEWEL IDE STUDY

This Jewel IDE Study was conducted in the United States from 12 January 2022 to 31 July 2023. The Study was designed to demonstrate the safety and clinical effectiveness of the Jewel P-WCD for use in patients at elevated risk of sudden cardiac arrest.

The Jewel IDE Study is registered on www.clinicaltrials.gov under NCT05201495.

2.1.2 STUDY DESIGN

- **Objectives:** Demonstrate the safety and clinical effectiveness of the Jewel P-WCD for use in patients at elevated risk of sudden cardiac arrest
- **Study Design:** Multi-center, prospective, single arm study

- **Patient Population:** Adult patients at risk for sudden cardiac arrest (SCA) who either are not candidates for or refuse an implantable defibrillator (ICD); patient baseline demographic characteristics are provided in Table 2.1

- **Endpoints:**
  The endpoints of this study were designed based on commercially available wearable defibrillator performance established in published clinical data.

Primary

- Inappropriate shock rate of no more than 2.0 inappropriate shocks per 100 patient-months using a one-sided upper 98% confidence interval.
- Rate of subjects experiencing clinically significant cutaneous adverse device effects (ADEs) of less than 15% using a one-sided, exact 98% upper confidence bound. *Note: A cutaneous ADE was considered "clinically significant" if it resulted in the subject being withdrawn from the clinical trial by the Investigator.*

Secondary

- A successful conversion of at least one shockable rhythm with a single salvo of up to 5 shocks.
- A compliance rate of greater than 14.1 average hours per day during the prescription wear period.

2.1.3 RESULTS

- The study achieved all primary and secondary endpoint criteria for success:
  - **Inappropriate shock rate:** 0.357 inappropriate shocks per 100 patient-months, with an upper 98% confidence interval of 1.526
  - **Clinically significant cutaneous ADEs:** 2.30%, with a one-sided upper 98% confidence bound of 4.80%
  - **Successful conversions of shockable rhythm with a single salvo:** 8 successful conversions were observed over the course of the trial. All successful conversions occurred with the first shock.
  - **Patient compliance:** Average compliance of 21.3 ± 4.48 hours (median:23.5, interquartile range:20.7, 23.9) per day during the prescribed wear period
- There were no serious adverse events related to the device and no deaths.

Table 2.1: Baseline Demographic Characteristics

Of 322 enrolled patients, 305 patients had completed the study and 290 patients had analyzable device data at the time of data cut. The demographics of these patients are summarized below.

Characteristic	Primary Analysis Population (N=290)
Age at Enrollment (Years), Mean ± SD	58.6 ± 13.0
Gender: Male (% of total)	200 (69.0%)
Ethnicity (Not Hispanic or Latino (% of total)	280 (96.6%)
Race, White (% of total)	212 (73.1%)

Characteristic	Primary Analysis Population (N=290)
Race, Black or African American (% of total)	67 (23.1%)
Race, Asian (% of total)	4 (1.4%)
Race, American Indian or Alaska Native (% of total)	0 (0.0%)
Race, Native Hawaiian/Other Pacific Islander (% of total)	0 (0.0%)
Race, Other (% of total)	8 (2.8%)
Body Mass Index (kg/m2), Mean ± SD	30.0 ± 6.7
Medical History	
Prior myocardial infarction (MI)	94/288 (32.6%)
Prior coronary artery bypass grafting (CABG)	34/288 (11.8%)
Prior percutaneous coronary intervention (PCI)	109/288 (37.8%)
Prior congestive heart failure (CHF)	207/288 (71.9%)
NYHA Class I	11/213 (5.2%)
NYHA Class II	76/213 (35.7%)
NYHA Class III	61/213 (28.6%)
NYHA Class IV	9/213 (4.2%)
Not Applicable	56/213 (26.3%)
History of atrial fibrillation (AF)	76/288 (26.4%)
Persistent	16/75 (21.3%)
Paroxysmal	59/75 (78.7%)
History of unstable angina	36/283 (12.7%)
Resolved	24/36 (66.7%)
Ongoing	12/36 (33.3%)
History of non-sustained ventricular tachycardia (NSVT)	58/288 (20.1%)
Resolved	20/58 (34.5%)
Ongoing	38/58 (65.5%)
History of ventricular tachycardia (VT)	62/288 (21.5%)
Resolved	24/62 (38.7%)
Ongoing	38/62 (61.3%)

Medical History	
History of sudden cardiac arrest (SCA)	27/288 (9.4%)
History of hypertension	204/288 (70.8%)
Resolved	6/203 (3.0%)
Ongoing	197/203 (97.0%)
History of smoking	129/288 (44.8%)
History of diabetes	100/288 (34.7%)
Type 1	1/100 (1.0%)
Type 2	99/100 (99.0%)

2.2 Jewel EP Lab Study

The Jewel EP Lab Study was conducted in the European Union from 27 November 2018 to 7 October 2021. The Study was designed to demonstrate the safety and clinical effectiveness of the Jewel EP Lab System, which is representative of the Jewel P-WCD, in terminating life-threatening VT or VF with a single transthoracic defibrillation shock.

The Jewel EP Lab Study is registered on www.clinicaltrials.gov under NCT05490459.

Study Design

- **Objectives:** Demonstrate the ability of the Jewel electrode patches and defibrillation waveform to successfully terminate life-threatening ventricular tachycardia (VT) and ventricular fibrillation (VF) using a single transthoracic defibrillation shock
- **Study Design:** Single center (EU), prospective, single arm study
- **Patient Population:** The study assessed 18 eligible adult patients (age 18 or older) scheduled for a standard EP clinical procedure where life-threatening VT or VF may spontaneously occur or may be induced; patient baseline demographic characteristics are provided in Table 2.2
- **Endpoints:** Percent of successful single shock terminations of life-threatening VT or VF. Based on commercially available wearable defibrillator performance as established in published clinical data, a goal of 62% successful conversions was established for the Jewel EP Lab Study.

Results

- The study achieved the pre-defined criteria for success and was terminated early
- The first shock success rate of the Jewel EP Lab System was 88.9%
- No adverse events or deaths were reported

Table 2.2: Baseline Demographic Characteristics

Variable	Per Protocol Subjects n=18
Gender, male (% of total)	15/18 (83%)
Average Age, years (range)	63.8 (28-80)
Race, white (% of total)	18/18 (100%)
Average Height, cm (range)	176.8 (160-190)
Average Weight, kg (range)	88.9 (58-129)
Average BMI (range)	28.3 (20.2-36.9)
Average Ejection fraction, % (range)	34 (20-55)
Medical History	
Recent myocardial infarction (% of total)	2/18 (11%)
Recent coronary artery bypass graft (% of total)	0/18 (0%)
Class IV chronic heart failure (% of total)	0/18 (0%)
Sudden cardiac arrest (% of total)	3/18 (17%)
Explants (% of total)	5/18 (28%)
Hypertension (% of total)	10/18 (56%)
History or current use of tobacco (% of total)	11/18 (61%)
Non-sustained ventricular tachycardia (VT) (% of total)	1/18 (6%)
VT (% of total)	2/18 (11%)
Diabetes (% of total)	5/18 (28%)
Atrial fibrillation (% of total)	3/18 (17%)
Unstable angina (% of total)	0/18 (0%)

3. DEVICE DESCRIPTION

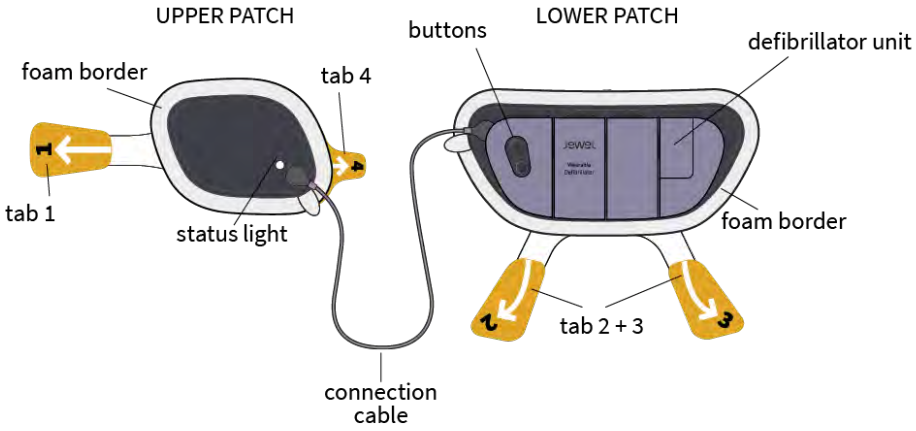
The Jewel Patch Wearable Cardioverter Defibrillator (Jewel P-WCD) is a non-sterile patient-worn device that provides continuous, automatic monitoring of cardiac rhythms to support rapid detection of life-threatening arrhythmias and provide treatment for those arrhythmias that are shockable.
The Jewel is designed to be applied directly to the patient's skin on the upper right chest and lower left torso, beneath the patient's clothing.

The Jewel consists of the following components and accessories provided to the patient:

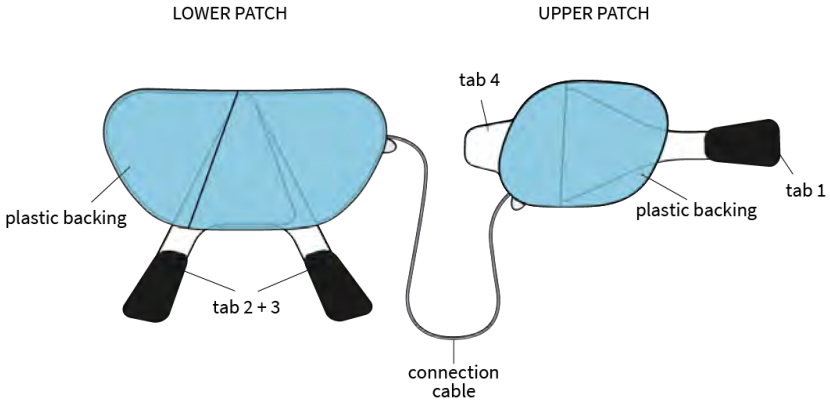
- Defibrillator Unit (re-used throughout the patient's prescription)
- Patch Unit (upper and lower adhesive electrode patches) (one-time use)
- Placement Accessory (used during patch application and replacement)

- Application and removal accessories
- Optional Jewel Mobile App (patient app)
- Report Generator

The Outer Side



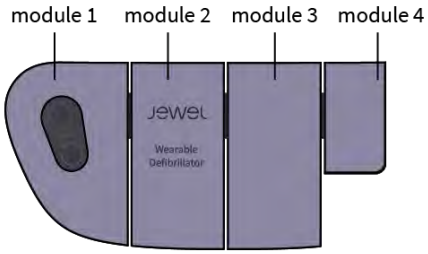
Skin Facing Side



The Jewel Defibrillator Unit and Patch Unit are designed to be worn by the patient continuously. Each Jewel Patch Unit may be worn and replaced on the 7th day of wear. If the Patch Unit is not replaced by the 8th day, the device will alert patient to replace the Patch Unit through audio alarms. The Defibrillator Unit is intended to be re-used with multiple Patch Units throughout the duration of the patient's prescription.

3.1 Defibrillator Unit

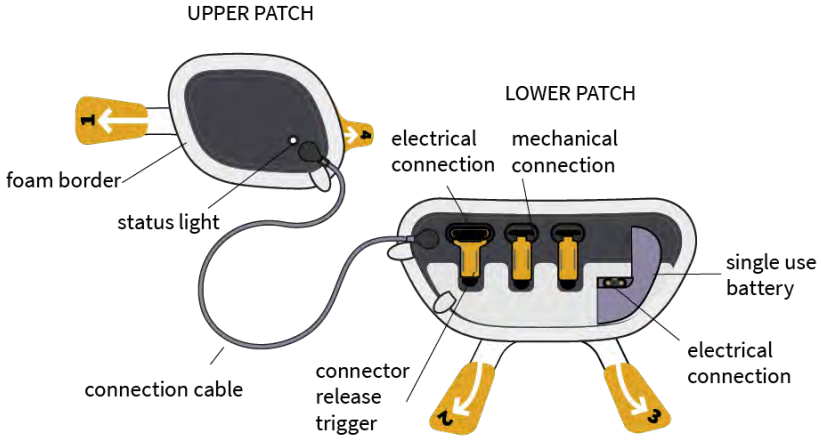
The Defibrillator Unit contains the electronics that monitor the heart and provide an electrical shock if needed. The Defibrillator Unit has four interfaces to connect to the Patch Unit and must be properly connected to the Patch Unit for the Jewel to operate as intended. The Defibrillator Unit is intended to be reused throughout a prescription.



There are TWO BUTTONS on the Defibrillator Unit that are used to turn the Jewel on, cancel an electrical shock, check the status of the Jewel and put the Jewel into removal mode.

3.2. Patch Unit

The Patch Unit consists of an upper and lower patch connected by a multi-conductor connector assembly. The Patch Unit connects to the Defibrillator Unit and has status lights, plastic backings and tabs. The Patch Unit is single-use and intended to be replaced after each wear.



- The **UPPER PATCH** is a single-use, conformable adhesive patch containing ECG electrodes and a defibrillation electrode. The adhesive patch is made up of various types of medical grade adhesive (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 the patient's upper right chest, below the collar bone.

- The **LOWER PATCH** 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 contains four connectors that interface with the Defibrillator Unit. The adhesive patch is made up of various types of medical grade adhesive (including hydrogel and

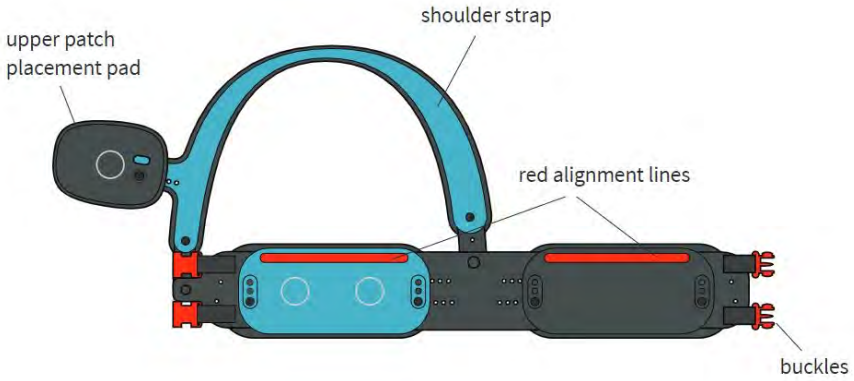
hydrocolloid) and contains some of the sensing electrodes and an electrical shock pad. The lower patch is approximately 5.3 inches x 11.3 inches and will be placed on the lower left torso.

- **STATUS LIGHTS** on the upper patch are used in conjunction with voice messages, audio tones, and vibration to communicate with the patient and bystanders.
- **PLASTIC BACKINGS** cover the adhesive on the upper and lower patches.
- **TABS** are attached to a portion of the plastic backing. Pulling the tabs removes the plastic backing from the Patch Unit to apply the Jewel to the body.

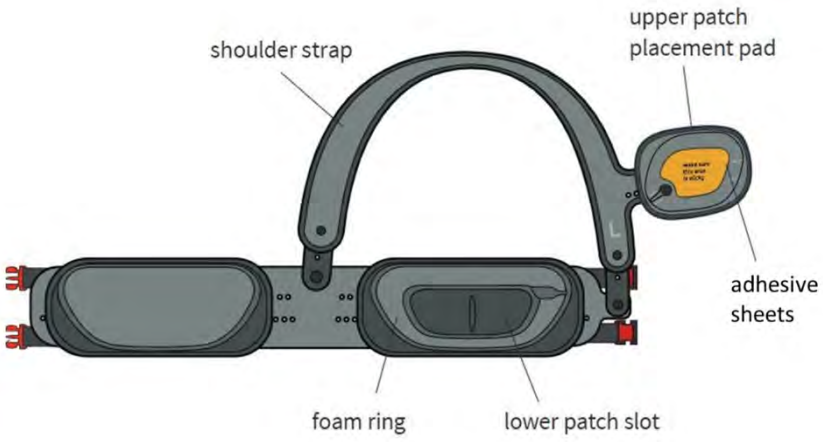
3.3 Placement Accessory

The Placement Accessory is used to help the patient apply the Jewel correctly and in the correct location on the body.

Outer Side



Skin Facing Side



Red Buckles and **Red Alignment Lines** help ensure the Placement Accessory is in the correct location before applying the Jewel.

3.4 Application and Removal Accessories

To support skin while applying and removing the Jewel, the patient may receive non-medical accessories. 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).

3.5 Mobile App (Optional)

The Mobile Application (App) is available for the iPhone and has the ability to connect the patient's phone to the Jewel through Bluetooth. Patients can check the Jewel status using the App. In the event of therapy delivery, if an internet connection is available, the App will upload Jewel data to the Report Generator so healthcare providers can view the Therapy Report.

The Mobile App is optional and is NOT required when using the Jewel.

The App includes two patient reference sections, the Status Section shows the current state of the Jewel and the Help Section provides basic information about the Jewel, daily use, application instructions, removal instructions, contact information, and troubleshooting.

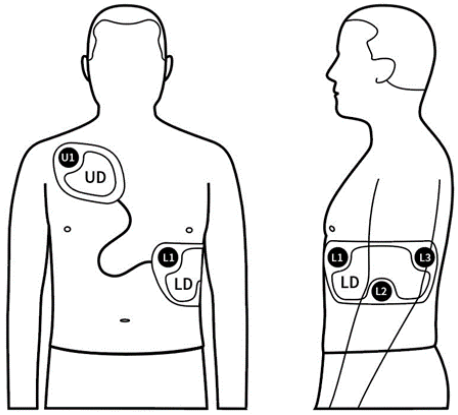
3.6. Therapy Report Generator (Optional)

When a patient receives therapy, the patient's physician may be notified that the patient has received a shock. For patients using the optional Mobile App, ECG information can be transmitted by the App automatically in the event of therapy delivery. For patients who are not using the App, an Element Science representative will need to extract the ECG data from the Jewel. Once the data is extracted from the Jewel, it can be transmitted to the Report Generator to develop a therapy report for the physician. Therapy reports can be viewed and downloaded (in PDF format) from any WiFi enabled device by logging into the clinical portal.

4. DETECTION AND THERAPY

4.1 Sensing Configuration

The Jewel
monitors a patient's ECG through five (5) electrodes located on the upper and lower Patch Unit.



4.2 Arrhythmia Detection

The Jewel employs a proprietary algorithm to detect and classify fast VT or VF versus cardiac rhythms that are non-life threatening and/or non-shockable. The algorithm uses several features extracted from sensed ECG to determine whether the ensuing rhythm is shockable or non-shockable.

Prior to delivering therapy, the Jewel must detect at least 49 continuous seconds of a shockable arrhythmia. When a shockable rhythm is detected, the Jewel initiates the charge cycle and, in parallel, the Jewel will initiate an alarm sequence to alert the patient that it is preparing to deliver a shock.

After the first shock has been delivered, the Jewel must detect a minimum of 32 seconds of a shockable arrhythmia within the next 40 seconds in order to deliver the additional four (4) shocks in the salvo.

Shockable, life-threatening arrhythmias that are morphologically consistent with:

- Rapid ventricular tachycardia (VT)
- Coarse ventricular fibrillation (VF)

Non-shockable, life-threatening arrhythmias:

The Jewel will identify asystole when it detects an ECG amplitude of less than 100 microvolts for at least 49 continuous seconds. If a shockable arrhythmia is detected prior to asystole detection, the Jewel will continue with therapy delivery.

4.3 Cardioversion / Therapy Delivery

The Jewel will attempt to cardiovert the rhythm and synchronize the shock within 60 milliseconds of the peak of the QRS complex. If the Jewel is unable to identify a regular rhythm during the ventricular arrhythmia, the Jewel will deliver an asynchronous defibrillation shock instead of a synchronized shock.

The Jewel delivers an initial therapeutic shock with a fixed energy of 150 joules using a biphasic truncated exponential (BTE) waveform using a constant energy pulse that is adjusted based on the transthoracic impedance of the patient at the time of therapy delivery.
Patient Impedance Limits: The Jewel will not deliver an electrical shock to resistance loads less than 25 ohms or greater than 450 ohms. From impedances of 200 ohms to 450 ohms, if the Jewel detects fast VT or VF, the Jewel will deliver a shock to attempt to convert the rhythm since the patient is unlikely to have other lifesaving options available. Essential performance: The delivered energy into load resistances of 25, 50, 75, 100, 125, 150, and 175 ohms does not vary from the rated energy by more than +/-15% at any energy level. When synchronization is attempted, the Jewel will deliver therapy 0 - 60ms after the peak of the R-wave.

4.4 Post Shock

After the initial therapeutic shock of 150 joules, if the Jewel continues to detect a shockable rhythm, the Jewel will re-initiate the alarm sequence and continue to deliver a salvo of up to four (4) additional BTE shocks of approximately 162 joules, totaling five (5) consecutive shocks (150, 162,162,162,162 joules).

In the event that the shockable rhythm is successfully converted to a non-shockable rhythm, but the patient experiences another episode of a shockable rhythm, the Jewel will continue to deliver additional salvos of shocks, each salvo starting with an initial shock of approximately 150 joules followed by up to four (4) additional shocks of approximately 162 joules. The Jewel is able to deliver ten (10) defibrillation shocks.

4.5 Report Generator

When a patient receives therapy, the patient's physician can be notified that the patient has received a shock and a therapy report is available for patients using the optional Mobile App. This information can be transmitted by the App automatically. For patients who are not using the App, an Element Science representative will extract the ECG data from the Jewel when the Defibrillator Unit is made available. Once the data is extracted from the Jewel, it can be transmitted to the Report Generator to develop a therapy report for the physician.

Therapy reports contain a digital representation of the ECG recording data received from Jewel devices in the event of Jewel-delivered defibrillation shock/s, in addition to basic patient information. The recording may include up to 60 seconds prior to the first defibrillation shock through up to 30 seconds after the final defibrillation shock.

Clinicians can use the internet to login to the clinical portal to view and download therapy reports (in PDF format).

4.5.1 THERAPY REPORT

The therapy report is comprised of the following sections:

- Patient information
- Most recent shock episode information
- Prior shock episodes (if any)

Patient Information
This section includes the current Jewel device worn by the patient as well as date of initial application. Note: The Therapy Report only shows the device history and shock episodes stored on the current device that the patient is wearing.

Most Recent Shock Episode
This section contains information regarding the most recent episode for which the therapy report was generated:

- Date of Initial Application (of current Jewel device)
- Total Days of Wear (days since the initial application of current Jewel Device)
- Most Recent Episode Description, which includes:
    - Date and time of the shock episode (UTC),
    - Number of shocks delivered and related energy in Joules,
    - Duration of shockable rhythm (defined as duration from onset of shockable rhythm to delivery of final shock) and
    - Days of wear at the time of the episode.

The episode summary is followed by ECG strips from the most recent shock episode, organized into three sections:

- Onset: two 8-second ECG strips showing the onset of the shockable rhythm.
- Final Shock: two 8-second ECG strips showing the final shock and the post-shock rhythm.
- Full Episode: full episode shown in compressed (16-second) ECG strips from onset of shockable rhythm until up to 30 seconds after the final shock is delivered.

Prior Shock Episodes
If the patient has previously received therapy from the same Jewel device, the therapy report will show compressed ECG strips (16-second) for those full episodes in reverse chronological order (most recent episodes will be displayed first).

Amplitude Scale
The amplitude scale (gain settings) for the ECG printouts is variable depending on the amplitude of the ECG recordings. Typical amplitude scales for ECG printouts are 10 mm/mV and 5 mm/mV for base to peak amplitudes of 1 mV and 2 mV, respectively.

Amplitude scale and recording speed for the ECG printouts are specified in mm/mV and mm/s as measured on paper when printing the downloaded therapy report PDF file in actual size.

5. PATIENT TRAINING

During the initial device placement and training session, Element Science certified personnel will train the patient on appropriate use of The Jewel and provide the Patient Guide. The Placement Accessory will be fitted for the patient during this visit. The Element Science Representative then will provide hands-on training for the patient, walking through application, removal, common alarms and other tasks performed during the Jewel prescription including operation and maintenance. For physician reference, the Application, Removal, and Notification instructions provided in the Patient Guide are also included in Appendix A of this document.

5.1. Patient Support and Reference Material

The following additional instructional and reference materials are available to patients and accessible online (available at www.elementscience.com/manuals).

- Patient Guide (complete instructions on assembly, wearing, and maintaining the Jewel)
- Instructions For Use
- Patient Training Videos

6. ALERTS AND NOTIFICATIONS

The Jewel may issue two types of notifications:

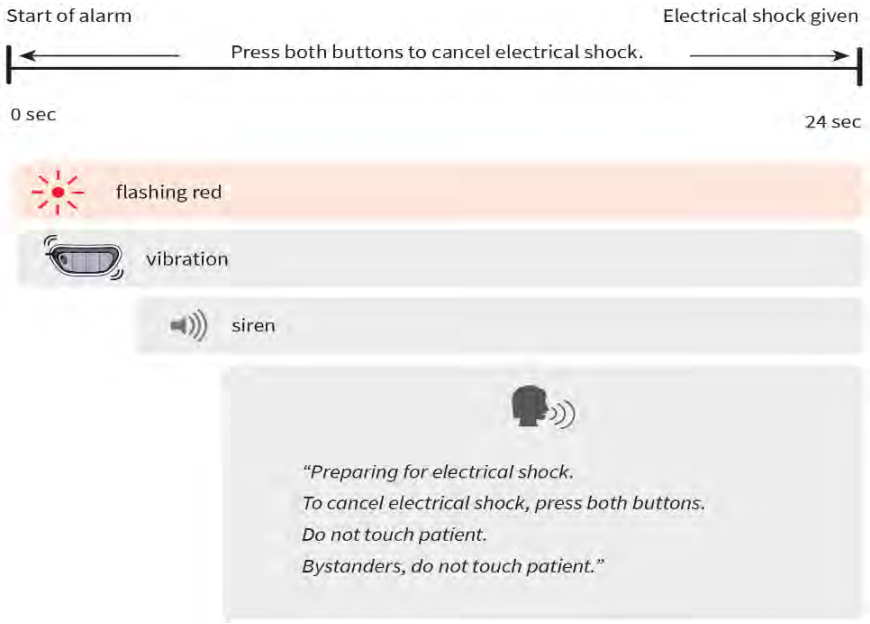
1. Heart rhythm alarms
2. Device status notifications

The Jewel communicates these alarms and notifications to the patient through tones, voice prompts, lights, and vibrations. Light notifications may be solid or flashing green, yellow or red:

- Green - no action required
- Yellow - action required
- Red - immediate action required

6.1 Heart Rhythm Alarms

A siren alarm plays when the Jewel detects ventricular tachycardia or ventricular fibrillation.



The Jewel will cancel a shock if a non-shockable rhythm is detected, or if the shock is deferred. If the patient is conscious, they can defer the shock. To defer therapy, the patient can press both buttons on the Defibrillator Unit simultaneously. Only the patient should defer therapy. If anyone other than the patient presses the buttons during the siren alarm, an electrical shock may not be given when needed.

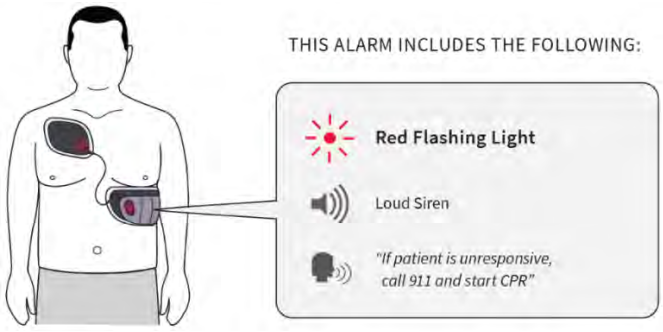
Notifications that occur after therapy has been deferred	
Solid green light	"Electrical shock canceled. Jewel is active." (Patient should continue wearing the Jewel)

If the patient is not conscious and has not deferred treatment, the Jewel will deliver therapy.

Notifications that occur after therapy has been delivered	
Flashing yellow light	“Electrical shock given. Seek emergency care.” (Patient should continue wearing the Jewel and seek emergency care)

EMERGENCY SERVICES REQUIRED ALARM

When the Jewel detects asystole OR after the Jewel has delivered all available electrical shocks, it will issue an emergency service required alarm.



6.2 Device Status Notifications

This section describes the notifications the Jewel will use to let a patient know its status. When the Jewel issues a status notification, the patient should:

1. Check the notification and voice prompt.
2. If a voice notification has been delivered, a status check will repeat the last voice alert. To complete a status check, press both buttons on the Defibrillator Unit and release after feeling a click.
3. Respond as instructed.

6.2.1 INDEX OF JEWEL ALARMS AND NOTIFICATIONS

Table 6.2a: Application Alarms and Notifications

Description	Notification	Voice Prompt
The Defibrillator Unit and Patch Unit are not assembled correctly	Flashing red	*No prompt: confirm Defibrillator Unit and Lower Patch are fully connected*
Contact Customer Service immediately	Flashing red + tone + vibration	Device is disabled and must be replaced; call customer service immediately

Description	Notification	Voice Prompt
Use a new Patch Unit	Flashing red + tone + vibration	Patches no longer working; replace patches immediately
Device is ready to be applied	Flashing green + tone + vibration	Jewel is in application mode; apply Jewel now using Placement Accessory
Device has been applied successfully and is warming up before becoming active	Solid green + tone	*No prompt; Jewel has been successfully applied but is not yet active (the Jewel is warming up and will become active in 2- minutes)*
Device is active	Solid green + tone	Jewel is active

Table 6.2b: Daily Wear Alarms and Notifications

Description	Notification	Voice Prompt
Patch(es) are losing contact with skin	*Press and Hold Alert* yellow + tone + vibration	Patches losing contact with skin; press and hold both patches
Elective Replacement Alert Patches must be replaced within 24 hours (this alert repeats every 6 hours).	Flashing yellow + vibration	Replace patches soon
Replace Patches Now Alert; patches must be replaced within 3 hours (this alert repeats every hour)	Flashing yellow + tone + vibration	Patches expired; replace patches now; to start removal mode, press and hold both buttons
Mandatory Replacement Alert Patches must be replaced immediately (this alert repeats every 20 minutes)	Flashing red + tone + vibration	Patches expired and no longer working; replace patches immediately; to start removal mode, press and hold both buttons
Device Disconnected Alert - first module	Flashing red + tone + vibration	Device is disconnected from patch and is unable to provide electrical shock; press first module of device.
Device Disconnected Alert - last module	Flashing red + tone + vibration	Device is disconnected from patch and is unable to provide electrical shock; press last module of device.
Contact Customer Service immediately	Flashing red + vibration	*No prompt*

Table 6.2c: Removal Alarms and Notifications

Description	Notification	Voice Prompt
Removal mode	Flashing red	To confirm removal mode, press and hold both buttons
Removal mode not confirmed	Flashing red	Removal mode not confirmed; to confirm removal mode, press and hold both buttons
Removal mode confirmed	Flashing red + tone	Jewel is in removal mode for 30 minutes; replace patches now
Device has confirmed it is no longer one the patient and is waiting for re-application	Flashing red + tone + vibration	Replace patches immediately

Table 6.2d: Other Alarms and Notifications

Description	Notification	Voice Prompt
Device is ready to be paired with the Mobile App	Flashing green + tone	Jewel is in pairing mode
Device is pairing with the Mobile App	Flashing green + tone	Jewel is in pairing mode; pairing Jewel now
Device is detecting magnetic interference	Flashing yellow + vibration	Jewel is detecting magnetic interference; move away from current location

7. TECHNICAL INFORMATION

7.1 Specifications

7.1.1 DEVICE SPECIFICATIONS

- Defibrillator Unit plastic housing dimensions: 8.6” x 3.8” x 1.4”
- Upper Patch dimensions: 6.8” x 5”
- Lower Patch dimensions: 11.3” x 5.3”
- Jewel weight: 500g
- Lower Patch Battery: 3 Single-cell lithium-manganese dioxide CR123A primary batteries, 3VDC nominal each, 1.5 Ah; total power approximately 9VDC and 4.5 Ah)
- Jewel Defibrillator Internal Battery: coin type lithium ion rechargeable battery 3.7V, 200 mAh

Device Notification Specifications

- Expected high and medium priority alert sound pressure levels: 68 dBA to 80 Dba.

7.1.2 DETECTION CRITERIA

This section provides information regarding the Jewel's algorithm's performance and test methods per 60601-2-4.

The Jewel employs a proprietary embedded algorithm to detect shockable arrhythmias, and uses several features extracted from sensed ECG to determine whether the ensuing rhythm is shockable or non-shockable. Performance has been evaluated using a Validation Dataset of electrocardiogram (ECG) samples. The Validation Dataset includes a total of 724 samples from a variety of sources, where each sample was at least 8 seconds long. All data was annotated based on adjudication by certified cardiologists or third party specialists in ECG rhythm adjudication. Data sources (from multi-function electrodes in the same orientation as the Jewel) included:

- ECG recordings collected from the Jewel electrode patches during the Jewel electrophysiology (EP) lab and IDE studies
- ECG recordings collected from public databases or provided by clinical sites via data sharing contract
- Digitized ECG recordings collected from publicly available medical journals.

The Jewel detection algorithm meets or exceeds the American Heart Association (AHA) recommendations for performance as required by IEC 60601-2-4, as shown in Table 7.1a, where samples are organized by rhythm types identified in the American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Effectiveness. "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety." Circulation 95, no. 6 (1997): 1677–82.

Table 7.1a: Rhythm types identified in the American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Effectiveness

Rhythm		Element Science Sample Size (multi-function electrodes)	AHA Performance Goal	Jewel Performance (Observed)	Jewel Performance 90% One-sided Lower Confidence Limit
Shockable	Coarse VF	203	> 90% Sensitivity	99.5% Sensitivity	97.8% Sensitivity
	Rapid VT	53	> 75% Sensitivity	100.0% Sensitivity	95.1% Sensitivity
Non-Shockable (306 Total)	NSR	135	> 99% Specificity	100.0% Specificity	98.0% Specificity
	AF, SB, SVT, HB, IV, PVC	51	> 95% Specificity	100.0% Specificity	95.0% Specificity
	Asystole	100	> 95% Specificity	97.0% Specificity	92.7% Specificity
Intermediate	Fine VF	133	Report Only	100.0 % Sensitivity	Not Required
	Other VT	26	Report Only	100.0% Sensitivity	Not Required

In addition to the above statistics, the overall Jewel algorithm performance has been summarized below:

- Overall Sensitivity: 99.8%
- Overall Specificity: 96.4%
- Overall Positive Predictive Accuracy: 97.4%
- Overall False Positive Rate:3.6%

7.1.3 SHOCK CRITERIA

- **Waveform**: Biphasic truncated exponential
- **Delivered energy accuracy**: First shock of a salvo at 150J (+/- 15%) at ambient temperature when discharged into 25, 50, 75, 100, 125, 150, 175 ohm resistive load. For shocks 2-5 of a salvo, 162J (+/- 15%) at ambient temperature when discharged into a 25, 50, 75, 100, 125, 150, 175ohm resistive load.
- **Delivery time**: The Jewel delivers the first shock of a salvo within 60 seconds of arrhythmia classification. For shocks 2-5 of a salvo, the Jewel is capable of delivering a shock within 35 seconds of the previous shock.
- **Charge time**: The Jewel requires 34 seconds or less to charge the capacitors with a newly replace battery or after six shocks after it has entered monitor mode.
- **Defibrillating peak output current:** Nominally 52.9A for a maximum joule defibrillating shock delivered into a 25ohm load.
- **Pulse per cardioverting / defibrillating sequence**: Conversion of the arrhythmia after a shock automatically precludes delivery of remaining shocks in the sequence.

- **Reset**: Following successful arrhythmia conversion, the software resets the pulse sequence, thereby enabling a new treatment sequence in the event of another detected arrhythmia.
- **Maximum number of defibrillation shocks from a new patch**: Per IEC 60601-2-4 Clause 201.102.3.2, Jewel is capable of delivering 20 shocks with a fully charged battery.

7.1.4 LOW BATTERY SHOCKS REMAINING

- **Elective Replacement Alert** indicates the Lower Patch is becoming less adhered to the body or that the battery is approaching Mandatory Replacement Alert but the Device can deliver up to 10 shocks (flashing yellow + tone + vibration).
- **Mandatory Replacement Alert** indicates the Lower Patch is not adhered to the body or the Device may no longer be capable of delivering 10 shocks (flashing red + tone + vibration).
- **Operating voltage**: 9V
- **Current rating**: 2.4A

7.1.5 WIRELESS TECHNOLOGY INFORMATION (MOBILE APPLICATION)

- **Wireless technology**: The Jewel device uses Bluetooth Low Energy (BLE) to communicate with the paired mobile device. The frequency band of transmission is BLE version 5.0, with a frequency of 2.4 Ghz and transmitting power of 0 dBm. BLE is a secure, industry-standard wireless communication technology widely used in commercial and medical applications, and readily available in mobile devices.
- **Quality of Service**: In the event of an electrical shock, the Jewel device will queue the treatment data if it is not connected to the mobile device. The Jewel will automatically reconnect to the paired mobile device when it is available. When the reconnection occurs, it will automatically send all pending treatment data to the ES Mobile App.
- **Operating distances and ranges**: Typical range is 50 m (150 ft) of direct line of sight. In the home or office, walls may considerably decrease this range.
- **Security Requirements**: All data messages are encrypted with industry standard hardware-based ECB block AES-128 encryption.
- **FCC labeling**: The BLE module has received Federal Communications Commission (FCC) CFR47 Telecommunications, Part 15 Subpart C “Intentional Radiators” modular approval in accordance with Part 15.212 Modular Transmitter approval.
- **Contains FCC ID**: 2AA9B05

7.1.6 OPERATING ENVIRONMENT

- **Temperature range**: 10 to 50°C (50 to 122°F)
- **Humidity range**: 15 to 95% relative humidity
- **Altitude**: sea level (1013 hPa equivalent pressure) up to 15,000 feet (572 hPa equivalent pressure)

7.1.7 STORAGE ENVIRONMENT

- **Temperature range**: 15 to 30°C (59 to 86°F)
- **Humidity range**: 5 to 95% relative humidity
- **Altitude**: sea level (1013 hPa equivalent pressure) up to 15,000 feet (572 hPa equivalent pressure)

7.1.8 TRANSPORTATION ENVIRONMENT

- **Temperature range**: -29 to 60°C (-20 to 140°F)
- **Humidity range**: 15 to 85% relative humidity
- **Altitude**: sea level (1013 hPa equivalent pressure) up to 14,000 feet (600 hPa equivalent pressure)

7.1.9 PRODUCT LIFETIME

- **Defibrillator Unit**: 3 years

7.1.10 IEC 60601-1 CLASSIFICATIONS FOR USE

- **Temperature associated with charging**: When charging prior to defibrillation in an environment with an ambient temperature of 37°C , the Upper Patch reaches a maximum temperature 41.9°C and the Lower Patch reaches a maximum temperature of 41.8°C. When charging prior to defibrillation in an environment with an ambient temperature of 50°C, the patch cable reaches a maximum temperature 55.9°C and the battery enclosure reaches a maximum temperature of 54.6°C.
- **Type of protection against electric shock**: internally powered.
- **Applied part**: the Jewel Upper and Lower Patches.
- **Degree of protection against electric shock**: defibrillation-proof type BF applied parts
- **Degree of protection against harmful ingress**: IP 24 protection against solid objects greater than 12.5mm and splashing/spraying water. The Jewel can be worn in the shower including high flow shower heads up to 3.3 gallons per minute and soapy water conditions. Avoid prolonged direct pounding water on the device.
- **Mode of operation**: continuous Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Hair Trimmer was excluded from UL investigation.

7.2 Conformance to Standards

The following standards were used during the design and development of the Jewel. Compliance with the applicable portions of these standards was verified in nonclinical lab tests.

Standard/Reference	Standard/Reference Title
AAMI EC12:2020	Disposable ECG Electrodes
AAMI EC53:2013/®2020	ECG Trunk Cables and Patient Lead wires
EN 55011:2016 + AMD2:2019	Industrial, scientific and mechanical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009(R)2014	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Standard/Reference	Standard/Reference Title
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-12:2021	Biological evaluations of medical devices- Part 12: Sample Preparation and Reference Materials
ISO 10993-23:2021	Biological Evaluation of Medical Devices - Part 23: Tests for Irritation
IEC 60529:2013-08 (Edition 2.2)	Degrees of Protection Provided by Enclosures (IP Codes)
IEC 60601-1:2005 + AMD1:2012	Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2014 + AMD1:2020 (Edition 4.1)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2020 (Edition 3.2)	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard - Usability
IEC 60601-1-8:2020 (Edition 2.2)	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard - General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-11:2015 + AMD1:2020 (Edition 2.1)	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard - Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-2-4:2010 + AMD1:2018 (Edition 3.1)	Medical Electrical Equipment – Part 2-4: Particular Requirements for Basic Safety and Essential Performance of Cardiac Defibrillators
IEC 60601-2-47:2012	Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
IEC 62304:2006 + AMD1:2015	Medical device software – Software life-cycle processes
IEC 62366-1:2015 + AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
ISTA 3A:2018	Packaged products for parcel delivery system shipments 70kg (150lb) or less
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer

Standard/Reference	Standard/Reference Title
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
ISO 27185:2012/(R)2017	Cardiac Rhythm Management Devices – Symbols to be used with cardiac rhythm management device labels, and information to be supplied – general requirements
IEC 60086-4:2019	Primary Batteries - Part 4 Safety of Lithium Batteries
IEC 62133-2:2017 / AMD1:2021	Secondary cells and batteries containing alkaline or other non- acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
FDA Code of Federal Regulations, Title 21, Part 830	Unique Device Identification
ISO 27001:2022	Information security, cybersecurity and privacy protection — Information security controls

7.3 Electromagnetic Compatibility (EMC) Testing

EMC testing results in accordance with the following:

Standard/Reference	Standard/Reference Title
CISPR 11:2003 + AMD1:2004	Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment
IEC 60601-1-2: 2014 + AMD1:2020 (Edition 4.1)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-11:2015 + AMD1: 2020 (Edition 2.1)	Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
AIM Standard 7351731, Rev 2.00, 2017	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

7.4 IEC 60601-1-2:2020 EMC Manufacturer's Declaration

Standard	Description	IEC 60601-1-2 Compliance Level	IEC 60601-1-2 Test Level
EMISSIONS			
CISPR 11	Radiated RF Emissions	Class B Group 1 tested at both min and max line voltage	Class B Group 1 tested at both min and max line voltage
IMMUNITY			
IEC 61000-4-2	ESD Immunity	±8 kV contact, ±15 kV air	±8 kV contact, ±15 kV air
IEC 61000-4-3	Radiated RF Immunity	80-2700MHz 20V/m home healthcare, 80% AM, 5Hz 385MHz :27 V/m, PM,18Hz 450MHz :28 V/m, FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz :9 V/m, PM, 217 Hz 810, 870, 930MHz :28 V/m, PM, 18Hz 1720, 1845, 1970MHz :28 V/m, PM, 217 Hz 2450MHz :28 V/m, PM, 217 Hz 5240, 5500, 5785MHz :9 V/m, PM, 217 Hz	80-2700MHz 20V/m home healthcare, 80% AM, 5Hz 385MHz :27 V/m, PM,18Hz 450MHz :28 V/m, FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz :9 V/m, PM, 217 Hz 810, 870, 930MHz :28 V/m, PM, 18Hz 1720, 1845, 1970MHz :28 V/m, PM, 217 Hz 2450MHz :28 V/m, PM, 217 Hz 5240, 5500, 5785MHz :9 V/m, PM, 217 Hz
IEC 61000-4-6	Conducted RF Immunity	3V rms 150kHz - 80 MHz, 80% amplitude modulation at 5Hz and 6 Vrms for ISM frequencies between 150kHz-80MHz, 6 Vrms for Amateur frequencies between 150kHz and 80 MHz	3V rms 150kHz - 80 MHz, 80% amplitude modulation at 5Hz and 6 Vrms for ISM frequencies between 150kHz-80MHz, 6 Vrms for Amateur frequencies between 150kHz and 80 MHz
IEC 61000-4-8	Power Frequency Magnetic Field Immunity	30 A/m, 50 and 60 Hz	30 A/m, 50 and 60 Hz
IEC 61000-4-39	Proximity Magnetic Field Immunity	30 kHz, CW, 8A/m 134.2 kHz, PM 2.1 kHz, 65 A/m 13.56 MHz, PM, 50 Hz, 7.5 A/m	30 kHz, CW, 8A/m 134.2 kHz, PM 2.1 kHz, 65 A/m 13.56 MHz, PM, 50 Hz, 7.5 A/m

7.5 RFID Immunity Standard AIM 7351731 Manufacturer's Declaration

Standard	Description	AIM 7351731 Compliance Level	AIM 7351731 Test Level
IMMUNITY			
ISO 14223	Magnetic Field Immunity	134.2 kHz@65A/m	134.2 kHz@65A/m
IEC 14443-3 (Type A)	Magnetic Field Immunity	13.56 MHz@7.5A/m	13.56 MHz@7.5A/m
IEC 14443-4 (Type B)	Magnetic Field Immunity	13.56 MHz@7.5A/m	13.56 MHz@7.5A/m
IEC 15693; ISO 18000-3 Mode 1	Magnetic Field Immunity	13.56 MHz@5A/m	13.56 MHz@5A/m
ISO 18000-3 Mode 3	Magnetic Field Immunity	13.56 MHz@12A/m	13.56 MHz@12A/m
ISO 18000-7	Magnetic Field Immunity	433 MHz @ 3V/m	433 MHz @ 3V/m
ISO 18000-63 Type C	Radiated RF Immunity	860-960 MHz@ 54 V/m	860-960 MHz@ 54 V/m
ISO 18000-4 Mode 1	Radiated RF Immunity	2.45 GHz@54V/m	2.45 GHz@54V/m

7.6 Defibrillating Pulse Waveforms

Table 7.6a: Nominal first shock waveform parameters

Nominal First Shock Waveform (150J) parameters for patient loads of 25, 50, 100, 150, and 200 ohms.

Patient Resistance (Ω)	Phase I Duration (ms)	Phase 2 Duration (ms)	Peak Current (A)
25	3	2.4	52.9
50	4.8	3	28.6
100	10.4	3	14.9
150	16.1	3	10.1
200	21.8	3	7.6

Table 7.6b: Nominal second through fifth shock waveform parameters

Nominal Second-Fifth Shock Waveform (162J) parameters for patient loads of 25, 50, 100, 150, and 200 ohms.

Patient Resistance (Ω)	Phase I Duration (ms)	Phase 2 Duration (ms)	Peak Current (A)
25	3.7	3	52.9
50	6.9	3	28.6
100	13.5	3	14.9
150	20.3	3	10.1
200	22	3	7.6

Essential performance: the delivered energy into load resistances of 25, 50, 75, 100, 125, 150, and 175 ohms does not vary from the rated energy by more than +/-15% at any energy level.

8. SYMBOLS GLOSSARY

This section defines the symbols used on the Jewel labels and packaging.

Symbol	Standard/Reference	Standard/Reference Title	Symbol Title	Explanatory Text
	ISO 15223-1, Ref. 5.1.1	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Manufacturer	Indicates the medical device manufacturer
	ISO 7000-3082	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.1.4	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Use-by date	Indicates the date after which the medical device is not to be used
	ISO 7000-2607	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.1.5	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Batch Code/Lot Number	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 7000-2492	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.1.6	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified
	ISO 7000-2493	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.1.7	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	ISO 7000-2498	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.2.7	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	ISO 7000-2609	Graphical symbols for use on equipment		

Symbol	Standard/Reference	Standard/Reference Title	Symbol Title	Explanatory Text
	ISO 15223-1, Ref. 5.2.8	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	ISO 7000-2606	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.3.1	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	ISO 7000-0621	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.3.2	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	ISO 7000-0624	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.3.4	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Keep dry	Indicates a medical device that needs to be protected from moisture
	ISO 7000-0626	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.3.7	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	ISO 7000-0632	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.3.8	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed
	ISO 7000-2620	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.4.2	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Do not re-use	Indicates a medical device that is intended for one single use only
	ISO 7000-1051	Graphical symbols for use on equipment		

Symbol	Standard/Reference	Standard/Reference Title	Symbol Title	Explanatory Text
	ISO 15223-1, Ref. 5.4.3	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	ISO 7000-1641	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.4.4	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	ISO 7000-0434A	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.4.12	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Single patient multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient
	ISO 7000-3706	Graphical symbols for use on equipment		
	ISO 15223-1, Ref. 5.7.7	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Medical device	Indicates the item is a medical device
	ISO 15223-1, Ref. 5.7.10	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	Unique device identifier	Indicates a carrier that contains unique device identifier information
	IEC 60601-1, Ref. Table D.1, Symbol 26	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	Defibrillation proof Type BF applied part	To identify a defibrillation-proof type BF applied part complying with IEC 60601-1
	IEC 60417-5334	Graphical Symbol for Use on Equipment		
	IEC 60601-1, Ref. Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	Refer to instruction manual/booklet	Follow instructions for use or follow electronic instructions for use
	ISO 7010-M002	Graphical symbols — Safety colours and safety signs — Registered safety signs		

Symbol	Standard/Reference	Standard/Reference Title	Symbol Title	Explanatory Text
IPN_1N_2	IEC 60601-1, Ref. Table D.3, Symbol 2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	Degree of Ingress Protection Provided by Enclosure	Manufacturer-determined degree of particle and water ingress protection, where... N1= degree of protection from particulates (scale of 0-6); and N2 = degree of protection from water (scale of 0-8) NOTE When a characteristic numeral is not required to be specified, it is replaced by the letter "X"
	IEC 60529	Degrees of protection provided by enclosures (IP Code)		
	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging equipment
	IEC 60601-1-2	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment
	IEC TR 60878	Graphical symbols for electrical equipment in medical practice		
	ISO 7000-5140	Graphical symbols for use on equipment		
	IEC-60417-5140			
	EN 50419	Marking of electrical and electronic equipment (EEE) in respect to separate collection of waste EEE (WEEE)	Recycle: Electronic Equipment	Do not dispose of this product in unsorted municipal waste stream
	21 CFR 801.109, Ref. 21 CFR 801.109(b)(1)	Prescription devices	Prescription only	Requires prescription in the United States
FCC ID:XXXXXXX	47 CFR 15.212, Ref. 47 CFR 15.212(a)(1)(vi)(A)	Modular Transmitters	Federal Communication Commission Identifier (FCC ID #)	Complies with United States Regulations for Radio Frequency Devices

Symbol	Standard/Reference	Standard/Reference Title	Symbol Title	Explanatory Text
	29 CFR 1910.1200, Section C.4.19 (Classified in Accordance with Appendix B.6)	Occupational Safety and Health Standards (OSHA), Hazard Communication Standard (HCS), Appendix C – Allocation of Label Elements, Section C.4.19 “Flammable Liquids”	Flammable liquid and vapor	Indicates the possible presence of the following; flammables, self reactives, pyrophorics, self-heating, emits flammable gas, organic peroxides.

APPENDIX A

This appendix contains instructions from Chapters 3 through 5 from the Jewel Patient Guide. For full instructions, see the Jewel Patient Guide.

3

3

APPLYING YOUR JEWEL

3.1 SKIN PREPARATION

HAIR TRIMMING

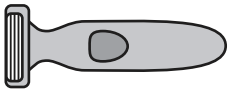
These steps cover trimming hair in the patch areas. If you do not have any hair on your chest or torso, skip to Preparing Skin with Skin Prep Mitts on the next pages.

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.

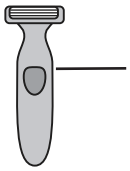
SUPPLIES NEEDED:

- 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.

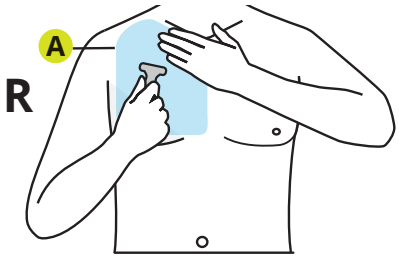
1



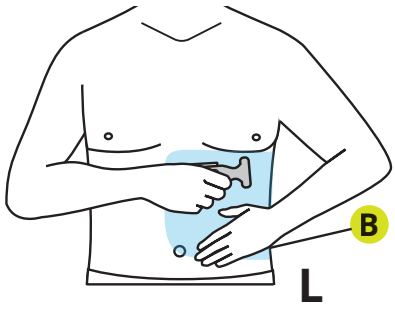
turn on trimmer

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

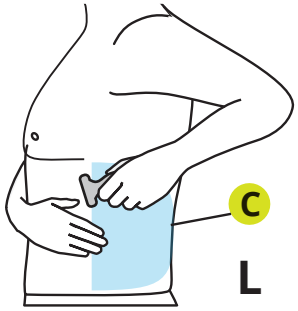
Trim hair close to skin in the following areas:



A. RIGHT CHEST
(Upper Patch area)

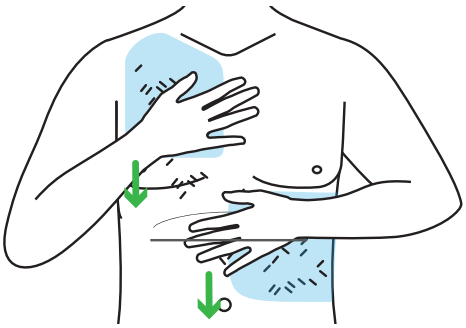


B. LEFT TORSO FRONT
(front of Lower Patch area)

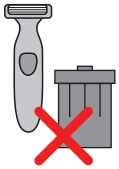


C. LEFT TORSO SIDE/BACK
(back of Lower Patch area)

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.

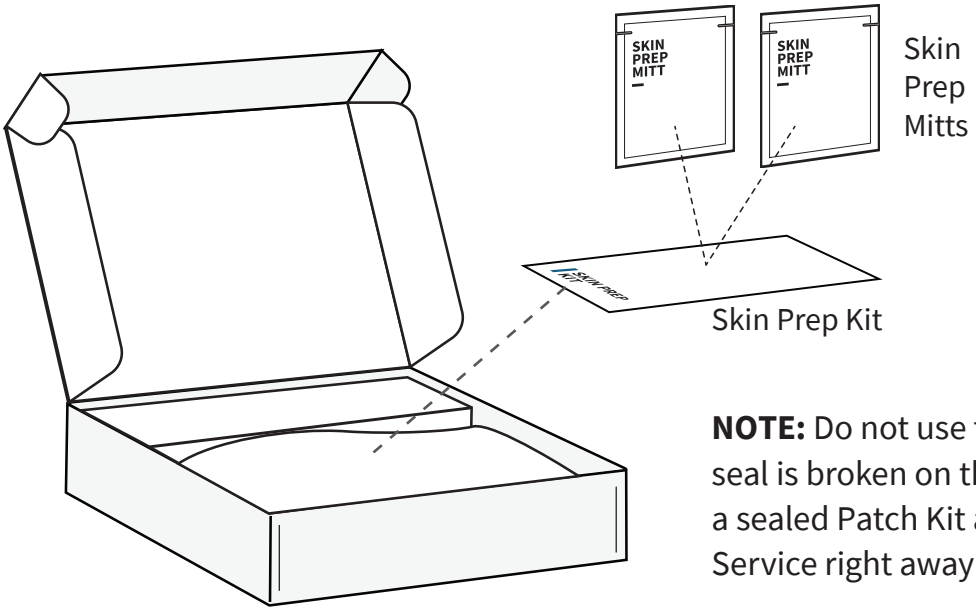
PREPARING SKIN WITH SKIN PREP MITTS

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:



Skin Prep Mitts

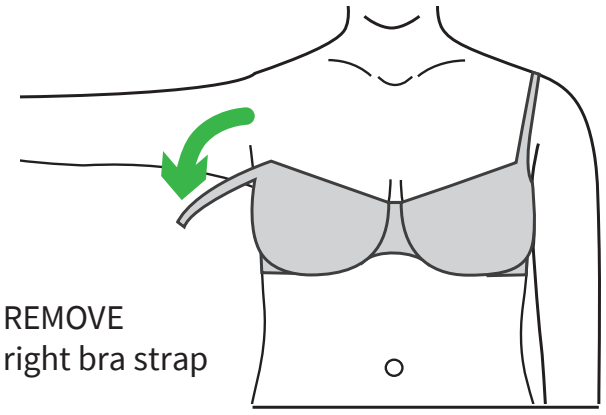
Skin Prep Kit

Patch Kit

NOTE: Do not use the Patch Kit if the seal is broken on the Patch Kit box. Use a sealed Patch Kit and contact Customer Service right away for replacements.

timer (not provided)

1

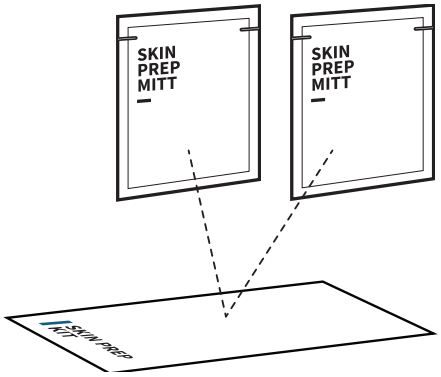


Remove all clothing and jewelry from upper body.

Do NOT wear a bra that cannot be unclasped. Your bra will become trapped under the Jewel when applied.

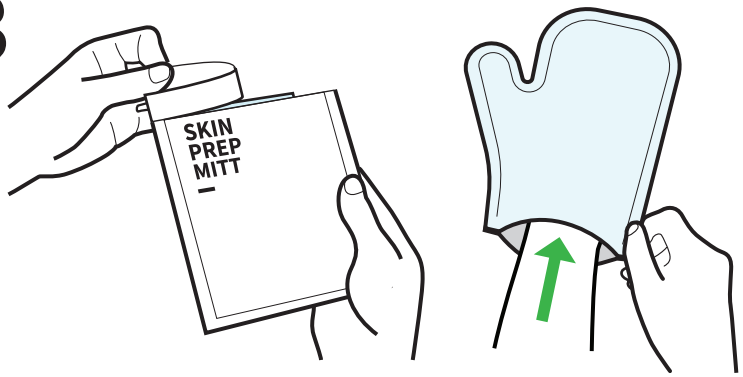
A bra is not required to be worn for skin prep or your Jewel application.

2



Remove two skin prep mitt packets from the box.

3

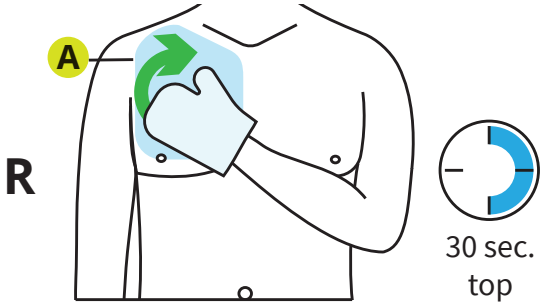


Take one mitt out of packages. Place mitt on your hand.

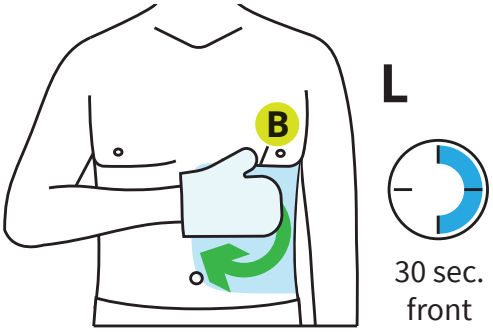
continue ⟶

4 Only one mitt is opened and used at a time.

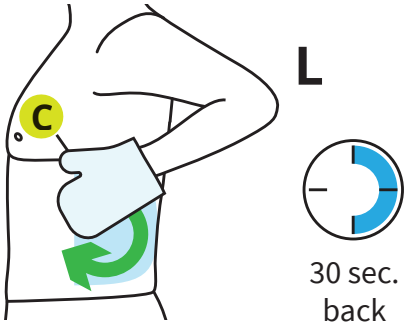
One mitt should be used for the Upper Patch, the second mitt should be used for the Lower Patch area. The Lower Patch mitt should be flipped so that the opposite side is used on the back.



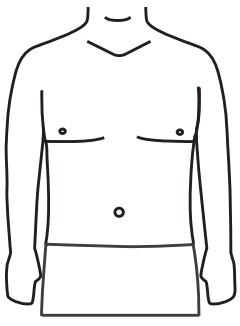
A. RIGHT CHEST
(Upper Patch area)



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



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



Skin preparation is complete when

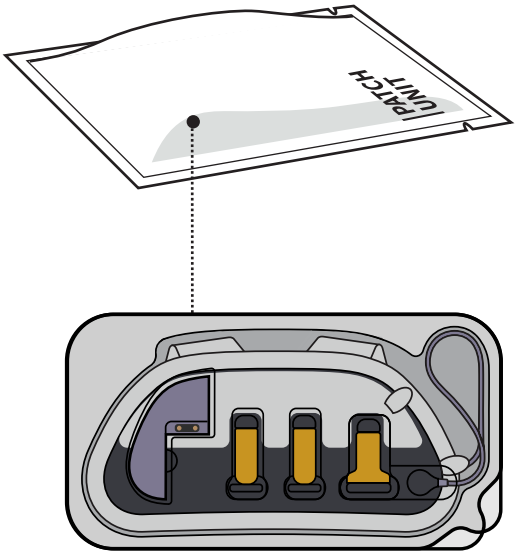
- hair is trimmed
- skin is clean and dry

3.2 JEWEL PREPARATION

SUPPLIES NEEDED:

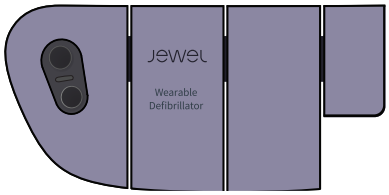
- Patch Unit
- Defibrillator Unit

PATCH UNIT POUCH

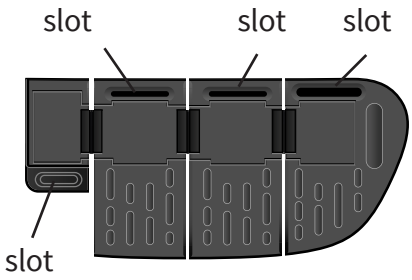


PATCH UNIT IN TRAY

DEFIBRILLATOR UNIT FRONT



DEFIBRILLATOR UNIT BACK



NOTE: Do not use the Defibrillator Unit if the seal is broken on the Defibrillator Unit box. Contact Customer Service right away for a replacement.

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

WARNING

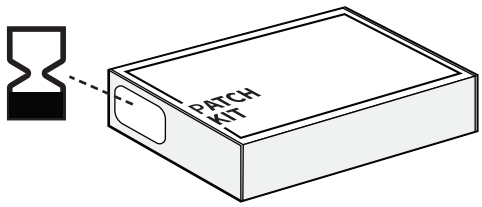
•**Do NOT apply the Patch Unit after the use by date.** Applying the Patch Unit after the use by (expiration) date could result in an electrical shock not given when needed and may impact product performance.

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

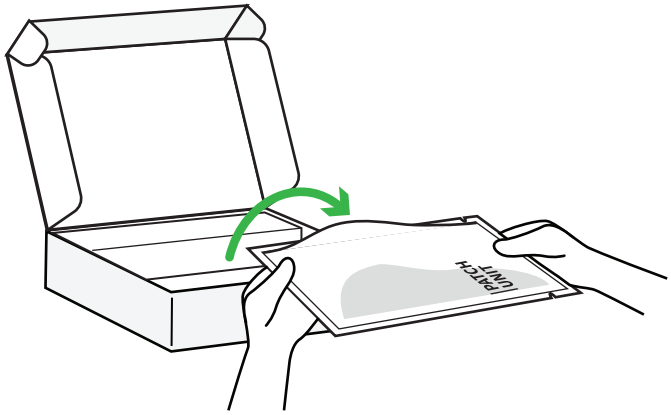
1



Confirm Use by date on outside of Patch Kit box before opening.

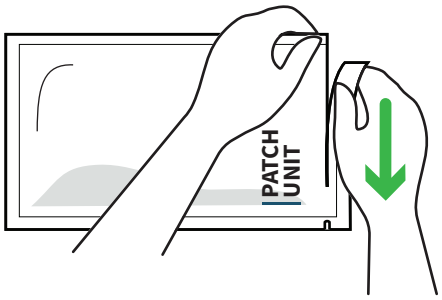
Apply the Jewel on or before the Use by date.

2



Open Patch Kit box and remove the sealed pouch.

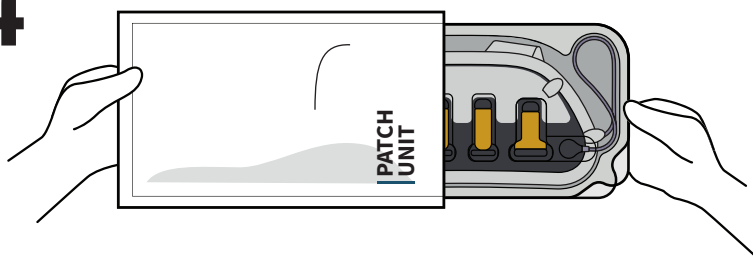
3



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.

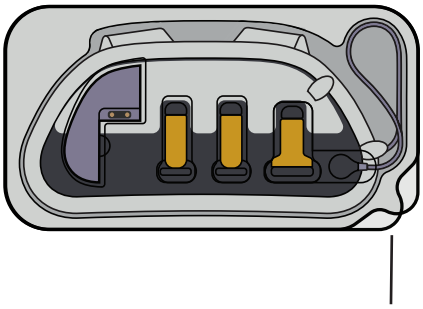
4



Remove patch tray from the pouch and place in front of you with the opening tabs to the right of you.

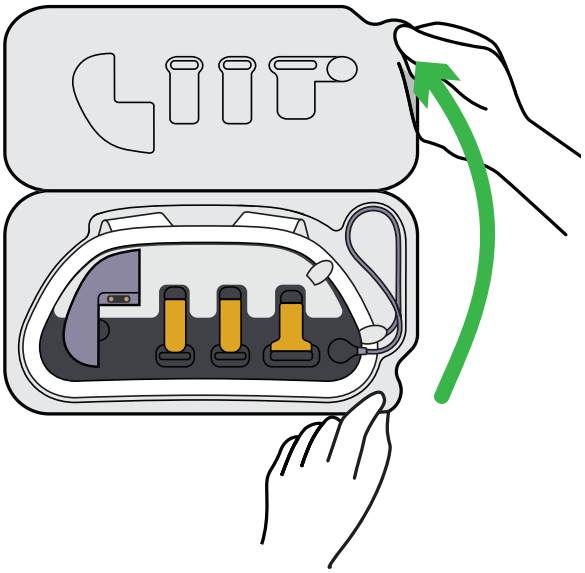
Make sure the surface you are using is clean.

5



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

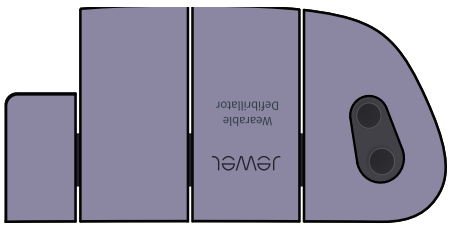
6



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

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

7

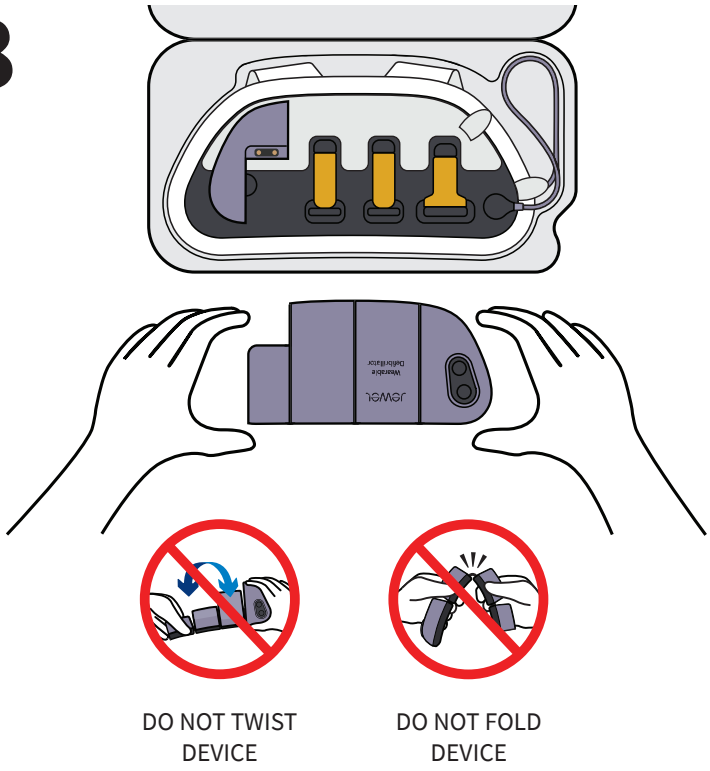


Position the Defibrillator Unit so that buttons are on the right side.

> **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 damage or break the device.

continue ⟶

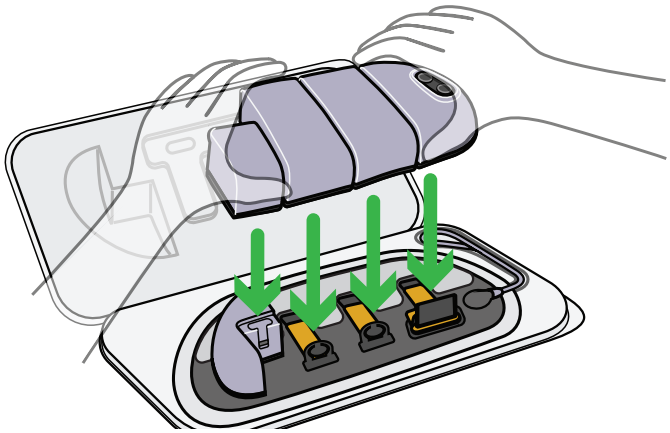
8



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.

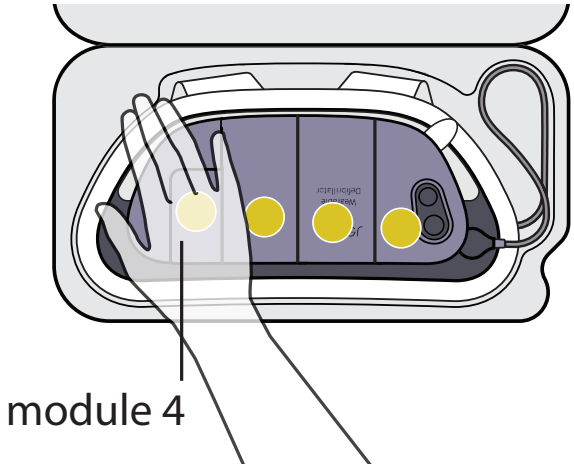
> **ATTENTION:** When the Defibrillator Unit is not on your body, hold it with both hands and keep it as flat as possible. Do not fold or twist the Defibrillator Unit.

9



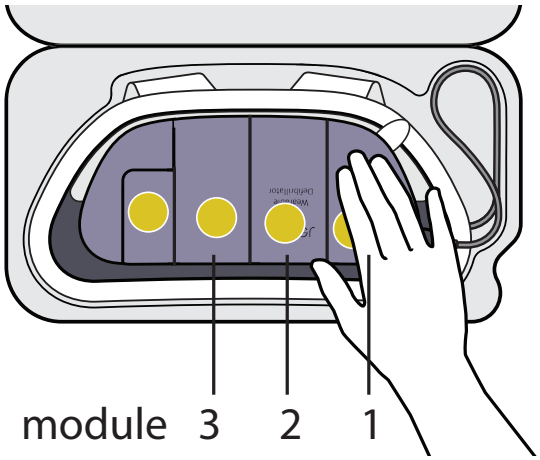
Gently lower the Defibrillator Unit making sure the connectors on the patch are guided into the slots.

10



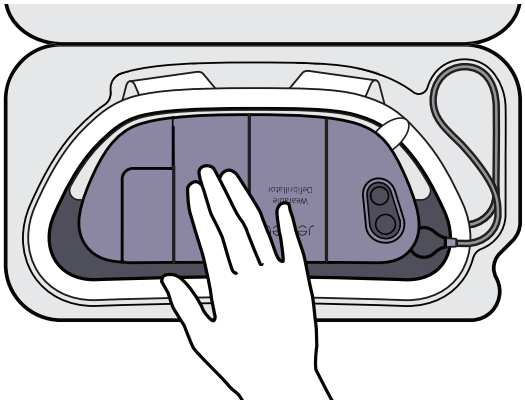
Press down on **module 4** with the palm of your hand until you hear a click.

11



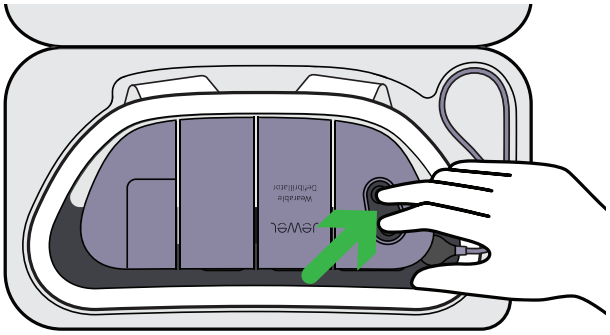
Press down on the remaining **modules 3, 2 and 1** until you hear each module click.

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.

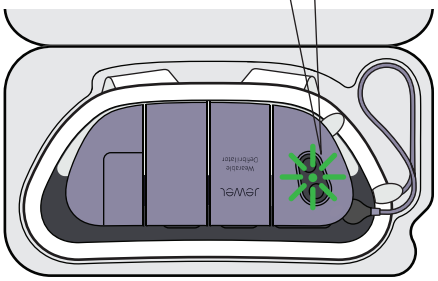
> **ATTENTION:** Make sure Jewel has been turned on before proceeding to next page.

continue ⟶

12

green flashing light

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



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

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

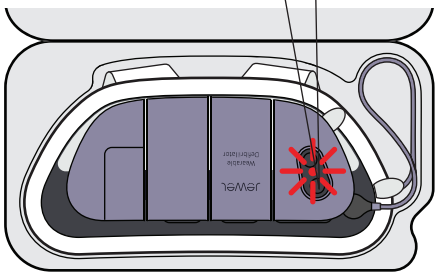
✓ JEWEL OK

Proceed with your Jewel application.

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

red flashing light

No voice prompt

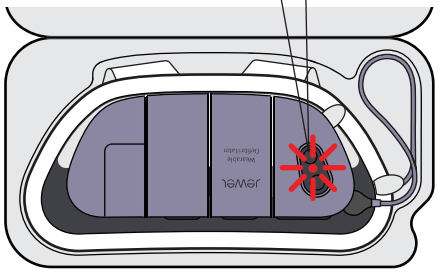


✗ ASSEMBLY INCOMPLETE

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."



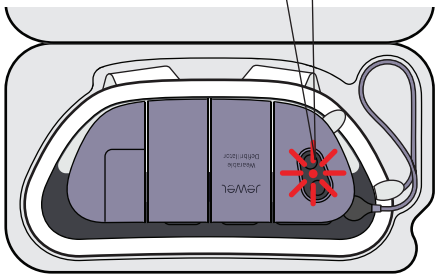
✕ DISCONNECTED

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."



✕ REPLACE DEVICE

Do not apply the Jewel.

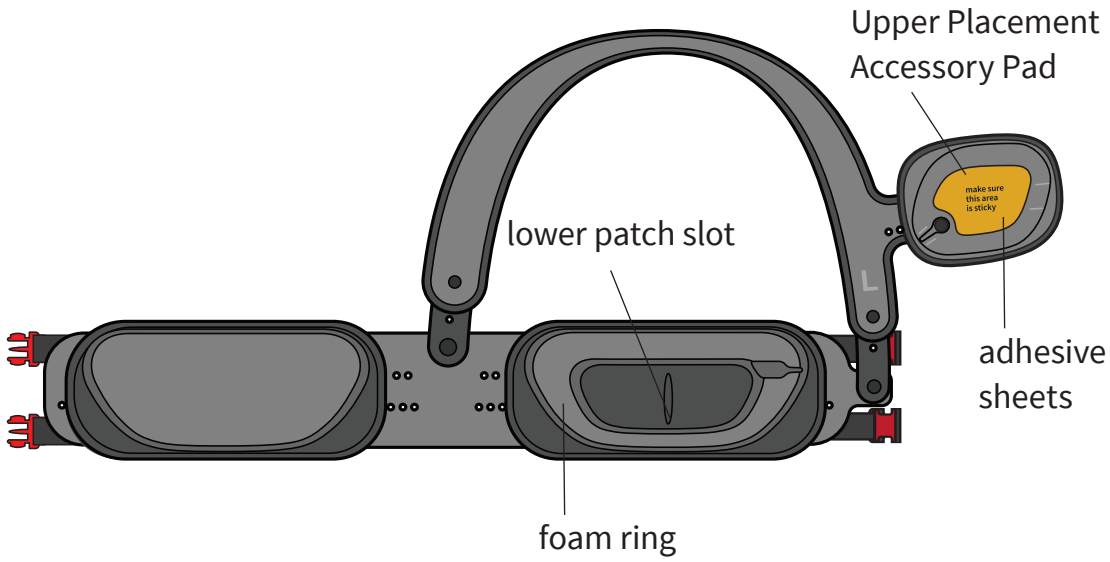
LOADING THE JEWEL INTO THE PLACEMENT ACCESSORY

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.

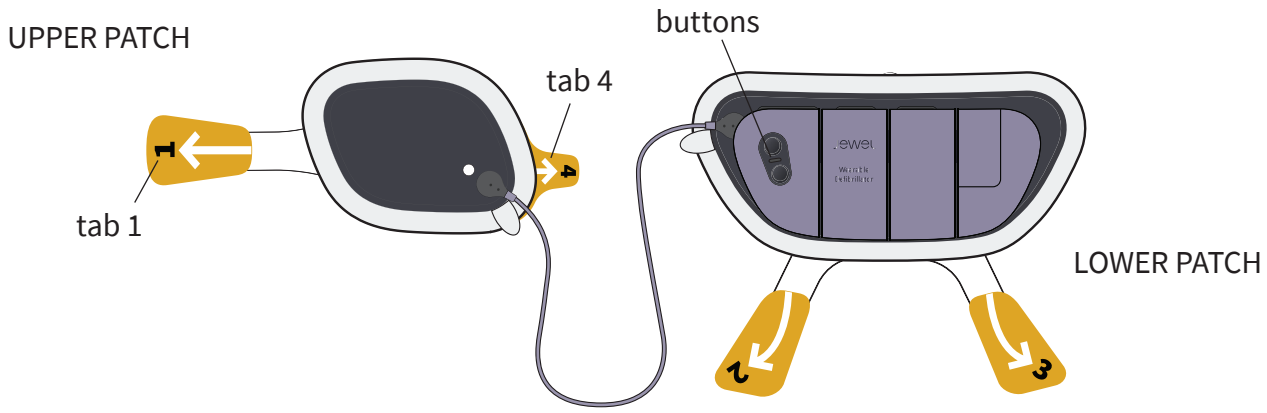
SUPPLIES NEEDED:

- The Jewel and the Placement Accessory

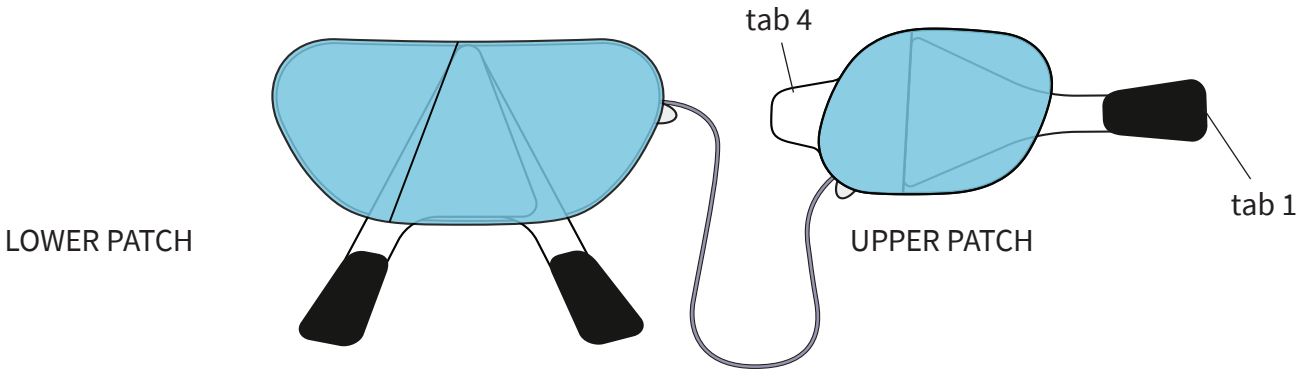
PLACEMENT ACCESSORY COMPONENTS TO KNOW:



THE JEWEL (OUTER SIDE) COMPONENTS TO KNOW:

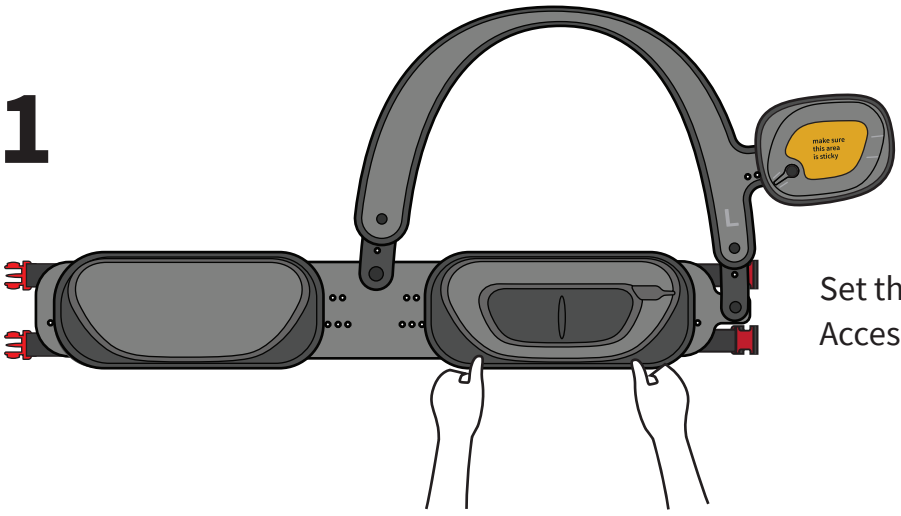


THE JEWEL (SKIN SIDE) COMPONENTS TO KNOW:



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

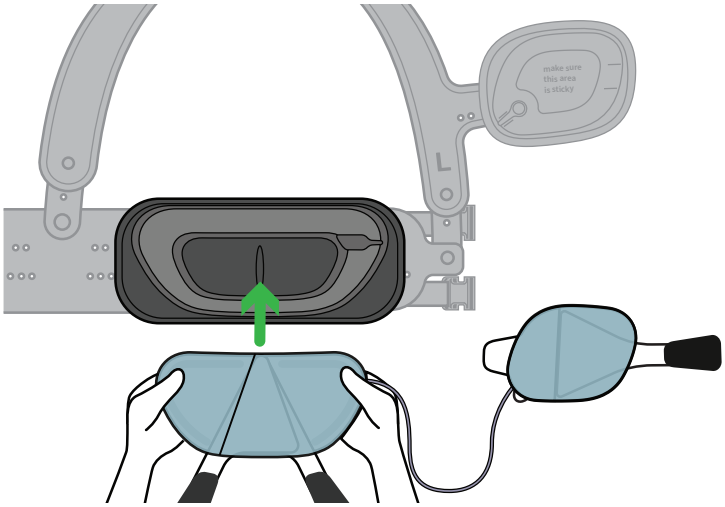
1



Set the unbuckled Placement Accessory on a flat surface.

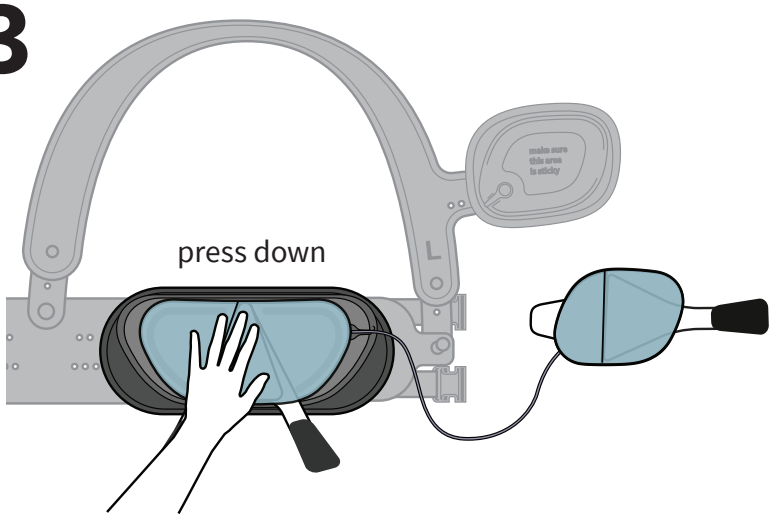
continue ⟶

2



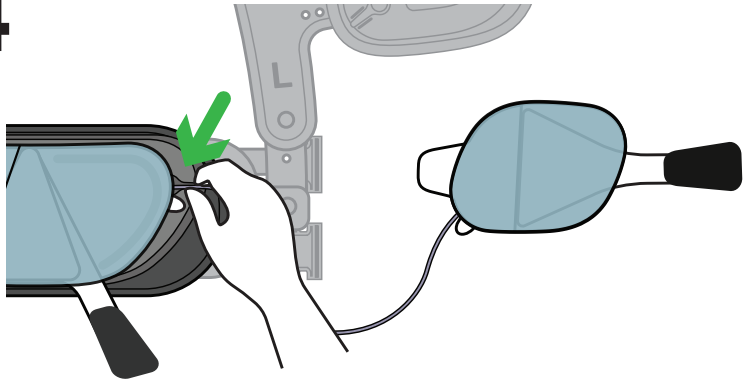
Hold the Lower Patch button side down. Place the Lower Patch into the slot.

3



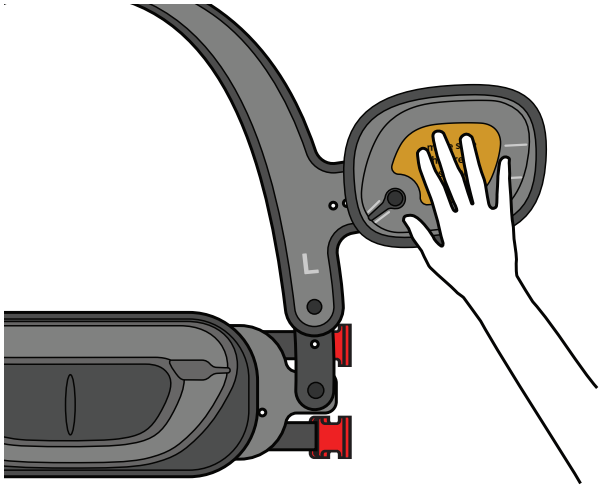
Press the Lower Patch into the slot until the patch is flush with the foam.

4



Check that the cable is resting in the cable slot.

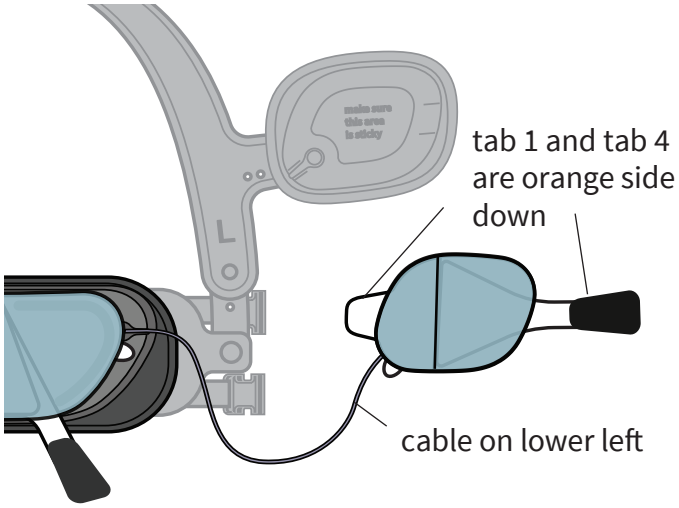
5



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

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

6

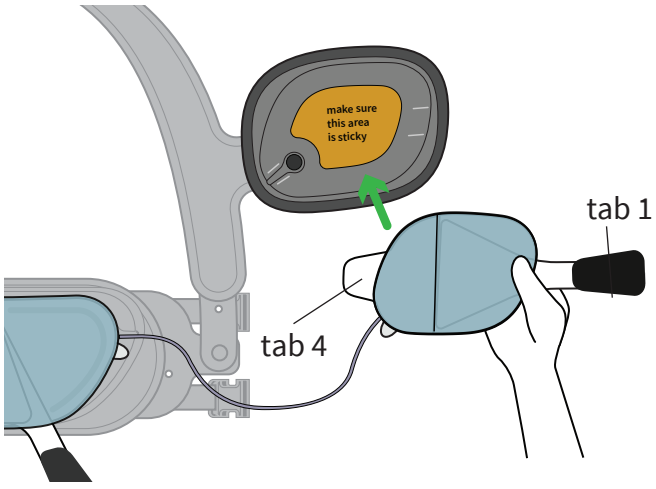


Check that the cable is not twisted before placing Upper Patch on upper pad.

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



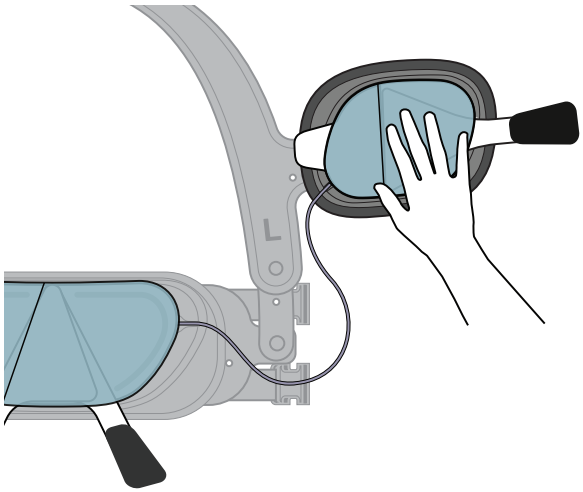
Align the Upper Patch so that:

- 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)

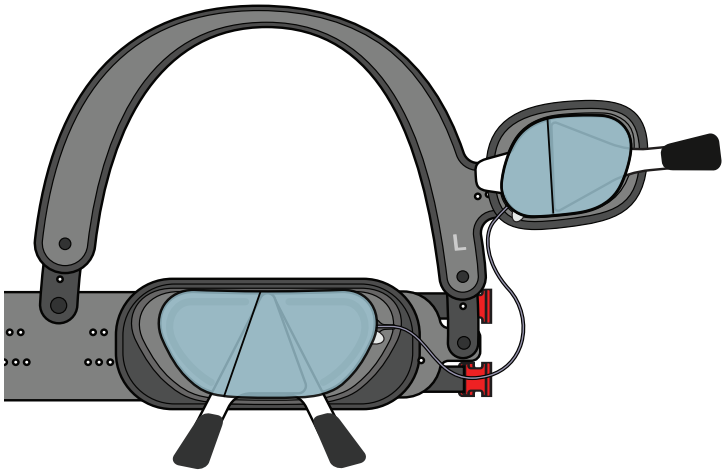
continue ⟶

8



Press the Upper Patch in place.

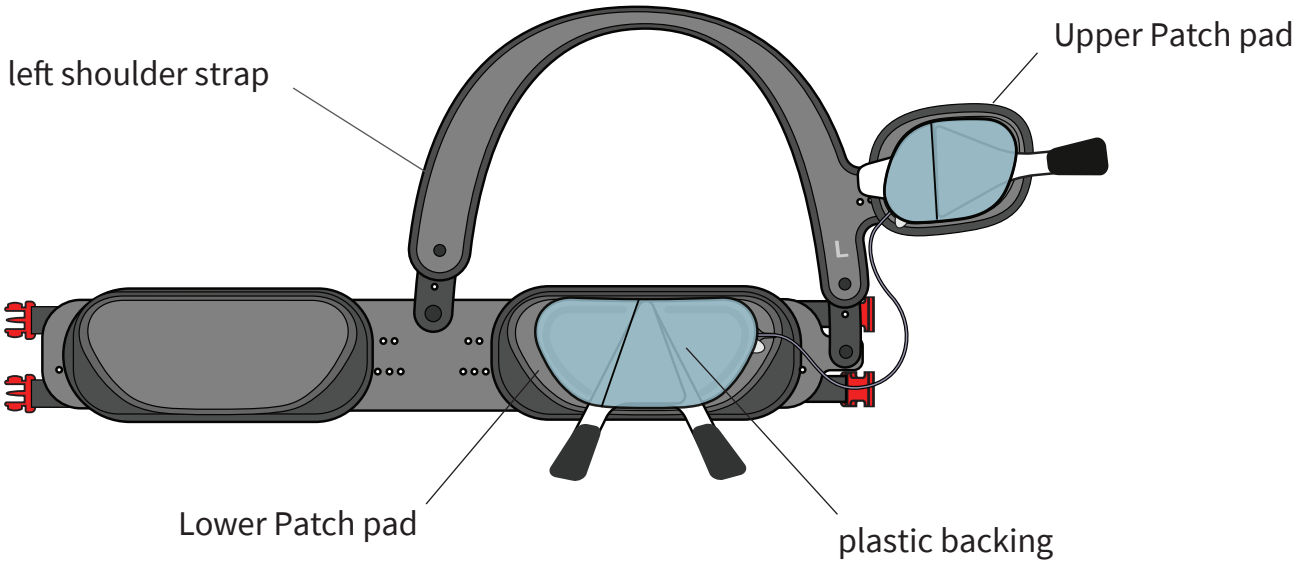
9



The Jewel loading is complete.

3.3 APPLICATION PREPARATION

PLACEMENT ACCESSORY COMPONENTS TO KNOW:

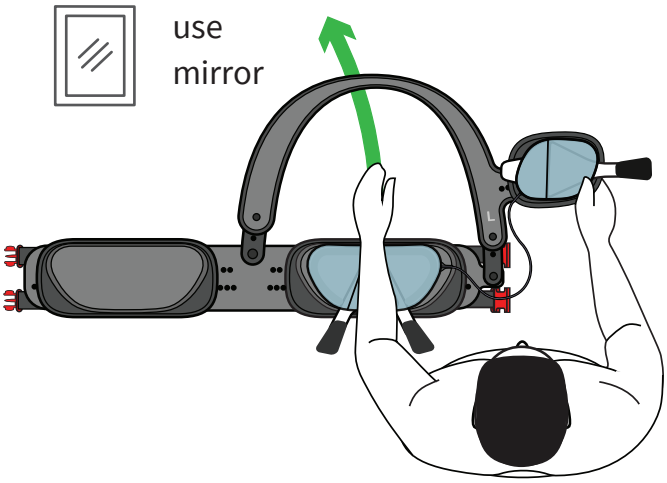


Make sure the plastic backings have not been crumpled and are intact before putting on the Placement Accessory.

PUTTING ON THE PLACEMENT ACCESSORY

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

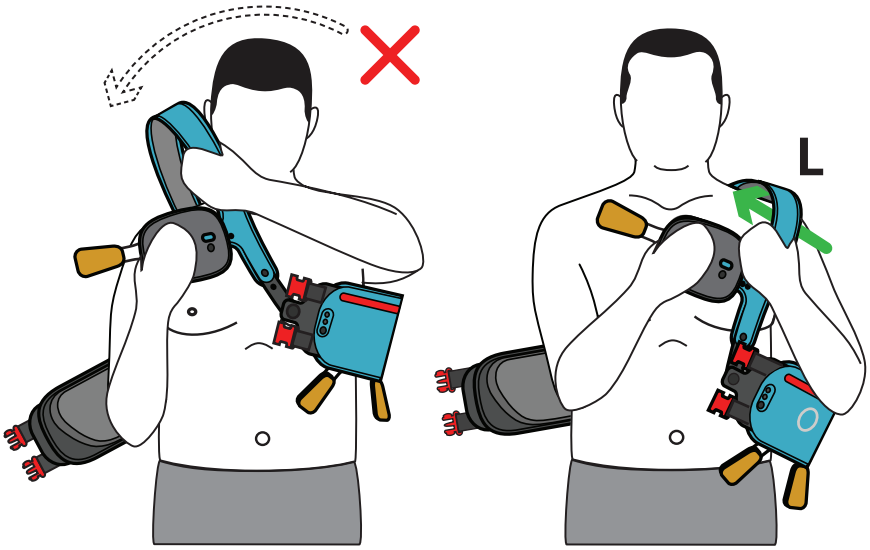
1



Lean forward.

Pull shoulder strap onto left shoulder.

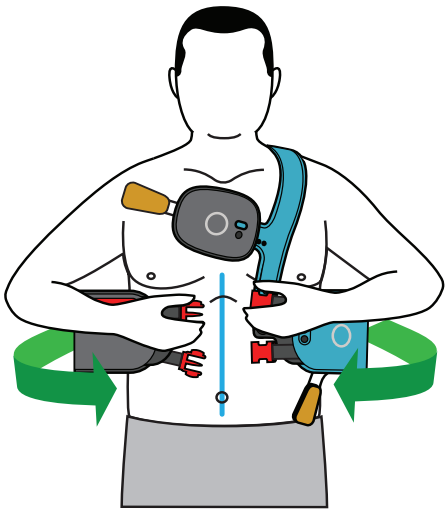
2



Position Upper Patch Placement Accessory onto your right chest area.

Do NOT put shoulder strap over your head.

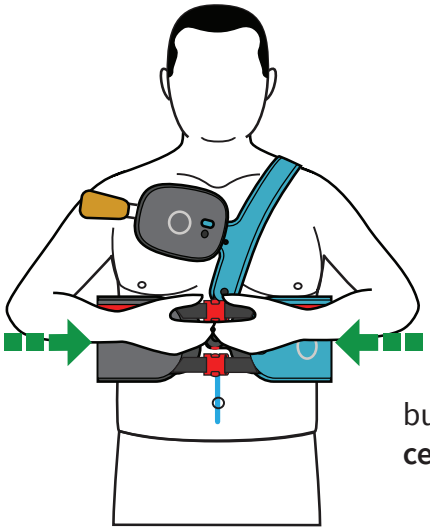
3



Hold both ends of the buckles.

Align the buckles to the centerline of your body.

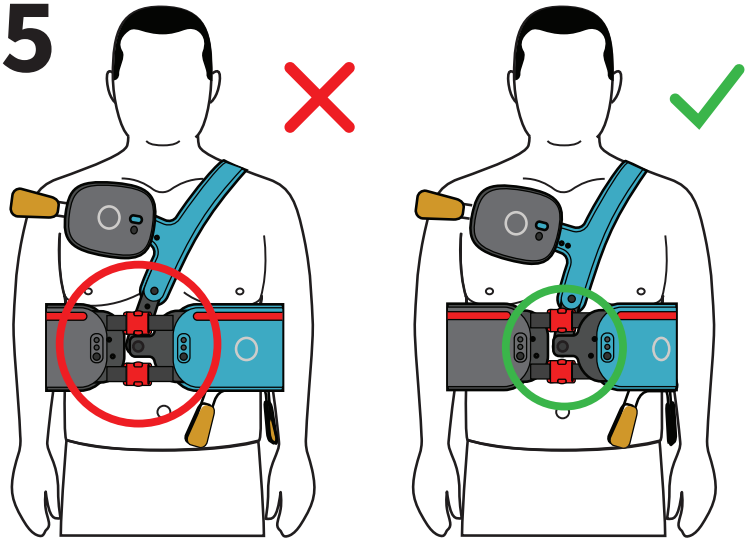
4



buckle at **centerline**

Fasten buckles.

5



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:

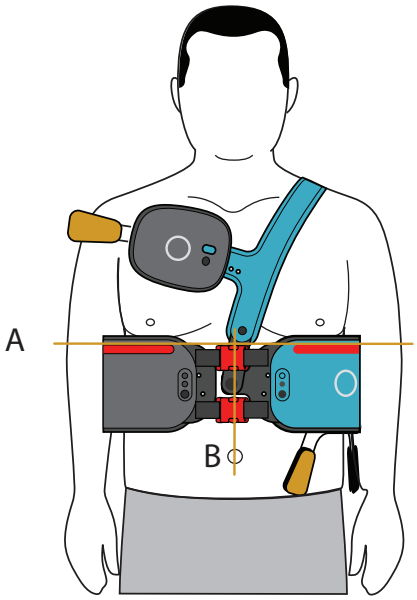
Use a mirror to see red lines while aligning the belt.

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

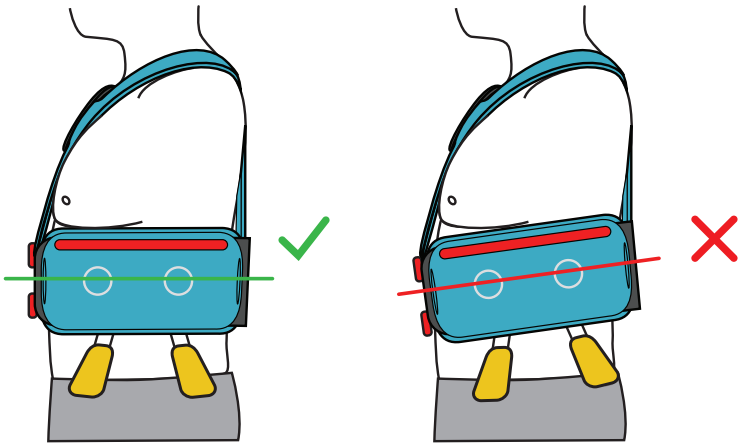


Align belt so that:

A. Red lines on belt are level and under chest/ breasts.

B. Red buckles are on centerline of body.

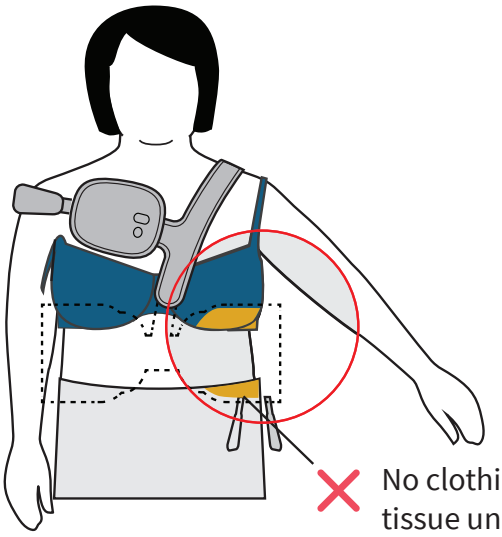
✕ do NOT pull tab 2 or 3



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

continue ⟶

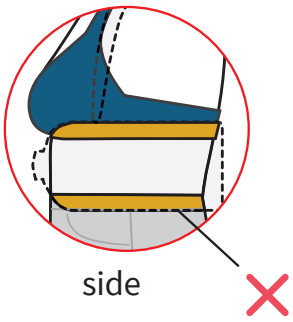
WOMEN:



No clothing or breast tissue under the belt

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



side

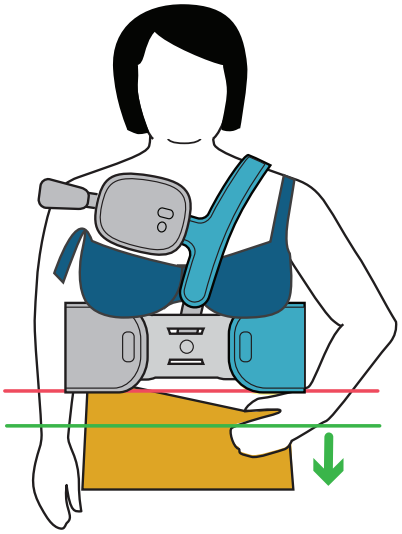
Lift any breast tissue under belt.

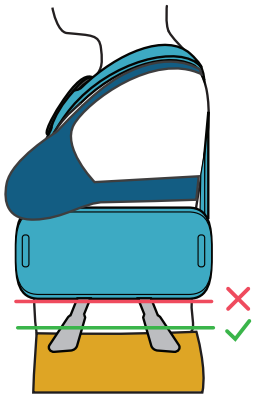
Pull bra cup at least 1 inch above belt.

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.

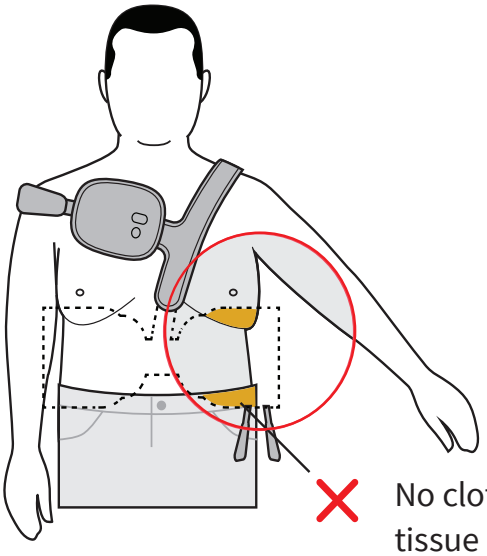
3





Pull clothing at least 1 inch below belt.

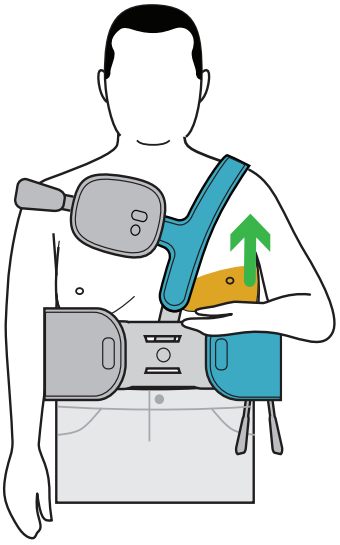
MEN:



No clothing or breast tissue under the belt

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.

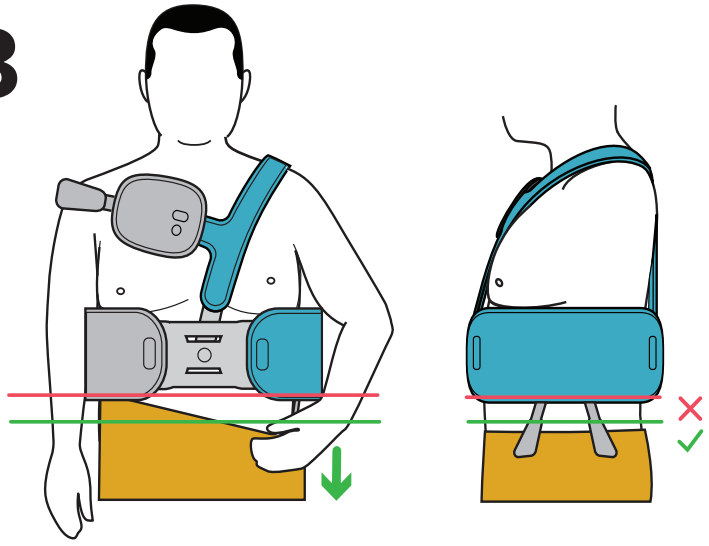
2



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.

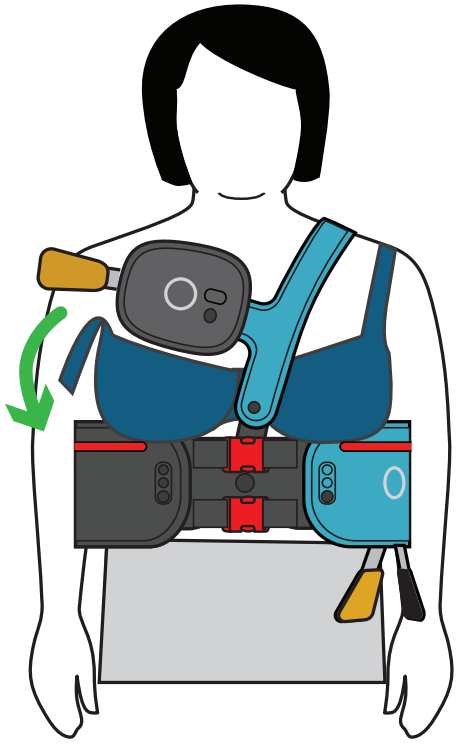
ALIGNING THE UPPER PLACEMENT ACCESSORY

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

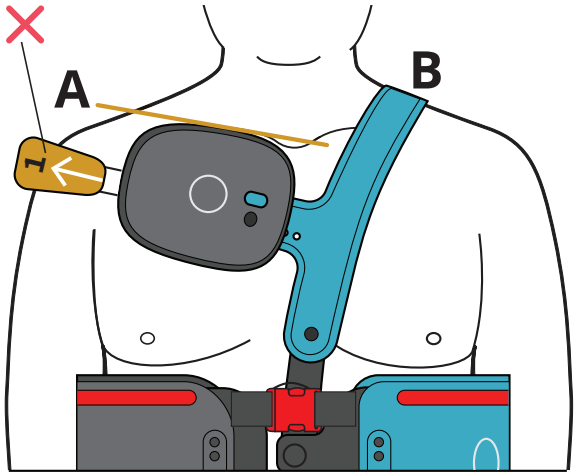


Remove jewelry from under the Upper Placement Accessory.

Women: Remove bra from under the Upper Placement Accessory.

2

do NOT
pull tab 1

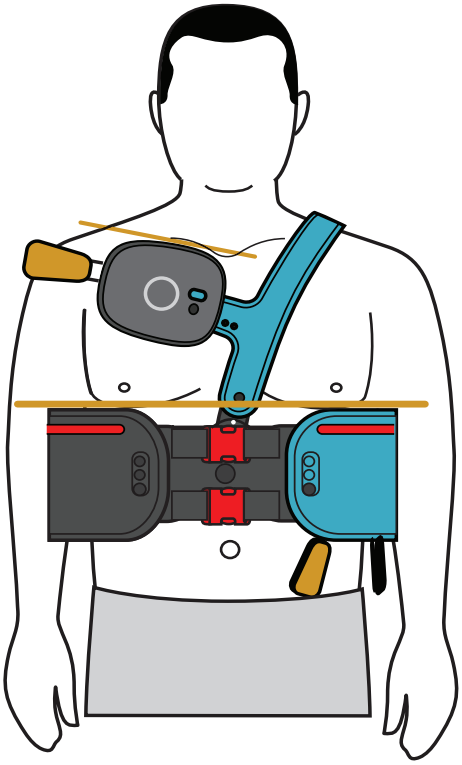


Align Upper Placement Accessory so that:

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.

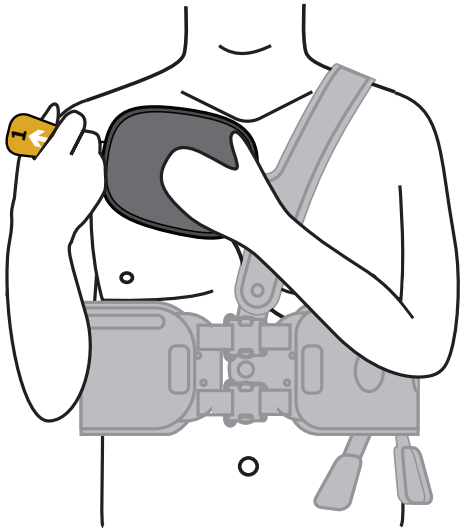


Placement Accessory Alignment complete.

3.4 APPLICATION

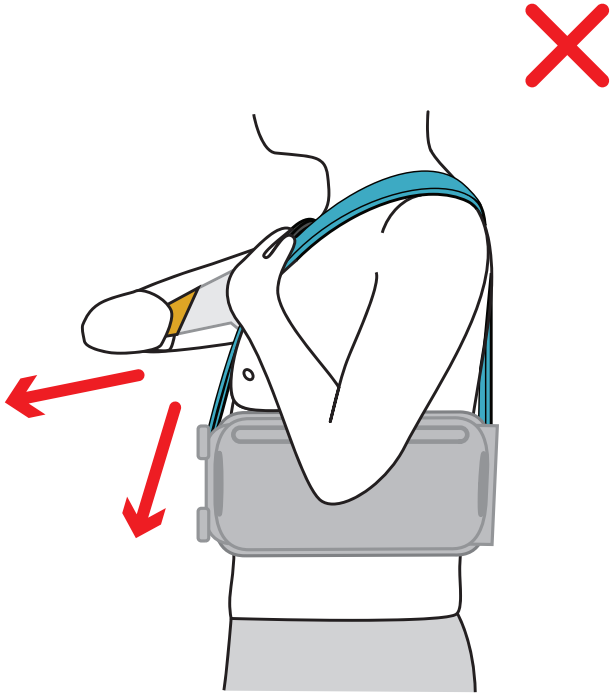
PULLING TAB 1

1



Gently rest hand on upper pad with left palm.

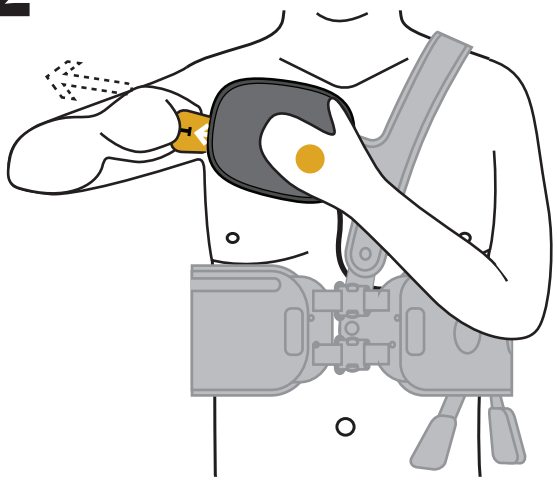
Grip tab 1 with right hand.



DO NOT pull tab 1 straight down or forward away from the body.

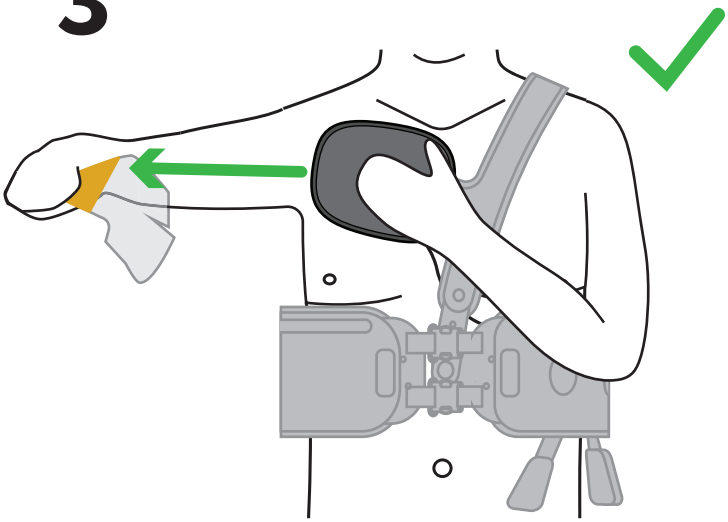
(This may result in a poor device application.)

2



Keep pad in place with left palm.

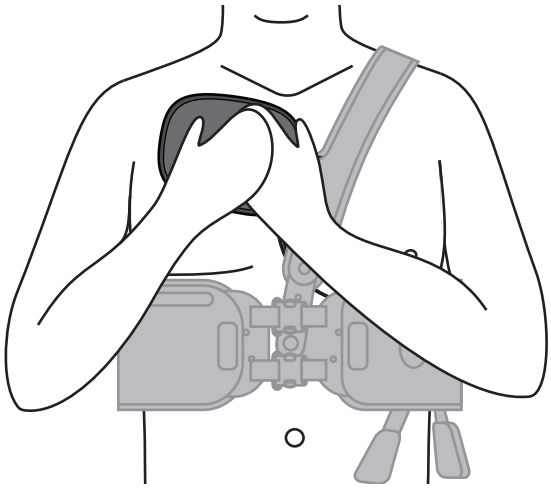
3



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

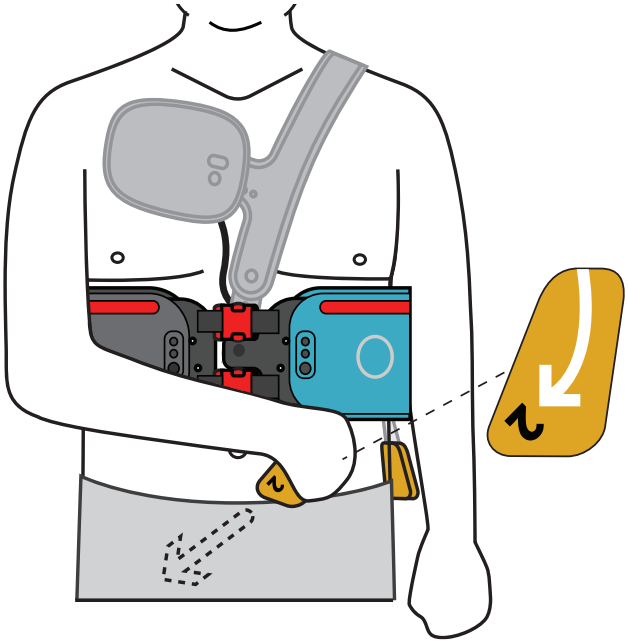


Press down on circle with both hands for 30 seconds to adhere patch to body.

continue ⟶

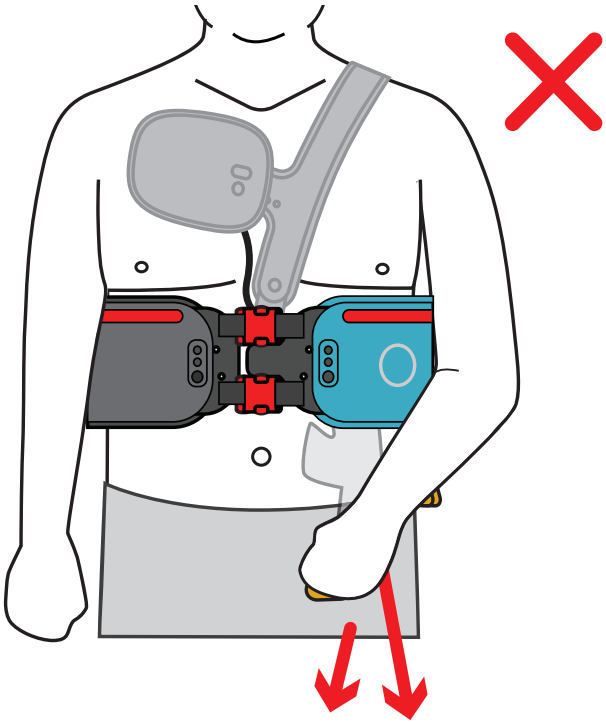
PULLING TAB 2

1



Grip tab 2 with right hand.

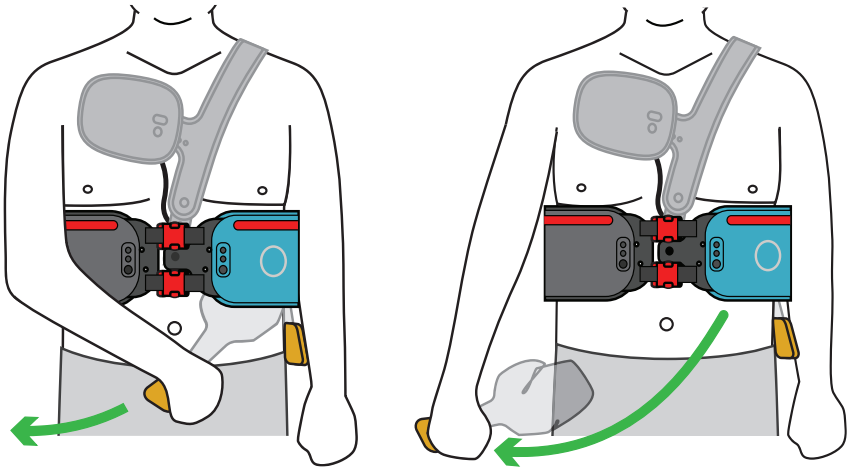
Keep left arm straight down. Do NOT apply pressure on the belt with your left arm.



Do NOT pull tab 2 with your left hand, straight down or forward away from body.

(This may result in a poor device application.)

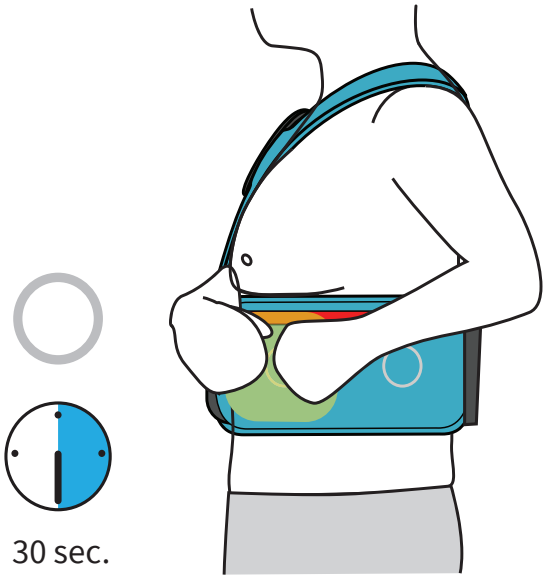
2



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

Discard tab 2.

3

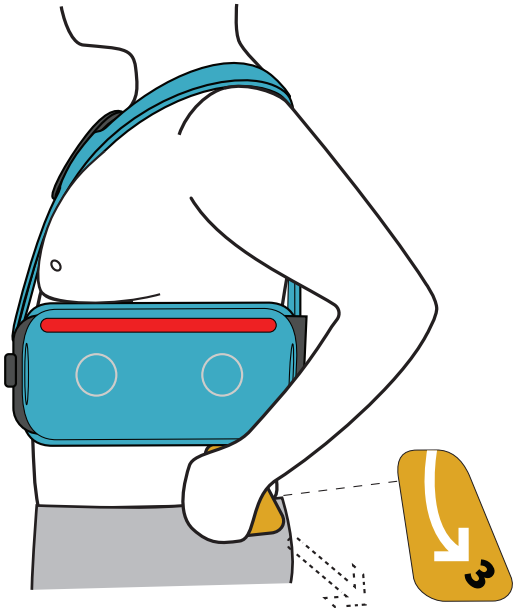


Press down for 30 seconds on circle (front left) to adhere patch to body.

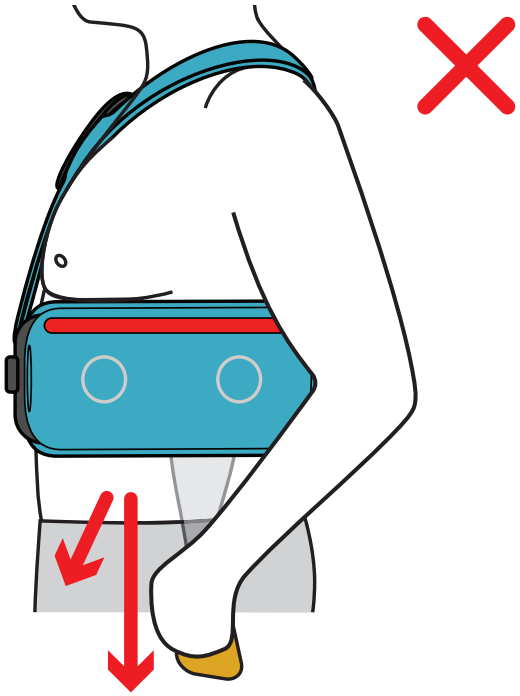
continue ⟶

PULLING TAB 3

1



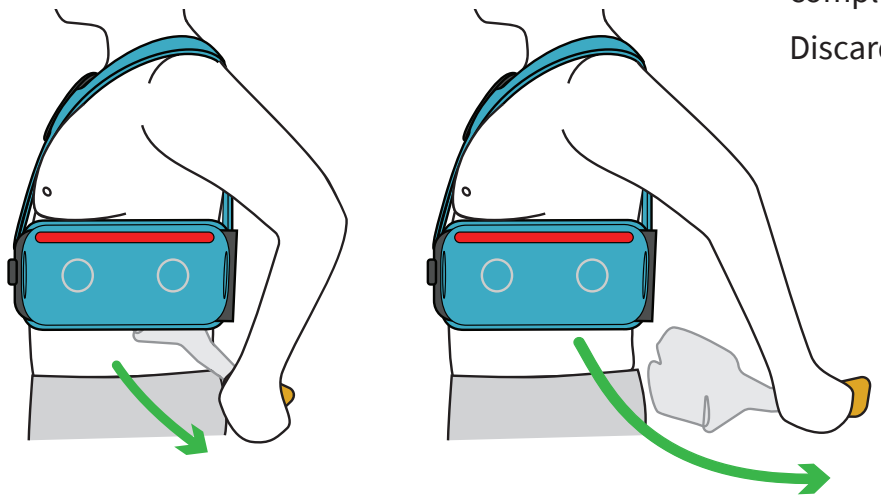
Grip tab 3 with left hand.



Do NOT pull tab 3 straight down or forward.

(This may result in a poor device application.)

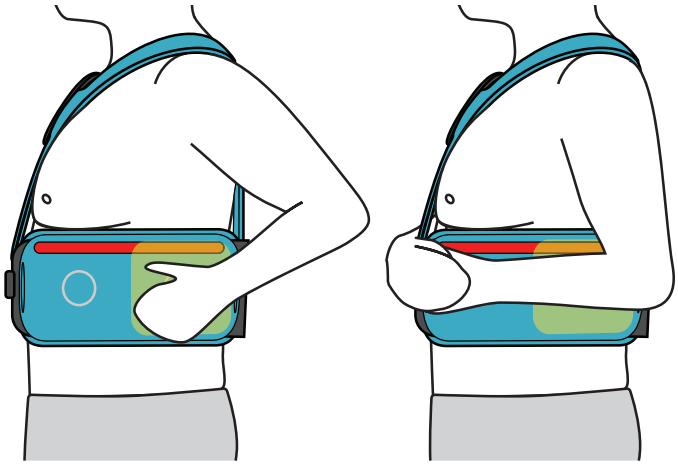
2



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.

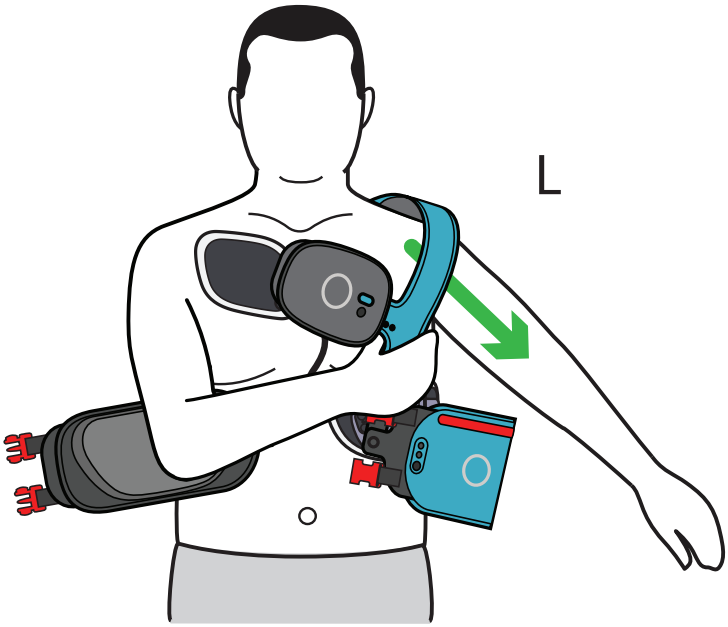
30 sec.

hand or inner arm.

continue ⟶

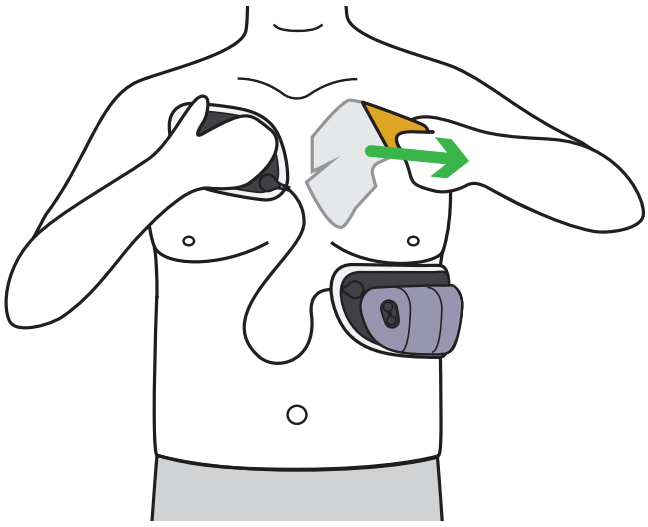
PULLING TAB 4

1



Take off the Placement Accessory.

2

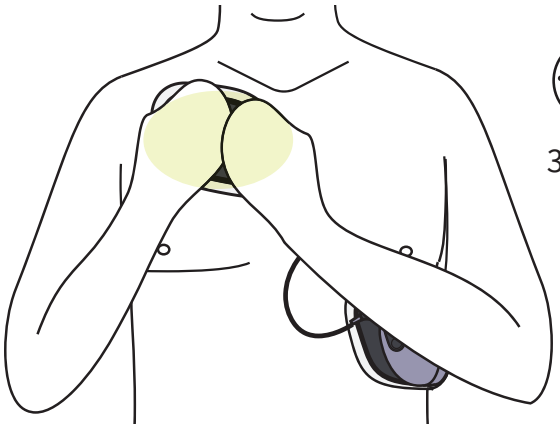


Pull tab 4 across the body in a continuous motion until the plastic backing pulls free.

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.

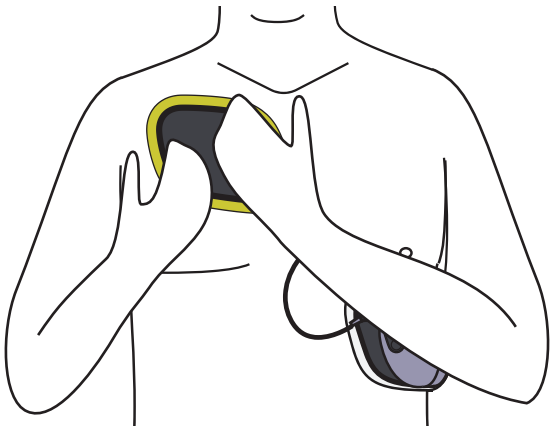
3



30 sec.

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

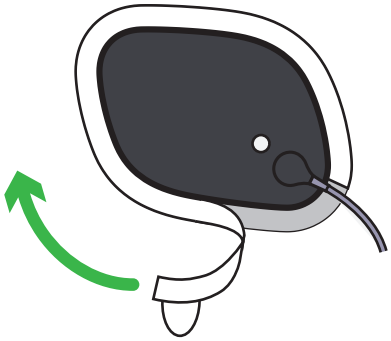
4



30 sec.

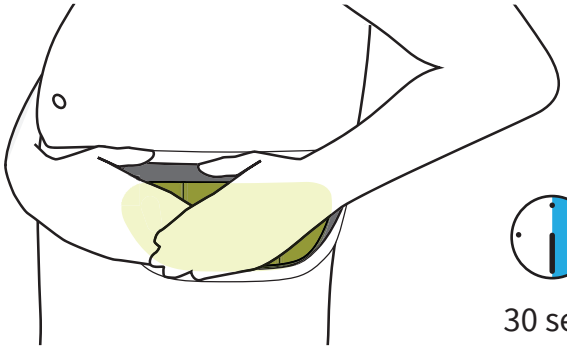
Smooth down patch fabric and white border for **30 seconds.**

5



Remove white foam border on edge of Upper Patch

6

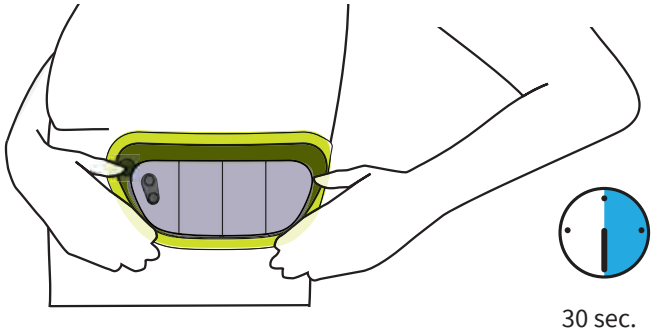


30 sec.

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

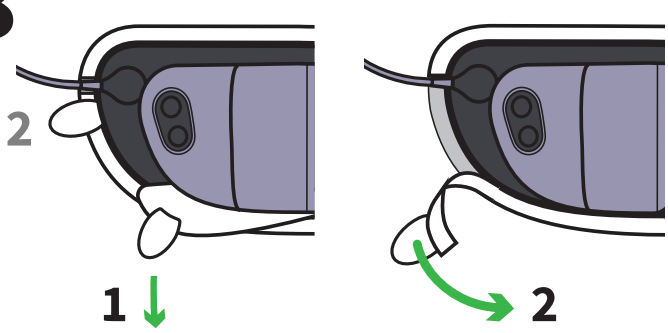
continue ⟶

7



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

8



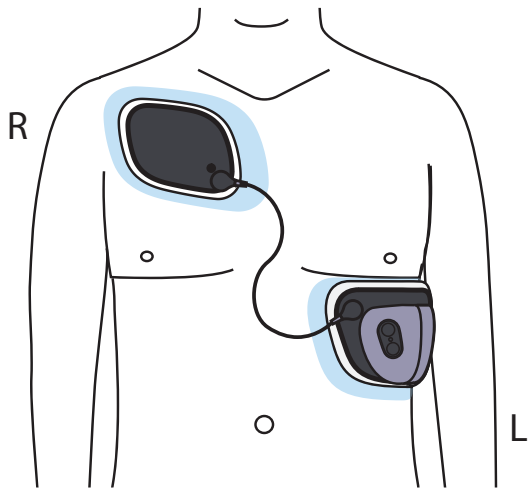
Remove white foam borders on edge of Lower Patch and under Defibrillator Unit.

WARNING

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

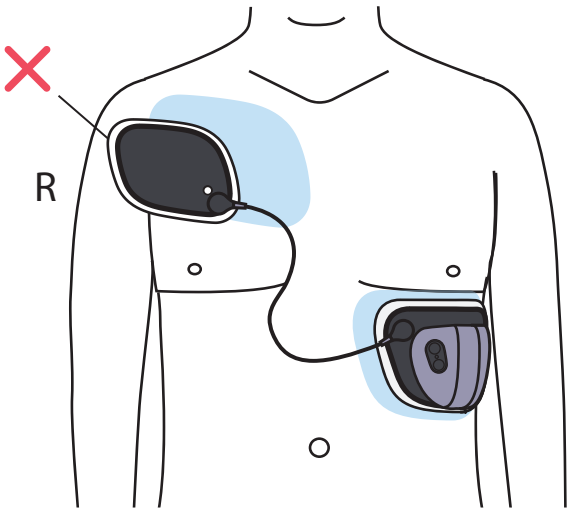
Always use the Placement Accessory while applying the Jewel and do NOT skip alignment steps. If the Placement Accessory is not aligned correctly, the Jewel may be applied in the wrong location. Applying the Jewel in the wrong location could result in an electrical shock not given when needed or in an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

9 CHECKING PATCH PLACEMENT



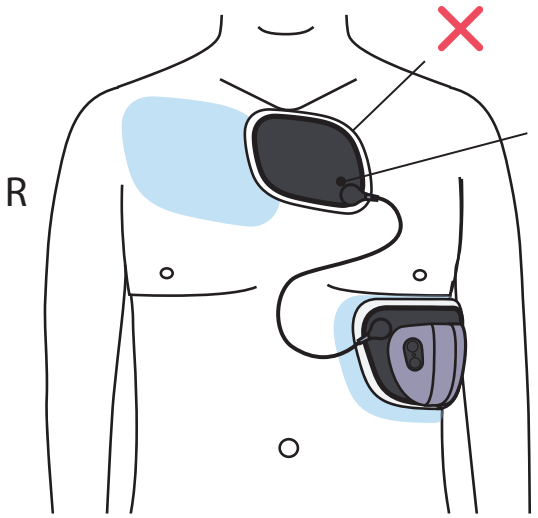
Check that the patches have been applied in the correct locations:

- 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.



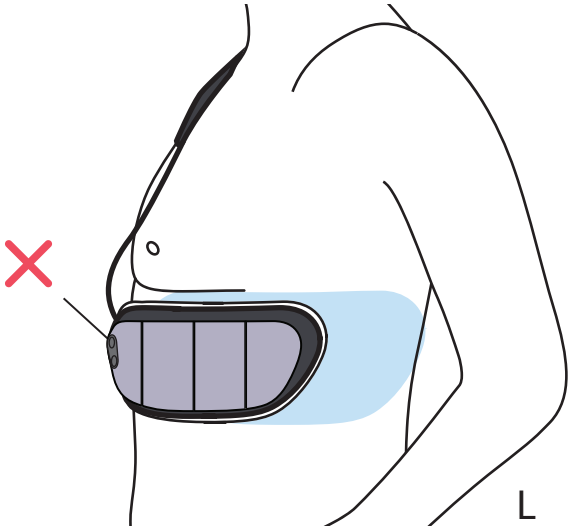
INCORRECT:

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



INCORRECT:

Status light on Upper Patch is over your centerline.



INCORRECT:

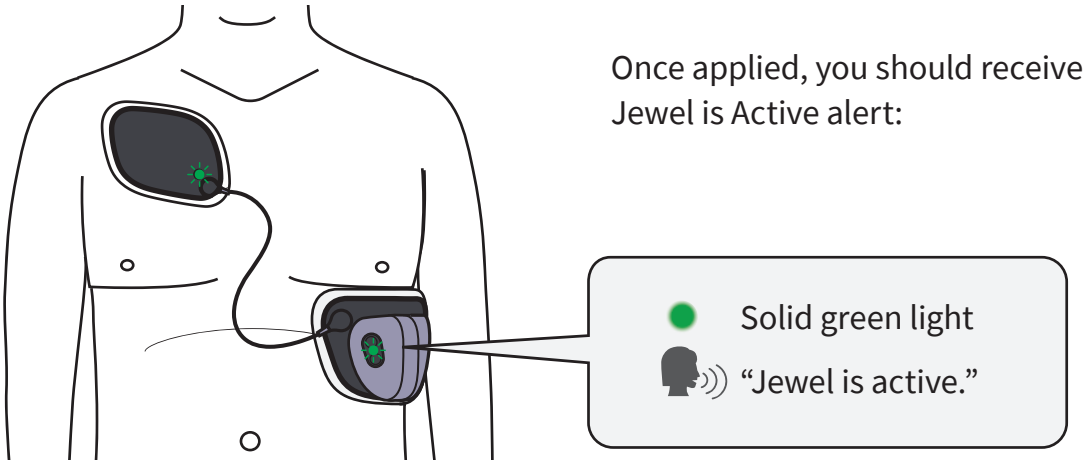
None of the Lower Patch plastic housings are under your arm.

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.*

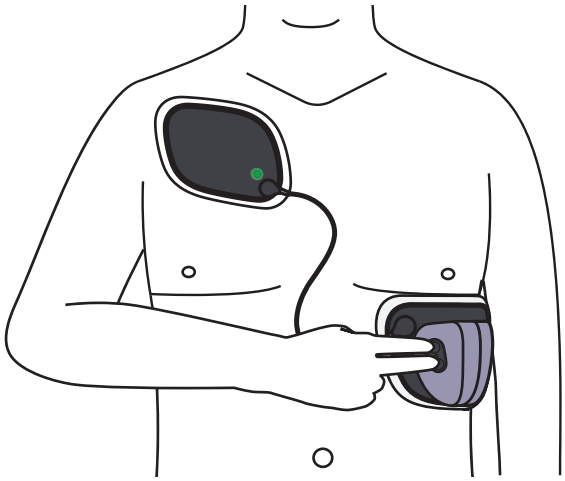
continue ⟶



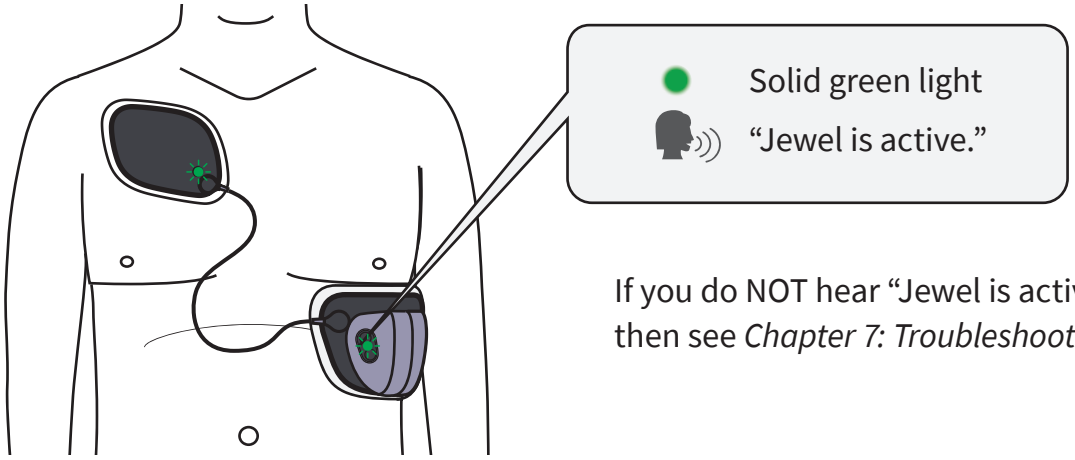
Once applied, you should receive the Jewel is Active alert:

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

10

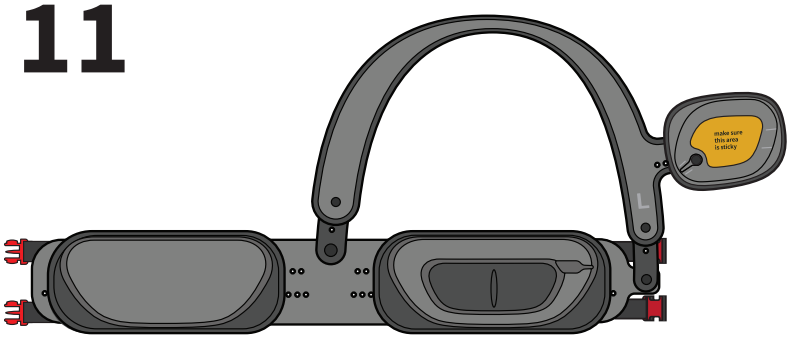


Complete a Status Check to confirm that the Jewel is monitoring: Press both buttons and release after you feel a click.

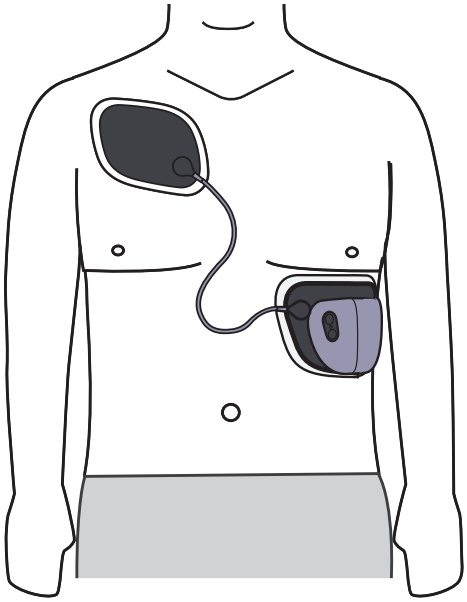


If you do NOT hear “Jewel is active” then see *Chapter 7: Troubleshooting.*

11



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



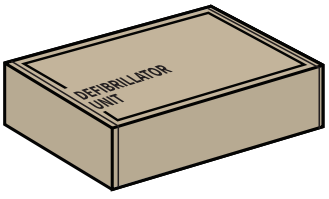
Application complete.

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.

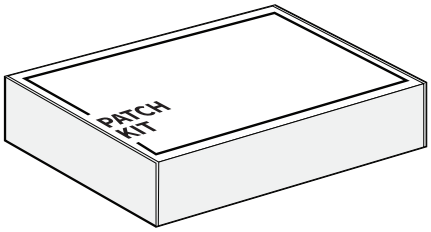
To remove your Jewel, see *Chapter 5: Removal*

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.

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4

4

NOTIFICATIONS

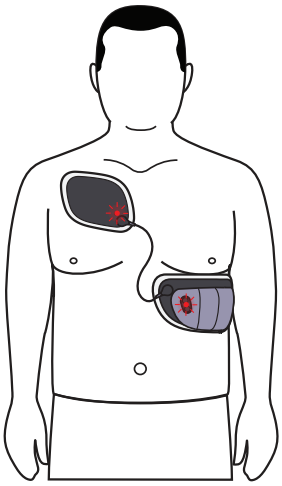
RESPONDING TO ALERTS AND ALARMS

4.1 WHAT ARE THE JEWEL NOTIFICATIONS?

HOW THE JEWEL COMMUNICATES

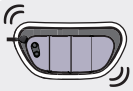
The Jewel communicates to you through tones, voice prompts, lights, and vibrations. Use this section to know what each alert and alarm means and how to respond.

SYMBOL GUIDE:



Tones

Voice Prompts



Vibration

Lights

LIGHT COLOR GUIDE:

RED LIGHT — Immediate Action Required

YELLOW LIGHT — Action Required

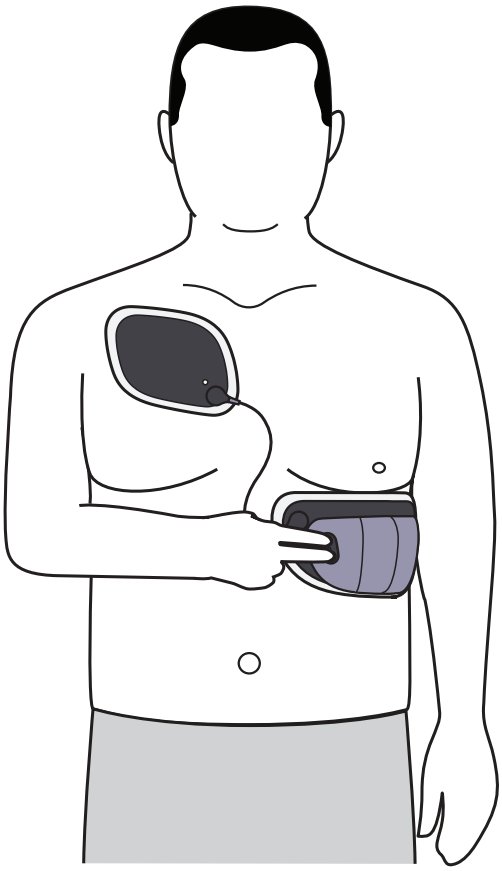
GREEN LIGHT — No Action Required

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.

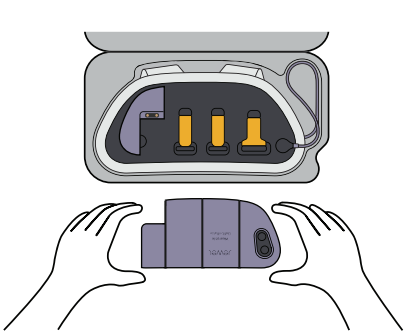
TO COMPLETE A STATUS CHECK:

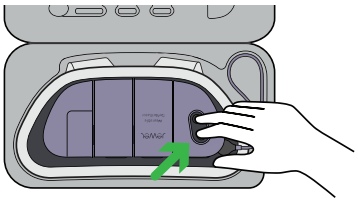
Press both buttons and release after you feel a click.

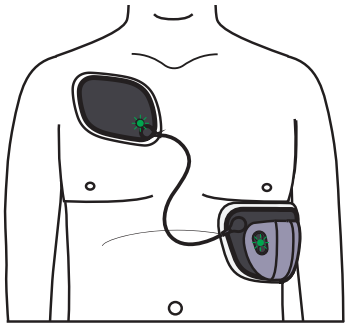


WEEKLY JEWEL NOTIFICATIONS

APPLICATION







SEE

HEAR

no voice prompt or tone

"Device is disabled and must be replaced. Call customer service immediately."

"Jewel is in Application Mode. Apply Jewel now using Placement Accessory."

tone

"Jewel is active."

Defibrillator Unit and Patch Unit are not assembled

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.

Jewel Turn On: Replace Device

The Defibrillator Unit is not working and should NOT be applied. Call Customer Service immediately to request a new Defibrillator Unit.

Application Mode

The Jewel is in Application Mode and has not yet detected that the Jewel has been applied yet.

Normalization

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.

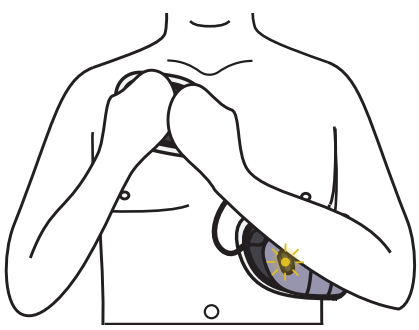
Jewel is Active

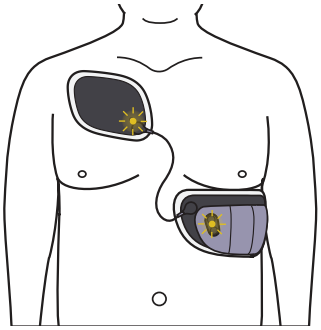
The Jewel has been successfully applied. The Jewel is now actively monitoring for specific life-threatening heart rhythms.

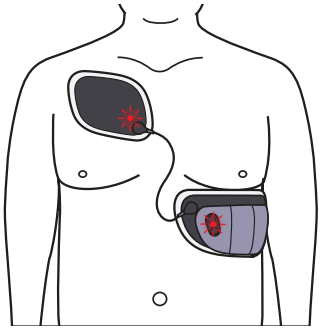
If the Jewel continues to play the Application Mode message, it means the Jewel is NOT active yet.

DURING WEAR

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







"Patches losing contact with skin. Press and hold both patches."

Press and Hold Alert

The Jewel has detected that the patches may be losing skin contact and need to be pushed back onto your skin.

"Replace Patches Soon."

Replace Patches Soon Alert

Patches must be replaced within 24 hours. This alert repeats every 6 hours.

"Patches expired. Replace Patches now."

To start Removal Mode press and hold both buttons."

Replace Patches Now Alert

Patches must be replaced within three hours. This alert repeats every hour.

"Patches expired and no longer working. Replace patches immediately."

To start Removal Mode press and hold both buttons.

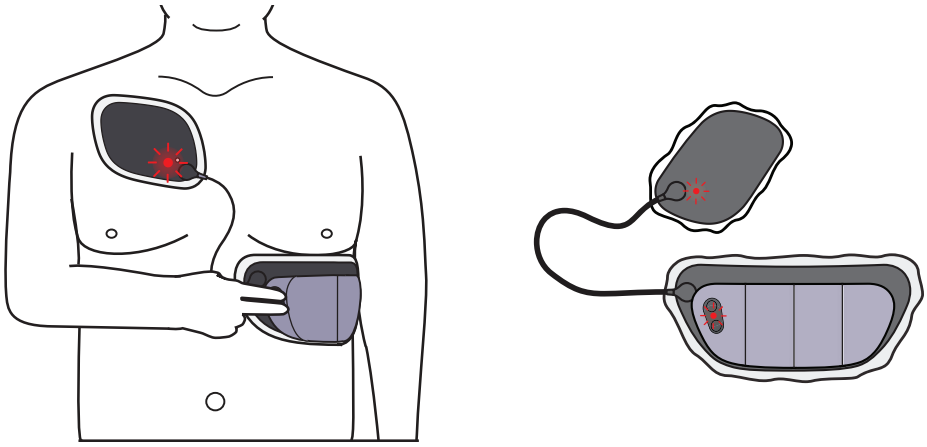
Replace Patches Immediately Alert

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.

continue ⟶

REMOVAL



SEE

HEAR

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

Removal Mode

The Jewel will prompt you again to press and hold both buttons for at least 5 seconds to confirm Removal Mode.

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

Removal Mode Confirmed

The Jewel is now in Removal Mode and cannot give you an electrical shock. You can now safely remove the Jewel from your body.

"Replace patches immediately."

Remove Patch Unit from Device

Finish removing the Jewel from your body.

After the Jewel has been completely removed, replace used Patch Unit with new Patch Unit.

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.

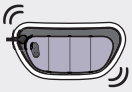
WARNING:

⚠ 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.

Start of alarm — Press both buttons to cancel electrical shock. — Electrical shock given

0 sec — 24 sec

 flashing red

 vibration

 siren

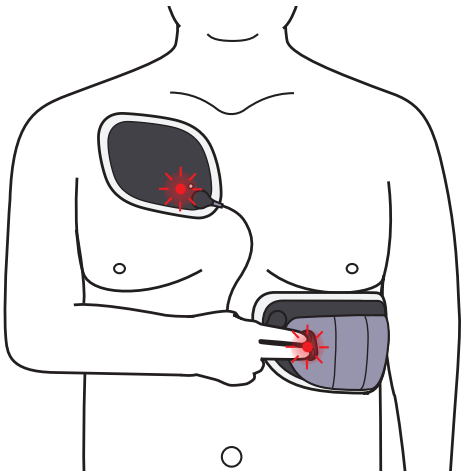
"Preparing for electrical shock.
To cancel electrical shock, press both buttons.
Do not touch patient.
Bystanders, do not touch patient."

IF YOU ARE CONSCIOUS:

Press both buttons immediately.

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.”

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.*

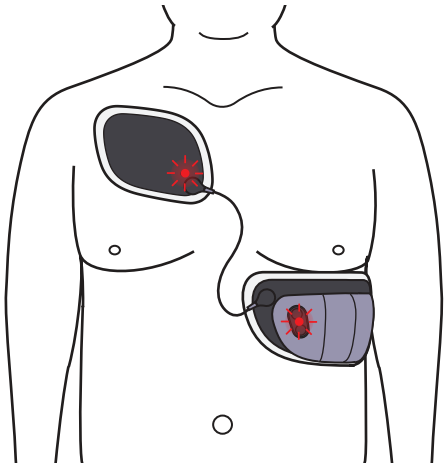
IF YOU ARE UNCONSCIOUS:

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.

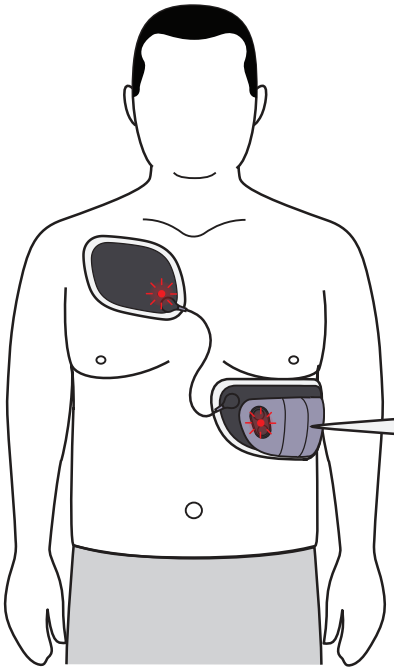


flashing yellow

"Electrical shock given. Seek emergency care."

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.

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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:	What it means:	What to do:
"Jewel is in Application Mode. Apply Jewel now using Placement Accessory."	The Jewel is in Application Mode but has not detected that it has been applied. The Jewel cannot give you an electrical shock.	Insert the Jewel into Placement Accessory and apply the Jewel now. See *Chapter 3: Application*

AFTER APPLYING THE JEWEL:

If you hear:	What it means:	What to do:
"Jewel is in pairing mode. Pairing Jewel now." "Pairing Successful" "Pairing Unsuccessful. Try again."	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.	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 *Chapter 1 Section 3* for help.

solid green light

AFTER THE JEWEL APPLICATION:

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

AFTER ELECTRICAL SHOCK CANCELED:

If you hear:	What it means:	What to do:
"Electrical shock canceled. Jewel is active."	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.	No action is needed. The Jewel is in monitoring mode.

flashing yellow light

WHILE WEARING THE JEWEL:

If you hear:	What it means:	What to do:
"Patches losing contact with skin. Press and hold both patches."	The Jewel has detected the patches are losing skin contact.	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. See *Chapter 5: Removal*
"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. See *Chapter 5: Removal*
"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:	What it means:	What to do:
"Electrical shock given. Seek emergency care."	The Jewel gave you an electrical shock. An electrical shock was given because the Jewel detected you had specific life-threatening heart rhythms.	You should keep wearing the Jewel and seek emergency care.

continue ⟶

flashing red light

AFTER JEWEL TURN ON:

If you hear:	What it means:	What to do:
"Device is disabled and must be replaced. Call Customer Service immediately."	Replace the Defibrillator Unit.	Do not apply the Jewel. Call Customer Service immediately to request a new Defibrillator Unit.
"Patches no longer working. Replace patches immediately"	Replace 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:	What it means:	What to do:
"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.	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.	Replace patches immediately. See *Chapter 5: Removal*
"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 *Siren Alarm Overview within this Chapter 4*
No voice prompts or tones. Red flashing light and vibration.	Replace the Defibrillator Unit	Call Customer Service immediately, because you need a replacement Defibrillator Unit

flashing red light

If you hear:	What it means:	What to do:
"If patient is unresponsive, call 911 and start CPR"	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.	If you, the patient, are conscious, replace the Patch Unit immediately. If patient is unconscious, bystanders should call 911 and start CPR. See *Emergency Services Required within this Chapter 4*
"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 *Chapter 5: Removal*
"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:	What it means:	What to do:
"Electrical Shock Given. Seek Emergency care. Patches expired and no longer working. Replace patches immediately."	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.	Seek emergency care. Replace Patch Unit if one is available.

continue ⟶

flashing red light

REMOVING THE JEWEL:

If you hear:	What it means:	What to do:
"To confirm Removal Mode, press and hold both buttons."	The Jewel needs you to confirm that you would like to put it into Removal Mode.	Press and hold both buttons to put the Jewel into Removal Mode. See *Chapter 5: Removal*
"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. See *Chapter 5: Removal*
"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. See *Chapter 5: Removal*
"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. See *Chapter 5: Removal*
"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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5

5
REMOVING & DISASSEMBLING
YOUR JEWEL

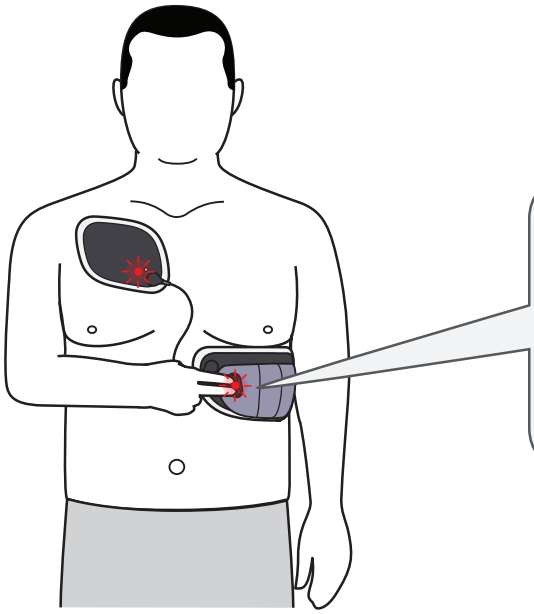
5.1 REMOVAL MODE

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:

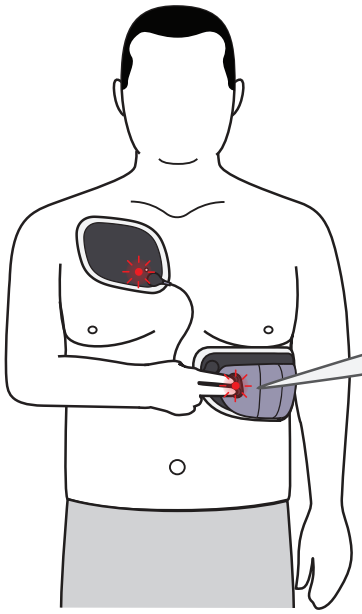
"To confirm Removal Mode, press and hold both buttons."

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:



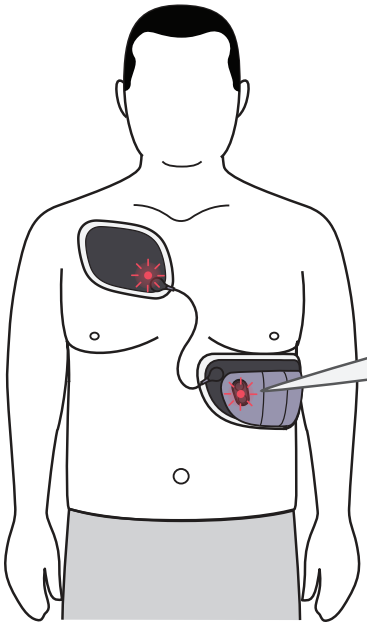
Press and hold both buttons again until you hear:

"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.

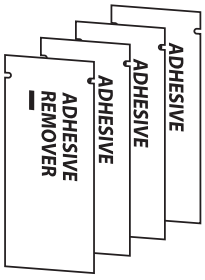
PATCH REMOVAL

These steps cover removing the Jewel.

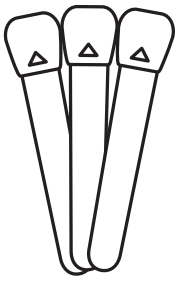
TIPS FOR THIS SECTION:

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.

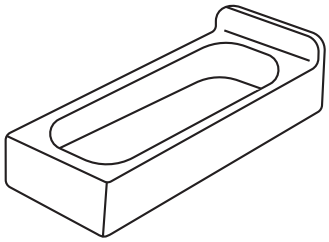
SUPPLIES NEEDED:



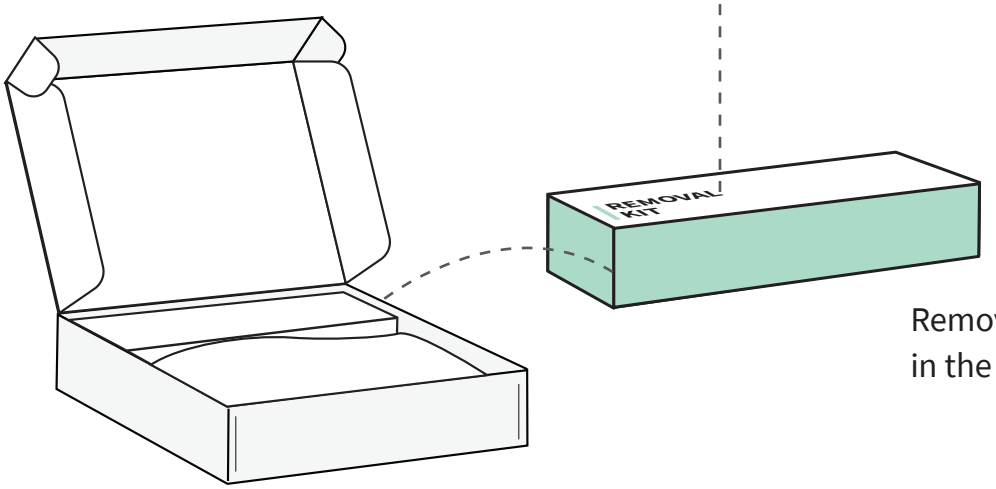
4 adhesive remover packets



3 foam tools



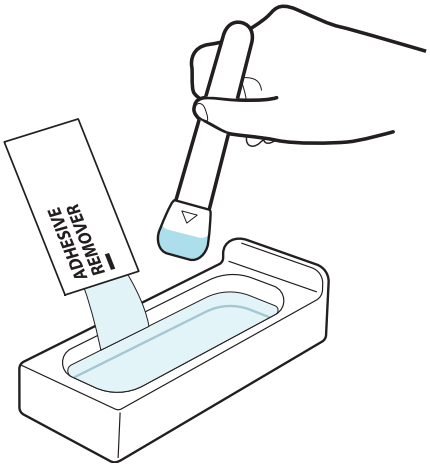
1 dish



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

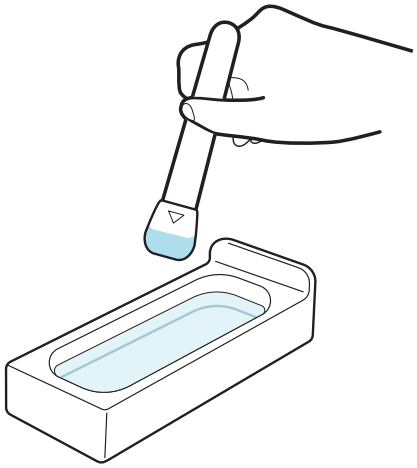


Remove dish from box.

Open two adhesive remover packets.

Pour adhesive remover into dish.

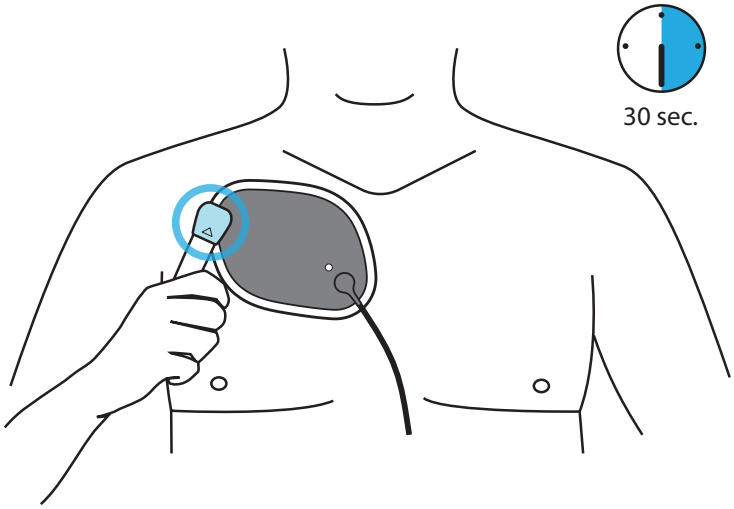
2



Dip foam tool into adhesive remover.

Repeat as needed.

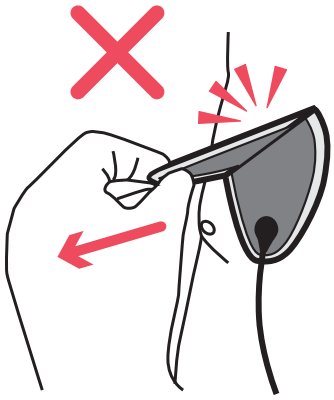
3



UPPER PATCH REMOVAL:

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

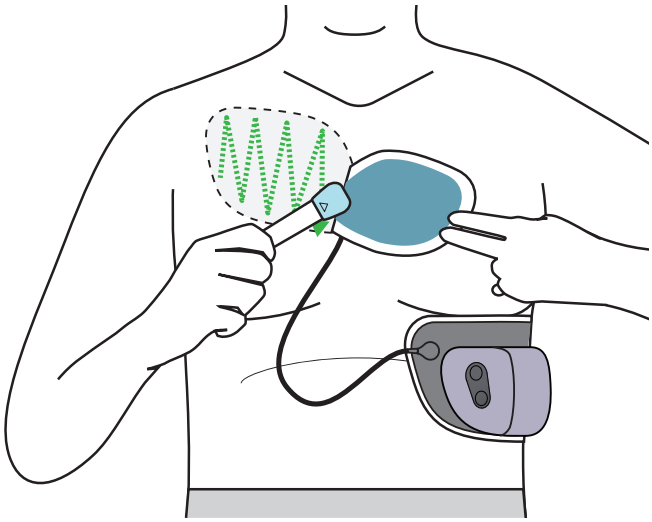
continue ⟶



Use adhesive remover and foam tool.

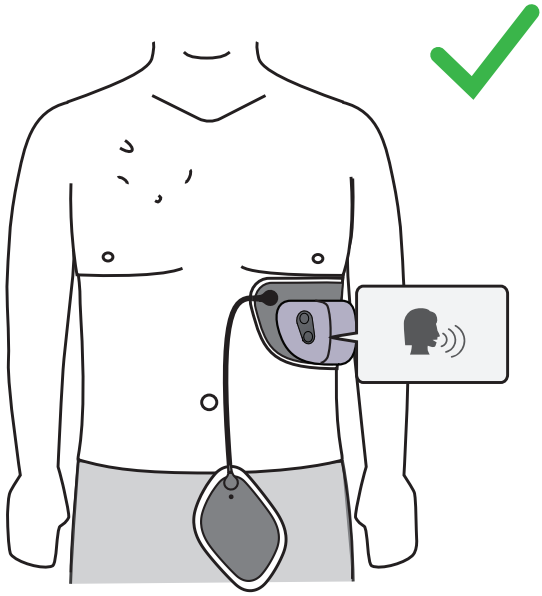
Do NOT rip patch off your skin.

4



Rub wet foam tool on crease between skin and patch.

5

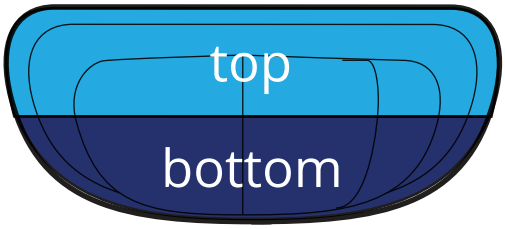


Repeat step 4 until the Upper Patch is fully detached from the skin.

Allow Upper Patch to hang when fully removed.

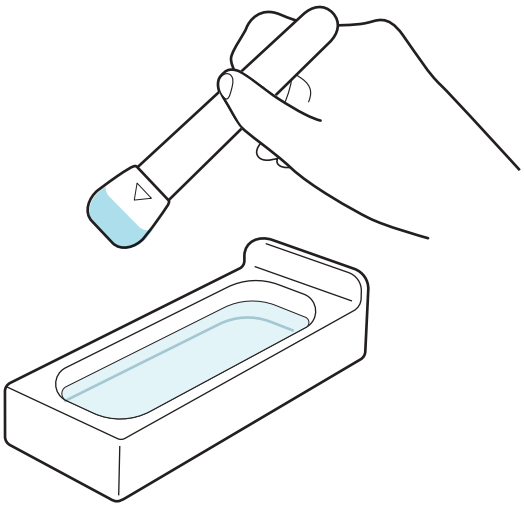
The Jewel may now say “Replace patches immediately.”

LOWER PATCH REMOVAL:



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

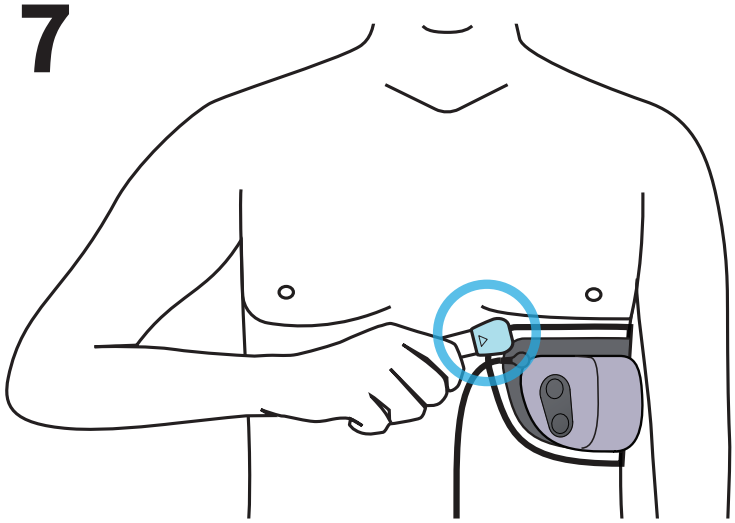
6



Use adhesive remover and foam tool.

Do NOT rip patch off your skin.

7

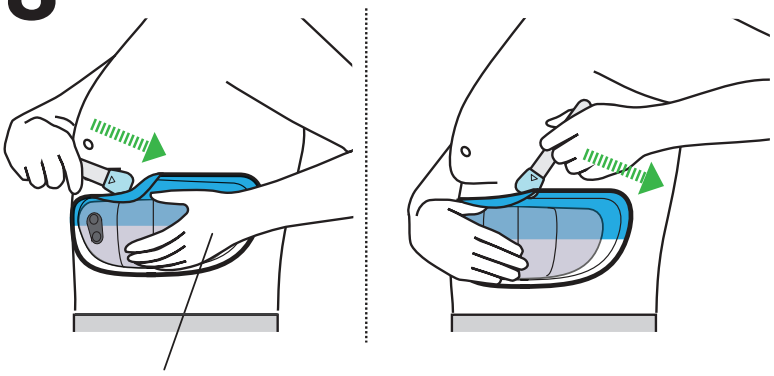


Rub wet foam tool on one spot for 30 seconds to lift an edge.

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

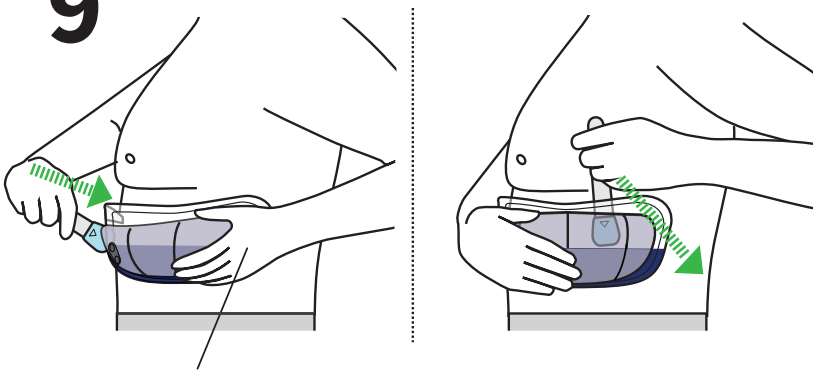


Start at front and move to back.

Rub wet foam tool on crease between skin and patch.

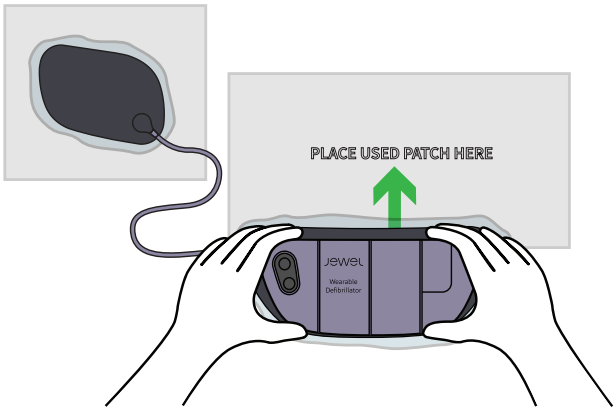
Continue until the top section is fully detached.

9



Repeat step 8 to remove the bottom section.

10

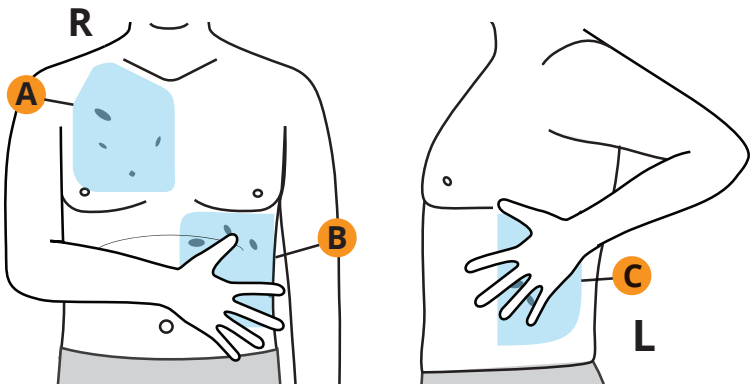


Place the Jewel onto two discard sheets and set aside.

ATTENTION: When the Defibrillator Unit is not on your body, hold it with both hands and keep it as flat as possible. Do not fold or twist the Defibrillator Unit.

REMOVING LEFTOVER ADHESIVE:

11



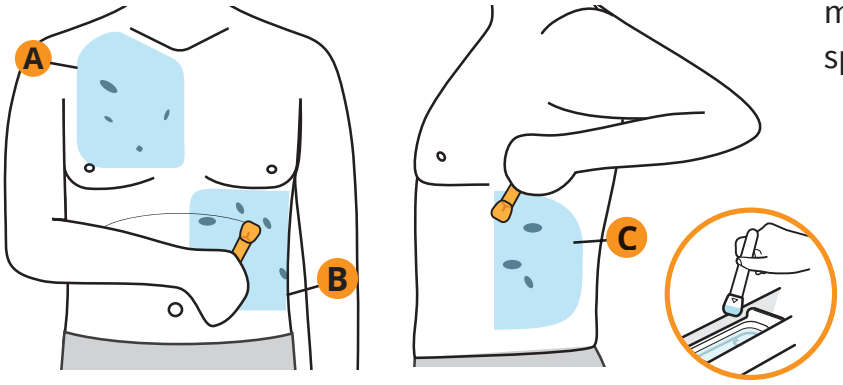
Feel for sticky spots of adhesive in the following areas:

A. Right chest (upper patch area)

B. Left torso front (front of lower patch area)

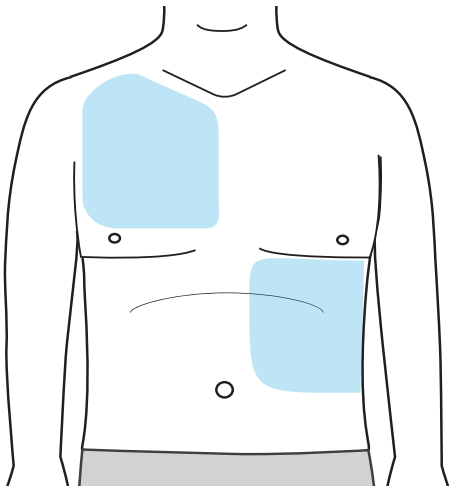
C. Left torso side/back (back of lower patch area)

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.

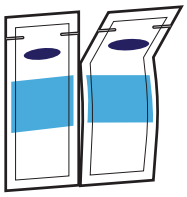
Repeat cleaning until these areas are no longer sticky.

continue ⟶

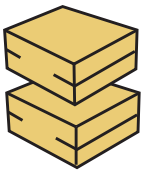
WASHING, RINSING, AND DRYING YOUR SKIN

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

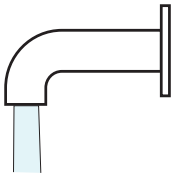
SUPPLIES NEEDED:



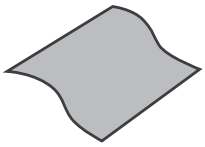
2 soap packets



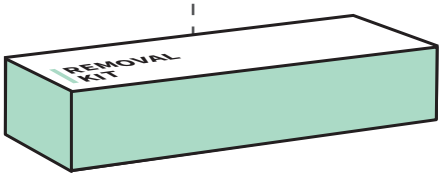
2 sponges



water
(not provided)

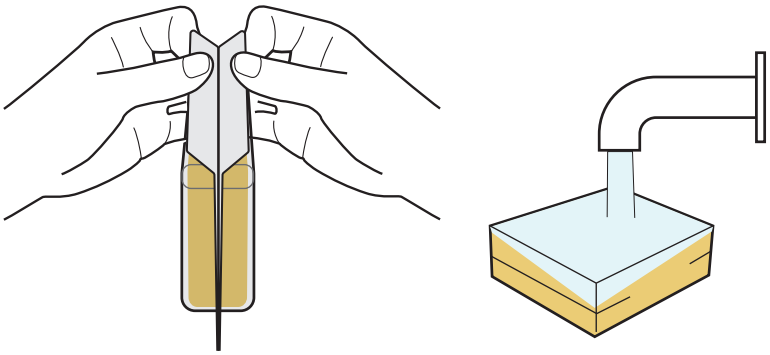


clean and dry towel
(not provided)



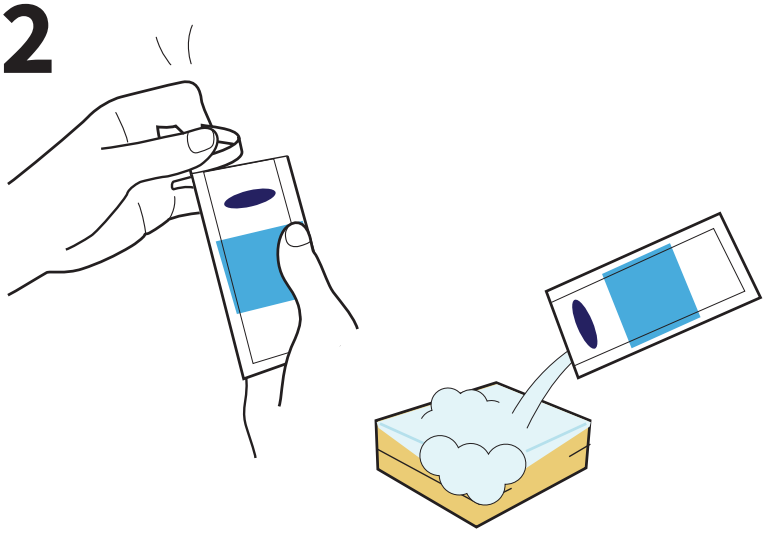
Removal Kit Box
(included in the Patch Kit box)

1 WASHING SKIN



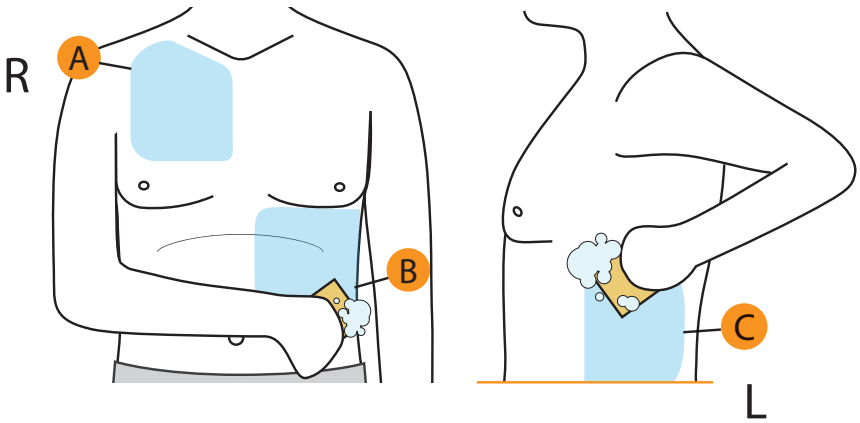
Open sponge packet.
Wet sponge with water.

2



Open soap packet.
Apply soap to sponge.

3



Clean skin with soapy sponge in the following areas:

A. Right chest (Upper Patch area)

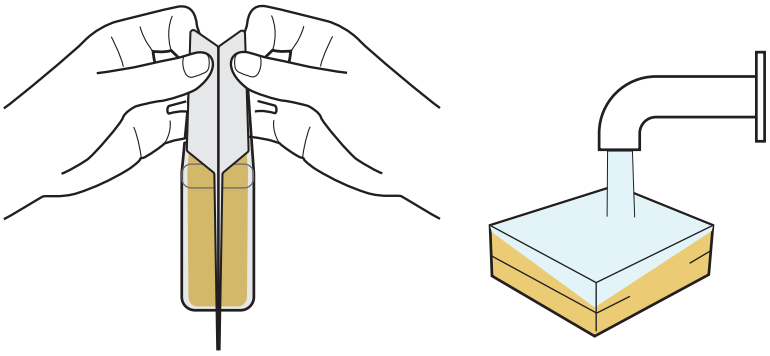
B. Left torso front (front of Lower Patch area)

C. Left torso side/back (back of Lower Patch area)

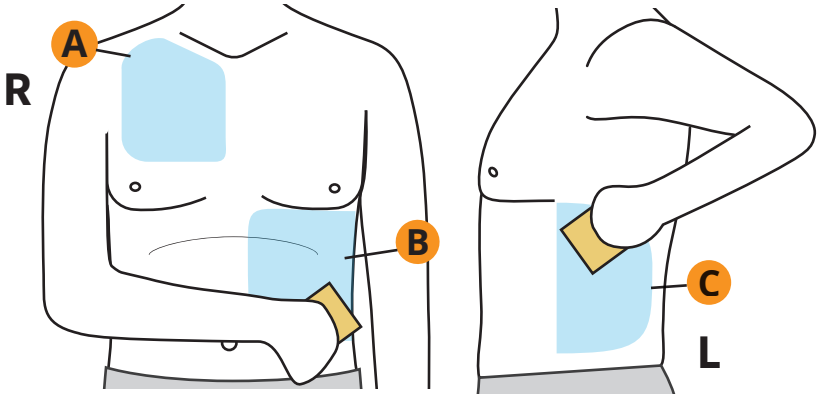
continue ⟶

4 RINSING SKIN WITH WATER:

Open new sponge packet.
Wet sponge with water.



5



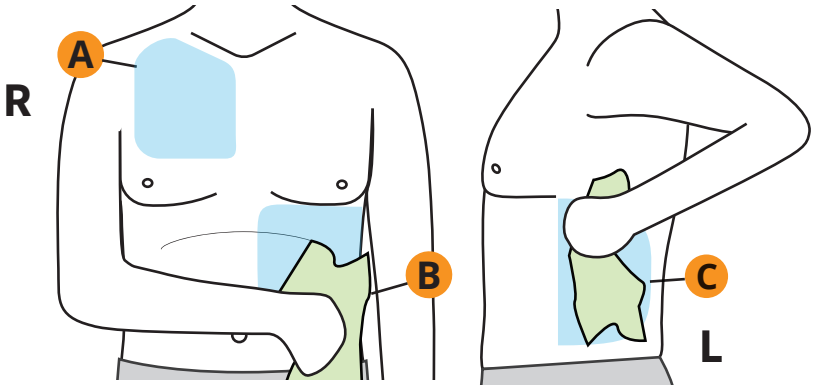
Rinse skin with wet sponge in the following areas:

A. Right chest (Upper Patch area)

B. Left torso front (front of Lower Patch area)

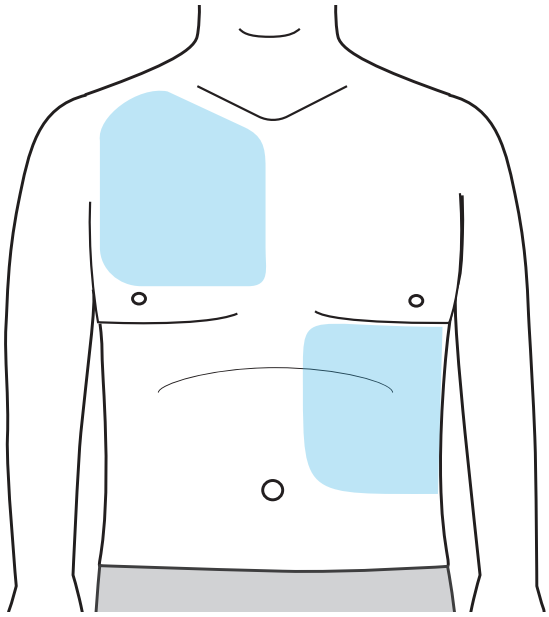
C. Left torso side/back (back of Lower Patch area)

6



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

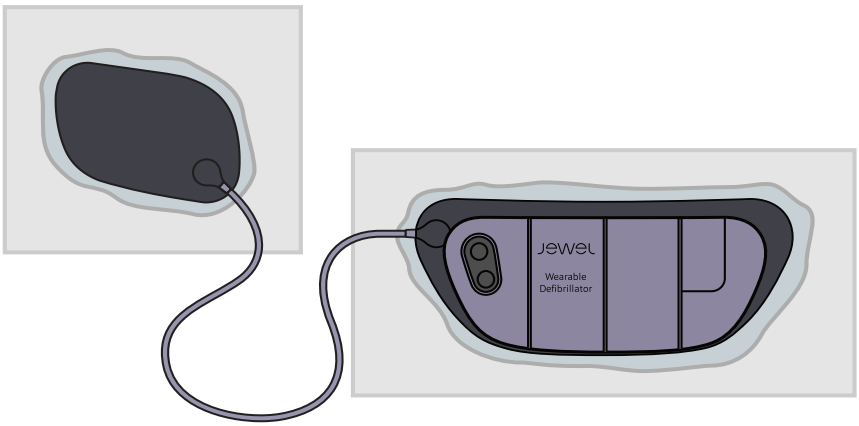
7



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.

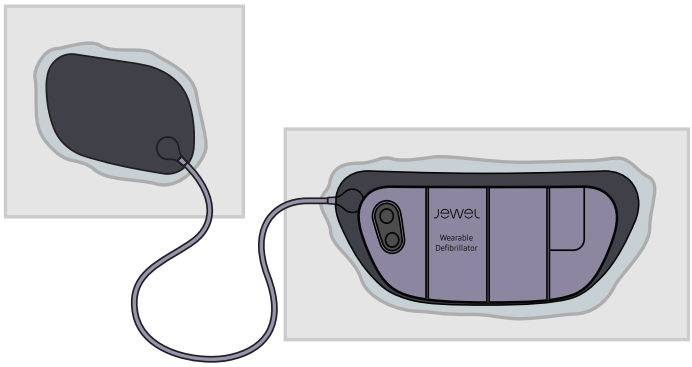


continue ⟶

5.3 DISASSEMBLE YOUR JEWEL

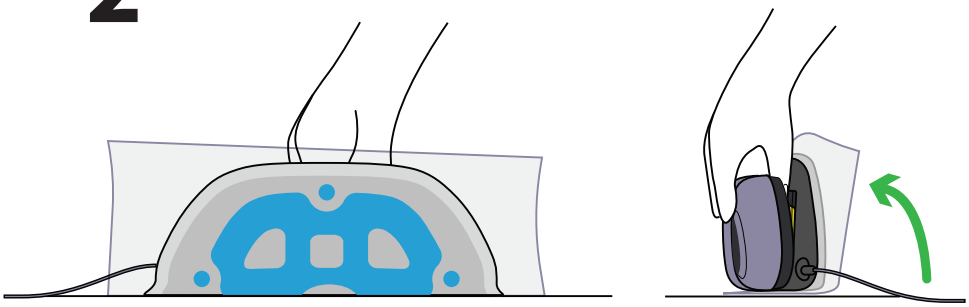
Note: It is important that the Defibrillator Unit remains completely dry and protected during disassembly steps. **Keep the Defibrillator Unit in a dust and lint-free environment when disconnected from the Patch Unit.** Accumulation of lint or dust within the electrical connections of the Defibrillator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

1



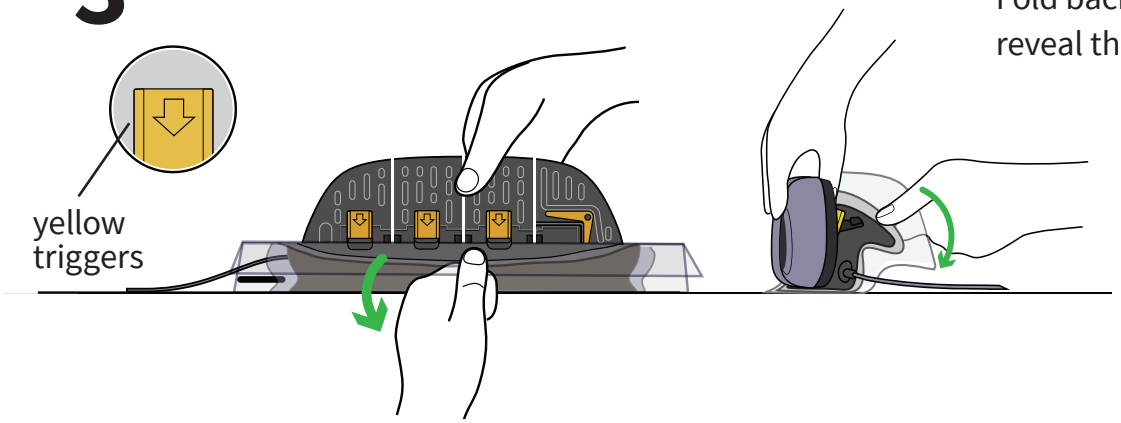
Place the Jewel in front of you with the cable on the left hand side and battery on the right before you start disassembling.

2



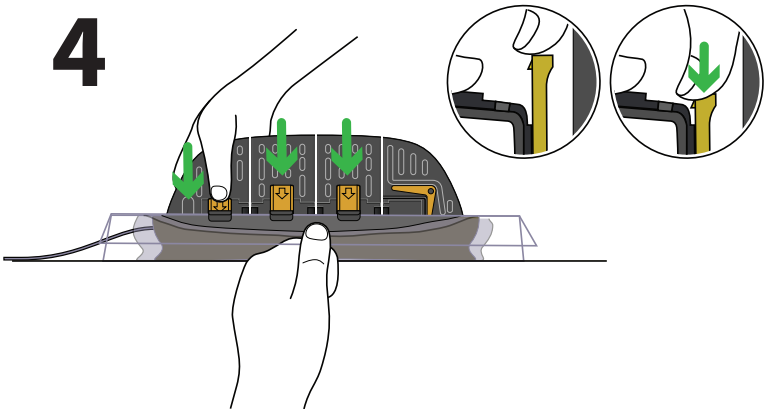
Tilt the Defibrillator Unit so that it is perpendicular to the table.

3



Fold back the Patch Unit to reveal the yellow triggers.

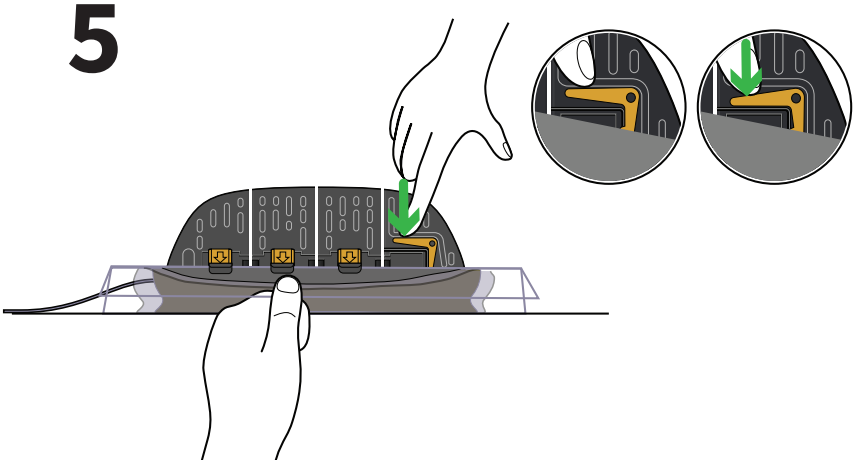
4



Push each yellow trigger down until you hear a click.

(The trigger should stay in place once pushed down.)

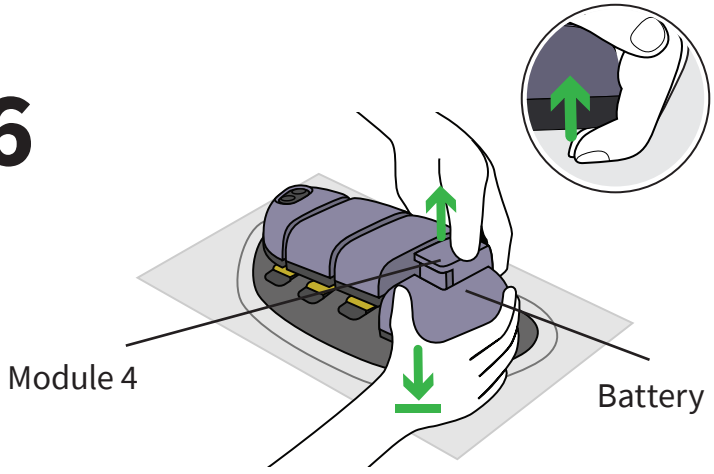
5



Push down the L shaped lever to unlock battery latch.

(The lever should stay in place once pushed down.)

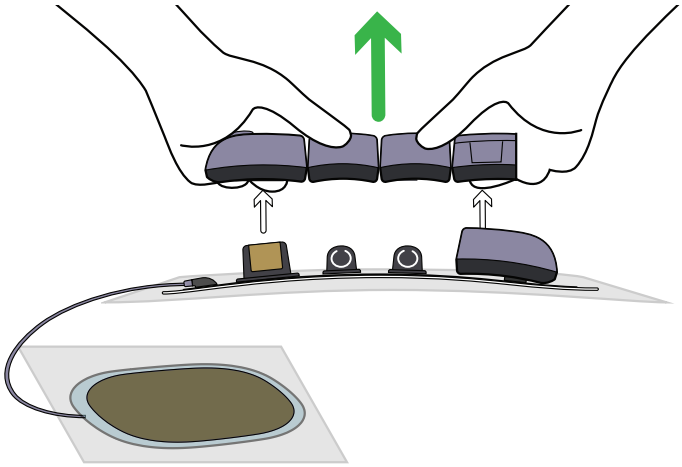
6



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.

continue ⟶

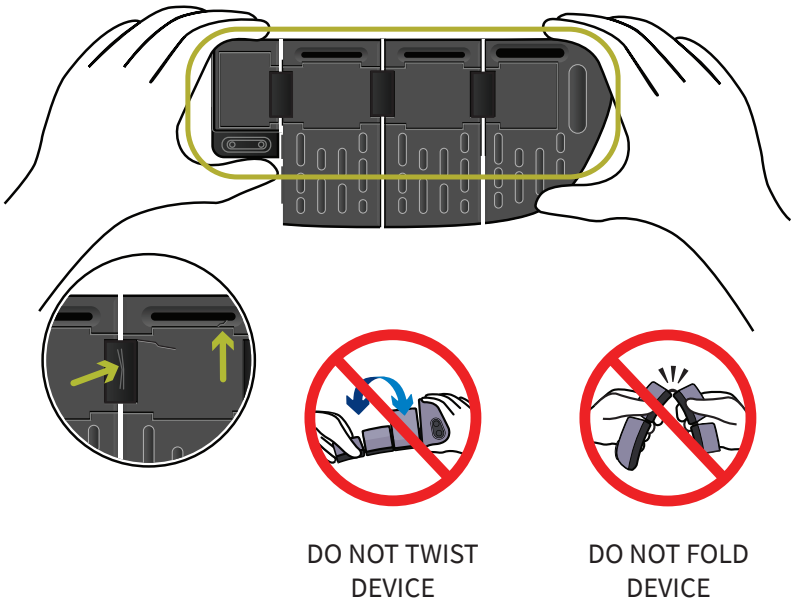
7



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.

ATTENTION: When the Defibrillator Unit is not on your body, hold it with both hands and keep it as flat as possible. Do not fold or twist the Defibrillator Unit.

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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PRODUCT DESCRIPTION

The Jewel Patch Wearable Cardioverter Defibrillator (P-WCD) is a wearable automated external defibrillator that provides continuous, automatic monitoring of cardiac rhythms to support rapid detection of life-threatening arrhythmias. If the Jewel detects life-threatening ventricular tachycardia (VT) or ventricular fibrillation (VF), it can deliver a defibrillation shock to the heart to restore a normal rhythm without further interaction from the patient or bystander.

INDICATIONS FOR USE

The Jewel Patch Wearable Cardioverter Defibrillator (P-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.

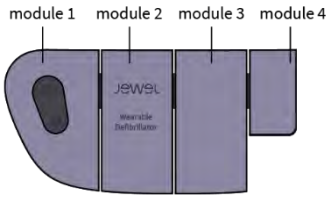
CONTRAINDICATIONS

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

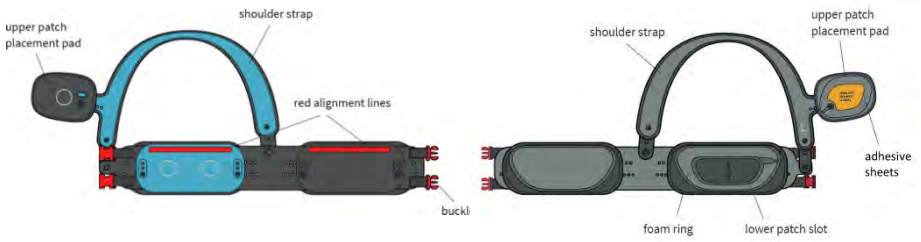
CONSIDERATIONS FOR PRESCRIBERS

The Jewel should not be used concurrently with unipolar or antitachycardia pacing configurations, or pacing with pulse artifacts greater than 0.5mV in any ECG lead. This artifact may interfere with the Jewel's ability to detect dangerous heart rhythms and could prevent shock delivery.

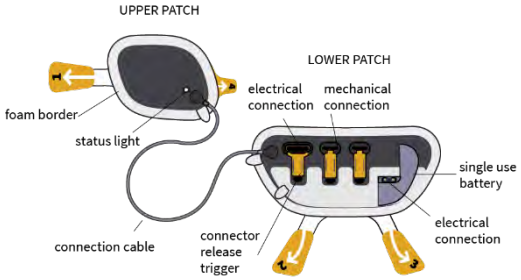
DEFIBRILLATOR UNIT



PLACEMENT ACCESSORY



PATCH UNIT



℞ ONLY

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

WARNINGS

- 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.
- 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 replace the Patch Unit when instructed to do so. The Patch Unit is single-use and is intended to be replaced after each wear.

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. More information can be found in the “Electromagnetic Interference” section of the Patient Guide.
- 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 high-frequency (HF) surgical equipment or the radio-frequency (RF) shielded room of a medical equipment (ME) system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- Portable radio-frequency (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, 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.
- The Jewel may ONLY be worn with ONE (1) FDA-cleared or FDA-approved, device CONCURRENTLY, which MUST be DEFIBRILLATION PROOF (meaning protected against the effects of defibrillation).
- Devices that are not DEFIBRILLATION PROOF (meaning protected against the effects of defibrillation) should not be worn with the Jewel.
- The Jewel's performance may be impacted if worn in conjunction with an implantable or transcutaneous electrical stimulating device.
- 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 was tested to demonstrate compliance to the emissions and immunity requirements of the following standard: RTCA DO-160G, Environmental Conditions and Test Procedures for Airborne Equipment, Section 20 (RF immunity) and Section 21 (RF emissions). RTCA DO-160G test results indicate potential susceptibility to electromagnetic disturbances from radio frequency emissions in a narrow frequency band from 400 MHz to 588 MHz. Devices which operate in this band include some meteorological and earth exploration satellites, astronomy radios, and broadcasting radios. In the extremely unlikely event these emissions do interfere with Jewel device performance, alarms will sound indicating this. In the unlikely event that the Jewel alarms indicate abnormal device performance during the landing and takeoff portions of a flight, press both buttons for at least 5-seconds to enter the mode (Removal Mode) to temporarily pause Jewel operation, then follow the audible instructions from the Jewel to confirm. No further action is necessary. The Jewel will automatically return to Monitor Mode after 30-minutes and will continue normal operation. After returning to Monitor Mode, if similar alarms resume, the device can once again be placed into Removal Mode.
- 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 and damage or break the device.
- 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. The patient should contact their doctor for any skin concerns.
- 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 damage or break the device.
- 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 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 damage or break the device.
- 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.

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.
- 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 Defibrillator Unit electronics immediately contact Customer Service at 1-800-985-5702 to replace your Defibrillator Unit.
- If you have any skin issues underneath the Patch Unit such as redness, bumps, inflammation, irritation, continue to wear the Jewel and contact your doctor.
- Patients can contact Customer Service if they need assistance, have questions, or require retraining for the Jewel use. Customer Service is available 24 hours a day, 7 days a week and can be reached by phone at 1-800-985-5702 and email at customerservice@elementsci.com.
- Always handle the Jewel carefully in order to avoid potential damage. When the Defibrillator Unit is not on your body, hold it with both hands and keep it as flat as possible. Do not fold or twist the Defibrillator Unit.

INSTRUCTIONS FOR USE

Application, daily use, removal and other instructions for the Jewel, its components and accessories are outlined in the Jewel Patch Wearable Cardioverter Defibrillator (P-WCD) Patient Guide and IFU which can be accessed at www.elementscience.com/manuals.

1 | **Initial Application**

a. Refer to Application Chapter in the Patient Guide for instructions.

b. Remove patch from packaging and assemble Defibrillator Unit to Patch Unit

c. Press and hold both buttons to turn on Jewel device and make sure it is in application mode.

d. Use the Placement Accessory when applying Jewel.

e. Once Jewel Upper and Lower Patches have been applied and the Jewel has entered monitoring mode, perform the following steps:

i. Make sure all the borders are flush to the skin and tabs have been removed.

ii. Press both buttons to complete Status Check.

2 | **Patch Replacement**

a. Refer to the Removal Chapter of the Patient Guide for instructions.

b. Jewel must be placed into removal mode. If not placed in removal mode, a potential shock may be delivered. To initiate removal mode, press and hold both buttons. Press both buttons again to confirm Removal Mode.

c. Use the Removal Kit when replacing patches.

Note: Do not apply patches over broken skin or open wounds.

d. Disassemble the Defibrillator Unit from the used Patch Unit by following the instructions in the Patient Guide.

e. Follow the instructions in the Application Chapter of the Patient Guide to assemble the Jewel device and apply new patches.

Note: When the Defibrillator Unit is not on your body, hold it with both hands and keep it as flat as possible. Do not fold or twist the Defibrillator Unit.

3 | **Disposal Instructions**

a. The Jewel Defibrillator Unit and Patches should be returned to Element Science for processing and proper recycling.

b. Refer to the Jewel Patch Wearable Cardioverter Defibrillator (P-WCD) Patient Guide or contact Element Science Customer Service for return instructions.

c. 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).

SAFETY AND EFFICACY DATA

The safety and effectiveness of the Jewel has been demonstrated in clinical studies. Clinical study information can be found in the Jewel Patch Wearable Cardioverter Defibrillator (P-WCD) Instructions for Use.

TECHNICAL INFORMATION:

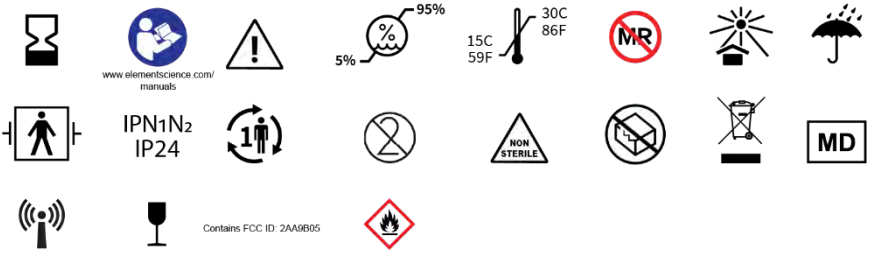
Detailed technical information can be found in the Jewel Patch Wearable Cardioverter Defibrillator (P-WCD) Instructions for Use.

CUSTOMER RESOURCES AND SUPPORT:

1-800-985-5702

customerservice@elementsci.com

www.elementscience.com



Instructions for Use: www.elementscience.com/manuals

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ELEMENT SCIENCE