Jewel

Jewel® Wearable
Cardioverter Defibrillator (WCD)

INSTRUCTIONS FOR USE

ELEMENT SCIENCE

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Rx Only Federal law restricts this device from being sold by or on the order of a physician.

IMPORTANT INFORMATION

Trademarks

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1. INTRODUCTION

The Jewel Wearable Patch Defibrillator (Jewel) 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 Wearable Patch Defibrillator 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 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

1.4 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.

1.4.1 WARNINGS

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

1.4.2 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.
- The Jewel must not be worn during magnetic resonance imaging (MRI), an X-ray, a computed tomography (CT) scan, radiation therapy, diathermy therapy, or a procedure requiring the use of electrocautery.

- The Jewel is suitable in hospital environments except near active HF surgical equipment, or the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- Portable RF communications equipment (including mobile phones and peripherals such as antenna cables and external antennas) should NOT be operated closer than 30cm (12 inches) to any part of the Jewel P-WCD, including cables.
- AVOID use of the Jewel adjacent to or stacked with other equipment. This may result in improper operation. If such use is necessary, observe the equipment to verify normal operation.
- No more than one FDA-cleared or FDA-approved, DEFIBRILLATION PROOF device should be used concurrently with the Jewel.
- The Jewel should NOT be used on patients with an implantable pacemaker that produces a pacemaker pulse artifact greater than 0.5mV on any Jewel ECG channel. Artifact may interfere with the system's ability to detect dangerous heart rhythms and prevent shock delivery.
- The Jewel should NOT be installed on an aircraft as "Airborne Equipment." The Jewel may be used by the patient while traveling by air.
- When wearing the Jewel do not pass through airport body scanners (backscatter x-ray or millimeter wave technologies).
- The Jewel should NOT be worn on railway systems while traveling internationally (outside of the United States).
- Do NOT use the Jewel in the presence of flammable agents or in an oxygen enriched atmosphere. This could present an explosion and fire hazard.
- Do NOT use accessories, transducers and cables other than those provided for use with the Jewel. This may result in increased electromagnetic emissions, decreased electromagnetic immunity and/or improper operation.
- Do NOT tamper, alter, drop, or abuse any part of the Jewel system. There are no user- serviceable components in the Jewel. Altering the Jewel could create an electrical safety hazard or malfunction, which may cause an electrical shock.
- The Jewel should NOT be used by patients with known allergies to medical grade adhesives and conductive hydrogels.
- Do NOT apply patches to broken, damaged skin or open wounds. This may result in damage to skin, infection or allergic dermatitis.
- Skin burns may occur due to heating of the device during charging prior to defibrillation.
- Do NOT touch the patient while an electrical shock is being given. Anyone touching the patient during an electrical shock may also receive an electrical shock.
- Do NOT remove the Patch Unit plastic backings until ready to apply the Jewel. Dust and lint may impact the Patch Unit adhesive's ability to stick to the body. Prolonged sunlight may degrade electrode signal quality and result in early Patch replacement.
- Do NOT place other electrodes or metal items in contact with the Jewel.
- Do NOT submerge the Jewel in water or any liquid. Submerging the Jewel may allow liquid to enter the device and could cause a malfunction.
- Do NOT dispose of or incinerate the Jewel Defibrillator Unit or Patch Units. The batteries contain lithium ion and must be returned to Element Science for proper disposal.
- Do NOT assemble or disassemble the Defibrillator Unit from the Patch Unit while in a wet or humid environment. This may damage the Defibrillator Unit.
- Do NOT touch the battery electrical connections or place anything in the recessed areas on the Patch Unit or Defibrillator Unit. This may result in skin injury or device malfunction.

1.4.3 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.

2. SAFETY AND EFFICACY DATA

2.1 Clinical Studies

The following clinical data demonstrates a reasonable assurance of safety and effectiveness of the Jewel Patch Wearable Defibrillator:

- 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 27 February 2023. The Study was designed to demonstrate the safety and clinical effectiveness of the Jewel Patch Wearable Defibrillator 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 Patch Wearable Defibrillator 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 2.1.1a

- **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 97% confidence interval.
  - Rate of subjects experiencing clinically significant cutaneous adverse device effects (ADEs) of less than 15% using a one-sided, exact 95% 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:** 0.197 shocks per 100 patient-months, with an upper 97% confidence interval of 1.293

  - **Clinically significant cutaneous ADEs:** 3.24%, with a one-sided upper 95% confidence bound of 6.30%

  - **Successful conversions of shockable rhythm with a single salvo:** 3 successful conversions were observed over the course of the trial; all conversions occurred with first shock

  - **Patient compliance:** Average compliance of 21.0 ± 4.90 hours (median: 23.5, interquartile range: 20.2, 23.9) per day during the prescribed wear period

- There were no serious adverse events related to the device and no deaths.

Table 2.1.1a: Baseline Demographic Characteristics

Of 244 enrolled patients, 185 patients had completed the study and 179 patients had analyzable device data at the time of data cut. The demographics of these patients are summarized below.

Characteristic	Primary Analysis Population (N=179)
Age at Enrollment (Years), Mean ± SD	60.0 ± 12.8
Gender: Male (% of total)	131 (73.2%)
Ethnicity (Not Hispanic or Latino (% of total)	174 (97.2%)
Race, White (% of total)	5/5 (100%)
Race, Black or African American (% of total)	41 (22.9%)
Race, Asian (% of total)	2 (1.1%)
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)	7 (3.9%)
Body Mass Index (kg/m2), Mean ± SD	29.8 ± 6.6
Medical History	
Prior myocardial infarction (MI)	61/178 (34.3%)
Prior coronary artery bypass grafting (CABG)	26/178 (14.6%)
Prior percutaneous coronary intervention (PCI)	65/178 (36.5%)
Prior congestive heart failure (CHF)	128/178 (71.9%)
NYHA Class I	5/134 (3.7%)
NYHA Class II	46/134 (34.3%)
NYHA Class III	41/134 (30.6%)
NYHA Class IV	6/134 (4.5%)
Not Applicable	36/134 (26.9%)
History of atrial fibrillation (AF)	54/178 (30.3%)

Persistent	10/53 (18.9%)
Paroxysmal	43/53 (81.1%)
History of unstable angina	20/173 (11.6%)
Resolved	12/20 (60.0%)
Ongoing	8/20 (40.0%)
History of non-sustained ventricular tachycardia (NSVT)	33/178 (18.5%)
Resolved	15/33 (45.5%)
Ongoing	18/33 (54.5%)
History of ventricular tachycardia (VT)	40/178 (22.5%)
Resolved	14/40 (35.0%)
Ongoing	26/40 (65.0%)
History of sudden cardiac arrest (SCA)	14/178 (7.9%)
History of hypertension	133/178 (74.7%)
Resolved	5/133 (3.8%)
Ongoing	128/133 (96.2%)
History of smoking	80/178 (44.9%)
History of diabetes	61/178 (34.3%)
Type 1	1/61 (1.6%)
Type 2	60/61 (98.4%)

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 Patch Wearable Defibrillator, 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 2.1.2a

- **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 2.1.2a: 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)	5/5 (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 Wearable Patch Defibrillator (Jewel) 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.

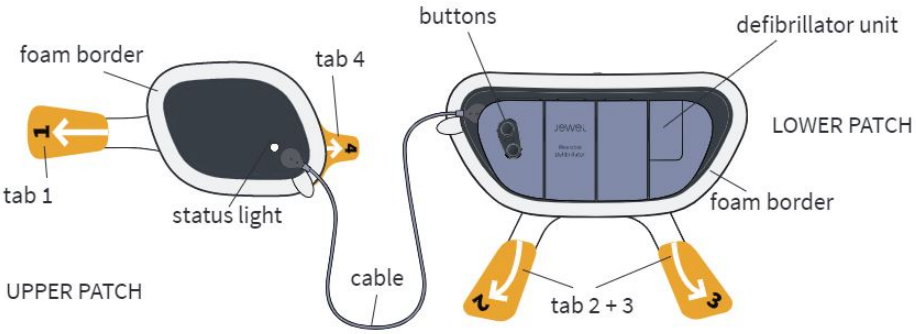
The Jewel is designed to be applied directly to the patient's skin on the upper right chest and lower left torso, beneath the patient's clothing.

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

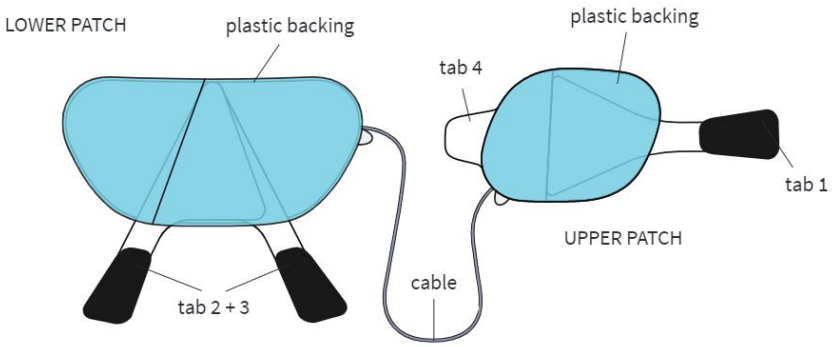
- Defibrillator Unit (re-used throughout the patient's prescription)
- Patch Unit (upper and lower adhesive electrode patches) (one-time use)
- Placement Accessory (used during patch application and replacement)
- Application and removal accessories
- Optional Jewel Mobile App (patient app)
- Report Generator

The Jewel Defibrillator Unit and Patch Unit are designed to be worn by the patient continuously. The Defibrillator Unit is intended to be re-used with multiple Patch Units throughout the duration of the patient's prescription.

The Outer Side

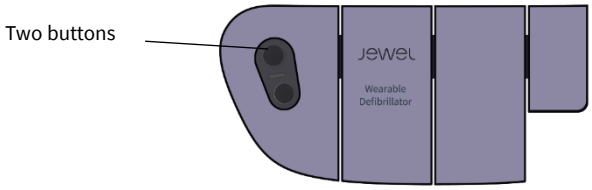


Skin Facing Side



3.1 Defibrillator Unit

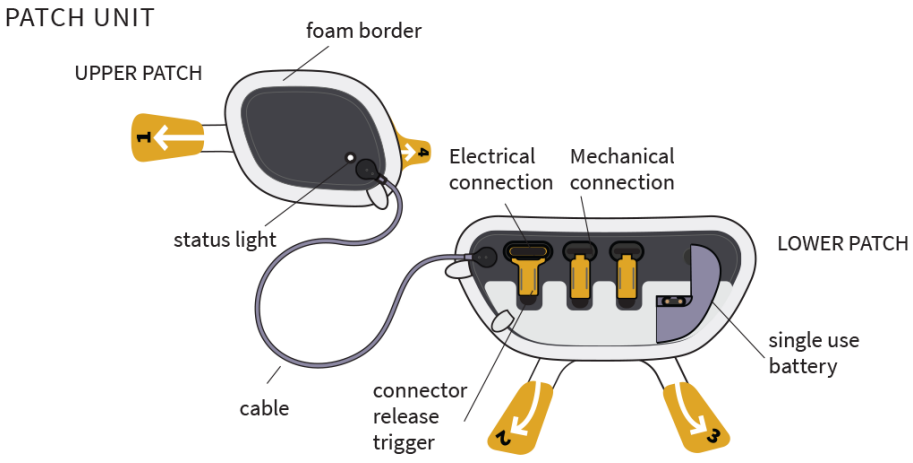
The Defibrillator Unit contains the electronics that monitor the heart and provide an electrical shock if needed. The Defibrillator Unit has four interfaces to connect to the Patch Unit and must be properly connected to the Patch Unit for the Jewel to operate as intended. The Defibrillator Unit is intended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

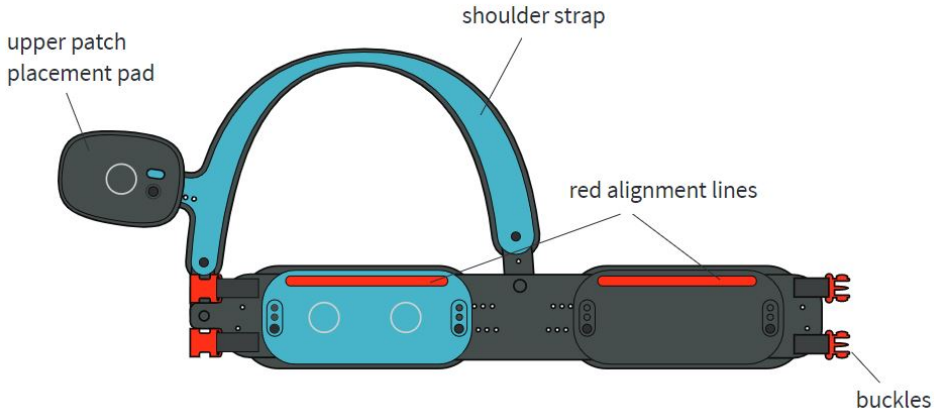


- The **UPPER PATCH** is a single-use, conformable adhesive patch containing ECG electrodes and a defibrillation electrode. The adhesive patch is made up of various types of medical grade adhesive (including hydrogel and hydrocolloid) and contains some of the sensing electrodes and an electrical shock 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.

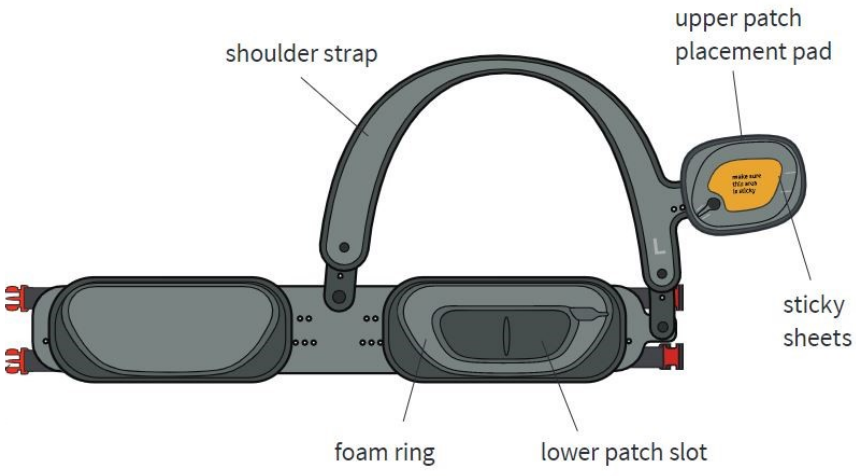
3.3 Placement Accessory

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.

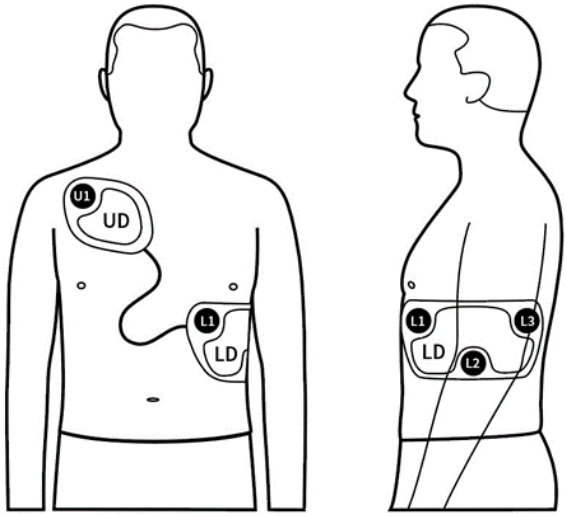
3.6. Therapy Report Generator (Optional)

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 Wearable Patch Defibrillator (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 with the R-peak of the QRS complex. This automatic synchronization delivers a cardioversion shock to a patient if R-peaks are detected, suggesting that the rhythm is life-threatening. If the cardioversion algorithm is not able to identify a regular R-peak during the ventricular arrhythmia, the Jewel will deliver an asynchronous defibrillation shock. The Jewel device

attempts to deliver the electrical shock within 60 milliseconds of the R-wave. If the Jewel cannot synchronize within 8 seconds, it delivers an unsynchronized electrical 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 Wearable Patch Defibrillator (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.

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:

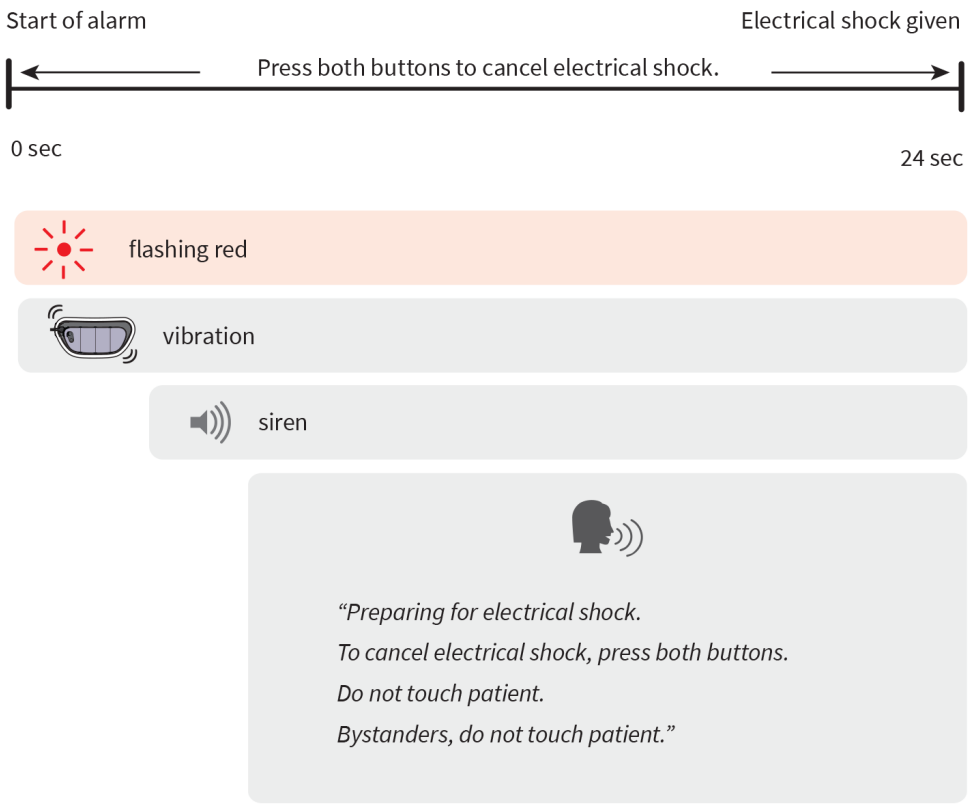
1. Heart rhythm alarms
2. Device status notifications

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.



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.

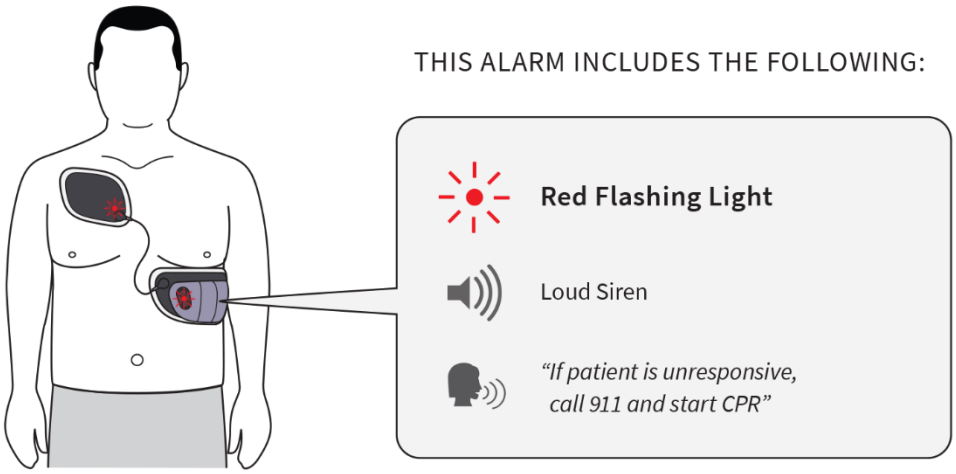
-Notifications that occur after therapy has been deferred-	
Solid green light	"Electrical shock canceled. Jewel is active." (Patient should continue wearing the Jewel)

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)

6.1 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 6.2.a: 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*
Device malfunction; contact Customer Service immediately	Flashing red + tone + vibration	Device is disabled and must be replaced; call customer service immediately
Patch Unit malfunction; 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 6.2.b: 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.
Defibrillator Unit Malfunction	Flashing red + vibration	*No prompt; Defibrillator Unit malfunction; patient should call Customer Service*

Table 6.2.c: 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 6.2.d: 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. Performance has been evaluated using a Test Dataset of electrocardiogram (ECG) samples. Samples are organized by rhythm types identified in the American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Effectiveness (Table 7.1.2a.). “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 7.1.2a: Rhythm types identified in the American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Effectiveness.

Rhythm	Test Sample Size	AHA AED Performance Criteria	Observed Performance	90% One-sided LCL

Shockable	Coarse VF	47	> 90% sensitivity	100%	94.56%
	Rapid VT	21	> 75% sensitivity	100%	88.59%
Non-Shockable	NSR	248	> 99% specificity	99.6%	98.21%
	AF, SB, SVT, HB, IV, PVC	145	> 95% specificity	97.93%	94.94%
	Other Non-Shockable	462	N/A	99.35% Specificity	98.39%
	Asystole	1	> 95% specificity	100%	N/A*
Intermediate	Fine VF	4	Report Only	75% Sensitivity	N/A*
	Other VT	17	Report Only	100% Specificity	86.27%

7.1.3 SHOCK CRITERIA

- **Waveform**: Biphasic truncated exponential
- **Delivered energy accuracy**: First shock at 150J (+/- 15%) at ambient temperature when discharged into 25, 50, 75, 100, 125, 150, 175ohm resistive load. For shocks 2-5, 162J (+/- 15%) at ambient temperature when discharged into a 25, 50, 75, 100, 125, 150, 175ohm resistive load.
- **Delivery time**: The Jewel delivers for the first shock a max joule shock within 60 seconds of arrhythmia classification. For shocks 2-5, the Jewel is capable of max joule shock within 35 seconds of the previous shock.
- **Charge time**: The Jewel Wearable Patch Defibrillator requires 25 seconds of charge time to be ready to deliver a shock with a newly replaced Patch Unit. After six shocks, it will be ready to deliver a shock within 29 seconds.
- **Defibrillating peak output current:** Nominally 62.4A 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**: Device is capable of delivering 10 shocks.

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 parts**: 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 water.
- **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.

AAMI EC12:2020	Disposable ECG Electrodes
AAMI EC53:2013/(R)2020	ECG Trunk Cables and Patient Leadwires
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
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
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

7.2.1 Electromagnetic Compatibility (EMC) Testing

EMC testing results in accordance with the following:

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

7.2.2 IEC 60601-1-2 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 10V/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 freq.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 freq.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

7.2.3 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

7.2.4 Electromagnetic Immunity Declaration for Life-supporting Equipment

Recommended separation distances between portable and mobile RF communications equipment and the Jewel

The Jewel P-WCD is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Jewel can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Jewel P-WCD as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter	**Separation Distance According to Frequency of Transmitter (meters)**			
	150kHz to 80MHz (Outside ISM bands)	**150kHz to 80MHz (Inside ISM bands)**	**80MHz to 800 MHz**	**800MHz to 2.7GHz**
W	**$d = 1.2\sqrt{P}$**	**$d = 1.2\sqrt{P}$**	**$d = 1.2\sqrt{P}$**	**$d = 2.3\sqrt{P}$**
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.20	1.20	1.20	2.30
10.00	3.79	3.79	3.79	7.27

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: Multiply distance by 39.37 to convert meters to inches.

Note 2: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 3: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 4: An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 5: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

7.2.5 Defibrillating Pulse Waveforms

Table 7.7a: 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	62.4
50	4.8	3	31.2
100	10.4	3	15.6
150	16.1	3	10.4
200	21.8	3	7.8

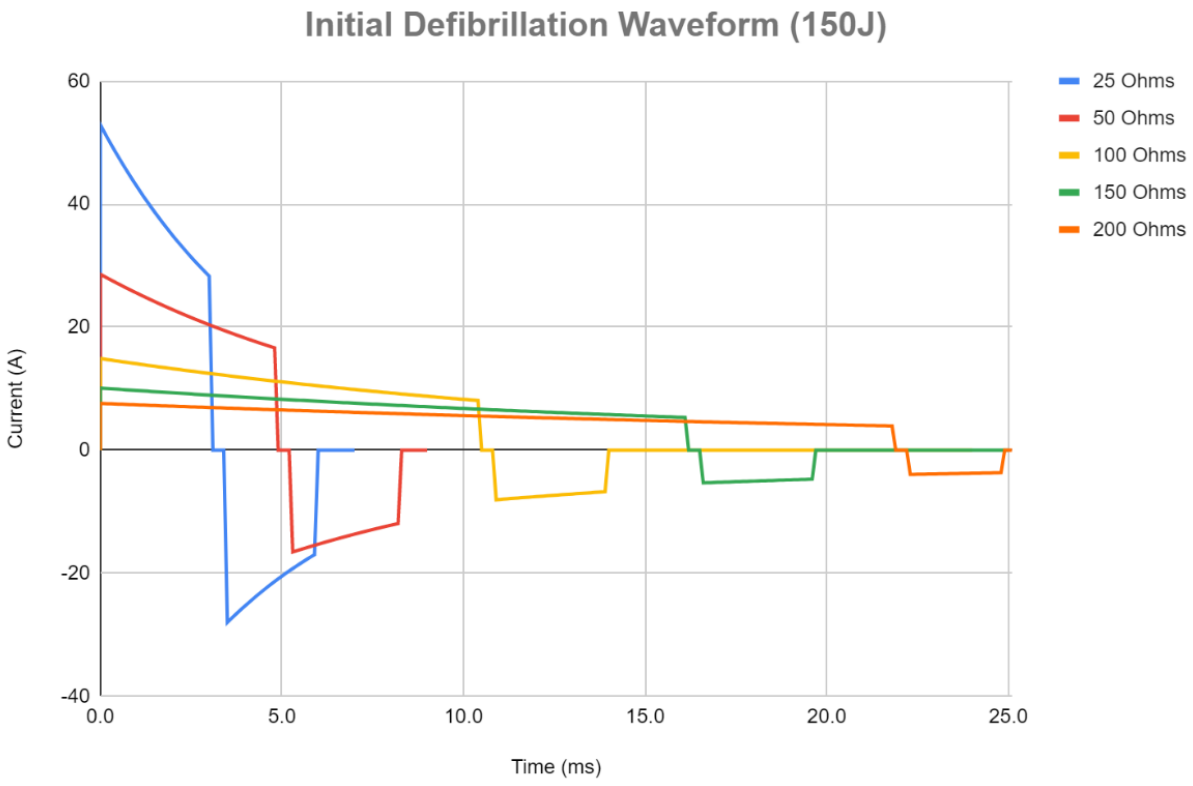


Table 7.7b: Nominal second through fifth shock waveform parameters

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	3.8	3	62.4
50	6.9	3	31.2
100	13.5	3	15.6
150	20.4	3	10.4
200	22	3	7.8

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

Table 8a: Symbols from standards

Symbol	Symbol title	Explanatory text
	Manufacturer	Indicates the medical device manufacturer.
	Catalog or model number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
		

	Use by	Indicates the date after which the medical device is not to be used.
 www.elementscience.com/manuals	Follow instructions for use or follow electronic instructions for use.	Indicated the need for the user to follow instructions for use.
 www.elementscience.com/manuals	Consult instructions for use or consult electronic instructions for use.	Indicates the need for the user to consult the instructions for use.
	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Storage humidity range	Indicates the range of humidity to which the medical device can be safely exposed.
	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed.
	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment.
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	Keep dry	Indicates a medical device that needs to be protected from moisture.

	Defibrillation proof Type BF applied part voltage	To identify a type BF applied part complying with IEC 60601-1.
IPN1N2	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".
	Single patient, multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Non sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Do not use if package is damaged and consult instructions for use.	Indicates a medical device that should not be used if the package has been damaged or opened.
	Recycle: Electronic Equipment	Do not dispose of this product in unsorted municipal waste stream.
	Medical device	Indicates the item is a medical device.
	Unique device identifier	Indicates a carrier that contains unique device identifier information.

	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.

Table 8b: Symbols not from standards

Symbol	Symbol title	Explanatory text
	Prescription only	Requires prescription in the United States.
FCC ID: OH2XXXX	Federal Communication Commission Identifier (FCC ID #)	Complies with United States Regulations for Radio Frequency Devices.
	Bluetooth® wireless or enabled technology	Bluetooth® wireless or enabled technology.
 FCC ID:2AA9B05	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing 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.
	Flammable	Indicates the possible presence of the following: flammables, self-reactive, pyrophoric, self-heating, emits flammable gas, organic peroxides.