

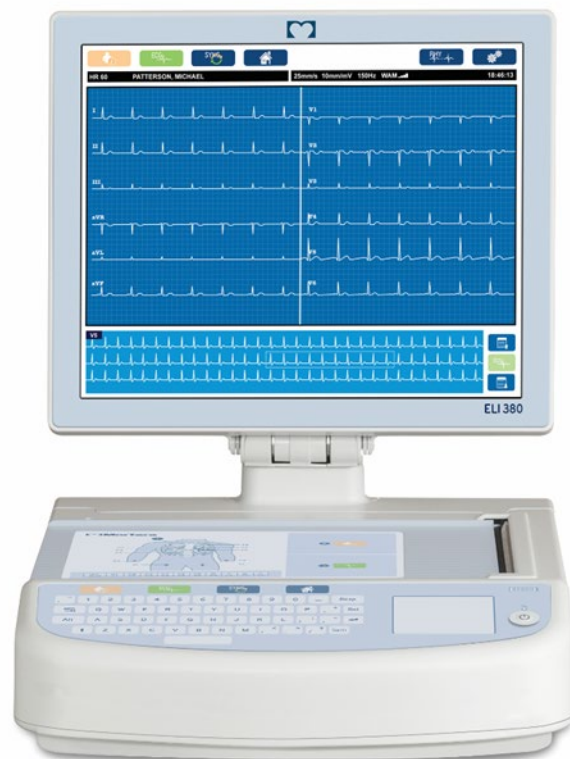


**Welch Allyn**

**ELI 380**

**Late Potential**

Software version 2.7.X



Addendum to **ELI 380**

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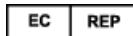
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# Table of Contents

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|   |          |
|---|----------|
| <b>Notices</b> .....                          | <b>4</b> |
| Manufacturer's Responsibility .....           | 4        |
| Responsibility of the Customer.....           | 4        |
| Equipment Identification .....                | 4        |
| Copyright and Trademark Notices .....         | 4        |
| Other Important Information.....              | 4        |
| Notice to EU Users and/or Patients .....      | 4        |
| <b>Warranty Information</b> .....             | <b>5</b> |
| Your Welch Allyn Warranty.....                | 5        |
| <b>User Safety Information</b> .....          | <b>6</b> |
| WARNINGS.....                                 | 6        |
| CAUTION .....                                 | 6        |
| <b>Equipment Symbols and Markings</b> .....   | <b>7</b> |
| Symbol Delineation .....                      | 7        |
| <b>Introduction and Operation</b> .....       | <b>8</b> |
| Manual Purpose .....                          | 8        |
| Late Potential (SAECG) .....                  | 8        |
| Signal Averaging .....                        | 9        |
| Patient Prep .....                            | 10       |
| Format.....                                   | 11       |
| Relearn .....                                 | 11       |
| End Test.....                                 | 11       |
| Starting a New Test on the Same Patient ..... | 11       |
| Exiting the Late Potentials Application ..... | 11       |
| Print.....                                    | 11       |
| Save .....                                    | 11       |
| Acquiring Late Potentials .....               | 12       |
| Acquisition Screen .....                      | 12       |
| Late Potential Directory.....                 | 13       |
| Edit patient demographic information: .....   | 14       |
| Erase record .....                            | 14       |
| Return Home .....                             | 14       |
| Print a copy of the Late Potential test ..... | 14       |
| Modify parameters and reanalyze .....         | 14       |
| Specifications .....                          | 15       |

# Notices

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## Manufacturer's Responsibility

Baxter is responsible for the effects on safety and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out only by persons authorized by Baxter.
- The device is used in accordance with the instructions for use.

## Responsibility of the Customer

The user of this device is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

## Equipment Identification

Baxter equipment is identified by a serial and reference number on the back of the device. Care should be taken so that these numbers are not defaced.

## Copyright and Trademark Notices

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## Notice to EU Users and/or Patients

Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

# Warranty Information

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## Your Welch Allyn Warranty

WELCH ALLYN, INC (hereinafter referred to as “Welch Allyn”) hereby warrants that Welch Allyn products (hereinafter referred to as “Product/s”) shall be free from defects in material and workmanship under normal use, service, and maintenance for the warranty period of such Product/s from Welch Allyn or an authorized distributor or representative of Welch Allyn. The warranty period is defined as twenty-four (24) months following the date of shipment from Welch Allyn. Normal use, service, and maintenance means operation and maintenance in accordance with appropriate instructions and/or information guides. This warranty does not apply to damage to the Product/s caused by any or all of the following circumstances or conditions:

- a) Freight damage;
- b) Parts and/or accessories of the Product/s not obtained from or approved by Welch Allyn;
- c) Misapplication, misuse, abuse, and/or failure to follow the Product/s instruction sheets and/or information guides;
- d) Accident; a disaster affecting the Product/s;
- e) Alterations and/or modifications to the Product/s not authorized by Welch Allyn;
- f) Other events outside of Welch Allyn’s reasonable control or not arising under normal operating conditions.

THE REMEDY UNDER THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT WITHOUT CHARGE FOR LABOR OR MATERIALS, OR ANY PRODUCT/S FOUND UPON EXAMINATION BY WELCH ALLYN TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Welch Allyn of any alleged defects promptly after discovery thereof within the warranty period. Welch Allyn’s obligations under the foregoing warranty will further be conditioned upon the assumption by the purchaser of the Product/s (i) of all carrier charges with respect to any Product/s returned to Welch Allyn’s principal place or any other place as specifically designated by Welch Allyn or an authorized distributor or representative of Welch Allyn, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Welch Allyn is limited and that Welch Allyn does not function as an insurer. A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Welch Allyn is not liable for loss, harm, or damage due directly or indirectly to an occurrence or consequence therefrom relating to the Product/s. If Welch Allyn should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Welch Allyn shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

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# User Safety Information

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**WARNING** Means there is the possibility of personal injury to you or others.



**CAUTION** Means there is the possibility of damage to the device.

**NOTE** Provides information to further assist in the use of the device.



## WARNINGS

- Reference the **ELI 380** User Manual for all warnings.
- Before attempting to use the device, the user must read and understand the contents of the user manual and any accompanying documents.



## CAUTION

- Reference the **ELI 380** User Manual for all cautions.

# Equipment Symbols and Markings

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## Symbol Delineation



**CAUTION** The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.

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**WARNING** The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. In addition, when used on a patient applied part, this symbol indicates defibrillation protection is in the cables.

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Indicates a separate waste collection is required for Waste of Electrical and Electronic Equipment (WEEE).

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Indicates compliance to applicable European Union directives.

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Refer to instruction manual / booklet.

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Medical Device

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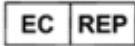
Model Number

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Reorder Number

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Authorized representative in the European Community

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Importer

# Introduction and Operation

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## Manual Purpose

This manual is intended to provide the user with information about:

- Understanding and using the **ELI 380** Late Potential (SAECG) option.
- The Late Potential (SAECG) feature is not available in the United States.

**NOTE** This manual may contain screen shots. Any screen shots are provided for reference only and are not intended to convey actual operating techniques. Consult the actual screen in the host language for specific wording.

## Late Potential [SAECG]

The **ELI 380** Late Potential (SAECG) option allows for patient ID entry and the acquisition, analysis, and printout of signal-averaged ECGs in order to detect ventricular late potentials. When acquiring late potentials, orthogonal bipolar leads XYZ are most commonly used.

Late potentials are low amplitude, relatively high-frequency bioelectric signals which can be detected at the end of the QRS. Late potentials can extend from the traditional end of a QRS (a few tens of milliseconds) into the ST segment. Late potential amplitude typically ranges from 1 to 20  $\mu$ V.

The presence of late potentials is generally accepted as indicating increased vulnerability to serious ventricular tachyarrhythmia's and as having significant correlation to inducing sustained ventricular tachycardia. Late potential is defined with the presence of any of the following three criteria:

- QRS duration longer than 114 milliseconds.
- Duration of a terminal QRS-interval signal of less than 40 microvolts and longer than 38 milliseconds.
- Root-mean-square amplitude (RMS) of less than 20 microvolts during the last 40 milliseconds of the QRS interval.

The Late Potential option displays averaged beats and filtered vector magnitude ECG data. All the measurements necessary to identify the existence of late potentials are displayed and printed. A printout to include non-filtered leads XYZ and the vector magnitude can be obtained at the end of the study.


From the home screen select the Late Potentials button located at the upper, middle screen. Once in the Late Potentials option, the user may return to the home screen for resting ECG acquisition at any time by selecting the Resting ECG button.

## Signal Averaging

Signal averaging is performed to reduce the level of noise that contaminates the ECG. The standard lead system for signal averaging is the uncorrected XYZ orthogonal lead system.


The application of signal averaging in electrocardiography allows for the detection of microvolt ( $\mu\text{V}$ ) level waveforms that are masked by noise when recorded with standard techniques. Sources of noise are muscle activity, electrodes, and amplifiers. Noise amplitude is typically 5 to 20  $\mu\text{V}$ .

During signal averaging, random noise (not synchronized with the QRS) is reduced in proportion to the square root of number of beats processed. The noise level can be lower than 1  $\mu\text{V}$  after averaging 100 to 500 cycles. (1  $\mu\text{V}$  = 1/100 of a millimeter on regular ECG paper.) The ELI 30 incorporates a state-of-the-art Baxter amplifier which guarantees low noise and high quality signal acquisition.

Select  to set various criteria to be used during the study:

- Late Potentials Filter Frequency (Hz)
  - Filter setting may vary between 25 and 100 Hz.
- Target Beat Count
  - Target beat count may vary between 1 and 9999 total beats acquired.
- Target Noise Level ( $\mu\text{V}$ )
  - Target noise levels may be selected from 0.001 to 99.999  $\mu\text{V}$ .

**NOTE** If the value for the Late Potentials Filter Frequency entered is below 25 Hz, the unit will automatically change the filter setting to 25 Hz. Likewise, if the filter frequency entered is above 100 Hz, the unit will automatically change the entry to 100 Hz.

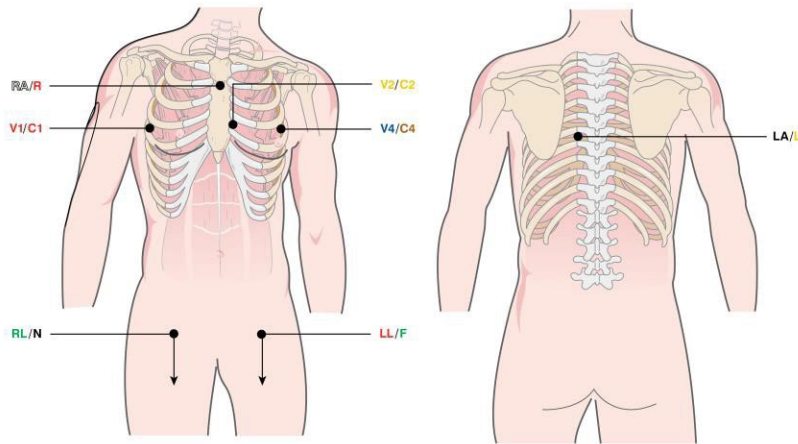
After a test has been acquired, select  to modify the following test parameters, after which the test will be reanalyzed:

- Late Potentials Filter Frequency (Hz)
  - Filter setting may vary between 25 and 100 Hz.

## Patient Prep

Careful skin preparation, a relaxed patient, and the use of good quality electrodes are essential to a good quality signal. Follow the skin preparation procedure explained in the ELI 380 User Manual. Prepare the electrodes and place them in the following positions:

- RA/R placed on the upper one third of the sternum
- LA/L placed posteriorly on the patient's back opposite V4
- LL/F placed in its normal position
- RL/N placed in its normal position
- V1/C1 placed in the fourth intercostal space in on the right midaxillary line
- V2/C2 placed in its normal position
- V4/C4 placed in the fourth intercostal space in on the left midaxillary line



Channel Designation

|      |    |    |    |     |    |    |    |
|------|----|----|----|-----|----|----|----|
| IEC  | C1 | C2 | C4 | R   | L  | N  | F  |
| AAMI | V1 | V2 | V4 | RAO | LA | RL | LL |

**NOTE** Leads V3, V5, and V6 are not used and do not generate lead fail messages.

$$\begin{aligned}
 X &= V4/C4 - V1/C1 \\
 Y &= LL/F - RA/R \\
 Z &= C2/V2 - LA/L.
 \end{aligned}$$

The XYZ leads are commonly combined to give the spatial vector magnitude which is a measure that sums the higher frequency information contained in all leads. Advantages of the vector magnitude over multiple ECG leads include analysis of a single ECG waveform and improved delineation of QRS offset. SAECG results are lead dependent and therefore comparative studies should be done if other electrode positions are used.

Once the patient is connected, the Start button will become active.

## Format

Modification of the display during Late Potential acquisition is achieved by positioning and selecting the cursor in the upper (grid) screen:

- Rhythm print speed may be changed between 5, 10, 25, and 50 mm per second.
- ECG display speed may be changed between 25 and 50 mm per second.
- Gain may be changed between 2.5, 5, 10, and 20 mm/mV.
- Plot filter may be changed between 0.05-40, 0.05-150, and 0.05-300 Hz.

## Relearn


The Relearn function allows for the deletion of the current QRS template and acquired data, and the ensuing re-acquisition of the QRS template with pertinent clinical data. The template will be used to execute the averaging process. The system might have problems acquiring the ECG due to poor signal quality. After Relearn, the system resets the QRS counting and the acquisition restarts.

## End Test


End Test ends the test before beat count criteria or RMS noise level have been obtained.

## Starting a New Test on the Same Patient

After acquiring a Late Potentials test on a patient, another test can be performed using the same patient and

associated demographic information. After the first test has been completed, select  then **Start**. The ELI 380 resets the QRS or acquired beat numbers and starts a new test. Follow the steps explained in *Acquiring Late Potentials*.

## Exiting the Late Potentials Application

To display the Standard Resting ECG Application screen at the end of the test, select , then **Resting ECG** located on the top of display panel.




## Print

Prints the final report.

## Save

The ELI 380 saves Late Potentials records automatically after acquisition without user prompting and are accessible in the Late Potential directory for viewing or printing.

## Acquiring Late Potentials

- Turn on the **ELI 380**.
- Select **Late Potentials** from the Home screen.
- Complete patient preparation, lead placement, and connection.
- Select  in the upper left corner. Fill in the patient information and select **Next**.
- Preview the ECG signal to check its quality. The patient must be relaxed and in a supine position.
- Select **Start** at the top of the display to begin acquiring late potential data.
- Use the **Relearn** function to acquire a new ECG template when the signals are good.
- Use  when the test parameters need to be modified with regard to late potential filter frequency, target beat count, or target noise level.
- Select **End Test** to complete the acquisition prior to meeting the criteria for beat count or RMS noise level.
- Use **Print** to obtain a hard copy of the report. The page includes XYZ averaged beats, vector magnitude signal, and measurement.
- Select  to go back to the real-time display, and select **Start** to begin another test. The **ELI 380** will automatically end the test when the user-defined criteria are met:
  - Total number of beats.
  - Target noise level.

## Acquisition Screen




The acquisition screen is divided into three sections:

- Signal preview with XYZ.
- SAECG median complex at 200 mm/sec and 40 mm/mV (default). Note, 4X gain setting is used for display of data.
- SAECG vector magnitude at 200 mm/sec and 1 mm/ $\mu$ V.

Clinicians can review the following information:

- Beats shows the total number of beats acquired and used in the analysis.
- RMS Noise (root mean square) displays actual running noise level and may display user-selected  $\mu$ V level to obtain.
  - RMS is the root mean square voltage of the QRS complex from onset to offset.
- Standard QRS Duration is presented in milliseconds.
  - QRS duration is measured from its onset to its offset.
- High Frequency QRS Duration is presented in milliseconds.
- RMS last 40 ms presents the measured amount of RMS over the last 40 ms.
  - RMS 40 is the root mean square voltage of the final 40 ms of the QRS complex.
- Durationunder40 $\mu$ V displays the late potential activity associated with the last 40 milliseconds of the vector magnitude waveform.
- Filter Frequency displays the current filter frequency.


Following Acquisition, the clinician or technician user can choose to do one of the following:

- Select  in the upper left corner to modify patient demographic information.
- Select **Erase** to erase the test, which will then bring the user back to the home screen.
- Select , which will automatically save the test and return the user to the home screen.
- Select **Print** to print the test.
- Select  to modify test parameters, and therefore reanalyze the study.

## Late Potential Directory


After a Late Potentials test has been acquired, the study is automatically saved in the Late Potential Directory after the Home button is selected.

To view the Late Potential Directory:

- From the home screen, select the Patient Information icon .
- In the Directory tab, a list of patients appears by Name, ID, DOB, and Last Acquisition.
- Select the desired patient.
- A pop-up window appears with all previous late potential test listed in order or last acquired to first acquired. Next to each test listed by date and time acquired, the status of the test is indicated and includes the following:
  - **Printed:** An X in this column indicates that the test has been printed.
  - **Transmitted:** this column does not apply to Late Potential tests.
  - **Deleted:** An X in this column indicates that the test has been marked for deletion and will be permanently deleted from the machine when space is needed in the memory for storage.
- The following actions can be completed within the pop-up window that shows previous tests:
  - Select **Erase All** to permanently delete all Late Potential tests associated with the selected patient.
  - Select **New LP** to begin a new Late Potential test using the same patient demographics as the patient selected.
  - Select **Done** to exit the pop-up window and return to the Late Potential Directory.

Upon selection of a Late Potential test from the Directory, the following may be completed using the listed steps:


## Edit patient demographic information:

- Select the  button
- When prompted, "Edit current late potentials demographics?" select **Yes**
- Modify demographics and select **OK** to save or **Cancel** to return to the report preview

## Erase record

- Select Erase on the top left corner of the screen
- When prompted "Erase late potentials record?" select **Yes** to erase or **No** to return to report preview


## Return Home

- Select  to return to the late potentials real-time view

## Print a copy of the Late Potential test

- Select **Print** to initiate a printout of the late potentials report

## Modify parameters and reanalyze

- Select  to modify the Late Potentials Filter Frequency.
- Select **OK** to accept the modification.
- The late potential test will be reanalyzed and with the new Late Potentials Filter Frequency.
- The reanalyzed test will automatically save in the place of the test with the previous parameters.

**NOTE** Selecting Erase will permanently delete the record from the device memory.

**NOTE** Only the Late Potentials Filter Frequency can be changed post acquisition, no other test parameters may be modified after the test has been completed.

## Specifications

| Feature                                       | Specification   |
|---|---|
| Frequency Response                            | 0.05 – 300 Hz   |
| Analysis sampling frequency                   | 1000 s/s  |
| Input signal resolution                       | 0.9375 $\mu\text{V}$ LSB  |
| Averaged signal resolution                    | 5 nV LSB  |
| Vector Magnitude signal resolution            | 5 nV LSB  |
| Heart rate range                              | 20 – 300 bpm  |
| QRS-amplitude range                           | 0.12 – 8 mV   |
| Target beat count selection                   | 1-9999  |
| Target noise level selection                  | 0.01 – 99 $\mu\text{V}$   |
| Leads used                                    | Bipolar X, Y and Z  |
| Display and print sensitivity                 | Raw data: 2.5, 5, 10 or 20 mm/mV<br>Average beat: 10, 20, 40 or 80 mm/mV<br>Filtered Vector Magnitude: 1 mm/ $\mu\text{V}$  |
| Display and print speed                       | Raw data: 5, 10, 25 and 50 mm/s<br>Average beat: 100 mm/s<br>Filtered Vector Magnitude: 200 mm/s  |
| Output Parameters                             | Number of beats averaged<br>RMS noise level ( $\mu\text{V}$ )<br>Unfiltered QRS duration<br>Filtered QRS duration<br>Filter Frequency<br>RMS voltage of terminal 40 ms of filtered QRS<br>Time that filtered QRS remains below 40 $\mu\text{V}$ |
| High Pass filter                              | Four pole Butterworth digital filter (24 dB/octave)   |
| Vector Magnitude Offset accuracy              | +/- 5 ms  |
| Within QRS High Frequency Signal Reproduction | +/- 3 $\mu\text{V}$   |

