



January 2017

**Important Technical Information:
Magnet Rate, Battery Voltage and ERI Indications:**

Important:

Magnet rate is not latched at ERI in the Affinity, Integrity, Identity, Frontier, Sustain, Verity, Victory, and Zephyr pacemaker families.

Magnet function is a standard feature in pacemakers used to assess and capture battery status. The magnet rate is considered a qualitative measurement and when transtelephonic monitoring (TTM) is used, the magnet rate is considered a primary indicator for device replacement. The measured battery voltage, battery impedance and battery current are considered to be a more appropriate indicator of actual battery condition.

Previous generations of St. Jude Medical pacemakers, such as Affinity, Integrity, Identity, Frontier, Sustain, Verity, Victory, and Zephyr models use a battery with Lithium/iodine battery technology which has predictable characteristics to help identify when a device needs to be considered for replacement due to battery utilization. Many factors including: programmed settings (amplitude, rate, and pulse width), lead impedances, and measurement/display tolerances play a role in determining device longevity and predictive indications of approaching elective replacement indicator (ERI). In the above referenced pacemaker families, the battery voltage is automatically measured every 23 hours and stored in device memory. Upon interrogation, the battery voltage displayed on the programmer is from the previously recorded daily measurement. The battery voltage displayed is based on the functional current level at the time of the daily battery check. In other words, if the pacemaker is inhibited at the time of the automatic measurement, the battery voltage and corresponding magnet rate may be higher as a result of lower current drain for the inhibited state. Conversely, if the device is pacing when the measurement is taken, a lower battery voltage will be recorded. Therefore the battery voltage measured and displayed by the programmer upon initial interrogation is not “real-time” and represents the last daily measurement taken by the device which may be up to 23 hours old. This effect of measurement taken at a time while the device is inhibited versus pacing may be more pronounced as the battery impedance increases as the device approaches ERI.

For the above referenced devices, ERI is indicated when any one or combination of the following conditions is identified: a battery voltage measurement is ≤ 2.50 volts, the demand rate is extended by 100ms, and/or an “ERI Indicated” message is displayed on the programmer upon interrogation. A magnet rate of 86.3 ppm or less indicates that ERI was identified during the last 23 hour measurement. Once ERI occurs, several features are automatically disabled to help ensure an adequate ERI to EOL replacement time is available. The disabled features include; Rate Response Sensor, Rest Rate, AF Suppression, and AutoCapture. Disabling these features at ERI and the demand rate extension by 100 ms, may in some cases allow the battery voltage to recover above 2.50 volts with a subsequent increase in magnet rate greater than 86.3 ppm even though the device has experienced an ERI trigger. This is what is referred to as a non-latching

ERI magnet rate. If the battery voltage recovers above 2.50 volts, the demand rate will remain extended by 100 ms and the disabled features will remain off until the user manually clears the ERI condition with a programmer and reprograms the parameters as desired. The demand rate extension of 100 ms can always be used as an indication of ERI even though the magnet rate may recover above the ERI magnet rate of 86.3 ppm. What this means is, that **once ERI has been triggered, the ERI magnet rate is not “latched” and in some cases may recover to a value above the ERI magnet rate.** Therefore, the magnet rate on the TTM will not show that ERI has been previously triggered and an in-office visit maybe needed to fully assess the battery status.

Once the ERI battery voltage remains at or below 2.50 volts a true ERI condition is present. At this point an expected ERI to EOL margin of approximately 3 months is magnet rate or demand rate is below ERI or ERI is indicated on an in-office programmer interrogation

In summary, the magnet rate is designed to show the user the relative condition of the battery voltage at the time of the last 23 hour measurement. The magnet rate is not latched at ERI and will only show an ERI magnet rate if the last daily measured battery voltage was ≤ 2.50 volts. The battery condition (and subsequent magnet rate) can fluctuate based on the factors mentioned above. For patients followed by TTM, an ERI indication can be routinely identified by a ERI rate on a magnet or demand ECG. If the demand and magnet rate ECGs differ in the assessment for ERI, then an in-office visit may be considered to confirm ERI.

Note: The newer generation St. Jude Medical pacemakers (Accent, Anthem, Endurity, Assurity, Allure and subsequent) use a Quasar Mid-Rate battery and the ERI magnet rate is latched once the device reaches elective replacement.

If you have any questions or would like to discuss this topic in greater detail, please do not hesitate to contact Technical Services:

Technical Services (U.S.)

Phone Number: 800.722.3774

Email: technicalservices@sjm.com

Technical Services (International)

Phone Number: +46.8.474.4147

Email: technical.support@sjm.com