SUMMARY

Boston Scientific PUNCTUA™, ENERGEN™, INCEPTA™, COGNIS® and TELIGEN® ICDs and CRT-Ds utilize battery voltage, charge time, and capacity consumed to calculate battery status. In these devices, a battery status of "Explant" indicates that device replacement must be scheduled.

Other Boston Scientific ICDs and CRT-Ds utilize two independent battery status monitors. Either **monitoring voltage or charge time** can trigger an Elective Replacement Indicator (ERI), which signals that device replacement should be scheduled.

Products Referenced

Boston Scientific ICDs and CRT-Ds.

See tables.

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the full instructions for use found at: www.bsci.com/ifu.

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

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker‡
ICD: Implantable Cardioverter Defibrillator

Contact Information

Americas
(Caribbean, and Central, North, and South America)
www.bostonscientific.com
Technical Services
LATITUDE® Clinician Support
1.800.CARDIAC (227.3422)
+1.651.582.4000
Patient Services
1.866.484.3268

Europe, Middle East, Africa
Technical Services
+32 2 416 7222
eurtechservice@bsci.com
LATITUDE Clinician Support
latitude.europe@bsci.com

Asia Pacific
Technical Services
+61 2 8063 8299
aptechservice@bsci.com
LATITUDE Clinician Support
latitude.asiapacific@bsci.com
japan.latitude@bsci.com (Japan)

Boston Scientific ICD and CRT-D Device Replacement Indicators

The following tables provide battery status information for applicable ICD and CRT-D device families. Each table contains battery status and the associated device behaviors.

INCEPTA™ / PUNCTUA™ / ENERGEN™ (ICD)
Models E050, E051, E052, E053, E140, E141, E142, E143, E160, E161, E162, E163
F140, F141, F142, F143, F050, F051, F052, F053, F160, F161, F162, F163

Battery Status	Device Behavior	How Battery Status is Derived
One Year Remaining	All therapy available. First 6 months, auto cap reform every 90 days. Second 6 months, auto cap reform every 30 days.	Capacity consumed* combined with battery voltage.
Explant	Device replacement must be scheduled. Sufficient battery capacity remains to monitor and pace 100% under existing conditions for three months and to deliver three maximum-energy shocks, or to deliver six maximum energy shocks with no pacing. 1.5 hours of RF/ZIP telemetry is available. No auto cap reforms.	– Capacity consumed* combined with battery voltage OR – Second‡ consecutive charge time > 15 sec
Battery Capacity Depleted	Device functionality is limited, and therapies can no longer be guaranteed. The patient should be scheduled for immediate device replacement. - Wanded telemetry interrogation only (RF telemetry is disabled) - Maximum-energy shocks and manual cap reform only (ATP therapy and low-energy shocks are disabled) - One ventricular zone (VF) with a rate threshold of 165 bpm - Brady Mode changes as follows: from Off → Off, AAI(R) → AAI, all others → VVI - LRL defaults to 50 ppm - Device programming (Brady Mode and Ventricular Tachy Mode can be programmed to Off; no other parameters are programmable) - The following features are disabled: – Daily measurement trends – Brady enhancement features – Episode storage – Diagnostics and EP tests – Real-time electrograms If the device reaches a point where insufficient battery capacity is available for continued operation, the device will revert to Storage Mode.	– 90 day timer from Explant OR – Capacity consumed* combined with battery voltage OR – Second‡ consecutive charge time > 30 sec

*Capacity consumed is the *energy used* while pacing and delivering shocks.
‡For a charge time greater than the charge time limit, a second confirmation cap reform is scheduled one hour later.

TELIGEN® (ICD) Models E102, E103, E110, E111, F102, F103, F110, F111		
Battery Status	Device Behavior	How Battery Status is Derived
One Year Remaining	All therapy available. First 6 months, auto cap reform every 90 days. Second 6 months, auto cap reform every 30 days.	Capacity consumed* combined with battery voltage.
Explant	Device replacement must be scheduled. Sufficient battery capacity remains to monitor and pace 100% under existing conditions for three months and to deliver three maximum-energy shocks or to deliver six maximum energy shocks with no pacing. 1.5 hours of RF/ZIP telemetry is available. No auto cap reforms.	– Capacity consumed* combined with battery voltage OR – Second‡ consecutive charge time > 15 sec
Battery Capacity Depleted	Device functionality is limited, and therapies can no longer be guaranteed. The patient should be scheduled for immediate device replacement. - Wanded telemetry interrogation only (RF telemetry is disabled) - Maximum-energy shocks and manual cap reform only (ATP therapy and low-energy shocks are disabled) - One ventricular zone (VF) with a rate threshold of 165 bpm - Brady Mode reverts to VVI if not Off - LRL defaults to 50 ppm - Device programming (Brady Mode and Ventricular Tachy Mode can be programmed to Off; no other parameters are programmable) - The following features are disabled: – Daily measurement trends – Brady enhancement features – Episode Storage – Diagnostic and EP tests – Real-time electrograms If the device reaches a point where insufficient battery capacity is available for continued operation, the device will revert to Storage Mode.	– 90 day timer from Explant OR – Capacity consumed* combined with battery voltage OR – Second‡ consecutive charge time > 30 sec

*Capacity consumed is the *energy used* while pacing and delivering shocks.
‡For a charge time greater than the charge time limit, a second confirmation cap reform is scheduled one hour later.

CONFIENT® RF HE (ICD) Models E030, F010, F030				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.89 V		≤ 12.0 sec
MOL1	All therapy available. Auto cap reform every 90 days.	2.89 V to > 2.75 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.75 V to > 2.60 V		> 12.0 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 90 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring under the following conditions: 100% DDDR BiV pacing at 60 ppm, 3.5V, 0.4 ms, 500 ohm pacing load; and six maximum energy charges. Replace the device before it reaches EOL. *NOTE: The pulse generator will not allow the ERI time period to extend beyond 93 days at which point EOL will be declared.*	2.60 V to > 2.40 V		> 13.1 Sec
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode and no ZIP telemetry is available.	≤ 2.40 V		> 30.0 sec

†The device will declare ERI when a charge time exceeding the ERI limit has been confirmed by a second charge (capacitor reform or therapeutic shock at maximum energy) above the ERI limit within a 24 hour period. End of Life (EOL) is declared if one charge time measurement exceeds the specified limit.

VITALITY® 2 EL DR/VR (ICD) Models T167, T177				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 9.0 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.48 V		> 9.0 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.48 V to > 2.17 V		> 13.1 sec and > 3.0 V > 18.9 sec and 3.0 V – 2.52 V > 13.1 sec and < 2.52 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.17 V		> 30.0 sec

VITALITY® 2 DR/VR (ICD) Model T165, T175				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 9.5 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.50 V		> 9.5 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.50 V to > 2.17 V		> 13.1 sec and > 3.0 V > 18.9 sec and 3.0 V – 2.53 V > 13.1 sec and < 2.53 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.17 V		> 30.0 sec

VITALITY® DR HE (ICD) Model T180				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 10.5 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.50 V		> 10.5 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 120 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 6 maximum-energy shocks.	2.50 V to > 2.20 V		> 14.6 sec and > 3.0 V > 26.1 sec and 3.0 V – 2.55 V > 14.6 sec and < 2.55 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.20 V		> 30.0 sec

†The device will declare ERI when a charge time exceeding the ERI limit has been confirmed by a second charge (capacitor reform or therapeutic shock at maximum energy) above the ERI limit within a 24 hour period. End of Life (EOL) is declared if one charge time measurement exceeds the specified limit.

VITALITY® DS DR/VR (ICD) Model T125, T135				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 9.5 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.48 V		> 9.5 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.48 V to > 2.17 V		> 13.1 sec and > 3.0 V > 18.9 sec and 3.0 V – 2.53 V > 13.1 sec and < 2.53 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.17 V		> 30.0 sec

VITALITY® EL (ICD) Model T127				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 9.0 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.48 V		> 9.0 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.48 V to > 2.17 V		> 13.1 sec and > 3.0 V > 18.9 sec and 3.0 V – 2.52 V > 13.1 sec and < 2.52 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.17 V		> 30.0 sec

VITALITY® VR/DR/DR+ (ICD) Models 1870, 1871				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.8 V		≤ 15.9 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.8 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.48 V		> 15.9 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.48 V to > 2.15 V		> 17.9 sec and > 3.0 V > 23.0 sec and 3.0 V – 2.53 V > 17.9 sec and < 2.53 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.15 V		> 30.0 sec

†The device will declare ERI when a charge time exceeding the ERI limit has been confirmed by a second charge (capacitor reform or therapeutic shock at maximum energy) above the ERI limit within a 24 hour period. End of Life (EOL) is declared if one charge time measurement exceeds the specified limit.

VENTAK® PRIZM® 2 DR/VR (ICD) Models 1860,1861				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 3.0 V		≤ 15.9 sec
MOL1	All therapy available. Auto cap reform every 90 days.	3.0 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.50 V		> 15.9 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.50 V to > 2.1 V		> 17.4 Sec
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.1 V		> 30.0 sec

VENTAK® PRIZM® VR HE/DR HE (ICD) Models 1852, 1853, 1857, 1858				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 3.0 V		≤ 15.9 sec
MOL1	All therapy available. Auto cap reform every 90 days.	3.0 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.45 V		> 15.9 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.45 V to > 2.1 V		> 17.9 Sec
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.1 V		> 30.0 sec

VENTAK® PRIZM®DR/VR (ICD) Models 1850, 1851, 1855, 1856				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 3.0 V		≤ 15.9 sec
MOL1	All therapy available. Auto cap reform every 90 days.	3.0 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.45 V		> 15.9 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.45 V to > 2.1 V		> 17.9 Sec
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.1 V		> 30.0 sec

†The device will declare ERI when a charge time exceeding the ERI limit has been confirmed by a second charge (capacitor reform or therapeutic shock at maximum energy) above the ERI limit within a 24 hour period. End of Life (EOL) is declared if one charge time measurement exceeds the specified limit.

INCEPTA™ / PUNCTUA™ / ENERGEN™ (CRT-D) Models N050, N051, N052, N053, N140, N141, N142, N143, N160, N161, N162, N163, N164, N165 P052, P053, P142, P143, P162, P163, P165		
Battery Status	Device Behavior	How Battery Status is Derived
One Year Remaining	All therapy available. First 6 months, auto cap reform every 90 days. Second 6 months, auto cap reform every 30 days.	Capacity consumed* combined with battery voltage.
Explant	Device replacement must be scheduled. Sufficient battery capacity remains to monitor and pace 100% under existing conditions for three months and to deliver three maximum-energy shocks or to deliver six maximum energy shocks with no pacing. 1.5 hours of RF/ZIP telemetry is available. No auto cap reforms.	– Capacity consumed* combined with battery voltage OR – Second‡ consecutive charge time > 15 sec
Battery Capacity Depleted	Device functionality is limited, and therapies can no longer be guaranteed. The patient should be scheduled for immediate device replacement. - Wanded telemetry interrogation only (RF telemetry is disabled) - Maximum-energy shocks and manual cap reform only (ATP therapy and low-energy shocks are disabled) - One ventricular zone (VF) with a rate threshold of 165 bpm - Brady Mode changes as follows: from Off → Off, from AAI(R) → AAI, from all others →VVI/BiV - LRL defaults to 50 ppm - Device programming (Brady Mode and Ventricular Tachy Mode can be programmed to Off; no other parameters are programmable) - The following features are disabled: – Daily measurement trends – Brady enhancement features – Episode storage – Diagnostics and EP tests – Real-time electrograms If the device reaches a point where insufficient battery capacity is available for continued operation, the device will revert to Storage Mode.	– 90 day timer from Explant OR – Capacity consumed* combined with battery voltage OR – Second‡ consecutive charge time > 30 sec
COGNIS® (CRT-D) Models N118, N119, N106, N107, N108, P106, P107, P108		
Battery Status	Device Behavior	How Battery Status is Derived
One Year Remaining	All therapy available. First 6 months, auto cap reform every 90 days. Second 6 months, auto cap reform every 30 days.	Capacity consumed* combined with battery voltage.
Explant	Device replacement must be scheduled. Sufficient battery capacity remains to monitor and pace 100% under existing conditions for three months and to deliver three maximum-energy shocks or to deliver six maximum energy shocks with no pacing. 1.5 hours of RF/ZIP telemetry is available. No auto cap reforms.	– Capacity consumed* combined with battery voltage OR – Second‡ consecutive charge time > 15 sec
Battery Capacity Depleted	Device functionality is limited, and therapies can no longer be guaranteed. The patient should be scheduled for immediate device replacement. - Wanded telemetry interrogation only (RF telemetry is disabled) - Maximum-energy shocks and manual cap reform only (ATP therapy and low-energy shocks are disabled) - One ventricular zone (VF) with a rate threshold of 165 bpm - Brady Mode reverts to VVI/BiV if not Off - LRL defaults to 50 ppm - Device programming (Brady Mode and Ventricular Tachy Mode can be programmed to Off; no other parameters are programmable) - The following features are disabled: – Daily measurement trends – Brady enhancement features – Episode Storage – Diagnostic and EP tests – Real-time electrograms If the device reaches a point where insufficient battery capacity is available for continued operation, the device will revert to Storage Mode.	– 90 day timer from Explant OR – Capacity consumed* combined with battery voltage OR – Second‡ consecutive charge time > 30 sec

*Capacity consumed is the *energy used* while pacing and delivering shocks.
‡For a charge time greater than the charge time limit, a second confirmation cap reform is scheduled one hour later.

LIVIAN® RF HE (CRT-D) Models H227, H229, H247, H249				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.89 V		≤ 12.0 sec
MOL1	All therapy available. Auto cap reform every 90 days.	2.89 V to > 2.75 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.75 V to > 2.60 V		> 12.0 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 90 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring under the following conditions: 100% DDDR BiV pacing at 60 ppm, 3.5V, 0.4 ms, 500 ohm pacing load; and six maximum energy charges. Replace the device before it reaches EOL. *NOTE: The pulse generator will not allow the ERI time period to extend beyond 93 days at which point EOL will be declared.*	2.60 V to > 2.40 V		> 13.1 Sec
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode and no ZIP telemetry is available.	≤ 2.40 V		> 30.0 sec

LIVIAN® RF (CRT-D) Models H220, H225, H240, H245				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.89 V		≤ 9.5 sec
MOL1	All therapy available. Auto cap reform every 90 days.	2.89 V to > 2.75 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.75 V to > 2.60 V		> 9.5 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 90 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring under the following conditions: 100% DDDR BiV pacing at 60 ppm, 3.5V, 0.4 ms, 500 ohm pacing load; and six maximum energy charges. Replace the device before it reaches EOL. *NOTE: The pulse generator will not allow the ERI time period to extend beyond 93 days at which point EOL will be declared.*	2.60 V to > 2.40 V		> 10.5 Sec
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode and no ZIP telemetry is available.	≤ 2.40 V		> 30.0 sec

CONTAK RENEWAL® 3 RF HE, CONTAK RENEWAL® 4 RF HE (CRT-D) Models H217, H219, H239				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 10.5 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.50 V		> 10.5 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.50 V to > 2.15 V		> 13.1 sec and > 3.0 V > 26.1 sec and 3.0 V – 2.55 V > 13.1 sec and < 2.55 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode. No ZIP telemetry available.	≤ 2.15 V		> 30.0 sec

†The device will declare ERI when a charge time exceeding the ERI limit has been confirmed by a second charge (capacitor reform or therapeutic shock at maximum energy) above the ERI limit within a 24 hour period. End of Life (EOL) is declared if one charge time measurement exceeds the specified limit.

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CONTAK RENEWAL® 3 RF, CONTAK RENEWAL® 4 RF (CRT-D) Models H210, H215, H230, H235				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 7.9 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.50 V		> 7.9 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.50 V to > 2.15 V		> 12.5 sec and > 3.0 V > 20.0 sec and 3.0 V – 2.55 V > 12.5 sec and < 2.55 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode. No ZIP telemetry available.	≤ 2.15 V		> 30.0 sec

CONTAK RENEWAL® 3 HE , CONTAK RENEWAL® 4 HE (CRT-D) Models H177, H179,H197, H199				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 12.0 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.50 V		> 12.0 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.50 V to > 2.18 V		> 13.1 sec and > 3.0 V > 26.1 sec and 3.0 V – 2.55 V > 13.1 sec and < 2.55 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.18 V		> 30.0 sec

CONTAK RENEWAL® 3, CONTAK RENEWAL® 4 (CRT-D) Models H170, H175, H190, H195				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 8.5 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.48 V		> 8.5 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.48 V to > 2.15 V		> 12.5 sec and > 3.0 V > 20.0 sec and 3.0 V – 2.53 V > 12.5 sec and < 2.53 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy shocks. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.15 V		> 30.0 sec

†The device will declare ERI when a charge time exceeding the ERI limit has been confirmed by a second charge (capacitor reform or therapeutic shock at maximum energy) above the ERI limit within a 24 hour period. End of Life (EOL) is declared if one charge time measurement exceeds the specified limit.

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CONTAK RENEWAL® 4 AVT® HE (CRT-D) Models M177, M179				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 12.0 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.50 V		> 12.0 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.50 V to > 2.18 V		> 13.1 sec and > 3.0 V > 23.0 sec and 3.0 V – 2.55 V > 13.1 sec and < 2.55 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy ventricular shocks and Atrial Mode is OFF. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.18 V		> 30.0 sec

CONTAK RENEWAL® 4 AVT® (CRT-D) Models M170, M175				
Battery Status	Device Behavior	Monitoring Voltage Indicator	OR	Charge Time Indicator†
BOL	All therapy available. Auto cap reform every 90 days.	> 2.80 V		≤ 8.0 sec
MOL1	All therapy available. Auto cap reform every 30 days.	2.80 V to > 2.65 V		N/A
MOL2	All therapy available. Auto cap reform every 30 days.	2.65 V to > 2.48V		> 8.0 sec
ERI	Device replacement should be scheduled. All therapy available. Auto cap reform every 30 days. Beeps 16 R-wave sync tones every 6 hours if Beep-On-ERI feature is programmed On. Three months of monitoring and 100% brady pacing (under nominal conditions) and 10 maximum-energy shocks.	2.48 V to > 2.18 V		> 12.0 sec and > 3.0 V > 20.0 sec and 3.0 V – 2.53 V > 12.0 sec and < 2.53 V
EOL	Replace the device as therapy cannot be guaranteed. No ATP or low-energy ventricular shocks and Atrial Mode is OFF. The device attempts to deliver the maximum-energy shocks unless there is insufficient battery capacity, at which time it will revert to storage mode.	≤ 2.18 V		> 30.0 sec

†The device will declare ERI when a charge time exceeding the ERI limit has been confirmed by a second charge (capacitor reform or therapeutic shock at maximum energy) above the ERI limit within a 24 hour period. End of Life (EOL) is declared if one charge time measurement exceeds the specified limit.

CRT-D Systems from Boston Scientific CRM

Indications and Usage

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

- Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms
- Left bundle branch block (LBBB) with QRS ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

Contraindications

There are no contraindications for this device.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have sterile external and internal defibrillator protection available during implant. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Do not subject a patient with an implanted pulse generator to diathermy, Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads.. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs.

For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implant and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/ precautions and adverse events. Rx only. (Rev. P)

NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/CRT-D-systems.html

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ICD Systems from Boston Scientific CRM

ICD Indications and Usage

ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. ICDs (i.e. Vitality AVT) with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have or are at risk of developing atrial tachyarrhythmias.

Contraindications

Use of ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system.. For single patient use only Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures. Always have sterile external and internal defibrillator protection available during implant. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Do not subject a patient with an implanted pulse generator to diathermy.. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias.. (applies to dual-chamber devices only.) Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads.
For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments follow-up testing; explant and disposal; post-therapy pulse generator follow-up. Advise patients to avoid sources of electromagnetic interference (EMI).

Potential Adverse Events

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system - patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/ precautions and adverse events. Rx only. (Rev. O)

NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/ICD-systems.html?