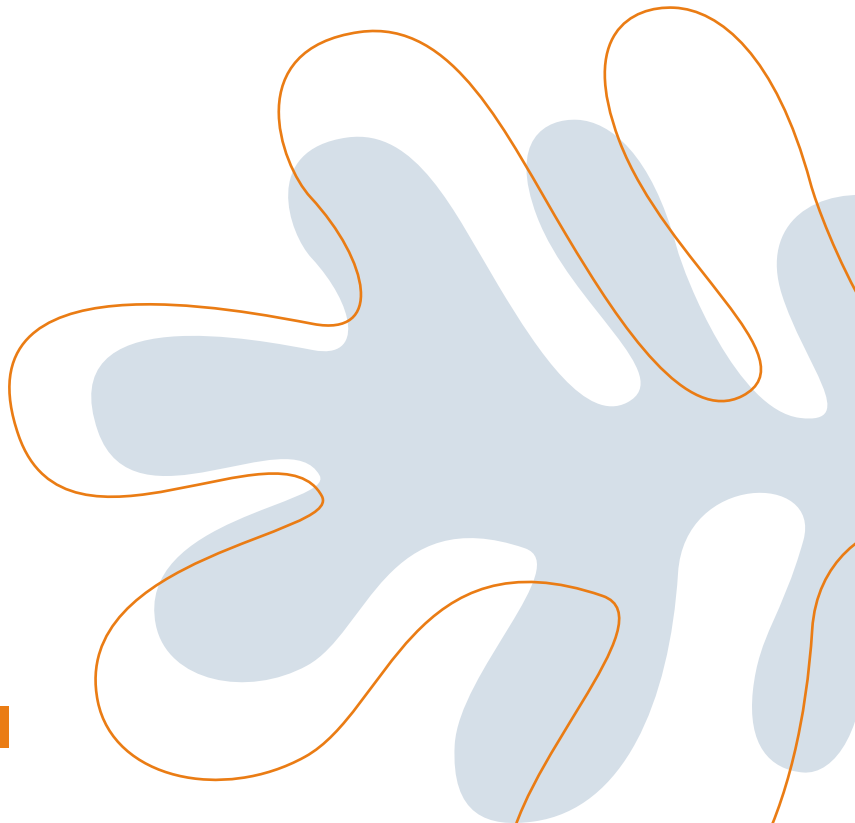




CRT-D MODEL 184I

TECHNICAL SPECIFICATIONS



SONR HEMODYNAMIC SENSOR (Based on cardiac contractility measurements at rest and exercise, SonR automatically adapts CRT parameters on a weekly basis)	
SonR CRT Optimization	OFF - Monitor - AV - AV+VV
Exercise AV opt. rate (min ⁻¹)	From 70 to 120 by steps of 5; 90
SonR signal recording during A and V arrhythmias	Up to 5 min
SonR contractility trend	Weekly average over last six months
RESYNCHRONIZATION PACING	
BASIC PARAMETERS	
Mode	<u>VVI</u> - VVIR - DDD - DDDR - DDD/DDIR - DDI - DDIR - SafeR - SafeR-R
V chambers	R+L , L+R, Right, Left
Basic rate (min ⁻¹)	From 30 to 90 by steps of 5 ; 60
Maximum rate (min ⁻¹)	From 100 to 145 by steps of 5 ; 120
Rate hysteresis (%)	0 - 5 - 10 - 20 - 35
Rest AV delay (ms)	30 - 40 - 45 - 55 - 65 - 70 - 80 - 85 - 95 - 100 - 110 - 115 - 125 - 135 - 140 - 150 - 155 - 165 - 170 - 180 - 190 - 195 - 205 - 210 - 220 - 225 - 235 - 250
Exercise AV delay (ms)	30 - 40 - 45 - 55 - 65 - 70 - 80 - 85 - 95 - 100 - 110 - 115 - 125 - 135 - 140 - 150 - 155 - 165 - 170 - 180 - 190 - 195 - 205 - 210 - 220 - 225 - 235 - 250
AVD Paced/Sensed Offset (ms)	0 - 10 - 15 - 25 - 30 - 40 - 45 - 55 - 65 - 70 - 80 - 85 - 95 - 100 - 110 - 115 - 125
VV delay (ms)	0 - 16 - 24 - 32 - 40 - 48 - 56 - 64
Atrial sensitivity (mV)	From 0.2 to 4 by steps of 0.2 ; 0.4
Atrial amplitude (V)	1 - 1.5 - 2 - 2.5 - 3 - 3.5 - 4 - 4.5 - <u>5</u> - 6
Atrial pulse width (ms)	0.12 - 0.25 - 0.35 - 0.5 - 0.6 - 0.75 - 0.85 - 1
Ventricular sensitivity (mV)	From 0.4 to 4 by steps of 0.2 ; 0.4
RV amplitude (V)	1 - 1.5 - 2 - 2.5 - 3 - 3.5 - 4 - 4.5 - <u>5</u> - 6
LV amplitude (V)	0.1 - 0.25 - 0.35 - 0.5 - 0.6 - 0.75 - 0.85 - 1 - 1.1 - 1.25 - 1.35 - 1.5 - 1.6 - 1.75 - 1.85 - 2 - 2.1 - 2.25 - 2.35 - 2.5 - 2.6 - 2.75 - 2.85 - 3 - 3.1 - 3.25 - 3.35 - 3.5 - 3.6 - 3.75 - 3.85 - 4 - 4.1 - 4.25 - 4.35 - 4.5 - 4.6 - 4.75 - 4.85 - <u>5</u> - 5.1 - 5.25 - 5.35 - 5.5 - 5.6 - 5.75 - 5.85 - 6 - 6.1 - 6.25 - 6.35 - 6.5 - 6.6 - 6.75 - 6.85 - 7
RV pulse width (ms)	0.12 - 0.25 - 0.35 - 0.5 - 0.6 - 0.75 - 0.85 - 1
LV pulse width (ms)	0.12 - 0.25 - 0.35 - 0.5 - 0.6 - 0.75 - 0.85 - 1 - 1.10 - 1.25 - 1.35 - 1.50 - 1.60 - 1.75 - 1.85 - 2
LV pacing polarity	LV Bipolar - LV tip to RV ring - LV ring to RV coil - LV tip to RV coil - LV ring to CAN - LV tip to CAN
POST-SHOCK MODE	
Mode	OFF - VVI - DDI - DDD
Duration	10s - 20s - 30s - 1min - 2min - 3min - 4min - 5min
Basic rate (min ⁻¹)	From 50 to 90 by steps of 5 ; 60
Rest AV delay (ms)	30 - 40 - 45 - 55 - 65 - 70 - 80 - 85 - 95 - 100 - 110 - 115 - 125 - 135 - 140 - 150 - 155 - 165 - 170 - 180 - 190 - 195 - 205 - 210 - 220 - 225 - 235 - 250
Exercise AV delay (ms)	30 - 40 - 45 - 55 - 65 - 70 - 80 - 85 - 95 - 100 - 110 - 115 - 125 - 135 - 140 - 150 - 155 - 165 - 170 - 180 - 190 - 195 - 205 - 210 - 220 - 225 - 235 - 250
AVD Paced/Sensed Offset (ms)	0 - 10 - 15 - 25 - 30 - 40 - 45 - 55 - 65 - 70 - 80 - 85 - 95 - 100 - 110 - 115 - 125
A amplitude (V)	1 - 1.5 - 2 - 2.5 - 3 - 3.5 - 4 - 4.5 - <u>5</u> - 6
A pulse width (ms)	0.12 - 0.25 - 0.35 - 0.5 - 0.6 - 0.75 - 0.85 - 1
RV amplitude (V)	1 - 1.5 - 2 - 2.5 - 3 - 3.5 - 4 - 4.5 - <u>5</u> - 6
LV amplitude (V)	0.1 - 0.25 - 0.35 - 0.5 - 0.6 - 0.75 - 0.85 - 1 - 1.1 - 1.25 - 1.35 - 1.5 - 1.6 - 1.75 - 1.85 - 2 - 2.1 - 2.25 - 2.35 - 2.5 - 2.6 - 2.75 - 2.85 - 3 - 3.1 - 3.25 - 3.35 - 3.5 - 3.6 - 3.75 - 3.85 - 4 - 4.1 - 4.25 - 4.35 - 4.5 - 4.6 - 4.75 - 4.85 - <u>5</u> - 5.1 - 5.25 - 5.35 - 5.5 - 5.6 - 5.75 - 5.85 - 6 - 6.1 - 6.25 - 6.35 - 6.5 - 6.6 - 6.75 - 6.85 - 7
RV pulse width (ms)	0.12 - 0.25 - 0.35 - 0.5 - 0.6 - 0.75 - 0.85 - 1
LV pulse width (ms)	0.12 - 0.25 - 0.35 - 0.5 - 0.6 - 0.75 - 0.85 - 1 - 1.10 - 1.25 - 1.35 - 1.50 - 1.60 - 1.75 - 1.85 - 2
ADVANCED BRADY FEATURES	
Smoothing	OFF - Very slow - Slow - Medium - Fast
Mode Switch	ON - OFF
Mode Switch Rate (min ⁻¹)	From 30 to 90 by steps of 5 ; 60
Anti-PMT protection	Termin - Reprog
Physical activity	Very low - Low - Medium - High - Very high
SafeR PARAMETERS	
Max. Pause (s)	2 - 3 - 4
Long PR: max (ms)	80 - 100 - 125 - 150 - 200 - 250 - 300 - 350 - 400 - 450 - 500
Long PR: min (ms)	80 - 100 - 125 - 150 - 200 - 250 - 300 - 350 - 400 - 450 - 500
AVB I switch	Rest+Exercise - Exercise

As-shipped values shown in **bold**. Nominal values shown underlined.

ARRHYTHMIA PREVENTION	
VENTRICULAR ARRHYTHMIA PREVENTION	
Atrial pacing on PVC	ON - OFF
Post extrasystolic pause suppression	ON - OFF
Acceleration on PVC	ON - OFF
Max acceleration rate (min ⁻¹)	From 60 to 145 by steps of 5 ; 100
ATRIAL ARRHYTHMIA PREVENTION	
Overdrive	ON - OFF
Max Overdrive rate (min ⁻¹)	80 - 90 - 100 - 110 - 130
PAC Pause Suppression	ON - OFF
VENTRICULAR ARRHYTHMIA DETECTION	
THERAPY ZONES	
Slow VT detection zone	Slow VT ON - Slow VT OFF
VT detection zone	VT ON - VT OFF
Fast VT / VF detection zone	Fast VT + VF ON - VF ON
Slow VT rate (lower limit) (min ⁻¹)	From 100 to 200 by steps of 5 ; 190
VT rate (lower limit) (min ⁻¹)	130 - 135 - 140 - 145 - 150 - 155 - 160 - 165 - 170 - 175 - 180 - 185 - 190 - 195 - 200 - 210 - 220 - 230
VF rate (lower limit) (min ⁻¹)	150 - 155 - 160 - 165 - 170 - 175 - 180 - 185 - 190 - 195 - 200 - 210 - 220 - 230 - 240
Fast VT rate (upper limit) (min ⁻¹)	155 - 160 - 165 - 170 - 175 - 180 - 185 - 190 - 195 - 200 - 210 - 220 - 230 - 240 - 255
Slow VT persistence (cycles)	4 - 6 - 8 - 12 - 16 - 20 - 30 - 50 - 100 - 200
VT persistence (cycles)	4 - 6 - 8 - 12 - 16 - 20 - 30 - 50 - 100 - 200
VF persistence (cycles)	From 4 to 20 by steps of 1 ; 6
DETECTION CRITERIA	
Slow VT and VT detection criteria	Rate Only - Stability - Stability+ - Stability/Acc - Stability+/Acc - PARAD - PARAD+
Fast VT detection criteria	Rate+Stability - Rate Only
Majority (X,Y): Y (cycles)	8 - 12 - 16
Majority (X,Y): X (%)	65 - 70 - 75 - 80 - 90 - 95 - 100
Window of PR association	63 ms
Window of RR stability for Slow VT and VT (ms)	30 - 45 - 65 - 80 - 95 - 110 - 125
Window of RR stability for fast VT (ms)	30 - 45 - 65
Prematurity acceleration (%)	6 - 13 - 19 - 25 - 31 - 38 - 44 - 50
Long cycle persistence extension (cycles)	From 0 to 16 by steps of 1 ; 10
Long cycle gap (ms)	15 - 30 - 45 - 65 - 80 - 95 - 110 - 125 - 140 - 155 - 170 - 190 - 205
Atrial monitoring	Yes - No
T-wave filter	Embedded
VENTRICULAR ARRHYTHMIA THERAPIES	
COMMON PARAMETERS	
Enable ATP therapy	Yes - No
Enable shock therapy	Yes - No
ATP pacing chamber	Right - Left - R+L
Pacing amplitude during ATP therapies	7 V
Polarity alternation (42 J)	Yes - No
Atrial coil (SVC) present	Yes - No
Active case	Yes - No
Shock configuration	Case to RV - SVC to RV - Case + SVC to RV - RV to Case - RV to SVC - RV to Case + SVC
Waveform	Constant tilt (50% - 50%)
SVC Exclusion (shock < 15J)	Yes - No
Stored energy for the shock MAX	42 J
Auto-Switch ATP	Yes - No
ATP PROGRAM PER ZONE (slow VT, VT, fast VT/VF)	
2 ATP programs	OFF - Burst - Burst+Scan - Ramp - Ramp+Scan
Number of sequences	1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 - 11 - 12 - 13 - 14 - 15
Cycles in first sequence	1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 - 11 - 12 - 13 - 14 - 15
Cycles added per sequence	0 - 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 - 11 - 12 - 13 - 14 - 15
Coupling interval (%)	50 - 55 - 60 - 65 - 70 - 75 - 80 - 85 - 90 - 95
Ramp decrement (per cycle) (ms)	0 - 4 - 8 - 12 - 16 - 20 - 30 - 40 - 50 - 60
Scan decrement (per sequence) (ms)	0 - 4 - 8 - 12 - 16 - 20 - 30 - 40 - 50 - 60
Time limit (min)	0.5 - 1 - 1.5 - 2 - 2.5 - 3 - 3.5 - 4
Minimum cycle length (ms)	95 - 110 - 125 - 140 - 155 - 170 - 190 - 205 - 220 - 235 - 250 - 265 - 280 - 295 - 310
SHOCK PROGRAM PER ZONE (slow VT, VT, fast VT/VF, VF)	
2 Shocks with programmable energy (J)	OFF - 0.5 - 0.8 - 1 - 1.3 - 1.5 - 2 - 2.5 - 3 - 3.5 - 4 - 5 - 6 - 7 - 8 - 9 - 10 - 12 - 14 - 16 - 18 - 20 - 22 - 24 - 26 - 28 - 30 - 32 - 34 - 42
Number of Shock Max (42J)	OFF - 1 - 2 - 3 - 4*
NOTES: In fast VT / VF zone : only one ATP program programmable, shocks mandatory and programmable. *In the VF zone, as-shipped and nominal value: 4 Shocks Max.	

ADVANCED SENSING PARAMETERS

ATRIAL REFRACTORY PERIODS

Atrial refractory period post ventricular sensing (ms)	45 - 65 - 80 - 95 - 110 - 125 - 140 - 155
Atrial refractory period post ventricular pacing (ms)	80 - 95 - 110 - 125 - 140 - 155
Post atrial sensing	47 ms
Post atrial pacing	109 ms

VENTRICULAR REFRACTORY PERIODS

Post ventricular sensing	95 ms
Post ventricular pacing	220 ms
Post atrial pacing (blanking)	16 ms
Committed period	95 ms

SENSITIVITY MARGINS

Atrial post pacing/sensing margin (mV)	From 0 to 1 by steps of 0.2 ; 0.4
Ventricular post pacing margin (mV)	From 0 to 2 by steps of 0.2 ; 0.8

RESPONSE TO NOISE

Automatic sensitivity on noise	ON - OFF
V pacing on noise	ON - OFF

(REMOTE) ALERTS & WARNINGS

BASIC PARAMETERS

RF for Remote Monitoring (1)	ON - OFF
Alerts (1)	ON - OFF

(1) Remote Monitoring and Remote Alerts are turned on automatically if Shocks are programmed ON

SYSTEM ALERTS

Battery depletion - RRT	ON - OFF
Device reset	ON - OFF
Excessive charge time (>25s)	ON - OFF
System integrity	ON - OFF

LEADS ALERTS

Abnormal A lead impedance	ON - OFF
Low limit (ohm)	200 - 250 - 300 - 350 - 400 - 450 - 500
High limit (ohm)	1500 - 1750 - 2000 - 2500 - 3000
Abnormal RV lead impedance	ON - OFF
Low limit (ohm)	200 - 250 - 300 - 350 - 400 - 450 - 500
High limit (ohm)	1500 - 1750 - 2000 - 2500 - 3000
Abnormal LV lead impedance	ON - OFF
Low limit (ohm)	200 - 250 - 300 - 350 - 400 - 450 - 500
High limit (ohm)	1500 - 1750 - 2000 - 2500 - 3000
Abnormal RV coil continuity	ON - OFF
Abnormal SVC coil continuity	ON - OFF
Abnormal shock impedance	ON - OFF

CLINICAL ALERTS

V Oversensing	ON - OFF
High AT/AF burden	ON - OFF
Limit (h in 24h)	0.5 - 1 - 3 - 6 - 12 - 24
Fast V rate during AT/AF	ON - OFF
Rate Limit (min ⁻¹)	80 - 90 - 100 - 110 - 120
Duration limit (h)	0.5 - 1 - 3 - 6 - 12 - 24
Limited % of V pacing in CRT	ON - OFF
Limit per 24 h (%)	50 - 70 - 80 - 85 - 90 - 95

THERAPY INFORMATION

ATP delivered	ON - OFF
Shock disabled	ON - OFF
Shock delivered	OFF, All shocks, Inefficient shock, Inefficient max shock



DIAGNOSTICS AIDA

(Automatic Interpretation for Diagnosis Assistance)

Automatic analysis

- Automatic analysis of stored data providing advices on device management on 3 domains: basic functioning, arrhythmia management, AV conduction

Programmable resolution

- Daily (6 months memory) or hourly (1 day memory)

Trending

- Summary screen with 6-months trends of heart rate, % pacing, VT/VF occurrence and AF burden

Sensing monitor

- Autosensing histograms of P & R wave amplitudes

Lead monitor

- Lead impedance and continuity curves

Arrhythmia diary

- A & V arrhythmia episode distribution and therapy analysis per zone

AV conduction analysis

- Type of block, circadian or activity distribution, progression over time

Arrhythmia episode documentation

- High resolution RV EGM and programmable channel A / RV coil-CAN / SVC coil-CAN / RV coil-SVC coil / LV bip / LV tip-RV ring / A ring-CAN / RV tip-CAN / RV ring-CAN / LV tip-CAN / LV ring-CAN:
 - EGM & Markers on A & V arrhythmia: up to 16 episodes and 25.6 min EGM
 - EGM & Markers on AV block switch and lead impedance rise: up to 10 episodes and 5 min EGM

DEVICE FOLLOW-UP

Overview screen

- All useful indicators gathered in one screen, to save time on device follow-ups when no further testing is required

Test Assistant

- Chained test sequence with automatic saving/printing of results

Sensing tests

- Real-time traces EGM channels: A / RV / A ring-CAN / RV coil-CAN / RV tip-CAN / RV ring-CAN / RV coil-SVC / SVC-CAN / LV / LV tip-RV ring / LV tip-CAN / LV ring-CAN
- Real-time SonR signal

Pacing tests

- Programmable heart rate, mode (A00/V00/D00) and initial amplitude

Electro-Physiologic Studies (EPS)

- VT, VF induction by programmed stimulation, T wave shock or 30 Hz pacing
- Ventricular ATP and shocks

Ready for Smartview remote monitoring

with Smartview home monitor

Ready for wireless interrogation and programming

with Orchestra Plus programmer equipped with Orchestra Plus Link accessory

6-YEAR WARRANTY*

PHYSICAL AND ELECTRICAL CHARACTERISTICS

DIMENSIONS	72.3 x 54.3 x 11.1 mm
WEIGHT	87 g
VOLUME	33 cc
CONNECTORS	1*DF4, 1*IS-1 bipolar (LV unipolar compatible), 1*SonR (IS-1 bipolar compatible)
BATTERY MODEL	Quasar High Rate - GB 3070
BATTERY CAPACITY	2192 mAh
LONGEVITY	10.0 years
Biventricular pacing in DDD mode, 30% in atrium, 100% in both ventricles, at 60 min ⁻¹ , 600 Ohm, A and RV pacing amplitude 2.5 V, LV pacing amplitude 3V, 0.35 ms 3 max shock per year, sensor OFF, SonR ON Remote: daily check, 4 follow-ups and 5 full alert reports per year, Wireless RF programming: 120 min. implantation, 15 min. discharge and 15 min. in-clinic quarterly follow-ups	

* Warranty applies regardless of the pacing conditions and therapy frequency. For more details please refer to following document supplies with the device: U666 – LIMITED WARRANTY for PLATINIUM ICD and CRT-D devices.

Refer to user's manual furnished with the device for complete instructions for use and intended uses and relevant warnings, precautions, side effects, and contraindications.

Not available for distribution or sale in the USA.



GLOBAL MARKETING
Sorin CRM SAS
4, avenue Réaumur
92140 Clamart
France

MANUFACTURED IN ITALY BY
Sorin Group Italia S.r.l.
Via Crescentino s.n.
13040 Saluggia (VC)
Italy

 **SORIN GROUP**
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www.sorin.com