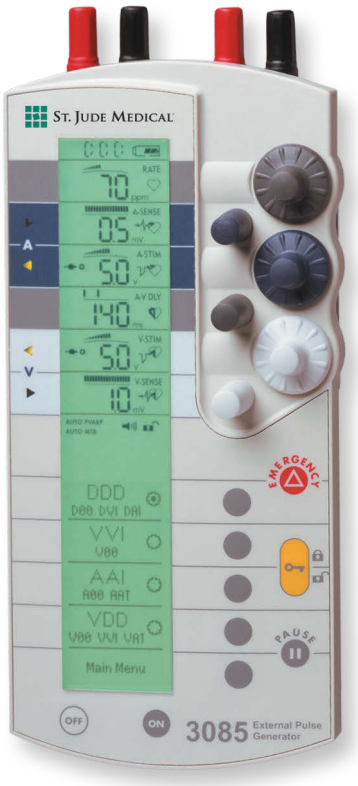
External Pulse Generator

DUAL-CHAMBER (DDD)

MODEL 3085



SPECIFICATIONS

- The Model 3085 dual-chamber external pulse generator (temporary pacemaker) is designed for safe and reliable temporary stimulation of the heart in cases of rhythm disturbances and conduction defects, and/or perioperative temporary heart stimulation.
- An extensive dual-chamber feature set offers:
  - A full array of mode choices, including a special DDD + AT mode specifically available for bi-atrial stimulation to help avoid atrial fibrillation.
  - Atrial auto-sensing for automatic adjustment of sensitivity.
  - Completely adjustable stimulation parameters (voltage and pulse width).
  - A wide base rate range of 30-220 ppm for appropriate pacing support for all therapy needs, including those of pediatric patients.
  - A max tracking rate of 80-230 ppm for maintaining AV synchrony.
  - A PV delay offset for supporting maximum cardiac output.
  - Extended PVARP for prevention of retrograde tachycardia.
  - Crosstalk protection to aid in preventing far-field sensing, which can result in asystole.
- Continuous, independent atrial and ventricular lead surveillance and an audible warning in the event of lead malfunction.
- The Auto Mode Switch/Noise Reversion feature responds to signals faster than 273 ppm with reversion to a non-tracking or asynchronous mode.
- Rapid atrial pacing rates (up to 1000 ppm) are available for pace-termination of atrial tachycardia.
  - Atrial overdrive/rapid pacing rates are independent of the selected stimulation rate.
- Eighteen (18) volts of output are available per channel for added security and reliability.
- Advanced circuitry promotes efficiency, allowing for good battery longevity.
- Standard 9 volt lithium or alkaline batteries are used, and the device features both visual and audible battery life indicators.
  - Stimulation is maintained for 30 seconds during battery changes.
- The Lock/Unlock feature prevents unintentional program changes.
- The Emergency Key feature immediately switches the Model 3085 temporary pacemaker to V00 or A00 pacing at a rate of 80 ppm, with output settings of 12 V or set value when higher, and a pulse width of 0.75 ms (V00) or 1.0 ms (A00), or set value when longer.
- Both intrinsic and paced activity is indicated with separate blinking LEDs; an audible tone can be added if desired.
- A straightforward graphical user interface and simple controls facilitate ease of use.
  - Dial controls allow quick access to and adjustment of the most important functions such as rate, output and sensitivity, while soft keys allow adjustment of other menu functions.
- Small size and lightweight design make the Model 3085 temporary pacemaker easy to store and transport.

Indications for Use: The Model 3085 external pulse generator/temporary pacemaker is designed to be used with cardiac stimulation lead systems for temporary atrial, ventricular or A V sequential stimulation. The Model 3085 has applications where such stimulation modes are indicated for therapeutic, prophylactic, or diagnostic purposes. Specific indications include, but are not limited to, the following:

- Sick sinus syndrome;
- Bradycardia with congestive heart failure;
- Complete heart block;
- Acute myocardial infarction complicated with heart block;
- Sinus bradycardia;
- Cardiac arrest with ventricular asystole;
- Atrial and/or ventricular ectopic arrhythmia;
- Postoperatively after cardiac surgery;
- Temporary application during implantation or exchange of a permanent pacemaker.

Indication for atrial overdrive stimulation:

- Supraventricular tachycardia.

Contraindications: There are no contraindications with regards to the use of the Model 3085 for temporary cardiac stimulation for therapy and prevention of arrhythmia. The state of health of the patient, however, can restrict the choice of operational mode and stimulation parameters. For example, a mode of operation with atrial sensing is not suitable or appropriate when atrial fibrillation occurs. This is due to excessive and chaotic frequency of detected fibrillation waves. Overdrive-stimulation therapy must only be used in the atrium. Overdrive-stimulation in the ventricle could cause life threatening ventricular fibrillation.

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PHYSICAL SPECIFICATIONS

Models	3085
Battery	Standard 9 V, alkaline or lithium
Battery Life Alkaline	Minimal 10 days (VVI, standard parameters), Minimal 8 days (DDD, standard parameters) Plus 1 day reserve after the first appearance of the battery change message
Battery Life Lithium	Minimal 19 days (VVI, standard parameters) Minimal 15 days (DDD, standard parameters) Plus 1 day reserve after the first appearance of the battery change message
Weight (g)	Approximately 490 (including battery)
Size (cm)	20 x 9.6 x 3.8 (7.75 in. x 4 in. x 1.5 in.)

PARAMETER SETTINGS

Modes	DDD, DDD + AT, DOO, DAT, DVI, DAI, VVI, VOO, VAT, AAI, AOO, AAT, VDD
Base Pacing Rates (ppm)	30-220
Upper Pacing Rates (MTR) (ppm)	80-230
Rapid Atrial Pacing Rates (ppm)	70-1000
AV Delay (ms)	5-400 (minimum 30 ms when atrial Auto Sense is activated)
PV Delay (ms)	AV delay-30 (minimum 5 ms when atrial Auto Sense is not activated, minimum 30 when atrial Auto Sense is activated)
Pulse Duration (ms)	0.05-1.50
Pulse Amplitude (V)	0.1-18
Atrial Sensitivity (mV)	0.2-20
Ventricular Sensitivity (mV)	1.0-20
Blanking Period (ms)	85 (atrial & ventricular), 55 (ventricular after atrial pacing)
Atrial Refractory Period (ms)	250 … 400 ms ± 5% (AAI, AAT), A-V interval plus PVARP (DDD, VDD, DAI, VAT, DAT)
PVARP (ms)	100-500 (absolute: 90 ms, relative: 90 ms)
Ventricular Refractory Period (ms)	250
Extended PVARP (After PVC) (ms)	500
Crosstalk Detection Window (ms)	40
Emergency Mode	V00 (A00), 80 ppm, 12 V or set value when higher, 0.75 ms (1.00 ms) or set value when longer
Runaway Protection (ppm)	235

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Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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