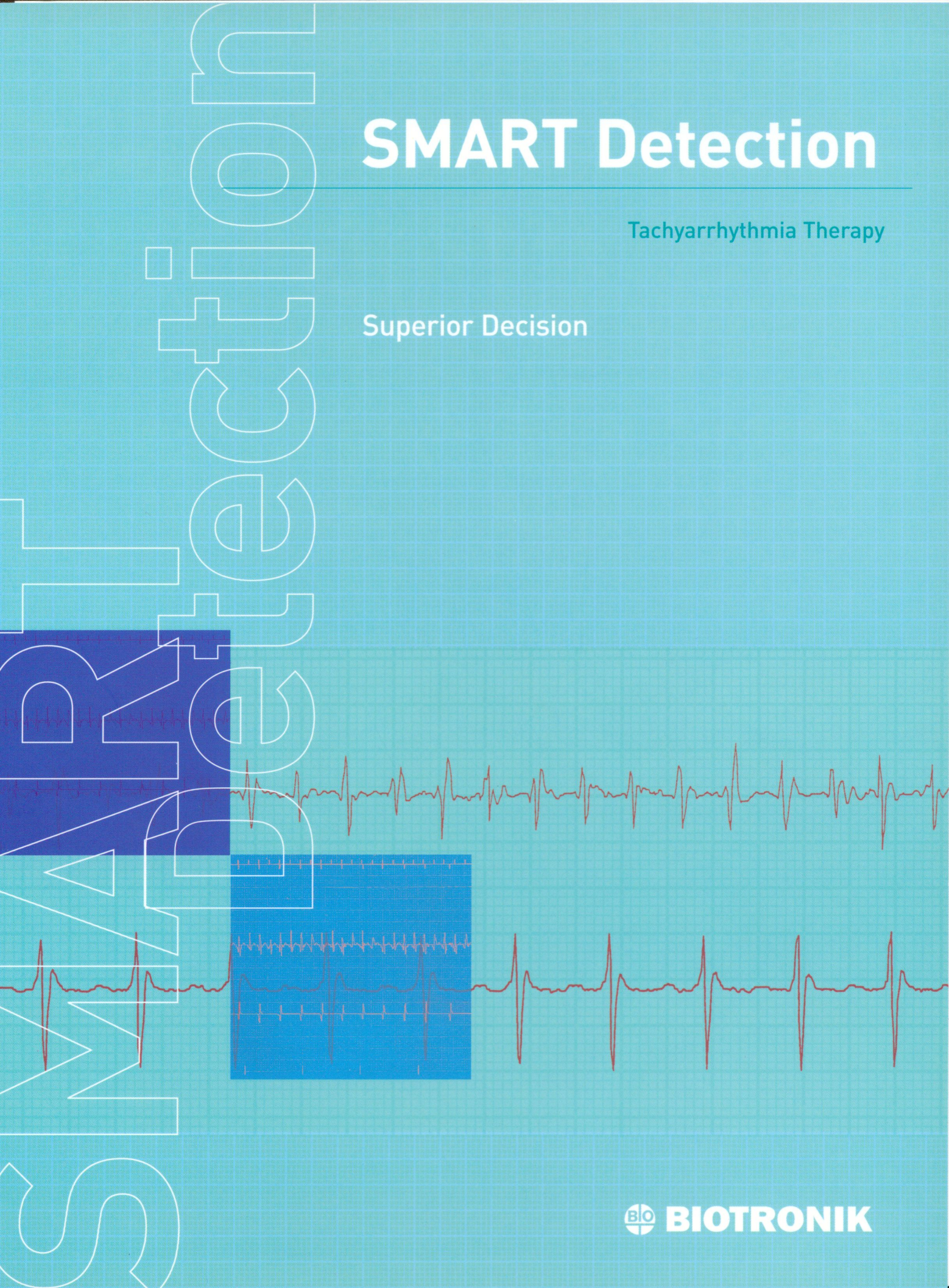


SMART Detection

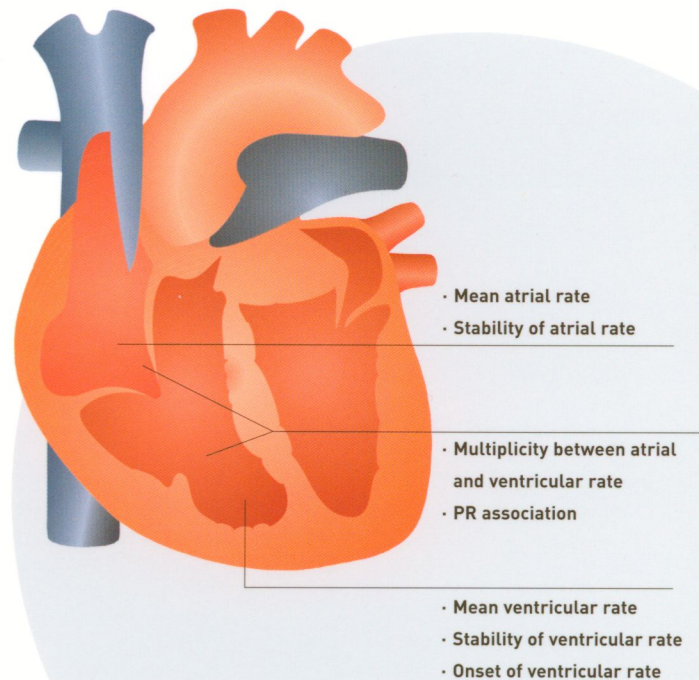
Tachyarrhythmia Therapy

Superior Decision



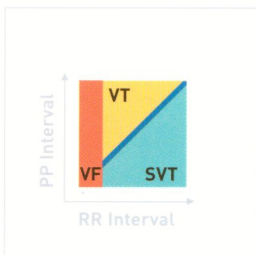
Superior Decision

SMART Detection™ discriminates safely and effectively. Preliminary results from a recent clinical trial show the absolute sensitivity for the detection of ventricular tachycardias (VT) and 93% specificity for the discrimination of supraventricular tachycardias (SVT). SMART Detection™ is implemented in BIOTRONIK's complete line of dual chamber ICDs.



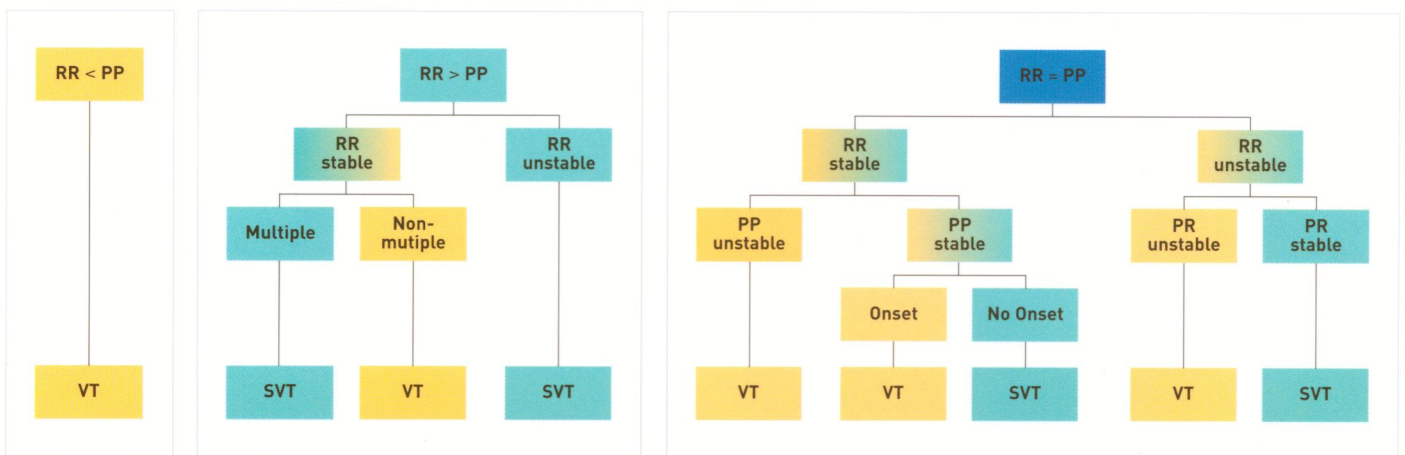
SMART compares the interval lengths and analyses rate stability, multiplicity and PR association.

intelligent

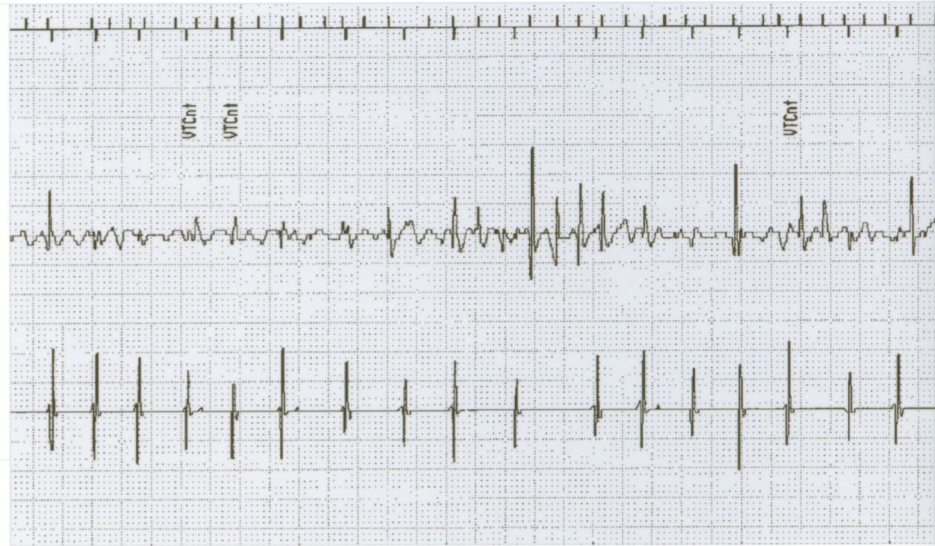
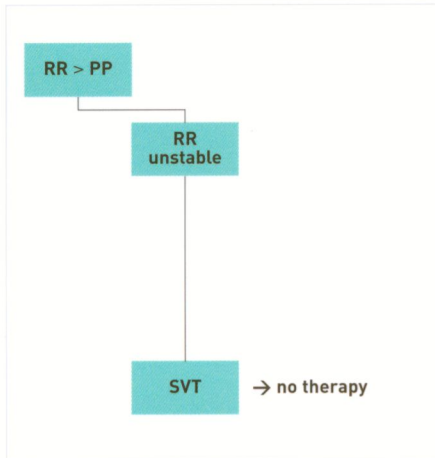
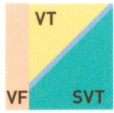


Rhythm Classification

SMART Detection™ analyses the interaction between atrial and ventricular rates. The classification is achieved by performing a test sequence using averaged PP and RR intervals. When a VT is determined, therapy is delivered. The SVT decision inhibits the therapy and is documented by IEGM recording.

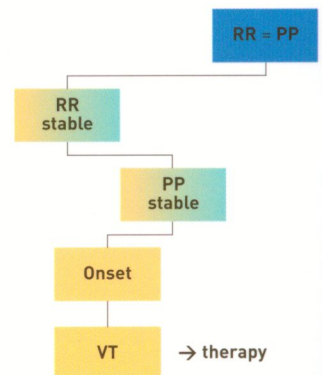
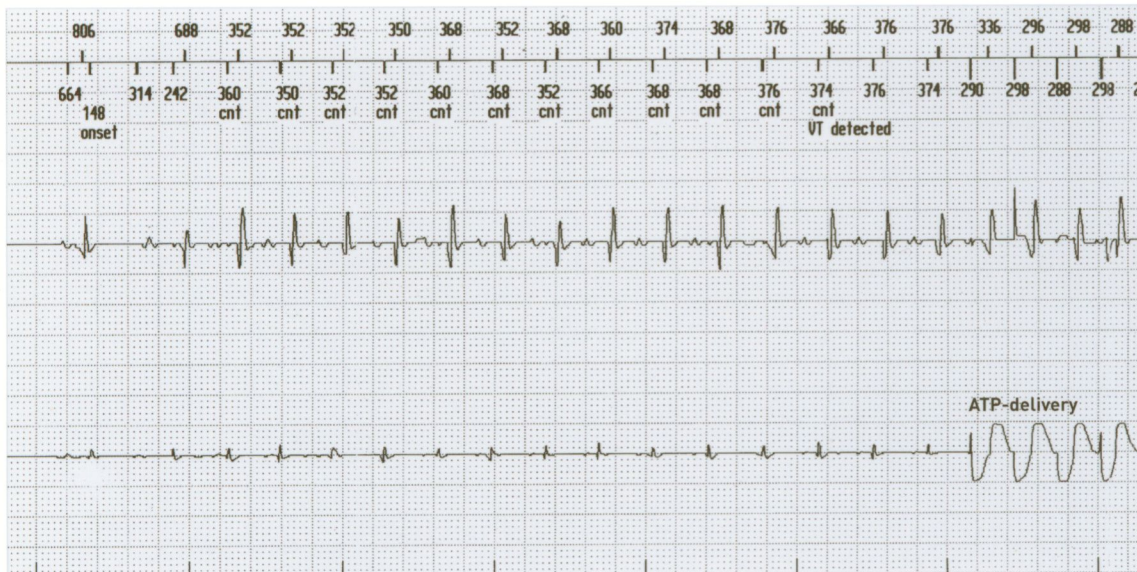


Atrial Fibrillation with Irregular Conduction

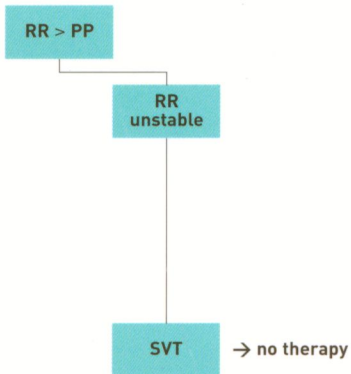
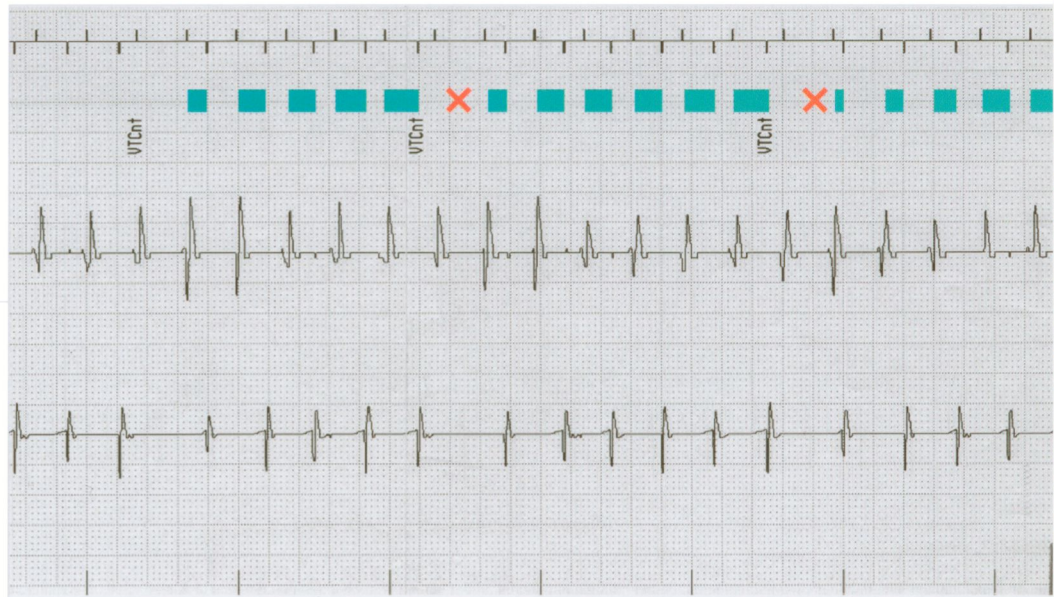
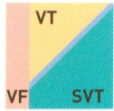


adequate

Ventricular Tachycardia with Retrograde Conduction

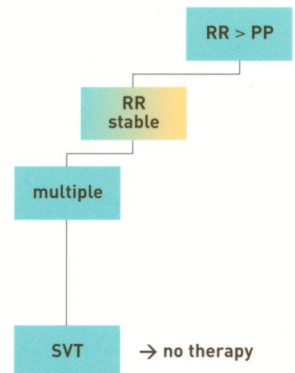
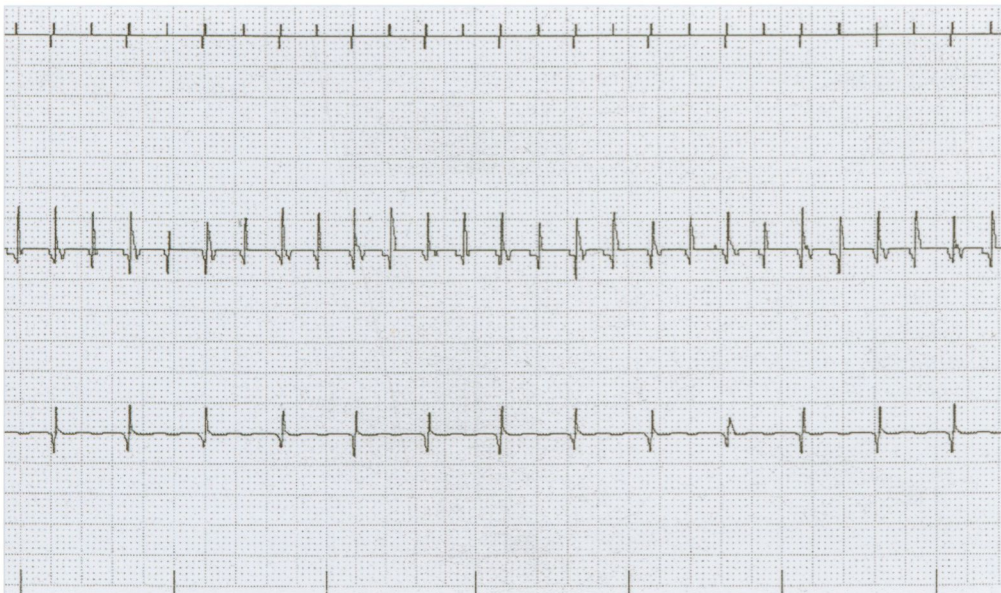
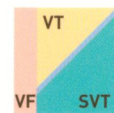


Atrial Tachycardia with Wenckebach Behaviour



safe

Atrial Flutter with 2:1 Conduction



Clinical Study

An international clinical multicenter study was conducted in accordance with FDA regulations. Two of the primary features investigated were sensitivity and specificity of the SMART Detection™ algorithm. The Phylax AV ICD system was implanted in a total of 128 patients between June 1998 and August 2000. Mean age, gender and history of these patients correspond to that of the general ICD patient population.

889 tachycardia episodes in 64 patients have been documented.
SMART was activated for 774 episodes.
SMART was deactivated for patients who suffered primarily from VF episodes.

sensitive

Age:	61 ± 11 years	
Sex:	male	112 (87.5%)
	female	16 (12.5%)
LVEF:	31 ± 11 %	
NYHA*:	class I	20 (14.8%)
	class II	75 (55.5%)
	class III	36 (26.7%)
	class IV	4 (3.0%)

* The sum is more than 128 because some patients were classified to be "between two classes".

100 % VT-Sensitivity
93 % SVT-Specificity

Results

The results show that the sensitivity of the SMART Detection™ algorithm for appropriately detecting VT was 100 %, whereby delivering all appropriate therapy. The specificity of 89.7 % was observed when all patient data profiles were considered. Inappropriate therapies can be reduced by optimising the programming (setting of onset delta, deactivation of safety timer). The specificity for optimised programming is 93.3 %.

effective

Inappropriate Therapies	
Safety Timer*	17 (2.2%) in 6 patients
No Onset*	11 (1.4%) in 5 patients
Wenckebach	4 (1.4%) in 1 patients
SVT in VF	4 (1.4%) in 1 patients
paroxysmal SVT with 1:1-conduction	4 (1.4%) in 1 patient
other	39 (5.9%) in 9 Patienten

* avoidable with optimised programming

References:

[1] C. Stellbrink, A. M. Sinha, B. Möx, L. Jordaens, B. Merkely, J. Gill,

Phylax AV Study Group

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[2] B. Merkely, J. Witte

Clinical results with the Dual-Chamber Cardioverter Defibrillator

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Progress in Biomed. Res. 5 (2), 107 – 112, 2000

[3] A. M. Sinha, C. Stellbrink, D. Karla, A. Hahn, P. Hanrath

Discrimination of Ventricular and Supraventricular Tachycardias with a New Detection Algorithm in a Dual Chamber ICD.

Herzschrittmacher 20 (3), 208 – 214, 2000

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