User Manual

STOCKERT 70

Radiofrequency Generator

$C \epsilon 0366$

Freiburg, June 26, 2000

Manufacturer

STOCKERT GmbH

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Tel. 800 729 9010
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CAUTION
**Federal law restricts this device to sale
by or on the order of a physician.**

STOCKERT 70
USER MANUAL
valid for
Software Version 001/032

Contents

Preface

With the purchase of the STOCKERT 70 you have acquired a device which is versatile and easy to use. All applications of radiofrequency ablation and temperature controlled ablation as well as impedance measurements can be performed. Device operation is very simple and will be described in the following chapters.

Chapter 1 describes the functional principle of various radiofrequency techniques. Understanding the **temperature control principle** is a prerequisite to maximize the use of the STOCKERT 70.

For practicing purposes, we recommend to test the device functions described in the user manual by using the enclosed accessories on a piece of raw meat or in liquid egg white. If the manual does not answer all of your questions you are welcome to contact us at the address below:

Yours sincerely,

STOCKERT GmbH

Manufacturer

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Bötzinger Straße 72
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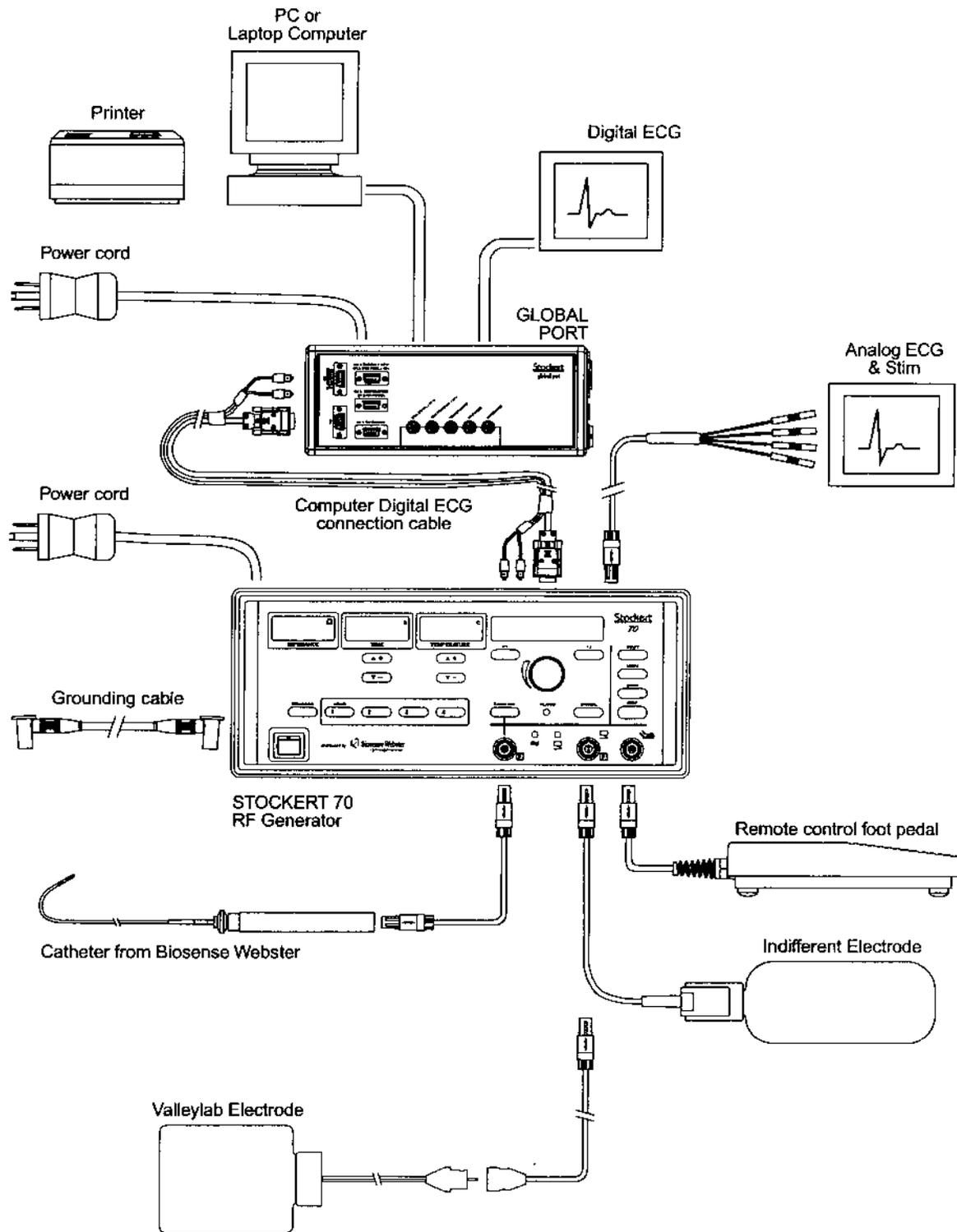Telefax +49-(0)761-20716-20
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Brief Device Description

The STOCKERT 70 RF Generator system consists of a radiofrequency generator and accessories intended for cardiac ablation applications. Its purpose is to generate RF energy for delivery to a site in the heart via a cardiac catheter over a specified time period (generally 60 to 90 seconds). The thermal energy at the site of application produces a lesion that interrupts a defective electrical conduction pathway in the cardiac wall. The Stockert 70 RF Generator is used in unipolar mode only, and includes functions for controlling temperature at the tip of the catheter, and for monitoring impedance and ECG signals. Ablation parameters, such as power, impedance, voltage, current, and temperature, can be recorded and displayed using the optional STOCKERT 70 GLOBAL PORT and an optional Personal Computer (PC) system.

The STOCKERT 70 RF Generator should be used only with a Biosense Webster Diagnostic/Ablation Deflectable Tip Catheter.

1.1 Figure 1. System Schematic

PC or
Laptop Computer

Printer

Digital ECG

Power cord

GLOBAL
PORT

Analog ECG
& Stim

Power cord

Computer Digital ECG
connection cable

Grounding cable

STOCKERT 70
RF Generator

Remote control foot pedal

Catheter from Biosense Webster

Indifferent Electrode

Valleylab Electrode

INTENDED USE / INDICATIONS

The STOCKERT 70 radiofrequency generator and accessory cable are indicated for use in conjunction with a Biosense Webster Diagnostic/Ablation Deflectable Tip catheter for cardiac ablation procedures.

CONTRAINDICATIONS

Do not use this device;

- in patients with active systemic infection;
- via the transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle or patch;
- via the retrograde transaortic approach in patients with aortic valve replacement.

WARNINGS AND PRECAUTIONS

GENERAL:

- Do not plug cables or leads directly into main power supply (i.e. wall outlet). Such action may result in patient electrocution.

- To avoid the risk of explosion, the Stockert 70 generator must not be used in rooms with flammable anaesthesia. The foot-pedal is suitable for use in operating rooms as it is a sealed unit.

- To avoid endangering the patient, all devices that are connected together must be as safe for the patient as specified in the IEC 601-1 and IEC 601-2. Please notice that there is a direct electric connection to the heart through the ECG connection cables of the STOCKERT 70; therefore, improper usage of these connections can be dangerous for the patient.

- The patient should not come into contact with metal parts that are grounded or have considerable ground capacity (e.g. operating table, supports etc.) For this purpose we recommend the use of antistatic drapes.

WARNINGS AND PRECAUTIONS SPECIFIC TO THE STOCKERT 70 RF GENERATOR

- To avoid system malfunction, do not connect the interface connector (optical fiber) for fiberoptics to external voltage. Use only the interface cable (no. M-5463-14) supplied with the converter to connect the 9 pin, D-type connector on the back of the STOCKERT 70 to the global port.

- To avoid low output or failure of the ablation device at normal operating setting, ensure there is appropriate positioning of the indifferent electrode and proper connection with the connecting cable. RF application will not start if the indifferent electrode is missing or connected improperly to the STOCKERT 70 RF generator.

- Use only the indifferent electrodes recommended by the manufacturer. The indifferent electrode will be monitored. As soon as the connection with the indifferent electrode is broken the device indicates this error with an "indifferent electrode" message flashing in the display, a flashing alarm indicator (red light), and a warning sound (see Chapter 10, page 45 "Error messages").

- This device is a non-ionizing emitter of radiation and may cause electromagnetic interference with other devices. In order to minimize the electromagnetic interference, the generator should be placed at least 4 feet away from any other electronic device.

- To avoid damage to the foot switch cable, do not carry the foot pedal by holding on only to the cable. Do not wrap the cable tightly around the foot pedal.

- To avoid the possibility of patient injury, the stimulator must be disconnected before radiofrequency energy is applied.

- To maintain system isolation, only Classified Medical Electrical Equipment may be connected to this unit. If the PC does not fulfil IEC 601-1 / UL 2601-1 Standards, then the distance between the PC and the patient must be at least 1.83 m (6 ft) and the PC system shall comply with UL 1950 / IEC 950. Medical equipment electrically connected to the STOCKERT 70 shall comply with IEC 601-1-1, the Standard for Medical Systems.

- To avoid damage, do not use acetone-containing agents to clean the generator. The device surface, including the front panel, can be cleaned with soap and a soft cloth dampened with water to disinfect.

WARNINGS AND PRECAUTIONS DURING ABLATION THERAPY

- Avoid high ablation temperatures. The displayed temperature is not the temperature of the tissue. It is the temperature of the electrode only and does not represent tissue temperature. High ablation temperatures may result in coagulum formation, charring of the cardiac tissue and substrates, and/or a vaporization of interstitial and intracellular fluid.

- To avoid char and coagulum during ablation, the generator power output should be set to the lowest possible setting.

- Avoid sudden impedance rise to minimize coagulum formation on the ablation electrode. Coagulum on the ablation electrode may result in decreased energy delivery and/or the potential for an embolic event.

- Avoid use of electrodes and probes of monitoring and stimulating devices that could provide paths for high frequency current. Reduce the burn hazard by placing the electrodes and probes as far away as possible from the ablation site and the dispersive electrode.

- Do not deliver RF energy with the catheter outside the target site to avoid patient or operator injury.

- Do not handle RF catheters during therapy to avoid patient or operator injury.

- To minimize ECG interference, the cables connecting the ablation electrodes should be positioned in such a way that they will neither touch the patient nor other cables. For optimal ECG recordings, unused active electrodes should be stored away from the patient.

- To minimize moisture affecting system performance, please make sure that the sterile catheters and the connectors of the cable are completely dry.

- Read and follow the Disposable Indifferent (dispersive) Patch (DIP) electrode manufacturer's instructions for use; the use of DIP electrodes which meet or exceed ANSI/AAMI HF-18 requirements is recommended.

- Be aware during ablation procedures that in patients with cardiac pacemakers or pacemaker leads, there is a risk of interference with the pacemaker function or damage to the pacemaker. In case of doubt consult the cardiology department.

- To avoid system malfunction and to maintain safety, all reusable accessories have to be checked regularly by visible inspections. No broken insulation of the wires is allowed.

- To avoid the risk of patient injury, it is required that only dedicated cables and connectors for the device type CF (safety class CF) be used.

Adverse Events

The STOCKERT 70 Generator was evaluated in a clinical study of 210 patients using the Biosense Webster Celsius™ Diagnostic/Ablation thermocouple or thermistor catheters. The majority of the patients were being treated for Wolff-Parkinson White Syndrome (WPW) or for the treatment of atrioventricular nodal re-entrant tachycardia (AVNRT).

5.1 Observed Adverse Events

Five patients were reported as having major adverse events, all of which were reported as procedure-related. Major and minor adverse events were classified according to the FDA's recommended definitions for evaluating ablation safety. The major adverse events, occurring within seven days post ablation, included pulmonary embolus/urinary tract infection, unintentional heart block, small ecchymosis/hematoma, deep vein thrombosis, and femoral artery pseudoaneurysm.

Thirteen minor adverse events (6.2%) were reported including small ecchymosis, superficial thrombophlebitis, pneumothorax, hematoma, pulmonary embolus, pain at catheter insertion site, chest pain, groin pain, transient 2:1 heart block, esophagitis, congestive heart failure, right occipital stroke, malignant lung/bronchial cancer.

Table 1. Observed Adverse Events

Categories are mutually exclusive. All patients treated with ablation (N=210)

Adverse Event	% patients	# patients	95% Confidence Interval*	
Minor	6.2 %	13/210	0.033	0.105
Major	2.4 %	5/210	0.008	0.057
Death	1.4 %	3/210	0.003	0.045

* Confidence intervals by exact (binomial) method

5.2 Potential Adverse Events

Adverse events (in alphabetical order) which may be associated with catheterization and ablation include:
- air embolism
- arrhythmias
- AV fistula
- cardiac perforation/tamponade
- cardiac thromboembolism
- cerebrovascular accident (CVA)
- chest pain/discomfort
- complete heart block
- coronary artery dissection
- coronary artery spasm
- coronary artery thrombosis
- hemothorax
- pericarditis
- pneumothorax
- pseudoaneurysm
- tamponade
- thrombi
- thromboembolism
- thrombosis
- transient ischemic attack (TIA)
- valvular damage
- vascular bleeding/local hematomas
- vasovagal reactions
- ventricular tachyarrhythmia

CLINICAL STUDIES

The Biosense Webster STOCKERT 70 Generator was studied to determine the safety and effectiveness of the generator, global port and interface cable in conjunction with the Biosense Webster Celsius™ Diagnostic/Ablation thermocouple and thermistor catheter for cardiac ablation.

Methods:
In this prospective, multicenter (ten centers) study, acute procedural success was defined as the complete elimination of WPW or AV conduction pathways, inability to re-induce AVNRT, or complete AV nodal block. Chronic success was defined as the absence of recurrence of the arrhythmia over a 3 month monitoring period.

Results:
Of the 230 patients enrolled, 210 patients underwent ablation and provided clinical data for assessment of safety. For the effectiveness endpoints, the patient count included all patients treated with the investigational device for an arrhythmia indicated in the study. Patients who began treatment with the investigational device but were switched to a non-investigational device were considered failures. Two hundred three (203) patients were treated with the investigational device for an arrhythmia indicated in the study and were assessed for effectiveness. The other 20 patients were discontinued prior to ablation for the reasons and occurrence indicated in the table below:

Table 2. Reasons for Discontinuation from the Study

Physician chose not to ablate (difficult pathway, close proximity to AV node, unusual location, or other)	2
Unable to induce protocol arrhythmia	8
Non-protocol arrhythmia	5
Appropriate cable equipment unavailable	5
Total number of discontinued patients	20

Slightly more than half (56%) of the patients were female and 44% of the patients were male. The percentages of male and female patients is consistent with the prevalence of the disease. Table 3 describes the patient population by indication and age.

Table 3. Enrollment and patient age by Indication (N=203)

Indication For treatment	Number of patients		Age of patients (years)	
	%	#	Mean	Range
WPW	25.6%	52/203	34.0	10-71
AVNRT	56.7%	115/203	50.6	7-82
AV Node Ablation	13.8%	28/203	66.3	22-90
WPW & Other[a]	0.5%	1/203	40.0	40-40
AVNRT & Other[b]	3.4%	7/203	50.1	20-66
Total	100%	203/203	48.2	7-90

[a] – Sinus node reentrant tachycardia

[b] – Atrial tachycardia (6 patients) and intra-atrial reentrant tachycardia (1 patient).

A total of 1,716 RF applications were delivered with a mean number of applications of 10.3 (range 1-60). Tables 4 and 5 summarize success by indication.

Table 4. Acute Success by Indication (N=203)

Indication	% patients	# patients	95% Confidence Interval	
WPW	94.2%	49/52	0.841	0.988
AVNRT	94.8%	109/115	0.890	0.981
AV Node Ablation	96.4%	27/28	0.817	0.999
WPW & Othera	100%	1/1	0.025	1.000
AVNRT & Otherb	100%	7/7	0.590	1.000
Total	95.1%	193/203	0.911	0.976

a – Sinus node reentrant tachycardia
b – Atrial tachycardia (6 patients) and intra-atrial reentrant tachycardia (1 patient).

Table 5. Chronic Success by Indication (N=203)

Indication	% patients	# patients	95% Confidence Interval	
WPW	92.2%	47/51	0.811	0.978
AVNRT	92.1%	105/114	0.855	0.963
AV Node Ablation	92.6%	25/27	0.757	0.991
WPW & Other[a]	100%	1/1	0.025	1.000
AVNRT & Other[b]	100%	7/7	0.590	1.000
Total	92.5%	185/200	0.879	0.957

[a] – Sinus node reentrant tachycardia

[b] – Atrial tachycardia (6 patients) and intra-atrial reentrant tachycardia (1 patient).

In separate clinical studies, Biosense Webster collected the clinical data shown in Table 6 which represents an acceptable historical control population. The same catheters were used in the control studies as in the STOCKERT RF generator study, but ablation was performed using other RF generators.

Table 6. Control Patient Population

STUDY ENDPOINT	ABLATION SYSTEM	# patients	% patients
Acute Success	Celsius Catheter + Radionics / Atakr / EPT-1000	676 / 734	92%
Chronic Success (3 Months)	Celsius Catheter + Radionics RF Generator	280 / 306	92%
Major Complications (Within 7 Days)	Celsius Catheter + Radionics / Atakr / EPT-1000	26 / 741	3.5%

The results from a comparison to the historical data are shown in Table 7.

Table 7. Device Performance Compared to Control Group

STUDY ENDPOINT	STOCKERT	CONTROL	ONE-SIDED 95% CONFIDENCE BOUND
Acute Success	95 %	92 %	93.9 %
Chronic Success	93 %	92 %	88.3 %
Major Complications	2.4 %	3.5 %	4.6 %

The safety and acute effectiveness results from the STOCKERT study were demonstrated to be statistically equivalent to the control data. However, for the chronic effectiveness endpoint the data did not demonstrate statistical equivalence to the control. The upper 95% confidence bound on the difference in proportions (control minus treatment) of 4.17% was just outside the prospectively defined 4% window of equivalence with the historical control. Nonetheless, the device's safety and effectiveness data was considered clinically acceptable.

6.1 Temperature Ramping Experience

Table 8 summarizes the various temperature ramping rates within the range of 12°C to 50°C that were used during ablation in a subset of 23 patients in the STOCKERT clinical study. The most common temperature ramp rate used was 20°C per second (60.9%, 14/23 patients).

Table 8. Temperature Ramping Rates

Temp. Ramping Rate	# Patients
12°C/sec	17.4% (4/23)
20°C/sec	60.9% (14/23)
30°C/sec	13.0% (3/23)
50°C/sec	4.3% (1/23)
12°C/sec and 20°C/sec	4.3% (1/23)
Total	100% (23/23)

7.1 Choosing Temperature Control versus Power Control

Temperature controlled ablation techniques

Temperature sensors measure the temperature at the electrode tip. The radiofrequency power is controlled automatically so that the desired temperature will not be exceeded. The temperature of the electrode tip can be kept at the desired value without the risk of char or coagulation.

Ablation time and temperature mainly determine the size of the lesion. A power limit may be set anywhere below the maximum output rating of the device (50 watts).

Power controlled ablation techniques

The radiofrequency power levels are set manually using values resulting from experience. Temperature of the tip is not controlled, however, if a temperature sensor is present, the generator will not exceed the cut-off temperature.

7.2 Anticoagulation Regimen

To avoid thromboemboli, intravenous heparin is used when entering the left heart during ablation, and many physicians prescribe aspirin, less often warfarin, for about 3 months afterward. No consensus yet exists about the need for short-term anticoagulation after ablation.

Left Heart Catheter Insertion

During the clinical study, systemic anticoagulation before intracardiac RF catheter ablation in the left heart was typically an initial intravenous heparin bolus of 3000 - 10,000 Units. Anticoagulation was maintained with an intravenous heparin drip or additional periodic intravenous boluses of heparin as necessary. Oral anticoagulation therapy may have been administered prior to ablation.

Investigators in the clinical trials typically prescribed long term (one to three months) anticoagulation therapy of one aspirin tablet daily, for patients undergoing left heart ablation, unless contraindicated.

Right Heart Insertion

During the clinical study, systemic anticoagulation was variable for patients undergoing intracardiac RF catheter ablation in the right heart. If used, systemic anticoagulation in the clinical study before ablation was typically an initial intravenous heparin bolus of 3000 - 10,000 Units followed by intravenous heparin drip or additional periodic intravenous boluses at a rate of 1000 Units/hour for the duration of the ablation procedure. Oral anticoagulation only, or no anticoagulation prior to ablation was also performed.

Long term anticoagulation therapy for patients undergoing right heart ablation was variable. Long term therapy of one aspirin tablet daily for patients undergoing right heart ablation may or may not be indicated.

CONFORMANCE TO STANDARDS

No performance standards have been established for radiofrequency generators under Section 514 of the Federal Food, Drug and Cosmetic Act. The STOCKERT 70 RF Generator meets the requirements of the following voluntary standards:

Standard:	Title:
ANSI/AAMI ES1:1993	Safe Current Limits for Electromedical Apparatus
ANSI HF-18	Electrosurgical Devices
FDA Draft Guidance	Cardiac Ablation Preliminary guidance (3/95)
EN60601 PT. 1	Medical Electrical Equipment – General Requirements for Safety
ISO 10013-1995	Guidelines for Developing Quality Manuals
IEC 60812 (1985)	Analysis Techniques for System Reliability – Procedure for FailureMode and Effects Analysis
EN 1441	Medical Devices – Risk Analysis
IEC 60601-1	Medical Electrical Equipment – General Requirements for Safety
IEC 60601-2	Medical Electrical Equipment General Requirements for Safety Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
IEC 60601-2-2	Medical Electrical Equipment Particular Requirements for the Safety of High Frequency Surgical Equipment
EN 46001	Specific Requirements for the Application of EN 29001 (ISO 9001) for Medical Devices
ISO 9001	Quality Systems; Model for Quality Assurance in Design, Development, Production, Installation, and Servicing

HOW SUPPLIED

The STOCKERT 70 RF Generator Ablation System is supplied with the following accessories:

- STOCKERT 70 RF-Generator with Software 1.032
- Shipping Case
- Power Cords (USA)(2 each)
- Remote Control Foot Pedal
- GLOBAL PORT Computer Interface
- Serial Computer Interface Cable D-Type
- GLOBAL PORT Digital-ECG Connection Cable
- Indifferent Patch-Electrodes, 3M, package of 5
- Indifferent Patch-Electrode Connection-Cable, 3M
- Valleylab Patch Cable
- ECG-Connection Cable (REDEL 10 --> 2mm Tip Pins) with protected Pins
- Grounding Cable
- User Manual
- Software EPWIN Version 3.010
- Spare Fuses

10.1 Maintaining Device Effectiveness

Handling radiofrequency ablation devices

In order to minimize the danger of accidental burns the STOCKERT 70 was designed for optimum safety.
See chapter 3, Design and Features.

Technical safety inspections

Important note: To ensure device safety, maintenance, repairs and technical safety inspections must only be performed by the manufacturer or an authority which has been expressively authorized by the manufacturer. The following inspections for technical safety must be performed at least every 12 months and after each repair in compliance with VDE 0750 and VDE 0751:

1.	General visual inspection
1.1	The type plate must be attached and legible
2.	Selector knob, fixation, connection
3.	Check RF connector for secure connection
4.	Check foot pedal connector for secure connection
5.	Check indifferent electrode connector for secure connection
6.	Check ECG and external stimulator connector for secure connection
7.	Check power cord connector
8.	Check equipotential connector for secure connection
9.	Test foot pedal function
10.	Select program menu with "MENU" key. Select test foot pedal in TEST MENU and activate pressing Start key. Install foot pedal and check the following display messages: - Is foot pedal open ? - Is foot pedal closed ? - Disconnect foot pedal and check display message
11.	Device leakage current measurement according to VDE 0751
12.	Patient leakage current measurement according to VDE 0751
12.1	Protective earth conductor impedance measurement according to VDE 0751
12.2	Insulation impedance measurement according to VDE 0751
12.2.1	Insulation impedance measurement mains against RF
12.2.1.1	Connector unipolar with indifferent electrode
12.2.2	Insulation impedance measurement RF output against housing
12.2.2.1	Connector unipolar with indifferent electrode
12.3	RF leakage current measurement (RF leakage current needs only be measured if other measurements deviate significantly from the above value)
13.	RF leakage current measurement with activated connector for indifferent electrode.
14.	RF leakage current measurement with unipolar catheter connected and maximum output according to VDE 0750 Part 202 Figure 104.
15.	Impedance measurement (Check measurement function at 100).
16.	Temperature control
17.1.1	Temperature measurement with temperature-controlled catheter at room temperature

17.1.2 Temperature measurement with temperature-controlled catheter at 70°C

17.1.3 Temperature measurement with temperature-controlled catheter at 100°C

18. Check connection of indifferent electrode

18.1 Connect unipolar catheter to connector
- Activate connector via key.
- Connect indifferent electrode cable without indifferent electrode.
- With indifferent not connected indifferent electrode display must blink.
- Short both connector contacts of indifferent electrode connector clips with conducting piece of metal.
- During short circuit condition indifferent electrode display must be continuous.

Accessories STOCKERT 70

19. Check power cord

20. Check connecting cable for indifferent electrode

21. Check foot pedal

22. Check TC/THR connecting cable

Repairs

For repairs, ship to Biosense Webster, Inc., at 3333 Diamond Canyon Road, Diamond Bar, CA 91765

Maintenance

If desired, a maintenance contract can be arranged with the manufacturer. This maintenance contract will include inspection of technical safety every 12 months.

Disposal

Please refer to your local requirements regarding the disposal of the RF ablation devices and accessories.

Handling the indifferent electrode

An indifferent electrode is required. It will be automatically activated (or deactivated) when a catheter is connected (or disconnected).

For optimal performance, the **indifferent electrode** should be applied close to the operating field. The figure below shows the recommended positions for the desired operating field.

Possible indifferent electrode locations on the patient's body
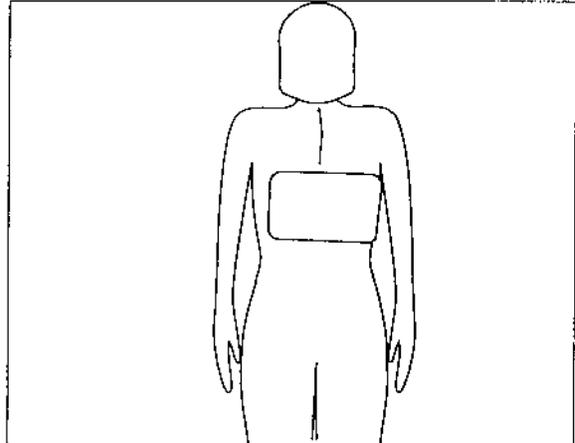
Self-adhesive indifferent electrode
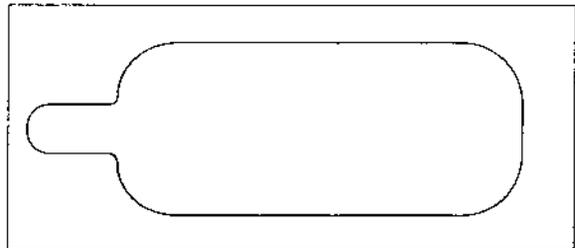
1. Design and features

The STOCKERT 70 is a universal device for all common intracardiac radiofrequency ablation techniques and fulfills the highest demands in safety, precision and ease of operation.

For clinical routine operation, only a few steps are necessary to operate the device.

Block diagram
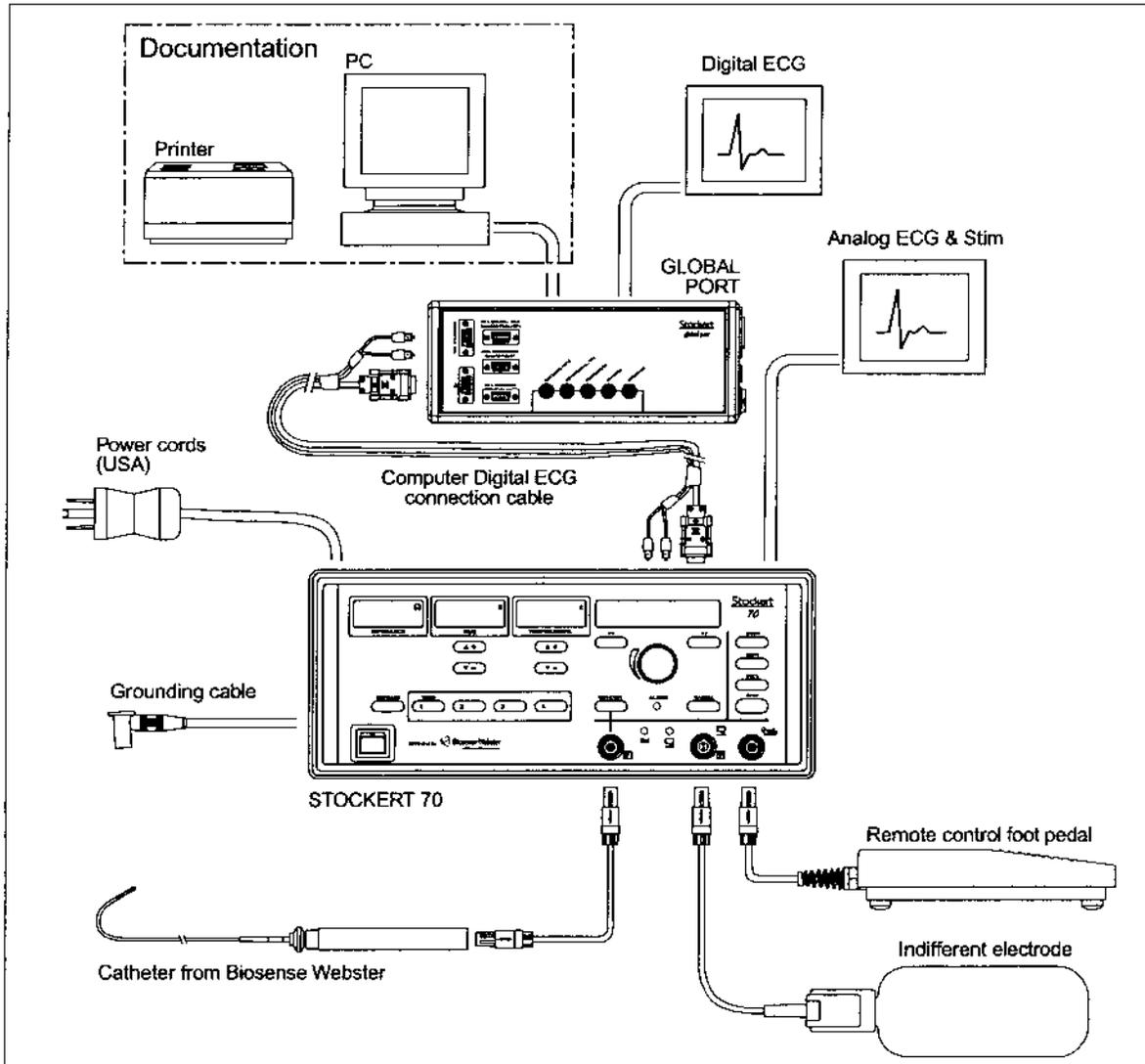
A central computer on the front panel organizes device operation so that if a certain component fails, operation may continue. Five additional microprocessors control the various functional groups, such as the control of the RF output, impedance calculation etc.

The STOCKERT 70 incorporates a special kind of memory module that retains settings and values after the device has been turned off. Only changes to certain settings that contribute to the safety and operation of the STOCKERT 70 device are reset to default values after switching the device off and on.

Operating errors and defective catheters or cables are identified and an error message is displayed. For a list of errors see Chapter 10, page 45.

2. Cleaning and disinfecting the device

Clean and disinfect the device with non-flammable and non-explosive agents only. Make sure that moisture is prevented from entering the device.

3. Protection against damage

Besides adequate operation and maintenance, effective protection of the device against damage includes installing the device in a safe place. Apart from fixing it on a safe surface, the RF ablation device must be protected from moisture, contamination and contact with flammable or explosive substances. To ensure adequate radiation of the heat produced by the device during operation, circulation of air around the device housing must not be obstructed.

Caring for the STOCKERT 70 connector system

If plugged in, the multi-pin connectors of the STOCKERT 70 are locked. In order to disconnect the plug its corrugated sleeve must be slid back.
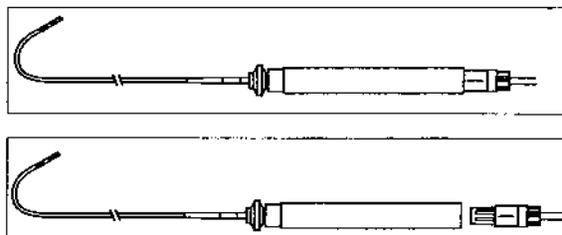
Caring for accessories

Please note the following to avoid premature wear of accessories:

Connecting cable for temperature-controlled ablation catheter
Clean and sterilize before and after use.

Connecting cable for indifferent electrode
Clean and sterilize before and after use.

Foot pedal
The surface of explosion-protected foot pedals can be disinfected with commercially available disinfectants.

Cleaning, disinfecting and sterilizing accessories

Cables and connectors must be cleaned and disinfected in a disinfectant solution before sterilization. To avoid damage to the plastic parts make sure to follow the manufacturer's instructions of the disinfectant on duration and concentration carefully.

For further instructions on the use of the accessory cable, please refer to the cable Instructions For Use.

10.2 Complete Device Description

The following is a list of accessories that accompany the STOCKERT 70 Generator System:

Note:
Use ONLY Biosense Webster and STOCKERT GmbH original accessories with the STOCKERT 70.

Foot pedal

    S-7005   Remote Control Foot Pedal

STOCKERT 70 connecting cable

    S-7004   US Power Cord, 3 m
    S-7009   Grounding Cable, 3 m

Biosense Webster Diagnostic/Ablation Deflectable Tip Catheters

Use only market approved Biosense Webster Diagnostic/Ablation Deflectable Tip Catheters in conjunction with the STOCKERT 70 RF Generator (Refer to the Biosense Webster product catalog for ordering information).

Indifferent electrodes

    S-7007   Indifferent Patch-Electrode, 3 M, package of 5
    S-7008   Indifferent Patch-Electrode Connection Cable, 3 M

Peripherials

    S-7015   ECG Connection Cable (Redel 9 –> 2 mm Tip Pins), 3 m
    S-7010   Software-EPWIN version 3.010

                  Fiberoptic PC-connection:

    S-7006   GLOBAL PORT Computer Interface
    S-7013   Serial Computer Interface Cable, D-type, 3 m
    S-7014   Global Port Digital ECG Connection Cable, 3 m

Diagram patient area

D-SUB 9-pol. for Computer Interface

OUTSIDE PATIENT AREA

PATIENT AREA

Global Port Digital ECG Connection Cable S-7014

US Power Cord S-7004

ECG Connection Cable S-7015

Grounding Cable S-7009

D-SUB 9-pol.

Redel green

2 mm Tip Pins for ECG

STOCKERT 70 S-7002

Redel grey 10-pol. 'A'-Keying

Redel red 10-pol. 'G'-Keying

Redel blue 2-pol. 'G'-Keying

Redel black 4-pol. 'G'-Keying

Catheter from BIOSENSE WEBSTER

Catheter / Generator Interface Cable C6-MR10/MSTK-S

Indifferent Patch Electrode Connection Cable S-7008

Remote Control Foot Pedal S-7005

3M Indifferent Patch Electrode S-7007

Blue Clip for 3M Indifferent Patch Electrodes

Redel blue 2-pol.

Remote Control Foot Pedal

ValleyLab Patch Cable S-7012

ValleyLab Electrode

Diagramm outside patient area

PATIENT AREA

OUTSIDE PATIENT AREA

⚠ Caution:
These accessories are not allowed to be used
in the patient area.

PC or Labtop or
Computer
RS 232 D-Interface

D-SUB
9-pol.
female
connector

Serial Computer
Interface Cable D-type
S-7013

D-SUB 9-pol.
male connector

D-SUB
male connector

Global Port
Digital ECG
Connection Cable
S-7014

D-SUB
9-pol.
female
connector

Stockert

GLOBAL PORT
Computer Interface
S-7006

US Power cord
S-7004

Units	Description	Length	Ordering #	
1	STOCKERT 70 System (Consists of following:)		S-7001	
1	STOCKERT 70 Generator with Software 1.032		S-7002	
1	Shipping case		S-7003	
1	US Power cord	3 m	S-7004	
1	Remote Control Foot Pedal		S-7005	
1	GLOBAL PORT Computer Interface		S-7006	
5	Indifferent Patch Electrodes, 3M, (Package of 5)		S-7007	
1	Indifferent Patch Electrode Connection Cable, 3M	3 m	S-7008	
1	Grounding Cable	3 m	S-7009	
1	Software-EPWIN version 3.010		S-7010	
1	User manual STOCKERT 70		S-7011	
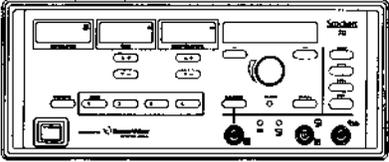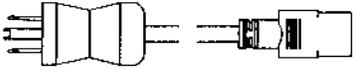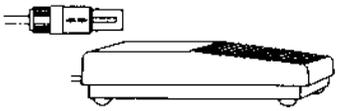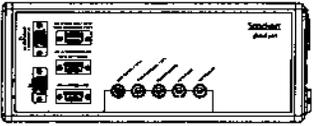
Units	Description	Length	Ordering #	
1	Valleylab Patch Cable	3 m	S-7012	
1	Serial Computer Interface Cable, D-type	3 m	S-7013	
1	GLOBAL PORT Digital ECG Connection Cable	3 m	S-7014	
1	ECG Connection Cable, Redel 9 -> 2mm Tip Pins	3 m	S-7015	
1	Catheter / Generator Interface Cable		C6-MR10/MSTK-S C10-MR10/MSTK-S	
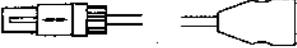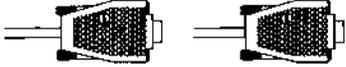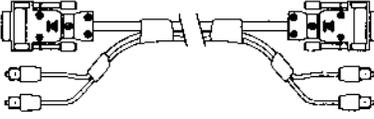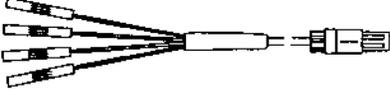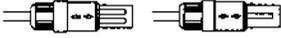
10.3 Directions for Use

Device set-up

Initial check

Upon receipt, the device should be checked for possible damage during shipment.

In the event the device was damaged during shipping contact your local Biosense Webster sales/customer representative for return information.

Installation

Connect the power cord and plug into a properly grounded AC electrical outlet. To insure proper grounding, the power cord plugs must be installed in an AC electrical outlet designated "hospital grade" or "hospital only".

Connecting cable and accessories

Use only the connecting cables and diagnostic/ablation catheters supplied or recommended by Biosense Webster.

Performance tests

Switch device on

After switching the device on, the green power indicator will illuminate. Immediately after switching the device on, a self-test will be performed. All internal device functions will be checked. Proper function is confirmed by displaying "Biosense Webster". If an error occurred, an appropriate error message will be displayed (see Chapter 10, page 45).

Performance test of accessories supplied

The Biosense Webster catheters are tested with the respective interface cables attached. An indifferent electrode must be used. The indifferent electrode flashing indicator shows proper accessory connection.

Important information for operation

Connection between device and ablation catheter

Connect the desired catheter to the device using the appropriate connecting cable.

Connecting temperature-controlled ablation catheters

The temperature-controlled ablation catheters are connected to the STOCKERT 70 using the connecting cable for temperature-controlled ablation catheters.

if the Catheter key is pressed the display will show the current selected catheter type. As soon as the Catheter key is pressed and held for 3 seconds the message "Select Catheter" will be displayed.
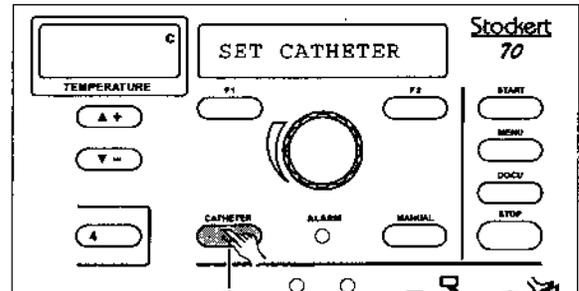
hold down for 3 seconds
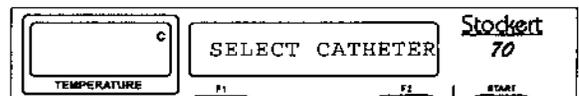
Select the appropriate catheter mode using the **SELECTOR KNOB.**

- Biosense Webster
- B/Webster Fast
- manual unipolar
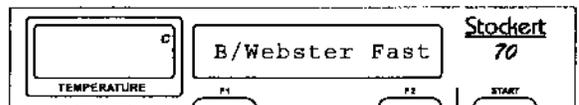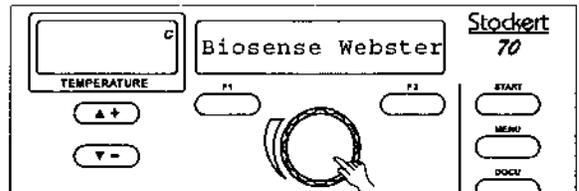
To program and confirm the selected mode, using the **SELECTOR KNOB**, press **STOP**. The appropriate user mode will change automatically with this sequence by the STOCKERT 70.
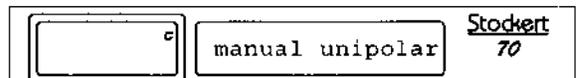
Programming MEMO keys

The STOCKERT 70 RF generator has 4 free-programmable memory keys.

Under these 4 memory keys, all RF generator parameters can be saved and retrieved except for the setup of the digital ECG.

When programming a memory key, first program the device to the setup and then push and hold the memory key for about 5 seconds.

While holding the memory key, an audible tone (4 consecutive beeps with a similar pitch) can be recognized. The memory key programming sequence is finished after a tone with a different pitch is recognized (5th beep - no further beeps are generated by the device).

To retrieve all saved parameters from one memory key just push the corresponding memory key for about One (1) second.

Push key for about 5 seconds

NOTE
The standard memory key on the left of the memory key bank is not programmable.
If this key is pushed the device will return to factory default setup.

(Please refer to section 12.1 of the Technical Reference Manual for parameters that can be saved in the "Memo" function).

General Diagram MainMenu

MAIN MENU

Temperature Menu
- Temp cut off: 47...[90]...95°C [1]
- Temperature ramp: [off]/0.02...50.00°C/S [0.02] [5]
- Temp.tendency Control: [OFF]/ON

Impedance Menu
- Max. Imped. cut-off: 50...[250]...300Ω/off [5]
- Min. Impedance cut off.: off/[20]...50...200Ω [5]
- Max. Delta Impedance: 1...[100]...999Ω/off [1]
- Impedance frequency: [50KHz]/500KHz

Display Menu
- Temp value & Power [ON]
- Voltage & Power off
- Current & Power off
- Disp. Precision [Standard]/Full

Printer Menu
- Docu Temperature off/[ON]
- Docu Impedance [off]/on
- Docu RF-Voltage [off]/on
- Docu RF-Current [off]/on
- Docu RF-Power [off]/on

Setup Menu
- Catheter application {Setup}
- Voltage Limiter 5...149.5V/[off] [0.5]
- Current Limiter 50...149mA/[off] [1]
- Value freeze time 0...999.9 s (0) [0.1]
- Docu after stop 0...999.9 s (3) [0.1]
- MEMO keys setup {Setup}
- Tone Volume 1...4...15 [1]
- ECG Gain Auto/0.5/[8]...18.0 [0.1]
- ECG polarity [not invers]/invers
- ECG Filter [off]/LP/BP/HP
- ECG mode [bipolar]/Ch2=uni
- ECG Marker [YES (Test)]/no
- INIT Interface

Test Menu
- Test Foot Pedal no/off/on
- Test Indifferent Electrode o.k./fault

Identification Menu
- Device name
- Serial no.
- Revision
- Date
- Customer .....
- Manufacturer .....
- Software Version Test {List}

US-Version

Explanation:
- [ ] Standard Setup
- / Switch
- ( ) Global setting
- □ Resolution
- { } Command

General Diagram MainMenu

Menu Programs

The menu programs allow the operator to use various testing and setting functions.

Pressing the **MENU** key accesses the menu function (MAIN MENU).
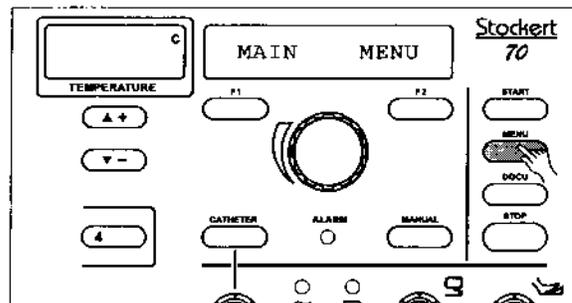
The individual Menu groups are selected using the **SELECTOR KNOB**. (e.g. IMPEDANCE MENU).
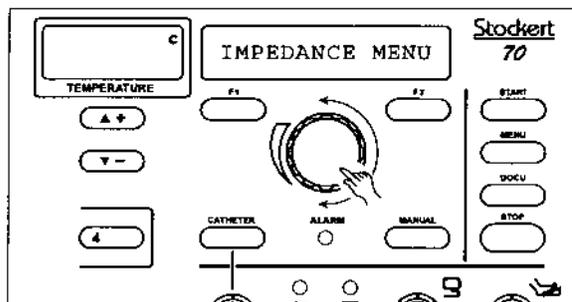
These groups are activated with the **START** key. (E.g. IMPEDANCE MENU --> max.Imp.cut-off:)
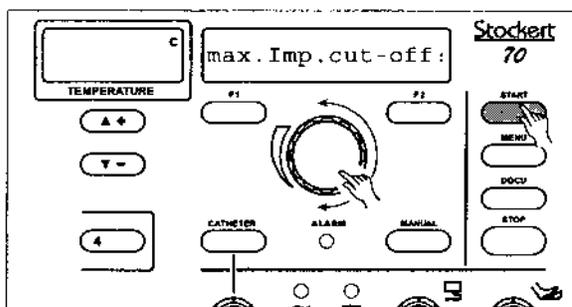
The SELECTOR KNOB can only be used to select the various parameter groups (e.g. IMPEDANCE MENU).
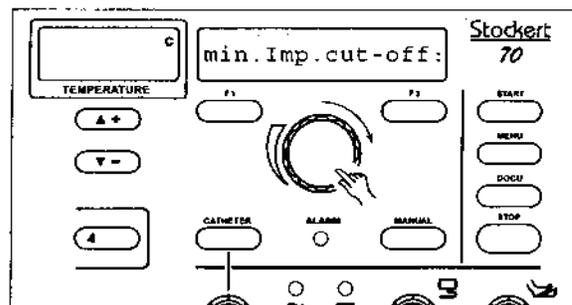
Activate the selected group by pressing the **START** key.

Activate the individual parameter settings with the **F1** and **F2** key or use the **SELECTOR KNOB** key to select individual settings.
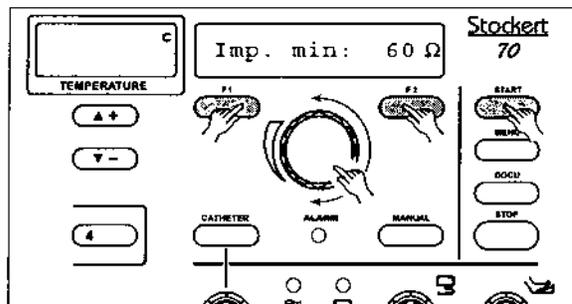
The **STOP** key returns you to the operating mode (ready mode) and saves all selected values or modes.
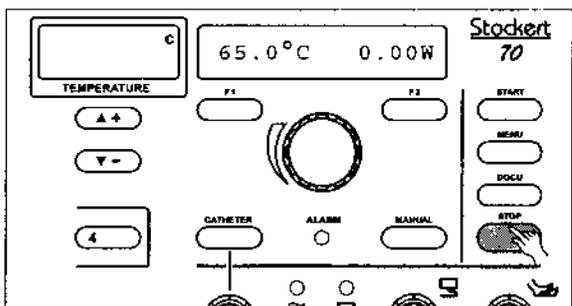
Temperature menu

TEMP. cut-off:

The temperature cut-off sets the maximum ablation temperature. The temperature value can be set using the **SELECTOR KNOB** after the **START, F1** or **F2** key has been pressed.

The maximum temperature to which the temperature cut-off can be set is 95 degrees Celsius.

If temperature increases during ablation (in manual mode) to a value higher than the one set for the temperature cut-off the STOCKERT 70 will be automatically deactivated.

The display will indicate the following message: "Temp.Limiter!"

When setting the nominal temperature in automatic mode you should keep in mind that the nominal temperature may only be set up to 5 degrees Celsius below the temperature set for the temperature cut-off. The temperature cut-off will only be active if a temperature-controlled ablation catheter is used.
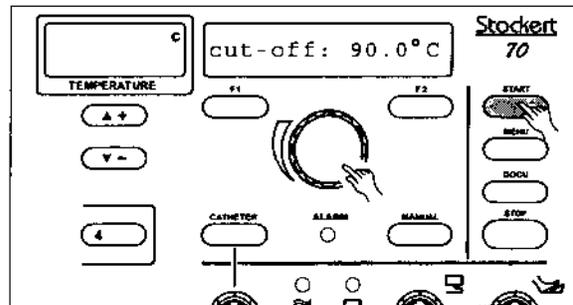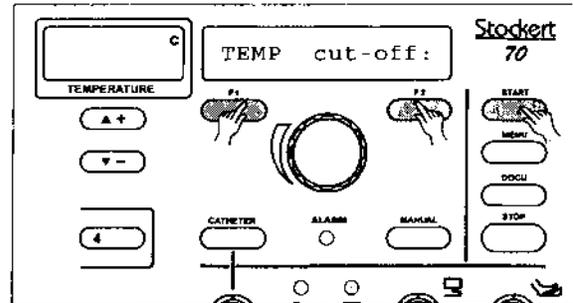
Temperature ramp

This function allows you to program desired temperature ramp.

To set temperature ramp

After pressing the F1 key a value from .02°C/s to 50°C/s can be set using the **SELECTOR KNOB***. For example, if a value of 12°C/s is selected, the temperature is increased by 12°C/s until the nominal temperature is reached. At this rate, it will take about 3 seconds to reach 70°C when starting at 37°C.

* Note:

The temperature ramp range of 12°C/s to 50°C/s was tested in the clinical study. Use of the temperature ramping function at a lower rate than 12°C/s is not recommended.
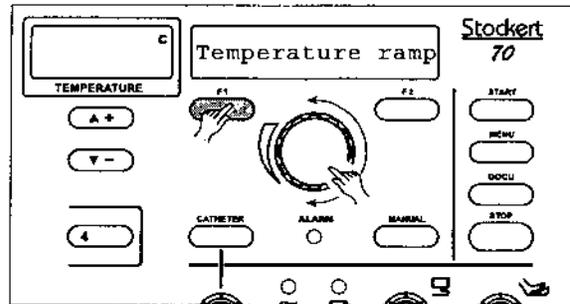
Deactivate temperature ramp

Pressing the **F1** key and turning the **SELECTOR KNOB** left side (anti clockwise) deactivates temperature ramp (Standard setting).
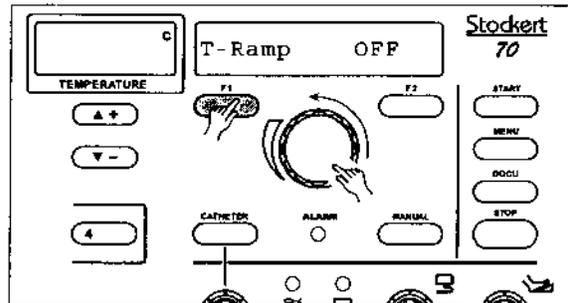
Temp. tendency CTRL

The Temperature tendency CTRL function monitors temperature increase during ablation.

If Temperature tendency CTRL is activated, ablation is automatically interrupted in the following cases:

  a) If temperature does not increase or increase is too low when output is delivered, the display will indicate the following message "catheter error".

  b) If the nominal temperature is exceeded by 3°C and for more than 0.5 sec, the display will indicate the following message "catheter error".

Temperature tendency CTRL is deactivated by pressing the F1 key and activated by pressing the F2 key (Standard setting: OFF).
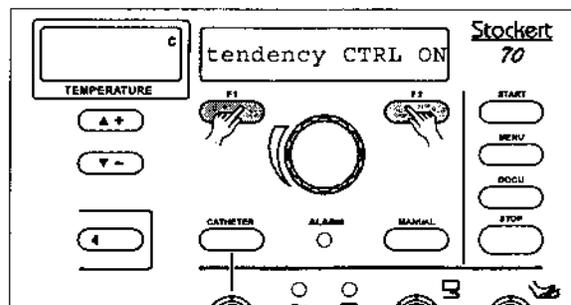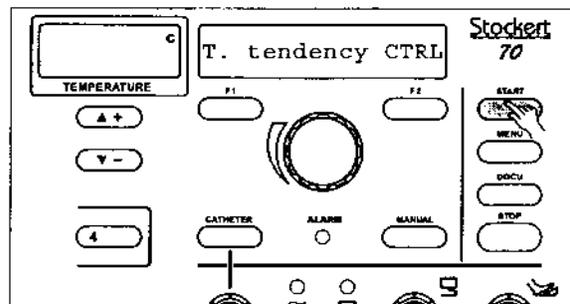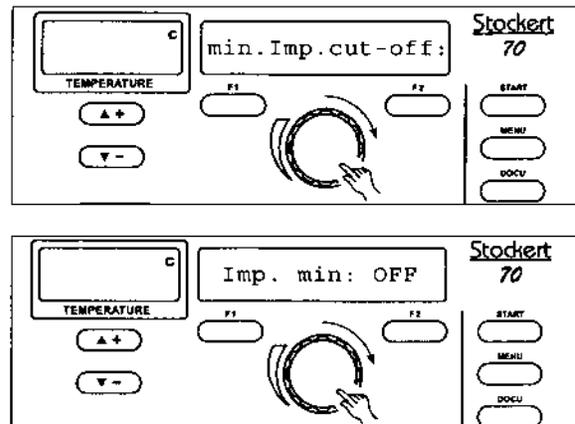
Impedance menu

Max. impedance cut-off

The max. impedance cut-off monitors impedance between the connected catheter and the STOCKERT 70. When impedance increases or is infinite (e.g. if the connection to the catheter is broken) the STOCKERT 70 will switch off automatically (see picture).

After pressing the **START** key the impedance value that will switch the STOCKERT 70 off can be set using the **SELECTOR KNOB**.
Standard value: 250
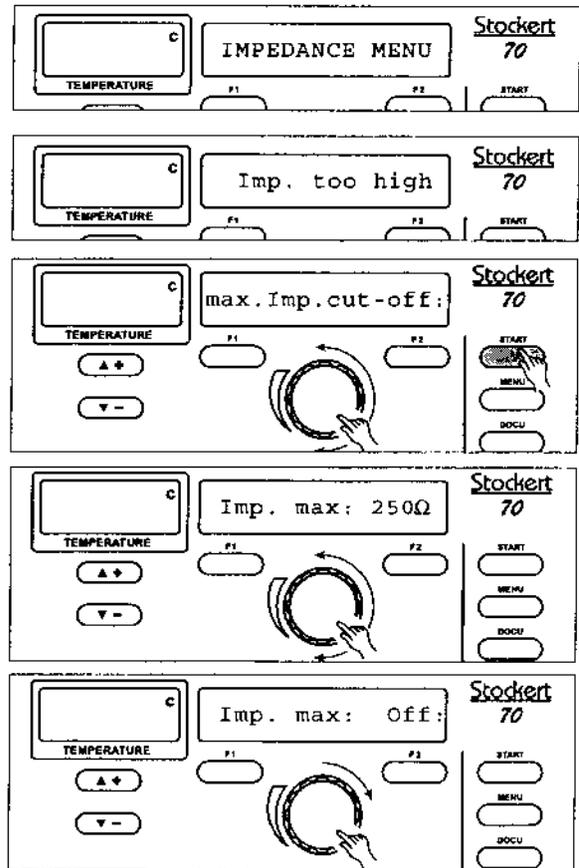
You can also switch off the impedance cut-off completely. To achieve this you must use the **SELECTOR KNOB** to set the device to the "**Imp.max: off**" setting which you will find after the lowest setting.

Min. impedance cut-off:

The min. impedance cut-off monitors impedance between the connected catheter and the STOCKERT 70. When impedance decreases the STOCKERT 70 will switch off automatically (see picture).

After pressing the **START, F1** or **F2** key the impedance value which will switch the STOCKERT 70 off can be set using the **SELECTOR KNOB**.
You can also switch off the impedance cut-off completely. To achieve this you must use the **SELECTOR KNOB** to set the device to the "**Imp.min: off**" setting which you will find after the lowest setting.
Standard value: 50

Delta impedance cut-off

The maximum delta impedance will monitor and iden-
tify a sudden impedance decrease or increase during
ablation. This feature can be used in addition to
switching off the device.

In order to calculate the Delta impedance, all
measured values of the previous 3 seconds of an
impedance measurement sequence are taken into
consideration.
A travelling window is thus created which can be used
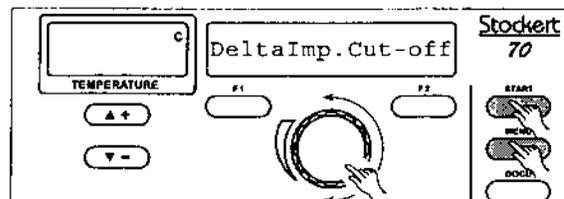to observe the Delta impedance.

Example

A selected value of 10 Ohms Delta Impedance will
interrupt RF application at the moment that the
measured impedance is retrospectively 10 Ohms
higher or lower than any measured impedance value 3
seconds prior to the measured value.

A slow, continous decrease for more than 10 Ohms
during a long period will not affect the RF application,
if the change in impedance during the prior 3 seconds
is smaller than the programmed value.
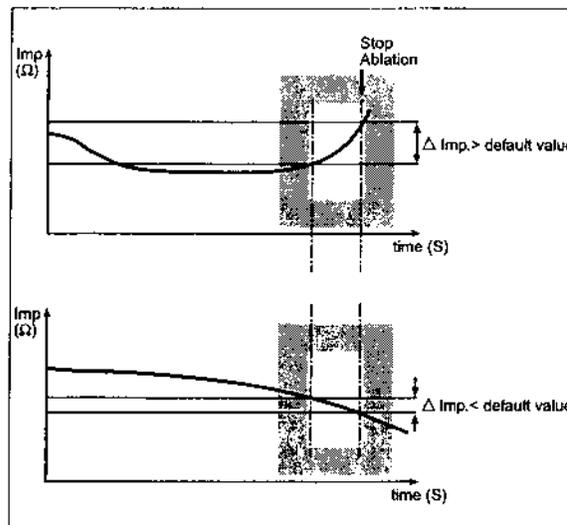
Programming the delta impedance cut-off

After pressing the **MENU** key select the **IMPEDANCE
MENU** and then "Delta Imp. cut-off". The **START** key
can be used with the **SELECTOR KNOB** to set the
max. delta impedance value which will switch the
STOCKERT 70 off.

Key occupation: Standard.......100   Δ Imp
                 F 1................100   Δ Imp
                 F 2................Imp Delta off

You can also switch the max. Delta impedance off
completely. To achieve this you must use the
SELECTOR KNOB to set the device to the "**Imp
Delta: off**" setting which you will find after the highest
setting.
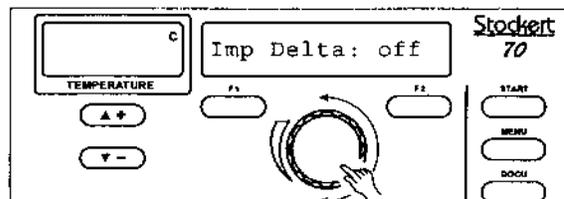
Impedance frequency

The impedance frequency selects the measurement
frequency for the displayed impedance value.
If 50 KHz is selected the STOCKERT 70 will measure
pre-, during and post ablation, the impedance with a
50 KHz measurement frequency.
If 500 KHz is selected, the STOCKERT 70 will
measure pre- and post ablation impedance with
50 KHz and calculates the impedance during ablation
with 500 KHz.
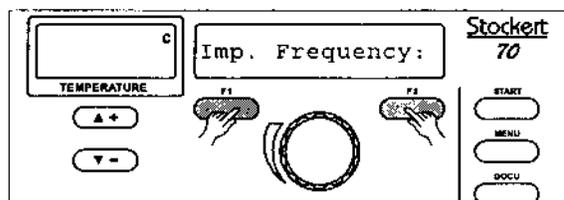
To select 50 KHz measurement frequency, select the
50 KHz with the **F1** key.
To select 500 KHz, press the **F2** key.

Standard setting: 50 KHz

3. Display pre-selection

With these 4 settings, the representation of temperature, voltage or current can be selected parallel to the output display by pressing **F1**. This display function can only be activated in manual mode in connection with a catheter.
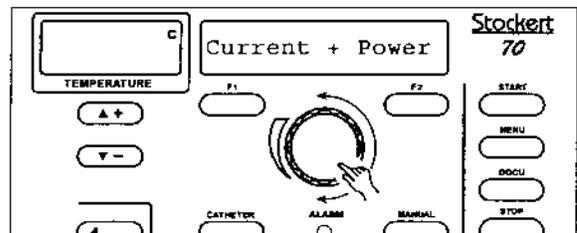
Default temperature (in degrees Celsius) and Power (in Watt) (default set-up)
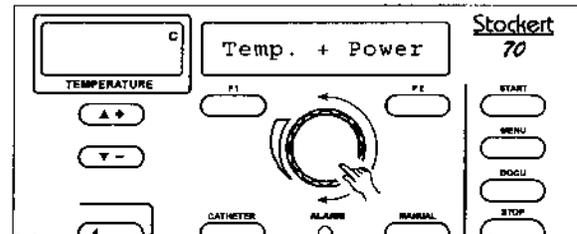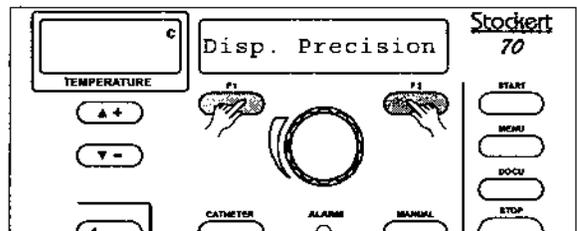

Voltage (in Volt) and Power (in Watt)
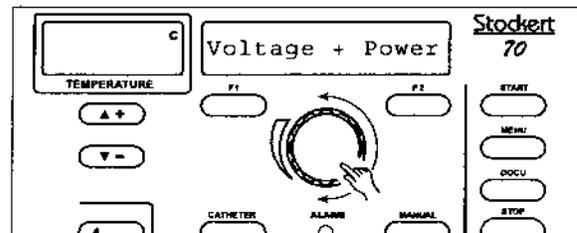
Current (in Millampere) and Power (in Watt)

The accuracy of the display window (number of spaces) can be adjusted.

There are two possibilities:

1. Key **F1** or **STANDARD**
   Standard resolution
   Time: 1 second; Temperature: 1°C

2. Key **F2**
   Full precision
   Time: 0.1 second; Temperature: 0.1°C
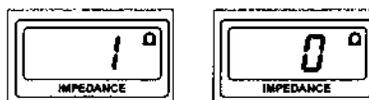
Printer menu

The **Printer menu** is a submenu which allows you to change settings that only apply to printer output.
This applies to DOS-based computers only.

Start by pressing the **MENU** key and select the Printer Menu using the **SELECTOR KNOB**.
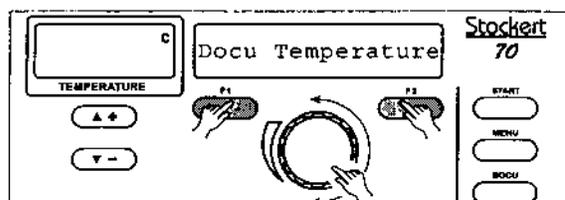Access the Printer menu with the **START** key.
In the Printer menu you can select the different settings using the **SELECTOR KNOB**. The **F1** (on) and **F2** keys (off) will activate or deactive the individual graphics.

The *activated* graphics will be displayed in the impedance display as "**1**".
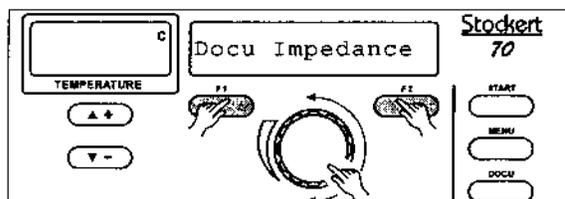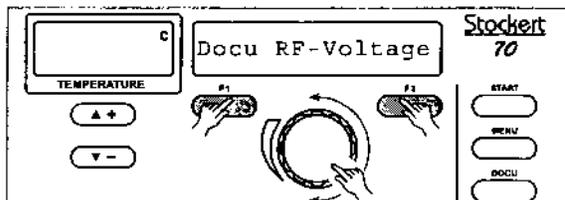All *deactived* graphics will be displayed as "**0**".
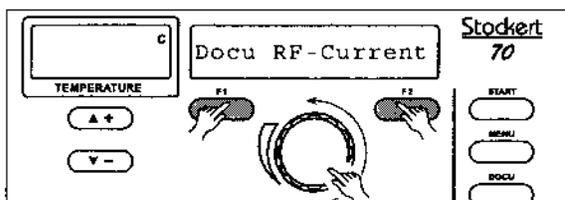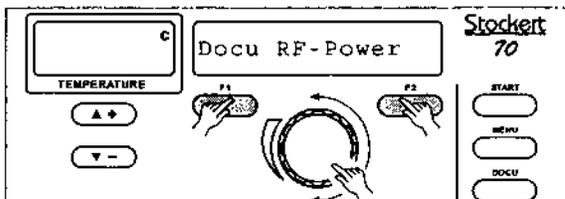

Temperature

Impedance (Ohm)

RF-Voltage (Volt)

RF-Current (Ampere)

RF-Power (Watt)

Docu after stop

With this function, it is possible to set the documentation time after pushing the STOP key.

Example:

The duration of one ablation is 60 seconds (Standard setting). The behavior of cooling should be displayed for 5 sec. after the ablation stops.
For this, set "Docu after Stop" to 5 seconds.
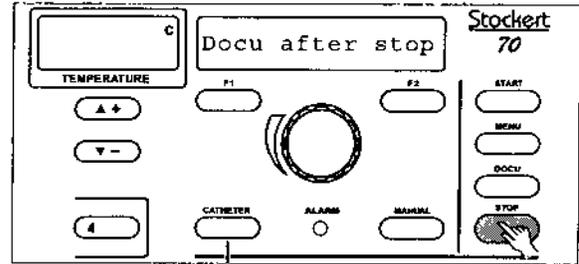
MEMO keys setup

All memory keys can be reset to the factory settings by pushing the F1 or F2 key.
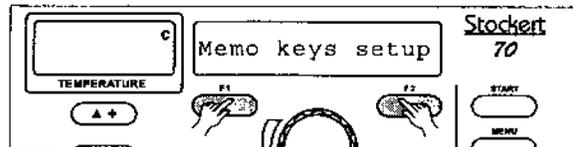
Tone volume

The **RF signal volume** can be adjusted.

After pressing the **F1, F2** or **START** key the selected volume will be indicated as a value 1...15 and can be heard accordingly (1 is the lowest tone and 15 is the loudest tone).
Use the **SELECTOR KNOB** to adjust the volume to the desired settings.
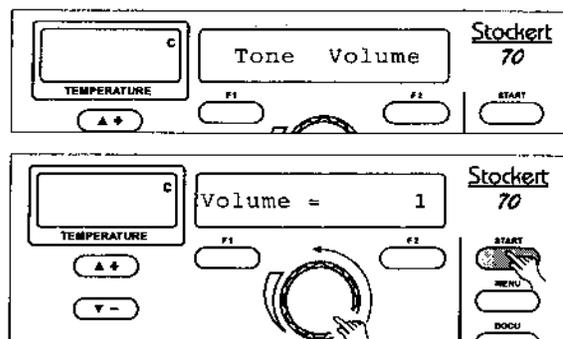
Programming of the integrated digital ECG

3 MENU selections belong to the integrated digital ECG:

ECG-Gain

The ECG offers 2 options to adjust the signal gain.

1. Automatic gain control

If the automatic gain control is selected the signal gain will be adjusted automatically through the integrated digital ECG.
An internal control algorithm is continually optimizing the gain if the signal amplitude changes during signal aquisition.
Therefore, the signal amplitude will maintain constant.

Selection:
Select the MENU option **"ECG Gain"**. Push the **START** key and select the appropriate value using the **SELECTOR KNOB**.
If the **SELECTOR KNOB** is turned to the left, the message **"ECG GAIN: AUTO"** will appear.
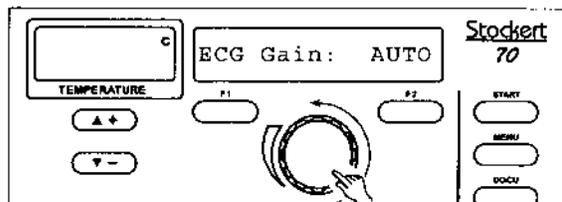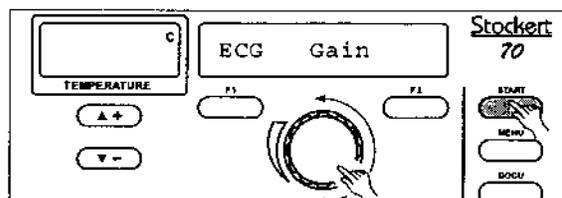
2. Fixed Gain Setting

If a fixed gain setting is preferred, proceed as described under section 1. Select the appropriate value using the **SELECTOR KNOB**.
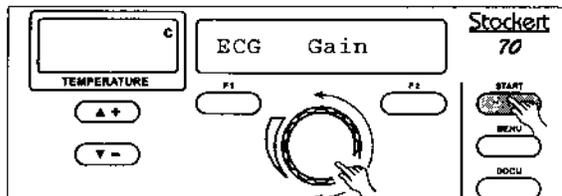
ECG-polarity

The ECG polarity is programmable. Please select the Menu option **"ECG polarity"** and access this option by pushing the **START** key. Select the appropriate value using the **SELECTOR KNOB**.
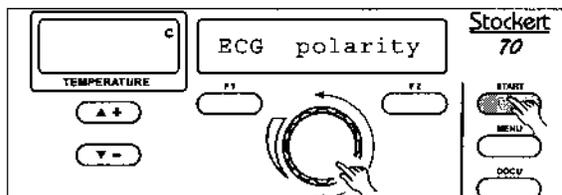
ECG-filter

The integrated digital ECG features digital filters. These filters can be programmed in a wide range. Select the MENU option **"ECG Filter"** and push the **START** key. The STOCKERT 70 displays a list of possible filter settings that can be selected using the **SELECTOR KNOB**. The first setting can be used to switch off all filters. The active filter setting is always displayed in bold.

Possible settings for each filters are as follows:

```
ECG LP ...1000Hz
```

```
ECG BP 80.1000Hz
```

```
ECG HP    80...Hz
```

ECG mode

This menu enables definition of the type of integrated digital ECG measurement.

Key F1 ....pure bipolar measurement

Key STANDARD......bipolar ECG derivation between Tip and Ring 2 on channel CH 1 and bipolar ECG derivation between Ring 3 and 4 on channel CH 2 of the GLOBAL PORT.

Key F2 ....mixed operation bipolar ECG derivation between Tip and Ring 2 on channel CH 1 and unipolar ECG derivation between Tip on channel CH 2 of the GLOBAL PORT.

ECG Marker

At the end of an RF charge application, ECG marker pulses are placed within the integrated digital ECG. These pulses are sent through all amplifiers and filters of the ECG in order to enable conclusions via the recorded ECG amplitudes. These pulses are usually generated; however, they can also be suppressed or tested here.

Key F1 or
Key STANDARD......Release of the ECG marker pulse

Key F2 ....Suppression of the ECG marker pulse

Key START ....After release of the ECG marker pulse, a continuous ECG marker sequence can be initiated by pressing the **START** key. This sequence supports the ECG device calibration.

Low Pass (LP)	
Frequencies up to the selected value can pass 1000 Hz can pass	10Hz, 30Hz, 80Hz, 100 Hz, 250Hz, 500Hz, 1000 Hz

Band Pass (BP)	
Frequencies within the selected range can pass	5-1000 Hz, 10-1000Hz, 30-1000 Hz, 80-1000Hz, 5-500 Hz, 10-500Hz, 30-500 Hz, 80-500Hz, 5-250 Hz, 10-250Hz, 30-250 Hz, 80-250Hz, 5-100 Hz, 10-100Hz, 30-100 Hz, 80-100Hz

High Pass (HP)	
Frequencies greater than the selected value can pass	10 Hz, 30 Hz, 80 Hz, 100 Hz, 250 Hz, 500 Hz, 1000 Hz

Test menu

Test foot pedal

Tests foot pedal functions. If activated the message "Test foot pedal" is displayed.

If the **START** key is pushed the message **"No Footswitch"** appears.

In case of not activating the footswitch the message "Footswitch off" will appear.

Otherwise the message **"Footswitch on"** will appear. If this is not the case the foot pedal connecting cable is disconnected or broken.
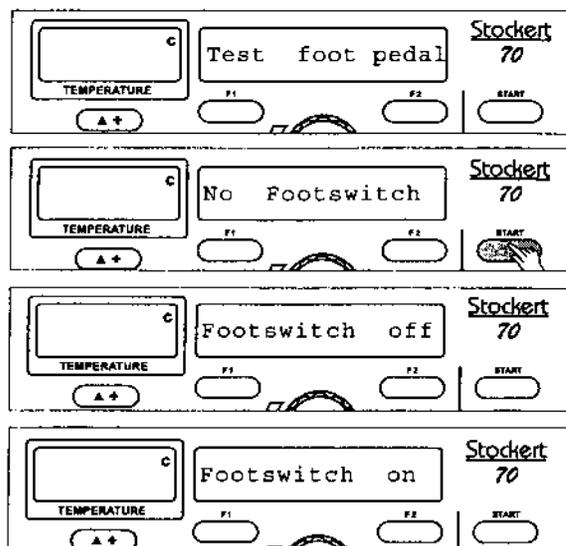
Test indifferent electrode

The measured value will appear in the impedance display.

Identification

The following device information can be read with the **SELECTOR KNOB**:

- Device name .... STOCKERT 70
- Serial number ...... ST xxxxx
- Version number
- Manufacturing date
- Distributor / customer specifications
- Manufacturer Stockert GmbH
- Select software versions

Error messages

Error messages	Cause of error / correcting error	Menu-Point
Indifferent elec (flashing)	Attempt to start device without indifferent electrode.	
Catheter error	No increase in temperature can be measured after output has been delivered. (Faulty catheter or inadequate placement of indifferent electrode)	
Temp. over-run	Set temperature has been exceeded by more than 3 degrees Celsius. (Temp. parameters not at optimum)	Temp tendency control
Temp. Limiter	Maximum ablation temperature set in temperature limiter has been exceeded.	TEMP cut-off:
Imp. too high	Impedance value set in impedance limiter has been exceeded. (Coagulation or interruption between catheter and device)	max.Imp. cut-off
Impedance too low	The impedance limiter for monitoring of the smallest allowable impedance value was too low.	min. Imp.cut-off
Error Imp Delta	The maximum allowable dynamic impedance change was exceeded.	max. Delta Imp.:

Fatal error messages

Alarm display (blinking)

Fatal error messages are indicated by a blinking alarm display and an error message.

Error 100 nnn . . . . Software error. Permitted storage capacity not achieved

Error 101 nnn . . . . Software error. Permitted storage capacity exceeded

Error 120 nnn . . . . Loss of data. ROM fault. Basis 0 computer

Error 121 nnn . . . . Loss of data. ROM fault. Basis 1 computer

Error 122 nnn . . . . Loss of data. ROM fault. Impedance computer

Error 126 nnn . . . . Loss of data. ROM fault. Display - computer

Error 127 nnn . . . . Loss of data. ROM error

Error 130 nnn . . . . Memory error. Basis 0 computer

Error 131 nnn . . . . Memory error. Basis 1 computer

Error 132 nnn . . . . Memory error. Impedance - computer

Error 136 nnn . . . . Memory error. Display - computer

Error 137 nnn . . . . Memory error. Documentation computer

Error 140 nnn . . . . Hardware error. Basis 0 computer

Error 141 nnn . . . . Hardware error. Basis 1 computer

Error 142 nnn . . . . Hardware error. Impedance - computer

Error 144 nnn . . . . Hardware error. Measurement - computer

Error 146 nnn . . . . Hardware error. Display - computer

Error 147 nnn . . . . Hardware error. Documentation computer

Impedance measurement

General information on impedance measurement

The measurement of tissue impedance, i.e. the electrical resistance of tissue, is designed for two applications:

1. For the differentiation of tissue types and placement of catheter tip.
2. For control of the lesion during RF ablation.

The STOCKERT 70 includes an impedance measurement unit.
With this measurement unit the tissue impedance between the following electrode surfaces of the ablation catheter can be measured:

Operating mode table:

Mode	Function	Active electrode
unipolar	from catheter tip to indifferent electrode	tip-indifferent electrode

Radiofrequency heating of tissue will change the impedance due to heating and dehydration of fluids.

During a temperature increase, tissue impedance decreases to its minimum value and remains constant at this value for some time. Thereafter, the impedance will increase based on the applied power. A quick impedance rise should be avoided if the desire is to generate further lesion growth. Therefore, the nominal ablation temperature should be chosen appropriately.
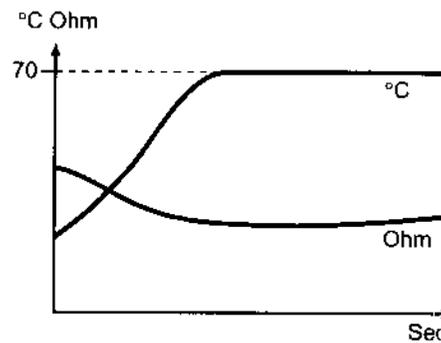
Preparation

For a unipolar ablation, the patient must be connected to an indifferent electrode.
After adequate placement, it is connected to the device with the indifferent electrode connection cable.
(See page 6, page 23)

Operation

The diagnostic/ablation catheter is connected to the device using the temperature-controlled ablation catheter connecting cable. After pressing the **CATHETER** key the message **"SELECT CATHETER"**will appear in the display. You can now use the **SELECTOR KNOB** to select the type of cardiac catheter connected. Then the activation key must be pressed which leads you to the operating mode for TEMPERATURE-CONTROLLED ABLATION WITH TEMPERATURE-CONTROLLED DIAGONSTIC/ABLATION CATHETERS.
(See Chapter 10, Operation)

Program sequences

Automatic temperature controlled mode ("F1" - nominal temperature & "F2" - 50 Watts),
with automatic adjustment of the RF generator and optimized increase depending on the selected catheter mode, or

Automatic temperature controlled mode with power limitation ("F2" - power limit preference),
with automatic adjustment of the RF generator and optimized increase depending on the selected catheter mode, or

Manual power controlled mode ("MANUAL"),
with manual RF generator adjustment in the conventional sense. Temperature is monitored only, but has no influence on the RF generator output.

Immediately after switching the device ON the system is set to automatic temperature controlled mode with power limitation (30 Watts).

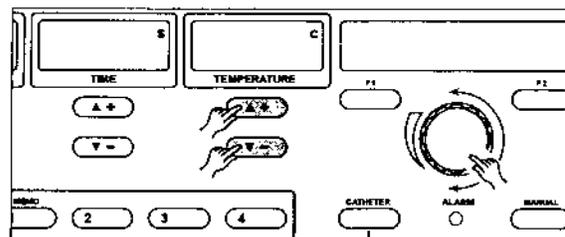## Note
With standard BIOSENSE WEBSTER diagnostic/ablation catheters, the maximum output is 50 Watts.

Programming of the nominal ablation temperature and the ablation time

The nominal ablation temperature can be set with the **TEMPERATURE** keys in steps of 5 degrees Celsius or continuously using the **SELECTOR KNOB**.

It is possible, however, to change the nominal ablation temperature during RF application.

The continuous selection during ablation works by pushing the function key **F1** and using the **SELECTOR KNOB**.

Note

The maximum programmable nominal ablation temperature will be limited through the "**Temp. Limit**". It is only possible to select a temperature that is 5 degrees Celsius below the programmed temperature limiter (see chapter 10, page 34, temperature limiter).
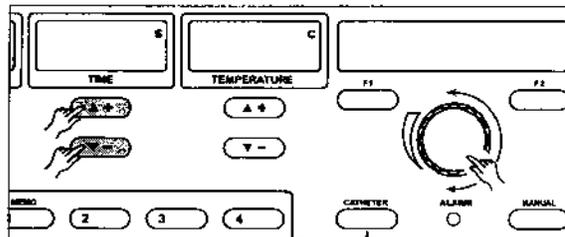
The **TIMER** keys can be used to program the appropriate ablation time in steps of 5 seconds up to 999 seconds.

To select continuous timer values use the **SELECTOR KNOB**.

Temperature controlled mode with power limitation

In automatic temperature controlled mode with power limitation the device will set the optimum RF output according to the selected catheter type. In any case, however, it will never exceed the selected power limit. Even if the nominal temperature is not reached due to unstable catheter contact, temperature is adjusted to the preset nominal value. Manual setting of output is not available in **automatic temperature controlled mode with power limitation**.

The **F1** key and the **SELECTOR KNOB** can be used to program and select the appropriate nominal ablation temperature. The display will highlight the nominal temperature as soon as the **F1** key is pressed.

The **F2** key and the **SELECTOR KNOB** can be used to program and select the appropriate maximum applied power. The display will highlight the maximum applied power as soon as the **F2** key is pressed.

The **SELECTOR KNOB** will change only the highlighted value. During ablation these values can be changed in similar described form, however, as soon as the power limit is changed the actual applied power will be displayed.

Manual mode

Use **SELECTOR KNOB** to adjust RF output in Watts. The temperature display indicates current temperature at catheter tip. Temperature is not adjusted automatically. It is recommended that one increase output carefully after ablation begins. The "**Temp. cut-off**" will limit maximum temperature in manual mode as well. Time delay for the selected electrode must be taken into consideration when setting output.
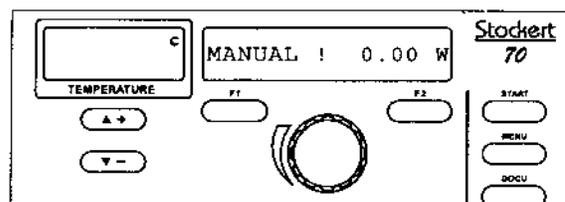
Note

With standard BIOSENSE WEBSTER catheters the maximum output is 50 Watts.

Start ablation with START / STOP keys

The **START** key starts ablation at the selected values. The **STOP** key interrupts current ablation procedure. Ablation time will remain at the current value.

The ablation process can be continued by pressing the **START** key again. If ablation time has run out ablation procedure will be stopped.
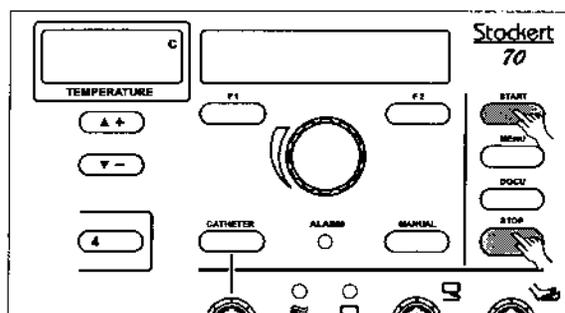
Start ablation with foot pedal

Pressing the **FOOT PEDAL** will start ablation. If foot pedal is released, the ablation procedure will be interrupted and the ablation timer is reset. If ablation time has run out ablation will be stopped. The end of ablation will be indicated by a beep.
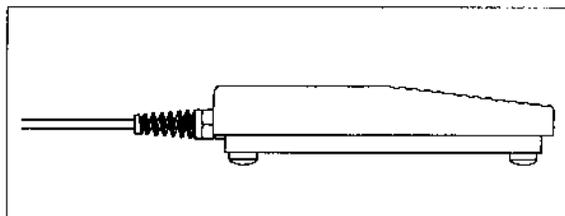
Note

After ablation time has run out ablation may be "prolonged" by pressing and holding the **START** key.

During ablation the programmed settings for nominal ablation temperature and ablation time can be adjusted without interrupting the ablation process using the corresponding ± key.

Documentation

Documentation with PC

Documentation is for each ablation may be obtained through a connected PC.

Connection of the PC is done according to the diagram in section 10, page 24.
To install the PC software, please refer to the installation notes on the installation diskette.

Technical Specifications

Impedance unit

Measurement current..............2uA, 50 kHz sinus

Measurement range....................0 ... 999 Ohms, resolution 1 Ohm

Ablation unit

Nominal temperature..................up to 85° C, resolution 0.1°C

Preset time..................................up to 999 sec., resolution 0.1 sec.

RF Frequency..............................500 kHz

RF output....................................50 Watts / 100 Ohms

RF Peak voltage..........................141 Vs max

Modes ....- Programmed thermoablation with temperature-controlled catheter
- Manual controlled thermoablation with temperature-controlled catheter

Documentation and interface

Memory area..............................up to 32 kbytes
Registration of all settings, display and measurement values

Interface ....Fiberoptic

Specification mains

Mains voltage.............................115/230 V, ± 15%

Max. input..................................50 / 60 Hz

Classification ....184 VA, see type label

Classification..............................Class 1/CF (according to IEC 601-1) CF

Classification..............................Class III; CF; (according to 93/42/EWG)

Weight.......................................22lbs. maximum

Dimensions.................................149 mm wide x 360 mm high x 258 mm deep

Safety requirements ....MDD / MPG / CE / UL

Warranty

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Controls

Front panel controls

1. Impedance display
2. Ablation timer display
3. Temperature display
4. Alphanumeric communication display
5. Timer increase
6. Timer decrease
7. Temperature increase
8. Temperature decrease
9. Function key F1, used for variaty of functions, depends on mode
10. Function key F2, used for variaty of functions, depends on mode
11. Start key, starts a selected application, e.g. Ablation
12. Menu key, activates the menu program
13. Documentation key, activates documention to the connected printer
14. Stop key, stops a running application or saves and confirms a selected value in one of the different menu programs
15. To program the device to nominal setup
16. Programmable Memory keys 1-4
17. Set Catheter key, to select connected catheter
18. Alarm indicator, displays failure modes
19. Manual key, to select manual mode during temperature mode
20. Ablation catheter connection
21. RF application indicator
22. Indifferent electrode indicator, used to identify correct connected indifferent electrode or indicates flashing that an indifferent electrode has to be connected
23. Indifferent electrode connection
24. Foot pedal connection
25. Selector knob for different functions, depends on mode
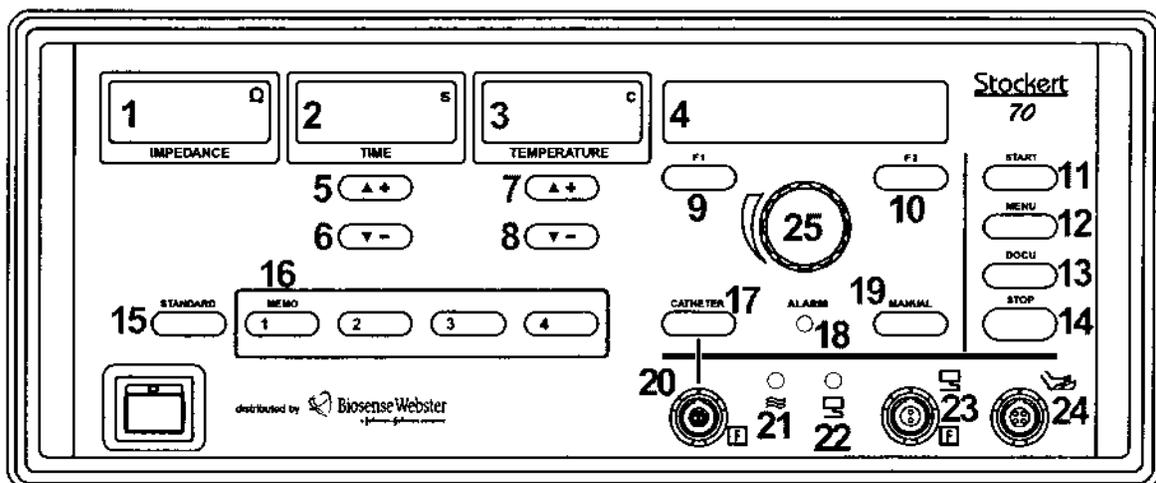
Back panel controls

1. Voltage selector 115/230 Volt
2. Power cord
3. Equipotential connector
4. Interface for fiberoptic
5. Type plate
6. External Stimulator / ECG-Recording connection
7. Digital ECG-Recording connection
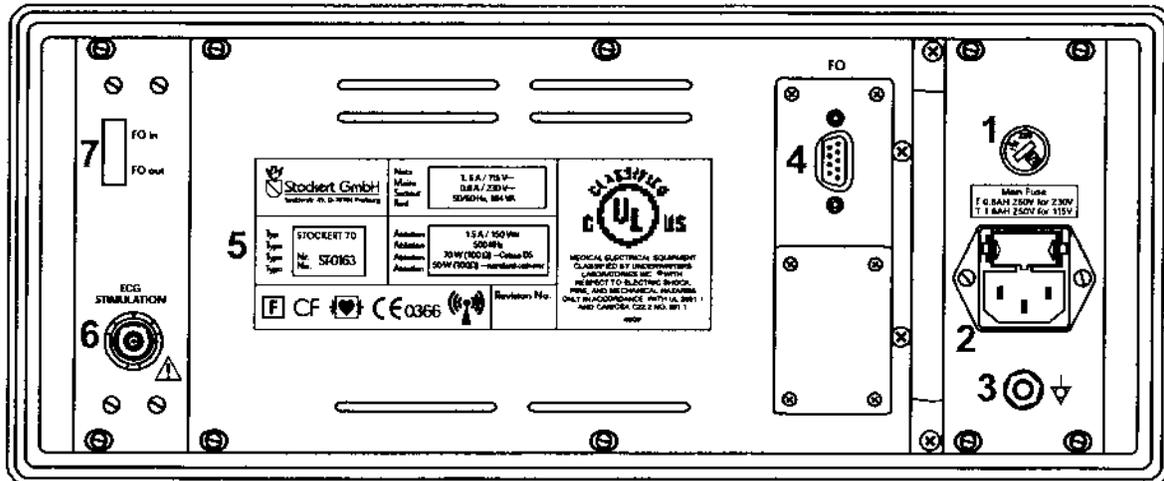
Symbols used on the STOCKERT 70
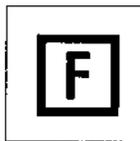
F	The indifferent electrode and the catheter connection of the STOCKERT 70 have zero voltage. It is not connected to common ground (EN 60 601 Part 2-2 6.1; for 19.101 b).
	Connections identified with this symbol are floating (no connection with common ground).
CF	The STOCKERT 70 is a CF device type. All leakage currents are extremely small. This allows the STOCKERT 70 to be used in direct contact with the open heart.
♥	All patient connections of the STOCKERT 70 are defibrillator proof.
(((•)))	The STOCKERT 70 emits non-ionized radiation. (EMV; IEC 878-03-04)
IPX 8	The foot pedal of the STOCKERT 70 is water resistant.
	Indifferent electrode
	Foot pedal
≋	Radio-frequency
⚠	Note for the user Before connection to these labelled connections please read the relevant sections in the user manual (see chapter 4, page 8, 9)
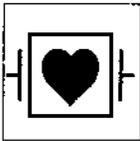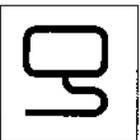
Output Specifications

STOCKERT 70 - Output Power
(unipolar)

STOCKERT 70 - Output Power
(unipolar)

Functional Principle GLOBAL PORT
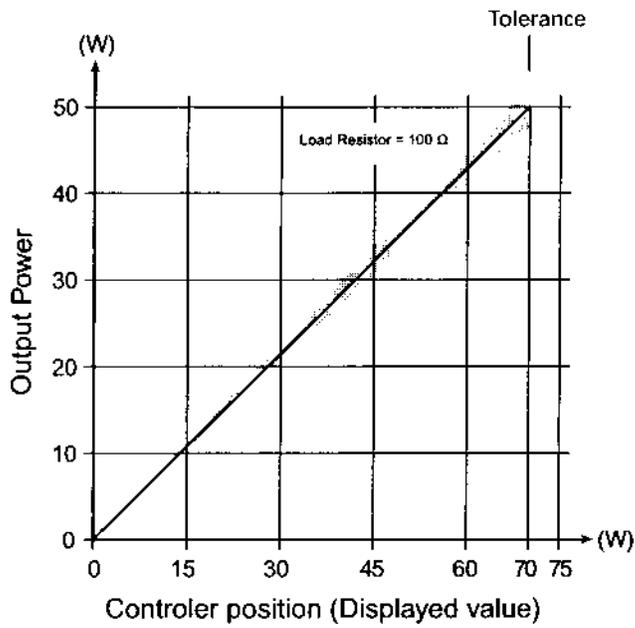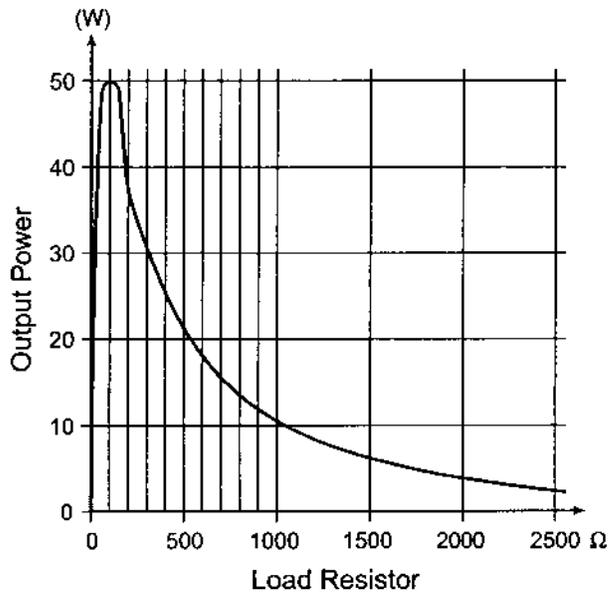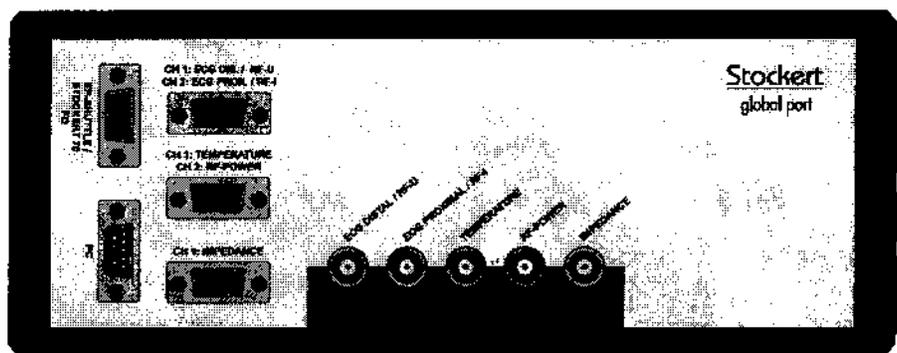
The GLOBAL PORT is the interface to the external presentation and document system for external digital and analog data. It is possible to record the catheter ECG data and all measurement data of the STOCKERT 70 using the five channels of the GLOBAL PORT.

The connection with the STOCKERT 70 is realized exclusively with light impulses which are transmitted over optical fibers. Therefore, the GLOBAL PORT is electrically isolated from the STOCKERT 70.

The output signals of the GLOBAL PORT will be generated in two parallel working formats:

1. **BNC connectors:**
   Amplified signal with 5V amplitude
   To be used for the connection with the external input channel of your ECG machine

2. **9 pole D-SUB connectors:**
   Small signal with 20 mV amplitude
   To be connected to the 2 mm tip pin interface of the ECG amplifier box.

Both signal outputs of the GLOBAL PORT can be used simultaneously. The small signal outputs are individual galvanic differentiated from the total system using optical fibers. Each 9 pin D-Sub connector carries 2 channels.

A digital communication with the central processing unit of the STOCKERT 70 will be realized using a 9 pole D-SUB optical fiber. The digital ECG is transmitted independent from this connection using a separate high speed optical fiber connection. The connection to the PC uses a standard RS232C data connection cable. The PC graphic software can be used to process the digital data of the STOCKERT 70.

Accessories

The GLOBAL PORT will be connected to the PC using the following accessories:

Product Specification	Order No.	Description respectively Function
1. Power cord	M-5463-04	Power supply
2. Computer / Digital ECG connection cable	M-5463-14	Connection between GLOBAL PORT and STOCKERT 70
3. Serial Computer Interface Cable	M-5463-13	Connection between GLOBAL PORT and PC

Using the GLOBAL PORT Interface

A calibration signal will appear on each channel after switching the GLOBAL PORT „ON".
This calibration signal contains 3 segments:

1. Display of all calibration pulses which will be generated during RF power application on each channel.

Channel number	Sequence								Unit
Ch1:	100	100	50	50	50	50	50	50	V
Ch2:	1000	1000	500	500	500	500	500	500	mA
Ch3:	100	100	50	50	50	50	50	50	°C
Ch4*:	70	70	50	50	25	25	10	10	W
Ch5:	1000	1000	500	500	250	250	100	100	

2. Channel ID. The channel number will be displayed through a pulse train which corresponds to the channel number:

Channel number	Sequence	Representative Amplitude
Ch1:	1 pulse	25 V
Ch2:	2 pulses	250 mA
Ch3:	3 pulses	25 °C
Ch4:	4 pulses	8 W
Ch5:	5 pulses	200

3. Signal amplitude dynamics of each channel in steps of 10 respectively 100:

Channel	Sequence										Unit
Ch1:	100	90	80	70	60	50	40	30	20	10	V
Ch2:	1000	900	800	700	600	500	400	300	200	100	mA
Ch3:	100	90	80	70	60	50	40	30	20	10	°C
Ch4*:	70	70	70	70	60	50	40	30	20	10	W
Ch5:	1000	900	800	700	600	500	400	300	200	100	

* NOTE:
The calibration signal will display an output level corresponding to 70 watts to allow correlation of the measured and recorded amplitude signals. The STOCKERT 70 RF generator is only capable of delivering 50 watts.

Calibration impulses during the ablation / data recording:

Voltage....................50 V
Current.....................500 mA
Temperature.............50 °C
Power.......................50, 25 and 10 W
Impedance...............500, 250 and 100

Operation

WARNING

Please recognize the information about mains voltage **before** switching the GLOBAL PORT "ON".
The GLOBAL PORT uses:

230 V AC 50 / 60 Hz
or   115 V AC 50 / 60 Hz

Please set the GLOBAL PORT to the correct mains voltage before switching it ON.

Please connect the power cable and switch the device ON. The green power control light must be on. The GLOBAL PORT is in self testing mode as long as the digital communication is not established or the STOCKERT 70 is OFF.

Connecting your ECG system to the GLOBAL PORT

The self testing mode of the GLOBAL PORT allows an easy adaptation to your ECG machine. Check the connection options to your ECG machine. If possible, you should always use the amplified signals with the ECG external input channels. The signals can be recorded using the corresponding BNC connection cables for the external input channels (e.g. 10 V input) of the ECG system. Therefore, please use the BNC connectors of the GLOBAL PORT. This external connection doesn't require an ECG amplifier input and is out-side the patient area. These connections can stay fixed with your ECG system.

A front amplifier connection is required, if your ECG machine has no external input channels. Therefore, you need a special interface cable. This cable allows the signals to be recorded potential free through the 2 mm tip pins using the sensitive input amplifier of your ECG machine.

Please set-up your ECG system according to the selected connection. A test signal is generated on all channels of the GLOBAL PORT as long as no additional connection (PC or STOCKERT 70) is exists. These test signals can be used to find the optimum set-up for the ECG machine.

The test signals have three segments:

1. Marker level, according to the channel
2. Channel ID: CH1: 1 pulse, CH2: 2 pulses...CH5: 5 pulses
3. Downwards counter in steps of 10 or 100 from the maximum recorded value

You should only continue the GLOBAL PORT set-up, if all required test signals are clearly visible on your ECG machine. Please save/backup the new configuration of your ECG system (set-up).

Operating the digital ECG

After switching the STOCKERT 70 ON the ECG amplifier will send continuous digital information using a light transmitter on the back-side of the device. This information contains the ECG signal. Please connect the transmitter and receiver using the connection cable (M-5463-14), confirm that the FO OUT and the FO IN connect into the corresponding inputs.

On the opposite end of the optical fiber you can see the light information on the **FO IN** connection of the optical fiber. Please, connect accordingly the **FO IN** and the **FO OUT** connector of the cable with the corresponding inputs of the GLOBAL PORT.

Now the ECG channels will appear on the ECG system.

If the catheter is not connected or is outside the patient body, a noisy interference signal will be visible. It is possible to connect a surface ECG to the catheter connection. The indifferent electrode however must be in contact with the patient.

Programming the amplifier on the STOCKERT 70

Please program the digital ECG of the STOCKERT 70 to "GAIN 2 mV", "no Filter", Polarity "not inverse" and "bipolar ECG" (refer to corresponding chapter of the users manual). The settings may require adjusting to match/synchronize with the patient ECG signals.

Connecting the STOCKERT 70 with the GLOBAL PORT

Please connect the 9 pole SUB-D connector of the cable (M-5463-14) on one side with the 9 pole SUB-D connector of the STOCKERT 70 and on the other side with the 9 pole SUB-D connection of the GLOBAL PORT. The correct connector on the GLOBAL PORT is labeled "EP-SHUTTLE / STOCKERT 70 FO".

Check the installation by programming the STOCKERT 70 to "MANUAL MODE". Connect a catheter and the indifferent electrode with the corresponding cables to the STOCKERT 70 and dip both into a can with salt water. Program the power output on the STOCKERT 70 to 0.00 Watts. Push the "START" key and observe the corresponding ECG channels for "Temperature" and "Impedance" markers. As long as the catheter is in salt water you can change the power output with the selector knob. Please notice the changes of the power output on the communication display.

If the digital ECG connection is interrupted (disconnect FO IN from the GLOBAL PORT), you can record the RF voltage and RF current on channel 1 (RF-U) and 2 (RF-I).

Connection to the PC

Please check correct connection according to the above description. Thereafter, connect the PC to the GLOBAL PORT using the cable (M-5463-13). Install the actual PC software on your computer and start the program.

Connection to the STOCKERT 70

The PC will download information from the PC-Shuttle after pushing the key "L" on the keyboard. If the connection is correct a graph will be displayed on the monitor with the corresponding time scale. To return to the PC main menu just push ESC.

Connection to the ECG amplifier

Push the key "P" (parameter) from the main menu followed by "O" (options). All ECG information will be now downloaded after pushing the key "I". If the high speed ECG connection is correctly installed a text information about the installed ECG system will be displayed. To return to the main menu just push ESC.

Additional Information

All components of the GLOBAL PORT system can be used independent.

Small configuration:
You can use the GLOBAL PORT without PC and digital ECG. Each component works independent.

ECG operation with RF-voltage and RF-current:
The independent recording of all signals allows to connect a second GLOBAL PORT for recording of digital ECGs. Therefore, RF-voltage and RF-current can be recorded in parallel.

Description of the calibration impulses

At the end of an ablation a calibration sequence will be generated. This calibration sequence allows correlation of the measured and recorded amplitude signals.

Calibration sequence post ablation data

The calibration sequence post ablation contains three segments:

1. Display of the calibration impulses during RF power application
2. Channel ID, which is displayed by a pulse train
3. Downwards counting to see signal dynamics

Detailed description:

RF Voltage Sequence	Channel 1 Pulse amplitude (positive and negative)										Unit
1.	100	100	50	50	50	50	50	50			V
2.	25										V 1 pulse
3.	100	90	80	70	60	50	40	30	20	10	V

RF current	Channel 2										Unit
1.	1000	1000	500	500	500	500	500	500			mA
2.	250	250									mA 2 pulses
3.	1000	900	800	700	600	500	400	300	200	100	mA

Temperature	Channel 3										Unit
1.	100	100	50	50	50	50	50	50			°C
2.	25	25	25								°C 3 pulses
3.	100	90	80	70	60	50	40	30	20	10	°C

Power	Channel 4										Unit
1.	70	70	50	50	25	25	10	10			W
2.	8	8	8	8							W 4 pulses
3.	70	70	70	70	60	50	40	30	20	10	W

Impedance	Channel 5										Unit
1.	1000	1000	500	500	250	250	100	100			
2.	200	200	200	200	200						5 pulses
3.	1000	900	800	700	600	500	400	300	200	100	

The five channels with their characteristic calibration sequences

CH 1 Voltage

CH 2 Current

CH 3 Temperature

CH 4 RF-Power

CH 5 Impedance
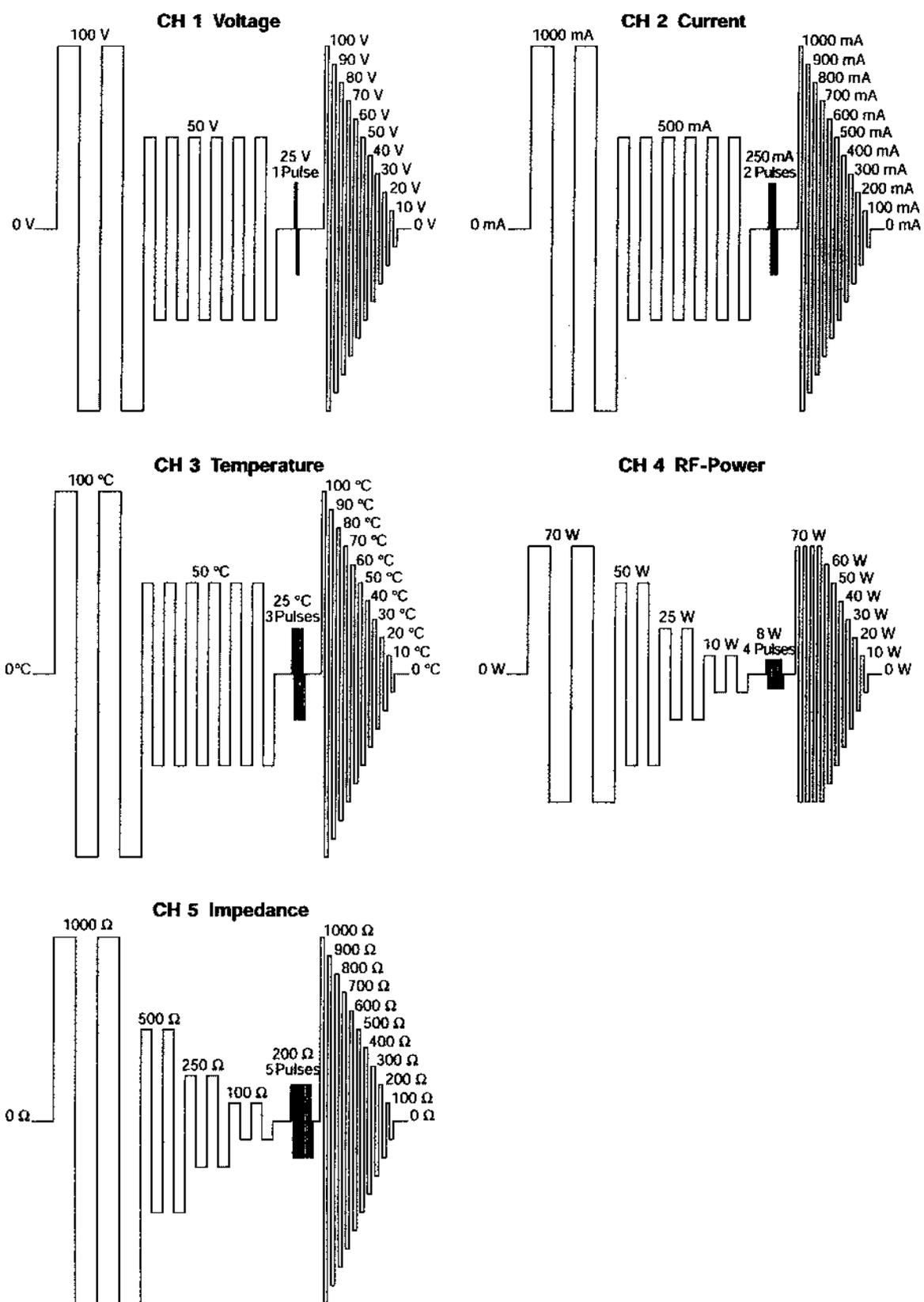
The calibration impulses during the RF application are displayed on the right site of each measured value impulse. All measurement impulses are displayed in alternate format.

Example:

Measurement n	Value	Amplitude	Calibration impulse
1	47°C	+47	0
2	48°C	-48	0
3	49°C	+49	0
4	50°C	-50	-50
5	51°C	+51	+50
6	52°C	-52	-50
7	53°C	+53	+50
8	54°C	-54	-50
9	55°C	+55	+50
10	49°C	-49	0
11	47°C	+47	0

Calibration steps of each channel:

Voltage:	0	50			V
Current:	0	500			mA
Temperature:	0	50			°C
Power:	0	10	25	50	W
Impedance:	0	100	250	500	

If the digital ECG is connected it will overwrite channel 1 (RF-U) and 2 (RF-I). At the end of each ablation a calibration sequence will be generated on the digital ECG which has 2 segments for calibration and channel ID.

| Segment	Function
1	Calibration impulse with 1 mV calibration amplitude
	A total of 8 pulses divided into 4 groups with 2 pulses are generated
2	Channel ID
	Channel 1: 1 pulse
	Channel 2: 2 pulses

The calibration impulses can be used to calculate the ECG amplitudes.

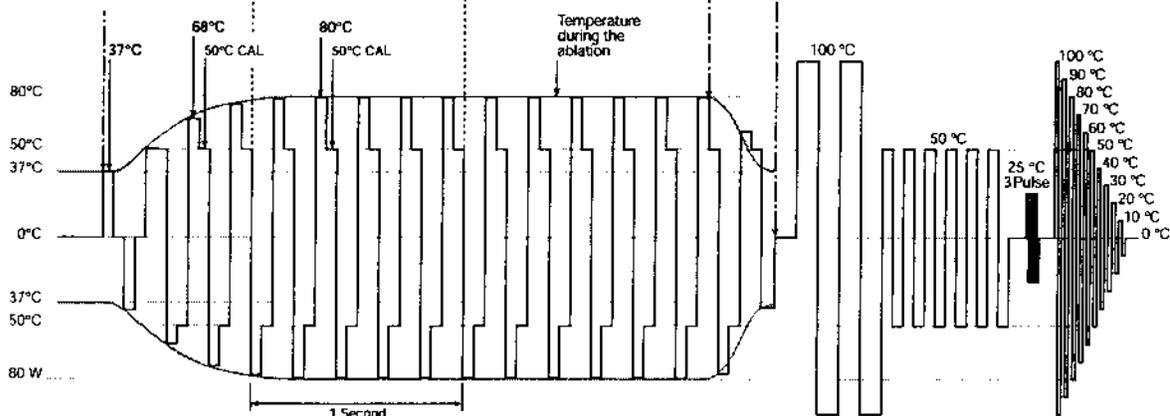NOTE: The channel ID can be displayed truncated due to the filter setting of the ECG.

1 mV Calibration pulses
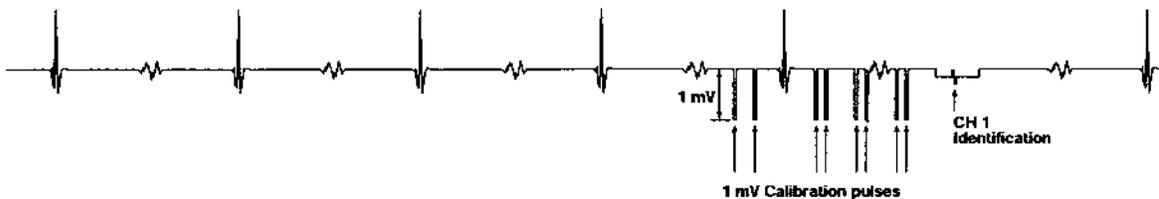
## Structure of the RF Power Curve

CH 4
RF-Power
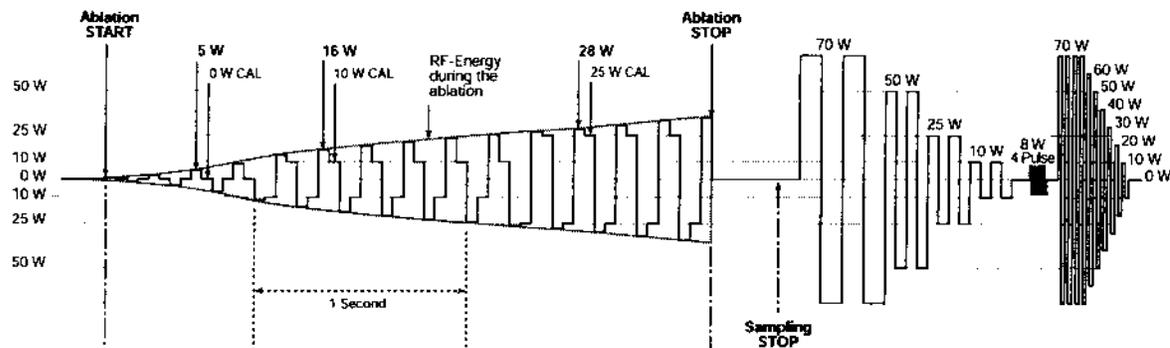
CH 3
Temperature Profile

The CH 4 RF power is shown in the figure.
As long as the RF output power under 10 W, an alternating pulse of 50 ms duration and an amplitude corresponding to the power supply are shown.

RF Power under 10 W

When under 10 W, the impulse after 50 ms returns to the zero line for another 50 ms before indicating the actual power by means of reversed polarity for an additional 50 ms
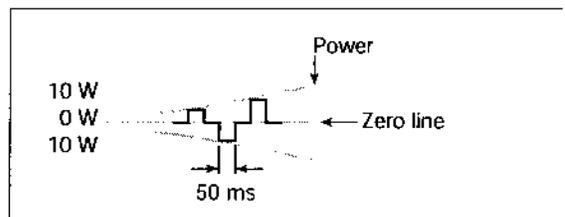
RF Power over 10 W

As soon as the power exceeds 10 W, the 10 W mark is indicated for calibration purposes immediately behind the pulse amplitude.
The remaining channels are shown analogue to the above.
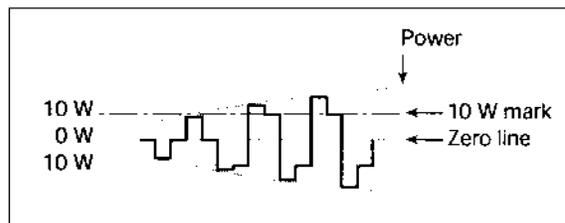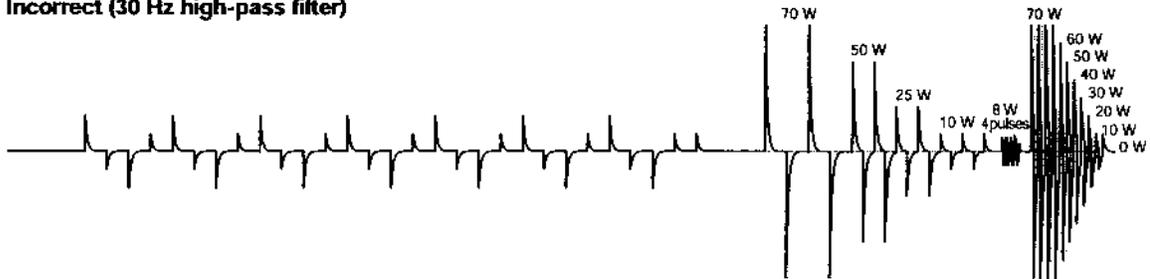
Failure treatment for the GLOBAL PORT

The connection of filters to the ECG device may lead to the distortion beyond recognition of the power, temperature, impedance, current and voltage curves.

Using CH 4, the effect of a 30 Hz high-pass filter is clearly shown in the following figures.
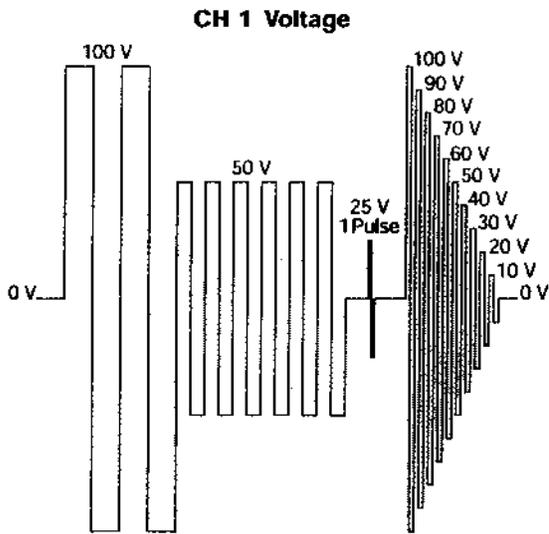
CH 4
Correction without filter
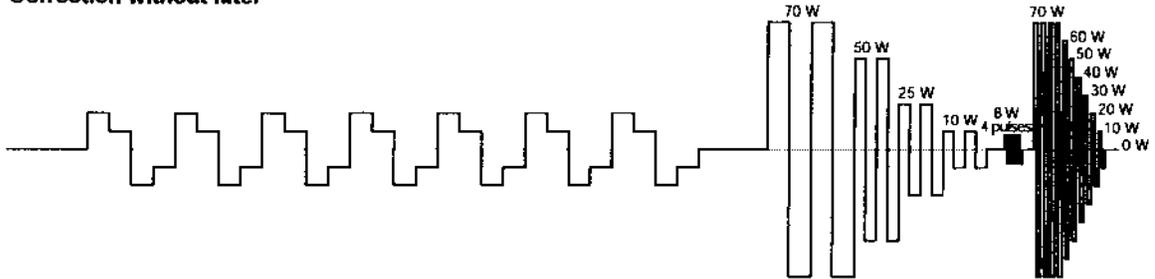
CH 4
Incorrect (30 Hz high-pass filter)

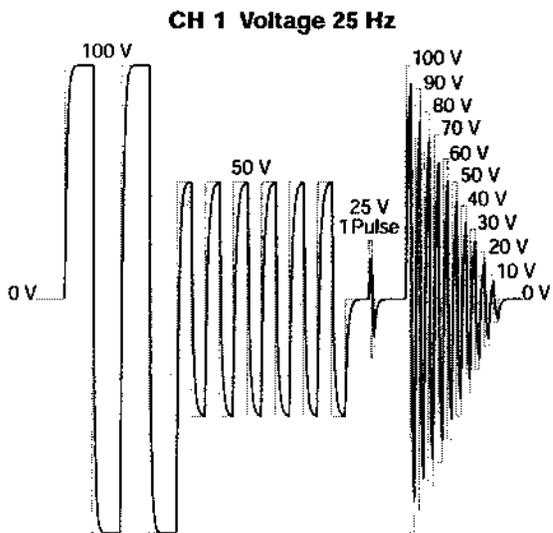Low-pass filters suppress the rapid sides of the impulse in the figure.

correct

CH 1 Voltage

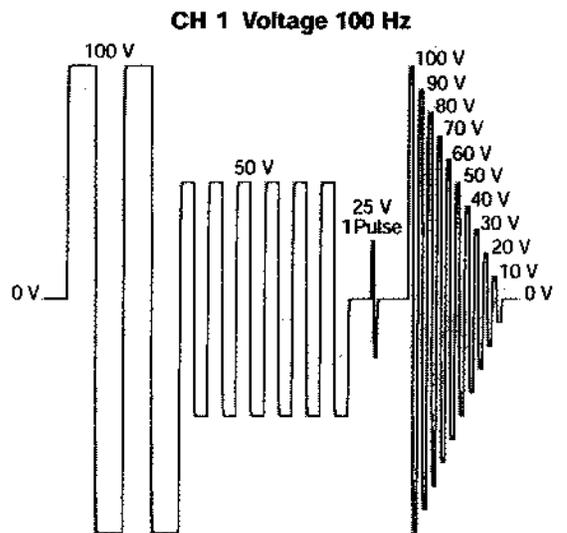
incorrect

CH 1 Voltage 10 Hz

incorrect

CH 1 Voltage 25 Hz

incorrect

CH 1 Voltage 100 Hz
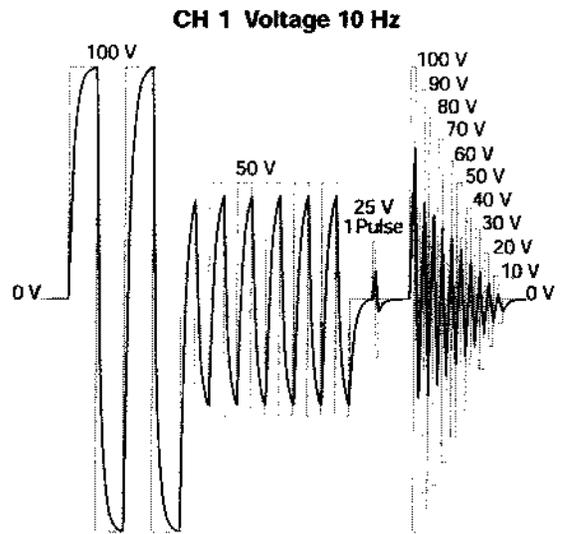
Figure: ECG, RF Power, Temperature
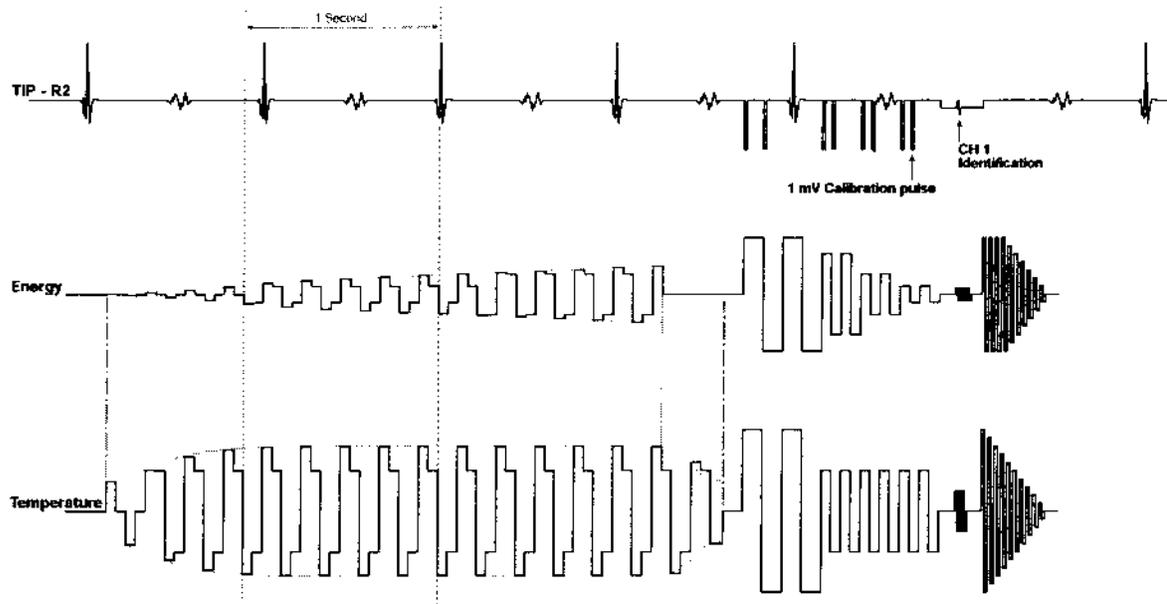
Technical Specifications

Power

Mains voltage ....230 V / 115 V
Mains frequency...................50 Hz / 60 Hz
Max. input..............................15 mA
Fuse.......................................100 mA
Classification ....Class 1

Dimensions

Length ....257 mm
Depth.....................................107 mm
Height....................................66 mm

Weight ....1100 gr

Digital inputs/outputs

PC...RS232 C
EP-SHUTTLE /
STOCKERT 70 FO................Special optical fiber
FO IN/OUT.............................Polymer optical fiber connection

BNC outputs

Voltage outputs ....max 5 Vss   typical 3 Vss
Resistance 500

D-SUB outputs:

CH 1/2 3/4 5.......................through special interface cable

EPWIN Software
Quick User Manual

Version 3.010

Contents

21.1 Introduction

General Information

This document describes Version 3.010 of EPWIN.

The STOCKERT 70 RF-Generator can be connected to an IBM personal computer (PC) or compatible computer system.

Hardware requirements

The following hardware is the minimum requirement to run the EPWIN software version 3.010.

Processor.....Intel Pentium 100 MHz (or compatible)
Memory.........16 Mbyte RAM
Hard disc......1 Gbyte capacity (500 Mbyte for patient data)
Video.............SVGA video board
Monitor.........15" SVGA colour monitor (resolution 800*600 pixel)
OS..................Windows 95 (windows 98 recommended)

NOTE
The EPWIN software version 3.010 will run also on systems below the above mentioned hardware (e.g. 486 DX) requirements, however, there might be device related and specific problems to this hardware which are not supported. Please contact your sales representative for further details.

The STOCKERT 70 windows software can be used to display and record the parameters voltage-, current-, temperature-, power- and impedance Vs time from the beginning to the end of each RF application. The software distributes on one 3.5" diskette.
The graphic must have a minimum of 16 bit (65536 colors or more).

Software requirements

Version 3.010 is developed and compiled to run only on 32 bit PC windows operating systems. Therefore, the minimum requirement to use this software is windows 95. The software was in addition tested to run on windows 98 and windows NT. If a former windows operating system software is used the software will not work.

In summary:

• Version 3.010 EPWIN runs on windows 95/98/NT operating systems

• Version 3.010 EPWIN will not run on windows 3.1 or 3.11 operating systems

The following files can be found on the data diskette:

Program name ....File type ....Description

setupex.exe ....Setup file.... ....Double click on this file and the EPWIN software will be installed

The following files will be created from the EPWIN software during start:

EPWINOP.INI..............Init file.......................c:\windows\epwin\.........Table of operators

EPWINRE.INI..............Init file.......................c:\windows\epwin\.........Table of catheters (reach)

EPWINTG.INI ....Init file.......................c:\windows\epwin\.........Ablation target table

EPWINU1.INI..............Init file.......................c:\windows\epwin\.........User1 table

EPWINU2.INI..............Init.file.......................c:\windows\epwin\.........User2 table

EPWINU3.INI..............Init.file.......................c:\windows\epwin\.........User3 table

EPWINU4.INI..............Init.file.......................c:\windows\epwin\.........User4 table

EPWIN.INI ....Init file.......................c:\windows\....................EPWIN setup table

EPWINxx.RES ....Language file...........c:\windows\epwin\.........EPWIN language module file (xx = country)

EPWIND.HLP..............Help file.......................c:\windows\epwin\.........German help file

EPWINE.HLP ....Help file.......................c:\windows\epwin\.........German help file

TIP.BMP......................Bit map file...............c:\windows\epwin\.........Regular tip bit map

SPLITTIP.BMP ....Bit map file...............c:\windows\epwin\.........Split tip bit map

Requests for EPWIN 2.xxx (for Windows 95 and Windows NT)

For this software version we recommend:

- minimum Pentium 200 MHz
- 64 MB RAM
- 2 GB HDD

look out:

EPWIN 1.xxx (for Windows 3.11) and EPWIN 2.xxx will not be further developed. Also this version doesn't support newer catheters.

If possible EPWIN 2.xxx (for Windows 95 and Windows NT) should be used.

21.2 Software set-up and installation

Installation

Start your computer and start windows 95, 98 or windows NT. Use the file manager or windows explorer. Select the setup icon on the EPWIN software diskette / CD by double clicking. Answer the questions from the setup program. After finishing the installation drag the EPWIN icon into the program manager desktop. Start the program by double clicking on the EPWIN icon. This will start the program. The following active desktop should become visible.
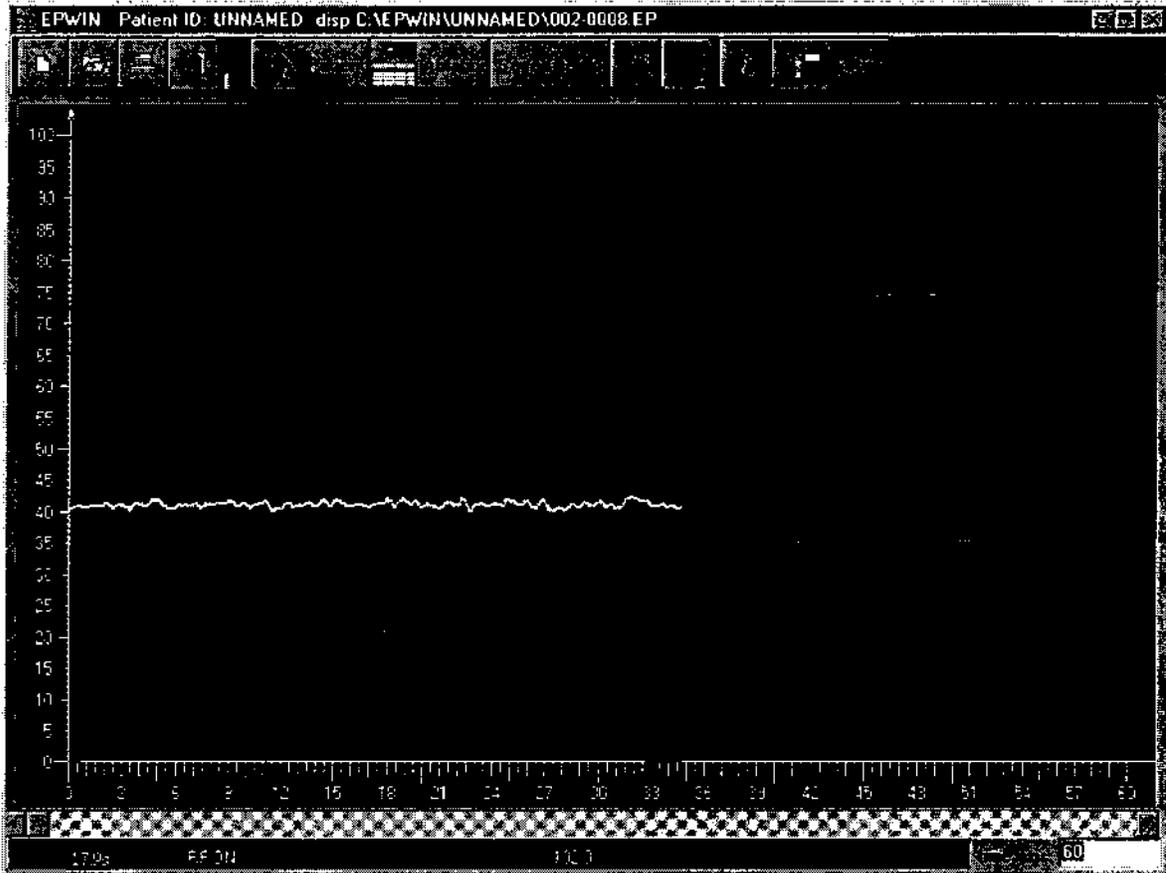

Picture 1: Start-up display respectively EPWIN active desktop

The EPWIN active desktop shows the following icons (from left to right):

Picture 2: Menu of active desktop

New page: Start new ablation procedure

New folder: Open an existing ablation file

Door: Exit the program

Patient: Patient information window (access to patient history and hospital/case information)

Ablation: Ablation information (Statistical summary of the individual ablation pulse and report)

Saved
setup: Opens/Saves specific setup information

37°C/17W: Opens/Closes online generator values in digital format

Cath. tip: Opens/Closes automatic tip temperature window

i: Information window about the current EPWIN software

setup: Opens a setup window

time axis: Defines the maximum timing of vertical X/Y graphs

Printing icon (occurs only after recording of ablation respectively if an existing file is loaded)
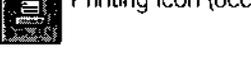
^ Yellow communication activity indicator

NOTE

There will be a printing icon in between the "open folder" icon and the "exit door" icon at the time an ablation was finished or a file has been loaded. If the connection between the generator and the PC is active and working a yellow indicator in between the "exit door" icon and "patient" icon will display communication activity (refer to picture 2).

The 3 vertical windows with the X/Y graphs are displaying analog information's as temperature, power and impedance. The horizontal bars on the left side are bar graphs which will display the individual measured value as bar graph. The bottom (Picture 3) will display the individual recorded value at the time of ablation as well as the corresponding retrospective value after ablation, if the cursor is placed at a specific time on the displayed curve.

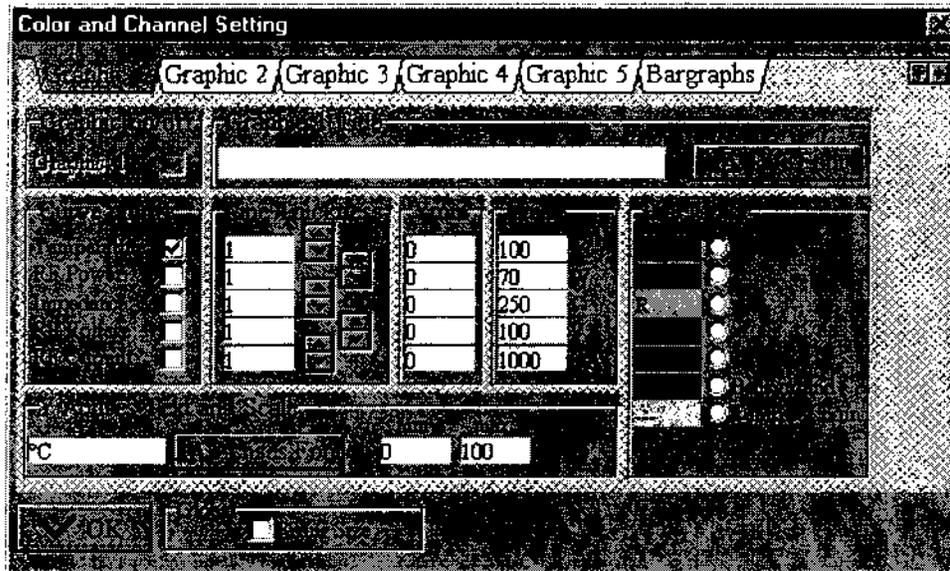The value in the time axis box (bottom right) represents the maximum time of the X-axis.

Picture 3: Value recording at bottom of active desktop

EPWIN Software set-up

Select the set-up Icon by clicking on the set-up icon in the upper right corner of the active desktop screen. The following window will occur:

Picture 4: Set-up window

The setup window contains a number of sheets for the setup of the EPWIN active desktop. Below is a list of the individual sheets which can be selected:

Graphic 1:   Setup sheet of first X/Y graph and color for all displayed values and bar graphs

Graphic 2:   Setup sheet for second X/Y graph

Graphic 3:   Setup sheet for third X/Y graph

Graphic 4:   Setup sheet for fourth X/Y graph

Graphic 5:   Setup sheet for fifth X/Y graph

Bargraph: Setup sheet for the bar graphs on the left

Value display: Setup sheet for the value display window

Glob.def.:   Setup sheet for global definitions like COM port

Language: Language module set-up sheet

Global port: Allows to adjust the marker output baseline of the global port interface

Graphic 1...5 sheet:

The Graphic 1...5 sheets determines the number of windows with X/Y graph present in the active desktop. You need to activate at least Graphic 1 (click in the Graphic 1 On/Off) area in the upper left corner. Each graphic window in the active desktop can be resized by positioning the cursor in-between two windows and dragging it to the new size (holding the left mouse key). If you don't want to change the size respectively want to freeze the size of the particular window click on "Fixing size" in the Global area of the Graphic 1...5 window. Graphic 1 corresponds to the lowest of the maximal 5 windows and graphic 5 to the top.

Graphic/Bargraph Colors:
The selected colors in the Graphic 1 sheet will determine the colours of the value display as well as the recorder display (bottom of active desktop) and the colours of the barographs (left of active desktop). The temperature bargraph colours needs to be selected in the bargraph sheet.

Scale and displayed axis resolution:
The scale and resolution can be selected individually. The Y axis scale needs to be selected in the "Y-axis text and scale" area at the bottom of the individual graphic sheet. It determines the start value and the max value of the displayed Y-axis.

The Ymin and Ymax selections (in the middle of the window) determines the corresponding start and end values of the Y graph. The Ymin value corresponds to the min value of the "Y axis text and scale". The Ymax value corresponds to the maximum value of the "Y axis text and scale". Therefore, this unique combination will determine the exact resolution of the Y value.

Example: The impedance should be displayed between 100..250 Ohms. The min value of the "Y axis text and scale" is set to 0 the max value is set to 100. Therefore, Y = 0 corresponds to 100 Ohms and Y = 100 corresponds to 250 Ohms. 1 ticker corresponds therefore to 1.5 Ohms impedance.

Impedance curve set-up
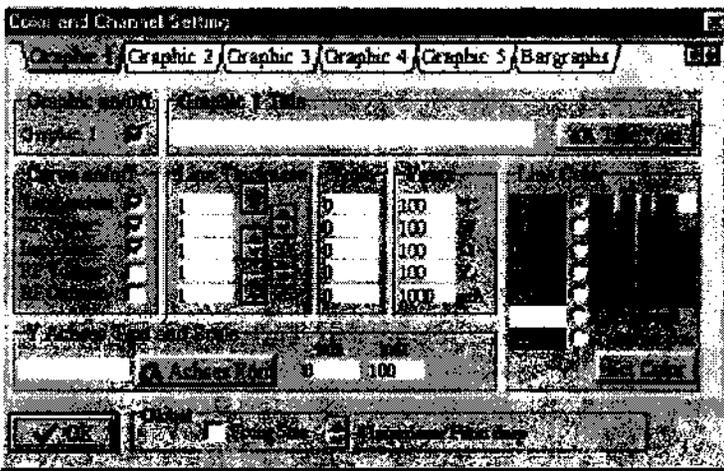
Picture 5: Impedance curve set-up

In order to analyse the high speed impedance data it is possible to retrospectively activate a filter function. This filter is located in the set-up window under the selection Global (bottom of Graphic screen). It can be selected from 1 - no filter (10 ms data recording) to 32 - strong filter (averaging impedance information down to all 600 ms).

Bargraph sheet

The bargraph window can be used to setup the bargraphs in the active desktop (left side). In the bargraph setup all bargraphs which will be visible in the active desktop can be selected by clicking on the individual parameter.
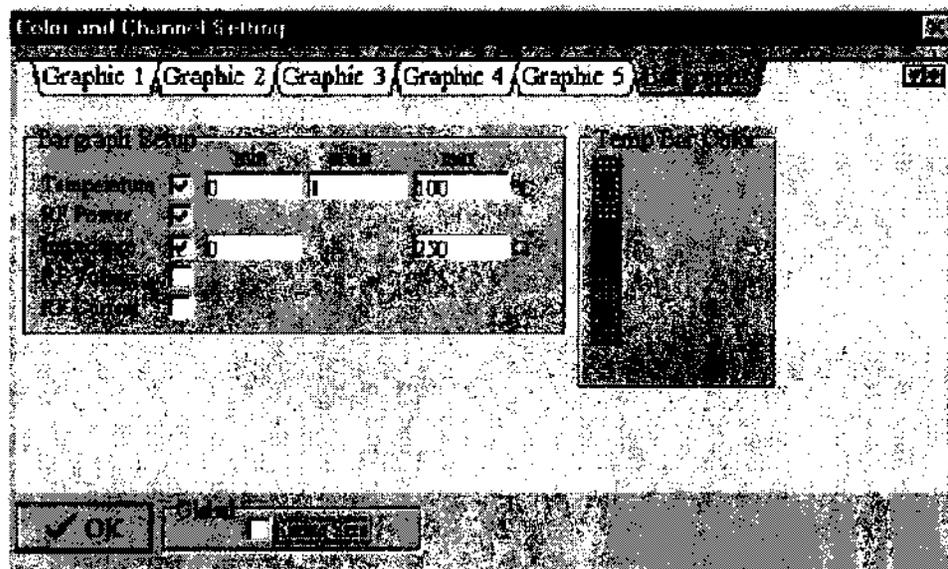
The "scale" in the bargraph setup determines the size of the temperature bar at the nominal temperature. If it is programmed e.g. to 5°C the colour at the nominal set point will be displayed as long as the temperature is ±2.5°C around the temperature set point. The "min" value determines the start of the bargraph and the "max" value the end. The scale is the resolution in between the minimum and maximum values.

Temperature bargraph colour setup

The colour at the bottom of the bar will determine the temperature below the nominal set point. The colour in the middle determines the bargraph colour at the set point and the top bargraph colour corresponds to a measured temperature above the set point (± scale value). To change the colour of the temperature bargraph double click on one of the 3 colours of the colour bar in the "Temp Bar Color". Select in the pop up window the new colour and press OK.

If "Fixing size" is selected the widths of the bargraphs in the active desktop can't be changed. If this parameter is not activated the bargraphs width can be changed by positioning the cursor in between the bargraphs and dragging the bargraph to the new size.

The bar graph colours other than temperature can be programmed by selecting the corresponding colour in the graphic 1 sheet.


Picture 6: Bargraph setup sheet

Value display

The value display setup determines the setup of the digital value display which can be activated in the active desktop. Only the selected parameters in the value display sheet will be visible in the active desktop. To do so select the parameter you would like to see.

If "Fixing size" is selected the size of the value display can't be adjusted in the active desktop.
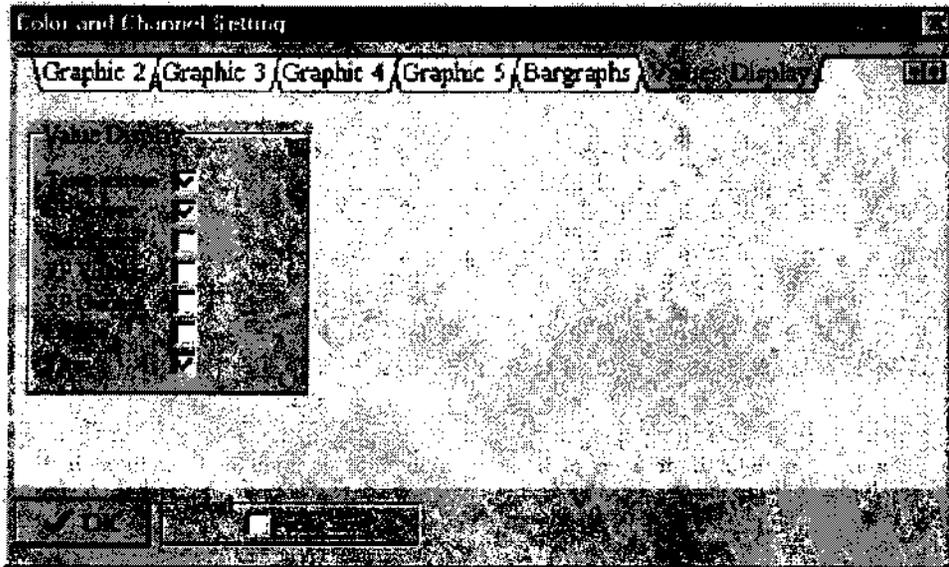

Picture 7: Value display

Global Def.

The sheet global definition (global def.) is used to setup the EPWIN software globally. The location field is used to define the hospital name, location and department, which will be printed as header on each print out. The button in the initial setup area is used to reprogram all parameters and settings to the default settings. The button in the hardware setup area is used to verify the serial link to the RF generator.

Three printer options can be selected: nil, grid and scale. If nil is selected, the X/Y graphs will be printed with a white background colour. If grid is selected a small grid in the background will be printed. In case of selecting scale, a scale will be printed on the paper side next to the X/Y graphs.
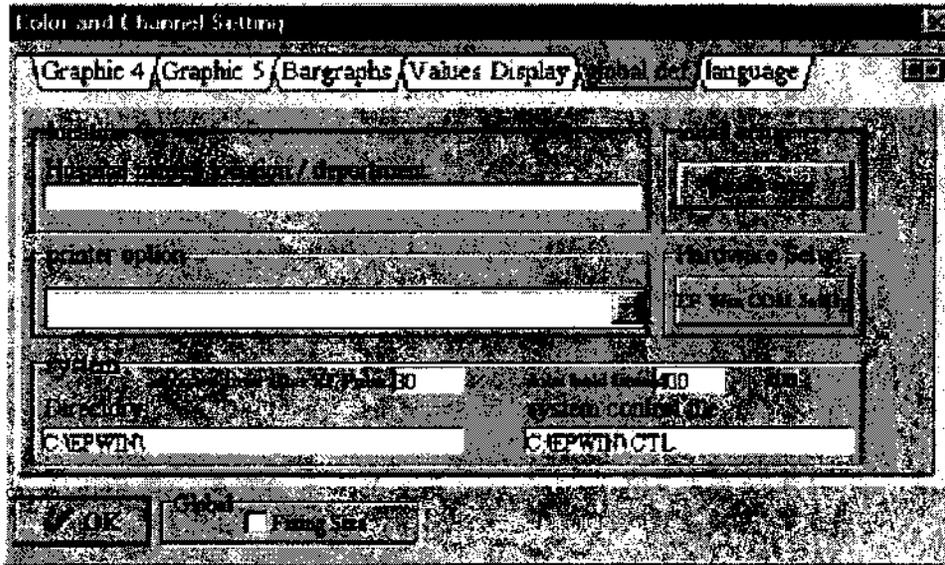

Picture 8: Global Definition Sheet

The system area allows to set the following options:

* autosave time after RF pulse: The programmed time will determine the time in seconds after which the software will automatically save the data to disk, if no further information is received from the RF generator.

* docu hold time: If the autorun demonstration file is activated and the user is operating the software in real mode, this parameter determines after which time in seconds the autorun demonstration will restart again (similar to a screen saver).

* The "directory" determines the working directory. The software will safe all files under this directory.
* The "system control file" determines the path to the autorun demonstration file.

Two additional buttons can be used to activate the following actions:

* "Default setup" in the initial setup area. If this button is pressed the default setup will be reloaded which will determine the setup of the active desktop display.

* "EPWIN COM setup" in the Hardware setup area. If this button is clicked a new window will open which displays the status of the serial link between the computer and the global port respectively RF generator. If the link is functional an ICON will be displayed in the right gray area showing the information flow between the different generator components. If the link is not established you will see a white ICON field.
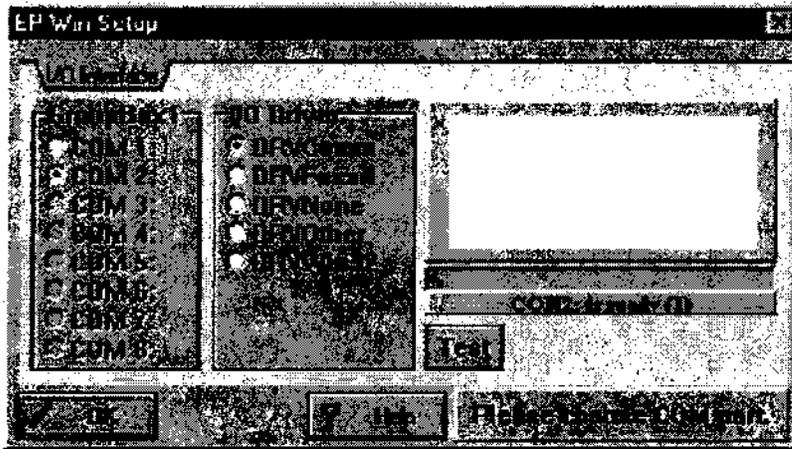

Picture 9: EPWIN setup window

The used serial port of the computer can be changed by clicking on the corresponding COM port in the GroupBox1 area. The I/O driver is usually the DRVComm driver and should not be changed. The connection can be checked by selecting the TEST Icon under the connection ICON.

Language Sheet

The language sheet allows to select the language of the EPWIN software.

The default language can be changed by selecting the corresponding file name and directory in which this file can be located. The Help location allows to select the corresponding help file.

Mark the US Generator check box to prepare the EPWIN software for the US generator STOCKERT 70.
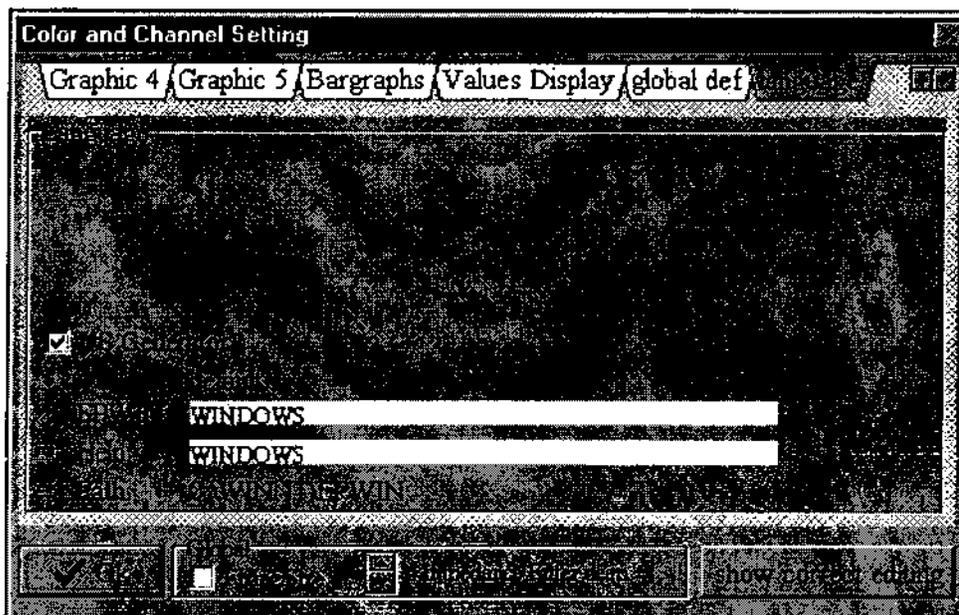
Picture 10: Language screen

Global Port sheet

The Global Port Interface can be used to generate a voltage marker which correlates to the measured signal of voltage, current, impedance, power and temperature. The zero offset voltage (baseline position) of these markers can be adjusted using this sheet.
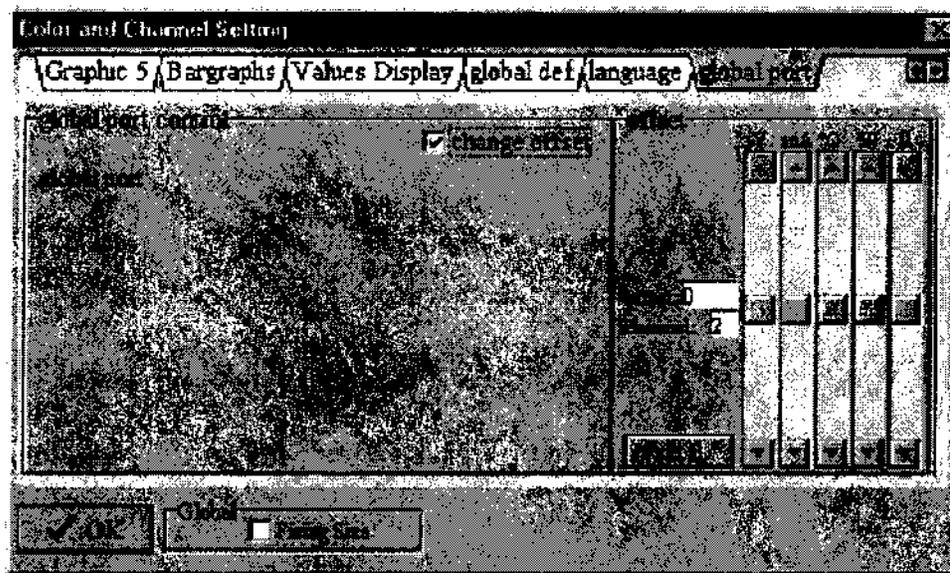
Picture 11: Global port sheet with offset programming

21.3. Patient Information Menu

 or

Select Patient

The patient information window will pop up every time the user selects the new sheet icon or selects the Patient icon. The patient information window is used to store clinical history and procedural information about the case. Three sheets can be selected: first the select patient screen will list all patients which are saved under the working directory path as specified in the working directory path of the global definition screen (setup). The patient data screen will list all patient relevant information (e.g. name, birthday, sex etc.). Patient info displays a list of operators and contains a memo field to save additional information.
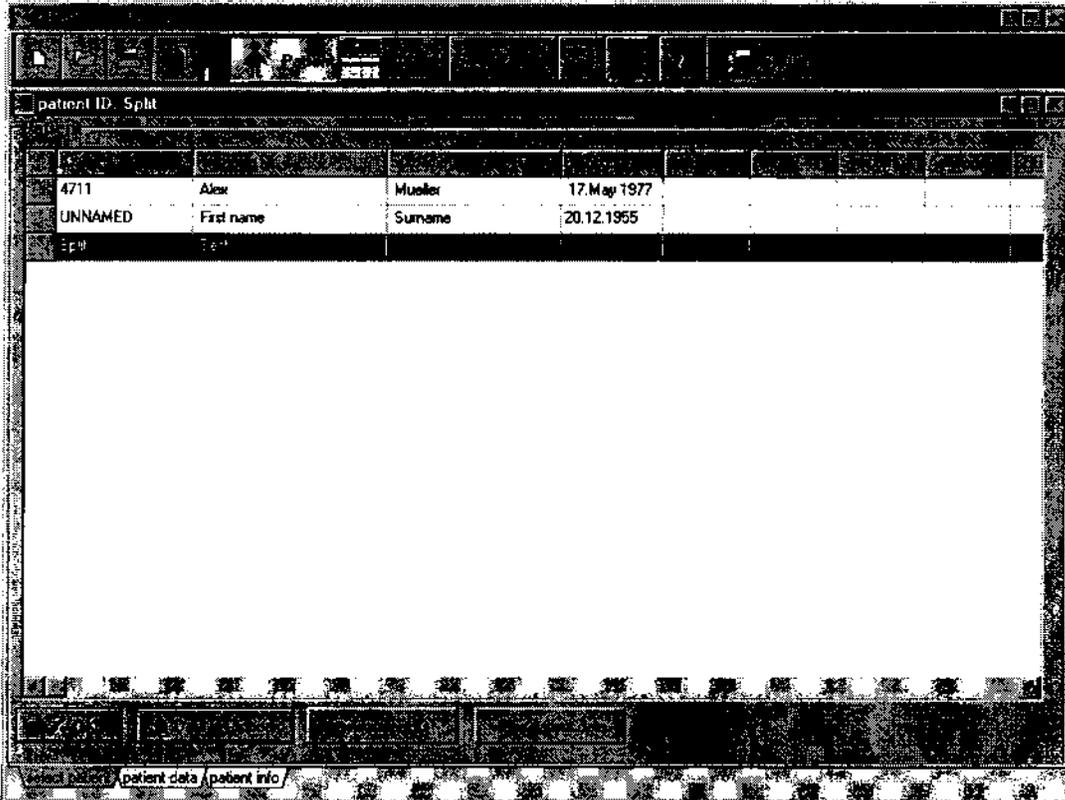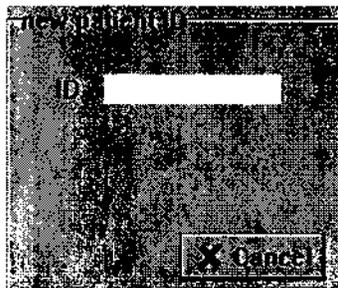

Picture 12: Patient information window with access to patient information and ethiology.

To select a specific patient, position the cursor on the corresponding patient ID. Now, if patient data or one of the possible sheets will be selected the corresponding information will be displayed in the selected window, too. If the new sheet icon is selected in the active desktop the patient information window will start, however, in top of this window will be a window asking for a new patient ID.
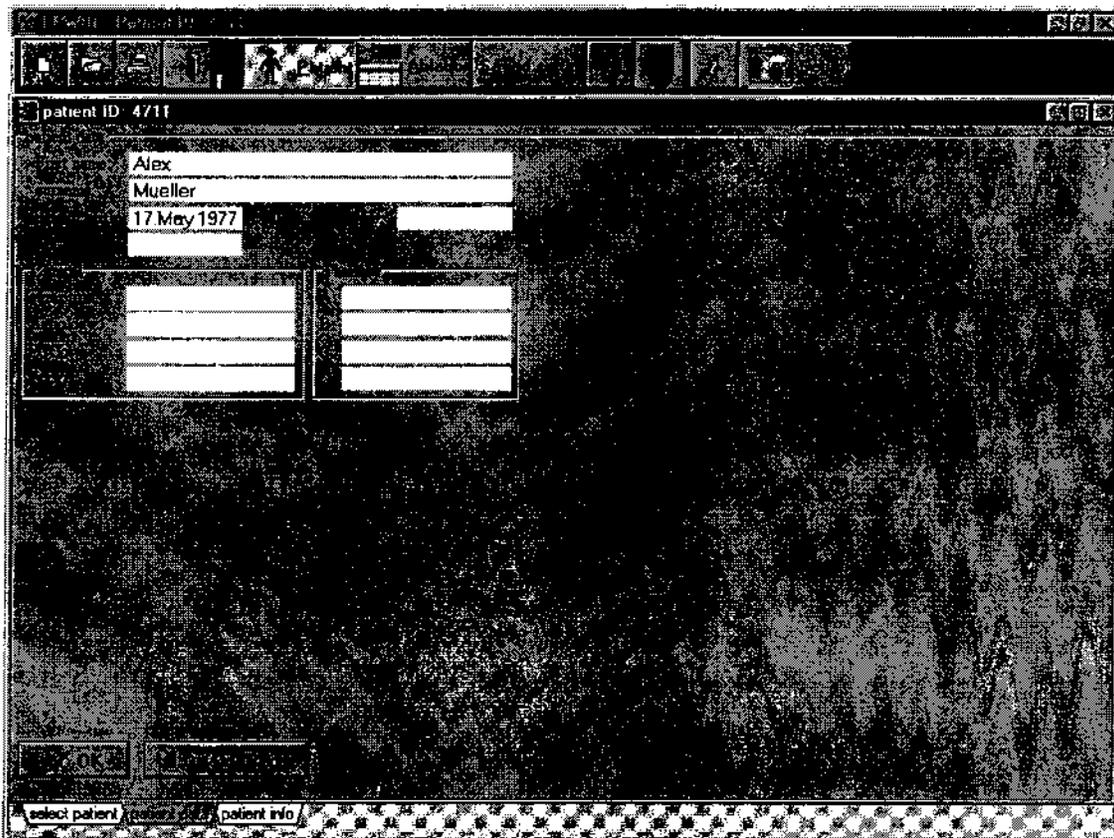As soon as this patient ID is confirmed by pushing the ENTER key a new ID will be created.
A maximum of 11 alphanumerical characters can be used for the patient ID.

Picture 13: New patient ID window

Patient Data

The patient data screen displays the patient data of the selected patient under patient information. This screen contains text fields. In case of creating a new patient the first and surname field needs always to be filled. The rest of the fields can be filled, however, don't have to.

Picture 14: Patient data screen

Patient info screen

The patient info screen can be used to save additional information from the patient as well as information. All fields displayed in this screen are text and note fields. Just select the field you would like to save information in an type the text to be saved. After exiting the patient screen the information will be saved into the patient folder.

Picture 15: Patient info screen

21.4 Ablation Information Window

Ablation

Procedure/RF pulse

All information related to the ablation of the patient will be visible in the ablation information window. In case that a patient is ablated during a second procedure the program automatically identifies the second procedure and will start a new session under the first session. The procedure counter will be increased by one.

NOTE
The differentiator is the date of the ablation!

000	0001	wait	29.10.99	11:35:34	Prof. Dr. XY				right anterior septal	Biosense Webster curve D
002	0012	nil	11.06.99	11:36:18	unnamed	manual unipolar	43	6		
002	0011	nil	11.06.99	11:35:02	unnamed	manual unipolar	812	26		
002	0010	nil	11.06.99	11:34:14	unnamed	manual unipolar	25	20		
002	0009	nil	11.06.99	11:32:48	unnamed	manual unipolar	27	12		
002	0007	nil	11.06.99	11:16:11	unnamed	Biosense Webster	1975	36		
002	0006	nil	11.06.99	11:06:36	unnamed	Biosense Webster	1104	23		
002	0005	nil	11.06.99	11:03:02	unnamed	Biosense Webster	217	6		
002	0004	nil	11.06.99	11:02:49	unnamed	Biosense Webster	114	5		
002	0003	nil	11.06.99	10:46:12	unnamed	Biosense Webster	288	11		
002	0002	nil	11.06.99	10:43:28	unnamed	Biosense Webster	170	7		
002	0001	nil	11.06.99	10:43:16	unnamed	Biosense Webster	136	6		
001	0001	nil	10.06.99	19:05:28	unnamed	Biosense Webster	135	6		
	0	0					0.0Joule	0.0		
default	*	*	*	*	*		>1W	>1sec	*	*

USER (report selected RF pulse)

Picture 16: Procedure/RF pulse screen

Generating reports

To generater a report first you need to select the pulses to be included. This is done by activating the filter mask or double clicking the individual pulse. Each selected pulses will be identified in the Status field by the word "selected". Only those pulses which are selected and therefore active will be used to create the report. The lowest field on the screen identifies the filters against which the individual pulse will be checked. If all criterias are logically true the pulse will be "selected". The following criteria options can be used in the filter mask:

*   - No criteria selected, all values are TRUE
>10   - Criteria is TRUE for all cases with a value greater than 10
<5   - Criteria is TRUE for all cases with a value smaller than 5

Filter select: Activates filter criteria and will display the selected pulses

Display filter state: Will display the selected pulses in a different colour

Sorted down: Will sort the selected pulses according to their procedural appearance

Edit mode: Allows to edit the discrete value of the individual pulse

Printer status mask: Allows to define the printer mask (which parameter of the selected pulses will be printed in the report and which parameter won't be printed).

The ablation table window

This window can be used to add certain information to the report (e.g. Operator, Target site, catheter reach, ablation mode, used system etc.). Each roll up window is activated by clicking on the right arrow field of each field. The arrow will open a list of possible selection options. It is possible to add values and information to all roll-up field.

After the first start these tables contain only nominal or no further information. To save your information in the corresponding field just select the text (highlight) with the cursor and double click with the left mouse button twice.
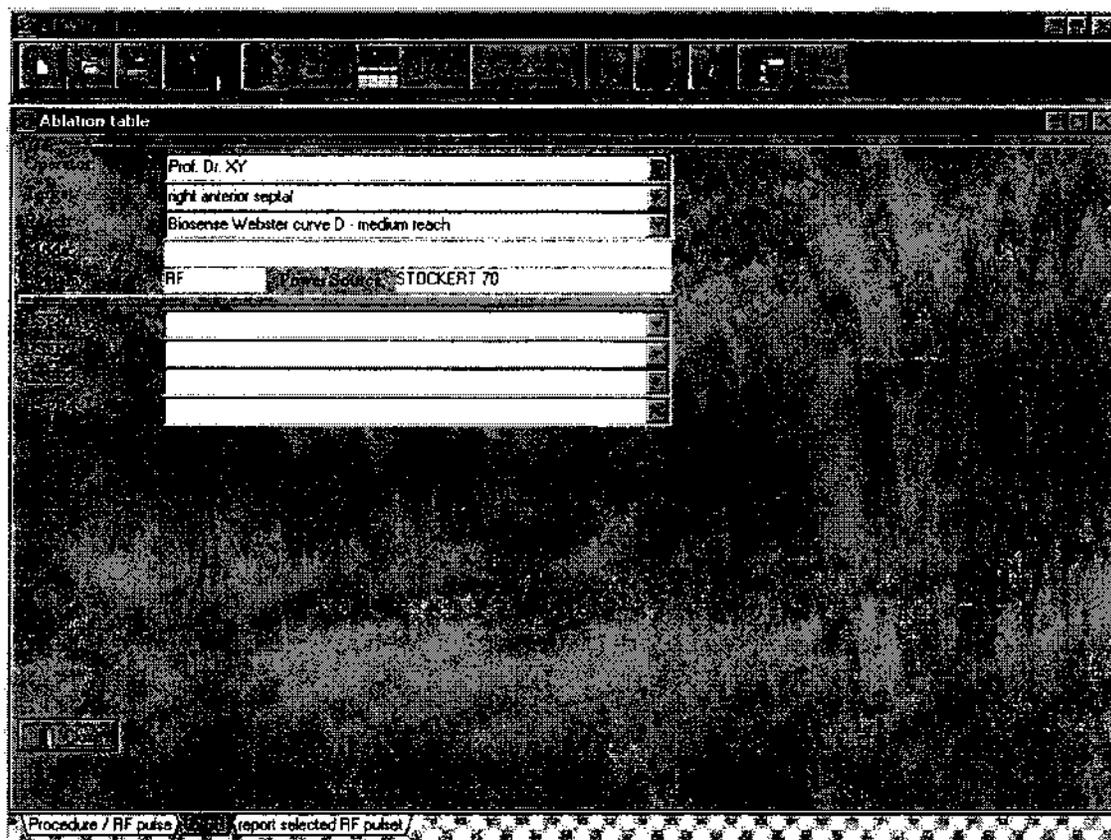

Picture 17: User screen

Report selected RF pulse

The "report selected RF pulse" window is used to display the report with all statistical values based on the selected pulses in the ablation information window.

If the marker "print selected only" is activated, only the pulses which are selected with the print mask will be printed in addition. If printing is selected the printer will first print the report followed by all selected pulses.
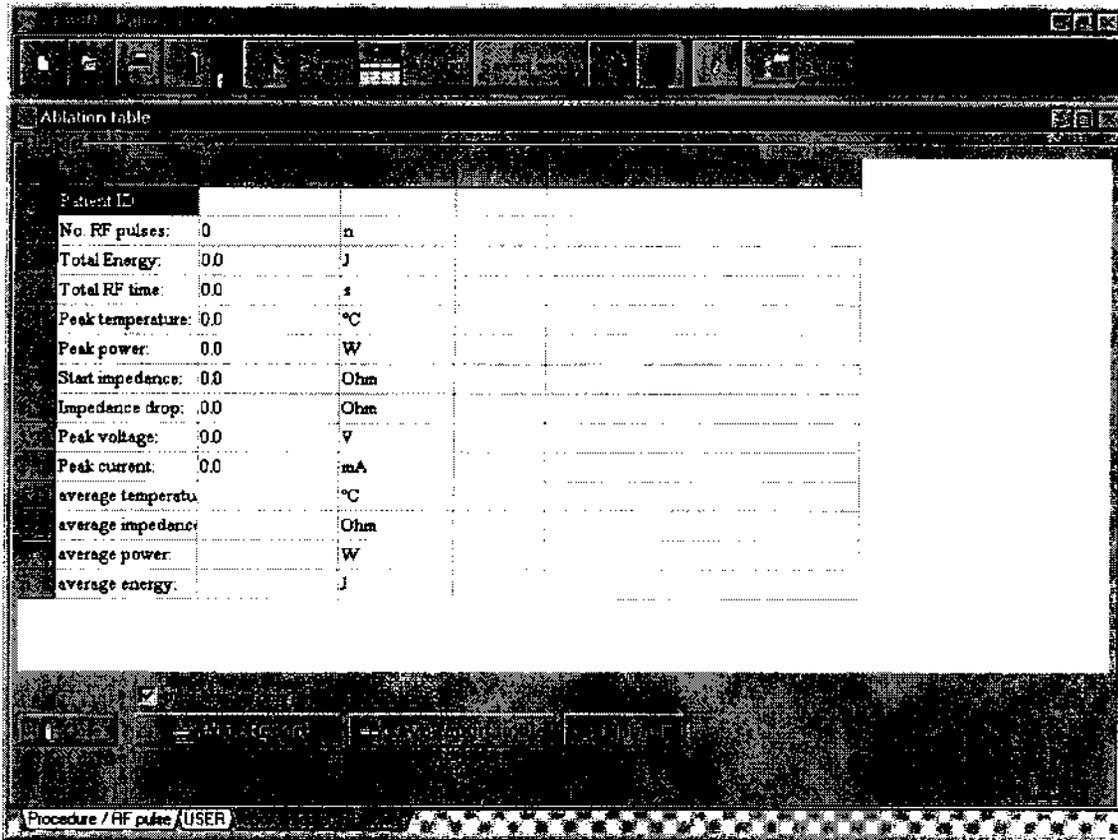
Picture 18: Report selected RF pulse window

The options to be selected in this window are: print report (will print all information on the connected LPT1 device), save report to file (will save the report and the pulse information in a user defined file) and finally clipboard which copies all information in the windows clipboard. From this clipboard the information can be transferred further into other applications, like MS Excel or MS Word.

21.5 Value Display

A digital value display can be activated with the Temperature/Power icon in the top row of the active desktop. The display will present all measured values in digital format.

If the cursor is positioned in the title bar of this window the position can be changed by dragging the window while holding the left mouse button pressed. You can also increase or decrease the text font by changing the size of the window. Therefore, position the cursor on the lower or right border and drag the window to the new size. If you would like to remove this window just click on the Temperature/Power icon in the top row of the active desktop again.

NOTE

The colours of the displayed values are the same as selected in the graph1 sheet of the setup window. The order of the display is: Ablation number, Impedance, Time, Sensortemperature
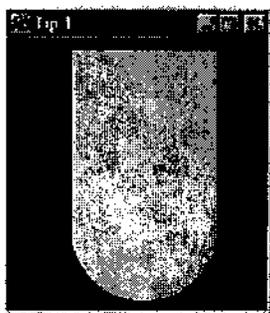

Picture 19: Value display

21.6 Catheter tip temperature icon

It is possible to visualize the tip temperature with the EPWIN software for catheters with 1 or more temperature sensors or split tip catheters. Therefore, click on the tip icon in the active desktop. The colour of the tip will change according to the measured tip temperature in the temperature bar.

Picture 20: Catheter tip temperature icon (4 mm)

The tip temperature indicator will change the corresponding colour according to the selected temperature bar indicator (on the left side of the main screen). It will display a red colour at the moment the sensor value approaches the temperature set-point.
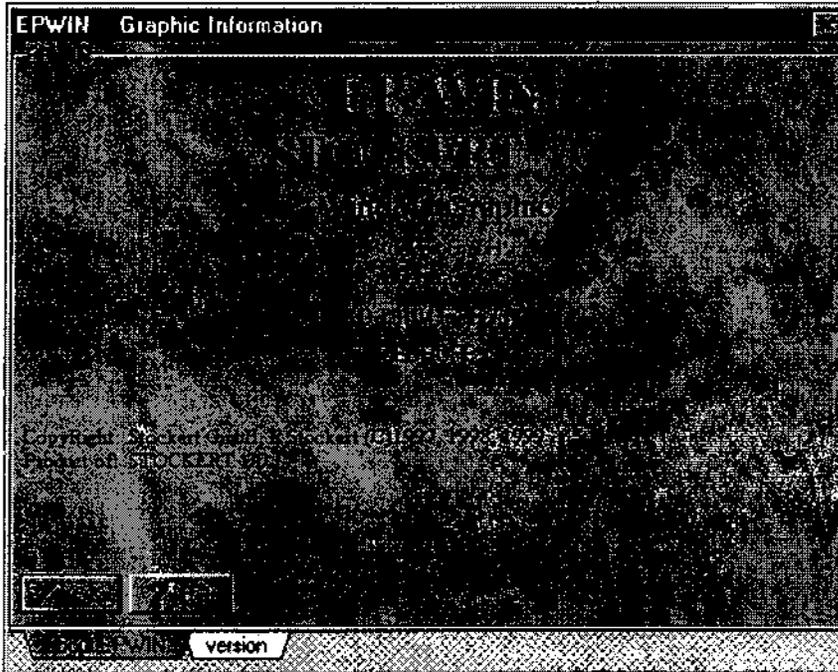
21.7 Information window

The information window can be activated by clicking the "i" icon in the active desktop. It displays several information sheets:

* The name and title of the software (about EPWIN)
* The revision of that software (Version)
* An overview of all catheters indicating the selected ablation catheter (STOCKERT 70)
* An overview of the programmed parameters in the RF generator (STOCKERT 70 setup)

NOTE: These windows are for information only!

Picture 21: Information window

21.8   Fast setup

Saved setup

The fast setup can be used to change quickly the programmed setup (screen layout, colours etc.). Therefore, after you have chosen your preferred setup you first need to save it. To do so click on the save button and assign an appropriate name for this setup. If you want this configuration to be loaded at startup you need to assign the name "default.epw".
To retrieve the saved setup, you just need to double click on the setup. The retrieval works automatically.
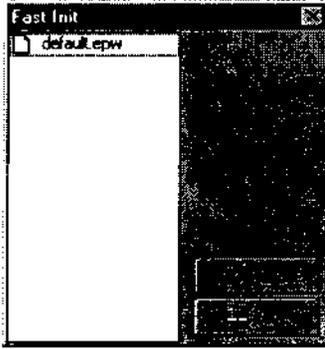
Picture 22: Fast init window

21.9 User example

This chapter summarizes the steps in order to perform an ablation procedure using the EPWIN software for documentation:

1. Setup the EPWIN software according to your personal preference

2. Select the new page icon in the top menu bar

3. Assign an alphanumeric ID number to your patient (maximum of 11 characters)

4. Press Enter

5. Assign the first and surname to your patient

6. Fill out the patient data and patient info screen

7. Start your ablation - each pulse will be automatically documented and recorded

8. After each pulse you can analyze the pulse by positioning the cursor in the X/Y graph

9. To print a report select the ablation information icon in the top menu bar

10. Double click with the pointer in the "status" field so that each pulse which you would like to be in the report is "selected".

11. Fill out the fields in the "user" sheet of the ablation information window and select thereafter the sheet "report selected RF pulse"

12. Select the "print" button

At the end of the procedure you need to select the "door" icon in the top menu bar to exit the program.

21.10 Summary of Hot Keys

F1 .... HELP

F2 .... New ablation file

F3 .... Open existing file

F4

F5 .... Open patient information window

F6 .... Ablation window

F7 .... Open fast init

F8 .... Open/close digital value display

F9 .... Print

F10 .... Exit

F11 .... Open setup window

F12 .... Open information window

CTRL+F12 .... Open catheter tip temperature window