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for a sustainable future

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TOGETHER
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22601

Biomedical Engineering Centers Program

BIH/97/044

WORKSHOP

May 18 – 25, 2001

Sarajevo, Tuzla, Mostar

Report by Edmund Meitz (KMB)

Introduction

In accordance with the revised work plan of the Project, a workshop was held May 18 – 25, 2001, at the BMECs in Sarajevo, Tuzla and Mostar as a follow-up to the workshop in March. The agenda included a second training for the vFM software and collective as well as individual maintenance management training for the staff of the BMECs.

At the end of the workshop in March the staff was briefed on tasks they were expected to carry out till the beginning of the workshop in May. As it turned out on May 18, the staff of BMECs had not completed their tasks according to the list of tasks to the projected extent. However, they had made considerable effort to adapt their work to the recommended procedures. Obviously, the existing organizational structure in the three Clinical Centers does not facilitate a fast move towards new procedures and programs. The administrative officials have yet to be convinced of the advantages of the new procedures, which will become visible only over the next years.

Since many of the new procedures are based on the use of the sophisticated vFM software, the additional software training was to improve the understanding and skills of the BMEC staff in applying the functions of the software to their daily work in maintenance management.

BMEC Sarajevo –May 18 - 25

The hardware and the furniture had been completely installed by May 18. The installation of the computer network has not yet been completed, due to a delay in the procurement of the components. The vFM software has been installed and is accessible to all staff members without a password. The staff had started inventorying the medical equipment of the clinics, but was not able to input the envisaged number of items of 1,000 units, which may be in part due to insufficient command of the software.

The flowchart samples for repair, preventive maintenance and safety checks had been prepared by KMB in Vienna and were sent to Sarajevo, but they had not been distributed to the BMECs in Tuzla and Mostar prior to the workshop. Describing the workflow by means of flowcharts turned out to be very difficult for the BMEC staff, but they were able to understand this process when it was demonstrated again during the workshop.

Mr. Sukalo, the National Project Coordinator, has received most of the quotations for testing and measuring instruments and toolkits, as inquired by UNIDO's procurement department. During the workshop, the selection of the tools was discussed and finalized.

The protocols for testing and measuring, which should have been established by the BMEC in Sarajevo, have not been presented. KMB will collect samples of such protocols and submit them to the BMEC.

The BMEC staff does not know the annual cost of spare parts, service contracts or staff labor. They apparently see establishing a maintenance budget not yet as a priority. This is due to the fact that the purchasing department of the Clinical Center is doing all major procurement of spare parts, as well as ordering external repair service. Consequently, only the purchasing department is familiar with the maintenance budget and the financial needs.

During the workshop the basic aspects for drafting a budget were explained, at least as a rough estimate of the maintenance costs for medical devices. In the future the BMEC will have to collect the financial figures from the purchasing department, as they are not routinely reported to the technicians.

BMEC Tuzla - May 21 - 22

At the Clinical Center Tuzla, the BMEC started to operate in the adapted premises shortly before our meeting on May 21. The rooms were renovated as planned, the workbenches were in the rooms and the staff was about to install the hardware. During the meeting the Director for Investments, Mr. Nurudin Atic, attested the importance of the BMEC Tuzla and promised the necessary support. The BMEC Tuzla prepared flowcharts of all main procedures. They were discussed in detail and, as an example, the process of a repair action was charted with the responsibilities defined accordingly.

Regarding the list of tasks as assigned in March, the BMEC Tuzla had collected some inventory data, but only on paper. No information had been input into the vFM database. Budget and measuring protocols had not been prepared, but were discussed during the workshop.

BMEC Mostar - May 23 - 24

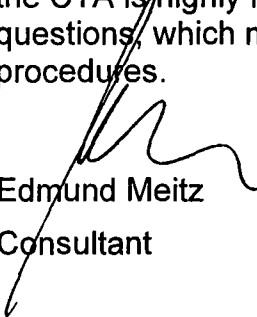
The new workshop in Mostar was already operating, equipped with the procured instrumentation. The hardware and the vFM software had been installed. Instead of the envisaged 1,000 units, approximately 100 pieces of equipment had been inventoried. With the improved software know-how comprehensive inventorying should now be possible. The BMEC staff had started a careful attempt in defining their procedures, but they were not able to finalize the work. In a several hours lasting brain-storming session the four major procedures were discussed in detail and adapted to the Clinic's system. The corresponding flowcharts are attached as an annex to this report.

BMEC Sarajevo May 24

Together with Mr. Temsch and Mr. Sukalo the list of additional tools and measuring devices was revised, considering the quotations received. The training plan for Dräger and Fresenius was specified and the participants of the training designated. The training courses will take place in autumn in Germany.

In conclusion, this was a very important and successful workshop, since all three BMEC were visited and their individual requirements were addressed.

Hopefully, the procurement of the measuring devices as well as the training will be completed as scheduled. A final visit of the BMECs in autumn by KMB together with the CTA is highly recommended, because it will give the staff a last opportunity to ask questions, which may arise during the implementation of the newly learned procedures.

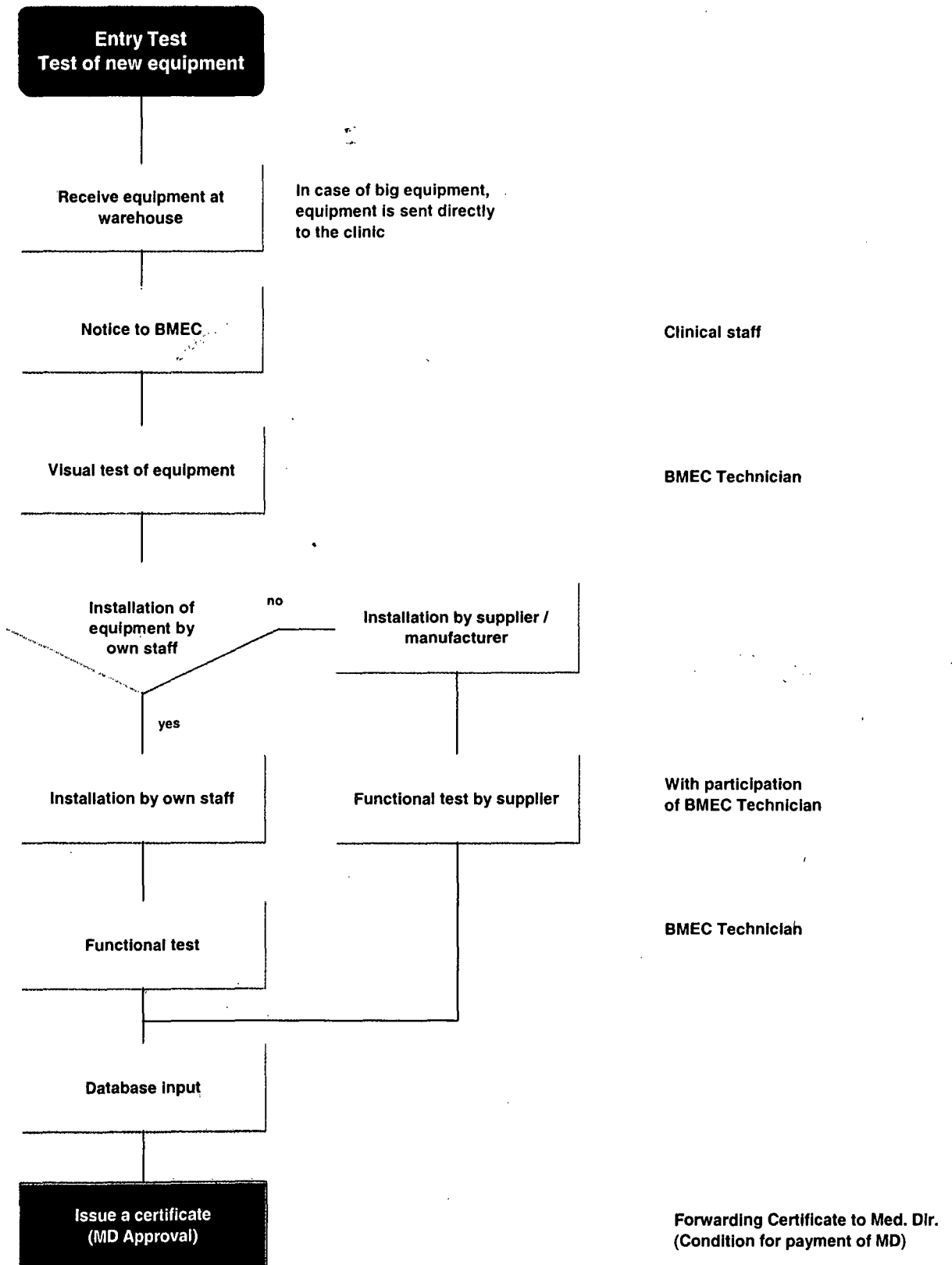


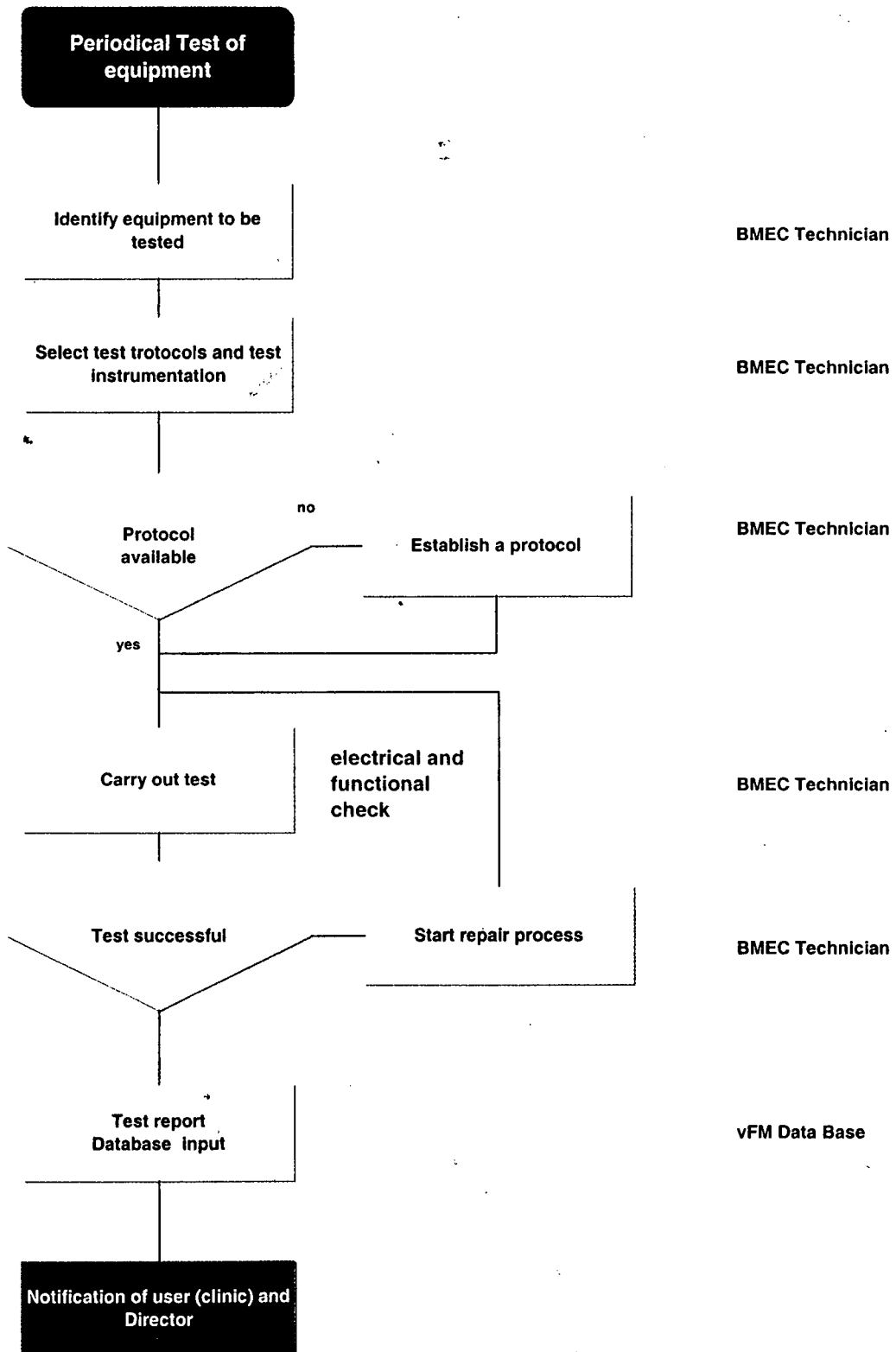
Edmund Meitz

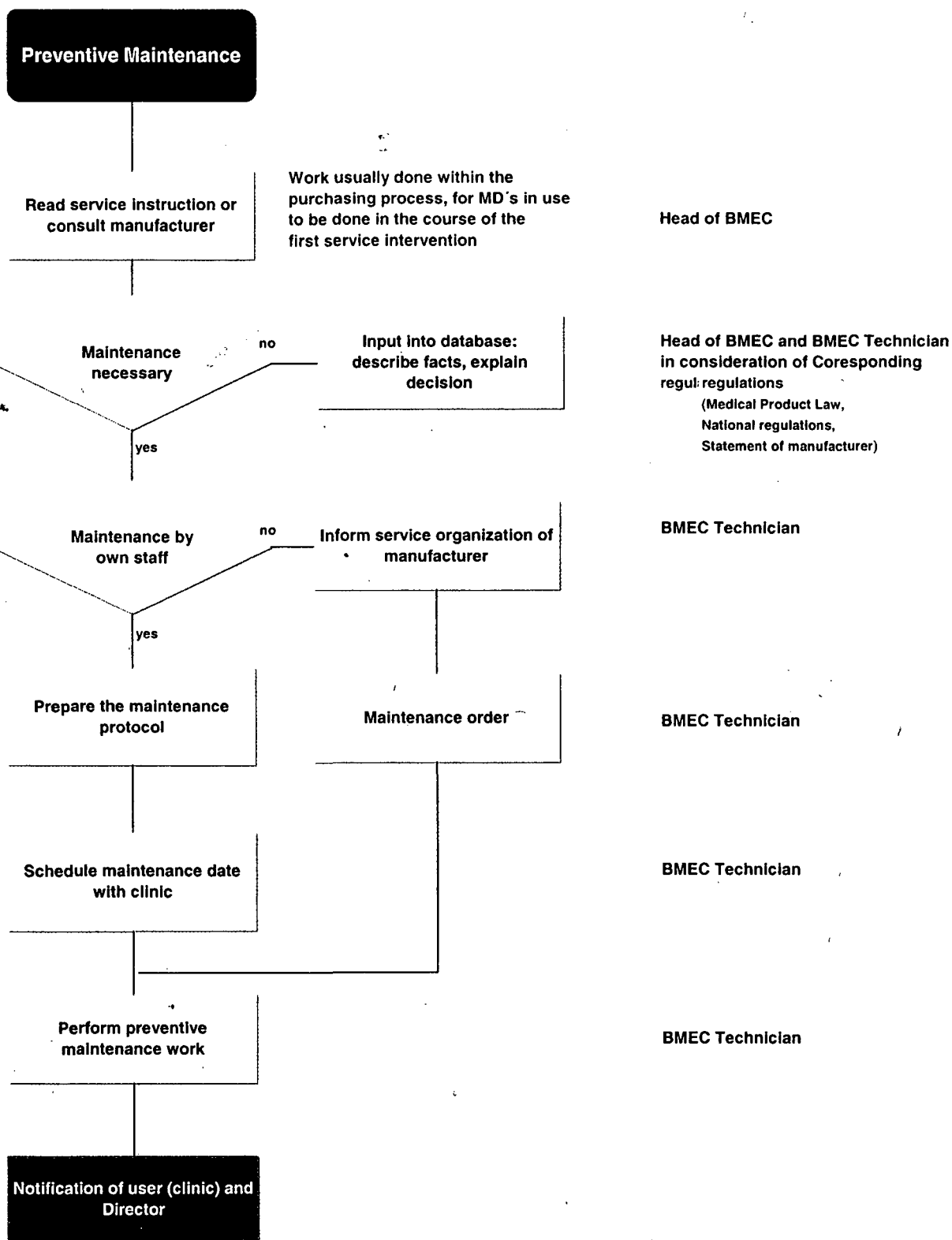
Consultant

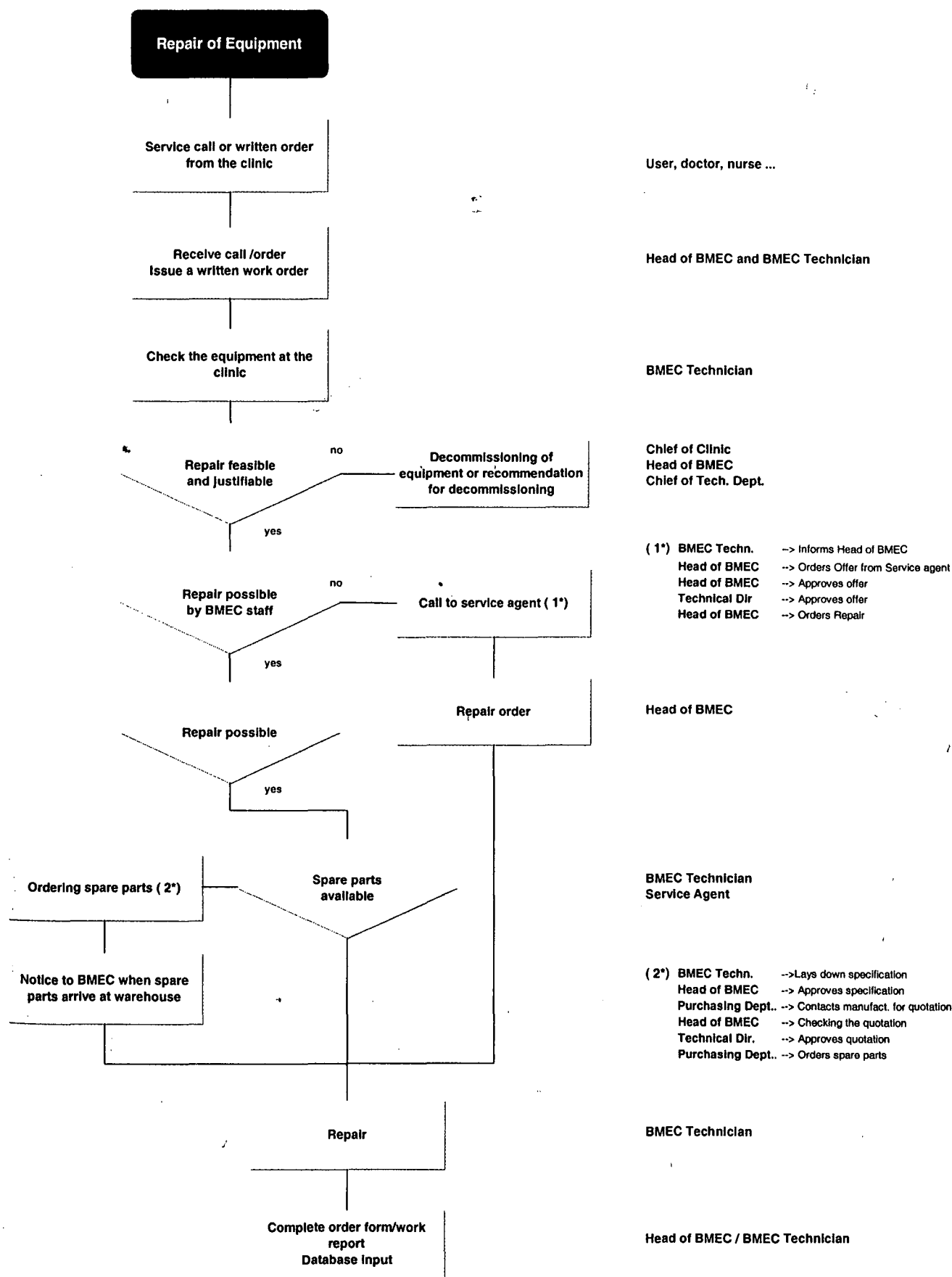
Travel Schedule for BiH, May 2002

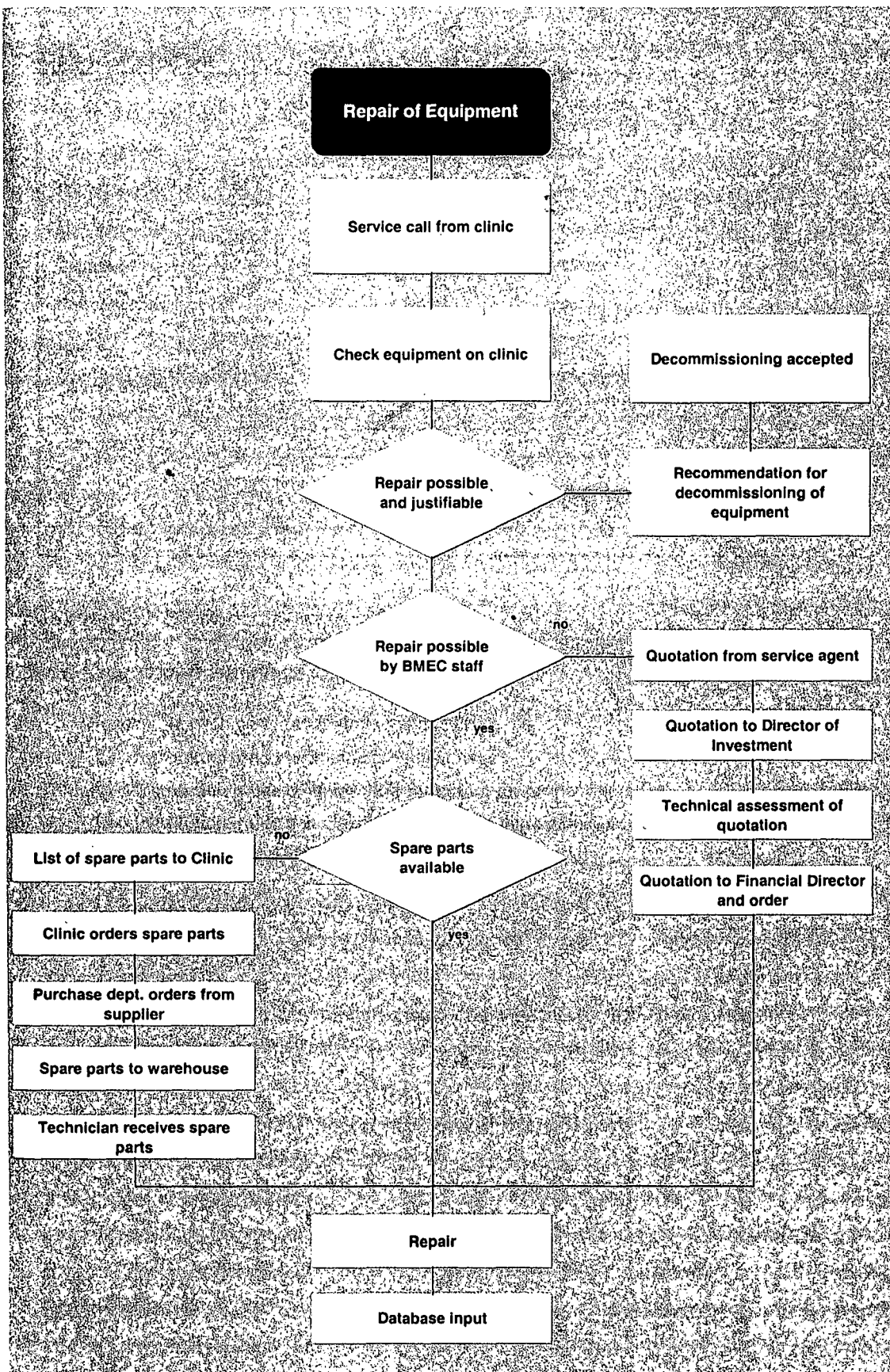
	Morning	Afternoon
Mon 14		Richard Temsch arrives in Sarajevo
Tue 15		Rainer Hutz arrives in Sarajevo
Wed 16	vFM Software Follow-Up Training for Sarajevo, Tuzla and Mostar (at BMEC Kosevo)	
Thu 17	vFM Software Training for Sarajevo, Tuzla and Mostar (at BMEC Kosevo)	
Fri 18	Evaluation and Discussion of Completed Tasks	Edmund Meitz arrives in Sarajevo
Sat 19		Rainer Hutz departs
Sun 20		
Mon 21	Travel to Tuzla	Evaluation and Discussion of Completed Tasks
Tue 22	Evaluation and Discussion of Completed Tasks	Return to Sarajevo
Wed 23	Travel to Mostar	Evaluation and Discussion of Completed Tasks
Thu 24	Evaluation and Discussion of Completed Tasks	Return to Sarajevo
Fri 25	Wrap-Up Meeting in Sarajevo	Edmund Meitz and Richard Temsch depart











User, doctor, nurse ...

BMEC Technician

SAFETY CONTROL OF MEDICAL ELECTRICAL EQUIPMENT

Data of equipment

Name of device:	<input style="width:100%;" type="text"/>		
Type number:	<input style="width:150px;" type="text"/>	Article number:	<input style="width:150px;" type="text"/>
Serial number:	<input style="width:150px;" type="text"/>	FDA number:	<input style="width:150px;" type="text"/>
Manufacturer:	<input style="width:150px;" type="text"/>	Country of manufacture:	<input style="width:150px;" type="text"/>
Supplier:	<input style="width:150px;" type="text"/>	Date of installation:	<input style="width:150px;" type="text"/>
Power supply:	<input style="width:100px;" type="text"/>	Class: <input style="width:50px;" type="text"/>	Type: <input style="width:50px;" type="text"/>
Hospital:	<input style="width:350px;" type="text"/>		Identification number
Clinical ward:	<input style="width:350px;" type="text"/>		<input style="width:150px;" type="text"/>
Accessory:	<input style="width:500px;" type="text"/>		
	<input style="width:500px;" type="text"/>		
	<input style="width:500px;" type="text"/>		

Inspection and Measurement

Defibrillator

1. Accompanying documents

Inspection of the accompanying documents

- C Instruction guide written in local language
- C Instruction guide contains all information for proper operation
- C Instruction guide contains the information concerning preventive inspection maintenance and spareparts

2. Inspection of the closed equipment

- Marking on the outside
- Marking of controls
- Short instruction for defibrillating/monitoring permanently marked on the equipment
- Indicator lights and push buttons
- Inspection of the enclosure and protective cover
- Inspection of the connection to supply
- Colours of insulation of conductors in supply cables and cords
- Inspection of cord and cable anchorages
- Inspection of the protection against ingress of liquids
- Inspection of the protection against mechanical hazards
- Inspection of fuse elements
- Inspection of the reverence concerning the necessity of a monthly functional test
- Inspection of the paddles (creepage distance)
- Inspection concerning malefunctions due to human errors (Part. requirements)

3. *Inspection of the inside of the equipment* (Not subject of periodical testings)

- Inspection of the requirements related to classification
- Markings on the inside
- Inspection of the constructional requirements
- Inspection of the internal wiring (mech. protection, insulation)
- Inspection of the protective earth conductor / protecting earth terminal
- Inspection of the creepage distances
- Inspection of mainparts, components and layout
- Inspection of the separation of mainpart and applied parts

4. *Electrical measurements*

- Resistance of the protective earth conductor
- Earth leakage current S.F.C.
- Enclosure leakage current S.F.C.
- Patient leakage current S.F.C.
- Patient auxiliary current

	m Ω
	m A
	m A
	m A
	m A

5. *Functional Tests* (according to the instruction guide)

E C G - Monitor / Recorder

- Heart rate meter
- Displayed parameters
- Heart rate alarm
- Sweep speed (monitor)
- Calibration signal
- Paper speed
- Automatic Recording (alarm triggered)
- Annotates

Defibrillator

- Function of the self test
- Charge control (control of display and lamps)
- Charge control (max. charge time < 15 s)
- Inspection of the operation modes
- Inspection of the synchronisation (SYNC - Pulse) if available
- Paddle contact indicator
- Automatic recharging / charge time
- Inspection of the battery charge indicator
- Internal discharge in the case of energy resetting

Measurement of delivered energy

	Preselected energy [Joule]	Measured energy [Joule]
10% of max. output energy		
50% of max. output energy		
Max. output energy		

Measuring equipment:

Safety tester	
Defibrillator tester	

Within the scope of above testings no faults have been located:

Within the scope of above testings the following faults have been located:

1.
2.
3.
4.

Classification of faults.: Fault causes no hazards for patient, user or invironment
 Fault may cause hazards

Operation of the equipment is possible
Putting the equipment out of operation is recommended
Operation of the equipment is not permitted

Date:

Testing engineer:

SAFETY CONTROL OF MEDICAL ELECTRICAL EQUIPMENT

Data of equipment

Name of device:	<input style="width:100%;" type="text"/>		
Type number:	<input style="width:150px;" type="text"/>	Article number:	<input style="width:150px;" type="text"/>
Serial number:	<input style="width:150px;" type="text"/>	FDA number:	<input style="width:150px;" type="text"/>
Manufacturer:	<input style="width:150px;" type="text"/>	Country of manufacture:	<input style="width:150px;" type="text"/>
Supplier:	<input style="width:150px;" type="text"/>	Date of installation:	<input style="width:150px;" type="text"/>
Power supply:	<input style="width:100px;" type="text"/>	Class: <input style="width:50px;" type="text"/>	Type: <input style="width:50px;" type="text"/>
Hospital:	<input style="width:350px;" type="text"/>		Identification number
Clinical ward:	<input style="width:350px;" type="text"/>		<input style="width:150px;" type="text"/>
Accessory:	<input style="width:100%;" type="text"/>		
	<input style="width:100%;" type="text"/>		
	<input style="width:100%;" type="text"/>		

Inspection and Measurement

Electrosurgery unit

1. Accompanying documents

Inspection of the accompanying documents

- C Instruction guide (in local language)
- C Instruction guide contains all information for proper operation
- C Instruction guide contains the information concerning preventive inspection maintenance and spareparts

2. Inspection of the closed equipment

- Marking on the outside
- Marking of controls
- Indicatorlights and push buttons
- Inspection of the enclosure and protective cover
- Inspection of the connection to supply
- Colours of insulation of conductors in supply cables and cords
- Inspection of cord and cable anchorages
- Inspection of the protection against ingress of liquids
- Inspection of the protection against mechanical hazards
- Inspection of fuse elements

3. *Inspection of the inside of the equipment* (Not subject of periodical testings)

- Inspection of the requirements related to classification
- Markings on the inside
- Inspection of the constructional requirements
- Inspection of the internal wiring (mech. protection, insulation)
- Inspection of the protective earth conductor / protecting earth terminal
- Inspection of the creepage distances
- Inspection of mainparts, components and layout
- Inspection of the separation of mainpart and applied parts

4. *Electrical measurements*

- Resistance of the protective earth conductor
- Earth leakage current S.F.C.
- Enclosure leakage current S.F.C.
- Patient leakage current S.F.C.
- Patient auxiliary current

	m Ω
	m A
	m A
	m A
	m A

5. *Functional Tests* (according to the instruction guide)

- Monitoring of electrode placement / disconnection
- Inspection of the footswitch
- Inspection of the electrode

Functional test with electrosurgery analyzer:

Power measurement:

Output power [W]	10 % of P max.		50 % of P max.		P max. [W]	
	preset	deliv.	preset	deliv.	preset	deliv.
Pure cut						
Coagulation						
Bipolar coag.						

Low frequency currents:

	10 % of	I [uA]	50%	I [uA]	P max.	I [uA]
	P max.		P max.			
Pure cut						
Coagulation						
Bipolar coag.						

Measuring equipment:

<i>Safety tester</i>	
<i>Electrosurgery analyzer</i>	

Within the scope of above testings no faults have been located:

Within the scope of above testings the following faults have been located:

- 1.
- 2.
- 3.
- 4.
- 5.

Classification of faults.: Fault causes no hazards for patient, user or environment
 Fault may cause hazards

Operation of the equipment is possible
Putting the equipment out of operation is recommended
Operation of the equipment is not permitted

Date:

Testing engineer:

SAFETY CONTROL OF MEDICAL ELECTRICAL EQUIPMENT

Data of equipment

Name of device:	<input style="width:100%;" type="text"/>		
Type number:	<input style="width:80%;" type="text"/>	Article number:	<input style="width:80%;" type="text"/>
Serial number:	<input style="width:80%;" type="text"/>	FDA number:	<input style="width:80%;" type="text"/>
Manufacturer:	<input style="width:80%;" type="text"/>	Country of manufacture:	<input style="width:80%;" type="text"/>
Supplier:	<input style="width:80%;" type="text"/>	Date of installation:	<input style="width:80%;" type="text"/>
Power supply:	<input style="width:80%;" type="text"/>	Class: <input style="width:40%;" type="text"/>	Type: <input style="width:40%;" type="text"/>
Hospital:	<input style="width:100%;" type="text"/>		Identification number <input style="width:100%; height: 20px;" type="text"/>
Clinical ward:	<input style="width:100%;" type="text"/>		
Accessory:	<input style="width:100%; height: 20px;" type="text"/>		
	<input style="width:100%; height: 20px;" type="text"/>		
	<input style="width:100%; height: 20px;" type="text"/>		

Inspection and Measurement

Infusion pump

1. Accompanying documents

Inspection of the accompanying documents

- C Instruction guide (in local language)
- C Instruction guide contains all information for proper operation
- C Instruction guide contains the information concerning preventive inspection maintenance and spareparts

2. Inspection of the closed equipment

- Marking on the outside
- Marking of Controls
- Operating instruction on the outside of the equipment
- Indicatorlights and push buttons
- Inspection of the enclosure and protective cover
- Inspection of the connection to supply
- Colours of insulation of conductors in supply cables and cords
- Inspection of cord and cable anchorages
- Inspection of the protection against ingress of liquids

- Inspection of the protection against mechanical hazards
- Inspection of fuse elements
- Inspection of the drop sensor
- Low battery charge warning
- Technical alarm
- Automatic switch over to battery operation in the case of power failure

3. *Inspection of the inside of the equipment* (Not subject of periodical testings)

- Inspection of the requirements related to classification
- Markings on the inside
- Earthing and potential equalization
- Inspection of the constructional requirements
- Inspection of the internal wiring (mech. protection, insulation)
- Inspection of the protective earth conductor
- Inspection of the creepage distances
- Inspection of mainparts, components and layout

4. *Electrical measurements*

- Resistance of the protective earth conductor
- Earth leakage current S.F.C.
- Enclosure leakage current S.F.C.

	m Ω
	m A
	m A

5. *Functional Tests* (according to the instruction guide)

- Function of the self test
- Function of the drop sensor
- Accumulated volume infused
- Infusion duration recall
- Elapsed time recall
- Flow rate (according to the following settings)
- Inspection of the density of the infusion set
- No flow with the pump out of action

Measurement of the flow rate

Preset flowrate	Value		Measured flowrate	
10 % of max. flowrate or max. drops/min.		ml/h		ml/h
		d/min		d/min
Max. flowrate		ml/h		ml/h
		d/min		d/min

d...drops

Occlusion alarm

 bar

End of infusion alarm

vis./aud.

Nurse call

vis./aud.

Bubble detector alarm

vis./aud.

Low battery alarm

vis./aud.

Alarm due to failure to validate programmed data

vis./aud.

Measuring equipment:

Within the scope of above testings no faults have been located:

Within the scope of above testings the following faults have been located:

1.
2.
3.
4.
5.
6.

Classification of faults.: Fault causes no hazards for patient, user or environment
 Fault may cause hazards

Operation of equipment is possible
Putting the equipment out of operation is recommended
Operation of the equipment is not permitted

Date:

Testing engineer:

3. *Inspection of the inside of the equipment* (Not subject of periodical testings)

- Inspection of the requirements related to classification
- Markings on the inside
- Inspection of the constructional requirements
- Inspection of the internal wiring (mech. protection, insulation)
- Inspection of the protective earth conductor /protecting earth terminal
- Inspection of the creepage distances
- Inspection of mainparts, components and layout

4. *Electrical measurements*

- Resistance of the protective earth conductor
- Earth leakage current S.F.C.
- Enclosure leakage current S.F.C.

	m Ω
	m A
	m A

5. *Functional Tests* (according to the instruction guide)

These instructions apply to incubators fitted with all options. Ignore tests which are not relevant.

- Check of the air filter
- Check of the air / oxygen system (measurement of oxygen concentration)
- Check of the airflow (function of fan)
- Function of skin temperature probe
- Check of the mattress elevator
- Inspection of the phototherapy unit (if available)
- Check of temperature insidehood
- Check of the alarm suppression (accoustic warning)
- Check of temperature adjustment (max. temperature)
- Check of temperature alarm
- Check of the power failure alarm
- Check of oxygen alarm

Measuring equipment:

<i>Safety tester</i>	
<i>Temperature meter</i>	
<i>Oxygen-meter</i>	

Within the scope of above testings no faults have been realized:

Within the scope of above testings the following faults have been realized:

- 1.
- 2.
- 3.

Classification of faults.: Fault causes no hazards for patient, user or environment
 Fault may cause hazards

Operation of the equipment is possible
Putting the equipment out of operation is recommended
Operation of the equipment is not permitted

Date:

Testing engineer:

SAFETY CONTROL OF MEDICAL ELECTRICAL EQUIPMENT

Data of equipment

Name of device:	<input type="text"/>		
Type number:	<input type="text"/>	Article number:	<input type="text"/>
Serial number:	<input type="text"/>	FDA number:	<input type="text"/>
Manufacturer:	<input type="text"/>	Country of manufacture:	<input type="text"/>
Supplier:	<input type="text"/>	Date of installation:	<input type="text"/>
Power supply:	<input type="text"/>	Class: <input type="text"/>	Type: <input type="text"/>
Hospital:	<input type="text"/>	Identification number	
Clinical ward:	<input type="text"/>	<input type="text"/>	
Accessory:	<input type="text"/>		
	<input type="text"/>		
	<input type="text"/>		

Inspection and Measurement

Patient monitor

1. Accompanying documents

Inspection of the accompanying documents

- C Instruction guide (in local language)
- C Instruction guide contains all information for proper operation
- C Instruction guide contains the information concerning preventive inspection maintenance and spareparts

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

2. Inspection of the closed equipment

- Inspection of the case for damage
- Marking on the outside
- Marking of controls
- Indicatorlights and push buttons
- Inspection of the enclosure and protective cover
- Inspection of the connection to supply
- Colours of insulation of conductors in supply cables and cords
- Inspection of cord and cable anchorages
- Inspection of the protection against ingress of liquids
- Inspection of protection against mechanical hazards

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

3. *Inspection of the inside of the equipment* (Not subject of periodical testings)

- Inspection of the requirements related to classification
- Markings on the inside
- Inspection of the constructional requirements
- Inspection of the internal wiring (mech. protection, insulation)
- Inspection of the protective earth conductor / protecting earth terminal
- Inspection of the creepage distances
- Inspection of mainparts, components and layout

4. *Electrical measurements*

- Resistance of the protective earth conductor
- Earth leakage current S.F.C.
- Enclosure leakage current S.F.C.
- Patient leakage current S.F.C.
- Patient auxiliary current

	m Ω
	m A
	m A
	m A
	m A

5. *Functional Tests* (according to the instruction guide)

- Heart rate [test is performed with ECG - generator]
- Patient alarm setup/limits
- Function of audible and visual alarms
- Function of operator controls
- Display of numerics
- Lead selection
- Alarm suppression
- Test/calibration signal
- Technical alarm's according to the operator's manual

Measuring equipment:

Within the scope of above testings no fault has been located:

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SAFETY CONTROL OF MEDICAL ELECTRICAL EQUIPMENT

Data of equipment

Name of device:	<input style="width:100%;" type="text"/>		
Type number:	<input style="width:15%;" type="text"/>	Article number:	<input style="width:15%;" type="text"/>
Serial number:	<input style="width:15%;" type="text"/>	FDA number:	<input style="width:15%;" type="text"/>
Manufacturer:	<input style="width:15%;" type="text"/>	Country of manufacture:	<input style="width:15%;" type="text"/>
Supplier:	<input style="width:15%;" type="text"/>	Date of installation:	<input style="width:15%;" type="text"/>
Power supply:	<input style="width:15%;" type="text"/>	Class: <input style="width:5%;" type="text"/>	Type: <input style="width:5%;" type="text"/>
Hospital:	<input style="width:40%;" type="text"/>	Identification number	
Clinical ward:	<input style="width:40%;" type="text"/>	<input style="width:30%;" type="text"/>	
Accessory:	<input style="width:100%;" type="text"/>		
	<input style="width:100%;" type="text"/>		
	<input style="width:100%;" type="text"/>		

Inspection and Measurement

Syringe pump

1. Accompanying documents

Inspection of the accompanying documents

- C Instruction guide (in local language)
- C Instruction guide contains all information for proper operation
- C Instruction guide contains the information concerning preventive inspection maintenance and spareparts

2. Inspection of the closed equipment

- Marking on the outside
- Marking of Controls
- Indicatorlights and push buttons
- Inspection of the enclosure and protective cover
- Inspection of the connection to supply
- Colours of insulation of conductors in supply cables and cords
- Inspection of cord and cable anchorages
- Inspection of the protection against ingress of liquids
- Inspection of the protection against mechanical hazards
- Inspection of fuse elements
- Low battery charge warning
- Technical alarm

3. *Inspection of the inside of the equipment* (Not subject of periodical testings)

- Inspection of the requirements related to classification
- Markings on the inside
- Earthing and potential equalization
- Inspection of the constructional requirements
- Inspection of the internal wiring (mech. protection, insulation)
- Inspection of the protective earth conductor
- Inspection of the creepage distances
- Inspection of mainparts, components and layout

4. *Electrical measurements*

- Resistance of the protective earth conductor
- Earth leakage current S.F.C.
- Enclosure leakage current S.F.C.

	m Ω
	m A
	m A

5. *Functional Tests* (according to the instruction guide)

- Function of the self test
- Manual release system
- Accumulated volume infused
- Infusion duration recall
- Elapsed time recall
- Flow rate (according to the following settings)

	Ch1	Ch2	Ch3

Preset flowrate	Value	Measured flowrate			
		Ch1	Ch2	Ch3	
Min. flowrate or 1 ml/h					ml/h
Max. flowrate					ml/h

Measurement of the occlusion detection

Occlusion alarm

			bar
--	--	--	-----

End of infusion alarm
 End of infusion prealarm
 Non - syringe alarm
 Disengaged mechanics alarm
 Alarm due to failure to validate programmed data

vis./aud.
 vis./aud.
 vis./aud.

Measuring equipment:

Within the scope of above testings no faults have been located:

Within the scope of above testings the following faults have been located:

1.
2.
3.
4.
5.
6.

Classification of faults.: Fault causes no hazards for patient, user or environment
 Fault may cause hazards

Operation of equipment is possible
Putting the equipment out of operation is recommended
Operation of the equipment is not permitted

Date:

Testing engineer:

SAFETY CONTROL OF MEDICAL ELECTRICAL EQUIPMENT

Data of equipment

Name of device:	<input style="width: 100%;" type="text"/>		
Type number:	<input style="width: 20%;" type="text"/>	Article number:	<input style="width: 20%;" type="text"/>
Serial number:	<input style="width: 20%;" type="text"/>	FDA number:	<input style="width: 20%;" type="text"/>
Manufacturer:	<input style="width: 20%;" type="text"/>	Country of manufacture:	<input style="width: 20%;" type="text"/>
Supplier:	<input style="width: 20%;" type="text"/>	Date of installation:	<input style="width: 20%;" type="text"/>
Power supply:	<input style="width: 15%;" type="text"/>	Class: <input style="width: 10%;" type="text"/>	Type: <input style="width: 10%;" type="text"/>
Hospital:	<input style="width: 100%;" type="text"/>		Identification number
Clinical ward:	<input style="width: 100%;" type="text"/>		<input style="width: 100%;" type="text"/>
Accessory:	<input style="width: 100%;" type="text"/>		
	<input style="width: 100%;" type="text"/>		
	<input style="width: 100%;" type="text"/>		

Inspection and Measurement

Respirator

1. Accompanying documents

Inspection of the accompanying documents

- C Instruction guide (in local language)
- C Instruction guide contains all information for proper operation
- C Instruction guide contains the information concerning preventive inspection maintenance and spareparts

2. Inspection of the closed equipment

- Marking on the outside
- Marking of controls
- Indicatorlights and push buttons
- Inspection of the enclosure and protective cover
- Inspection of the colours of the gas supply tubes
- Inspection of the connectors of the gas supply tubes (non - interchangeable)
- Inspection of the connection to mains supply
- Colours of insulation of conductors in supply cables and cords
- Inspection of cord and cable anchorages
- Inspection of the protection against ingress of liquids
- Inspection of the protection against mechanical hazards
- Inspection of fuse elements

3. *Inspection of the inside of the equipment* (Not subject of periodical testings)

- Inspection of the requirements related to classification
- Markings on the inside
- Inspection of the constructional requirements
- Inspection of the internal wiring (mech. protection, insulation)
- Inspection of the protective earth conductor / earth terminal
- Inspection of the creepage distances
- Inspection of mainparts, components and layout

4. *Electrical measurements*

- Resistance of the protective earth conductor
- Earth leakage current S.F.C.
- Enclosure leakage current S.F.C.
- Patient leakage current S.F.C.
- Patient auxiliary current

	m Ω
	m A
	m A
	m A
	m A

5. *Functional Tests* (according to the instruction guide)

- Parameter settings
- Function of the corresponding alarms
- Leakage test
- Gas supply alarm
- Apnoe alarm
- Checking pressure relief
- Main failure alarm

Safety tester	
Test lung	
Oxygen meter	

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Power supply:	<input type="text"/>	Class:	<input type="text"/>
		Type:	<input type="text"/>
Hospital:	<input type="text"/>		Identification number
Clinical ward:	<input type="text"/>		<input type="text"/>
Accessory:	<input type="text"/>		
	<input type="text"/>		
	<input type="text"/>		

Inspection and Measurement

Transportable steam sterilizer

1. Accompanying documents

Inspection of the accompanying documents

- C Instruction guide (in local language)
- C Instruction guide according to the Particular requirements
- C Instruction guide contains the information concerning preventive inspection maintenance and spareparts

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

2. Inspection of the closed equipment

- Marking on the outside
- Marking of controls
- Indicatorlights and push buttons
- Inspection of the enclosure and protective cover
- Inspection of the connection to mains supply
- Colours of insulation of conductors in supply cables and cords
- Inspection of cord and cable anchorages

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

3. Inspection of the inside of the equipment (Not subject of periodical testings)

- Inspection of the requirements related to classification
- Markings on the inside
- Inspection of the constructional requirements

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

- Inspection of the electrical requirements according to the Particular requirement
- Inspection of the constructional requirements according to the Particular requirements
- Inspection of the over pressure protection devices
- Inspection of the door and the vessel
- Inspection of the water reservoir
- Inspection of the internal wiring (mech. protection, insulation)
- Inspection of the protective earth conductor / earth terminal
- Inspection of the creepage distances
- Inspection of mainparts, components and layout

4. *Electrical measurements*

- Resistance of the protective earth conductor
- Earth leakage current S.F.C.
- Enclosure leakage current S.F.C.

	m Ω
	m A
	m A

5. *Functional Tests (according to the instruction guide)*

- Temperature of the water reservoir after a 12 times discharge
- Test of the over temperature protection device
- Measurement of the overpressure protection device
- Measurement of the thermal insulation
- Verifying of the operating cycle conditions (according Table 1 of the Part. requirements)

	° C

Safety tester	
Temperature meter	
Pressure meter	

Within the scope of above testings no faults have been realized:

Within the scope of above testings the following faults have been realized:

1.
2.
3.
4.
5.
6.

Classification of faults.: Fault causes no hazards for patient, user or environment
 Fault may cause hazards

Operation of the equipment is possible
Putting the equipment out of operation is recommended
Operation of the equipment is not permitted

Date:

Testing engineer: