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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 Tuzia - 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.

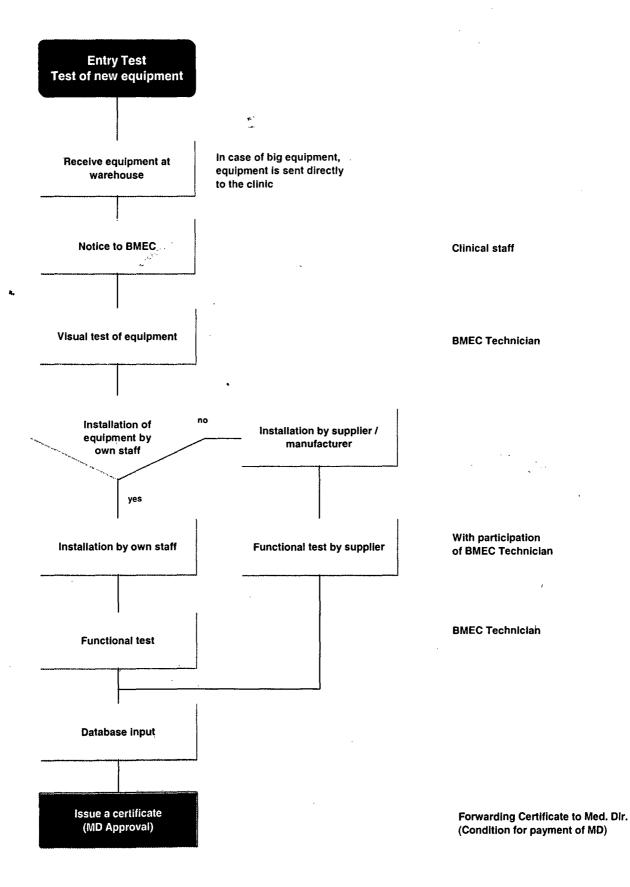
Hopefully, the procurement of the measuring devices as well as the training will be completed as scheduled. A final visit of the BMECs in autumn by KMB together with the CTA is highly recommended, because it will give the staff a last opportunity to ask questions, which may arise during the implementation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

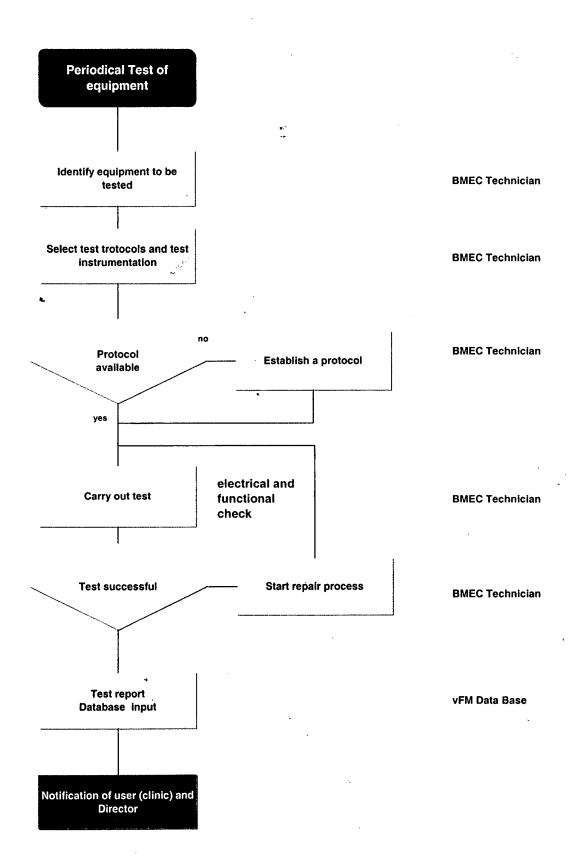
Edmund Meitz

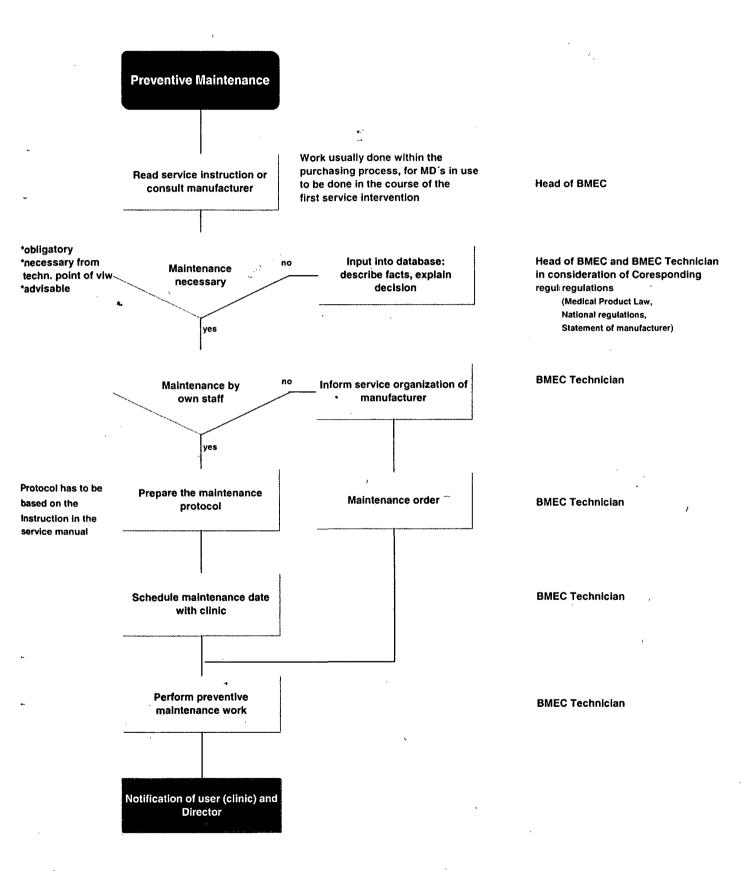
Consultant

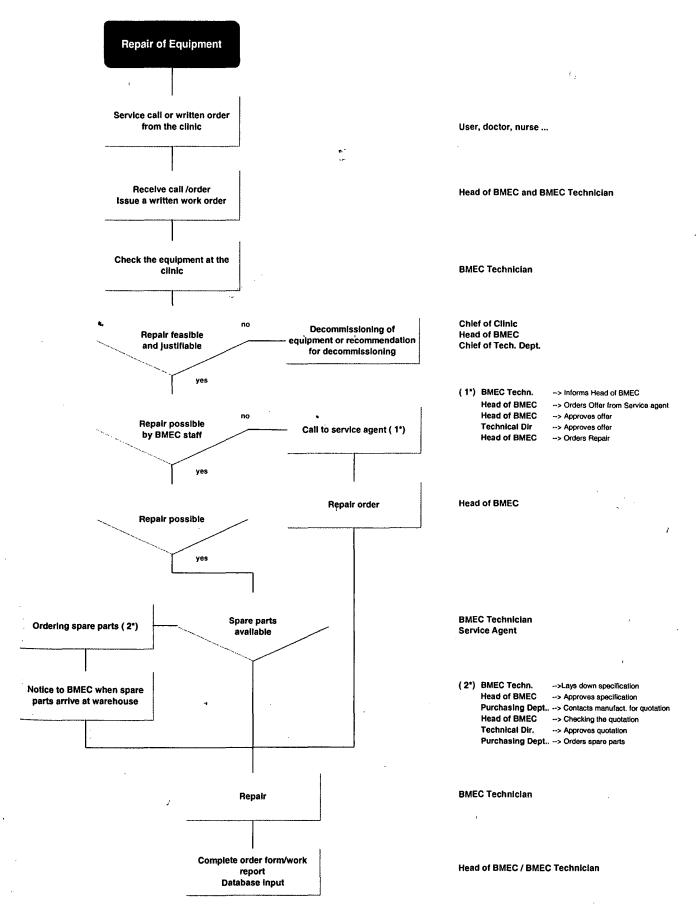
Travel Schedule for BiH, May 2002

	Monding	Affernoon
Mon 14	ojanii karantikata madikata katikata madala katikata madala madala madala katikata madala katikata madala kati Ba	Richard Temsch arrives in Sarajevo
Tue 15		Rainer Hutz arrives in Sarajevo
Wed 16	vFM Software Follow-UpTraining for Sarajevo, Tuzla and Mostar (at BMEC Kosevo)	evo, Tuzla and Mostar (at BMEC Kosevo)
Thu 17	vFM Software Training for Sarajevo, Tuzla and Mostar (at BMEC Kosevo)	uzla and Mostar (at BMEC Kosevo)
なが、特別		Edmund Meitz arrives in Sarajevo
Fit 18	Evaluation and Discussion of Completed Tasks	Rainer Hutz departs
Sat 19		
Sun 20		
Mon 2t	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

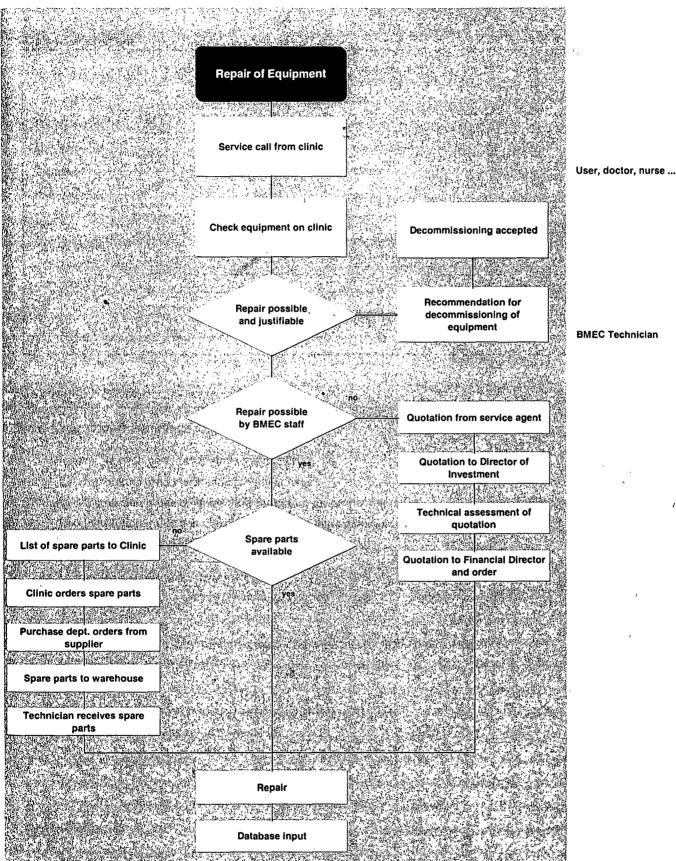








cedure of Repair of Medical Equipment - Result of Workshop in Tuzla May 22nd



ta of equipmer		
lame of device:		
Type number:	Article number:	
Serial number:	FDA number:	
	Country of manufacture:	
Manufacturer:		
Supplier:	Date of installation:	
Power supply:	Class: Type:	
lospital:	Identifi	cation number
Clinical ward:		
looonon <i>:</i>		
Accessory:		
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	ving documents	Defibrillati
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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

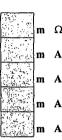
Resistance of the protective earth conductor

Earth leakage current S.F.C.

Enclosure leakage current S.F.C.

Patient leakage current S.F.C.

Patient auxiliary current



5. Functional Tests

(according to the instruction guide)

ECG-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	Measured
	energy [Joule]	energy [Joule]
10% of max. output energ	gy	
50% of max. output energ	gy	
Max. output energy		

Measuring	eauinm	ent:

Safety tester	
Defibrillator tester	

Within the scope of above	testings no faults have been located:	- 1	
Within the scope of above	testings the following faults have been located:		
1			
Classification of faults.:	Fault causes no hazards for patient, user or invironment Fault may cause hazards		
Operation of the equipment ou Putting the equipment ou Operation of the equipment	nt of operation is recommended		
Date:	Testing engineer:		′

Data of equipmen	<u>t</u>		
Name of device:			
Type number:		Article number:	
Serial number:		FBA number:	
Manufacturer:		Country of manufacture:	
Supplier:		Date of installation:	
Power supply:	Class:	Type:	<u> </u>
Hospital:			Identification number
Clinical ward:			
Accessory:	,		
4.			
Inspection and M	easurement .	•	Electrosurgery unit
			The Additional Section Control of the Control of th
1. Accompany	ring documents		
	the accompanying document		्र सन्दर्भ
_	on guide (in local language)		
	on guide contains all informa		
	on guide contains the informa ance and spareparts	ation concerning preventive inspe	ction
manicon	ance and spareparts		
2. Inspection	of the closed equipment		
Marking on t			
Marking of c	ts and push buttons		
	f the enclosure and protective	cover	
-	f the connection to supply		
•	sulation of conductors in sup	ply cables and cords	100 mg
	f cord and cable anchorages	• •	
-	f the protection against ingres	s of liqids	ree
-	f the protection against mecha	-	
Inspection of	f fuse elements		

<i>3</i> .	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	
Fu	nctional test with electrosurgery analyzer:	
		•

Power measurement:

Output power	10 % of	10 % of P max.		50 % of P max.		P max. [W]	
[W]	preset	deliv.	preset	deliv.	preset	deliv.	
Pure cut					* * * * /		
Coagulation		(A)			FG 7.85		
Bipolar coag.	(977.5.39 s		\$.				

Low frequency currents:

	10 % of	I [uA]	50%	I [uA]	P max.	I [uA]
	P max.		P max.			
Pure cut	A .		4		2015	
Coagulation	\$ - \$\$\disp\{\frac{1}{2}}\$.					
Bipolar coag.	, , , , , , , , , , , , , , , , , , ,	٠, -,		11 1.45 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		

Mea	suring	equipn	ient
1.100		Adambii	

Savety tester	
Electrosurgery analyzer	

Within the scope of above testings no faults have been located:	
Within the scope of above testings the following faults have been lo	cated:
1. 2. 3. 4. 5. 5.	
Classification of faults.: Fault causes no hazards for patient, use Fault may cause hazards	r or invironment
Operation of the equipment is possible Putting the equipment out of operation is recommended Operation of the equipment is not permitted	
Date: Testi	ng engineer:

Name of device:				
Type number:		Article number:		
Serial number:		FDA nµmber:		
Manufacturer:		Country of manufacture:		
Supplier:		Date of installation:		
Power supply:	Class	s: Type:		
Hospital:			Identificati	on number
Clinical ward:				
Accessory:				
	ying documents	· ·	<u></u>	Infusion pum
I. Accompany Inspection of Construction Cons	ying documents f the accompanying docum ion guide (in local languag ion guide contains all infor ion guide contains the info		pection	Infusion pum
Inspection of C Instruction C	ying documents f the accompanying docum ion guide (in local languag ion guide contains all infor	ge) mation for proper operation rmation concerning preventive insp	pection	Infusion pum
Inspection of Construction Cons	ying documents If the accompanying documents If the accompan	ge) mation for proper operation rmation concerning preventive insp	pection	Infusion pum
Inspection of Construction Cons	ying documents If the accompanying documents If the accompan	ge) mation for proper operation rmation concerning preventive insp	pection	Infusion pun
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Inspection of Colours of inspection of Colours of Colou	f the accompanying documion guide (in local languagion guide contains all informance and spareparts of the closed equipments the outside Controls struction on the outside of the and push buttons f the enclosure and protect f the connection to supply insulation of conductors in second	ge) mation for proper operation rmation concerning preventive insp nt the equipment tive cover supply cables and cords	pection	Infusion pun
Inspection o C Instructi C Instructi C Instructi mainten 2. Inspection Marking on Marking of Operating in Indicatorligh Inspection o Colours of in Inspection o	f the accompanying documion guide (in local languagion guide contains all informance and spareparts of the closed equipments the outside Controls struction on the outside of the and push buttons f the enclosure and protect f the connection to supply	ge) rmation for proper operation rmation concerning preventive insp nt the equipment ive cover supply cables and cords	pection	Infusion pun

	Inspection of the protection against mechanical hazards			77.7
	Inspection of fuse elements			
	Inspection of the drop sensor			
	Low battery charge warning			1.4.2.3.3
	Technical alarm			
	Automatic switch over to battery operation in the case of	nover failure		7
	rationalic switch over to battery operation in the case of	power randic	· · · · · · · · · · · · · · · · · · ·	Carrier .
<i>3</i> .	Inspection of the inside of the equipment	(Not subject of pe	eriodical testings)	
	Inspection of the requirements related to classification			
	Markings on the inside			<u> </u>
	Earthing and potential equalization		,	
	Inspection of the constructional requirements			
	Inspection of the internal wiring (mech. protection, insula	tion)		
	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			m Ω
	Earth leakage current S.F.C.			m A
				III A
	Enclosure leakage current S.F.C.			m A
5.	Functional Tests (according to the instruction	on 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	Measured]	
	ا س	l I	l .	

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

d...drops

Occlusion alarm			bar
End of infusion alarm Nurse call Bubble detector alarm Low battery alarm Alarm due to failure to	validate programmed data	vis./aud. vis./aud. vis./aud. vis./aud. vis./aud.	
Measuring equipment:	r.		
Within the scope of above to	estings no faults have been locat	ed:	
Within the scope of above	estings the following faults have	been located:	
1			
Classification of faults.:	Fault causes no hazards for pati Fault may cause hazards	ent, user or environment	
Operation of equipment is Putting the equipment ou Operation of the equipme	t of operation is recommended	•	
Date:	,	Testing engineer:	

lame of device:		
Type number:	Article number:	
Serial number:	FDA number:	
Manufacturer:	Country of manufacture:	and an arrangement of the second
Supplier:	Date of installation:	
Power supply:	Class: Type:	
Hospital:	_lde	ntification number
Clinical ward:		
Accessory:		
nspection and N		Infant incub
_	nying documents	
	of the accompanying documents	
	tion guide (in local language)	
C Instruct	tion guide contains all information for proper operation tion guide contains the information concerning preventive inspection nance and spareparts	
	of the closed equipment	
2. Inspection	i of the closed equipment	
-	the outside	
Marking on Marking of	the outside Controls	
Marking on Marking of Indicatorlig	the outside Controls hts and push buttons	
Marking on Marking of Indicatorlig Inspection o	the outside Controls hts and push buttons of the enclosure and protective cover	
Marking on Marking of Indicatorlig Inspection of	the outside Controls hts and push buttons of the enclosure and protective cover of the connection to supply	
Marking on Marking of Indicatorlig Inspection of Colours of inspections of the Marking on the Marking on the Marking of the Marking on the Marking of the Marking of the Marking of the Marking on Marking of the Mark	the outside Controls hts and push buttons of the enclosure and protective cover of the connection to supply insulation of conductors in supply cables and cords	
Marking on Marking of Indicatorlig Inspection of Colours of inspections of the Marking on Marking of the Marking	the outside Controls hts and push buttons of the enclosure and protective cover of the connection to supply	
Marking on Marking of Indicatorlig Inspection of Colours of inspection of the Inspec	the outside Controls hts and push buttons of the enclosure and protective cover of the connection to supply insulation of conductors in supply cables and cords	
Marking on Marking of Indicatorlig Inspection of Colours of Inspection o	the outside Controls hts and push buttons of the enclosure and protective cover of the connection to supply insulation of conductors in supply cables and cords of cord and cable anchorages	
Marking on Marking of Indicatorlig Inspection of Colours of inspection o	the outside Controls hts and push buttons of the enclosure and protective cover of the connection to supply insulation of conductors in supply cables and cords of cord and cable anchorages of the protection against ingress of liquids	
Marking on Marking of Indicatorlig Inspection of Colours of inspection o	the outside Controls this and push buttons of the enclosure and protective cover of the connection to supply insulation of conductors in supply cables and cords of cord and cable anchorages of the protection against ingress of liquids of the protection against mechanical hazards of fuse elements	
Marking on Marking of Indicatorlig Inspection of Colours of Inspection o	the outside Controls this and push buttons of the enclosure and protective cover of the connection to supply insulation of conductors in supply cables and cords of cord and cable anchorages of the protection against ingress of liquids of the protection against mechanical hazards of fuse elements	

<i>3</i> .	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
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:
	Savety tester
	Temperature meter
	Oxygen-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. 3. 3. 3. 3. 3. 3. 3. 3. 3. 3. 3. 3.	
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:	

Name of device:		
Type number:	Article number:	
Serial number:	FDA number:	
Manufacturer:	Country of manufacture:	
Supplier:	Date of installation:	
Power supply:	Class: Type:	
Hospital:	Ide	ntification number
Clinical ward:		
Accessory:		,
Accessory.		
77		
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Inspection C Instruc C Instruc C Instruc	of the accompanying documents ction guide (in local language) ction guide contains all information for proper operation ction guide contains the information concerning preventive inspection	
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Inspection C Instruction C Instruction C Instruction C Inspection Inspection Marking of	of the accompanying documents ction guide (in local language) ction guide contains all information for proper operation ction guide contains the information concerning preventive inspection enance and spareparts of the closed equipment of the case for damage on the outside	
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Inspection C Instruct C Instruct C Instruct C Instruct Mainte 2. Inspection Marking of Marking of Indicatorli Inspection Inspection	of the accompanying documents ction guide (in local language) ction guide contains all information for proper operation ction guide contains the information concerning preventive inspection chance and spareparts of the closed equipment of the case for damage on the outside of controls ghts and push buttons	
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Inspection C Instruct C Instruct C Instruct C Instruct Mainte 2. Inspection Marking of Marking of Indicatorli Inspection Colours of Inspection Inspection Inspection Inspection Inspection Inspection Inspection Inspection	of the accompanying documents ction guide (in local language) ction guide contains all information for proper operation ction guide contains the information concerning preventive inspection chance and spareparts of the closed equipment of the case for damage on the outside of controls ights and push buttons of the enclosure and protective cover of the connection to supply f insulation of condoctors in supply cables and cords	

3.	Inspection of the inside of the equipment (Not subject of periodical testing	gs)
•	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	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1
	Inspection of the creepage distances Inspection of mainparts, components and layout	
	inspection of maniparts, components and tayout	
4.	Electrical measurements	
	Resistance of the protective earth conductor	m Ω
	Earth leakage current S.F.C.	m A
	Enclosure leakage current S.F.C.	m A
	Patient leakage current S.F.C.	m A
	Patient auxiliary current	m A
	s.	
	•	
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	(2.00 mg/s) (2.00 mg/s) (3.00 mg/s)
	Measuring equipment:	
11 7	ithin the scope of above testings no fault has been located:	<u> स्थित्</u>
	unio de scope of above festings no fabil das debi located.	173.5 (2.1)

1.	e scope of above							
2.							hariti,	
3. ; 4. ;					erengennenie Est		a i	
5.							**********	
6.			,		19 ***********************************			
		F. '						
		. .						
assifica	ation of faults.:	Fault causes no hazards Fault may cause hazard		user or en	vironme	nt		
peratio	on of equipment equipment out o	Fault may cause hazard	s	user or en	vironme	nt		
peratio	on of equipment equipment out o	Fault may cause hazard is possible f operation is recommen	s	user or en	vironme	nt		
peratio	on of equipment equipment out o	Fault may cause hazard is possible f operation is recommen	s	user or en	vironme	nt		

Data of equipmen	nt	
Name of device:		
Type number:	Article number:	
Serial number:	FDA number:	
Manufacturer:	Country of manufacture:	
Supplier:	Date of installation:	
Power supply:	Class: Type:	
Hospital:	(2) 日本教育教育 (22) (1) (2) (2) (2) (4) (4) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4	Identification number
Clinical ward:		
Accessory:		
8.		
nspection and M	leasurement	Syringe pump
1. Accompan	ying documents	
Inspection o	f the accompanying documents	
_ ~	ion guide (in local language)	
_	ion guide contains all information for proper operation	
	ion guide contains the information concerning preventive	inspection
mainter	nance and spareparts	
2. Inspection	of the closed equipment	
Marking on	the outside	
Marking of		and reality
	hts and push buttons	
-	f the enclosure and protective cover	1 (1) (1) (1) (1) (1) (1) (1) (1) (1) (1
•	of the connection to supply	
	nsulation of conductors in supply cables and cords of cord and cable anchorages	
-	of the protection against ingress of liqids	
	of the protection against mechanical hazards	
_	of fuse elements	And Color
-	charge warning	
Technical a	larm	

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.

۰ ۵	
mΩ	
m A	4.
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 foolowing settings)

Ch1	Ch2	Ch3
		(1 y 6) (1 y 6)
		300

Preset		Mea	sured flo	wrate	
flowrate	Value	Ch1	Ch2	Ch3	
Min. flowrate					
or 1 ml/h		• ?	ارگيا ۽ ا	estop .	ml/h
Max. flowrate		21			
	man for	*5	The State	and the second s	ml/h

VΛ	easurement	of the	acclusion	dataction

Occlusion alarm

1			
 5 .		9	bar
 	1. 12.2	1.0	 ~

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

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

i kita	
	11 10° 6. 40 6. 55 - 66
38.50 F/S	1973
7. S.	

Measuring equipment	t :	
Vithin the scope of above	e testings no faults have been located:	
Vithin the scope of above	e testings the following faults have been located:	
1. 2. 3. 4. 5. 6.		
lassification of faults.:	Fault causes no hazards for patient, user or environment Fault may cause hazards	
Operation of equipment outting the equipment of the equipment of the equipment of the equipment.	out of operation is recommended	
Pate:	Testing engineer:	

Data of equipmen	<u>it</u>	
Name of device:		
Type number:	Article number:	
Serial number:	FDA number:	
Manufacturer:	Country of manufacture:	
Supplier:	Date of installation:	
Power supply:	Class: Type:	
Hospital:	Ide	ntification number
Clinical ward:		
Accessory:		
•		
L		
Inspection and M	easurement .	Respirator
1. Accompan	ying documents	
	f the accompanying documents	
_	on guide (in local language)	
	on guide contains all information for proper operation	
	ion guide contains the information concerning preventive inspection	
mamten	ance and spareparts	
2. Inspection	of the closed equipment	
No. of Control of	de esta de	F10.0710.27
Marking on Marking of o		
_	its and push buttons	
_	f the enclosure and protective cover	
-	f the colours of the gas supply tubes	
-	f the connectors of the gas supply tubes (non - interchangeable)	
	f the connection to mains supply	
	nsulation of conductors in supply cables and cords	
-	f cord and cable anchorages	
	f the protection against ingress of liquids	
	f the protection against mechanical hazards	
Inspection o	f 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

2.1.1		
	m	Ω
	m	A
	m	A
	m	A
	m	A

5. Functional Tests (according to the instruction guide)

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



Savety tester	
Test lung	
Oxigen meter	

1.			
2.			
3.			agamatan
4. 5.			
6.			* 6 (6) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1
lassifi	ication of faults.:	Fault causes no hazards for patient, user or invironment Fault may cause hazards	
lassifi	ication of faults.:		
perat utting	د. tion of the equipm g the equipment ou	Fault may cause hazards	

Name of device:						
Type number:	Article number:	1. A STATE OF THE				
Serial number:	FDA number:					
Manufacturer:	Country of manufacture:	**************************************				
Supplier:	Date of installation:					
Power supply:	Class: Type:					
Hospital:	Identification i	numher				
Clinical ward:		iluliibei				
minoai waru.						
Accessory:						
4.						
Inspection of	f the accompanying documents					
C Instructi C Instructi C Instructi	f the accompanying documents on guide (in local language) on guide according to the Particular requirements on guide contains the information concerning preventive inspection					
C Instructi C Instructi C Instructi mainten	f the accompanying documents on guide (in local language) on guide according to the Particular requirements					
C Instructi C Instructi C Instructi mainten C Inspection Marking on the Marking of the Inspection of Inspection of Colours of Colo	on guide (in local language) on guide according to the Particular requirements on guide contains the information concerning preventive inspection ance and spareparts of the closed equipment the outside					
C Instructi C Instructi C Instructi mainten C Inspection Marking on the Marking of the Indicatorligh Inspection of Colours of in Inspection of	f the accompanying documents on guide (in local language) on guide according to the Particular requirements on guide contains the information concerning preventive inspection ance and spareparts of the closed equipment the outside controls ts and push buttons of the enclosure and protective cover of the connection to mains supply assulation of conductors in supply cables and cords	25)				

Inspecti Inspecti Inspecti Inspecti Inspecti Inspecti Inspecti		ch. protection, insulation) ductor / earth terminal				
4. Electri	cal measurements					
Resistan	ice of the protective earth con	ductor	m Ω			
Earth le	Earth leakage current S.F.C.					
Enclosu	re leakage current S.F.C.		m A			
5. Functio	onal Tests (according to	the instruction guide)				
Temper	ature of the water reservoir af	fter a 12 times discharge	°C			
Test of	Test of the over temperature protection device					
Measure	Measurement of the overpressure protection device					
Measure	ement of the termal insulation	•	557			
Verifyir	ng of the operating cycle cond	litions (according Table 1 of the Part. requirements)				
	Savety tester					
	Temperature meter		,			
	Pressure meter					
Within the s	cope of above testings no fau	lts have been realized:				
Within the s	cope of above testings the fol	llowing faults have been realized:				
1.			and the state of t			
2.			La Land Tag			
3.						
4.	Section of the sectio					
5. [

Classification of faults.:	Fault causes no hazards for patie Fault may cause hazards	nt, user or invironment	3
Operation of the equipm Putting the equipment of Operation of the equipment	it of operation is recommended		
Date:		Testing engineer:	