# Form B03





Quantum Medical Solutions sdn bhd transcending boundaries, transforming life

Format Ref: - QMS/TSD-022 Rev.01

Work Order No.	PWO371612	Schedule Month	June 2018						
Work Order Date	01/06/2018	Completed Date	13-06-2018						
Clinic Name	Klinik Kesihatan Pesta / Kampung Ken	Clinic Code	JHR015						
BE No.	JHNMOP051	Distict	BATU PAHAT						
BE Category	Monitoring Systems, Physiologic	WO Assigned to	MUHD SHADRUL.						
Ownership	Existing Equipment	Purchase	New						
BE Condition	✓ Active	BER Proposed							
Work Order Type	✓ Preventive Maintenance (PM)	Third Party Calibration (TPC)							
Work Order Type	Routine Inspection (RI)	Statutory Certification (SC)							
Reschedule Date									
BE Third Party Calibration / Statutory Certification Details									
Company Name	NA -	Cal / Cert Date	ND /						
Contact Number		Cal / Cert Expiry Date							
Corrective	b done as per checklist. Unit tested functioning go  Maintenance / Breakdown  r Availability: Yes / NA	od & ready to use.  Manufacturer :  Modal :  Serial No :							
Schedule Maintenan	ce Execution Details								
SI No	QMS Engineer / Technician Name	Date	Start Time End Time						
	MUHD SHADRUL.	13-08-7018	3 12:02 16:02						
	6								
		х							
Customer Remarks									
NA.									
Engineer / Technician S Name Date	Signature 13/06/2018	Customer Signature  Name  Nur Hazirah Nece Abdullah  (No. Pendararan Penuh: 54451)  ururawat U29  KK kg. Kajangan Dato Onn  Seal							
	MM MEDICAL SOLUTION D SHAZRUL BIN MOHD SAMSURI OMEDICAL TECHNICIAN	Seal	( 4 7						

First Verification

QMS Circle Incharge

RAZILA MISKAN
Biomedical Engineer (Circle In-Charge)
Quantum Medical Solutions Sdn. Bhd.

Final Verification QMS State Incharge

Miller of Augusti Stable as say such



# KEMENTERIAN KESIHATAN MALAYSIA

MEET Planned Preventive Maintenance Checklist Monitoring Systems, Physiologic BE CODE: 12-636

CHECKLIST NO: CL-101-000 REV.000

PAR	T 1 ASSET DET	TAILS														
WOR	K ORDER NO	<b>&gt;</b>	bma 3	7161	<b>J</b> ·							ASSET NO	•	THNWOL	2 05	51
MANU	JFACTURER	<b>&gt;</b>	Mindr	29								MODEL	<b>&gt;</b>	ipm 10	)	
FREQ	UENCY	•	3 MONTH	ILY (	) 6	MON	ITHL	Y ( )		12 MONTHLY	( √ )	PPM HOURS	<b>&gt;</b>	1.00		
PAR	T 2 SPECIAL P	RECA	UTION		XI											
If there	If there is evidence of body fluid contamination, submit the device for cleaning and decontamination before inspecting it.															
Wear appropriate Personnel Protection Equipment (PPE) during work.																
Wear	Wear grounded electrostatic wristband when handling PCB or electronic components.															
Refer to the safety procedure for additional precautions and guidance as per manufacturer guidelines.																
Make sure the test equipment used are duly calibrated.																
LVI W	T 3 TEST APPA	700	S													
Tick (	√) where appropi	riate				60.000					F100	SECURITION BOARS				
NC	NO ASSET NO				DESCRIPTION						SERIAL NO			CALIBRATION DUE ON		
1	TEFSA			ELECTR	ICAL SAF	ETY	ANAL	YZER			3226908			(0/11/2018		
2	TEESA	810	574	PATIENT SIMULATOR						10/1	2/20	18 8				
3	TEESA	013	36	OXYGEN SATURATION/PULSE RATESIMULATOR				MULATOR	3233028		10/15/18.		18.			
4	TEESA	018	16	NIBP AN	ALYZER						323	3078		10 1:	2/201	18
PAR	T 4 QUALITATI	VE TA	SKS	10170	11977					14223						
Tick (	√) where approp	riate			PASS	FA	П	NA						PASS F	AIL	NA
										F:W: / O	corono apres	L all		()	\ /	
	Chassis - verify poleanliness and o				(//)	(	)	(	8	Fittings/Connec		кап		( / ) (	) (	
	Mount/ Fasteners ntegrity	s - verif	y physical		(/)	(	)	(	9	Controls/Switco operation of co		proper		(/) (	) (	)
3 (	Cables - verify in	tegrity			( /	(	)	(	10	Indicators/ Dis operation	plays - verify	illumination and		( / ) (	) (	)
4 <i>A</i>	AC Plug - verify i	ntegrity	′		(/)	(	)	(	) 11	Alarms - verify automatic activ		ation and		<b>(</b> /) (	) (	)
	Power Cord - ver ntegrity	ify prop	oer insulati	on and	(/)	(	)	(	) 12	Cuff & hose - v		tivity and		(/) (	) (	)
	Strain Relief - ve	-500	ysical integ	grity at	( /)	(	)	(	) 13	ECG cable - vi				( / ) (	) (	)
6	Circuit Breaker/ F external circuit br external fuse				(/)	(	)	(	) 14	SPO² probe - sand condition	verify proper	operation		(/)(	) (	)
PART 5 PREVENTIVE MAINTENANCE TASKS																
Tick (	√) where approp	riate														
					DONE	DOI 100		NA								
	Clean the exterio equipment	r and i	nterior of th	ne .	( / )	(	)	(	)							
2 1	Battery - check/ r	eplace	***		(/)	(	)	(	) No	**If you h		defined as NOT A				



13-06-2018

DATE:

#### KEMENTERIAN KESIHATAN MALAYSIA

MEET Planned Preventive Maintenance Checklist Monitoring Systems, Physiologic

BE CODE : 12-636

CHECKLIST NO: CL-101-000 REV.000

WORK ORDER NO ▶ PART 6 QUANTITATIVE TASKS Tick ( $\sqrt{}$ ) where appropriate Units / Set Measured Limit/Tolerance PASS FAIL NA Description UOM Values Values (/) ( ) ( ) NIBP Pressure (Systolic/Diastolic) 20 75-85 1 mmHg 50 45 - 55 (/) ( 50 ) ( 120 115 - 125 (/) ( ) ( ) mmHg 70 (**/**) ( ) ( ) 65 - 75 70 200 (/) ( 200 195 - 205 ) ( mmHg 150 (/) ( 145 - 155 150 ) ( ) bpm 29 - 31 (/) ( ) ( ) Heart Rate Accuracy bpm 60 (/) ( ) ( ) 59 - 61 mad 120 118 - 122 ) ( ) 120 (/) ( 80 78 - 82 SpO2 Accuracy % 80 (/) ( ) ( ) 90 88 - 92 (/) ( ) ( ) 98 96 - 100 % (/) ( ) ( ) PART 7 ELECTRICAL SAFETY TEST ELECTRICAL SAFETY TEST, (attach report) Tick ( $\sqrt{\ }$ ) where appropriate Standard use : Result: IEC 62353 PASS ☐ IEC 61010 ☐ FAIL □ NA ☐ IEC 60601 PART 8 NOTES MA FUNCTIONING NOT FUNCTIONING CORRECTIVE MAINTENANCE REQUIRED NEXT PPM DATE - JUNE 19 WORK ORDER NO ▶\_ PPM has been performed in accordance to the checklist and the equipment is functioning to the intended purpose. COMPLETED BY: MUHO SHADRUL .

### Test Setup

#### **DUT** Information

Operator ID:

Equipment Number: JHNMOP051

Calibration Tech:

DINA

Serial Number:

Calibration Date:

9/10/2017

Manufacturer:

**MINDRAY** 

Firmware Version: Serial Number:

2.08.01

Model:

iPM10

3226906

Location:

KK PESTA

Date & Time:

06/13/2018 & 15:10

Other:

JOB Name:

## Template Information

Template Name:

JHNMOP051

Standard:

IEC60601-1-2nd Ed

Pause after Power ON: NO

Pause before Power O NO

Power ON delay:

2

Power OFF delay:

0

Test Speed:

Test Mode:

AUTO

Halt on Test Failure:

**NORMAL** YES

Multi PE Test:

NO

Include Time:

YES

Multi Resstore:

WORST/LAST

Insulation Resistance \ 500V

Reverse Polarity:

Multi Enclosure Test: NO

Classification:

YES

### PLC Configuration-Applied part setup

AP Name AP Type

AP Num

#### **ESA615 Test Results**

Test Name	Value	High Limits Low Li	mits Status		
Protective Earth Resistance	0.591 Ohr	r 0.2 -	F		
Insulation Resistance			Р		
Mains to Protective Earth	999 MOhr	1	Р		
Mains to Non-Earth Accessible Conductive Par	999 MOhr	1	Р		
Mains Voltage			Р		
Live to Neutral	248.0 V	- :-	Р		
Neutral to Earth	1.8 V		Р		
Live to Earth	247.5 V		Р		
Equipment Current	0.0 A	<u>.</u>	Р		
Earth Leakage Current			Р		
Normal Condition	15.1 uA-O	1 500 -	Р		
Open Neutral	29.4 uA-O	1000 -	Р		
Open Neutral- Reversed Mains	29.6 uA-O	1000 -	Р		
Normal Condition- Reversed Mains	15.1 uA-O	500 -	Р		
Enclosure Leakage Current P					

Normal Condition	0.1 uA-OP	100 -	Р
Open Earth	15.1 uA-Ol	500 -	Р
Open Neutral	0.1 uA-OPI	500 -	Р
Open Neutral- Reversed Mains	0.2 uA-OPI	500 -	Р
Normal Condition- Reversed Mains	0.1 uA-OPI	100 -	Р
Open Farth- Reversed Mains	15.3 uA-OI	500 -	Р

Signature

