MANAGING MEDICAL DEVICE SAFETY & QUALITY

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www.bme.boun.edu.tr

EU-MDD
EU-MDR

are intended to harmonise the laws relating to medical devices within the European Union. Regulation (EU) 2017/745 is a regulation of the European Union on the clinical investigation and sale of medical devices for human use.

TİTCK

Regulating medicinal products and medical devices for human use.

TÜRKAK

Turkish Accreditation Agency.
Deals with ISO 9001 and ISO 14001 Management System Certificates
Test Reports, Calibration Certificates
Inspection Reports

FDA

The United States **Food and Drug Administration** (**FDA** or **US FDA**) is a federal agency of the Department of Health and Human Services.

TSE
TÜRK STANDARDLARI ENSTİTÜSÜ

The Institute of Turkish Standards is a public standards organization whose mission is to increase the competitiveness of Turkey, facilitating trade on national and international levels and develop society's standard of living by providing standardization and conformity assessment in diverse fields.

ISO 17025 : The quality management standard, implemented to standardize the technical requirements and requirements of management system, intended for research laboratories.

It defines a set of rules and criteria for studies that are planned, performed and monitored in production or research, and their results are recorded, reported and archived. It is possible to trace the course of the study or its complete reconstruction.

ISO 13485: The regulatory requirements are intended to ensure that manufacturers consistently design, produce and place onto the market medical devices that are safe and fit for their intended purpose.

ISO 9001 is a **globally recognized standard for quality management**. It helps organizations of all sizes and sectors to improve their performance, meet customer expectations and demonstrate their commitment to quality. Its requirements define how to establish, implement, maintain, and continually improve a quality management system (QMS).

Objective

Low Risk

- Patient Risks
- User Risks
- Insurance Risks
- Hospital Risks

Effective Usage

- Correct Diagnosis
- Fast Treatment

Profit

- High Yield
- Low Cost

Method

Medical Device Calibration

- Instrument Tune up
- Maintenance

(MDD : “Notified Body”)

Medical Device Calibration Validation

- Calibration Validation
- Performance Measurement

Satandards
Recommendatations
Traceability

Model 1

EU-MDD
EU-MDR

HOSPITAL

- QA
- ISO9001
- ISO17025

Device Manufacturer Dealer

- Calibration

TİTCK

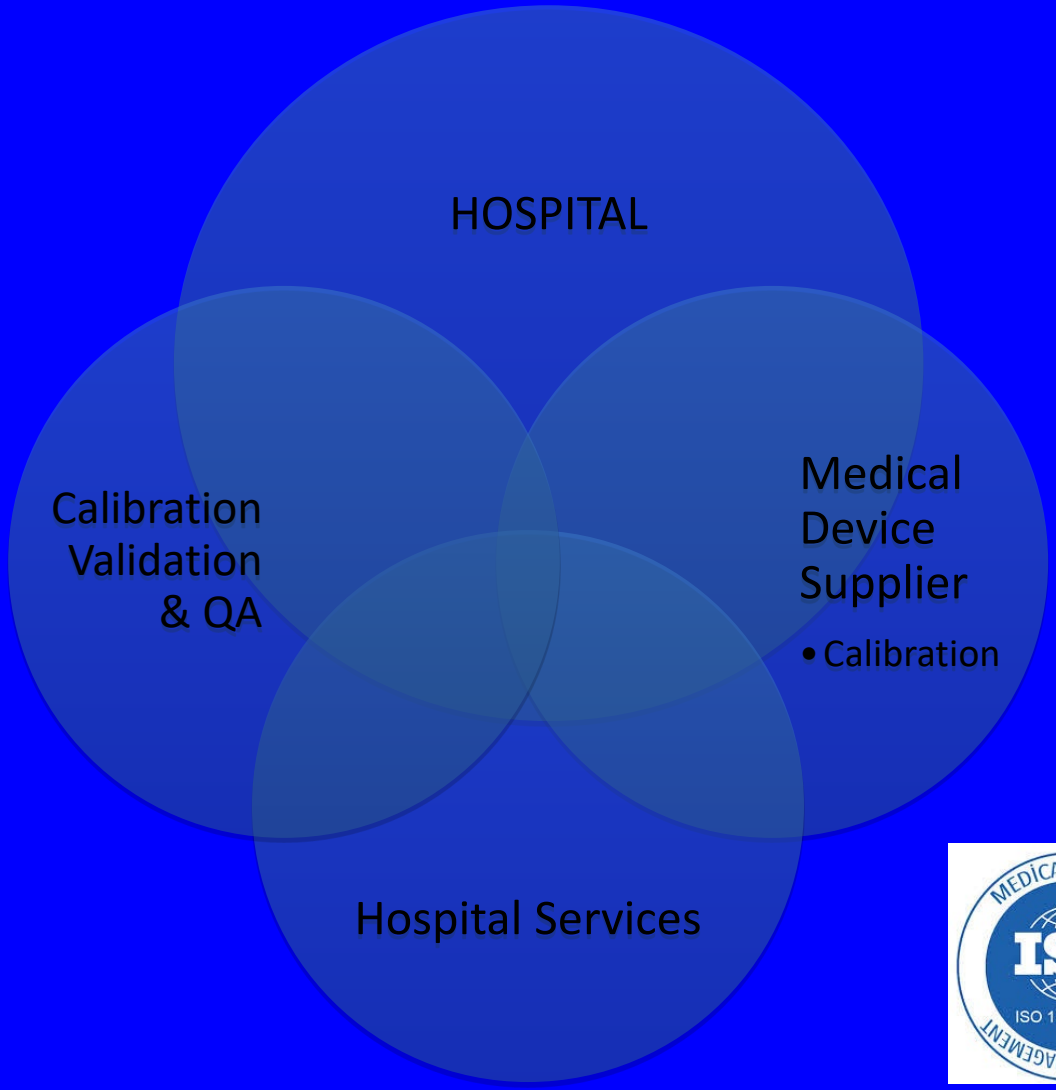
TÜRKAK

FDA

TSE
TÜRK STANDARDLARI ENSTİTÜSÜ

Model 2 (Ideal)

EU-MDD
EU-MDR



Quality Accreditation

Accreditation of healthcare facilities , improve the quality of patient care; assisting international health care organizations, public health agencies, health ministries, and others in evaluating, improving, and demonstrating the quality of patient care; and enhancing patient safety.

Joint Commission International

THE JOINT COMMISSION
NATIONAL QUALITY APPROVAL

ACCREDITATION CANADA

DNV
US Centers for Medicare & Medicaid Services
ACCREDITED
Hospital
Quality & Patient Safety

TÜV SÜD

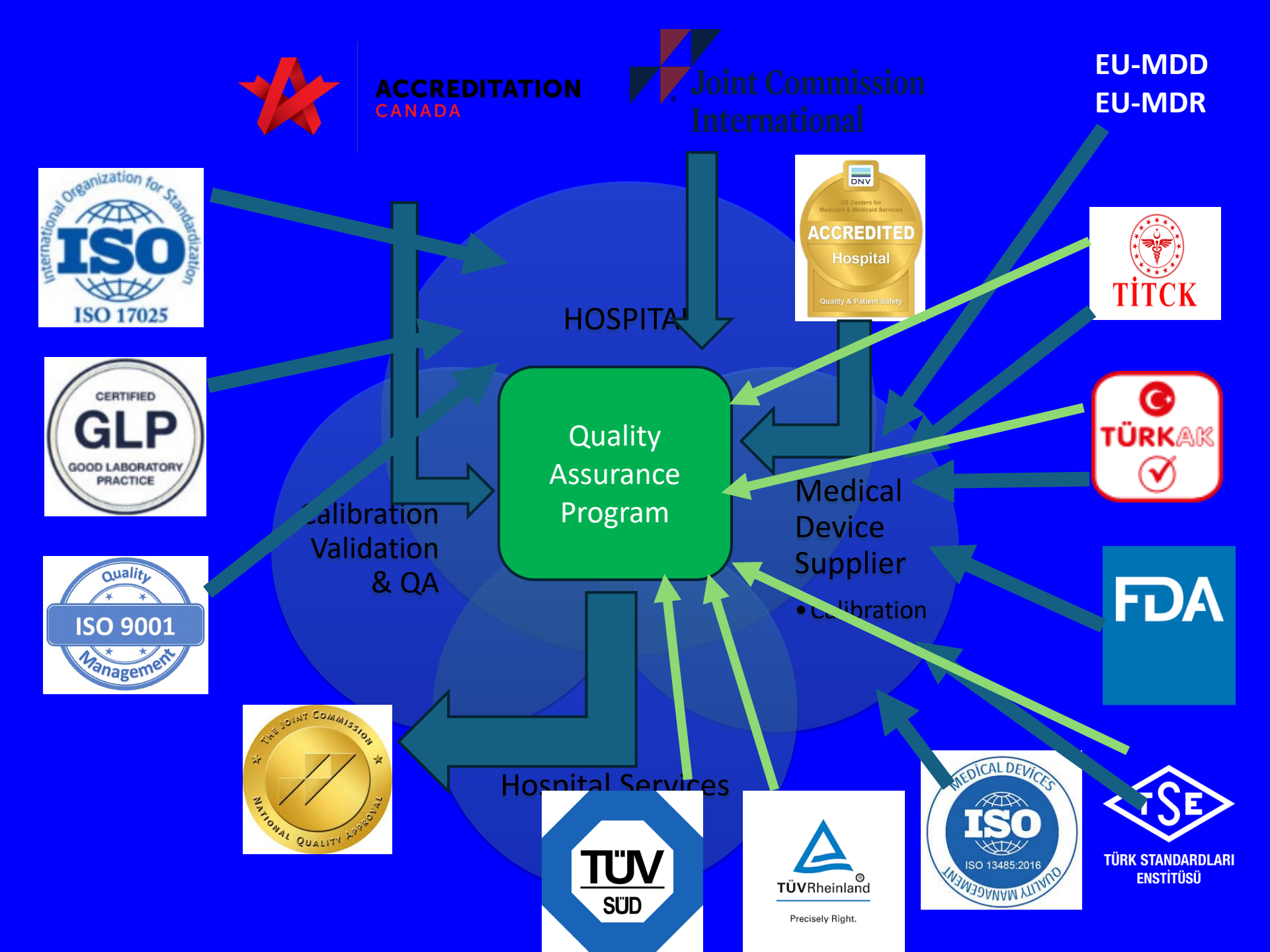
TÜVRheinland
Precisely Right.

TSE
TÜRK STANDARDLARI ENSTİTÜSÜ

TÜRKAK

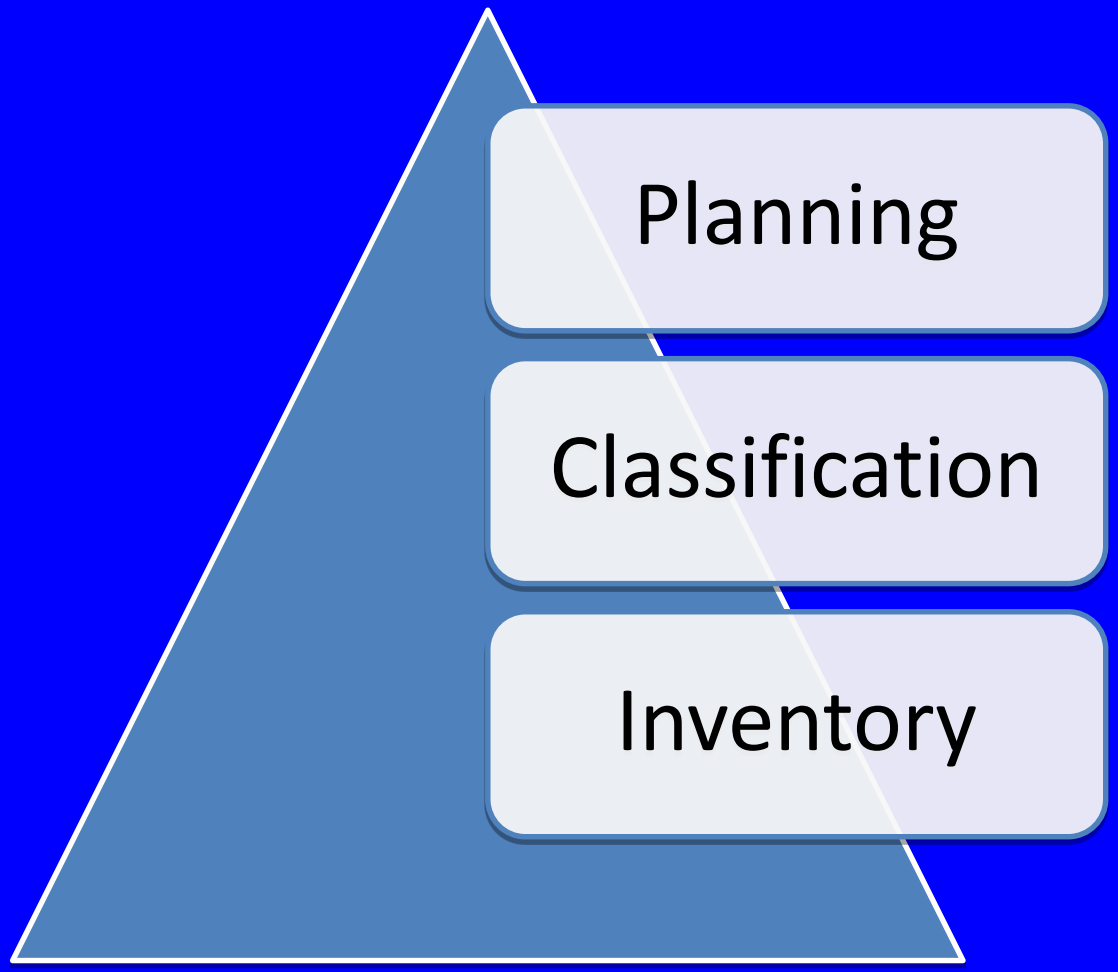
TİTCK

PATIENT SAFETY & QUALITY OF CARE
NABH
(ENTRY LEVEL)
PRE ACCREDITED


ACCREDITATION CANADA
Joint Commission International
EU-MDD
EU-MDR
ISO 17025
CERTIFIED GLP GOOD LABORATORY PRACTICE
ISO 9001 Quality Management
THE JOINT COMMISSION NATIONAL QUALITY APPROVAL
DNV US Centers for Medicare & Medicaid Services ACCREDITED Hospital Quality & Patient Safety
TİTCK
TÜRKAK
FDA
MEDICAL DEVICES ISO ISO 13485:2016 QUALITY MANAGEMENT
TSE TÜRK STANDARDLARI ENSTİTÜSÜ
TÜV SÜD
TÜVRheinland Precisely Right.
HOSPITAL
Quality Assurance Program
alibration Validation & QA
Medical Device Supplier
• Calibration
Hospital Services

Medical Device Quality Assurance Program

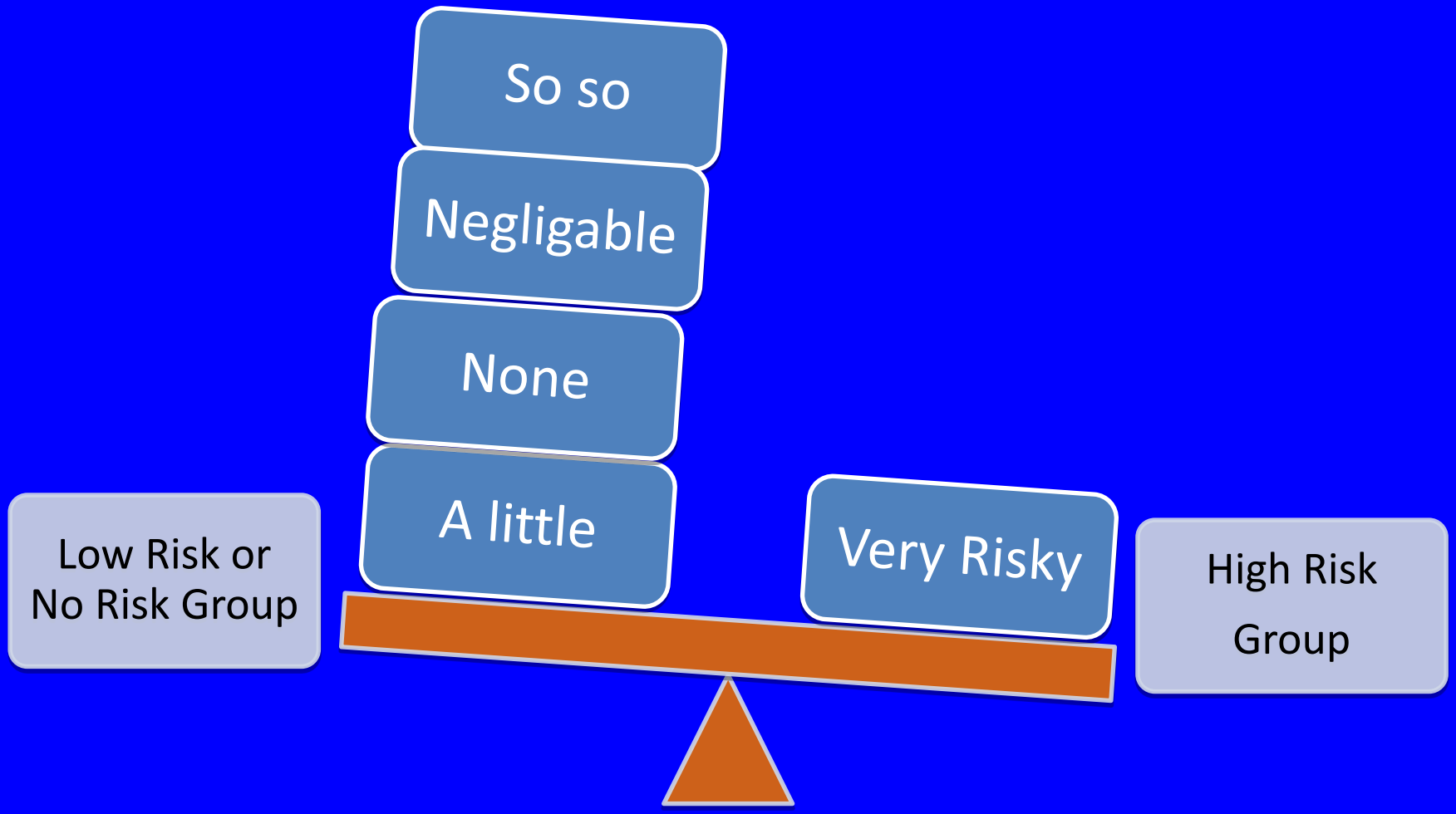
METHOD



Inventory (LIL)

Localtion	• Building, Service, Room, Lab, OR, ER, Mobile, etc.
Identity	• Device Name, Manufacturer, Model, Serial No, BMID No
Label	• UMDNS, GMDNS • Barcode Labeling, BMID No, Calibration Status

RISK CLASSIFICATION



High-Risk Medical Devices (ECRI)

https://home.ecri.org/blogs/ecri-blog

- Anaesthesia Devices and Vaporizers,
- Anesthesia Ventilators,
- Neonatal Apnea Monitors,
- Emergency and endotracheal aspirators,
- Autotransfusion Units, Defibrillators, Diagnostic Radiology Devices,
- Nuclear Medicine Devices Electrocauteries, Fetal Monitors, Heart-lung bypass units, Hemodialysis units, Moisturizers Hypo and Hyperthermia devices, Incubators, Infusion pumps, Intra-aortic balloon pumps,
- Surgical lasers,
- Pulse oximetry,
- Oxygen monitors and analyzers,
- Pacemakers,
- Peritoneal Dialysis units,
- Phaco emulsification units,
- Physiological (bedside) monitors,
- Baby warmers,
- Radiographic contrast dye injectors,
- Cardiac resuscitators,
- Pulmonary resuscitators,
- EtO, steam sterilizers,
- Tracheal suction regulators,
- Pneumatic turnstiles,
- Oxygen and Carbon dioxide monitors,
- Ventilators, etc.
- .
- . (Life-Saving Devices)

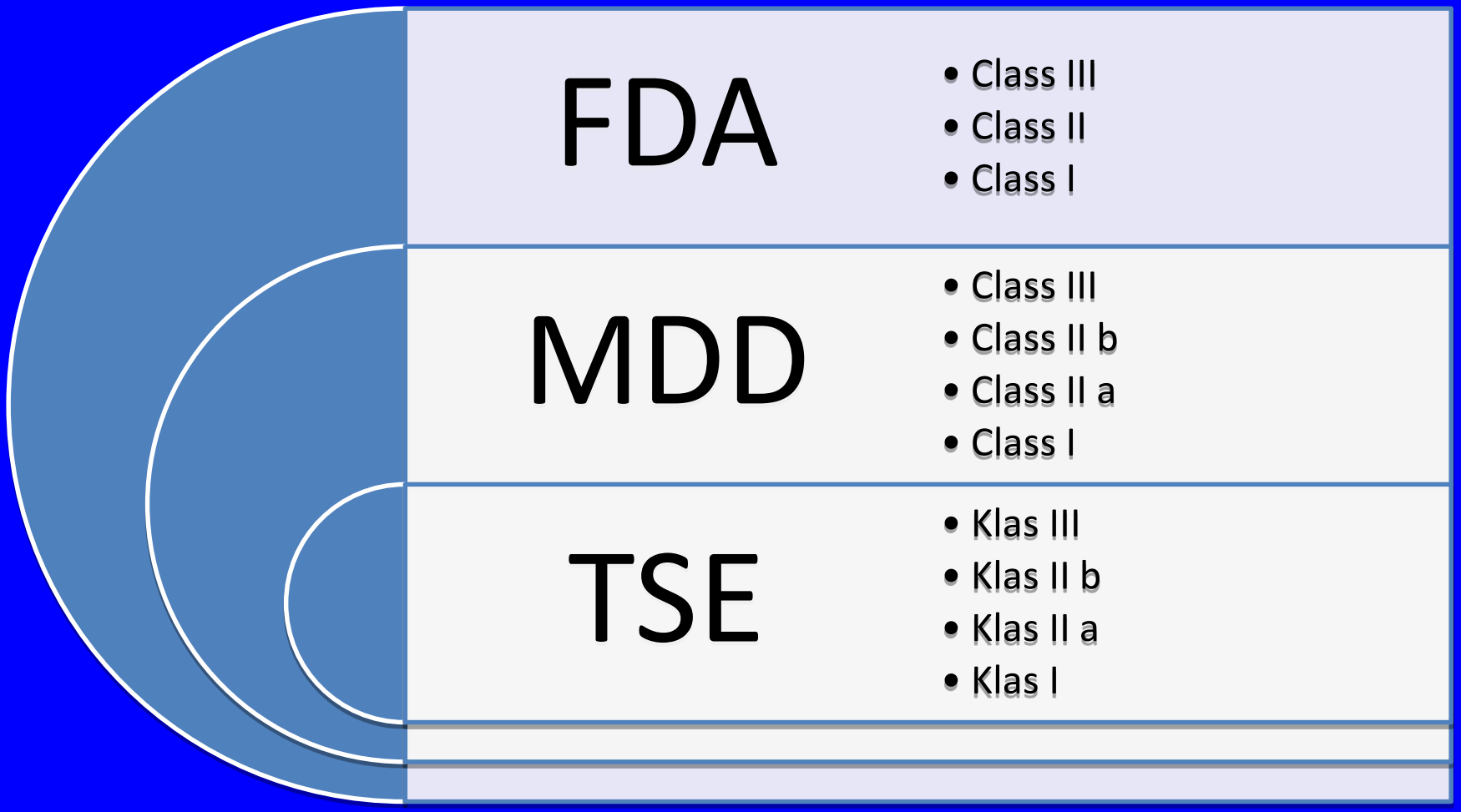
Medium Risk Medical Devices(ECRI)

- Portable ECG recorders,
- Aspirators
- Blood bank refrigerators,
- Blood gases and pH analyzers,
- Noninvasive blood pressure monitors,
- Blood heaters,
- Kapnogfars,
- Units that measure cardiac output,
- Centrifuges Clinical laboratory equipment,
- Cryosurgery devices,
- ECG devices,
- Electroconvulsive therapy devices,
- Electromyography devices,
- Endoscopy devices,
- Evoked potentials measuring devices,
- Lithotripsy devices,
- Oxygen-air mixers,
- Phonocardiography devices,
- Phototherapy devices,
- Pressure transducers,
- Lung function analyzers,
- Dedents (air, oxygen, vacuum) Weighing devices (for hemodialysis and neonatal services)
- Laser smoke exhaust systems,
- Special care beds
- Surgical drills and saws,
- Body temperature monitors
- Traction units (physical therapy) Tredmil,
- Ultrasonic imaging systems,
- Vectorcardiography devices, etc.

Low-Risk Medical Devices(ECRI)

- Diathermy devices,
- Patient beds with electric motors,
- Aspirators (low volume) Recirculating fluid pumps,
- Electronic scales,
- Patient examination lights,
- Fiberoptic light sources,
- Isolated electrical power distribution systems,
- Paraffin baths,
- Pumps (chest) Sphygmomanometer,
- Stimulators (physical therapy),
- Surgical lamps,
- Surgical microscopes,
- Operating tables,
- Ultrasonic humidifiers,
- Ultrasonic physical therapy devices,
- Gypsum cutters, etc.

Other Classifications



Classification made by the Healthcare Facility:

The the frequency of calibration measurement and whether a device will be included in the calibration measurement program are decided based on:

- Feature and Function,
- Clinical Applications
- Importance of Preventative Maintenance
- Calibration Risks of use,
- Considering the past Accidents and Cases.

Device Management Coefficient

Medical devices with a Device Management Coefficient of 12 or more are included in the Quality Maintenance and Calibration Measurement program.

Device Function Score (10)

Device Risk Score (5)

+ Preventative Maintanance Need Score(5)

Device Management Coefficient (20)

The Joint Commission Plant, Technology&Safety Management series, 1989, "Clinical Equipment Management", L. Fennigkoh and B. Smith.

Device Description and Function (50% weighted)

Score	Description
10	Life Savers
9	For Surgical and Intensive Care Purposes
8	Physical Therapy
7	Surgery and Patient Monitoring
6	Other Physiological Monitors
5	Analytical Laboratory
4	Laboratory Instruments and Supplies
3	Computers
2	Belonging to the patient (registered in the hospital inventory)
1	Other

Clinical Applications and Risks (25% Weighted)

Points	Risks:
5	Death of the Patient
4	Injury to Patient or User
3	Incorrect Treatment / Misdiagnosis
2	Delays/Disruptions in Diagnosis and Treatment
1	The Risks Don't Matter

Necessity of Preventive Maintenance and Calibration Measurements (25% Weighted)

5	**Very Important**	6
	(Pneumatic, mechanical, fluid-containing systems, Hemodialysis, Intra aortic Balloon Pump, etc.)	
4	**Moderately Important**	6
	(Infusion Pumps, Monitors, etc.)	
3	.....	6
2	.....	12
1	**Minimally Important**	12
	(Refractometer, Light Sources, Bain-Marie Bath,..)	

Examples of Medical Devices

Device	Function	Risks	Importance of Pr Maintenance	Sum	P.Maintenance Frequency
ECG Recorder					
X-Ray Machine					
.....					
.....					
.....					
.....					
.....					
.....					
Bedside Monitor					
Ventilator Device					
Infusion Pump					
Centrifuge Device					

Examples of Medical Devices

Device	Function	Risks	Importance of Pr Maintenance	Sum	P.Maintenance Frequency
ECG Recorder	6				
X-Ray Machine	7				
.....	6				
.....	10				
.....	10				
.....	10				
.....	8				
.....	10				
Bedside Monitor	7				
Ventilator Device	10				
Infusion Pump	9				
Centrifuge Device	4				

Examples of Medical Devices

Device	Function	Risks	Importance of Pr Maintenance	Sum	P.Maintenance Frequency
ECG Recorder	6	3			
X-Ray Machine	7	4			
.....	6	3			
.....	10	5			
.....	10	5			
.....	10	5			
.....	8	4			
.....	10	5			
Bedside Monitor	7	3			
Ventilator Device	10	5			
Infusion Pump	9	3			
Centrifuge Device	4	3			

Examples of Medical Devices

Device	Function	Risks	Importance of Pr Maintenance	Sum	P.Maintenance Frequency
ECG Recorder	6	3			
X-Ray Machine	7	4			
.....	6	3			
.....	10	5			
.....	10	5			
.....	10	5			
.....	8	4			
.....	10	5			
Bedside Monitor	7	3			
Ventilator Device	10	5			
Infusion Pump	9	3			
Centrifuge Device	4	3			

Examples of Medical Devices

Device	Function	Risks	Importance of Pr Maintenance	Sum	P.Maintenance Frequency
ECG Recorder	6	3	4		
X-Ray Machine	7	4	3		
.....	6	3	3		
.....	10	5	4		
.....	10	5	5		
.....	10	5	4		
.....	8	4	4		
.....	10	5	4		
Bedside Monitor	7	3	3		
Ventilator Device	10	5	5		
Infusion Pump	9	3	2		
Centrifuge Device	4	3	5		

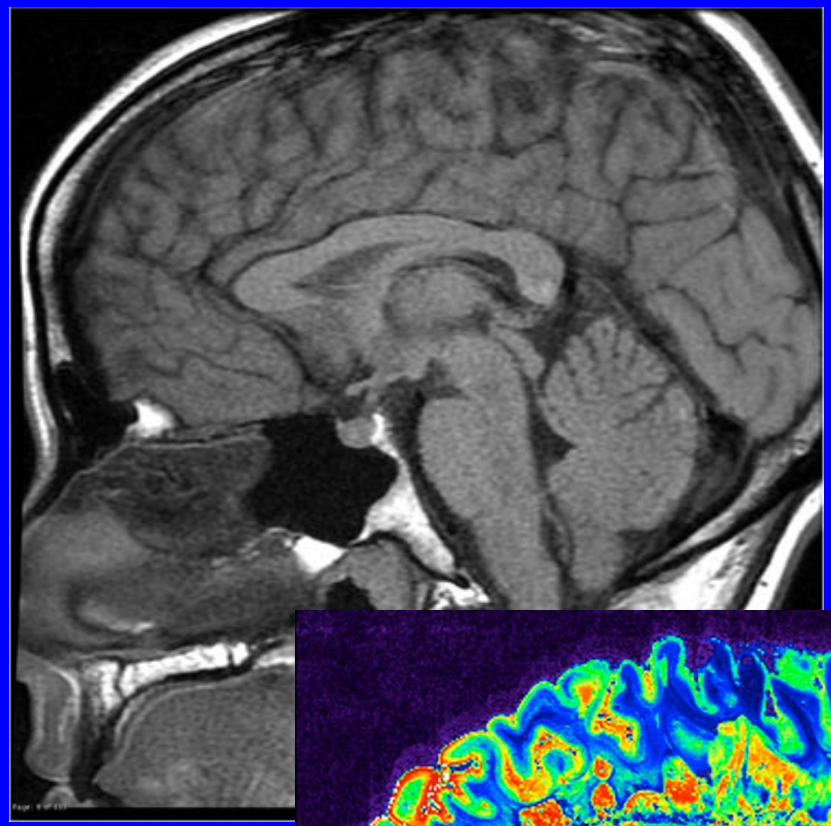
Examples of Medical Devices

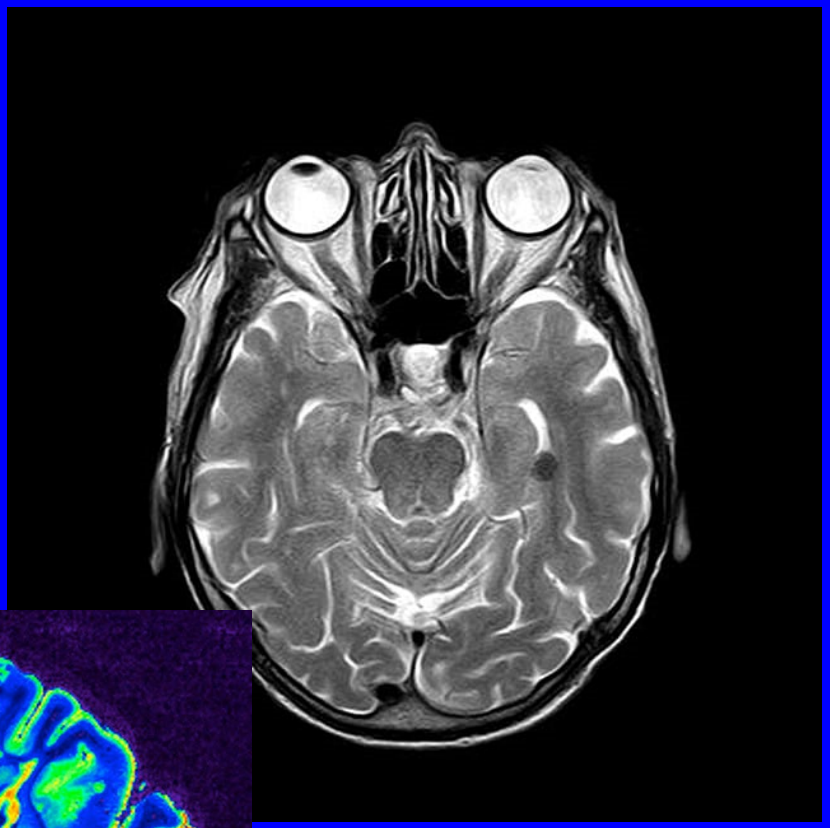
Device	Function	Risks	Importance of Pr Maintenance	Sum	P.Maintenance Frequency
ECG Recorder	6	3	4	13	
X-Ray Machine	7	4	3	14	
.....	6	3	3	12	
.....	10	5	4	19	
.....	10	5	5	20	
.....	10	5	4	19	
.....	8	4	4	16	
.....	10	5	4	19	
Bedside Monitor	7	3	3	13	
Ventilator Device	10	5	5	20	
Infusion Pump	9	3	2	14	
Centrifuge Device	4	3	5	12	

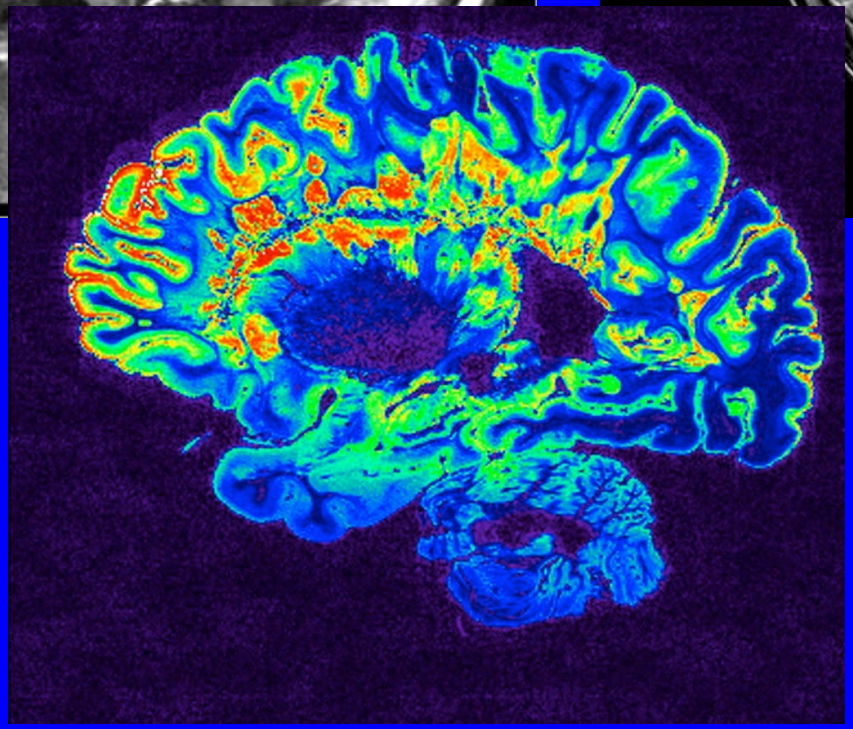
Examples of Medical Devices

Device	Function	Risks	Importance of Pr Maintenance	Sum	P.Maintenance Frequency
ECG Recorder	6	3	4	**13**	6 mnt
X-Ray Machine	7	4	3	**14**	12 mnt
.....	6	3	3	**12**	12 mnt
.....	10	5	4	**19**	6 mnt
.....	10	5	5	**20**	6 mnt
.....	10	5	4	**19**	6 mnt
.....	8	4	4	**16**	6 mnt
.....	10	5	4	**19**	6 mnt
Bedside Monitor	7	3	3	**13**	12 mnt
Ventilator Device	10	5	5	**20**	6 mnt
Infusion Pump	9	3	2	**14**	12 mnt
Centrifuge Device	4	3	5	**12**	6 mnt

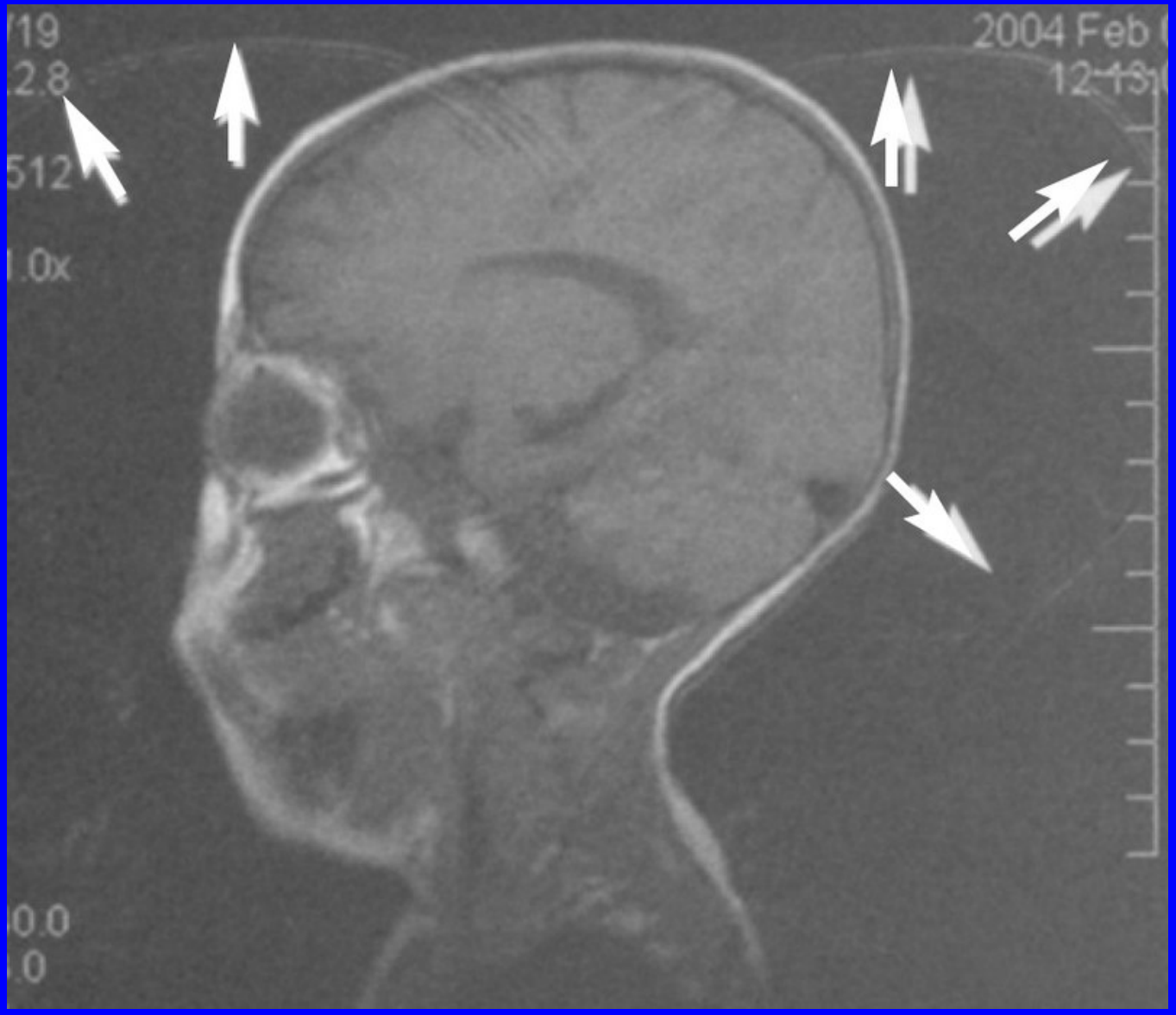
Ex1: Magnetic Resonance Imaging







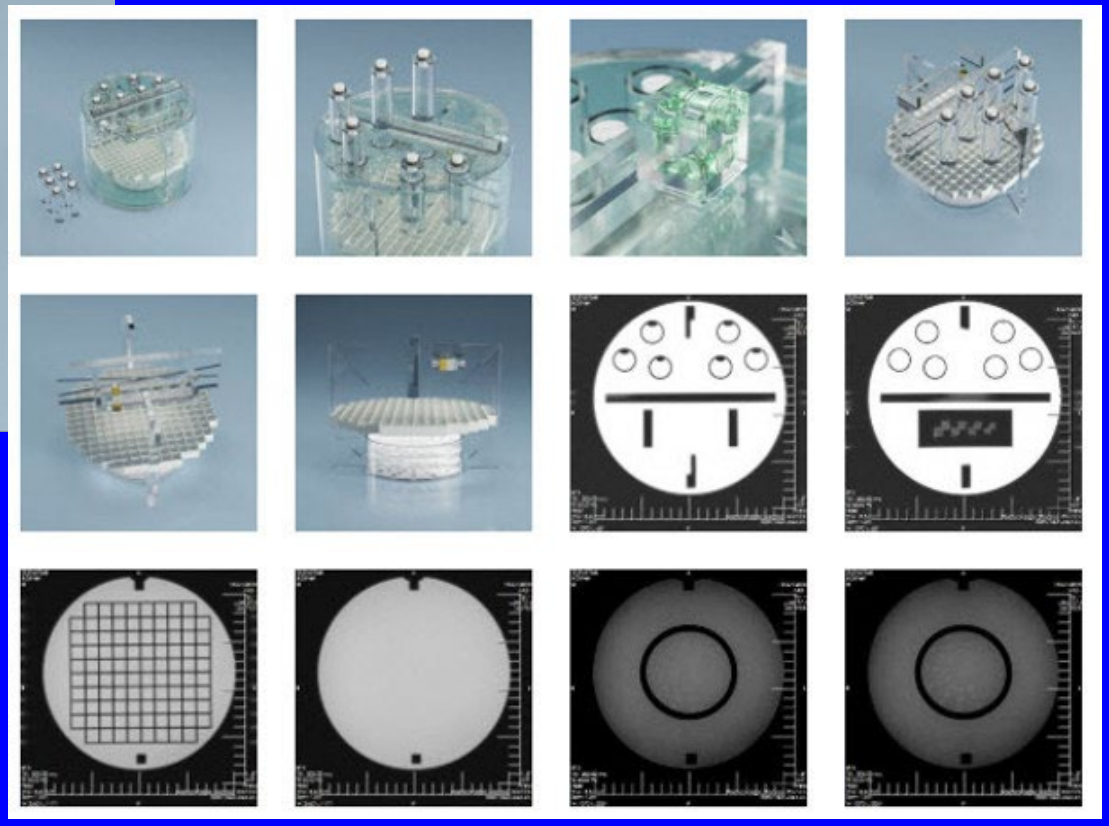
MRI Artifacts: GIBBS



Non Invasive Measurements

Phantoms

https://cspmedical.com/pro-mri-phantom/



Quality Sequences

Calc_Artifacts 2011-12-14 12:12:59

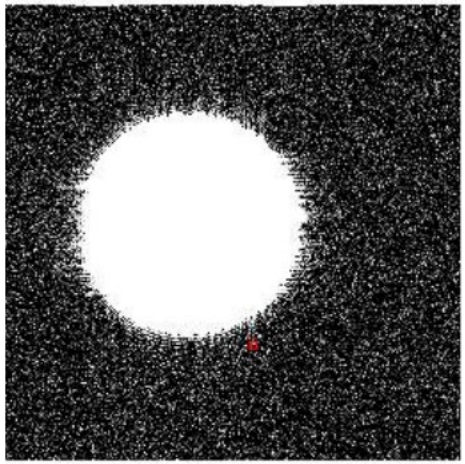
Log-File

Performing Sagittal artifacts measurement.

Image: Orientation Sagittal, 1. Echo

Image: file:/C:/MedCom/service/html...QA/Customer/Body/SfpCa
Window: 14 Center: 16
Message:

Image Display:



SeriesLoid Local
ImageNumber 1
256 * 256 (Lines
FoV 500.0 * 500.(
TR 600.00 TE 35
Sagittal
Patient position H
2011-12-14 12:1
sequence calcar

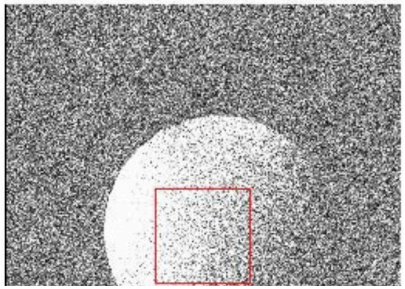
Evaluation for coil element: SH1.

SN evaluation

Series: 2, Image 1/4 of protocol 005_ShoulderArray_all_Tra_sn.edb

Image: file:/C:/MedCom/service/html...ray/SfpCoilCheckLocalCoils/gfx/qa_2011-07-21-164659-1.ima
Window: 98 Center: 49
Message:

Image Display:



SeriesLoid Local 2.0.77175111
ImageNumber 1
256 * 256 (Lines * Columns)
FoV 200.0 * 200.0 (width * heigth)
TR 300.00 TE 10.00
Transversal
Patient position HFS
2011-07-21 16:48:53
sequence sn

S/N and Brightness Results

	Value	Low Spec	High Spec
Protocol	005_ShoulderArray_all_Tra_sn		
S/N	2.68	45.00	
Brightness	97.76	350.00	1400.00

Results of coil-element SH1 are NOT in Specification!

Quality Sequences

Measure Protocol: 005_CP_FlexLarge_Tra_sn.edb.

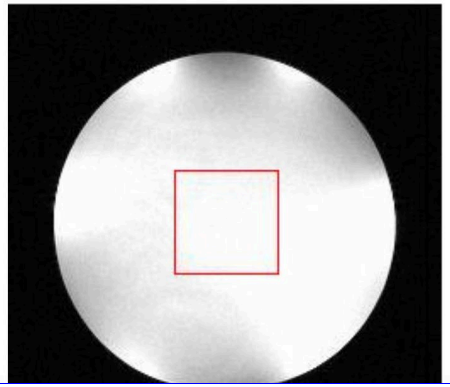
Evaluation for coil element: FL.

SN evaluation

Series: 1, Image 1/1 of protocol 005_CP_FlexLarge_Tra_sn.edb

Image: file:/C:/MedCom/service/html...rge/SfpCoilCheckLocalCoils/gfx/qa_2011-07-21-151918-1.ima
Window: 896 Center: 448
Message:

Image Display:



SeriesLoid Local 2.0.77135067
ImageNumber 1
256 * 256 (Lines * Columns)
FoV 200.0 * 200.0 (width * heigth)
TR 300.00 TE 10.00
Transversal
Patient position HFS
2011-07-21 15:25:25
sequence sn

S/N	59.73	48.00	
Brightness	896.22	350.00	1500.00

Results of coil-element FL are in Specification!

BOĞAZİÇİ ARGE
Biyomedikal Mühendislik ve Yönetim Danışmanlığı San. Tic. Ltd. Şti.

MRI KALİTE KONTROL VE KALİBRASYON ÖLÇÜMLERİ FORMU

Referanslar:
i. ACR Magnetic Resonance Imaging Quality Control Manual 2001
ii. AAPM, Quality Assurance Methods and Phantoms for MRI, 1990
iii. [redacted]

KULLANILDIĞI YER:	[redacted]
MARKASI:	[redacted]
MODELİ:	[redacted]
SERİ NO:	[redacted]
BMAE No.:	**RAD 18108 01**
TEST CİHAZLARININ ADI:	
MARKASI	[redacted]
MODELİ:	MRI PAHNTOM SETİ
SERİ NO:	
İŞİ YAPAN:	**MEHMED ÖZKAN**
TARİH:	**5. Eylül 2014**

GÖRÜŞLER/UYARILAR:
1- endorektal fantom çalışmıyor.
2- Küçük Omuz bobini S/N uygun değil.
3- Bobinlerin ön temizliklerine ve bakımına özen göstermek gerekiyor.
4- Klima su damlatıyor.
5- Sistem sık sık hasta butonu alarmı veriyor.

UYGUNLUK	
Uygun	x
Uygun Değil	

Uygunluk Küçük Omuz ve Endorektal bobinler için geçerli değildir.

BOĞAZİÇİ ARGE
Biyomedikal Mühendislik ve Yönetim Danışmanlığı San. Tic. Ltd. Şti.

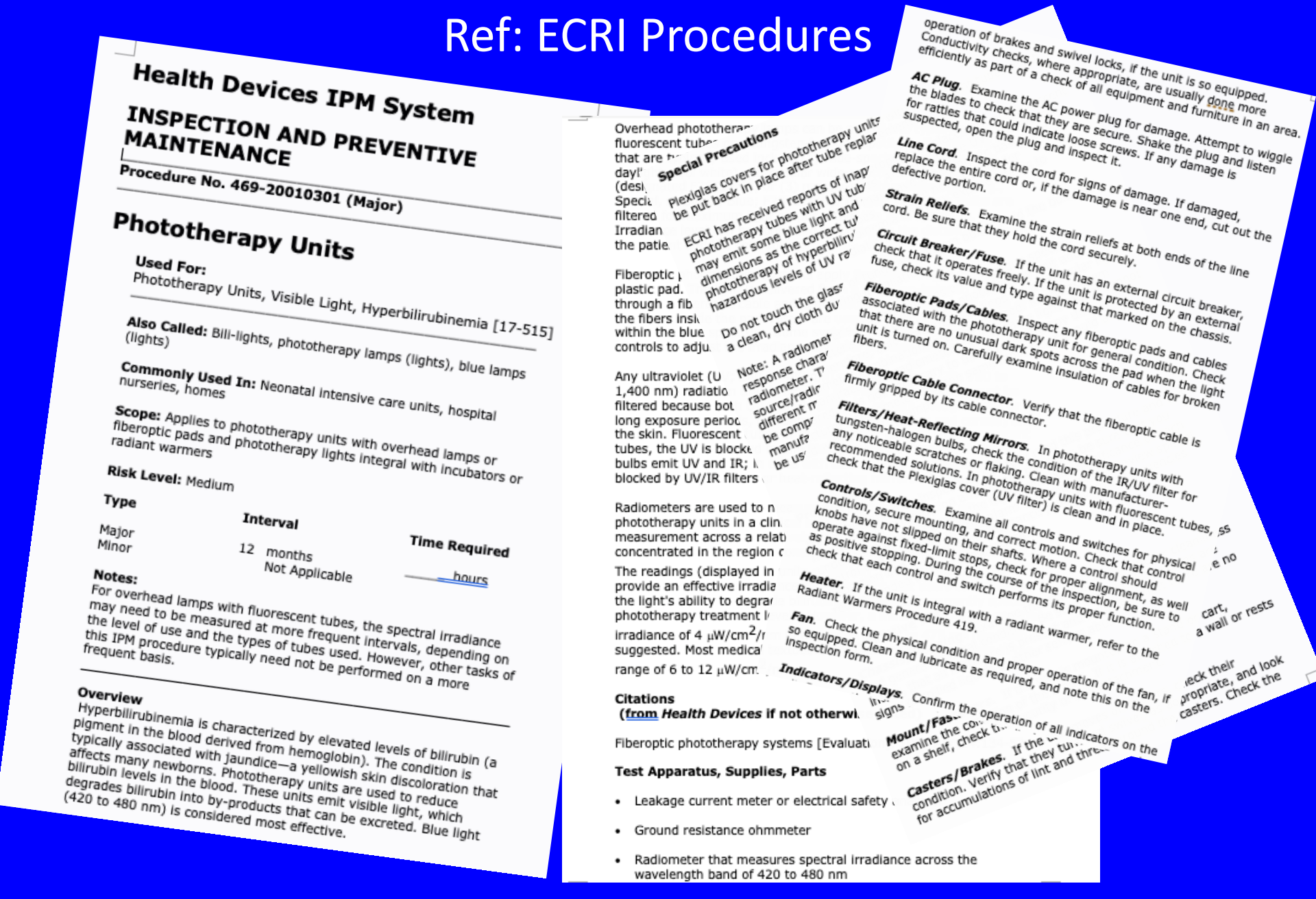
Model / Test	Uygunluk	Açıklama
Artifact Testi	**Uygun**	
CP Breast (Meme)	**Uygun**	
Double Loop Left	**Uygun**	
Double Loop Right	**Uygun**	
Body Matrix Coil	**Uygun**	
PA Matrix Coil Feet First	Uygun	
PA Matrix Coil Head First	**Uygun**	
Head Matrix Coil	**Uygun**	
Body Coil	**Uygun**	
Spine Matrix Coil	**Uygun**	
CP Extremity (Diz)	**Uygun**	
Endorektal Coil	Uygun Değil	Fantom Çalışmıyor
CP Flex Large	**Uygun**	
CP Flex Small	**Uygun**	
Neck Matrix Coil	**Uygun**	
Omuz / Shoulder Large	***Uygun***	
Omuz / Shoulder Small	*Uygun* değil	
Flex Loop Large	***Uygun***	
Flex Loop Small	***Uygun***	

Example 2: Phototherapy Device

Apparatus	Function	Risks	Importance of P Maintenance	Sum	Period
Phototherapy Device	6	3	4	**13**	6 mnt

- Ref

Ref: ECRI Procedures



Health Devices IPM System

INSPECTION AND PREVENTIVE MAINTENANCE

Procedure No. 469-20010301 (Major)

Phototherapy Units

Used For:
Phototherapy Units, Visible Light, Hyperbilirubinemia [17-515]

Also Called: Bili-lights, phototherapy lamps (lights), blue lamps (lights)

Commonly Used In: Neonatal intensive care units, hospital nurseries, homes

Scope: Applies to phototherapy units with overhead lamps or fiberoptic pads and phototherapy lights integral with incubators or radiant warmers

Risk Level: Medium

Type	Interval	Time Required
Major	12 months	hours
Minor	Not Applicable	

Notes:
For overhead lamps with fluorescent tubes, the spectral irradiance may need to be measured at more frequent intervals, depending on the level of use and the types of tubes used. However, other tasks of this IPM procedure typically need not be performed on a more frequent basis.

Overview
Hyperbilirubinemia is characterized by elevated levels of bilirubin (a pigment in the blood derived from hemoglobin). The condition is typically associated with jaundice—a yellowish skin discoloration that affects many newborns. Phototherapy units are used to reduce bilirubin levels in the blood. These units emit visible light, which degrades bilirubin into by-products that can be excreted. Blue light (420 to 480 nm) is considered most effective.

Special Precautions

Plexiglas covers for phototherapy units be put back in place after tube replac

ECRI has received reports of inap phototherapy tubes with UV tub may emit some blue light and dimensions as the correct tu phototherapy of hyperbiliru hazardous levels of UV ra

Do not touch the glass a clean, dry cloth du

Note: A radiomet response chara radiometer. T source/radi different m be comp manufa be us

operation of brakes and swivel locks, if the unit is so equipped. Conductivity checks, where appropriate, are usually done more efficiently as part of a check of all equipment and furniture in an area.

AC Plug. Examine the AC power plug for damage. Attempt to wiggle the blades to check that they are secure. Shake the plug and listen for rattles that could indicate loose screws. If any damage is suspected, open the plug and inspect it.

Line Cord. Inspect the cord for signs of damage. If damaged, replace the entire cord or, if the damage is near one end, cut out the defective portion.

Strain Reliefs. Examine the strain reliefs at both ends of the line cord. Be sure that they hold the cord securely.

Circuit Breaker/Fuse. If the unit has an external circuit breaker, check that it operates freely. If the unit is protected by an external fuse, check its value and type against that marked on the chassis.

Fiberoptic Pads/Cables. Inspect any fiberoptic pads and cables associated with the phototherapy unit for general condition. Check that there are no unusual dark spots across the pad when the light unit is turned on. Carefully examine insulation of cables for broken fibers.

Fiberoptic Cable Connector. Verify that the fiberoptic cable is firmly gripped by its cable connector.

Filters/Heat-Reflecting Mirrors. In phototherapy units with tungsten-halogen bulbs, check the condition of the IR/UV filter for any noticeable scratches or flaking. Clean with manufacturer-recommended solutions. In phototherapy units with fluorescent tubes, check that the Plexiglas cover (UV filter) is clean and in place.

Controls/Switches. Examine all controls and switches for physical condition, secure mounting, and correct motion. Check that control knobs have not slipped on their shafts. Where a control should operate against fixed-limit stops, check for proper alignment, as well as positive stopping. During the course of the inspection, be sure to check that each control and switch performs its proper function.

Heater. If the unit is integral with a radiant warmer, refer to the Radiant Warmers Procedure 419.

Fan. Check the physical condition and proper operation of the fan, if so equipped. Clean and lubricate as required, and note this on the inspection form.

Indicators/Displays. Confirm the operation of all indicators on the

Mount/Fas

Casters/Brakes. If the

Citations
(**from *Health Devices* if not otherwi**

Fiberoptic phototherapy systems [Evaluati

Test Apparatus, Supplies, Parts

- Leakage current meter or electrical safety
- Ground resistance ohmmeter
- Radiometer that measures spectral irradiance across the wavelength band of 420 to 480 nm

TOOLS

ISO 60601 Electric Safety

Incubator Radiant Warmer Analyzer

Phototherapy Radiometers
400-480 nanometers

BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

PHOTOTHERAPY DEVICE
PREVENTIVE MAINTENANCE AND CALIBRATION MEASUREMENTS FORM

REFERANS: ECRI PREVENTIVE MAINTENANCE&INSPECTION

WHERE USED:	
BRAND:	
MODEL:	
SERIAL NO:	
BMAE No.:	
NAME OF TEST DEVICES:	
BRAND	
MODEL:	
SERIAL NO:	
BY/SIGNED:	
DATE:	VALIDITY PERIOD: 6 Months

REMARKS:

PASS	
DON'T PASS	

1.	FIGURAL TESTS	Passed	Not	Important Considerations
1.1	CHASSIS			
1.2	CARRIER PARTS			
1.3	FIXED HOLDER PART			
1.4	POWER PLUG			
1.5	EELECTRIC CONNECTION CABLE			
1.6	STRAIN PROTECTORS			
1.7	FUSES			
1.8	FAN			
1.9	CABLES			
1.10	CONNECTIONS/CONNECTORS			
1.11				
1.12				
1.13	CONTROLS / SWITCHES			
1.14	UV LAMP			
1.15				
1.16				
1.17				
1.18	INDICATORS/COUNTER			
1.19				
1.20	ALARMS			

1.6	STRAIN PROTECTORS			
1.7	FUSES			
1.8	FAN			
1.9	CABLES			
1.10	CONNECTIONS/CONNECTORS			
1.11				
1.12				
1.13	CONTROLS / SWITCHES			
1.14	UV LAMP			
1.15				
1.16				
1.17				
1.18	INDICATORS/COUNTER			
1.19				
1.20	ALARMS			
1.21	AUDIBLE ALERTS			
1.22	LABELING			
1.23	ACCESSORIES (Phototherapy Lamps, Oxygen Cylinders, Flow Meters)			
1.24	BASİNET / MATTRESS			
1.25				

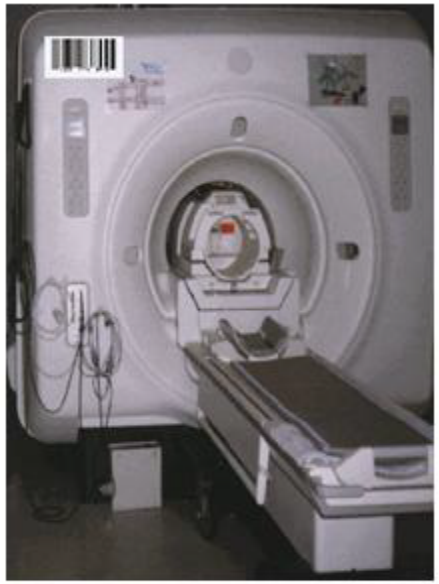
2.	MEASUREMENTS	Passed	Failed	Sonuçlar
2.1	GROUNDING RESISTANCE (<0.3 Ohms) Appliance power plug between ground end and chassis			attached is the Electrical Safety Form.
2.2	CHASSIS LEAKAGE ELECTRIC CURRENT (<100 mA)			attached is the Electrical Safety Form.
2.3	UV LAMP (The UV lamp is replaced every 800 hours.]			Counter:
2.4				

3.	PREVENTIVE MAINTENANCE	Passed	Failed	Açıklamalar
3.1	APPLIANCE CLEANING (Exterior, inside, Lenses, reflectors, heating element, cooling fan)			
3.2	DEVICE CALIBRATION IF DEEMED NECESSARY			
3.3	BATTERY MAINTENANCE			

2.	MEASUREMENTS	Passed	Failed	Results			
2.1	GROUNDING RESISTANCE (<0.3 Ohms) Appliance power plug between ground end and chassis			*			
2.2	CHASSIS LEAKAGE ELECTRIC CURRENT (<100 mA)			*			
2.3	UV LAMBASI [Dräger says Photo-Terapy 4000 UV lamps should not be used for more than 1000 hours.]			Usage Hours Counter			
				Final Lamp Change Value:			
				Now			
				Difference:			
2.4	SPECTRAL IRRADIATION Recommended Measuring Distance: 40 cm (bed-lamp) Method of administration: Inside the incubator			Measuring Distance (cm):			
				µW/cm²/nm	Base Value	Measurement	%
	Edge Point Measurements: Each measurement is 4 µW/cm2/nm Each measurement should not be less than 20% stronger than the first (reference) measurement. When the bed is divided into squares of 10x10cm2, the maximum value is in the center. For the Draeger 4000, the Right-Left crosses receive 91% of the light according to the CENTER, and the Lower-Upper averages receive 67% of the light (±5%).			LEFT EDGE CENTER			
				RIGHT EDGE CENTER			
				TOP EDGE MEDIUM			
				BOTTOM EDGE MIDDLE			
				CENTER			
	AVERAGE (edges and center) ≥ 6 µW/cm²/nm ≤ 12 µW/cm²/nm			AVERAGE			

Envanter Modülü

- PPC
  - Envanter Girişi
  - Envanter Takibi
  - Barkod Cihaz Tanıma



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Kalibrasyon Ölçüm: Şekilsel Test

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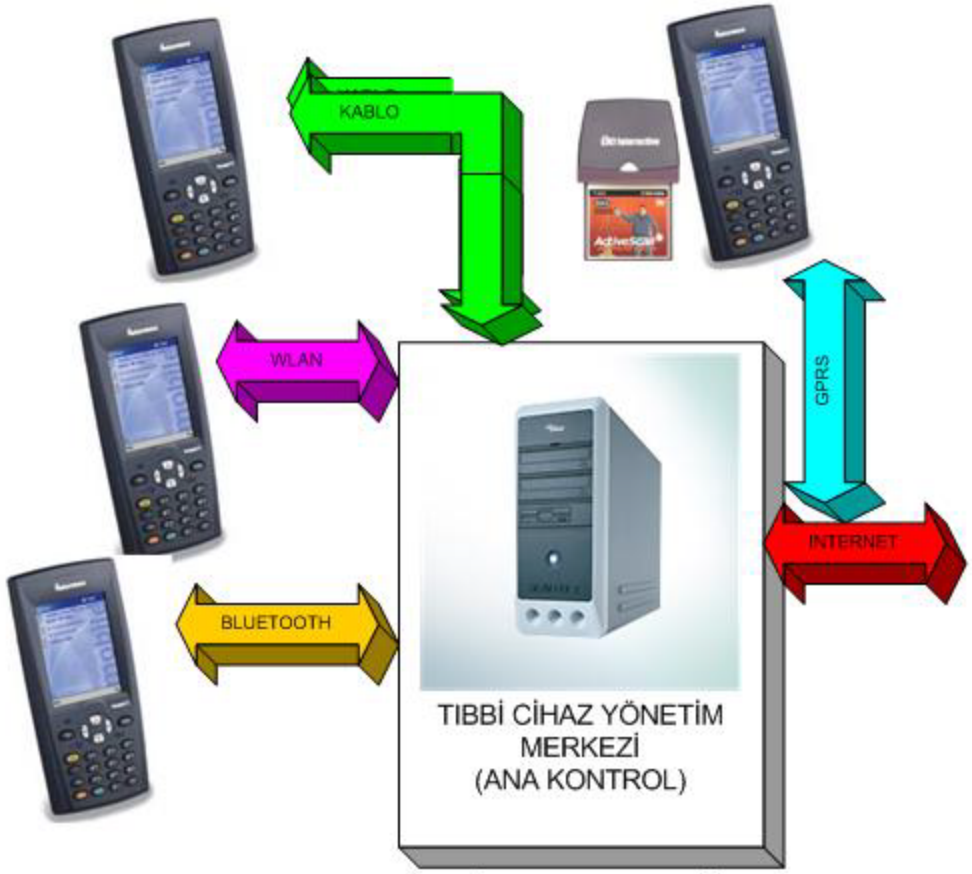
Kalibrasyon Ölçüm: Ölçümler

Envanter Modülü

- Sunucu Senkronizasyonu



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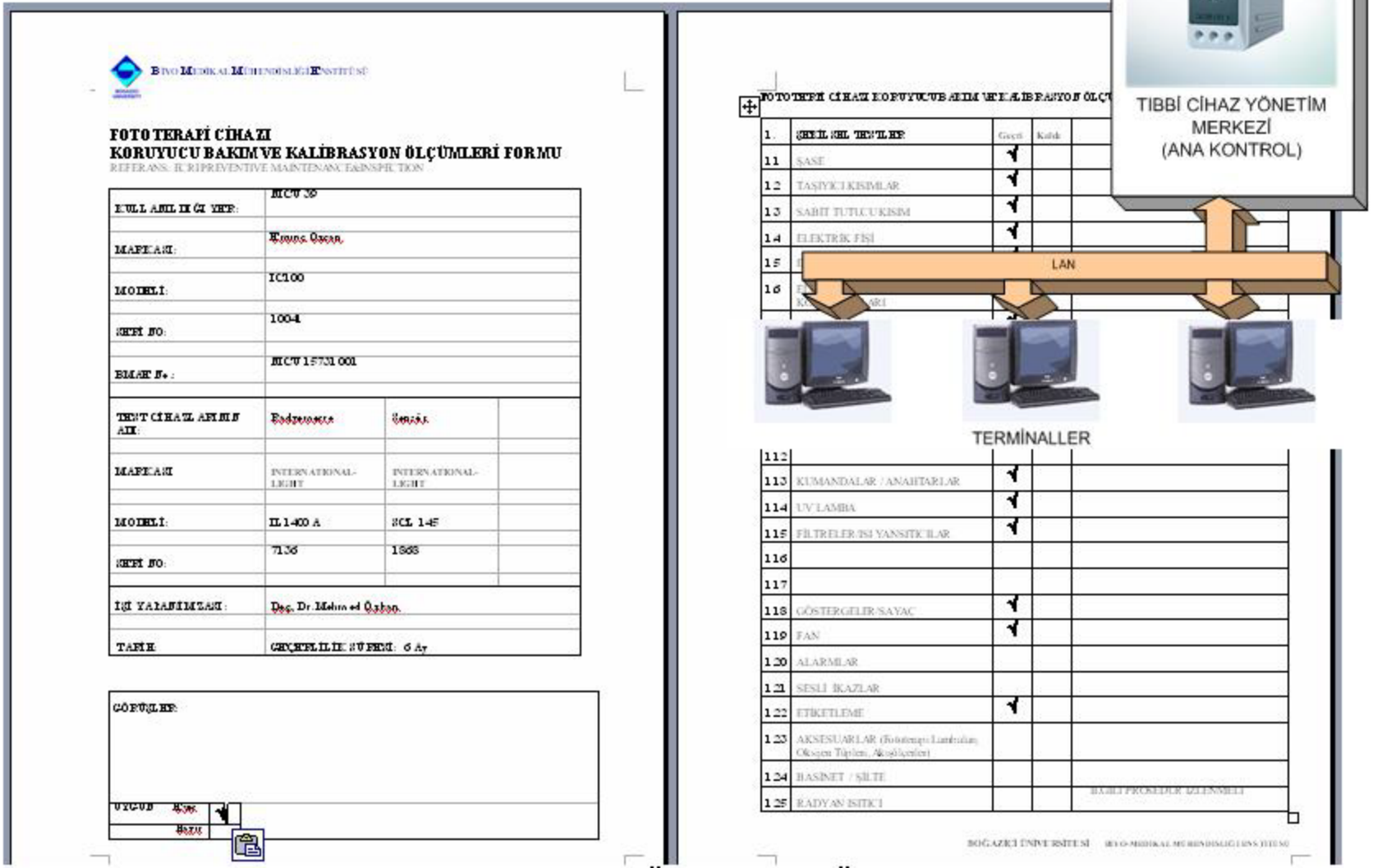
Rapor Modülü



BİYO MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

FOTOTERAPİ CİHAZI
KORUYUCU BAKIM VE KALİBRASYON ÖLÇÜMLERİ FORMU
REFERANS: IEC PREVENTIVE MAINTENANCE INSPECTION

KULLANILDIĞI YER:	MCV 30		
MARKASI:	Ecoms Ozcan		
MODELİ:	IC100		
SERİ NO:	1004		
BİMAR No:	MCV 15731 001		
TEST CİHAZI ANALİZ ADI:	Radiometer	Sensis	
MARKASI	INTERNATIONAL-LIGHT	INTERNATIONAL-LIGHT	
MODELİ:	IL 1400 A	SCL 145	
SERİ NO:	7136	1868	
İŞİ YAPANIN ADI:	Doç. Dr. Mehmet Özkan.		
TARİH:	GEÇERLİLİK SÜRESİ: 6 Ay		

GÖRÜŞLER:

UYGUN Evet ☑ Hayır ☐

FOTOTERPİ CİHAZI KORUYUCU BAKIM VE KALİBRASYON ÖLÇ

		Geçerli	Kalıb	
1.	GENEL KISIM TESTLERİ			
11	ŞASE	☑		
12	TAŞIYICI KISIMLAR	☑		
13	SABİT TUTUCU KISIM	☑		
14	ELEKTRİK FİŞİ	☑		
15				
16	KONTROL KARTI			
112				
113	KUMANDALAR / ANAHTARLAR	☑		
114	UV LAMBA	☑		
115	FİLTRELER/ISI YANSITICILAR	☑		
116				
117				
118	GÖSTERGELER/SAYAÇ	☑		
119	FAN	☑		
120	ALARMLAR			
121	SESLİ İKAZLAR			
122	ETİKETLEME	☑		
123	AKSESUARLAR (Bedeninizi Lambaları, Oksijen Tüpleri, Aksesuarları)			
124	BASINÇ / ŞİLTE			
125	RADYAN ISITICI			HABİLİ PROSEDÜR DÜZENLİLİ

BOĞAZİÇİ ÜNİVERSİTESİ BİYO-MEDİKAL MÜHENDİSLİĞİ ENSTİTÜSÜ

TIBBİ CİHAZ YÖNETİM MERKEZİ (ANA KONTROL)

LAN

TERMİNALLER

Mehmed Özkan, Yekta Ülgen
Boğaziçi Ü. Biyo-Medikal Mü. E.

Rapor Modülü

FOTOTERAPİ CİHAZI KORUYUCU BAKIM VE KALİBRASYON ÖLÇÜMLERİ FORMU

2.	ÖLÇÜMLER	Geçti	Kaldı	Sonuçlar
2.1	**TOPRAKLAMA DİRENCİ (<0.3 Ohm)** Cihaz elektrik fişi toprak ucu ile şase arası	√		Ekte **Elektrik Güvenliği Formunda** verilmiştir.
2.2	**ŞASE KAÇAK ELEKTRİK AKIMI (<100 µA)**	√		Ekte **Elektrik Güvenliği Formunda** verilmiştir.
2.3	**UV LAMBASI** **[UV lambası 800 saatte bir veya üretici firmanın ön gördüğü süre içinde değiştirilir.]**			Kullanım Saat Sayacı Halen: / En Son Lamba Değişim Değeri
2.4	**SPEKTRAL IŞIMA**			ÖLÇÜMLER (µW/cm²/nm)
	Bütün ölçümler için: ≥ 4 µW/cm²/nm	√		SOL ORTA: 7,38 / 7,40 / 7,36 — SAG ORTA: 9,71 / 9,70 / 9,73
	Bütün ölçümler için: ≥ 4 µW/cm²/nm	√		UST ORTA: 6,0 / 6,2 / 6,1 — ALT ORTA: 6,2 / 6,0 / 6,1
	Bütün ölçümler için: ≥ 4 µW/cm²/nm	√		MERKEZ: 9,21 / 9,22 / 9,20
	ORTALAMA ≥ 6 µW/cm²/nm ≤ 12 µW/cm²/nm	√		

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Thank you !