

02 Oktober 2021



Peran Keselamatan Alkes Dalam Mewujudkan Keamanan Pasien Secara Optimal

Dr. H.Hendrana Tjahjadi, S.T, M.Si

Hospital Engineering Forum 2021

Indonesian Association Hospital Engineering



Curriculum Vitae

Name: Dr.H. Hendrana Tjahjadi, S.T, M.Si

Current Designation: Universitas Pertahanan

Education Background:

S2 Teknik Biomedis Universitas Indonesia

S3 Teknik Elektro Universitas Indonesia

Work Experience :

1994 – Biomedical Engineer

Medical Equipment's Inventor (Ventilator, HFNC, Pulse Oximeter, Vital Sign Monitor, ect)

Tenaga Ahli Uji kesesuaian Pesawat Sinar-X BAPETEN

Dosen Tetap Universitas Pertahanan

Organization Experience :

Ketum ALFAKES (Asosiasi Lab kalibrasi Alat Kesehatan Swasta)

OUTLINE

01 Latar Belakang

02 Hak Alkes

03 Inventory

04 Preventive Maintenance

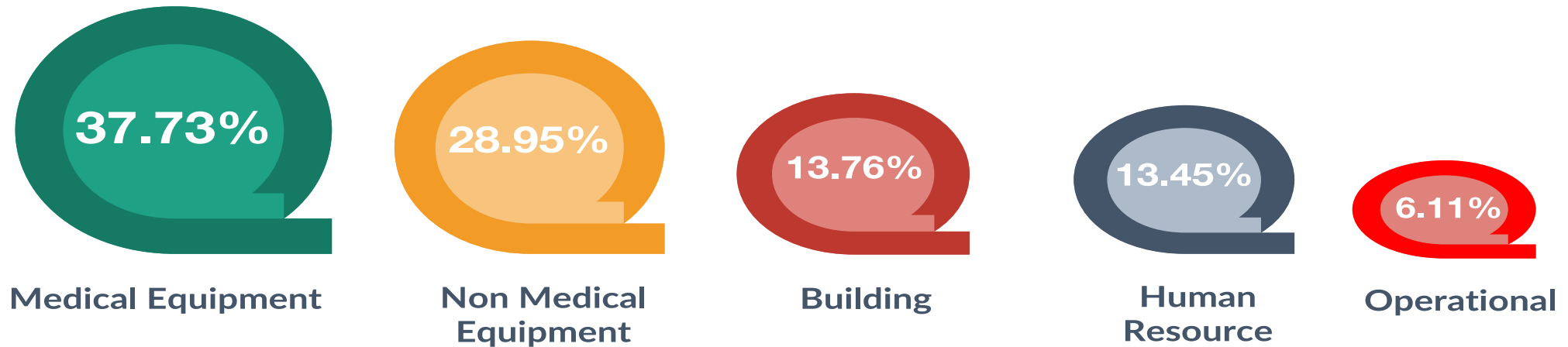
05 Kalibrasi

06 Recall

1

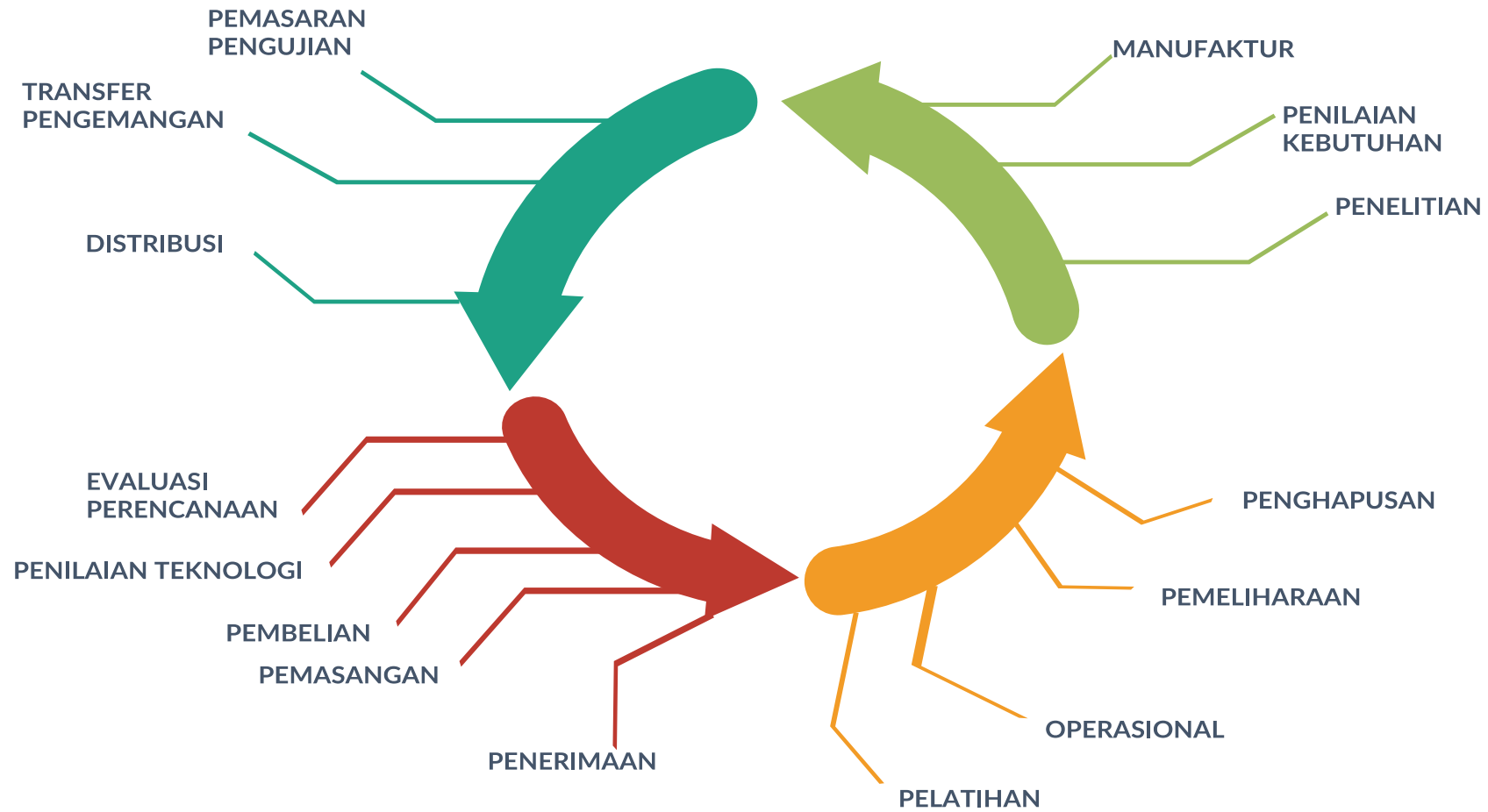
LATAR BELAKANG

INFRASTRUKTUR RUMAH SAKIT

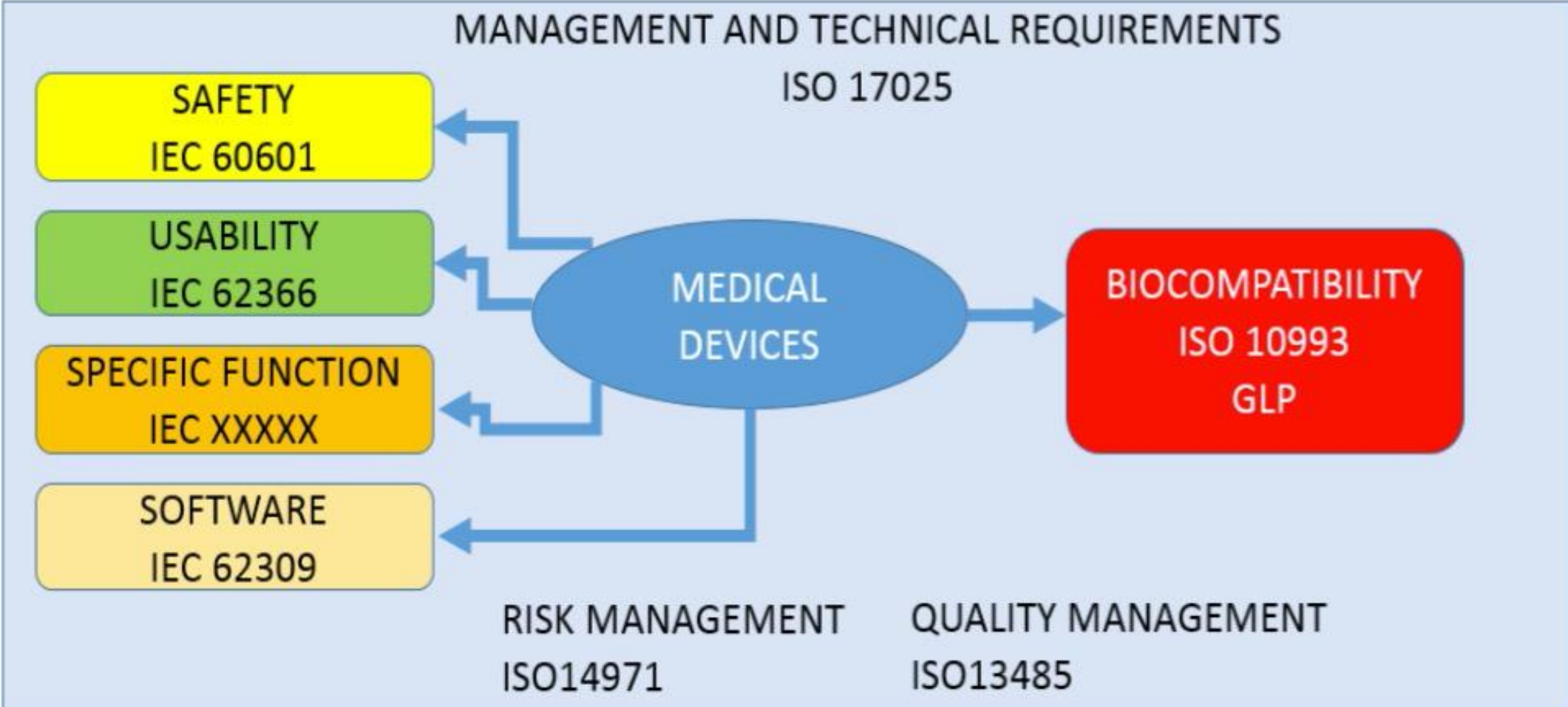


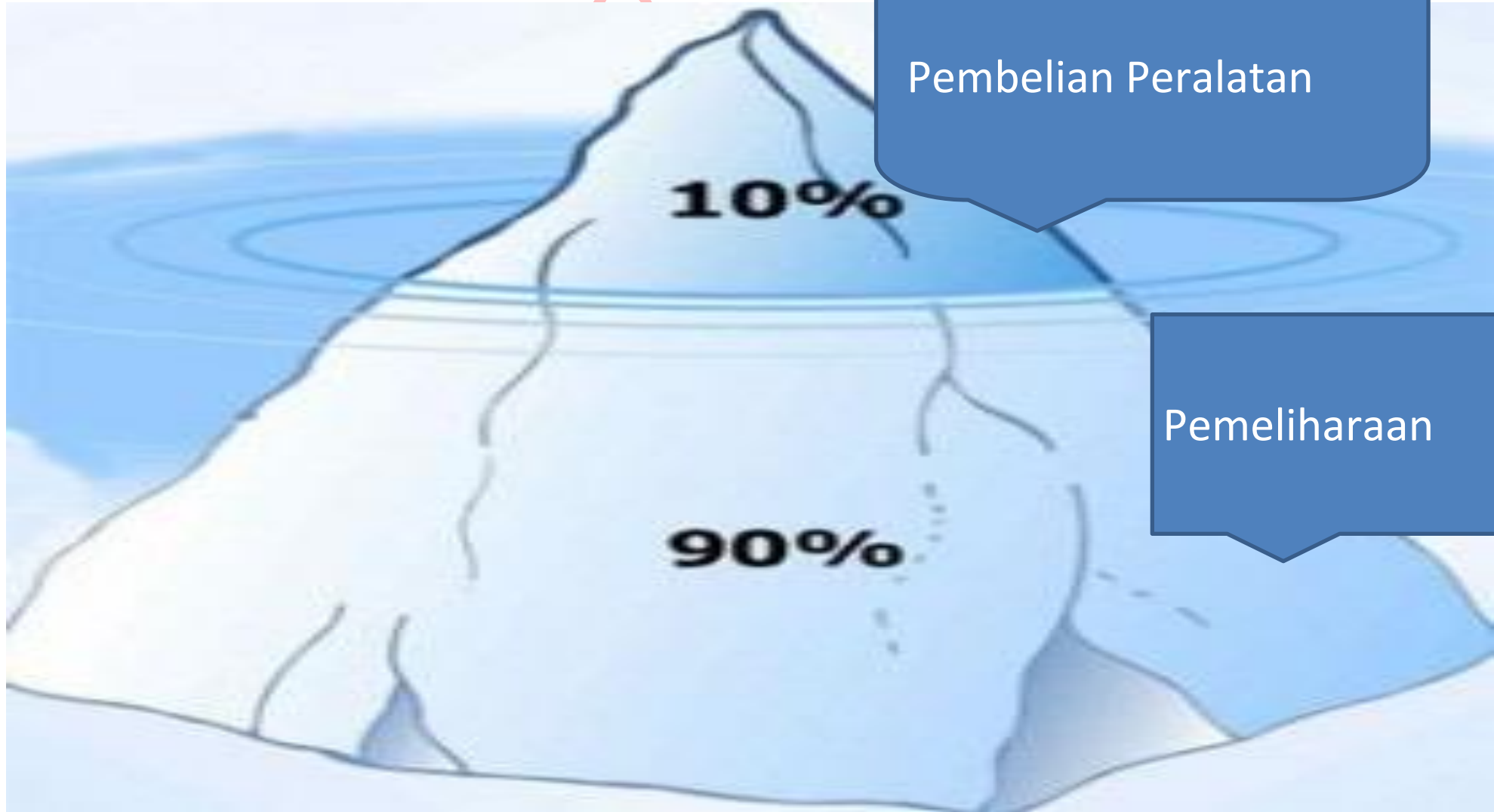
Source: Profil Kesehatan Indonesia Tahun 2008, Departemen Kesehatan Indonesia (Depkes 2009)

SIKLUS ALAT KESEHATAN

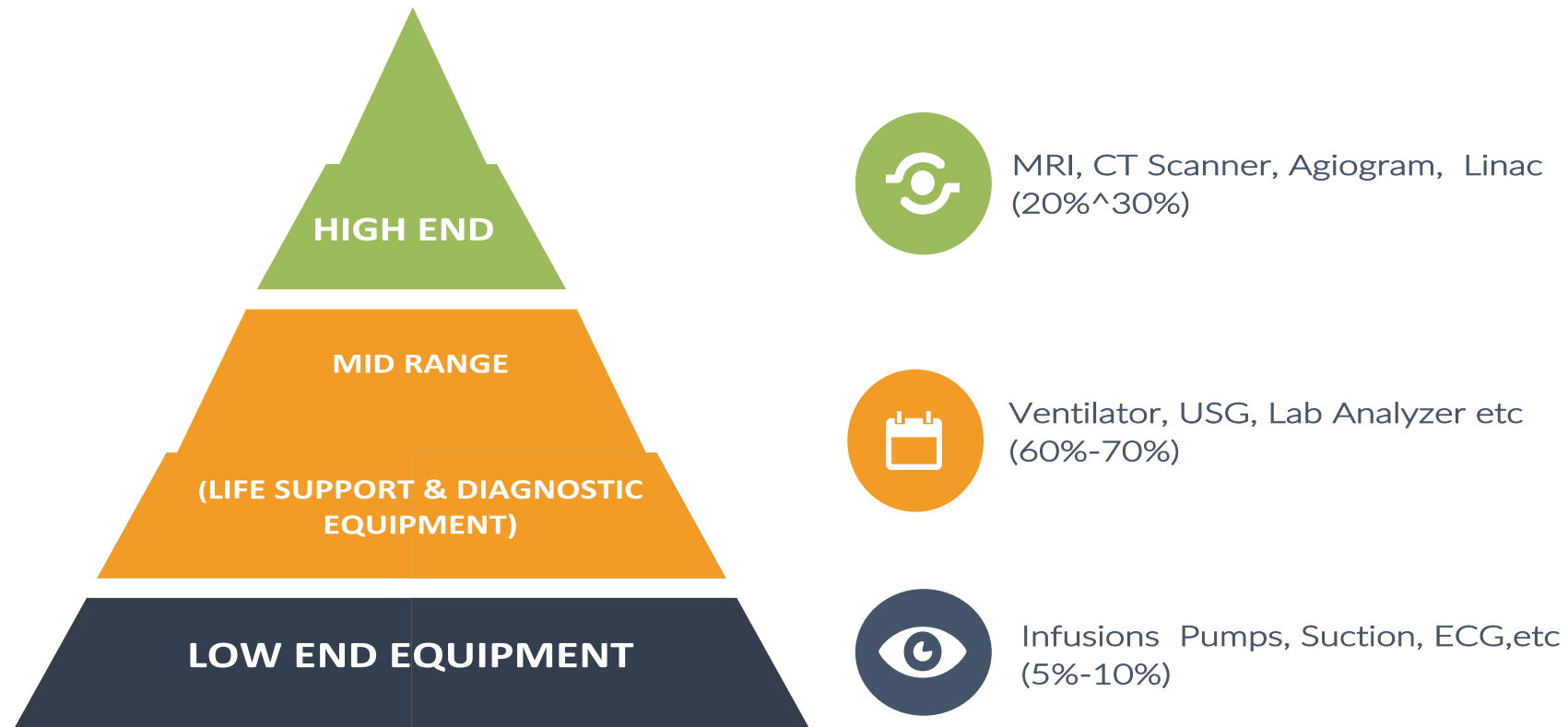


Medical Devices Testing





PERBANDINGAN KINERJA PELAKSANAAN MANAJEMEN PEMELIHARAAN



DARI SISI PEMBIAYAAN MENJADI PIRAMIDA TERBALIK

Contoh Kasus



Kebakaran baby inkubator (meninggal)

Pemeliharaan, pengujian / kalibrasi secara berkala akan akan menghindarkan KTD



Kebakaran infant warmer

CONTOH ALAT TANPA PEMELIHARAAN

KABEL ECG







Recommended uptime target for active medical device

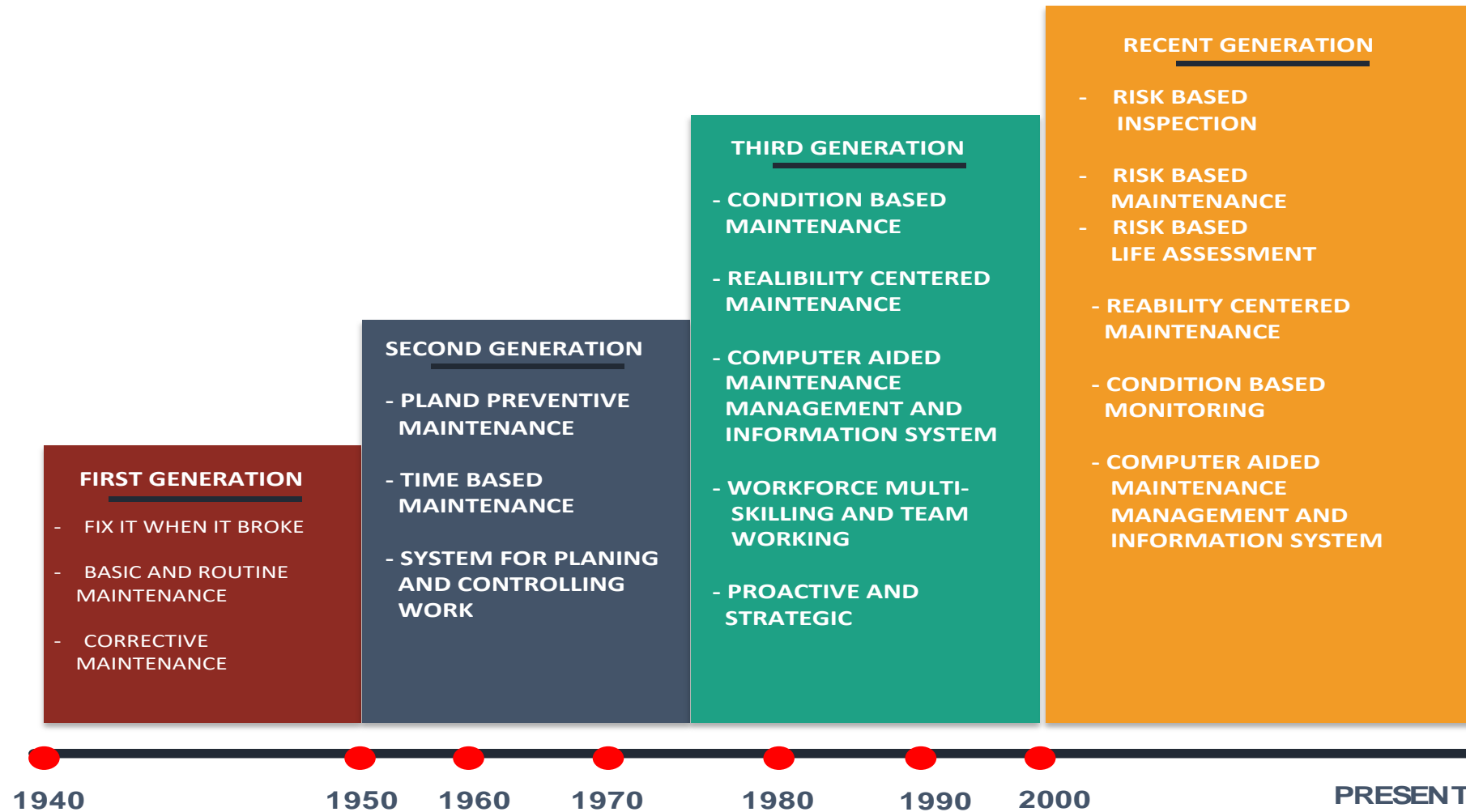
Table H.1. Recommended uptime target for active medical device

1. Therapeutic equipments	Group	Operating hours	Operating hours/week (Days)	Uptime equipment < 5 years	Uptime equipment 5 to 10 years
Anaesthesia units and vaporisers	C	24	7	99 %	95 %
Anaesthesia ventilator	C	24	7	99 %	95 %
Aspirators	C	24	7	99 %	95 %
Alternating pressure mattress	P	12	6	96 %	92 %
Defibrillators	C	24	7	99 %	95 %
Diathermy unit	C	24	7	99 %	95 %
Dental Equipment	P	24	7	96 %	92 %
Electrosurgical units	C	24	7	99 %	95 %
Haemodialysis units	C	24	7	99 %	95 %
Humidifiers	C	24	7	99 %	95 %
Hypo/hyperthermia units	C	24	7	99 %	95 %
Incubators	C	24	7	99 %	95 %
Infusion controllers/pumps	C	24	7	99 %	95 %
Lasers	C	24	7	99 %	95 %
Lithotripters	C	12	6	99 %	95 %
Pacemakers	C	24	7	99 %	95 %
Peritoneal dialysis unit	C	24	7	99 %	95 %
Phototherapy units	C	24	7	99 %	95 %
Radiant warmers	P	24	7	96 %	92 %
Radiographic dye injection	C	24	7	99 %	95 %
Resuscitators	C	24	7	99 %	95 %
Radiotherapy equipments	P	12	6	96 %	92 %
Surgical drills and saws	C	24	7	99 %	95 %
Stimulators	P	12	6	96 %	92 %
Surgical tables	C	24	7	99 %	95 %
Traction units	P	12	6	96 %	92 %
Ventilators	C	24	7	99 %	95 %
Ultrasonic nebulisers	P	12	7	96 %	92 %
Ultrasonic therapy	P	12	6	96 %	92 %

DIS
DIS
2

HAK ALKES

MAINTENANCE HISTORY



HAK PERALATAN KESEHATAN

1

PROGRAM
KALIBRASI

2

PROGRAM
MAINTENANCE

3

PROGRAM
INSPEKSI

4

SERVICE/
SPARE
PARTS

5

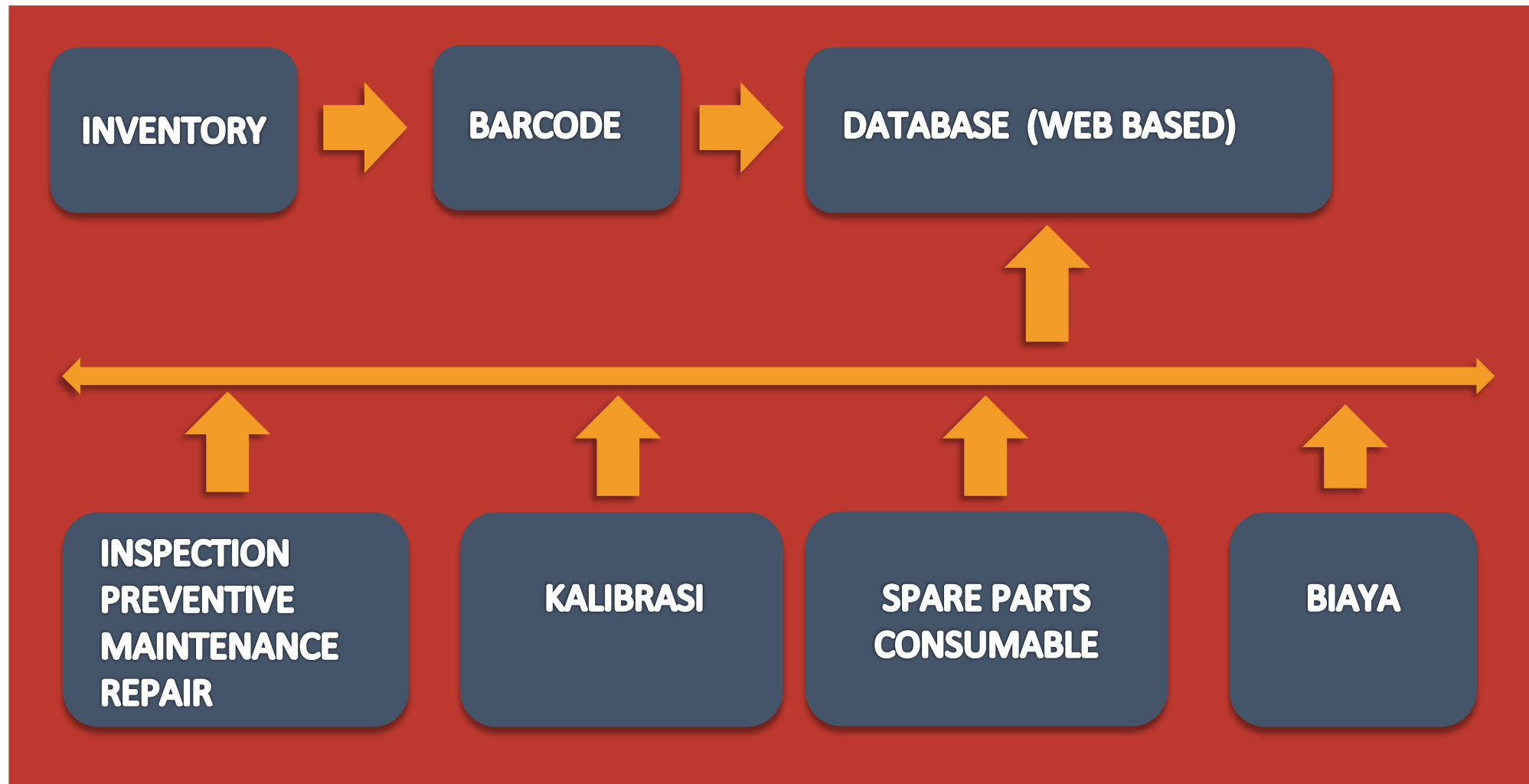
INVENTORY/
CONSUMABLE

DIS

DIS

3

INVENTORY



Contoh Halaman web : Detail Asset

nationalmed = acrosser SBC = goldwei = armkits = rfid = akbi = Qoo10-Indon...ing Market Recognized ...s Standards

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Menu Utama **Alat Medis** Detail Asset

iNvo
Detail Asset
Alat Medis


Monday, 14 Oct 2013
12 : 04 PM
Log In : Dept Penunjang Medis
LOG OUT

- Nama Alat : Infusion Pump
- Merk : SK
- Model : SK - 6001
- S/N : 432000342
- Tahun Pembelian : 2008
- Harga Perolehan : RP 32.000.000
- Status Kalibrasi : Terkalibrasi
Expired : **Mei 2014**
- LOKASI INSTALASI : Ruang ICU

Kebutuhan Konsumable
Jadwal Maintenance
History Alat

PENCARIAN LAIN
SCAN BARCODE

EDIT DATA



Contoh Halaman web : Status Kalibrasi

nationalmed = acrosser SBC = goldwei = armkits = rfid = akbi = Qoo10-Indon...ing Market Recognized ...s Standards

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Menu Utama **Alat Medis** Status Kalibrasi

iNvo
STATUS KALIBRASI

Monday, 14 Oct 2013
12 : 04 PM
Log In : IPSRS ELEKTOMEDIK
LOG OUT

No	Barcode No	Nama Ruangan	Nama Alat	Merk	Type	SN	Tanggal Kalibrasi	Status Kalibrasi
1	110010290320	Ruang Perawatan Bayi	Bed Side Monitor	Mindray	MEC-2000	CV-98102714	3-Aug-13	●
2	110010290321	Ruang Perawatan Bayi	Suction	Thomas	Medipump	0000257-0884	3-Aug-13	●
3	110010012932	Ruang Perawatan Bayi	USG	Mindray	Z6	ZH-1112-06	3-Aug-13	●
4	20010000517	Ruang Perawatan Bayi	Baby Incubator	GEA-Medical	YP-100	01080104035	3-Aug-13	●
5	110010290309	Ruang Perawatan Bayi	Baby Incubator	GEA-Medical	YP-101	01080104036	15-Oct-13	●
6	110010290331	Ruang Perawatan Bayi	Baby Incubator	GEA-Medical	YP-102	01080104037	15-Oct-13	●
7	20010000590	Ruang Perawatan Bayi	Baby Incubator	GEA-Medical	YP-103	01080104038	15-Oct-13	●
8	110010290327	Ruang Perawatan Bayi	Baby Incubator	GEA-Medical	YP-104	01080104039	15-Oct-13	●
9	110010290329	Ruang Perawatan Bayi	Baby Incubator	Thermocoat	Series-2	83249A90	15-Oct-13	●
10	20010001429	Ruang Perawatan Bayi	Baby Incubator	Issolette	C-86	11052	15-Oct-13	●
11	20010001379	Ruang Perawatan Bayi	Baby Incubator	Issolette	C-86	11053	27-Nov-13	●
12	110010230267	Ruang Perawatan Bayi	Baby Incubator	Issolette	C-87	11054	27-Nov-13	●
13	110010290332	Ruang Perawatan Bayi	CPAP	Sechrist	3500HZ	H66966	27-Nov-13	●
14	110010290323	Ruang Perawatan Bayi	CPAP	Sechrist	3500HZ	H65340	27-Nov-13	●
15	110012241679	Ruang Perawatan Bayi	Syringe Pump	Terumo	TE-331	08120224	27-Dec-13	●
16	110010290305	Ruang Perawatan Bayi	Syringe Pump	Terumo	TE-331	08120019	27-Dec-13	●
17	20010000524	Instalasi Bedah Sentral	Blood Pressure Monitor	DataScope	Accutorr 2A	10847IA	27-Dec-13	●
18	110010290316	Instalasi Bedah Sentral	Blood Pressure Monitor	DataScope	Accutorr 2A	10852IA	27-Dec-13	●
19	110010290310	Instalasi Bedah Sentral	Blood Pressure Monitor	DataScope	Accutorr 3A	H1138-J3	27-Dec-13	●
20	110010290311	Instalasi Bedah Sentral	Blood Pressure Monitor	DataScope	Accutorr 2A	10845IA	27-Dec-13	●
21	110010290303	Instalasi Bedah Sentral	ECG Monitor	DataScope	Accutorr 2A	10856IA	27-Dec-13	●
22	20010000577	Instalasi Bedah Sentral	ECG Monitor	Micromon	7141	83978	27-Dec-13	●
23	110010290319	Instalasi Bedah Sentral	ECG Monitor	Micromon	7141	83969	27-Dec-13	●
24	110010290308	Instalasi Bedah Sentral	Vaporizer Isoflourane	TAEMA	Vapal 3	00110505L	27-Dec-13	●
25	20010000034	Instalasi Bedah Sentral	Vaporizer isoflourane	TAEMA	Vapal 3	00100505L	27-Dec-13	●

← → **PENCARIAN LAIN**

LAMPIRAN USIA TEKNIS ALAT KESEHATAN

No	Medical Equipment	Life in Years	Life in Units	Unit Of Measure
1	Absorptiometer, Dual Photon, X-Ray	8	200.800	Exposure
2	Absorptiometer, Single Photon, X-Ray	8	200.800	Exposure
3	Aerator	12	24.096	Hours
4	Air Compressor	15	30.120	Hours
5	Air Sampler	10	20.080	Hours
6	Alcohol Analyzer	8	16.064	Hours
7	Amalgamator	6	12.048	Hours
8	Amino Acid Analyzer	8	16.064	Hours
9	Analyzer, Alcohol	8	16.064	Hours
10	Analyzer, Amino Acid	8	16.064	Hours
11	Analyzer, Antibody Susceptible	8	16.064	Hours
12	Analyzer, Blood Gas / Ph	8	16.064	Hours
13	Analyzer, BUN	8	16.064	Hours

No	EM Number	Nama Alat	Merk	Type	Nomor Seri	Lokasi	Tahun Pengadaan	usia teknik
1	< 12	Microscope Lab	Zeiss	OPMI Pico	6613011427	P. THT IRJ	2003	12
2	< 12	AQUADES	MILIPORE			GD. Farmasi	2000	10
3	< 12	ASPERISIS	FENWAL	4R4580	D0905M4078	UTD	2010	10
4	< 12	AUDIO TREATER	OG GIKEN	EP 502	91028E		1978	10
5	< 12	AUTO STAINER	LEICA	JTOSTAINER X	XL 079096	PA	1997	10
6	< 12	AUTO TRACK	OG GIKEN	01-110	90080 E		1978	10
7	< 12	AUTOMATIC TANGENT SCREEN/ KAMPI M	TAKAGI	ATS 85	991026	P. Mata	1983	10
8	< 12	Automatic Tissue Embelding	Leica	EG 1160	386 21438	PA	1997	10
9	< 12	Automatic Tissue Processor	Leica	TP 1010	4260686	PA	1997	10
10	< 12	Automatic Tissue Processor	Reichert	to Kinette 20	7210007		1997	10
11	< 12	BLANKET WARMER	BLANKET ROLL			IBS	2012	10
12	< 12	BLOOD COLLECTION MIXER	FENWAL	CM-323	10094333	UTD	2010	10
13	< 12	BLOOD DONOR CHAIR	MAX			UTD	2010	10
14	< 12	BLOOD DONOR CHAIR	MAX			UTD	2010	10
15	< 12	BLOOD DONOR CHAIR	MAX			UTD	2010	10
16	< 12	BLOOD DONOR CHAIR	MAX			UTD	2010	10
17	< 12	BLOOD DONOR CHAIR	MAX			UTD	2010	10
18	< 12	BLOOD DONOR CHAIR	MAX			UTD	2010	10
19	< 12	BOR AIR	SYNTHES			IBS	2005	10
20	< 12	BOR AIR	AESCULAVE			IBS	1997	10
21	< 12	BOR AIR	AESCULAVE				2013	10
22	< 12	BOR AIR (MASTOID)	AESCULAVE			IBS	1997	10
23	< 12	BOR LISTRIK	BOLJIN			IBS	2012	10
24	< 12	BOR LISTRIK	BOLJIN			IBS	2012	10
25	< 12	BOR MINI DRILL	SYNTHES			IBS	1995	10

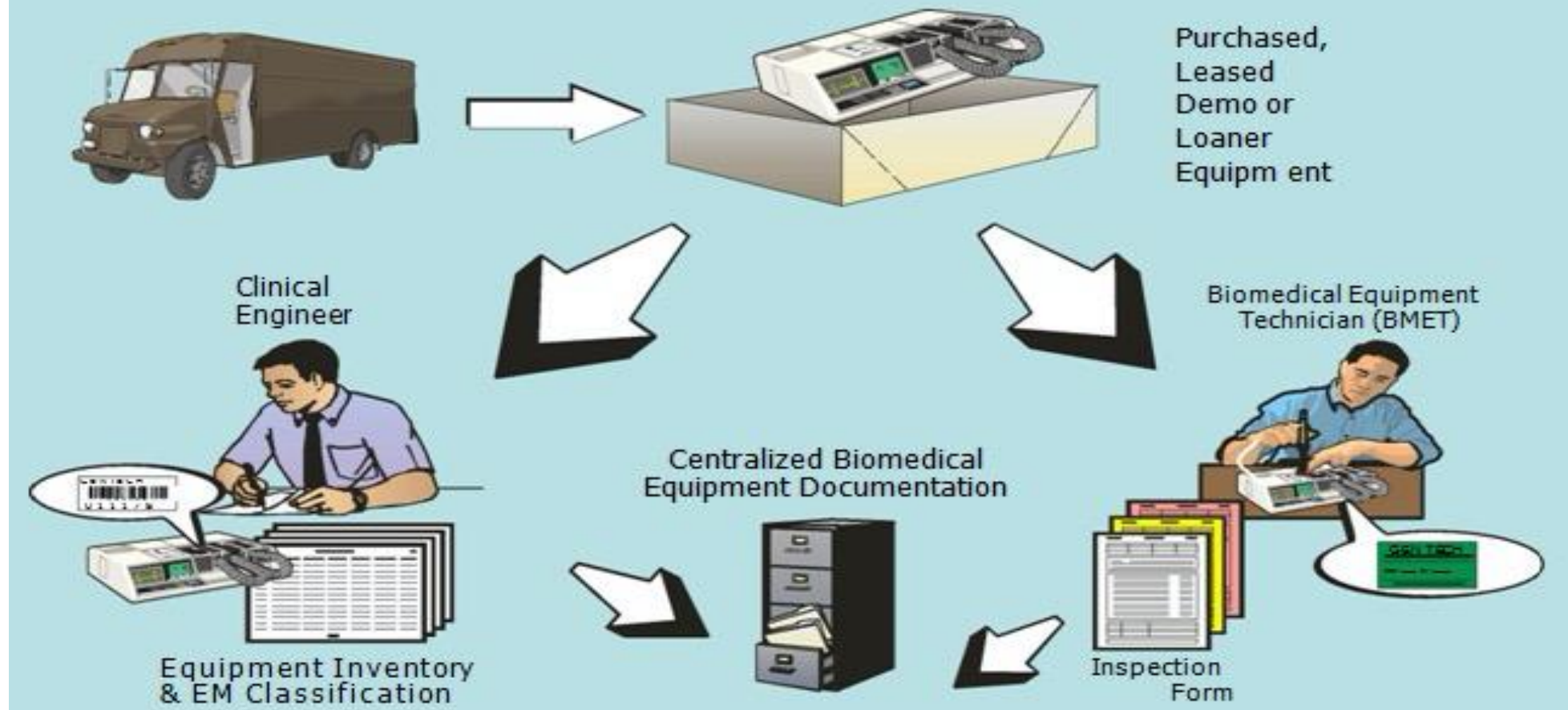
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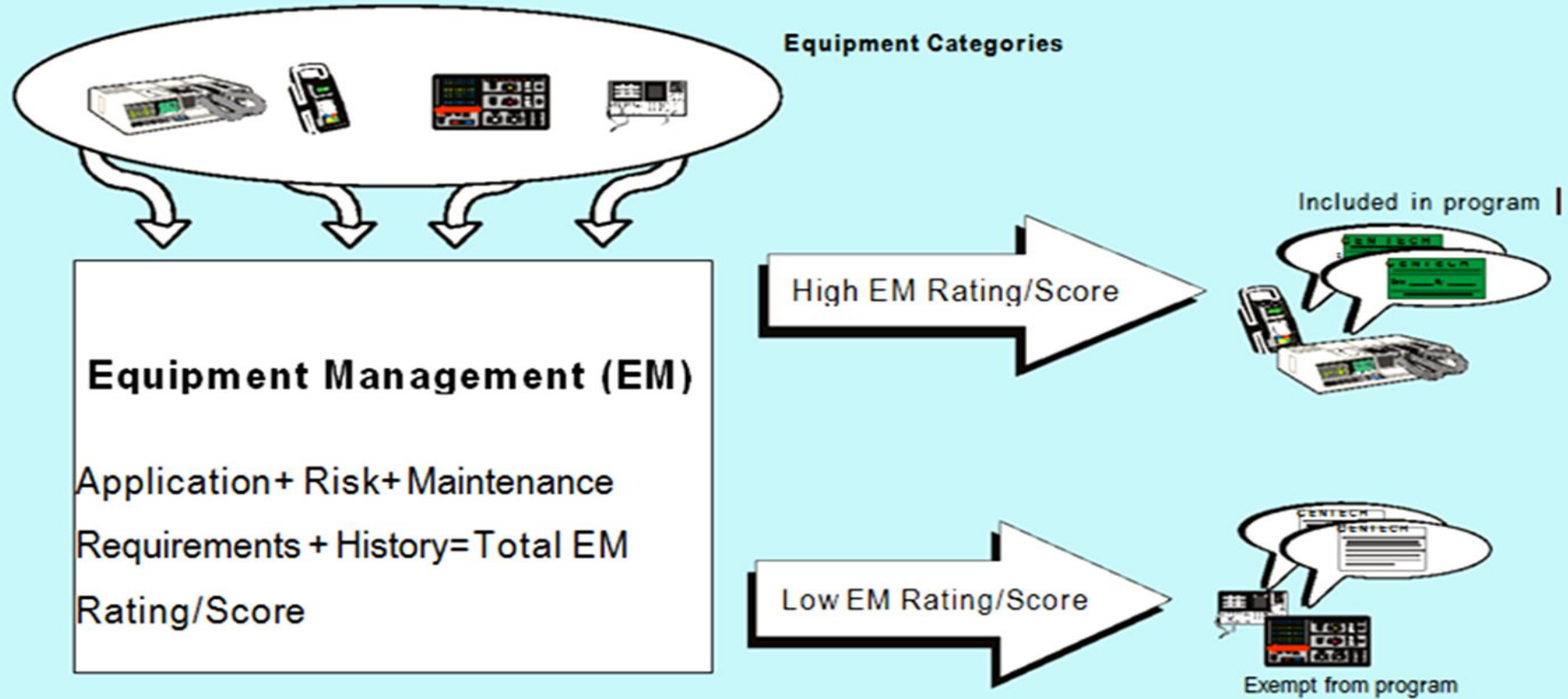
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PREVENTIVE MAINTENANCE

Incoming Inspection of Biomedical Equipment



Equipment Management Program



Equipment Management (EM) Number WHO

EM number :

EM # = Function # + Clinical Application # + Maintenance # + History #

Peralatan dengan angka EM ≥ 12 harus dimasukkan ke dalam daftar peralatan yang wajib dilakukan preventive maintenance.

Function Number

Category	Function description	Point score
Therapic	Life support	10
	Surgical and intensive care	9
	Physical therapy and treatment	8
Diagnostic	Surgical and intensive care monitoring	7
	Additional physiological monitoring and diagnostic	6
Analytical	Analytical laboratory	5
	Laboratory accessories	4
Miscellaneous	Computers and related	3
	Patient related and other	2

Clinical Application Number

Description of use risk	Point score
Potential patient death	5
Potential patient or operator injury	4
Inappropriate therapy or misdiagnosis	3
Equipment damage	2
No significant identified risk	1



Maintenance Number

Maintenance requirement	Point score
Extensive: routine calibration and part replacement required	5
Above-average	4
Average: performance verification and safety testing	3
Below-average	2
Minimal: visual inspection	1

History Number

Average equipment failures	Factor
Significant: more than one every 1 months	+2
Significant: more than one every 3 months	+1
Significant: more than one every 6 months	0
Significant: more than one every 9 months	-1
Significant: more than one every 12 months	-2

Device description	Equipment function	Clinical application	Maintenance requirement	Incident history	EM #	Inspection	Inspection frequency
Anaesthesia machine	10	5	5	0	20	I	T
Anaesthesia vaporizer (enflurane/ethrane)	9	5	3	-2	15	I	S
Arthroscopic surgical unit	9	4	2	-2	13	I	A
Breast pump	3	4	3	-2	8	N	-
Aspirator, mobile	8	5	4	-1	16	I	S
Blood warmer	9	4	3	-1	15	I	S
Bonesaw	9	4	2	-2	3	I	A
Blood pressure module	7	3	2	0	12	I	A
Camera, video, medical	6	3	3	0	12	I	A
Castcutter	2	4	3	-2	7	N	-
Castcuttervacuum	2	2	3	-2	5	N	-
Cardiac output computer	7	3	2	0	12	I	A
Computer, micro (pc)	3	3	1	-2	5	N	-
Cryosurgical unit	9	4	3	-1	15	I	S
Defibrillator/monitor	9	5	4	0	18	I	S
Electrocardiograph, 3-channel	6	3	5	2	16	I	S
Endoscopic video system	6	3	3	0	12	I	A
Electrosurgical unit	9	4	3	0	16	I	S
Fetal monitor	7	3	3	0	13	I	A
Humidifier, heated	8	3	3	1	15	I	S
Hypo/hyperthermia machine	9	4	5	0	18	I	S
Light, surgical portable	2	4	3	-1	8	N	-
Light source, fibre optic	7	3	3	-2	11	N	-
Microscope, ophthalmicslit lamp	6	3	3	-2	10	N	-

Anesthesia Unit Vaporizers

Used For:
Anesthesia Unit Vaporizers [10-144]

Also Called: By trade names (e.g., Fluotec 5, Vapor 19.1, Tec 6), which are registered trademarks and should be used only when referring to the specific devices

Commonly Used In: Operating rooms, emergency rooms, delivery rooms, trauma rooms, and any areas requiring the administration of an inhalation agent (with anesthesia units)

Scope: Applies to the various anesthesia vaporizers used to deliver a known concentration of vaporized liquid anesthetic

Risk Level: ECRI Recommended, High; Hospital Assessment, _____

Type	ECRI-Recommended Interval*	Interval Used By Hospital	Time Required
Major	6 months	___ months	___ - ___ hours
Minor	NA	___ months	___ - ___ hours

* Additional periodic calibration and preventive maintenance is normally required annually or biannually (see manufacturer's recommendation). Only qualified personnel trained and experienced in this function should perform this additional servicing.

Overview

An anesthesia unit vaporizer is used to vaporize a liquid anesthetic agent and deliver a controlled amount to the patient.

According to the American Society for Testing and Materials (ASTM) standard ASTM F1161-88, anesthetic agent vaporizers are required to be concentration calibrated (i.e., a calibrated knob controls the output concentration). Older vaporizers, such as the Copper Kettle and the Vernitrol, do not have a single control for selecting the concentration of anesthetic vapor. Where possible, these units should be removed from service. Contemporary concentration-calibrated vaporizers are of two types: variable bypass and heated blender.

Conventional (variable-bypass) vaporizers. In a variable-bypass vaporizer, the total background gas flow that enters the unit is split into two streams. The

smaller stream, which acts as the carrier gas, passes through the vaporizing chamber containing the anesthetic agent and becomes saturated with agent vapor; the remainder of the gas bypasses this chamber. A wick may be used in the vaporizing chamber to provide increased surface area for efficient evaporation of the drug and saturation of the carrier gas. The saturated carrier gas leaves the chamber and mixes with the bypass gas. One adjustment is made to set the desired concentration. This adjustment simultaneously balances the carrier and bypass flows to produce the blend required for the set concentration. The mixture exits the vaporizer and is delivered from the anesthesia machine as the fresh gas to be inspired by the patient.

Evaporation of the liquid agent contained in the chamber is driven by heat absorbed from the walls of the vaporizer; consequently, when evaporation is occurring, the vaporizer and its contents cool. Because the equilibrium vapor pressure of an agent changes

Inspection and Preventive Maintenance System

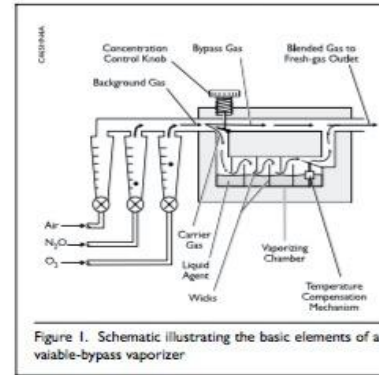


Figure 1. Schematic illustrating the basic elements of a variable-bypass vaporizer

with temperature, a temperature-sensitive mechanism is used to automatically adjust the carrier and bypass flows to compensate for temperature changes. Figure 1 presents a schematic of a variable-bypass vaporizer.

Desflurane (heated-blender) vaporizers. Desflurane, a volatile inhalation anesthetic marketed by Ohmeda Pharmaceutical Products Division under the trade name Suprane®, has characteristics that differ markedly from those currently in use — enflurane, halothane, and isoflurane; for example, its low solubility allows rapid induction of and emergence from anesthesia. Thus, by increasing the speed of recovery, desflurane has the potential to shorten hospital stays (although this has not yet been consistently demonstrated).

The boiling point of desflurane — 22.9°C at 760 mm Hg — is just above room temperature; therefore, small increases in ambient temperature or decreases in atmospheric pressure can cause it to boil. Also, because of desflurane's high minimum alveolar concentration, or MAC (i.e., its low potency), evaporation of sufficient agent to achieve a given anesthetic effect would require much more heat absorption from the vaporizer than occurs with other agents. Furthermore, the change in vapor pressure of desflurane per change in temperature is as much as three times that for the other volatile agents at sea-level atmospheric pressure. These profound effects of temperature and ambient pressure on the vapor pressure of desflurane make stabilizing the delivered concentration at a set point extremely difficult in a passive mechanical system, such as a variable-by-

pass vaporizer. As a result, the variable-bypass design was abandoned for desflurane, and Ohmeda developed a new vaporizer, the Tec 6, based on a heated-blender design. Figure 2 shows a schematic of this vaporizer.

A version of the Tec 6 (also manufactured by Ohmeda) has been adapted for Drager machines and is compatible with the Drager triple-exclusion interlock system. As of this writing, neither Drager nor Siemens has developed its own desflurane vaporizer.

A desflurane vaporizer requires electrical power to heat the agent to a thermostatically controlled 39°C, producing a stable, saturated vapor pressure of 1,500 mm Hg. No wick is used, and no carrier gas enters the sump chamber. Instead, a stream of vapor under pressure flows out of the sump; this stream blends with the background gas stream, which originates from the anesthesia machine's flowmeters, to achieve the desired concentration.

The background gas stream passes through a fixed-flow resistor, producing a back pressure upstream of this resistor that is proportional to the background gas flow. The desired desflurane concentration is set on the dial of the adjustable metering valve in the vapor stream; this setting produces a predetermined aperture. The pressure in the vapor upstream of the aperture and the back pressure in the background gas stream are continually sensed by a differential pressure transducer. The transducer controls a pressure-regulating valve in the vapor stream between the sump

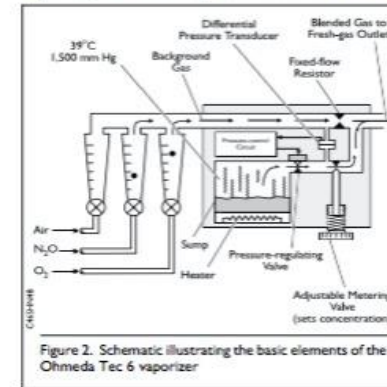


Figure 2. Schematic illustrating the basic elements of the Ohmeda Tec 6 vaporizer

PEDOMAN PENGELOLAAN PERALATAN KESEHATAN DI FASILITAS PELAYANAN KESEHATAN



DIREKTORAT BINA PELAYANAN PENUNJANG MEDIK DAN SARANA KESEHATAN
DIREKTORAT JENDERAL BINA UPAYA KESEHATAN

2015

- Anggaran yang terlalu rendah (*under-estimate*) akan menghasilkan pemeliharaan yang tidak berjalan dengan baik
- Anggaran yang terlalu tinggi (*over-estimate*) akan menjadi tidak efisien dan bisa mengganggu pelayanan penting lainnya yang memerlukan anggaran.

Perkiraan biaya pemeliharaan selama setahun adalah sekitar 5% sampai 6%¹⁰ dari nilai investasi peralatan medis. Biaya pemeliharaan juga dapat dihitung dengan cara yang lebih spesifik berdasarkan kebutuhan rutin tahun sebelumnya serta standar kebutuhan pemeliharaan dari setiap peralatan. Besaran biaya pemeliharaan peralatan medis masing-masing rumah sakit bisa berbeda.

Annualized Investment Cost atau biaya investasi disetahunkan adalah suatu metode untuk menghitung "penggunaan" biaya investasi pada tahun berjalan. Metode ini seperti menghitung biaya depresiasi atau penyusutan pada sistem akunting keuangan.

Annualized Investment Cost menggunakan prinsip Nilai Sekarang (*Present Value = PV*) akan lebih rendah dibanding dengan Nilai Dimasa Depan (*Future Value = FV*), karena adanya infasi nilai uang serta dihitung dengan memperhatikan usia pakai serta usia teknis suatu peralatan kesehatan.

Maksimum Biaya Pemeliharaan

Pelaksanaan kegiatan pemeliharaan peralatan medis tentu membutuhkan biaya, terutama pada saat harus melakukan perbaikan atas bagian yang rusak. Perhitungan Batas Maksimum Biaya Pemeliharaan (*Maximum Maintenance Expenditure Limit = MMEL*) adalah suatu cara untuk menghitung biaya yang masih dapat diterima untuk memperbaiki atau memelihara suatu peralatan medis di rumah sakit.

¹⁰ Caroline Temple-Bird, *How to Manage* Series for Healthcare Technology, Ziken International Consultants Ltd, Lewes, UK

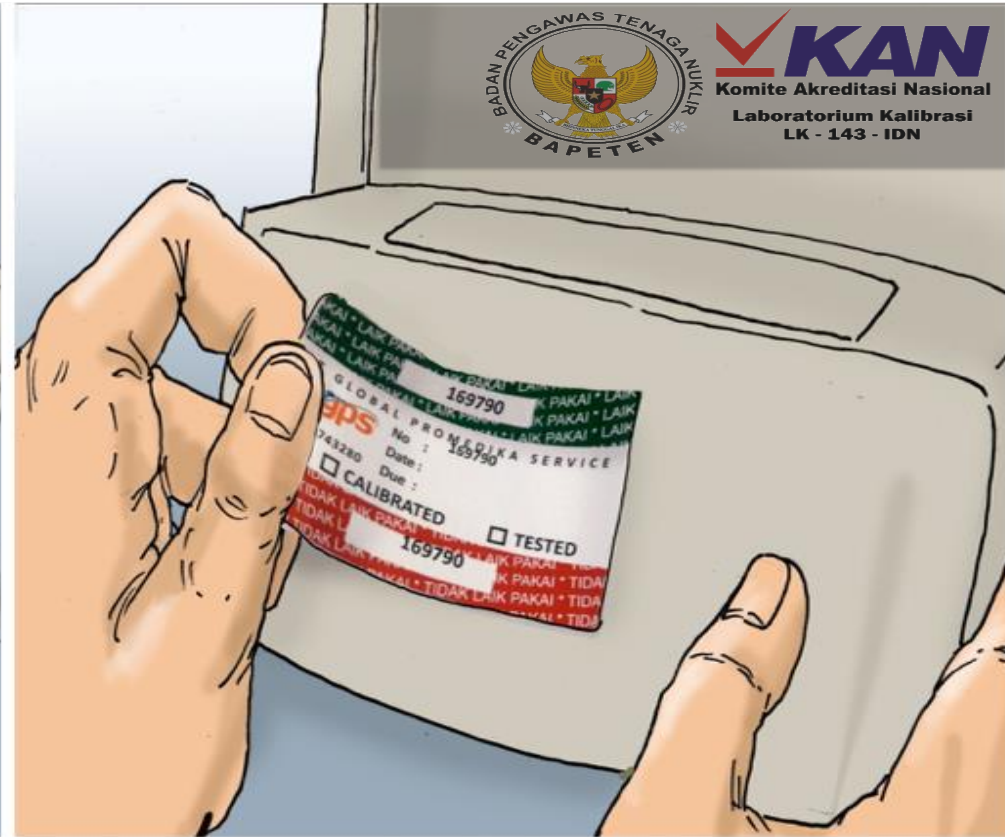


DIS

DI

5

KALIBRASI



Electrical Safety Analyzer

Fungsinya : Digunakan untuk pengujian terhadap standar keamanan listrik.

Contoh : membandingkan hasil batas standart keamanan kelistrikan



Vital Sign Simulator

Fungsinya : Digunakan untuk mensimulasikan dan menguji 12-lead EKG, aritmia, non-invasive blood pressure(NIBP),SpO2,dan suhu.



DIS

DIS

6

RECALL

Equipment Hazard/Recall Program

Manufacturer Recalls & Alerts



FDA Enforcement Reports



ECRI/Health Devices Alerts



Centralized Biomedical Equipment Documentation



Clinical Engineer



Biomedical Equipment Inventory

Action Reports



CONCLUSION

Aspek keamanan ALKES menjadi prioritas utama dalam mewujudkan keamanan pasien.

Kesalahan diagnosa karena rendahnya akurasi ALKES akan menyebabkan kesalahan terapi.

Membutuhkan komitmen bersama untuk mewujudkan program pemeliharaan dalam menjamin keamanan ALKES



Thank You

SECARA
"LINE"
SECARA

