

LAMPIRAN-LAMPIRAN

Lampiran 1.

Tabel 7. Data dekontaminasi sabun pada permukaan keramik

Luas dan Bahan	Laju cacah per detik (dps)							
	I	II	III	IV	V	VI	VII	VIII
±5 x 2,5 cm keramik 1,68 mCi	1448	200	140	46	30	30	28	22
	1440	220	134	44	32	28	28	20
	1452	210	136	46	30	28	24	16
	1440	208	150	50	34	24	20	24
	1446	216	156	52	30	30	18	24
Rerata	1445,2	210,8	143,2	47,6	31,2	28	23,6	21,2

Rerata cacah latar (Σ_{bg}) = 14 dps, rerata cacah (Σ_{rc}) 1,68 mCi = 6400 dps.

Tabel 8. Data dekontaminasi sabun pada permukaan vynil

Luas dan Bahan	Laju cacah per detik (dps)							
	I	II	III	IV	V	VI	VII	VIII
±5 x 2,5 cm Vynil 1,68 mCi	1200	240	180	170	160	120	84	52
	1230	250	176	174	173	128	78	42
	1216	246	180	170	156	118	70	60
	1210	238	184	176	166	110	80	46
	1208	256	182	170	168	116	70	38
Rerata	1212,8	246	180,4	172	164,6	118,4	76,4	47,6

Rerata cacah latar (Σ_{bg}) = 14 dps, rerata cacah (Σ_{rc}) 1,68 mCi = 6780 dps

Tabel 9. Data dekontaminasi sabun pada permukaan kaca

Luas dan Bahan	Laju cacah per detik (dps)							
	I	II	III	IV	V	VI	VII	VIII
±5 x 2,5 cm kaca 1,68 mCi	1480	580	420	40	40	40	30	20
	1468	600	400	52	42	30	24	18
	1450	620	410	48	40	38	24	18
	1480	610	390	50	40	38	22	16
	1472	600	400	50	40	36	30	20
Rerata	1470	602	404	48	40,4	36,4	26	18,4

Rerata cacah latar (Σ_{bg}) = 14 dps, rerata cacah (Σ_{rc}) 1,68 mCi = 6420 dps

Tabel 10. Data dekontaminasi detergen pada permukaan keramik

Luas dan Bahan	Laju cacah per detik (dps)							
	I	II	III	IV	V	VI	VII	VIII
±5 x 2,5 cm keramik 1,68 mCi	1340	110	90	74	58	44	34	24
	1360	118	82	70	64	40	34	20
	1352	114	94	68	50	48	32	26
	1350	114	90	70	60	40	30	20
	1348	110	88	64	52	40	34	22
Rerata	1350	113,2	88,8	69,2	56,8	42,4	32,8	22,4

Rerata cacah latar (Σ_{bg}) = 14 dps, rerata cacah (Σ_{rc}) 1,68 mCi = 6840 dps

Tabel 11. Data dekontaminasi detergen pada permukaan vynil

Luas dan Bahan	Laju cacah per detik (dps)							
$\pm 5 \times 2,5 \text{ cm}$	I	II	III	IV	V	VI	VII	VIII
Vynil	1460	128	118	104	78	56	48	38
	1470	120	118	108	78	64	40	38
	1472	138	112	100	70	52	48	36
1,68 mCi	1468	122	110	104	70	66	48	38
	1466	120	110	102	72	66	42	34
Rerata	1467,2	125,6	113,6	103,6	73,6	60,8	45,2	36,8

Rerata cacah latar (Σbg) = 14 dps, rerata cacah (Σrc) 1,68 mCi = 6450 dps

Tabel 12. Data dekontaminasi detergen pada permukaan kaca

Luas dan Bahan		Laju cacah per detik (dps)							
$\pm 5 \times 2,5$ cm		I	II	III	IV	V	VI	VII	VIII
, kaca 1,68 mCi		1200	382	280	228	184	80	48	28
		1228	388	278	236	176	78	46	34
		1218	388	268	224	188	88	40	20
		1220	382	282	230	170	82	52	22
		1210	386	286	226	184	80	40	22
Rerata		1215,2	385,2	278,8	228,8	180,4	81,6	45,2	25,2

Rerata cacah latar (Σbg) = 14 dps, rerata cacah (Σrc) 1,68 mCi = 6400 dps

Tabel 13. Data dekontaminasi pembersih lantai pada permukaan keramik

Luas dan Bahan		Laju cacah per detik (dps)							
±5 x 2,5 cm		I	II	III	IV	V	VI	VII	VIII
keramik 1,68 mCi		1660	762	460	106	64	54	40	30
		1680	768	464	100	60	50	48	36
		1668	774	456	116	60	58	50	36
		1674	766	458	102	58	50	46	40
		1670	778	460	110	70	50	46	34
Rerata		1670.4	769.6	459.6	106.8	62.4	52.4	46	35.2

Rerata cacah latar (Σbg) = 14 dps, rerata cacah (Σrc) 1,68 mCi = 6810 dps

Tabel 14. Data dekontaminasi pembersih lantai pada permukaan vynil

Luas dan Bahan		Laju cacah per detik (dps)							
±5 x 2,5 cm		I	II	III	IV	V	VI	VII	VIII
Vynil 1,68 mCi		1200	320	220	180	140	120	120	120
		1214	318	220	190	154	114	118	128
		1228	324	218	192	148	122	124	128
		1220	328	216	192	140	120	122	124
		1224	328	220	184	146	120	124	118
Rerata		1217,2	323,6	218,8	187,6	145,6	119,2	121,6	123,6

Rerata cacah latar (Σbg) = 14 dps, rerata cacah (Σrc) 1,68 mCi = 6510 dps

Tabel 15. Data dekontaminasi pembersih lantai pada permukaan kaca

Luas dan bahan $\pm 5 \times 2,5$ cm	Laju cacah per detik (dps)							
	I	II	III	IV	V	VI	VII	VIII
Kaca 1,68 mCi	1280	770	550	350	76	50	38	24
	1282	768	554	358	76	52	30	20
	1278	772	556	360	72	52	38	30
	1278	768	558	348	74	58	38	28
	1290	778	552	352	78	50	38	26
Rerata	1281,6	771,2	554	353,6	75,2	52,4	36,4	25,6

Rerata cacah latar (Σ_{bg}) = 15 dps, rerata cacah (Σ_{rc}) 1,68 mCi = 6390 dps



Lampiran 2

Tabel 16. Konversi satuan tradisional dan satuan internasional (Statkiewicz 1983).

1 roentgen (R)	2,58 x 10 ⁻⁴ C/kg udara
	86,9 erg/gram udara
1 milliroentgen (mR)	1 / 1000 R (10 ⁻³ R)
1 rad	100 erg/gram
	1 / 100 J/kg
	1 / 100 Gy
	1 sentigray
1 millirad	1 / 100 rad
1 rem	1 / 100 J/kg
	1 / 100 Sv
	1 sentisievert (cSv)
	10 millisievert (mSv)
1 millirem	1 / 100 rem
1 eksposi (satuan internasional)	1 C/kg = 1 / 2,58 x 10 ⁻⁴ R
1 coulomb	1 ampere second
1 coulomb per kilogram udara	1 eksposi (satuan internasional)
	1 / 2,58 x 10 ⁻⁴ R
1 gray	1 J/kg
	100 rad
	10 desigray
	100 sentigray
	1000 milligray
1 seivert	1 J/kg (untuk sinar-x QF = 1)
	100 rem
	10 desisievert
	100 sentisievert
	100 millisievert
1 erg	10 ⁻⁷ J
1 joule	10 ⁻⁷ erg
	1 newton per meter
	6,24 x 10 ¹⁸ eV

Lampiran 3

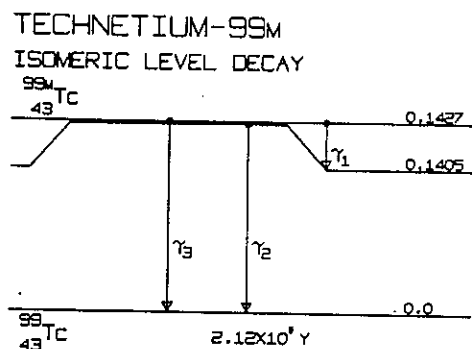
Tabel 17. Satuan kuantitas radiasi

Tipe radiasi	Kuantitas	Satuan tradisional	Satuan Internasional	Medi Pengukur	Efek Pengukuran
X atau γ	eksposi	roentgen (R)	Coulomb per kilogram (C/kg)	udara	Ionisasi udara
Semua radiasi ionisasi	Dosis serap	rad	Gray (Gy)	Sembarang obyek	Jumlah energi yang terserap obyek
Semua radiasi ionisasi	Dosis ekuivalen	Rem	seivert (Sv)	Jaringan tubuh	Efek biologi



Lampiran 4

Gambar 19. Grafik keluaran zat radioaktif Tc^{99m}

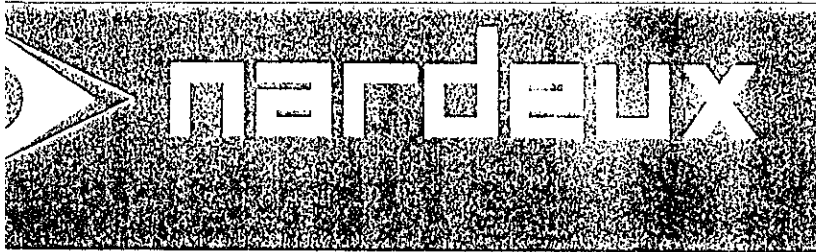


***OUTPUT DATA**

43 TECHNETIUM 99M HALF LIFE = 6.03 HOURS
DECAY MODE- ISOMERIC LEVEL

RADIATION	MEAN NUMBER/ DISINTE- GRATION	MEAN ENERGY/ PAR- TICLE	EQUI- LIBRIUM DOSE CONSTANT
	n_i	$\bar{E}_i$ (MeV)	Δ_i (g-rad/ uCi:h)
GAMMA 1	0.0000	0.0021	0.0000
M INT CON ELECT	0.9860	0.0016	0.0035
GAMMA 2	0.0787	0.1405	0.2630
K INT CON ELECT	0.0913	0.1194	0.0232
L INT CON ELECT	0.0116	0.1377	0.0034
M INT CON ELECT	0.0039	0.1400	0.0011
GAMMA 3	0.0003	0.1426	0.0001
K INT CON ELECT	0.0088	0.1215	0.0022
L INT CON ELECT	0.0035	0.1398	0.0010
M INT CON ELECT	0.0011	0.1422	0.0003
K ALPHA-1 X-RAY	0.0441	0.0183	0.0017
K ALPHA-2 X-RAY	0.0221	0.0182	0.0008
K BETA-1 X-RAY	0.0105	0.0206	0.0004
KLL AUGER ELECT	0.0152	0.0154	0.0005
KLX AUGER ELECT	0.0055	0.0178	0.0002
LMM AUGER ELECT	0.1093	0.0019	0.0004
MXY AUGER ELECT	1.2359	0.0004	0.0011





Portatif - Autonome - Etanche

Adaptation possible de tous détecteurs

Dynamique de mesure : 0 à 10'000 imp.s⁻¹

Autonomie : 8 à 12 h (selon le type de sonde)

Masse : 4,9 kg

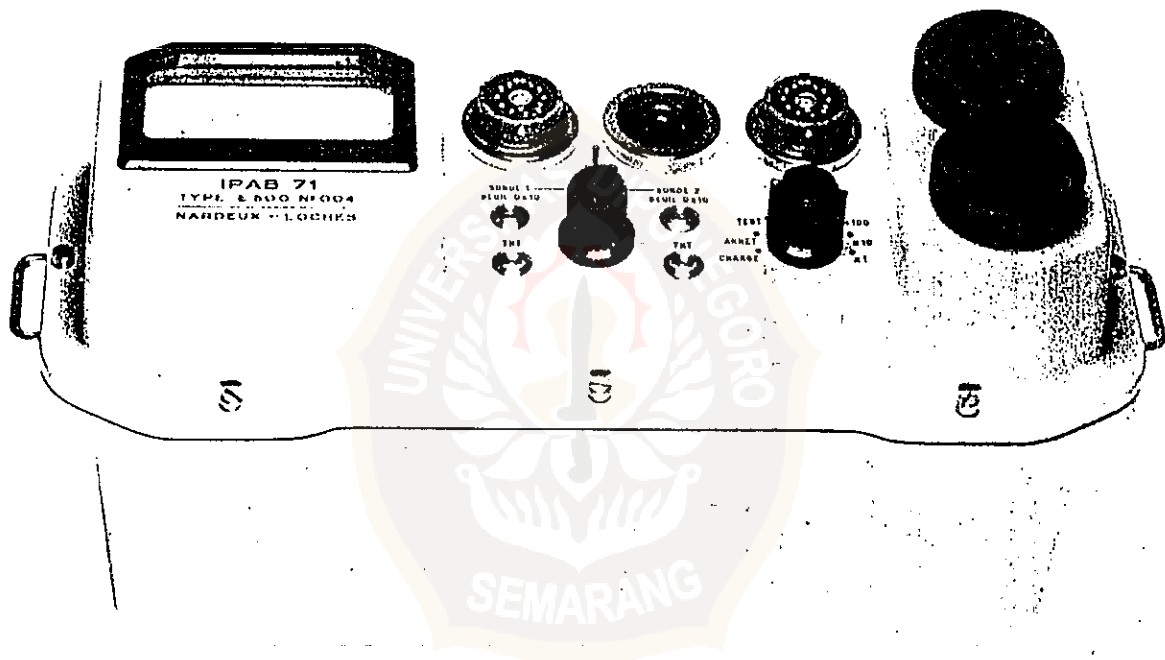
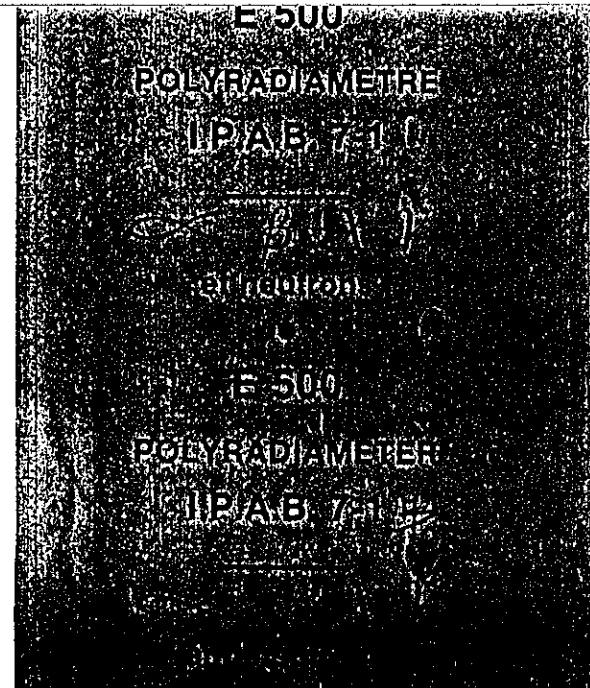
Portable, independent, hermetic.

Possible adaptation of all detectors.

Measuring dynamics : 0 to 10 000 imp.s⁻¹

Battery life : 8 to 12 h. (according to the type of probe)

Weight : 4,9 kg



L'I.P.A.B. 7-1 est destiné à détecter et à mesurer, au moyen de sondes spécialisées, l'intensité des rayonnements alpha - bêta - X - gamma et neutrons, issus de surfaces contaminées ou de générateurs de radiations, (sources, réacteurs, accélérateurs de particules, générateurs X, etc.).

L'appareil comprend une électronique mixte à transistors et circuits intégrés logée dans un boîtier en polyester stratifié moulé. Les sondes, dont le nombre est fonction de l'utilisation, se connectent indifféremment sur l'une ou l'autre des deux entrées commutables.

L'I.P.A.B. 7-1 s'adapte aisément aux différentes utilisations, fixes ou mobiles, selon qu'on le destine à l'intervention sur le site ou au contrôle de contamination de surface ou du personnel (mains - pieds - vêtements) tout en conservant l'interchangeabilité dans ces fonctions.

The I.P.A.B. 7-1 is used for detecting and measuring, with specialised probes, the intensity of the alpha-beta-X gamma radiations and neutrons coming from contaminated areas or radiation generator (sources, reactors, particle accelerators, X generators, etc.).

The unit includes mixed electronics, with transistors and integrated circuits, placed in a molded case of stratified plastic. The probes, which number depends on the use, are indifferently connected on one or the other of the two switchable inputs.

The I.P.A.B. 7-1 can be easily adapted to the different uses, either fixed or moving ones ; were it be used for an intervention on the spot or for a checking of surface area or staff contamination (hands - feet - clothes), it keeps interchangeable in its functions.

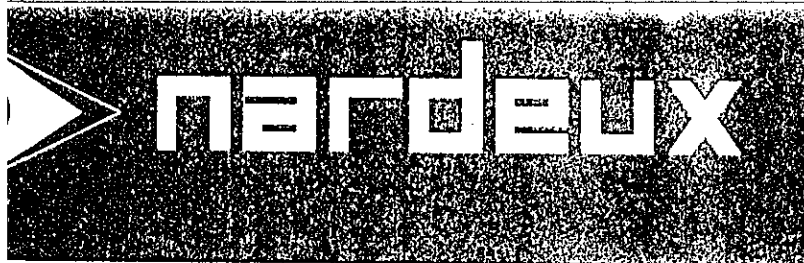
TABLEAU des SONDES ADAPTABLES sur I.P.A.B.7-1

Nature de la mesure	Type de la sonde	Réf.	Type du détecteur	Caractéristiques de la sonde
α	S.I.A. 71	E 519	S	Ø 70 mm - SZn (Ag)
	S.A.S. 3	E 497	J	Semi-conducteur Ø 4 mm
	S.P.A.A. 13-71	E 706	C.P.A.	2 x C.P.A. pour contrôle des semelles
	S.A.P. 100	E 511	C.P.A.	100 cm ² contrôle surfaces et vêtements
	S.A.P. 400	E 512	C.P.A.	400 cm ² contrôle surfaces et mains
CONTAMINATIONS	S.I.B. 2	509601	G.M.	2 x 3 B 17 C - 56 mg.cm ⁻² . Surfaces et vêtements
	S.I.B. 3	509602	G.M.	2 x 3 B 17 CM - 28 mg.cm ⁻² . Surfaces et vêtements
	S.C.B. 2	510601	G.M.	3 x 3 B 17 C - contrôle surfaces et mains
	S.C.B. 3	510602	G.M.	3 x 3 B 17 CM - contrôle surfaces et mains
	S.P.B.G. 1-71	E 704	G.M.	4 x 3 B 17 C - contrôle des semelles
β mous	S.I.B.M. 1-71	E 520	G.M.	Compteur cloche 13 AP7. 1,5 à 2 mg.cm ⁻²
DEBITS	X SX 1	E 488	S	32 x 3 mm. Scint. INa (TI) fenêtre Be
D'EXPOSITION	γ SG 3	E 463	S	32 x 25 mm. Scint. INa (TI)
NEUTRONIQUE	S.N.T. 2	E 661	S. ¹⁰ B	Ø 32 mm neutrons thermiques
	S.N.T. 3	E 662	S. ¹⁰ B	Ø 14 mm neutrons thermiques
	S.N. 3.SI	E 650	He	3 sphères interchangeables : 63 - 107 - 254 mm

Pour plus d'informations, consulter la documentation des sondes

TABLE of the PROBES FITTING on I.P.A.B.7-1

Measuring type	Type of the probe	Ref.	Type of the detector	Characteristics of the probe
α	S.I.A. 71	E 519	S	Ø 70 mm - SZn (Ag)
	S.A.S.3	E 497	J	Semi-conductor - Ø 4 mm
	S.P.A.A. 13-71	E 706	C.P.A.	2xC.P.A. for soles checking
	S.A.P. 100	E 511	C.P.A.	100 cm ² surface & clothes checking
	S.A.P. 400	E 512	C.P.A.	400 cm ² surface & hands checking
CONTAMINATIONS	S.I.B. 2	509601	G.M.	2x3 B 17 C-56 mg.cm ⁻² -surface & clothes
	S.I.B. 2	509602	G.M.	2x3 B 17 CM-28 mg.cm ⁻² -surface & clothes
	S.C.B. 2	510601	G.M.	3x3 B 17 C-surface & hands checking
	S.C.B. 3	510602	G.M.	3x3 B 17 CM-surface & hands checking
	SPBG1-71	E 704	G.M.	4x3 B 17 C-soles checking
β soft	S.I.B.M.1-71	E 520	G.M.	13AP7 bell counter-1,5 to 2 mg.cm ⁻²
EXPOSURE	X SX1	E 488	S	32x3 mm - INa (TI) flasher Be window
FLAWS	γ SG3	E 463	S	32x25 mm - INa (TI) flasher
NEUTRONICS	S.N.T. 2	E 661	S. ¹⁰ B	Ø 32 mm thermic neutrons
	S.N.T.3	E 662	S. ¹⁰ B	Ø 14 mm thermic neutrons
	S.N.3.SI	E 650	He	E removable spheres : 63/107/254 mm



Contamination de zone ou de vêtements type SIB2
éf. 509.601 — Type SIB3 réf. 509.602

Contamination de surfaces ou des mains type SCB2
éf. 510.601 — Type SCB3 réf. 510.602

Contamination des semelles type SPBG1-71 réf. E 704

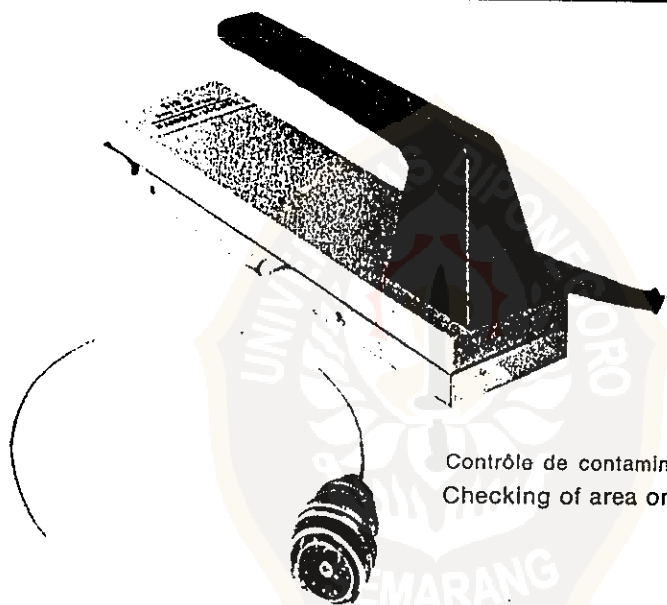
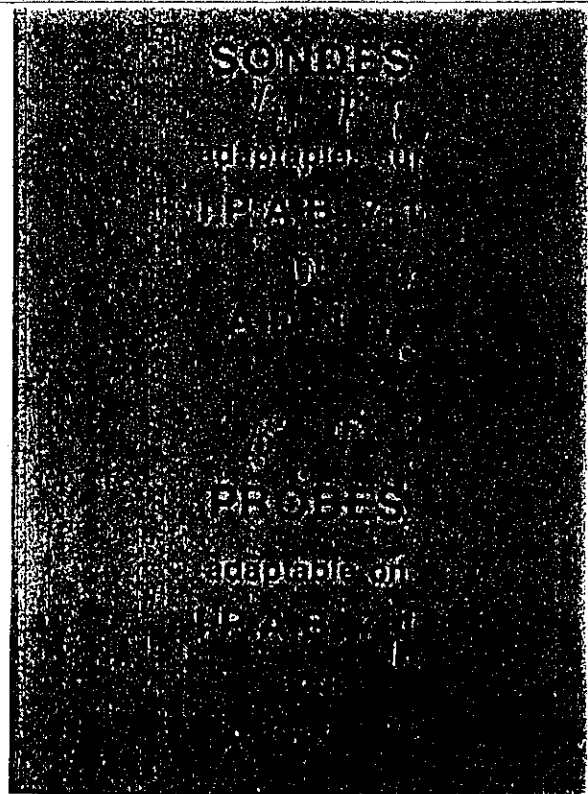
Sonde « bêta mou» type SIBM1-71 réf. E 520

Area or clothes contamination : SIB 2 type ref. 509601 —
SIB 3 type ref. 509602

Surface areas or hands contamination : SCB 2 type
ref. 510601 — SCB 3 type ref. 510602

Soles contamination : SPBG1-71 type ref. E 704

Soft Beta » probe : SIBM 1-71 type ref. E 520.



Contrôle de contamination de zone ou de vêtements
Checking of area or clothes contamination

S.I.B. 2 réf. 509.601 — Contrôle de contamination
(Sonde moyenne surface) de zone ou de vêtements

- Détection : 2 compteurs Geiger-Muller type 3B 17 C
montés en parallèle
épaisseur de la paroi : 56 mg.cm⁻²
- Grille inox 0,8-1 mm ; transparence 68 %
- Surface sensible : 52,5 cm²
- Rendement : 8,6 % 2 π pour ⁹⁰Sr + ⁹⁰Y
13,7 % 2 π pour ³²P
1 imp.s⁻¹ $\rightarrow$ 1,2.10⁻⁵ μ Ci.cm⁻² de ⁹⁰Sr + ⁹⁰Y
1 imp.s⁻¹ $\rightarrow$ 7,5.10⁻⁶ μ Ci.cm⁻² de ³²P
- Mouvement propre : 3 à 4 imp.s⁻¹
- Limite inférieure d'énergie bêta : 250 KeV
Limite inférieure d'énergie gamma : 10 KeV
- Seuil de détection avec écran : 2 MeV gamma
- Dimensions : L = 220 mm - l = 70 mm - H = 90 mm
avec poignée
- Masse : 0,730 kg
- Alimentation : 500 volts.

S.I.B.2 ref. 509601 — Checking of area or clothes
(medium surface area probe) contamination.

- Detection : 2 Geiger Müller counters, type 3 B 17 C,
parallélly connected.
Thickness of the wall : 56 mg.cm⁻²
- Stainless-Steel grid 0,8-1 mm transparency 68 %
- Sensitive area : 52,5 cm²
- Efficiency : 8,6 % 2 π for ⁹⁰Sr + ⁹⁰Y
13,7 % 2 π for ³²P
1 imp.s⁻¹ $\rightarrow$ 1,2.10⁻⁵ μ Ci.cm⁻² of ⁹⁰Sr + ⁹⁰Y
1 imp.s⁻¹ $\rightarrow$ 7,5.10⁻⁶ μ Ci.cm⁻² de ³²P
- Background : 3 to 4 imp s⁻¹
- Beta power lower limit : 250 keV
Gamma power lower limit : 10 keV
- Detection threshold with screen : 2 MeV gamma
- Measures : Length : 220 mm - Width : 70 mm - Height :
90 mm with handle
- Weight : 0,730 kg
- Power supply : 500 volts.



PT. BATAN Teknologi

Nuclear Technology Products & Services

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7560562 Ext. : 2089
Fax : (62-21) 7566646, 7560928

SERTIFIKAT KENDALI KUALITAS ^{99m}Tc

Nomor Batch : **9I02P100**

1. Ukuran Generator : 415 mCi, Tanggal : 06-09-1999 Pukul : 09:00 WIB
2. % Yield : 89,28 %
3. pH : 6,0
4. Kemurnian Radiokimia : 99,84 % dari total aktivitas pada ^{99m}TcO₄⁻
5. Kemurnian Radionuklida :

⁹⁹ Mo	: 0,017769	μ Ci/mCi	^{99m} Tc pada 8 jam setelah elusi
¹⁰³ Ru	: TTD	μ Ci/mCi	^{99m} Tc pada 8 jam setelah elusi
¹³¹ I	: 0,001512	μ Ci/mCi	^{99m} Tc pada 8 jam setelah elusi
⁸⁹ Sr	: TTD	μ Ci/mCi	^{99m} Tc pada 8 jam setelah elusi
⁹⁰ Sr	: TTD	μ Ci/mCi	^{99m} Tc pada 8 jam setelah elusi

Jumlah pemancar gamma
yang lain : 0,001691 μ Ci/mCi ^{99m}Tc pada 8 jam setelah elusi

Waktu elusi : 5 menit Tanggal : 02-09-1999 Pukul : 13:54 WIB

6. Kemurnian Kimia :
Kandungan Al³⁺ : < 2 ppm
7. Sterilitas : Steril (Sterilitas Eluat tidak dijamin setelah hari ke 10)

8. Uji Pirogen : Bebas Pirogen



PT. BATAN Teknologi
Divisi Produksi Radioisotop
Jaminan Kualitas

DISETUJUI OLEH :


DRS. MOERIDUN
Manager QA

TANGGAL : 03-09-1999

Scanning post-injection is optional at about 1-4 hours. Delayed administration of the drug over a period of 30 seconds is recommended.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

HOW SUPPLIED : Technetium Tc-99m Medronate Kit is supplied as a sterile, pyrogen-free kit containing 10 vials. Each 5 ml vial contains 6.8 mg methylen diphosphonic acid and 0.6 mg stannous chloride. The pH has been adjusted to 4-8 with either HCl or NaOH prior to lyophilization. Following lyophilization, the vials are sealed under a nitrogen atmosphere.

Direction

Preparation of Technetium Tc-99m Medronate kit is done by the following aseptic procedure :

1. Remove the central metal disc from the Technetium Tc-99m Medronate kit vial and swab the top of the vial closure with alcohol to sterilize surface.
2. Place the vial in a suitable radiation shield suitably labeled and identified. With a sterile syringe, aseptically obtain 2-8 ml of a suitable, oxidant-free sterile non-pyrogenic sodium pertechnetate Tc-99m Injection.
3. Aseptically add the sodium pertechnetate Tc-99m solution to the vial.
4. Swirl the contents of the vial for one minute and let stand 1-2 minutes.
5. Record date and time of preparation.
6. Aseptically withdraw material for use within six (6) hours of preparation. This preparation contains no bacteriostatic preservative.
7. Do not use more than six hours after preparation.
3. Do not use if solution is cloudy.

IVILF Dose TECHNETIUM 99m MEDRONATE KIT

DIAGNOSTIC - FOR INTRAVENOUS
USE

DESCRIPTION

The kit consist of 10 unitdose reaction vials each containing a sterile, pyrogen - free Lyophilized mixture of 6.8 mg methylen diphosphonic acid, 0.6 mg stannous chloride under a nitrogen atmosphere. Prior to lyophilization the pH was adjusted with hydrochloric acid and/or sodium hydroxide. When sterile, pyrogen-free sodium pertechnetate Tc-99m in, isotonic saline is added to the vial, a chelate Tc-99m Medronate is formed.
Administration is by intravenous injection for diagnostic use. The product as supplied is sterile and pyrogen-free.

PHYSICAL CHARACTERISTICS :

Technetium Tc-99m decays by isomeric transition with a physical half-life of 6.02 hours. Photons that are useful for detection and imaging studies is listed in Table I.

TABLE I. Principle Radiation Emission Data

Radiation	Mean % Disintegration	Mean Energy (ke V)
Gamma-2	88.96	140.5

1. Martin, M.J., ed., Nuclear Decay Data for Selected Radionuclides, p. 24, ORNL 5114, March 1976.

Technetium Tc-99m Medronate is prepared by adding 2-8 ml of oxidant-free sodium pertechnetate Technetium Tc-99m solution to the vial and swirling for about one minute. Shielding should be utilized when preparing the Technetium Tc-99m Medronate.

External Radiation

The specific gamma ray constant for Technetium Tc-99m is 0.8 R/millicurie-hr at 1 cm. The first half value layer is 0.2 mm of Pb. To facilitate control of the radiation exposure from millicurie amounts of this radionuclide, the use of 2.7 mm thickness of Pb will attenuate the radiation emitted by factor of 1,000.

TECHNETIUM Tc-99m Unit Dose MDP TECHNETIUM 99m MEDRONATE KIT

DIAGNOSTIC - FOR INTRAVENOUS
USE



For ordering or technical information,
contact manufacturer :

**RADIOISOTOPE PRODUCTION CENTRE
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0.2	0.5
0.8	10 ⁻¹
1.6	10 ⁻²
2.5	10 ⁻³
3.3	10 ⁻⁴

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals after the time of calibration are shown in table III

TABLE III. Physical Decay Chart : Technetium Tc-99m, Half-life 6.02 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
-5	1.778	5	0.562
-4	1.585	6	0.501
-3	1.413	7	0.447
-2	1.259	8	0.398
-1	1.122	9	0.355
0*	1.000	10	0.316
1	0.891	11	0.282
2	0.794	12	0.251
3	0.708	18	0.126
4	0.631	24	0.063

*Calibration time

The components of the Technetium Tc-99m Medronate Kit are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions should be used during addition of pertechnetate solution and the withdrawal of doses for patient administration.

Radiation Dosimetry

The effective half-life was assumed to be the physical half-life for all calculated values. About 50 % of each dose of Technetium Tc-99m Medronate is retained in skeleton, and about 50 % is excreted into the bladder. The estimated absorbed dose to an average patient (70 kg) from an intravenous injection of a maximum dose of 20 millicuries of Technetium Tc-99m Medronate are shown in Table IV.

Total Body	0.13
Bone Total	0.70
Red Marrow	0.56
Kidneys	0.80
Liver	0.06
Bladder Wall	2.60 4.8 hr void 6.20
Ovaries	0.24 2 hr void 0.34 4.8 hr void
Testes	0.16 2 hr void 0.22 4.8 hr void

Method of calculation : A Schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, p. 7, 1968

CLINIC PHARMACOLOGY : Following intravenous administration of Technetium Tc-99m Medronate, skeletal uptake occurs as a function of blood flow to bone and bone efficiency in extracting the complex. Bone mineral crystals are generally considered to be hydroxyapatite and the complex appears to have an affinity for the hydroxyapatite crystals in bone.

Clearance of the complex from blood is rapid following intravenous administration. Up to 50 % of the injected dose is usually cleared by urinary excretion within the first 3-6 hours. Bone uptake is usually 40-50% within 3 hours following intravenous administration.

INDICATION AND USAGE : Technetium Tc-99m Medronate may be used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINDICATIONS : None known

WARNINGS : This class of compound is known to complex cations such as calcium. Particular caution should be used with patients who have, or who may be predisposed to, hypocalcemia (i.e. alkalosis).

This radiopharmaceutical drug product should not be administered to children, to pregnant women or to nursing mothers, unless the expected benefit to be gained out-weighs the potential risk.

capacities should be performed during the first few (approximately 10) days following the onset of menses.

PRECAUTIONS :

General

Technetium Tc-99m Medronate as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often there after as possible for the next 4-6 hours.

This preparation contains no bacteriostatic preservative. Technetium Tc-99m Medronate should be formulated within six (6) hours prior to clinical use.

Pregnancy Category C

Adequate reproductive studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc-99m Medronate should be used in pregnant women only when clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. As a general rule nursing should not be undertaken while a patient, is on the drug since many drug are excreted in human milk.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTION : No Adverse reactions specifically attributable to the use of Technetium Tc-99m Medronate have been reported.

DOSAGE AND ADMINISTRATION : The suggested dose range for i.v. administration, after reconstitution with oxidant-free sodium pertechnetate Tc-99m injection, to be employed in the average patient (70 kg) is :