NRC FORM 7
(02-2016)
10 CFR 110

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR NRC EXPORT OR IMPORT LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S)

(See Instructions on Pages 4 and 5)

APPROVED BY OMB: NO. 3150-0027 EXPIRES: 11/30/2018

Estimated burden per response to comply with this mandatory collection request: 2.4 hours. This submittal is reviewed to ensure that the applicable statutory, regulatory, and policy considerations are satisfied. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001,or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0027), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

PART A. FOR NRC USE ONLY	☑ PUBLIC OR ☐ NON-PUBLIC	DATE RECEIVED
		APR 07 2017 SZF
LICENSE NUMBER	DOCKET NUMBER	ADAMS ACCESSION NUMBER
XB1335	11006260	

PART B. TO BE COMPLETED FOR ALL LICENSES, AMENDMENTS, RENEWALS, OR CONSENT REQUESTS

(If more space is needed to complete any of the items, use Pages 3-4 first, and then attach additional sheets, if necessary.)

1. NAME AND ADDRESS OF APPLICANT/LICENSEE	1a. NAME OF APPLICANT'S CONTACT	1b. APPLICANT'S REFERENCE NUMBER
Philips Electronics North America Corporation LLC 3000 Minuteman Rd. M/S 109-Exports (Tax) Andover, MA 01810 U.S.A.	Rita Mihalek	NRC1075 CU
	1c. PHONE NUMBER (917) 573-4252	1d. FAX NUMBER
	1e. E-MAIL ADDRESS rita.mihalek@philips.com	

2. TYPE OF ACTION REQUESTED *(Check One)*

☑ EXPORT (Parts B, C, E) ☐ IMPORT (Parts B, D, E) ☐ AMENDMENT/RENEWAL Current License Number: ☐ CONSENT REQUEST (Parts B, C) Current License Number:

3. CONTRACT NUMBER(S)	4. FIRST SHIPMENT DATE	5. LAST SHIPMENT DATE	6. PROPOSED EXPIRATION DATE
12CATE2054291ME	Feb 1, 2017	Dec. 31, 2027	Dec 31, ~~2017~~ 2027

Per T/S Call w/applicant

PART C. TO BE COMPLETED FOR EXPORT LICENSES, AMENDMENTS, OR RENEWALS

(If more space is needed to complete any of the items, use Pages 3-4 first, and then attach additional sheets, if necessary.)

7. NAME(S) / ADDRESS(ES) OF SUPPLIERS AND/OR OTHER PARTIES TO THE EXPORT	8. NAME(S) / ADDRESS(ES) OF INTERMEDIATE FOREIGN CONSIGNEE(S)	9. NAME(S) / ADDRESS(ES) OF ULTIMATE FOREIGN CONSIGNEE(S)
Eckert & Ziegler Isotope Products 24937 Avenue Tibbitts Valencia, CA 91355 USA See page 3	Philips Medical Systems Nederland BV Veenpluis 4-6 5684 PC Best Netherlands See page 4	MediCuba S.A. Calle 2, No. 352, e/ 15 y 17, Vedado Habana Cuba See page 4

7a. FUNCTION(S) PERFORMED/SERVICE(S) PROVIDED	8a. INTERMEDIATE USE(S)	9a. ULTIMATE END USE(S)
Manufacturer/Supplier	Purchase, Sale and Export	Medical device calibration and reference

10. DESCRIPTION OF RADIOACTIVE MATERIALS, SEALED SOURCES, NUCLEAR FACILITIES, EQUIPMENT, OR COMPONENTS; FOR NUCLEAR EQUIPMENT INCLUDE TOTAL DOLLAR VALUE OF EQUIPMENT FOR EXPORT	10a. MAX TOTAL VOLUME / ELEMENT WGT (KG), OR TOTAL ACTIVITY (TBq)	10b. MAX ENRICHMENT OR WGT %	10c. MAX ISOTOPE WGT (KG)
One (1)Set for Calibration Consists of the following: -MMS05-022-10U : 6 x Sodium-22 (Na-22) sealed source marker for calibration and reference. See page 3 -HEGL-0136 : 1 x Sodium-22 (Na-22) line sealed source for calibration and reference. See page 3 Desired: 36 sets total	6 x 370kBq = 2220kBq per 1 set / Total for 36 sets = Total 7.99E-5TBq) 1 x 3.7TBq @ set (36 x 3.7E-6TBq = Total 1.33E-4TBq)	N/A	N/A

11. FOREIGN OBLIGATIONS (BY COUNTRY AND BY PERCENTAGE OF MAXIMUM TOTAL VOLUME)

N/A

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XB1335	11006260		

PART D. TO BE COMPLETED FOR IMPORT LICENSES, AMENDMENTS, OR RENEWALS

(If more space is needed to complete any of the items, use Pages 3-4 first, and then attach additional sheets, if necessary.)

12. NAME(S) / ADDRESS(ES) OF FOREIGN SUPPLIERS AND/OR OTHER PARTIES TO IMPORT	13. NAME(S) / ADDRESS(ES) OF INTERMEDIATE CONSIGNEE(S)	14. NAME(S) / ADDRESS(ES) OF ULTIMATE U. S. CONSIGNEE(S)

12a. NRC EXPORT LICENSE NUMBER(S) *(if applicable)*	13a. LICENSE NUMBER(S) / EXPIRATION DATE(S)	14a. LICENSE NUMBER(S) / EXPIRATION DATE(S)
	13b. INTERMEDIATE USE(S)	14b. ULTIMATE END USE(S)

15. DESCRIPTION OF RADIOACTIVE MATERIALS, SEALED SOURCES, NUCLEAR FACILITIES	15a. MAX TOTAL VOLUME / ELEMENT WGT (KG), OR TOTAL ACTIVITY (TBq)	15b. MAX ENRICHMENT OR WGT %	15c. MAX ISOTOPE WGT (KG)

16. FOREIGN OBLIGATIONS (BY COUNTRY AND BY PERCENTAGE OF MAXIMUM TOTAL VOLUME)

PART E. TO BE COMPLETED FOR ALL LICENSES, AMENDMENTS, RENEWALS OR CONSENT REQUEST(S)

17. ADDITIONAL INFORMATION PROVIDED ON PAGES 3, 4, AND/OR ON SEPARATE SHEETS?	☑ YES ☐ NO	17a. COPIES OF RECIPIENTS' AUTHORIZATIONS PROVIDED?	☐ YES ☐ NO

18. CERTIFICATION: **I, the applicant's authorized official, hereby certify that this application is prepared in conformity with Title10, Code of Federal Regulations, and that all information provided is correct to the best of my knowledge.**

18a. PRINT NAME AND TITLE OF AUTHORIZED OFFICIAL	18b. SIGNATURE -- AUTHORIZED OFFICIAL	18c. DATE
Rita Mihalek Senior Customs Analyst	Rita Mihalek	3/27/2017

APR 07 2017 Recd SZF

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U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR NRC EXPORT OR IMPORT LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S) (Continued)

LICENSE NUMBER	DOCKET NUMBER	ADAMS ACCESSION NUMBER	
XB1335	11006216D.		☑ PUBLIC OR ☐ NON-PUBLIC

ADDITIONAL INFORMATION *(Reference applicable block numbers from page 1 and/or page 2 for each entry)*

Page 1, Block 1: Philips [redacted] North America [redacted] LLC ("PNA") located in Andover, Massachusettes, is the U.S. arm of Royal Philips, headquartered in Amsterdam, Netherlands, and represents all Philips affiliates in matters of U.S. export licensing. PNA is the applicant, but Philips Medical Systems Nederland BV is the purchaser, reseller and exporter of the sources in Block 10 and Block 10a to their preferred distributor in Cuba in Block 9, who will distribute to hospital end-users listed on page 4 under page 1 block 9.

Page 1, Block 10: -MMS05-022-10U/989605600151 Na-22: per source: 1 x 10uCi (370kBq = 3.7E-7TBq) / 6 in one set = 6 x 370kBq = 2220kBq / for total 36 sets = 216 x 370kBq = 79920kBq = 0.00007992TBq = 7.99E-5TBq

-HEGL-0136/989605600211 Na-22: per source: 1 x 100uCi (3.7MBq = 3.7E-6TBq) / 1 in one set / for total 36 sets = 36 x 3.7MBq = 0.0001332TBq = 1.33E-4TBq

Page 1, Block 7: Additional Eckert & Ziegler entities, including IDB Holland, who may be selling to Philips Medical Systems Nederland BV:

Eckert & Ziegler is Philips preferred supplier of calibration sources for their PET CT imaging systems. IDB Holland BV is a major E&Z distributor in the Netherlands that Philips may also purchase from.

Eckert & Ziegler Nuclitec GmbH
Gieselweg 1
38110 Braunschweig, Federal Republic of Germany

Eckert & Ziegler Medizintechnik AG
Robert-Roessle-Str. 10
13125 Berlin, Federal Republic of Germany

Eckert & Ziegler CESIO
Radiova 1
1020227 Prague 10, Czech Republic

Eckert & Ziegler Isotope Products SARL
12 Avenue des Tropiques
Hightec Sud - Batiment B
91955 Courtaboeuf Cedex, France

Eckert & Ziegler Analytics
1380 Seaboard Boulevard
Atlanta, GA 30318 USA

Eckert & Ziegler's Distributor/Supplier in the Netherlands (also a manufacturer):

IDB Holland BV
Weverstraat 17
5111 PV
Baarle-Nassau, Netherlands

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APPLICATION FOR NRC EXPORT OR IMPORT LICENSE, AMENDMENT, RENEWAL, OR CONSENT REQUEST(S) (Continued)

LICENSE NUMBER	DOCKET NUMBER	ADAMS ACCESSION NUMBER	☑ PUBLIC OR ☐ NON-PUBLIC
XB1335	11006260		

ADDITIONAL INFORMATION *(Reference applicable block numbers from page 1 and/or page 2 for each entry)*

Page 1, Block 8: Additional Intermediate Foreign Consignees:

Philips Medical Systems Nederland BV
Boschdijk 525
5621 JG Eindhoven, Netherlands

Page 1, Block 9: Additional Ultimate Consignees and End-Users:

1) Hospital C.Q. Hermanos Almeijeiras
San Lazaro 701, Centro Habana,
Ciudad de la Habana, Cuba

2) Hospital CIMEQ
Calle 216 esquina a 13 Reparto Siboney,
Ciudad de la Habana, Cuba

3) Instituto Nacional de Oncologia (INOR)
Calle 29 esquina a F. La Habana,
Ciudad de la Habana, Cuba

4) Hospital Oncologico Conrado Benitez Garcia
Avenida Libertadores y P. Marti
Santiago de Cuba, Cuba

5) Hospital General Docente Vladimir Ilich Lenin
Avenida Lenin No 4
Holguin, CP 50100, Cuba

6) Hospital Docente Asistencial Celestino Hernandez Robau
Cuba No. 564 entre Barcelona y Hospital
Villa Clara - Santa Clara, Cuba

PHILIPS

Philips North America LLC

U.S. Customs & Export Controls Department
3000 Minuteman Road, Tax Department
Andover, MA 01810

March 27, 2017

VIA On-Line Application to:
The U.S. Department of Treasury
Office of Foreign Assets Control

VIA Federal Express 7787 4438 0310 to:
U.S. Nuclear Regulatory Commission
Deputy Director,
Office of International Programs – Licensing Requests
11555 Rockville Pike
Rockville, MD 20852-2738

LETTER OF EXPLANATION – To OFAC VIA On-Line Application Ref: NRC1087 Cuba
To NRC License Application Submission Ref: NRC1075 Cuba - via FedEX

Action: Request to authorize "Philips" to export calibration and reference sealed sources to Cuba that are controlled for export by the Nuclear Regulatory Commission and required to calibrate a PET-CT medical imaging device according to manufacturers' instructions.

To Whom It May Concern:

Update To NRC: Our prior draft submission to the NRC was dated November 22,2016. This Letter of Explanation is identical to the November 22nd letter except as indicated as follows. This mailing contains todays' date. Due to a tax restructuring, Philips Electronics North America Corporation ("PENAC") has become Philips North America LLC ("PNA LLC") effective March 1, 2017. Our matching OFAC application of November 22, 2016, was assigned Case No. CU-2016-337083-1. We are pleased to submit herewith our formal NRC application for export license to Cuba. Thank you for your consideration.

This is our Letter of Explanation with uploaded supporting documentation seeking review and approval from the U.S. Department of Treasury, Office of Foreign Assets Controls, and the Nuclear Regulatory Commission for the export of required calibration sources for nuclear medical PET CT systems installed and to-be installed in Cuba.

I. BACKGROUND:

Philips North America LLC (formerly Philips Electronics North America Corporation), (collectively,

"PHILIPS"), on behalf of all PHILIPS directly held U.S. affiliates and associated non-US operations, respectfully submitted this specific license application on-line to the Department of the Treasury, Office of Foreign Assets Control (OFAC) in accordance with 31 CFR Part 515 of the Cuban Assets Control Regulations and to the Nuclear Regulatory Commission in accordance with 10 CFR Part 110.28, on November 22, ~~2017~~ 2016. Headquartered in Andover, Massachusetts, Philips North America LLC is the U.S. arm of Royal (Koninklijke) Philips of the Netherlands, and represents all PHILIPS domestic and foreign affiliates in matters of U.S. export licensing.

Per phone conversation w/ applicant 4/13

A draft copy of our completed NRC Form 7 application is provided in Appendix 1 for the dual purpose of an OFAC license review and also an NRC pre-submission-review. It is clear to Philips that the NRC first requires an OFAC authorization prior to the issuance of an NRC license. Therefore, Philips is making every effort to apply for these two licenses as simultaneously as possible.

Philips Medical Systems Nederland B.V., (collectively, "PHILIPS"), on behalf of all Royal Philips directly held Netherlands affiliates and associated non-Netherlands operations, is an additional applicant named in this application. Headquartered in Best, the Netherlands, Philips Medical Systems Nederland B.V., is a subsidiary of Koninklijke (Royal) Philips N.V.

Philips Medical Systems Nederland BV is a subsidiary of Royal (Koninklijke) Philips N.V. ("PHILIPS") and is a leading health technology company focused on improving people's health and enabling better outcomes across the health continuum from healthy living and prevention, to diagnosis, treatment and home care. PHILIPS is a leader in diagnostic imaging, image-guided therapy, patient monitoring and health informatics, as well as in consumer health and home care.

Philips Medical Systems Cleveland, dba Philips Healthcare, is the manufacturer of the Philips Family of Advanced Molecular Imaging PET CT Systems. Current models in this family include Gemini, Ingenuity and Vereos.

Philips Medical Systems Nederland BV, Philips North America LLC and Philips Medical Systems Cleveland are directly or indirectly owned subsidiaries of Royal (Koninklijke) Philips N.V. Collectively, all are affiliates of Royal (Koninklijke) Philips N.V. and known collectively as "PHILIPS".

II. ISSUE:

PHILIPS legally delivered one (1) Philips Advanced Molecular Imaging Systems PET CT, (Gemini) to INOR hospital in Cuba. Three (3) more Philips PET CT systems are authorized by BIS licenses and contracted for future installation to Hermanos Ameijeiras and CIMEQ hospitals in Cuba. (See contract provided in Appendix 6). A further two (2) more PET CT systems are possible future installations at possibly Hospital Oncologico Conrado, Hospital General Docente Vladimir Ilich Lenin or at Hospital Docente Asistencial Celestine Hernandez Robau. (See Figure 1).

Philips PET CT medical system equipment is authorized to Cuba via a U.S. Department of Commerce, Bureau of Industry and Security (BIS) individual valid license and an OFAC General License (see Figure 1). However, the calibration and reference sources used in the PET CT for calibration purposes (see Figure 2) are controlled by the Nuclear Regulatory Commission and the Office of Foreign Assets Control. At issue is the possibility to secure a sustainable authorization from both the NRC and OFAC to supply the required sources needed for calibration of PET CT systems at Cuban hospitals over the next ten (10) years (see Figure 3).

Up until recently, Philips had no PET CT scanners installed at Cuban hospitals. Today there is one (1) installation and in the near future we hope to have up to six (6) systems installed. It is unrealistic to think that PHILIPS can sustain the required supply of source sets to Cuba without assistance from U.S. source manufacturer, Eckert & Ziegler. Eckert & Ziegler is PHILIPS' preferred supplier of medical device sources to all non-sanctioned countries and PHILIPS is hopeful it can obtain the required U.S. government authorizations to offer Eckert & Ziegler sources to PHILIPS customers in Cuba. Without this authorization, PHILIPS will be greatly challenged to find a substitute supplier on the world market.

A set of sources as described in Figure 2 is required at the time of PET CT installation and every two (2) years thereafter according to Philips manufacturers' instructions. Replacement is done at the half-life of the sources because after two (2) years these sources no longer contain activity to support calibration. Based on a forecast of a total of six (6) PET CT systems in Cuba in the next two (2) years, we are requesting 36 source sets which would calibrate the system(s) up to approximately 2027 – 2029, (see Figure 3). The requested quantity and the ten-year (10) year expiration date (December 31, 2027) is to allow a buffer for unforeseen events or delays in manufacturing and installation. We believe this is a logical and reasonable calculation on the demand for equipment and sources given the current economic and political situation.

PHILIPS

III. TRANSACTION DETAILS:

If an OFAC and an NRC license is granted, Philips' distributor in Cuba, MediCuba S.A., will order from Philips Medical Systems Nederland BV the PET CT calibration and reference source sets required for the PET CT systems at Cuban hospitals in Figure 1. Philips Medical Systems Nederland BV will in turn order the source sets from either Eckert & Ziegler or Eckert & Ziegler's distributor, IDB Holland BV. Eckert & Ziegler or IDB Holland will sell to Philips Medical Systems Nederland BV and expedite export and handling on Philips behalf directly to MediCuba in Cuba.

MediCuba is Cuba's government-owned import-export firm for medicines, pharmaceutical raw materials and reagents, medical equipment and suppllies, parts and accessories. Today MediCuba, an integral part of the Ministry of Public Health, has the task of effectively ensuring the imported supplies demanded by primary, secondary and tertiary health care facilities. MediCuba is very interested in purchasing Philips Advanced Molecular Imaging (PET CT) Systems for Cuban hospitals.

MediCuba is authorized by Cuba's National Centre for Nuclear Safety (CNSN) to handle and distribute the calibration sources in this license request. (See Certified Translation from CNSN provided in Appendix 4). The CNSN procedures are in conformity with the Code of Conduct on the Safety and Security of Radioactive Sources and supplementary Guidance on the Import and Export of Radioactive Sources, of the International Atomic Energy Agency (IAEA), and with the nuclear non-proliferation commitments under the treaties on non-proliferation and prohibition of nuclear weapons in Latin America and the Caribbean. MediCuba will be responsible for the transport and handling to the hospitals identified in Figure 2 where the PET-CT scanners are located. (See Eckert & Ziegler End-User Statements provided in Appendix 5).

The initial payment for the PET CT medical system is 100% paid upon export shipment via a confirmed Letter of Credit paid at sight. Included in this payment for the equipment is the cost of our 1-year warranty and the cost of our extended 4-year warranty. The warranty and extended warranty covers the cost of the initial Na-22 source set at installation and two more source sets every other year over the course of the four years extended warranty. After the extended warranty expires, MediCuba can order the sources directly or they can order through Philips (Customer Service Agreement) and pay with a confirmed Letter of Credit and Philips will order the sources from Eckerty & Ziegler for drop shipment directly to Cuba.

PHILIPS

IV. DESCRIPTION OF PET CT SCANNER(S) SYSTEMS IN CUBA:

Philips Family of Advanced Molecular Imaging (AMI) Systems, Series 882/881; – CCAT G152417 – EAR99 - is a diagnostic imaging system that combines Positron Emission Tomography (PET) and Computed Tomography (CT) systems. For example: PET/CT; PET/MR; SPECT/CT imaging systems in the Philips Family of Nuclear Medicine systems. Family includes series Ingenuity, TrueFlight, Gemini, Precedence, Vereos. Includes PROS-TRP 870. (See PET CT product information provided in Appendix 3.)

Figure 1: List of current, future and projected plan to export six (6) PET CT scanners to Cuba

Contract #	BIS License#	Expiration	OFAC License#	AMI System	Hospital	Installed?
12CATE2054291ME	D505366 CLE0786	4/30/15	GL 31 CFR 515.533	Gemini TF64 PET CT	INOR, Cuba	YES
12CATE2054291ME	D1020740 PMU0976	6/30/17	GL 31 CFR 515.533	Gemini TF64 or Ingenuity 128 or Vereos	Hermanos Ameijeiras, Cuba	Future
12CATE2054291ME	D1049694 PMU1046	03/31/18	GL 31 CFR 515.533	Gemini TF64 or Ingenuity 128 or Vereos	CIMEQ, Cuba	Future
12CATE2054291ME	D1049693 BST1047	03/31/18	GL 31 CFR 515.533	Gemini TF64 or Ingenuity 128 or Vereos	CIMEQ, Cuba	Future
TBD	TBD	TBD	TBD	Gemini TF64 or Ingenuity 128 or Vereos	Hospital Oncologico Conrado, Benitez Garcia	Maybe
TBD	TBD	TBD	TBD	Gemini TF64 or Ingenuity 128 or Vereos	Hospital General Docente Vladimir Ilich Lenin	Maybe
TBD	TBD	TBD	TBD	Gemini TF64 or Ingenuity 128 or Vereos	Hospital Docente Asistencial Celestino Hernandez Robau	Maybe

Clarification to Contract No 12CATE2054291ME: The Cuba-Venezuela transaction under this contract is pending authorization under OFAC Case number CU-2015-324607-1 of December 10, 2015. This license application is only for transactions in and for Cuba.

V. DESCRIPTION OF SOURCES FOR CALIBRATION and REFERENCE (NRC-Appendix L) for export to Cuba:

Figure 2: One (1) set consists of six (6) x disks and one (1) x rod

ID#	Description	Unit(s) per Set	Total Activity per Set	Quantity	Total Activity per Quantity
MMS05-022-10U	Sodium-22 (Na-22) sealed QC point disk source	1 set = 6 disks	6 x 3.70kBq = 2220kBq	36 sets	216 x 370kBq = 79920kBq = 0.00007992TBq = Total 7.99E-5TBq
HELG-0136	Sodium-22 (Na-22) line sealed point rod source	1 set = 1 rod	3.7 MBq=3.7E-6TBq	36 sets	36 x 3.7E-6TBq = 0.0001332TBq = Total: 1.33E-4TBq

The sources described in Figure 2 and destined for the systems and hospitals described in Figure 1 require an Nuclear Regulatory Commission license to Cuba and are listed on NRC – Appendix L. These souces are manufactured by Eckert & Ziegler Isotopes Products, a U.S. company and sold either directly to PHILIPS or to PHILIPS via their distributor, IDB Holland BV, a Dutch company located in Baarle-Nassau, Netherlands. (See sources product information provided in Appendix 2).

Figure 3 :

ILLUSTRATIVE PROJECTION FOR DELIVERY OF SOURCES OVER 10 YEAR OBLIGATION PERIOD								
Hospitals:	INOR	HA	CIMEQ	HA Swap Transfer in Country to OTH Hosp	Other Hospital	Other Hospital	Set to be delivered per year	
2013	Installed							
2014								
2015								
2016								
2017		X	X				2	
2018	X			X			4	
2019		X	X		X	X	8	
2020	X			X			10	
2021		X	X		X	X	14	
2022	X			X			16	
2023		X	X		X	X	20	
2024	X			X			22	
2025		X	X		X	X	26	
2026	X			X			28	
2027		X	X		X	X	32	
2028	X			X			34	
2029		X	X		X	X	38	

Legend: Shaded area = 10 year from installation obligation to provide system parts

X (black) = cost covered by payment via L/C *at time of purchase* consists of a 1 year warranty and optional 4 yr extended warranty. (All warranty agreements made at time of purchase). These shipments are Free of Charge.

X (red) = (no warranty) cost covered by payment via L/C under 'Customer Service Agreement' made anytime *after time of purchase*. These shipments are Free of Charge. OR, no 'Customer Service Agreement' and cost covered by payment of via L/C at the time of purchase. These shipments are charged.

VI. Designated Contact:

Additional information covering any aspect of this license request is available upon specific request to Rita Mihalek at 917-573-4252 or at rita.mihalek@philips.com. In addition, we would welcome the opportunity to provide OFAC with an oral presentation in connection with this application as provided in 31 CFR 501.801(b)(3).

Thank you for your consideration of our license request.

Respectfully submitted,

Philips Corporate Fiscal Global Trade & Customs

Rita Mihalek | Senior Customs Analyst | Philips North America LLC | U.S. Trade & Customs/Export Control
3000 Minuteman Road | Tax Dept.| Andover, MA 01810-1099 | ☎:917-573-4252 ✉: rita.mihalek@philips.com

Enc: Attachment: This LOE,
- Appendix 1: Completed Signed NRC Application Form 7 of March 27, 2017
- Appendix 2: Source Sets Product Information
- Appendix 3: High Lever Overview of Philips Family of Advanced Molecular Imaging Systems, Gemini, Ingenuity, Vereos Series 882/881
- Appendix 4: Certified Translation from CNSN
- Appendix 5: Eckert & Ziegler End-User Statements
- Appendix 6: Contract 12CATE2054291ME

Cc:: F.Timmermans, A.Deaconu, K.Terricciano, V.Antonissen

APPENDIX 1

COMPLETED SIGNED NRC APPLICATION FOR 7 DATED MARCH 27, 2017

APPENDIX 2

SOURCE SETS PRODUCT INFORMATION

MMS05-022-10U: SODIUM-22 (Na-22) SEALED SOURCES (Eckert & Ziegler)

HELG-0136: SODIUM-22 (Na-22) SEALED SOURCES (Eckert & Ziegler)

XLR 1075 CU NRC AND OFAC H-LIST - LIST OF ITEMS TO BE EXPORTED FROM THE NETHERLANDS TO CUBA
PET Sources XLR 1075

Line item	Philips Product #	EZ Product Code	Description	EZ Model #	Isotope Name	Nuclide	Nominal Activity mCi/uCi	Nominal Activity MBq/kBq/TBq	System Requires	Quantity Desired	MAX Total Volume	Element wgt (kg), or Total Activity (TBq)	Recommended Replacement	SSDR	Sold As	CE Marked Y/N	Application	PET System used in	Unit Price US$	Extended Price XLR 1075	Total Quantity/price
																					252/$900,000.00
1	989605600151	MMS05-022-10U	Multi-Modal Disc Source - Sealed source marker for calibration and reference.		Sodium-22	Na-22	0.01/10	0.37/370	6	**216**		3,7MBq	2 yrs	N/A	each	Y	QC	Gemini TF	**$20,000**	**$720,000**	
2	989605600211	HEGL-0136	Line Sealed Source for calibration and reference.		Sodium-22	Na-22	0.1/100	3.7/3700	1	**36**		370kBq	2 yrs	N/A	each	Y	QC	Gemini PET/CT	**$5,000**	**$180,000**	
																				$900,000.00	

http://www.ezag.com/home/products/isotope_products/medical_imaging_sources/pet_sources/pet_application_guide/

Gemeni TF/LXL	
Annual Replacement	Qty
HEGL-0136 Na-22, 100uCi, Quality Control Source	1
MMS05-022-10U Na-22, 10uCi, multi modal QC source	6

Gemini TF / LXL	PET	HEGL-0136	1	QC Rod	Na-22	100uCi(3.7MBq)	Nominal
		MMS05-022-10U	6	Multi Modal QC Disc	Na-22	10uCi(370kBq)	Nominal
Ingenuity TF	PET	HEGL-0136	1	QC Rod	Na-22	100uCi(3.7MBq)	Nominal
		MMS05-022-10U	6	Multi Modal QC Disc	Na-22	10uCi(370kBq)	Nominal

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Specifications:

Qty	Product code	Description	Delivery time
6	NA22#MMS05-022-10U	SOURCE DE CALIBRATION POUR TEP PHILIPS GEMINI TF+GXL ACTIVITE : 0.01 mCi / 0.37 MBq	10 to 12 weeks
1	NA22#HEGL-0136 3,7MBQ	SOURCE DE CALIBRATION TEP POUR PHILIPS GEMINI TF ACTIVITE : 0.1 mCi / 3.7 MBq	10 to 12 weeks

Details:

Line Source

Model: HEGL-0136

Na-22 line source for Gemini and Precedence systems

3,7 MBq

50-0-2130NM

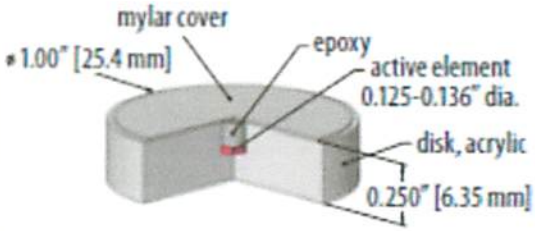
Spot marker

Model: MMS05-022-10U

Na-22 spot marker MMS05 high resolution for Gemini and Precedence systems

3,7 MBq

50-0-2130NM



3/57

REV.	ECO NO.	REVISION	DRAWN	CHECKED	APPROVED	DATE
B	2013571	RELEASE	B.E.LITHEIAN	J.GRIESNER	S.PLUMMER	5-9-98

NOTES:

1: PACKAGE AND INDENT. PART NO. ENGRAVE: MANUFACTURERS NAME, ISOTOPE, ACTIVITY, REFERENCE DATE AND SERIAL NO. CHARACTERS .06 HIGH X .003 DEEP MAX. - BLACK FILL

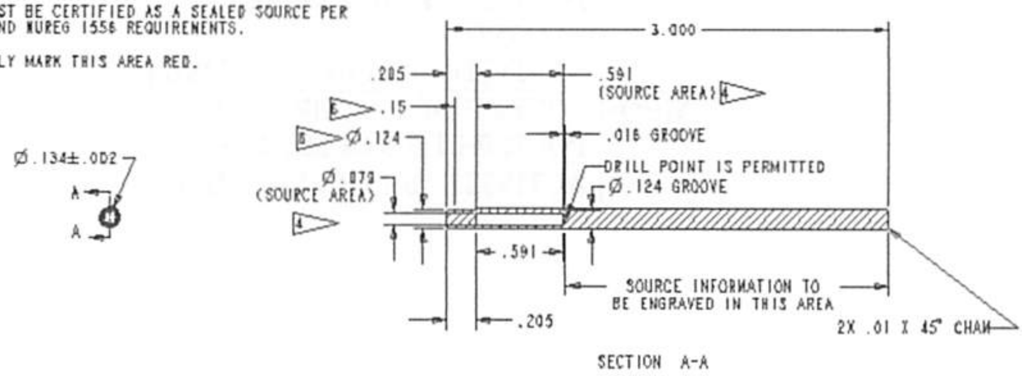
2: FUSION WELD PLUG IN PLACE. (OR EQUIVALENT)

3: STAINLESS STEEL TUBE - PER ISOTOPE PRODUCTS LABORATORIES, BURBANK, CALIF., 91504 - MODEL NO. HEGL-0136

4: Na-22. ACTIVE ELEMENT, 100 uCi +/- 15% ACTIVITY

5: SOURCE MUST BE CERTIFIED AS A SEALED SOURCE PER ISO2919 AND NUREG 1556 REQUIREMENTS.

6: PERMANENTLY MARK THIS AREA RED.



Pro/INTRALINK REVISION.VERSION AND RELEASE LEVEL		
PART/ ASSY REVISION.VERSION	B.D	Production
DRAWING REVISION.VERSION	B.D	Production

Stephen J. Curtis

Material: SEE NOTES

Finish: SEE NOTES

Philips Medical Systems (Cleveland), Inc.

Name: SOLID SOURCE, 100 uCi Na-22

Scale: 2.000 | B | Number: 989605600211 | Sheet: 1 of 1 | Rev: B

PILOTFIRE 2.0

DO NOT SCALE

REV.	ECO NO.	REVISION	DRAWN	CHECKED	APPROVED	DATE
A	2005171	RELEASE	T.FURST	DH-HUA TING	G.COOLEY	6/13/03
B	2009318	CLARIFY DIMENSIONS	D. BECKWITH	J. LONCZAK	S. PLUMMER	03/01/05

NOTES:

1 LOAD ACTIVE ELEMENT (10uCi OF Na22) INTO THE CENTER BORE.

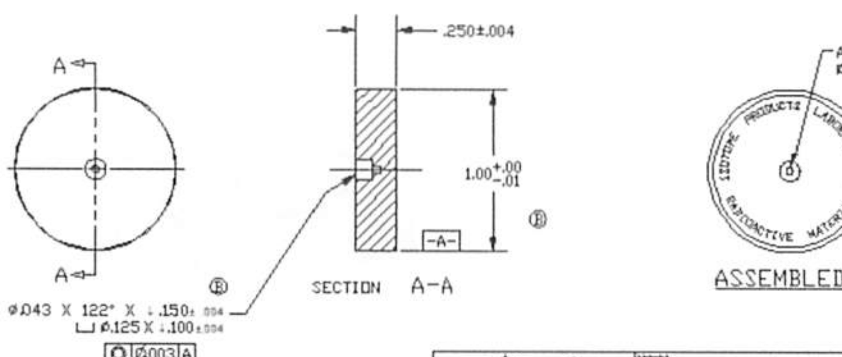
2 EPOXY FILL FLUSH TO 0.25 AND CURE AS REQUIRED.

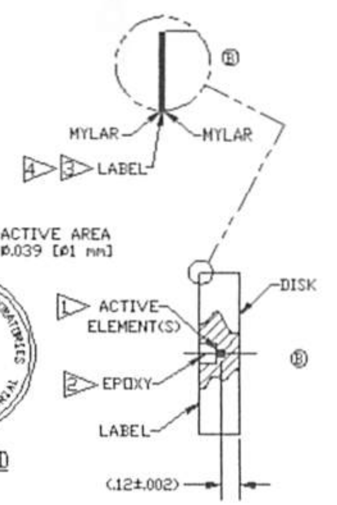
3 COVER ACTIVE AREA WITH A BASE LAYER OF MYLAR, LABEL AND A PROTECTIVE LAYER OF MYLAR.

4 LABEL SOURCE DISK WITH SERIAL NUMBER, NUCLIDE, ACTIVITY STRENGTH AND DATE OF MANUFACTURE.

5) VENDOR INFORMATION: ISOTOPE PRODUCTS LABORATORIES P/N MMS05-022-10U

(B) 24937 AVENUE TIBBITS VALENCIA, CA 91355





Material: GLASS-FILLED TEFLON

Philips Medical Systems (Cleveland), Inc.

Name: POINT SOURCE DISK, 10uci Na22

Scale: 2X (B) | B | Number: 4535 679 48061 | Sheet: 1 of 1 | Rev: B

Software: ACAD 2002

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APPENDIX 3

HIGH LEVEL OVERVIEW OF PHILIPS FAMILY OF ADVANCED MOLECULAR IMAGING SYSTEMS

GEMINI, INGENUITY, VEREOS

SERIES: 882/881

CCAT:

Main Article Group Systems: 82 and 870

NM, Advanced Molecular Imaging

FRU	Description	Material Number	Item	Technical Data	Qty	from	up to	Vendor Code	Sort
	ARC 3000 & 4000 Parts Finder								000010
	Atlas & Pegasys								000020
	Cpet Allegro Gemini Parts Finder								000030
	Cirrus & Argus								000050
	Dual Head Genesys Parts Finder								000060
	GeminiDual								000070
	Single Head Genesys Parts Finder								000080
	Transcams Parts Finder								000090
	Vertex Classic Parts Finder								000100
	Vertex Plus Solus Cardio Parts Finder								000110
	RTP_PROS Parts Manual	870							000120
	PrismXP	88202							000130
	Forte with Atlas	882020							000140
	Forte with Power Pack	882020P							000150
	Skylight	882050							000160
	Axis	882130							000180
	Irix	882140							000190
	Gemini	882160							000200
	CardioMD Series I and II	882170							000201
	Pegasys Sunblade 150	882240							000210
	MOSAIC	882270							000220
	Forte with Jetstream	882290							000230
	Gemini 16 Power	882300							000240
	JetStream Cardiology Workstation	882310							000241
	Forte with Jetstream AZ	882320							000250
	Precedence	882350							000260
	INGENUITY PET/MR SYSTEM	882380							000270
	Gemini GXL	882410							000280
	TruFlight Select	882438							000290
	CardioMD Series III	882450							000291
	Ingenuity TF PET/CT	882456							000292
	GEMINI TF 16	882473							000300
	Gemini TF 64	882474							000310
	GEMINI TF BIG BORE PET/CT SYSTEM	882476							000320
	BrightView	882480							000330
	BrightView XCT	882482							000340

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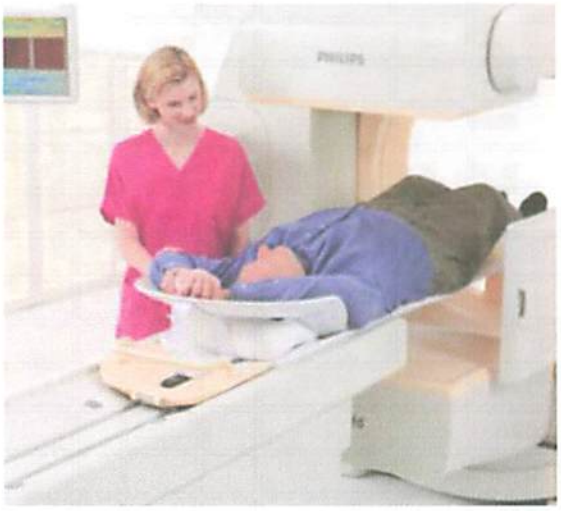
PHILIPS

Main Article Group 882

Advanced Molecular Imaging



Imaging 2.0 introduces a new era in imaging

Imaging 2.0 is a revolutionary approach to a healing environment that focuses on the patient, with greater clinical integration and collaboration to naturally result in less cost and greater efficiency. Look for meaningful tools to increase clinical performance and reduce dose throughout the cycle of care in oncology, cardiology, and neurology.

PET/CT ▸

Powered by Astonish TF to improve contrast resolution and speed, this comprehensive family of products supports oncology, radiation oncology, cardiology, neurology, and molecular imaging applications.

PET/MR ▸

A hybrid modality so original and resourceful that it offers Astonish TF Time-of-Flight technology combined with the superb soft tissue imaging of Achieva 3.0T MRI in a whole-body footprint.

SPECT/CT ▸

Fits you like no other and provides innovative, integrated solutions to give you the tools you need to help diagnose abnormalities early in disease progression.

Workflow solutions ▸

With workflow tailored to you, Philips offers a user-friendly processing and viewing environment for a comprehensive portfolio of Nuclear Medicine (SPECT and PET) and CT applications on one workspace.

http://www.healthcare.philips.com/main/products/nuclearmedicine/

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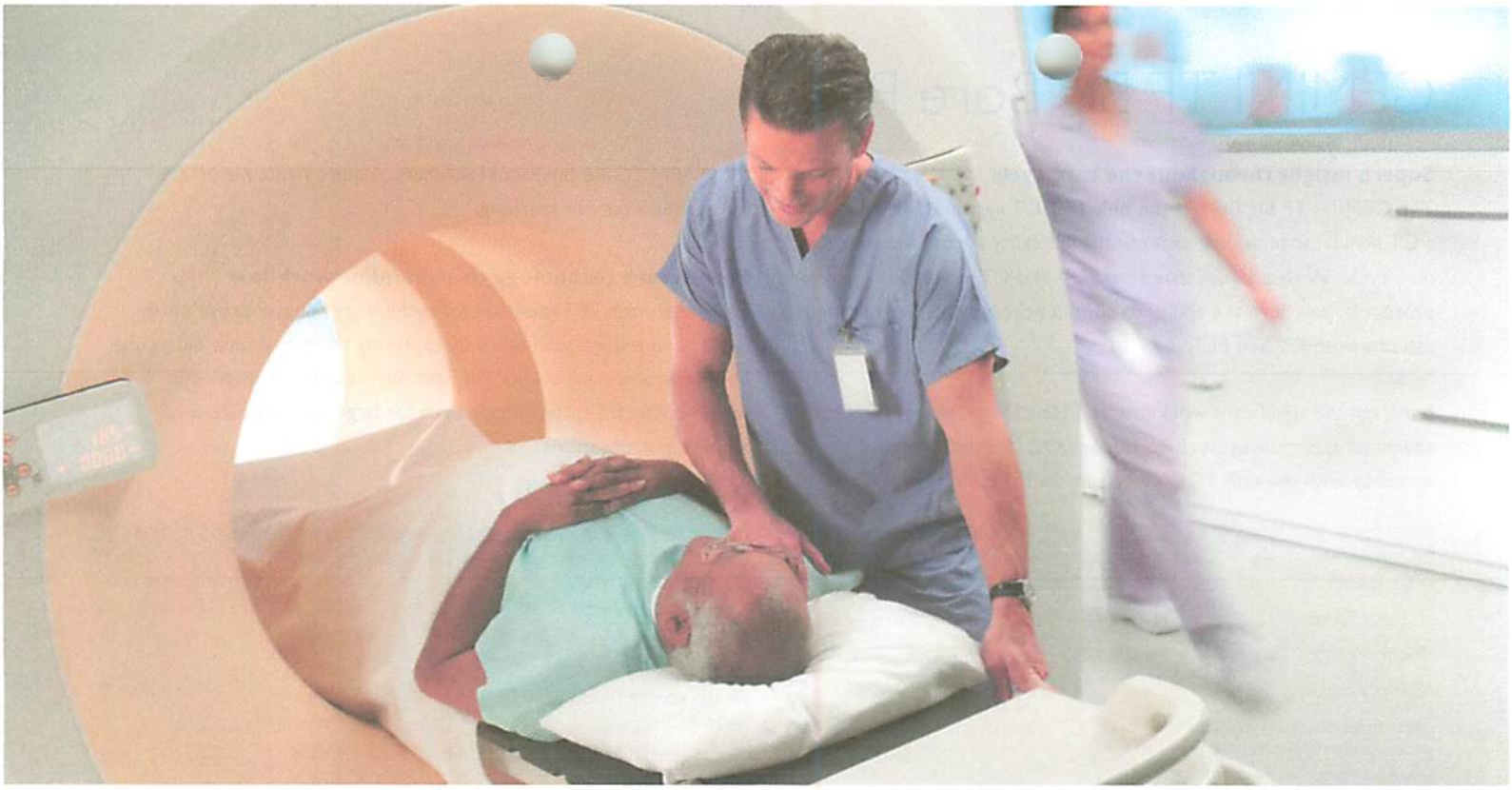

Open up your possibilities

Philips GEMINI TF Big Bore PET/CT specifications

When it comes to streamlining staging, planning, therapy, and follow-up in oncology care, the Philips GEMINI TF Big Bore gives you a flexible solution that lets you do more for patients, efficiently. Combining a CT simulator with state-of-the art PET imaging allows for the integration of molecular information into the radiation therapy planning process. The full 85 cm bore diameter for both PET and CT allows patients to be positioned in the same manner for both simulation and therapy. The rigid table design meets AAPM TG-66 guidelines for positioning accuracy and the 60 cm true CT scan FOV gives you the same capabilities as a premium CT simulator. Astonish TF Time-of-Flight (TOF) technology improves contrast resolution up to 30% compared to non-TOF and provides reconstruction times as fast as 30 seconds per bed.

Key advantages

- Full 85 cm bore diameter for both PET and CT allows positioning consistency between simulation and therapy
- Rigid table design meets stringent AAPM TG-66 guidelines for positioning accuracy
- Astonish TF provides up to 30% improved contrast resolution compared to non-TOF PET

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PHILIPS

sense and simplicity

GEMINI TF Big Bore PET

Superb insight throughout the care cycle

The GEMINI TF Big Bore is the only PET/CT system built with a CT simulator providing exceptional flexibility across the oncology care cycle. With a 60 cm true scan FOV and CT simulation protocols, you have the ability to conduct therapy planning scans utilizing both CT and PET.

Leverage the significant workflow and clinical advantages of our advanced applications, such as Tumor LOC. Further improve accuracy with the only PET/CT system with a table that meets the AAPM TG-66 positional accuracy requirements necessary for absolute patient marking.

Proprietary technology to streamline workflow

Philips Astonish TF Time-of-Flight technology helps improve image quality and reduce scan times by capturing the actual time difference between coincident events. Perform high-resolution, diagnostic whole-body PET scans quickly, even for large patients, across a range of applications.

System overview	
PET platform	Astonish TF
CT platform	Brilliance CT Big Bore
Patient port	85 cm for PET and CT
Gantry cooling	Air-cooled
Attenuation correction	CT
Patient handling system	
Maximum patient weight	227 kg (500 lb)
Vertical travel	47.1 cm
Patient scan range	190 cm
Horizontal speed	185 mm/s
Minimum table height	55.9 cm
AAPM TG-66 positional accuracy	Yes
PET detector design	
Detector design	PIXELAR
Number of crystals	28,336
Crystal size	4 x 4 x 22 mm
Crystal material	LYSO
Number of detector rings	44
Hygroscopic	No
Number of PMTs	420
Ring diameter	90 cm
Transaxial FOV	67.6 cm
Axial FOV	18 cm
Coincidence window size	3.8 ns[1]
Lower level discriminator	460 keV

[1] With 57.6 cm field of view

[2] PET performance specifications represent typical values measured following the methodology of NEMA standard publication NU 2-2007, unless otherwise noted

NEMA performance specifications[2]	
System sensitivity	6600 cps/MBq (center) 6700 cps/MBq (10 cm)
Trans spatial resolution @ 1 cm with LOR[3]	4.7 mm 4.3 mm
Trans spatial resolution @ 10 cm with LOR[3]	5.1 mm 4.7 mm
Axial spatial resolution @ 1 cm With LOR[3]	4.7 mm 4.3 mm
Axial spatial resolution @ 10 cm With LOR[3]	5.2 mm 4.7 mm
Peak noise equivalent count rate – 1R (NECR)	90 kcps @ 14 kBq/ml
Clinical noise equivalent count rate (NECR)[3]	60 kcps @ 5.3 kBq/ml
Max trues	210 kcps
Scatter fraction	26%
System energy resolution	11.7%
Time-of-Flight performance[2]	
Timing resolution	495 ps
Sampling rate	25 ps
Sensitivity gain[4]	2-5x, depending on patient size
System sensitivity	17800 cps/MBq (center) 18000 cps/MBq (10 cm)
Peak NECR	240 kcps @ 14 kBq/ml
Clinical NECR[5]	160 kcps @ 6 kBq/ml
TOF localization accuracy	7.43 cm

[3] Incorporating the effects of Line of Response (LOR) reconstruction

[4] Effective sensitivity gain defined as a ratio between patient size and Time-of-Flight localization accuracy

[5] NEC at a 10 mCi clinical imaging dose for FDG whole body studies in an average patient (73 kg/160 lb)

PET acquisition and reconstruction

- 3rd generation Philips Time-of-Flight technology
- Static, dynamic, and gated acquisition
- List mode acquisition for all protocols
- List mode Time-of-Flight reconstruction
- Fully 3D Line of Response (LOR) processing
- High definition PET reconstruction
- Concurrent acquisition and reconstruction
- CT attenuation correction, including algorithms for metal and contrast artifact reduction

PET software processing

- Comprehensive PET/CT review tools
- Automated 3D contouring

Optional

- Advanced automated registration with CT, MR, and SPECT
- Cardiac perfusion and viability analysis
- Quantitative brain analysis

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GEMINI TF Big Bore CT

Generator	
The Brilliance generator uses modern, low-voltage slip ring technology to provide constant high voltage to the CT X-ray tube assembly.	
Output capacity	60 kW
kV	90, 120, 140 kVp
mA	20-500 mA; 1 mA increment

MRC X-ray tube	
The exceptional heat management demands of multislice imaging calls for an exceptional tube. With its patented spiral groove bearing design, the Philips MRC tube dissipates heat as rapidly as it is collected, with an effective heat storage capacity far superior to a conventional ball bearing design. Additional features include: • Motion-free focal spot enhances image quality • Absolute noiseless design • 2nd generation of MRC tube technology built on proven record of performance and reliability	
Effective heat storage capacity	26 MHU
Anode storage capacity	8.0 MHU
Anode max cooling rate	1608 kHU/min
Large focal spot (IEC)	1.0 mm x 1.0 mm
Small focal spot (IEC)	0.5 mm x 1.0 mm
Anode diameter	200 mm
Anode rotation speed	105 Hz (6300 RPM)
Target angle	7°
Focus-detector distance	1183 mm
Focus-isocenter distance	645 mm

Dynamic focal spot
Enables ultra-high spatial resolution in axial and spiral scanning by sampling two fan beams alternately, doubling the reconstruction data samples.

Tach Technology
Our patented Tach Technology is a complete, high-speed, multichannel data acquisition system (DAS) in a single 8 mm x 8 mm chip. The chip replaces multiple cables and large computer cards seen in conventional multislice CT detector assemblies and delivers a virtually perfect direct digital signal.

Detector	
Our patented detector design enables high-quality images while reducing patient dose.	
Material	Solid-state GOS
Number of elements	19,584 (39,168 effective with DFS)
Dynamic range	1,000,000 to 1
Slip ring	Optical – 2.5 Gbps transfer rate

Data sampling rate	
Up to 5280 views/revolution/element	
360° rotation time	0.44s
Slice collimation	2 x 0.6 mm, 16 x 0.75 mm, 16 x 1.5 mm, 8 x 3.0 mm, 4 x 4.5 mm

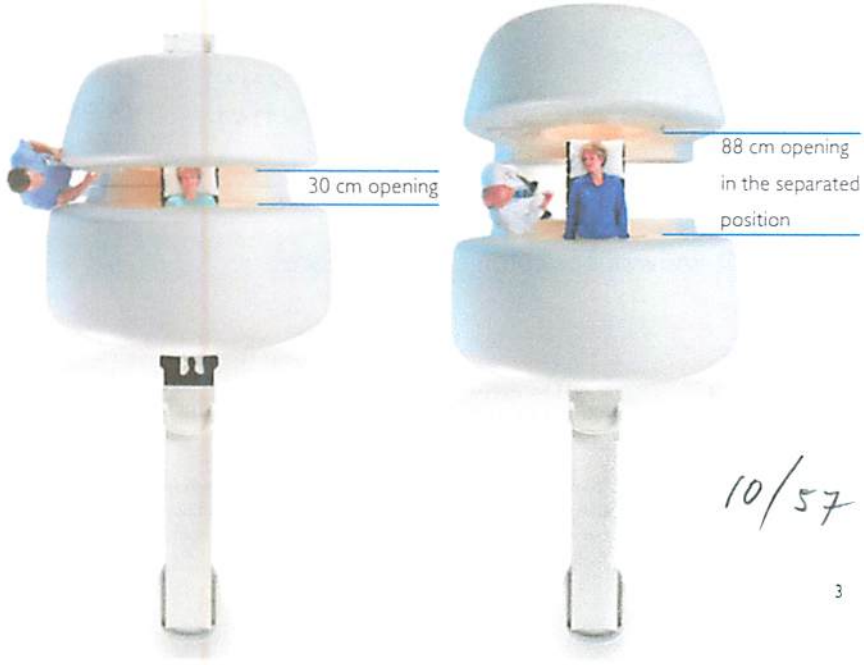
Slice thickness	
Spiral mode	0.65 – 7.5 mm variable
Axial mode	0.75 – 12 mm
Scan angles	240°, 360°, 420°
Scan field of view	250, 350, 500, 600 mm
Display field of view	Up to 70 cm

Image quality	
Spatial resolution (high)	15.0 Lp/cm @ cut-off
Spatial resolution (standard)	12.0 Lp/cm @ cut-off
Noise	0.27% as measured on the Philips system phantom (21.6 cm water equivalent)
Low contrast resolution	4.0 mm @ 0.3% as measured on the 20 cm CATPHAN phantom
Absorption range	-1024 to +3072 Hounsfield units

Dose levels	
CTDIvol – head	10.17 mGy/100 mAs
CTDIvol – body	5.27 mGy/100 mAs

Exclusive OpenView gantry

- Designed to enhance the patient experience, especially for claustrophobic and pediatric patients, and provide patient access to clinicians
- Gantries further separate for expanded access and other clinical applications



Philips GEMINI TF Big Bore makes molecular imaging in radiation therapy a reality.

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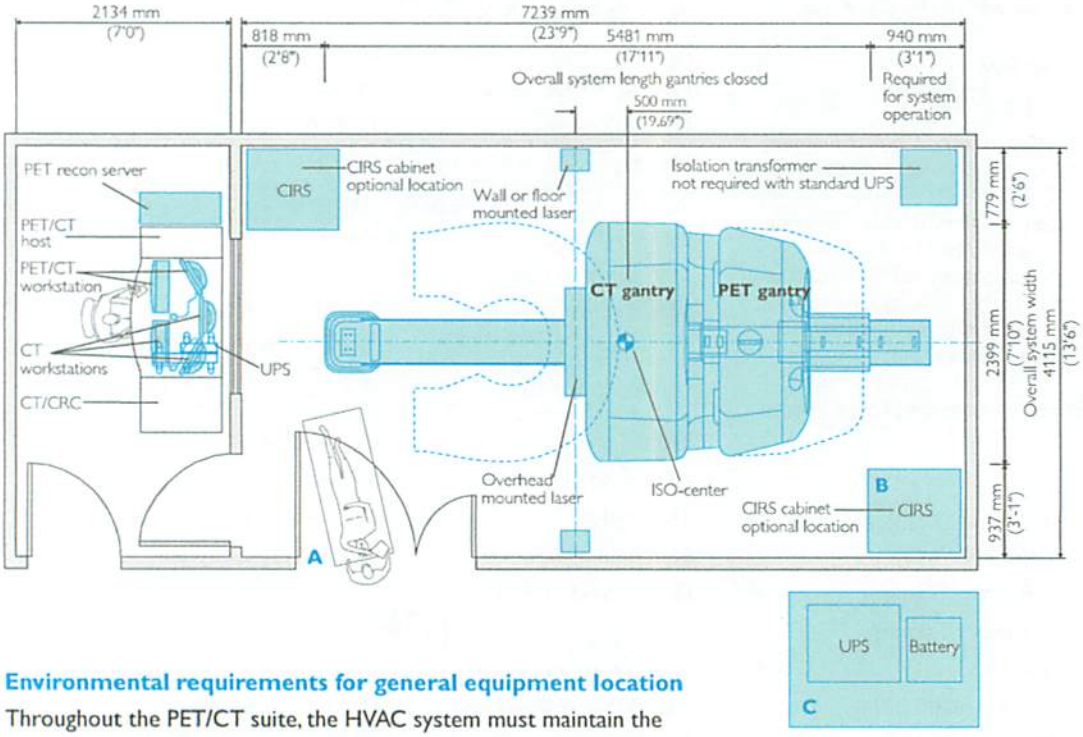
GEMINI TF Big Bore gantry and site planning



A. Recommended scanner room openings

1829 mm (6'0") opening off a 1829 mm (6'0") corridor.
1524 mm (5'0") opening off a 2438 mm (8'0") corridor.

B. CIRS cabinet

May be remotely located within 22860 mm (75 cable feet) of the workstation assemblies and the gantry.

C. UPS system and battery

Minimum area for any Philips approved version UPS is 2134 mm (7'0") x 1524 mm (5'0"). UPS HVAC: 6000 BTUs. Standard UPS system, exact UPS, and battery location shall be determined by customer. Largest UPS (50 Hz version) shown.

Environmental requirements for general equipment location

Throughout the PET/CT suite, the HVAC system must maintain the temperature between 15°C (59°F) to 24°C (75°F). Humidity must be between 35% and 70%, non-condensing. These requirements are 24 hours per day, 7 days per week.

Power requirements	
Main type	Three phase
Room supply voltage	200 – 500 VAC
System voltage, PET/CT (after LM transformer or UPS)	480 VAC +/- 10%
Frequency	50 or 60 Hz, nominal
Power quality	Refer to IEC 61000-4-4 and IEC 61000-4-5
Distribution transformer	100 kVA (minimum)
Minimum room size	
Exam room	7239 x 3810 mm (23'9" x 13'6")
Control room	2134 x 3810 mm (7'0" x 12'6")

Scanner characteristics	
Gantry dimensions (couch home), H x W x D	219 x 239 x 548 cm (86 x 94 x 215 in)
Weight	3863 kg (8500 lb)
Power requirements, PET/CT	100 kVA (maximum)
Heat load (all components)	35,750 BTU/hr
PET/CT system	25,950 BTU/hr
Reconstruction cabinet	5,300 BTU/hr
Control room computers	4,500 BTU/hr

Detailed site planning requirements are documented in the Planning Reference Data (PRD) guide and are available upon request.

Please visit www.philips.com/geminitfbigbore

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Ingenuity TF PET/CT

Meaningful advances take Ingenuity

You've asked us to design answers to the most challenging issues you're facing right now: Accuracy, speed, and dose. This is the result. Ingenuity TF allows you to choose the right scan for your patient without trading off quality or patient dose. Combining the high-fidelity imaging performance of Astonish TF with the latest in Ingenuity CT innovation, including iDose^4, iPatient and SyncRight, Ingenuity TF offers you exceptional image quality, extremely fast scans, and the ability to choose the right dose – without compromise.

Astonish TF
Astonish TF is the next evolution in Time-of-Flight (TOF) technology. With up to 30% improved contrast over non-TOF, Astonish TF provides enhanced lesion detectability with reconstruction speeds as fast as 30 seconds/bed.

iPatient
Philips iPatient is an advanced platform that puts you in control of enhancing your PET/CT system today, while getting you ready for the challenges of tomorrow.

iDose^4
The system also features iDose^4, an iterative reconstruction technique that gives you control of the dial so you can personalize image quality based on your patients' needs at low dose.

Full-fidelity imaging accuracy
PET imaging is evolving from qualitative imaging to quantitative performance. Astonish TF utilizes full listmode capabilities, allowing for fast scans, and exceptional image quality that combine to provide greater accuracy in quantitative assessment.

Speed with purity
With the new Astonish TF design, Ingenuity TF allows you to see fully reconstructed images within minutes of acquisition. Our proprietary reconstruction technology provides the benefits of TOF technology without the sacrifice of speed.

Economic value
With Ingenuity, advances in technology also make sense economically, delivering the results-based scanning you demand.

http://www.healthcare.philips.com/main/products/nuclearmedicine/products/pet/Ingenuity/

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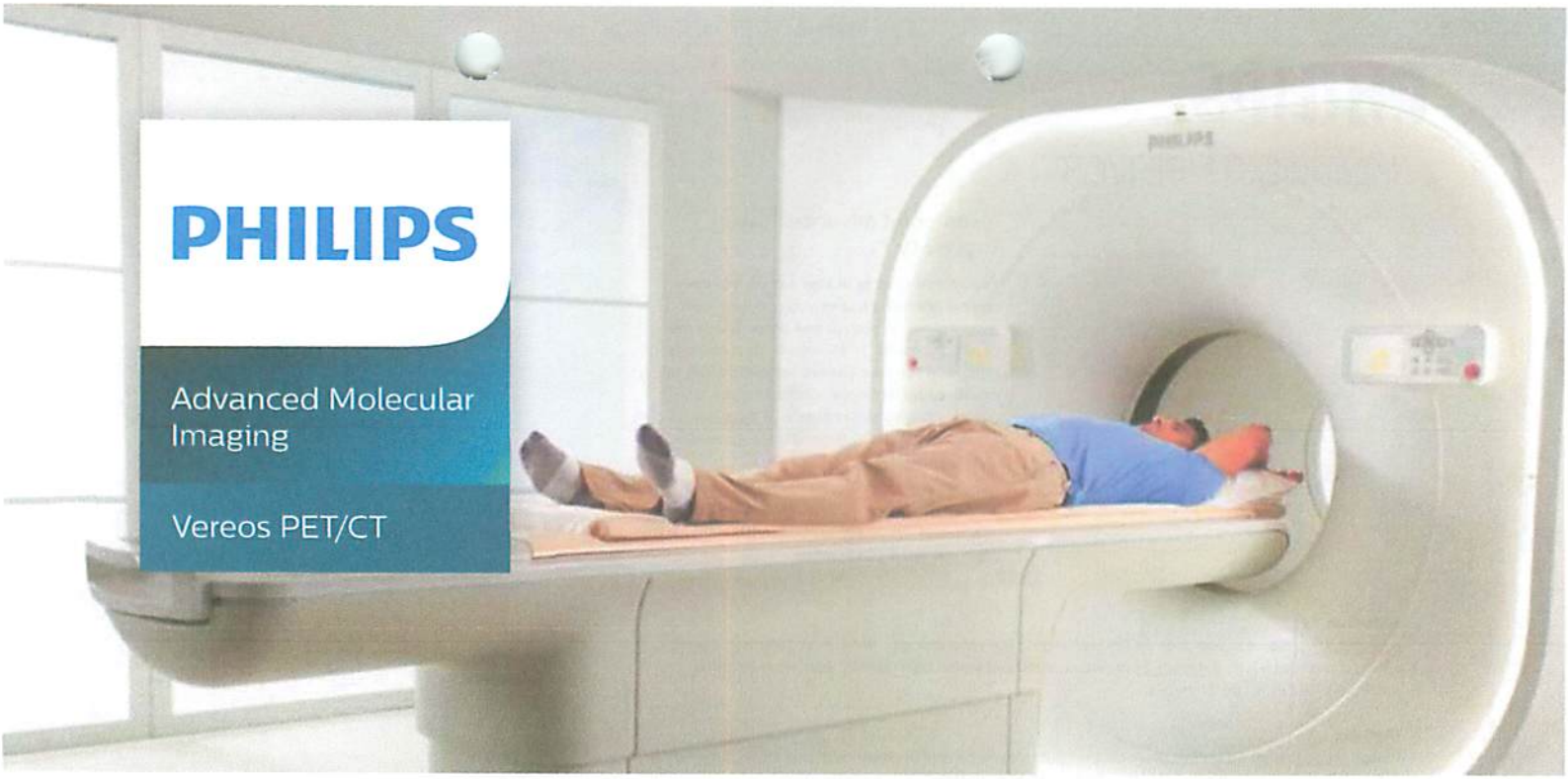

Truly **digital** PET imaging

Philips proprietary Digital Photon Counting technology

Vereos PET/CT is the first commercially available scanner to offer truly digital PET, resulting in significantly improved performance compared with an analog system.* Digital PET is made possible through a number of advances, including proprietary digital photon counting (DPC), 1:1 (pronounced "one-to-one") coupling between the scintillator element and the light-sensing element, and faster Time-of-Flight (TOF) technology.

Philips DPC technology was developed to overcome the limitations of conventional photomultiplier technology. DPC in combination with 1:1 coupling and enhanced TOF allows the Vereos system to offer approximately double the volumetric resolution, sensitivity gain, and accuracy of a comparable analog system.*

Overcoming limitations of conventional PET

Key advances contribute to the high level of performance of Vereos digital PET/CT:

1. Digital photon counting (DPC)
2. Detector tile design
3. DPC and 1:1 coupling
4. Factors influencing performance specifications
5. Timing resolution and TOF technology
6. Point spread function (PSF) technology
7. Technology pillars supporting improved performance

Vereos PET/CT specifications

Preliminary performance data, subject to change.

Number of detectors	23,040
System spatial resolution	4.1 mm
Effective system sensitivity**	22.0 kcps/MBq
Effective peak NECR**	650 kcps @ 50 kBq/mL
Maximum trues	> 675 kcps
System timing resolution	325 ps
Quantitative accuracy	± 5%

*GEMINI TF

**Effective gain defined as a ratio between patient size (20 cm diameter used in these specifications) and TOF localization accuracy.

Digital photon counting (DPC)

At the heart of the digital PET system is Philips proprietary digital photon counting (DPC) technology. This was developed in order to overcome the limitations of conventional photomultiplier technology.

During a PET scan, detectors need to be able to accurately pick up and locate the pairs of high-energy photons that are emitted when positrons, produced by the decay of the radioactive tracer that is introduced into the body before the scan, interact with electrons in the body. Scintillating crystals are used to collect these pairs of high-energy photons and convert them to visible light, which is then picked up by a light sensor, with the output being an electronic signal (ultimately used to construct the resulting image).

Different types of light sensors have been developed over the years: arrays of photomultiplier tubes (PMTs), avalanche photodiodes (APDs), analog silicon photomultipliers (SiPMs), and now – as used in the Vereos PET/CT system – DPC technology.

The older technologies have limitations. PMTs are widely used today, and were the foundation of PET imaging. However, PMT design has reached its limits in counting performance, due to the relatively large size of the device and the timing resolution.

APDs have been used in PET systems for many years, but although they have a higher sensitivity than PMTs, APDs offer lower internal gain and no TOF capability.

Analog SiPMs use single photon avalanche diode (SPAD) arrays. These are capable – as the name suggests – of detecting single photons. However, when used in conventional analog SiPMs, the pulses generated by multiple photon detections (avalanche diode breakdowns) are combined into an analog output signal that requires extensive off-chip processing to produce a photon count and time of arrival for the photon (see **Figure 1**). Also, analog noise interferes with the signal, making it even harder to exactly determine the number of photons and the time of arrival.

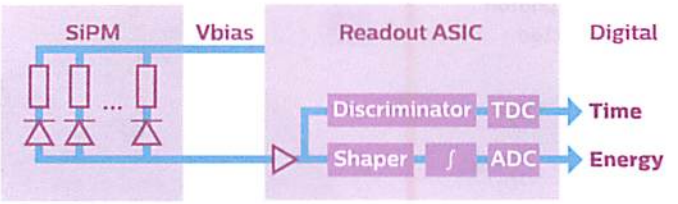

Figure 1 Processing of the analog signal in conventional analog SiPMs. Reproduced from: Frach T, Prescher G, Degenhardt C. Silicon photomultiplier technology goes fully digital. Electronic Engineering Times Europe, January 2010.

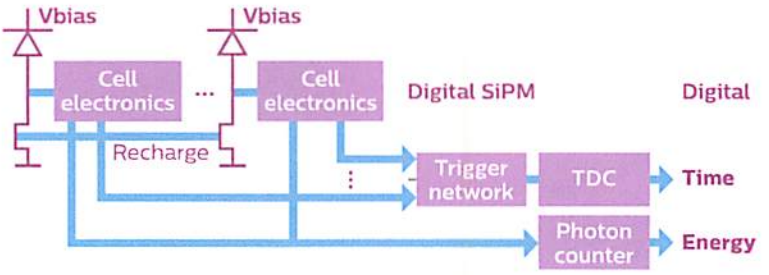

Figure 2 Digital in/digital out photon counting in digital SiPMs. Reproduced from: Frach T, Prescher G, Degenhardt C. Silicon photomultiplier technology goes fully digital. Electronic Engineering Times Europe, January 2010.

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In contrast to analog SiPMs, the digital SiPMs seen in Philips DPC technology enable the detection and counting of the breakdown of individual SPADs on-chip. Light photons produced by the scintillator are counted directly by the chip, yielding a pure binary signal (0 or 1). This is achieved without the need for amplification or off-chip analog-to-digital processing of the signal (see **Figure 2**), minimizing signal noise.

Conventional CMOS (complementary metal-oxide-semiconductor) process technology is used to combine SPADs and low-voltage CMOS logic on the same silicon substrate. With both the sensor and the data processing now on a single silicon chip, photon counting in ultra-low light levels (down to single photons) is faster, more accurate, and fully scalable.

In practice, how are the DPC measurements made?

During a scan, when the first photon reaches a sensor the integrated (on-chip) photon counter increases to 1, and the integrated timer measures the arrival time of the first photon (**Figure 3**, top left). When the second and third photons hit sensors, the photon counter increases to 2 and 3 respectively (**Figure 3**, top right and bottom left). At the end of the desired length of the detection process, the values of the photon counter and timer can be read (**Figure 3**, bottom right).

Data acquisition is initiated by a trigger signal, generated when the number of photons detected in a pixel becomes higher than the configured trigger threshold.

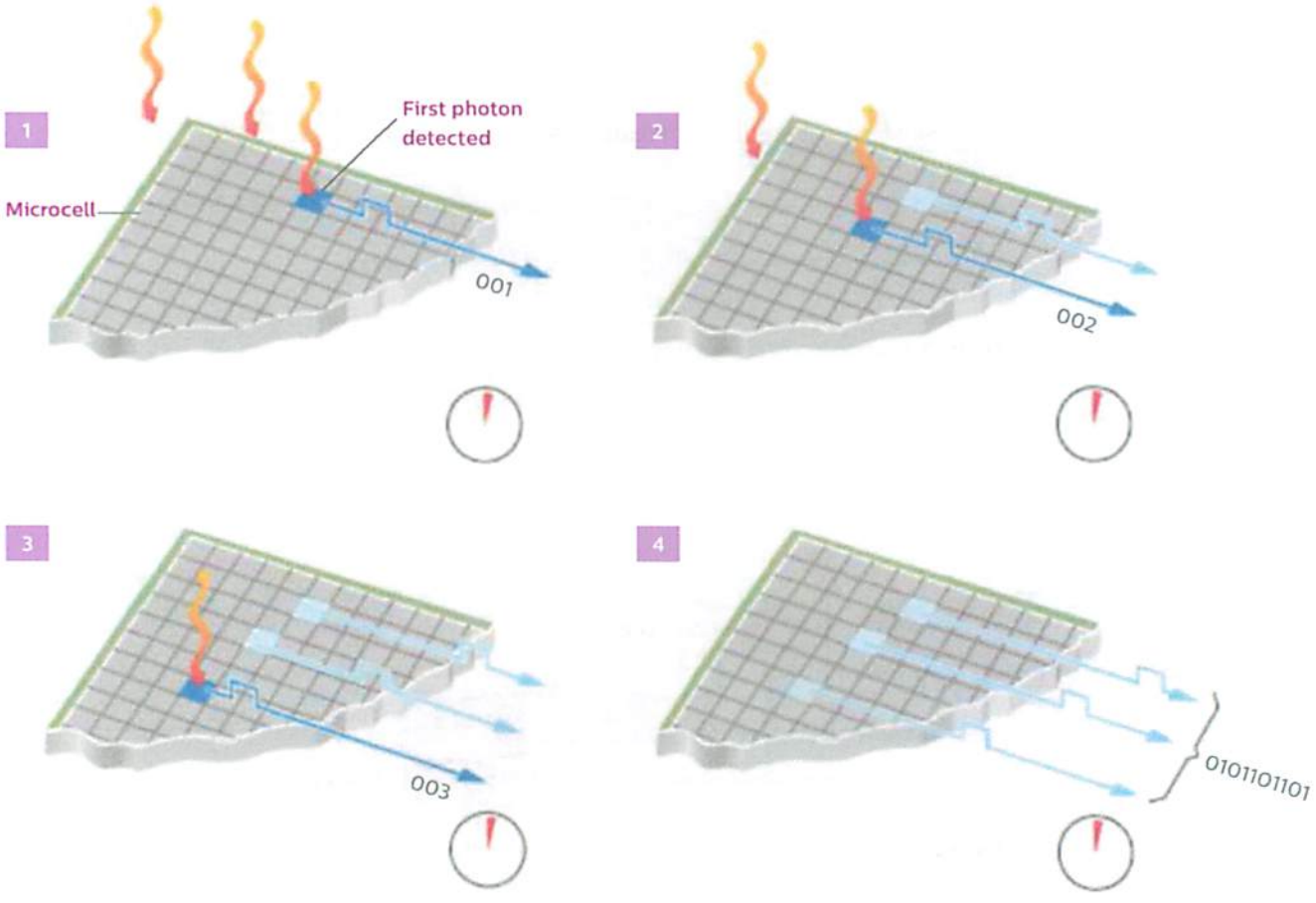

Figure 3 Digital photon counting in practice, showing the arrival and detection of individual photons, and timing measurements.

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Detector tile design

The DPC technology used in the Vereos system takes the form of highly integrated arrays, or tiles, that contain more than 200,000 cells, each of which is capable of detecting a single photon.

Each tile consists of 16 independent die sensors, arranged in a 4 x 4 matrix. Each die sensor consists of four pixels, arranged in a 2 x 2 matrix. Each of these pixels contains 3,200 cells.

Each of the four pixels on a die has a photon count value. Each die contains a pair of time-to-digital converters, which generate a single timestamp for registered photon detection events.

The generation of a trigger signal – when the number of photons detected in a pixel becomes higher than the configured threshold – prompts a timestamp to be saved, and begins a validation process to detect a user-configured number of further photons within a certain time. If this validation threshold is exceeded, there is a subsequent integration period before a readout process sends data (four photon count values – one per pixel on the die – and one timestamp per event) to a readout buffer. After readout, the cells are recharged so that the die is ready for further data acquisition. Cells are also recharged immediately if the original event is not validated. **Figure 4** shows the full data acquisition sequence, and the timings involved.

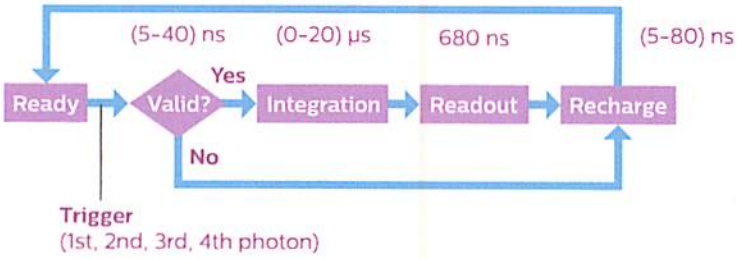

Figure 4 The data acquisition sequence within each die in a digital SiPM.

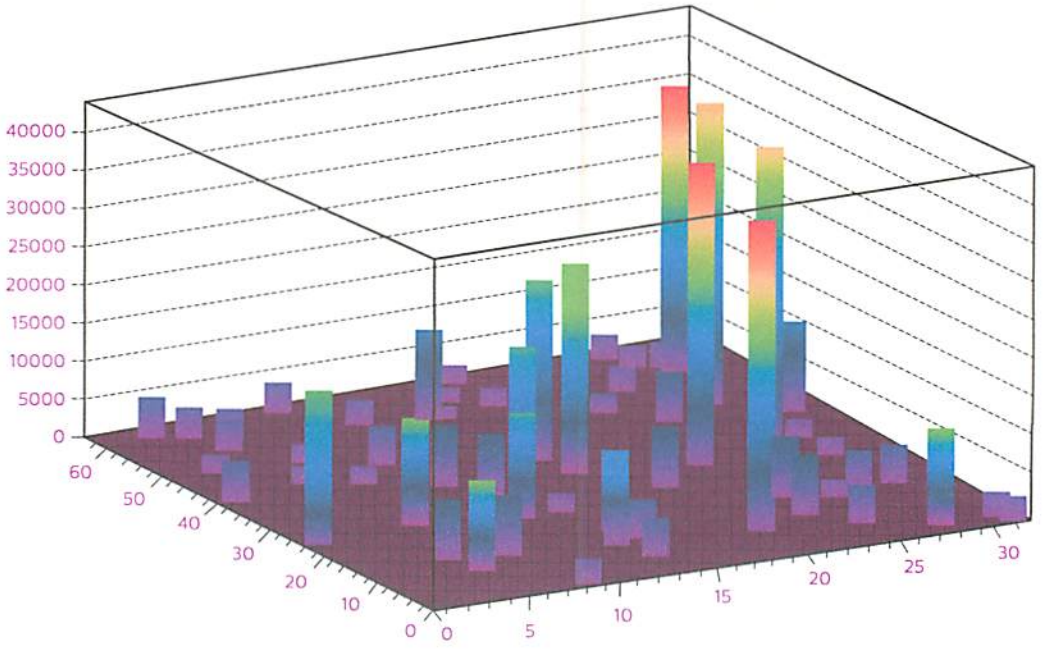

Figure 5 Dark counts of cells in a sub-pixel, at room temperature. Reproduced from Haemisch Y et al. Physics Procedia 2012;371546-60.

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The design of the DPC technology allows every cell to be individually activated or inactivated. This means that background noise – the dark count rate – can be measured and managed effectively.

By switching on and off each individual cell, in a fully dark environment, a map of dark counts can be produced automatically by the system (see **Figure 5** for an example). A cumulative logarithmic plot of dark counts (see **Figure 6**) shows that the overall dark count rate is greatly reduced by switching off the noisiest cells.

The DPC technology is also much less sensitive to temperature variations than conventional analog SiPMs. In analog SiPMs, the temperature dependence of the ionization coefficients and holes in silicon leads to a temperature-dependent drift in each sensor's breakdown voltage and a change in gain. In DPC technology, any shift in breakdown voltage must exceed the threshold voltage of the CMOS inverter before the count rate is affected since the logic gate just looks for voltage above or below the CMOS threshold, not the amount of charge.

The implications of DPC and 1:1 coupling will be discussed in the next section.

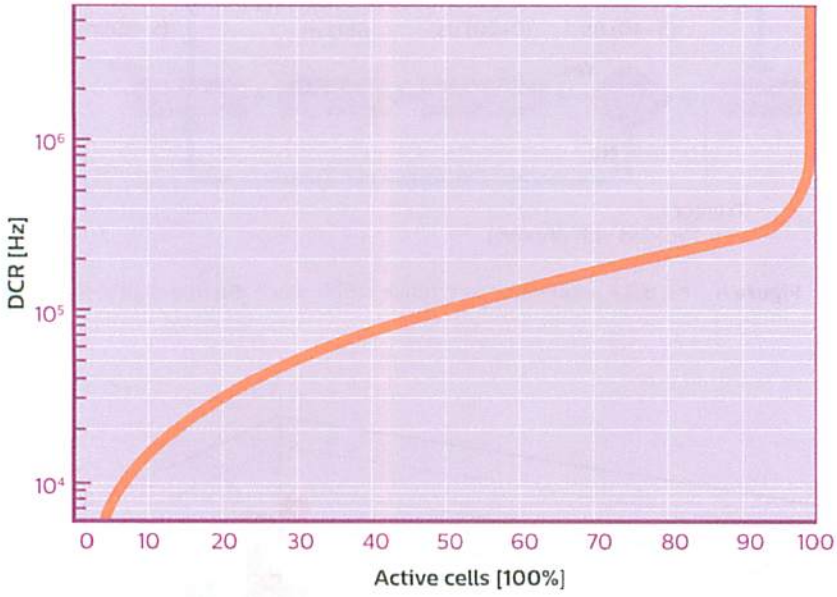

Figure 6 **A cumulative logarithmic plot of dark count rate as a function of the number of active cells.** Reproduced from Haemisch Y, et al. Physics Procedia 2012;37:1546-60.

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DPC and 1:1 coupling

In the detectors used in the Vereos PET/CT system, each scintillator is connected to a single detector pixel. This is called 1:1 coupling (see **Figure 7**).

The 1:1 coupling of scintillator crystals to detectors, coupled with fast timing resolution, reduced pile-up effects, and TOF benefits, allows for a much higher count rate capability compared to analog* systems.

The direct 1:1 coupling also results in an improved spatial resolution. The final spatial resolution of a PET image is the result of multiple factors, some related to the annihilation events and interactions (such as non-co-linearity of annihilation photons, and the positron range), and others related to the detection system (such as the scintillation crystal size and crystal identification, or decoding). In the Vereos system, with 1:1 coupling, the contribution of the decoding is eliminated. A related improvement comes from the elimination of distortions and edge effects in the decoding. PMT-based detectors typically have worse resolution directly underneath the tubes and at the edges of the field of view. With 1:1 coupling, the crystal identification is uniform across the entire detector, resulting in a more uniform image.

Because they are pixelated, the digital detectors in Vereos also show a uniform response across their surface, and across the entire field of view. This is in contrast to analog PMT-based systems that use Anger logic for crystal identification, where the response varies across the detector and is worse directly underneath the PMTs and at the edge of the field of view. 1:1 coupling eliminates this effect in Vereos.

Users will also benefit from Vereos' high peak true rate (≥ 675 kcps), also known as the maximum true rate. This is the maximum count rate of true coincidences, which occurs at a certain level of activity, beyond which the system is paralyzed. With Vereos, researchers can perform high count rate studies, such as short-lived isotope dynamic and bolus imaging, while maintaining sensitivity – important for quantitative accuracy.

> "There is non-uniform behavior across PMT-based detector modules that impacts image quality and quantitation. With Philips digital photon counting technology, we deliver uniformity throughout."
>
> *Chi-Hua Tung, Director*
> *Advanced Molecular Imaging, Philips*

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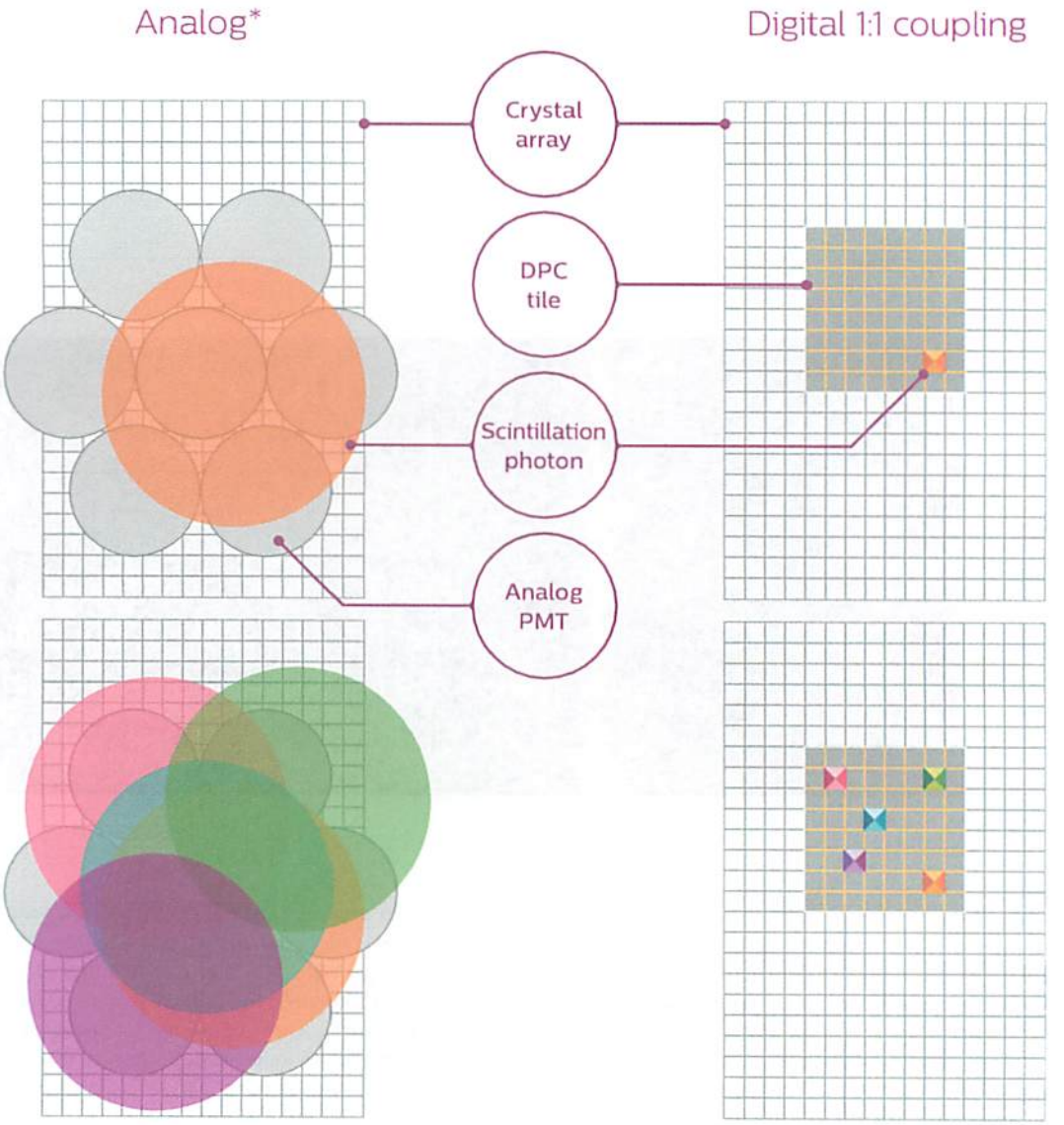

Figure 7 Comparison of analog* and digital photon counting. A PMT covers multiple crystals in the analog* system, while the digital system shows 1:1 coupling between scintillator crystals and single photon counters.

*GEMINI TF

Factors influencing performance specifications

A number of different factors influence and enhance the performance specifications of the DPC technology used in the Vereos system.

List mode-based TOF reconstruction

Vereos uses list mode TOF reconstruction. The list mode reconstruction method does not require any binning of the raw data. Event location and time of flight information are retained without degradation from binning, providing exceptional image quality and quantitation.

Energy resolution and spectrum/system dead time

The 1:1 coupling and sharp detection pulses seen with the DPC technology in Vereos effectively eliminates problems caused by coincident event pile-ups and electronic drift seen with analog systems. These problems can occur in analog* systems if there is a high level of activity and two or more events are detected almost simultaneously. In terms of resolution and the energy spectrum, pulse pile-up and drift cause good counts to be pushed out of the observed energy window, in favor of scatter counts. In terms of system dead time, the overlapping of the distributions for almost simultaneous events means a loss of sensitivity and the system will be partially dead at high count rates.

Comparison of dead time factors**

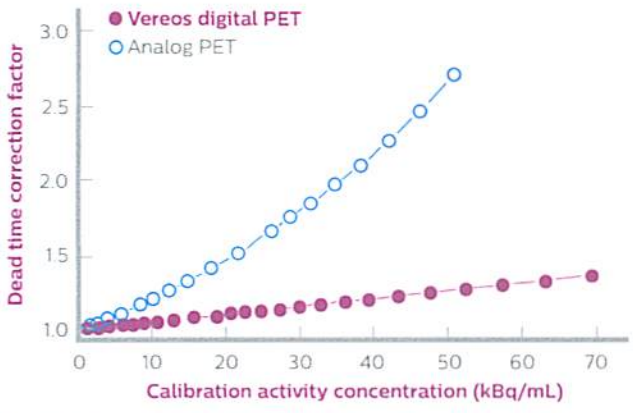

Figure 8 Comparison of dead time correction factors measured on Vereos digital PET and analog PET (Ingenuity TF).

The benefits of 1:1 coupling in terms of dead time are further illustrated by a plot of dead time factors against activity concentration for Vereos and an analog* system (see **Figure 8**). Dead time factors are defined as the inverse of the actual measured counts divided by the expected counts. As **Figure 8** indicates, at a clinical activity concentration of 10 kBq/ml which is typical of most whole body studies, Vereos has a deadtime factor of 1. In contrast, we see a higher dead-time factor of 1.17 for the analog* system. This effectively translates into an additional 17% sensitivity gain for Vereos.

Sensitivity measurement

NEMA (National Electrical Manufacturers Association) sensitivity is a measure of a system's ability to convert positron emissions to raw counts. However, this measure was developed for analog systems and does not take into account the quality of counts, such as the impact of TOF, the spatial resolution, and the degradation with high count rate (or dead time). Therefore, for superb sensitivity, obtaining good counts is more important than obtaining many mixed counts.

Digital PET offers real sensitivity gains, largely due to the application of TOF. The effective sensitivity gain is $D/\Delta x$, where D is the object diameter and Δx is position uncertainty along the line of response, equal to the speed of light (c) multiplied by time resolution divided by 2 ($\Delta t/2$).

Calculations for a range of object diameters show a TOF gain with Vereos of 3.9 for an object with a diameter of 20 cm, 5.8 for an object with a diameter of 30 cm, and 7.7 for an object with a diameter of 40 cm – objects approximately representing a brain, small body, and large body respectively [Philips, data on file].

Reconstruction and noise

The process of reconstruction involves mathematically estimating the original radioactivity distribution, based on the collected dispersed data. This brings with it penalties in terms of noise. However, Vereos' 1:1 coupling of crystals to sensors, better TOF resolution, and more uniform detector response reduce the reconstruction noise. Less noise translates into increased sensitivity.

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* Ingenuity TF

** Results are based on a uniform phantom (20 cm diameter and 30 cm long). Vereos results are preliminary and may be changed

Timing resolution and TOF technology

In conventional non-TOF PET, the image reconstruction process must assume that there is a uniform probability that the annihilation event occurs at any one point along the line of response (LOR). This major limitation has been overcome by the development of TOF technology.

Vereos has a fast timing resolution of just 325 ps (currently the fastest resolution on the market). This is the minimum time interval between two photon events required for them to be recorded as separate events. In systems with fast timing resolution, TOF is able to be used to locate each annihilation event on a specific part or segment of the LOR. The difference in flight time for the two photon events is used to produce a more localized distribution of probabilities (see **Figure 9**). For Vereos, the TOF localization accuracy is 4.9 cm.

This has the effect of improving effective sensitivity and image quality, and the speed of processing. With effective sensitivity gain defined as $D/\Delta x$ (where D is the object diameter and Δx is position uncertainty along the LOR), reducing the position uncertainty through the application of TOF leads to a real sensitivity gain.

Calculated effective sensitivity gains for Vereos, due to the benefits of TOF technology, demonstrate greater gains for larger diameter objects: 3.9 for a 20 cm diameter, rising to 7.7 for a 40 cm diameter [Philips, data on file]. TOF may be particularly beneficial in larger, heavier patients, as increased levels of attenuation and scatter in these patients would typically result in poor quality PET images in the absence of TOF.[1]

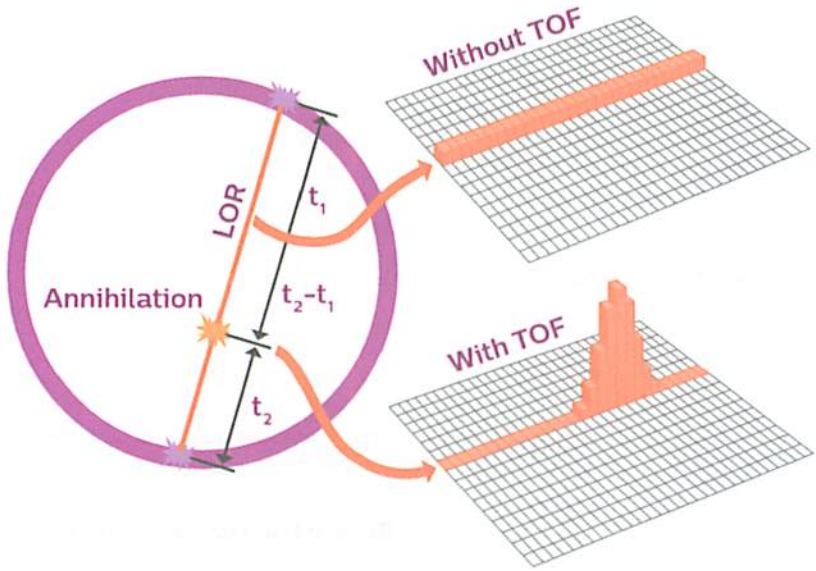

Figure 9 How TOF technology can lead to improved localization of the annihilation event along the LOR.

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[1] El Fakhri G, et al. Improvement in lesion detection with whole-body oncologic time-of-flight PET. J Nucl Med. 2011;52:347-53.

Point spread function (PSF) technology

Vereos makes use of a point spread function (PSF) algorithm to correct for partial-volume effects in PET images. PET spatial resolution can be influenced by factors such as the positron range (which is radioisotope-dependent), non-co-linearity of annihilation photons, crystal/detector size, and reconstruction parameters such as voxel dimensions and the use of post-filters.

PET scanner resolution can therefore be spatially variant, resulting in blurred images if not corrected for. A system's PSF is determined by imaging point-sources at many different locations within the scanner, producing a three-dimensional PSF. Correcting for this PSF allows users to retrieve images that closely match the true object scanned (see **Figure 10**).

Experience with PSF correction in the analog Ingenuity TF PET/CT system has demonstrated good improvement in image resolution and quantification. The same method is applied in Vereos. Overall, PSF needs to be used carefully, as it can significantly influence quantitative accuracy. Users can adjust two parameters: the number of iterations and a regularization factor. Evaluations using phantoms and clinical patients suggest that 1-2 PSF iterations is sufficient to recover resolution, with more iterations leading only to increased noise in the final image. Choosing PSF regularization values similar to the resolution of the scanner (in this case 6-8 mm for clinical images) provided good resolution without excessive noise or quantification errors.

The effects of applying various values for iteration and regularization in PSF correction can be seen in the following images from a phantom study (**Figure 11**).

In addition, Vereos has the ability to reconstruct images with a voxel size of 1 mm (for clinical brain images and research-only 1 mm body images), which further minimizes pixel sampling errors and improves image quality.

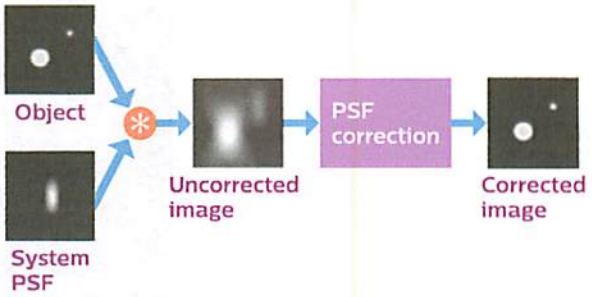

Figure 10 Correcting for a system's PSF provides superb image clarity.

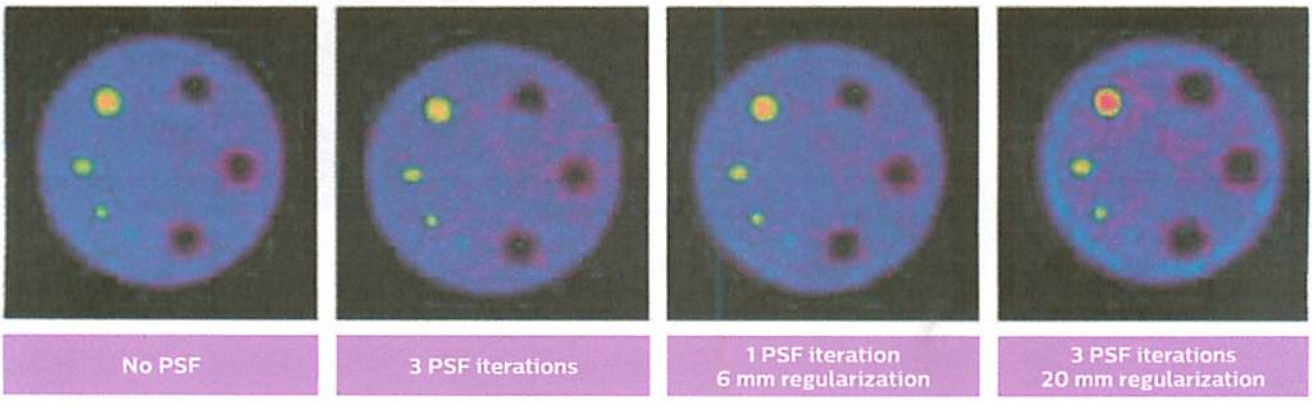

Figure 11 Transverse slices of 2 mm voxel ACR (American College of Radiology) phantom images, for various PSF iterations and levels of regularization. Reproduced from Narayanan M, Perkins A. Resolution recovery in the Ingenuity TF PET/CT. Data originally courtesy of the Hospital of the University of Pennsylvania.

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Technology pillars supporting improved performance

The Vereos system has approximately double the volumetric resolution, sensitivity gain, and accuracy of a comparable analog* system. These benefits are gained through the advantages offered by DPC technology, enhanced TOF, and 1:1 coupling.

The improved volumetric resolution is largely due to 1:1 coupling. The overall resolution is typically expressed as the full width at half maximum (FWHM), which has been calculated as 69 mm^3 for Vereos. The 1:1 coupling improves overall volumetric resolution through the gains in spatial resolution seen across the entire field of view.

Most of the improved sensitivity gain seen with Vereos is attributed to the application of TOF to more accurately locate each annihilation event along the line of response (LOR). The result is less dispersed data and improved image contrast. The remaining improvement is provided by reduced dead time.

Sensitivity gains have been measured for a range of object sizes. For a typical patient body size (Δ30 cm), the Vereos system showed a sensitivity gain of 5.8, compared with a gain of 3.3 with the analog system* (both compared with non-TOF). With the additional 20% to 25% sensitivity gain due to less dead time, the overall clinical sensitivity gain is about a factor of 2. Such improvements in sensitivity produce high quality images (see **Figure 12**).

Vereos has improved quantitative accuracy of +/- 5% when compared to +/- 10% seen with the analog system.* This improvement is primarily the result of the uniform detector response enabled by 1:1 coupling and the enhanced detector efficiency normalization algorithm.

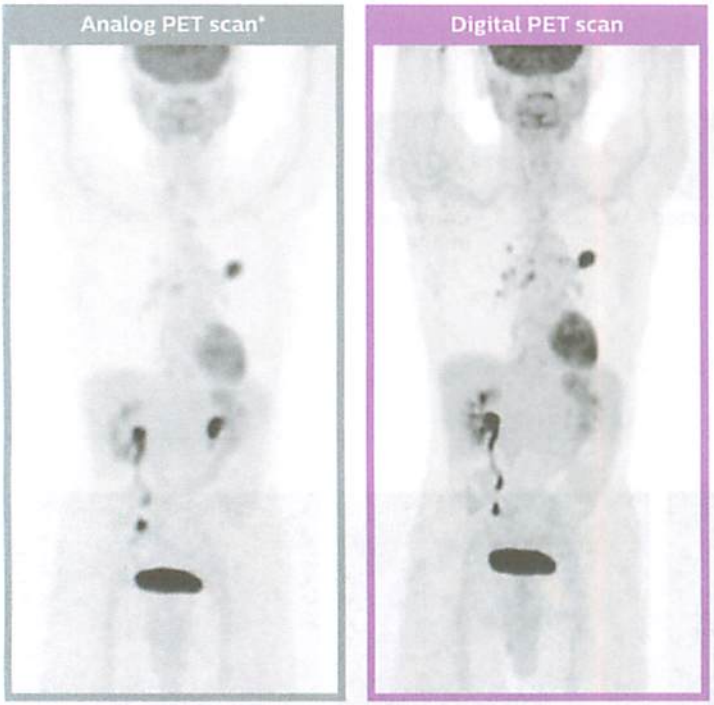

Figure 12 Sensitivity gain is approximately doubled with the Vereos system compared with the analog GEMINI TF 16 system.

> "With 1:1 coupling, we get not just more information but enhanced information and more certainty. We're better able to identify the source of the annihilation event, improving the volumetric resolution."
>
> *Chuck Nortmann, Clinical Product Manager Advanced Molecular Imaging, Philips*

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*GEMINI TF
Sample images acquired in a clinical study of the Vereos PET/CT system at University Hospitals Case Medical Center.
Investigational device limited by law to investigational use.

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www.philips.com/VereosPETCT

Printed in The Netherlands.
4522 991 18531 * MAY 2016

APPENDIX 4

CERTIFIED TRANSLATION FROM CNSN

RWS Group Ltd, of Europa House, Chiltern Park, Chiltern Hill, Chalfont St Peter, Buckinghamshire, United Kingdom, hereby declares that, to the best of its knowledge and belief, the following document, prepared by one of its translators competent in the art and conversant with the English and Spanish languages, is a true and correct translation of the accompanying document in the Spanish language.

S. J. SANDRON

Manager - UK Translation Division

I do hereby certify that this document)
is signed by SABINE JOSEE SANDRON)
for and on behalf of RWS Group Ltd)
at Gerrards Cross, Buckinghamshire)
on the 7th day of May 2013)

PETER DAVID WILKINSON

NOTARY PUBLIC OF GERRARDS CROSS ENGLAND

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NATIONAL NUCLEAR SAFETY CENTER

Ministry of Science, Technology and Environment
National Nuclear Safety Center

Calle 28 No. 504 entre 5ta y 7ma. Miramar. Habana. CP. 11 300. Cuba
Telephone: 53 (7) 203 1935-37. Fax: 53 (7) 202-3166. Email: direccioncnsn@orasen.co.cu

CD00412

CNSN/-451
Havana, 3 August 2012
"54th Year of the Revolution"

Mr. Vincent Antonissen
Director, Business Development,
Philips

Subject: The Nuclear Regulatory Framework in the Republic of Cuba

Dear Sir

This Authority, the National Nuclear Safety Center (Centro Nacional de Seguridad Nuclear - CNSN), has received information concerning the future importation and installation in Cuba of hybrid TF64 PET/CT systems produced by Philips. As compliance with the regulations that apply in our country regarding the introduction of this new technology is both necessary and important, may I take this opportunity to provide you with some information on the relevant legal provisions in Cuba.

Decree-Law No 207 "On the Use of Nuclear Energy", issued by the President of the Council of State and the Council of Ministers on 14 February 2000, is the supreme law governing this matter in Cuba. It lays down the basic provisions governing the use of this form of energy in our country and includes the key provisions in the following articles:

Scope of application

ARTICLE 2. This Decree-Law applies to all government entities, private entities, international joint ventures or wholly foreign-owned firms, natural persons or legal persons, whether Cuban or foreign, which are resident or have representation in the national territory and which, in any area over which the Republic of Cuba exercises rights of sovereignty and jurisdiction, carry out activities relating to the use of nuclear energy. Such activities include:

b) the design, manufacture, construction, assembly, purchase, import, export, distribution, sale, loan, hire, receipt, siting, location, bringing into service, possession, use, exploitation, maintenance, repair, transfer, dismantling, transport, storage and disposal of ionizing radiation sources, and any activity involving such sources;

The Regulatory Authority

ARTICLE 4. The Ministry of Science, Technology and Environment is the body responsible for directing, executing and monitoring State and Government policy concerning the use of nuclear energy and carries out regulation and monitoring of the safety of nuclear energy use and accounting and control of nuclear materials through the ***National Nuclear Safety Center.***

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ARTICLE 9. Executing activities relating to use of nuclear energy ***will require official authorization,*** *to be* ***issued by the National Nuclear Safety Center.***

ARTICLE 10. The Ministry of Science, Technology and Environment establishes the necessary requirements and procedures in respect of applications for the authorizations referred to in the preceding article, and for their award, amendment, renewal, suspension or withdrawal.

By virtue of these powers the Ministry of Science, Technology and Environment (CITMA) issues regulations to supplement the aforementioned Decree-Law No 207, and the National Nuclear Safety Center issues technical and procedural standards setting out the details of the provisions laid down in the regulations.

Thus **CITMA Resolution No 334/2011, "Regulations Governing the Notification and Authorization of Practices and Activities Relating to the Use of Ionizing Radiation Sources"**, lays down the requirements for applications for Permits and Licenses to undertake the activities defined in Article 2 b) above, including the documentation to be provided in support of the corresponding application.

Consequently, in order to practice Nuclear Medicine a Construction License, Operating License or Definitive Closure License must be obtained, depending on the stage of the operation. Other technical requirements that apply to equipment, facilities and operations involved in the practice of Nuclear Medicine are laid down in CNSN Resolution No 40/2011, "Safety Guidance for the Practice of Nuclear Medicine".

All the aforesaid regulations are in the public domain and have been publicized, and organizations undertaking activities relating to the use of ionizing radiation in this country, such as hospitals and public health institutions, are aware of them.

It is important to note that bodies such as the Center for Medical and Surgical Research (Centro de Investigaciones Médico Quirúrgicas - CIMEQ), the Clinical and Surgical Hospital "Hermanos Ameijeiras" (Hospital Clínico Quirúrgico "Hermanos Ameijeiras") and the National Oncology and Radiobiology Institute (Instituto Nacional de Oncología y Radiobiología - INOR), which are seeking to install TF64 PET/CT equipment produced by Philips, have licenses to perform the Practice of Nuclear Medicine in accordance with the available technology and have on their staff Doctors, Medical Physicists, and Electro-Medical Technicians and Engineers with Individual Licenses to practice Nuclear Medicine granted by the CNSN.

Our specialists are at your disposal if you require any further information regarding the requirements of this Authority.

Sincerely yours,
[Illegible signature]
[Stamp of the CNSN]
Luisa Aniuska Betancourt Hernández
Director
CNSN

AE1030-D
26/9/12

CENTRO NACIONAL DE SEGURIDAD NUCLEAR

Ministerio de Ciencia, Tecnología y Medio Ambiente
Centro Nacional de Seguridad Nuclear

Calle 28 No. 304 entre 5ta y 7ma. Miramar. Habana. CP. 11 300. Cuba
Teléfono: 53 (7) 203 1935-37. Fax: 53 (7) 202-3166. E-mail: direccioncnsn@orasen.co.cu

CD00412

CNSN/-451
La Habana, 3 de Agosto de 2012
"Año 54 de la Revolución"

Sr Vincent Antonissen
Director, Business Development.
Philips

Asunto: Sobre el Marco Regulador Nuclear en la República de Cuba.

Estimado señor:

Esta Autoridad, el Centro Nacional de Seguridad Nuclear (CNSN), ha tenido información sobre la futura importación e instalación en Cuba de sistemas Híbridos TF64 PET/CT producidos por Philips. Considerando la necesidad e importancia de que la asimilación de esta nueva tecnologia se realice cumpliendo lo establecido en las regulaciones vigentes en nuestro país, aprovecho la oportunidad para imponerlo sobre algunos particulares relativos al marco legal cubano al respecto

En Cuba el Decreto-Ley Nro. 207 "Sobre el Uso de la Energía Nuclear", norma legal suprema sobre esta materia, dictada por el Presidente del Consejo de Estado y de Ministros, en fecha 14 de febrero del 2000, establece los aspectos fundamentales que rigen el uso de esta energia en nuestro país, entre estos aspectos se destacan los prescritos en los artículos siguientes:

Sobre el Ámbito de Aplicación:

ARTICULO 2. El presente Decreto-Ley se aplica a todas las entidades estatales, privadas, asociaciones económicas internacionales o empresas de capital totalmente extranjero, personas naturales o jurídicas, nacionales o extranjeras, radicadas o con representación en el territorio nacional que realicen en cualquier espacio en que la República de Cuba ejerza derechos de soberanía y jurisdicción, actividades relacionadas con el uso de la energía nuclear, las cuales incluyen:

b) diseño, fabricación, construcción, montaje, compra, importación, exportación, distribución venta, préstamo, alquiler, recepción, emplazamiento, ubicación, puesta en servicio, posesión, uso, explotación, mantenimiento, reparación, transferencia, desmontaje, transportación, almacenamiento y evacuación de fuentes de radiaciones ionizantes, así como cualquier actividad donde intervengan éstas;

Sobre la Autoridad Reguladora

ARTICULO 4. El Ministerio de Ciencia, Tecnología y Medio Ambiente es el organismo encargado de dirigir, ejecutar y controlar la política del Estado y del Gobierno en relación con el uso de la energía nuclear y ejecuta la regulación y el control de la seguridad del uso de la energía nuclear y la contabilidad y control de los materiales nucleares a través del ***Centro Nacional de Seguridad Nuclear***

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Sobre las Autorizaciones para el Uso de la Energía Nuclear

ARTICULO 9 Para la ejecución de actividades relacionadas con el uso de la energía nuclear ***se precisará de una autorización oficial*** *que será* ***expedida por el Centro Nacional de Seguridad Nuclear.***

ARTICULO 10 El Ministerio de Ciencia. Tecnología y Medio Ambiente establece los requisitos y procedimientos necesarios para la solicitud, otorgamiento. modificación. renovación. suspensión o revocación de las autorizaciones a las que se refiere el artículo anterior

Al amparo de estas facultades el Ministerio de Ciencia, Tecnología y Medio Ambiente (CITMA) dicta las normas reglamentarias que complementan el referido Decreto Ley Nro 207 y el Centro Nacional de Seguridad Nuclear dicta las normas técnicas y de procedimiento que detallan lo dispuesto en las normas reglamentarias

En tal sentido la **Resolución Nro. 334/2011 del CITMA "Reglamento Sobre Notificación y Autorización de Prácticas y Actividades Asociadas al Empleo de Fuentes de Radiaciones Ionizantes"** establece los requisitos de la solicitud de Permisos y Licencias para desarrollar las actividades definidas en el Artículo 2 b) antes expuesto incluyendo la documentación de apoyo a la solicitud que corresponda

Consecuentemente. la práctica de Medicina Nuclear requiere la obtención de Licencias de Construcción. Operación o Cierre definitivo. en dependencia de la etapa en cuestión Otros requisitos técnicos aplicables a los equipos. instalaciones y operaciones en la práctica de Medicina Nuclear se establecen en la Resolución Nro 40/2011 del CNSN "Guía de Seguridad para la Práctica de Medicina Nuclear"

Todas las regulaciones referidas son públicas. han sido difundidas y son de conocimiento de las entidades que realizan prácticas asociadas al empleo de las radiaciones ionizantes en el país como los hospitales e instituciones de Salud Pública

Es importante destacar que entidades como el Centro de Insvestigaciones Médico Quirúrgicas (CIMEQ) el Hospital Clínico Quirúrgico "Hermanos Ameijeiras" y el Instituto Nacional de Oncología y Radiobiología (INOR) que pretenden instalar equipos TF64 PET/CT producidos por Philips poseen Licencias para desarrollar la Práctica de Medicina Nuclear acorde con la tecnología disponible y cuentan en su staff con Médicos. Físicos Médicos. Tecnólogos e Ingenieros electromédicos con Licencias Individuales otorgadas por el CNSN, para realizar la práctica de Medicina Nuclear

Sepa usted que puede contactar con los especialitas de nuestra institución en caso que lo desee, a los fines de esclarecer lo que se requiera por esta Autoridad.

Respetuosamente.

Ing Luisa Aniuska Betancourt Hernández
Directora
CNSN

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APPENDIX 5

ECKERT & ZIEGLER END-USER STATEMENTS

Eckert & Ziegler
Isotope Products

END-USER STATEMENT

NOTE: All lines must be completely filled in Roman letters and in English, wherever possible. No PO boxes; provide cross streets where only PO boxes are available.

1. CONSIGNEE / DISTRIBUTOR / IMPORTER INFORMATION

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COMPANY NAME	ADDRESS LINE 1
CONSIGNEE Job Title	ADDRESS LINE 2
TELEPHONE	CITY / STATE / POSTAL CODE
FAX or E-MAIL	COUNTRY
COMPANY WEBSITE *(if available)*	

2. END USER INFORMATION (PERSON WHO WILL BE USING THE PRODUCT)

END USER *(First Name, Middle Initial, Last Name)* Dr. Luis Curbelo Alfonso	
COMPANY Instituto de Oncología y Radiobiología NAME	ADDRESS Calles F y 29. Vedado. Plaza. LINE 1
END USER PET/CT GEMINI TF 64 Job Title	ADDRESS LINE 2
TELEPHONE (+537) 836 4941	CITY / STATE / POSTAL CODE La Habana, 10400
FAX or E-MAIL dinor@infomed.sld.cu jgg@infomed.sld.cu	COUNTRY Cuba
COMPANY WEBSITE *(if available)*	

3. USE OF ITEMS BY END USER NAMED IN SECTION 2

DEPARTMENT PRODUCT WILL BE USED IN Nuclear Medicine Departament
EZIP MODEL(S) ORDERED
SPECIFIC APPLICATION (END USE) OF THE PRODUCT Only clinical use

4. STATEMENT OF END USER

We certify the following:

- The goods will not be re-routed or exported to US embargo countries per US NRC 10 CFR 110.28 and BIS export control regulations. The US embargo countries include: Cuba, Iran, Iraq, North Korea, Sudan, and Syria.
- We will not re-sell and/or re-export to, or use products containing Special Nuclear Material (plutonium, uranium-233, or uranium enriched in the isotopes uranium-233 or uranium-235) in countries classified under restricted destinations (**Afghanistan, Andorra, Angola, Burma (Myanmar), Djibouti, India, Israel, Oman, Pakistan, and Libya**) in accordance with U.S. NRC (10CFR110.29).
- The goods described above are for our own use at the address given above and will not be re-exported or sold for export.
- The goods are properly licensed and approved for use at the address in Section 2.
- The goods will not be used for purposes associated with chemical, biological or nuclear weapons or missile production or for missiles capable of delivering such weapons.
- These goods, or a replica of them, will not be used in any nuclear explosive activity or unsafe-guarded nuclear fuel cycle activity.
- All of the facts contained in this statement are true and correct to the best of our knowledge and we do not know of any additional facts which are inconsistent with the above statement. We shall promptly send a supplemental statement to EZIP, disclosing any change of facts or intention set forth in this statement which occurs after the statement has been prepared and forwarded.

SIGNATURE OF END USER

Eckert & Ziegler Isotope Products	**END-USER STATEMENT**

DATE: April 17,2013

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Eckert & Ziegler Isotope Products	**END-USER STATEMENT**

NOTE: All lines must be completely filled in Roman letters and in English, wherever possible. No PO boxes; provide cross streets where only PO boxes are available.

1. CONSIGNEE / DISTRIBUTOR / IMPORTER INFORMATION

CONSIGNEE *(First Name, Middle Initial, Last Name)* MEDICUBA, SA	
COMPANY NAME MEDICUBA, SA	ADDRESS LINE 1 2, entre 17 y 15, Vedado
CONSIGNEE Job Title MEDICUBA, SA	ADDRESS LINE 2
TELEPHONE (+537)	CITY / STATE / POSTAL CODE 10400, La Habana
FAX or E-MAIL msuarezm@infomed.sld.cu masuarez@gcatesa.sld.cu	COUNTRY CUBA
COMPANY WEBSITE - *(if available)*	

2. END USER INFORMATION (PERSON WHO WILL BE USING THE PRODUCT)

END USER *(First Name, Middle Initial, Last Name)* Departamento de Medicina Nuclear	
COMPANY NAME HCQ "Hermanos Ameijeiras"	ADDRESS LINE 1 San Lázaro NO 704 Esq. Belascoaín, Centro Habana
END USER Job Title PET/CT GEMINI 64TF	ADDRESS LINE 2
TELEPHONE (+537) 8761790, 8761110	CITY / STATE / POSTAL CODE 10400, La Habana
FAX or E-MAIL jmn@hha.sld.cu adlin@infomed.sld.cu direccion@hha.sld.cu	COUNTRY Cuba
COMPANY WEBSITE www.hospitalameijeiras.sld.cu *(if available)*	

3. USE OF ITEMS BY END USER NAMED IN SECTION 2

DEPARTMENT PRODUCT WILL BE USED IN Nuclear Medicine Departament with PET/CT Gemini 64TF equipment
EZIP MODEL(S) ORDERED
SPECIFIC APPLICATION (END USE) OF THE PRODUCT QC of PET/CT equipment

4. STATEMENT OF END USER

We certify the following:

- The goods will not be re-routed or exported to US embargo countries per US NRC 10 CFR 110.28 and BIS export control regulations. The US embargo countries include: Cuba, Iran, Iraq, North Korea, Sudan, and Syria.
- We will not re-sell and/or re-export to, or use products containing Special Nuclear Material (plutonium, uranium-233, or uranium enriched in the isotopes uranium-233 or uranium-235) in countries classified under restricted destinations (Afghanistan, Andorra, Angola, Burma (Myanmar), Djibouti, India, Israel, Oman, Pakistan, and Libya) in accordance with U.S. NRC (10CFR110.29).
- The goods described above are for our own use at the address given above and will not be re-exported or sold for export.
- The goods are properly licensed and approved for use at the address in Section 2.
- The goods will not be used for purposes associated with chemical, biological or nuclear weapons or missile production or for missiles capable of delivering such weapons.
- These goods, or a replica of them, will not be used in any nuclear explosive activity or unsafe-guarded nuclear fuel cycle activity.

Eckert & Ziegler Isotope Products	**END-USER STATEMENT**

- All of the facts contained in this statement are true and correct to the best of our knowledge and we do not know of any additional facts which are inconsistent with the above statement. We shall promptly send a supplemental statement to EZIP, disclosing any change of facts or intention set forth in this statement which occurs after the statement has been prepared and forwarded.

SIGNATURE OF END USER

Dr. Alfredo González Lorenzo, Director, HCQ "Hermanos Ameijeiras"

DATE: 10/abril/2013

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Eckert & Ziegler Isotope Products	**END-USER STATEMENT**

NOTE: All lines must be completely filled in Roman letters and in English, wherever possible. No PO boxes; provide cross streets where only PO boxes are available.

1. CONSIGNEE / DISTRIBUTOR / IMPORTER INFORMATION

CONSIGNEE *(First Name, Middle Initial, Last Name)*	
COMPANY NAME	ADDRESS LINE 1
CONSIGNEE Job Title	ADDRESS LINE 2
TELEPHONE	CITY / STATE / POSTAL CODE
FAX or E-MAIL	COUNTRY
COMPANY WEBSITE *(if available)*	

2. END USER INFORMATION (PERSON WHO WILL BE USING THE PRODUCT)

END USER *(First Name, Middle Initial, Last Name)* Manuel Cepero Nogueira	
COMPANY NAME Hospital CIMEQ	ADDRESS LINE 1 Calle 216 esq.11B, Siboney, Playa
END USER Job Title Director	ADDRESS LINE 2
TELEPHONE (537)8581000	CITY / STATE / POSTAL CODE La Habana, PC: 6096
FAX or E-MAIL (537)2739086	COUNTRY CUBA
COMPANY WEBSITE *(if available)*	

3. USE OF ITEMS BY END USER NAMED IN SECTION 2

DEPARTMENT PRODUCT WILL BE USED IN	PET/CT Scanner
EZIP MODEL(S) ORDERED	Gemini TF 64
SPECIFIC APPLICATION (END USE) OF THE PRODUCT Calibration of PET/CT Scanner	

4. STATEMENT OF END USER

We certify the following:

- The goods will not be re-routed or exported to US embargo countries per US NRC 10 CFR 110.28 and BIS export control regulations. The US embargo countries include: Cuba, Iran, Iraq, North Korea, Sudan, and Syria.
- We **will not re-sell and/or re-export to, or use products containing Special Nuclear Material** (plutonium, uranium-233, or uranium enriched in the isotopes uranium-233 or uranium-235) in countries classified under restricted destinations (**Afghanistan, Andorra, Angola, Burma (Myanmar), Djibouti, India, Israel, Oman, Pakistan, and Libya**) in accordance with U.S. NRC (10CFR110.29).
- The goods described above are for our own use at the address given above and will not be re-exported or sold for export.
- The goods are properly licensed and approved for use at the address in Section 2.
- The goods will not be used for purposes associated with chemical, biological or nuclear weapons or missile production or for missiles capable of delivering such weapons.
- These goods, or a replica of them, will not be used in any nuclear explosive activity or unsafe-guarded nuclear fuel cycle activity.
- All of the facts contained in this statement are true and complete to the best of our knowledge and we do not know of any additional facts which are inconsistent with the above statement. We shall promptly send a supplemental statement to EZIP, disclosing any change of facts or intention set forth in this statement which occurs after this statement has been prepared and forwarded.

SIGNATURE OF END USER

DATE: 12 de abril de 2013

REPÚBLICA DE CUBA
CENTRO DE INVESTIGACIONES MÉDICO QUIRÚRGICAS
DIRECCIÓN

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APPENDIX 6

CONTRACT 12CATE2054291ME

OF THE FIRST PARTY: **Philips Medical Systems Nederland B.V.**, having its registered office at Veenpluis 4-6, 5684 PC Best, The Netherlands ("Philips") acting also for the benefit of its affiliated Philips Healthcare companies, Commercial Register in the Chamber of Commerce Eindhoven no. 17060498, with account number: 46.53.93.373 in The Royal Bank of Scotland, Rotterdam, Netherlands, Beneficiary: Philips Medical Systems Netherlands B.V., IBAN Number: NL78RBOS0465393373, SWIFT Code: RBOSNL2A, Advising Bank: Commerzbank, Germany,(or equivalent to be decided by VENDOR) represented in this act by Mr. Javier Lozada, in his capacity as proxy holder, Attorney in fact, that he certifies by means of a document that he presents and withdraws in this act, hereinafter referred to as **THE VENDOR.**

AND OF THE SECOND PARTY:The Trading company importer and exporter of medical products, MEDICUBA S.A, in future, buyer, with registered office at calle 18 No.306, between 3rd and 5th, Playa, Havana, Cuba, constituted under the deed no. 239 of 6 April 2009 of the notary of the Ministry of Justice of the Republic of Cuba, which was registered to the days, April 6, 2009 volume XXIV, Folio 20, sheet 22, as registration first, of the Central mercantile registry in charge of the Ministry of Justice, registered at the Chamber of Commerce in the national register of exporters and importers Tomo XIII, Folio 023, dossier No. 594, with number of identification tax 30001859614, licensed bank to operate in freely convertible currency (g) 0900610005, Cuban convertible pesos bank account number 0300000003966825 in the branch Miramar bank financial international S.A calle 18 111 e / 1st and 3rd, Playa, Havana, and Cuban pesos number 0524420038180010 in the Bank Metropolitan S.A branch 244, 31 and 42, beach, has investment in Cuban convertible pesos with number 0300000003985522, ONE 241.4.60588 code; This Act represented by Fernando Martin Garcia, in his capacity as President and Luis Oliveros as Vice President.

BOTH PARTIES: Mutually recognizing each others personality and the representation with which they appear, to all legal effects they declare and agree to the following:

I- OBJECT OF THE CONTRACT:

1.1. - THE VENDOR agrees to sell to THE PURCHASER, and THE PURCHASER, agrees to buy from THE VENDOR, under the conditions stipulated herein, goods, in the amounts, denominations and conformity with the technical norms and specifications, quality characteristics and details that are indicated in the appendices attached to this Contract and which form an integral part of same.

II- CONTRACT PERFECTION AND TRANSFER OF OWNERSHIP OF GOODS:

2.1. - This Contract will be considered to be perfected on the moment of its signing by BOTH PARTIES.

2.2. - THE VENDOR is under the obligation to return the original, signed, that was sent to him for acceptance prior to the date of total or partial shipment as agreed.

2.3.- The transfer of ownership for goods which are object of this contract will become effective with the delivery of same by THE VENDOR to THE PURCHASER.

III- DELIVERY PLACE AND CONDITIONS:

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3.1. - The goods shall be delivered by THE VENDOR, **CFR Havana for the 3 systems with destination Cuba / CFR Caracas for the 3 systems with destination Venezuela**, pursuant to INCOTERMS 2000.

3.2. - During the navigation and transport of the goods to the port, or in the case that it will be necessary to make transfers, it is forbidden for the aircraft or vessel named above to land in ports or airports belonging to the United States of America and/or territories or waters under its jurisdiction.

IV- VALUE OF THE CONTRACT

4.1. - The value of the goods, object of this Contract, in the agreed upon sales conditions is **13.324.500 EUR**. (price excludes the Electa respiratory Gating Option from offer JWVA-2012-07-03 (version 17).

The first irrevocable (confirmed) letter of credit (immediate payment "At Sight" upon presentation of shipping documents to the confirming bank) of the amount of 2.097.417 EUR will be opened immediately upon signing of the formal contract. The time the L/C will remain open will be 180 days.

The following 5 irrevocable (confirmed) letters of credit (immediate payment "At Sight" upon presentation of shipping documents to the confirming bank) will be opened 60 days before planned shipment of the systems and each L/C should remain valid and open for minimum 120 days.

The following amounts are applicable per L/C:

First L/C (Cuba):	**2.097.417 EUR**
Second L/C (Cuba):	**2.097.417 EUR**
Third L/C (Cuba):	**2.097.417 EUR**
Fourth L/C (Venezuela):	**2.344.083 EUR**
Fifth L/C (Venezuela):	**2.344.083 EUR**
Sixt L/C (Venezuela):	**2.344.083 EUR**
Total:	**13.324.500 EUR**

V- DATES AND TERMS OF DELIVERY:

5.1. - The goods must be delivered according to the site readiness of the hospitals.
The first system is planned for delivery 4-6 months after receipt of the first letter of credit, delivery and planned delivery subject to receiving a formal US Export license.
Second system planned 2 months after the first shipment, and 3rd system 4 months after the first shipment (all subject to site readiness and US export license).
Planning on delivery of the 3 systems for Venezuela is subject to assigning hospitals and site readiness and a delivery schedule will be provided in due course (all deliveries are subject to site readiness and US export licenses).
Purchaser will have the right to update and delay the planned delivery schedule, with 30 days prior notice to the Vendor, to facilitate and adapt the delivery schedule to the local site readiness.
Purchaser and Vendor may determine in course of execution to update hospital locations. Prior notice by Purchaser to Vendor is mandatory. In case of any changes, the international and US export control regulations are applicable.

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VI- CONDITIONS AND FORMS OF PAYMENT:

6.1. - **Payment for the goods shall be carried out by irrevocable Letter of Credit via a Bank to be assigned and agreed by Purchaser and Vendor.**

6.2. - Payment currency shall be EURO.

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6.3. - Payment shall be carried out against presentation of the following documents:

a) ORIGINAL AND TWO COPIES OF THE BILL OF LADING, CONSIGNED TO MEDICUBA S.A., INDICATING IN THE BOX " DECLARED VALUE FOR CARRIAGE" THE VALUE OF GOODS BEING SHIPPED BY THIS DOCUMENT
b) ORIGINAL AND TWO COPIES OF THE PACKING LIST,SPECIFYING THE CONTRACT NUMBER, THE CONTENT, GROSS AND NET WEIGHT OF EACH BUNDLE AND ITEM, TOTAL NUMBER OF PIECES, AND TOTAL GROSS WEIGHT.
c) ORIGINAL AND TWO COPIES OF THE COMMERCIAL INVOICE, DETAILING EMBARKED GOODS SHIPPED, CONTRACT NUMBER, GROSS WEIGHT IN KILOGRAMS, NUMBER OF BUNDLES, TYPE OF PACKAGING (BALING), COUNTRY OF ORIGIN, TYPE OF CURRENCY OF THE TRANSACTION, VALUE OF THE FREIGHT.
d) ORIGINAL AND TWO COPIES OF THE CERTIFICATE OF ORIGIN, ISSUED BY THE CHAMBER OF COMMERCE OF THE SELLER'S COUNTRY, SPECIFYING THE COUNTRY OF ORIGIN OF THE GOODS.
e) ORIGINAL OF THE QUALITY CERTIFICATE ISSUED BY THE MANUFACTURER.
f) ORIGINAL OF INSURANCE POLICY
g) COPY OF THE INVOICE ISSUED BY THE CARRIER OR FORWARDER WHO WAS IN CHARGE OF THE TRANSPORTATION OF GOOD
h) COPY OF THE CERTIFICATE OF INSPECTION SSUED BY THE INSPECTION AGENCY AGREED
i) RECEIPT OF THE SENDING TO THE BUYER BY EXPRESS COURIER OF A SET OF THE SHIPPING DOCUMENTS REQUESTED IN THIS CONTRACT.

6.4.- THE VENDOR will compensate THE PURCHASER for extra expenses, including any damages that are incurred by or on THE PURCHASER, due to the delay in the agreed upon documents, as well as any errors in these.

6.5. - THE VENDOR is obligated to ensure that in the Shipping Document, in the case of air shipments, the value of the goods under this agreement is noted in the box "Declared Value for Carriage" and will respond to THE PURCHASER for any damages incurred by the non-compliance of this obligation.

VII- PACKING:

7.1. - Goods must be packed SO THAT THE GOODS ARE PROTECTED AGAINST BLOWS AND ANOTHER SOURCE OF DAMAGE.

7.2. - Goods must be packaged and wrapped in such a way as to ensure preservation, safety and integrity of the cargo during its handling, transport, possible transfers, as well as blows, other kinds of damage, corrosion and climatic conditions, keeping in mind the length of time of the journey and any inclement weather condition. They must be conditioned for handling by loading and hoisting machinery.

7.3. - THE VENDOR will ensure due protection for the goods so that they will get to THE PURCHASER in good condition, and he will be responsible for any loss, damage or shortage that may result because of deficient packing.

7.4. - Labeling of the products, as well as any writing on the packages and boxes will be in the SPANISH or ENGLISH language, being SPANISH preferable.

7.5.- THE VENDOR will guarantee that the merchandise that requires refrigeration or freezing, have an appropriate packing as well as that contains coolant, a meter of temperature and to mark each bundle with the required temperature and reflected this temperature in the air waybill.

7.6. - Each product will be labeled with the following information in SPANISH or ENGLISH language:

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a) Supplier name
b) Product name.
c) Batch number.
d) Production date
e) Manufacture date.
f) Expiry date.
g) Net weight.
h) Quantity.
i) Storage conditions.
j) Name and country of the manufacturer.
k) Marks.

7.7. The batch design should contain the following requirements:

a) Product,
b) Production Date,
c) Changes in the raw materials,
d) Changes of production machineries,
e) Changes in the work day,
f) Changes in the sterilization sequence,

7.7.1 THE VENDOR should guarantee that the batch design allows THE BUYER to carry out an efficient sampling to the moment to inspect the products, based on the norm ISO 2859

7.8.- The packing of goods employed by THE VENDOR if were manufactured with wood, must be marked according to the Standard NIMF Nr. 15, evidencing that such packings have been treated following the procedures approved in the mentioned Standard. The Certificate issued by the authority in charge in the country of THE VENDOR must be sent as well with the rest of shipping documents indicated in this contract according to the mentioned Standard.

VIII- LABELING:

8.1. - THE VENDOR is obliged to securely affix a copy of the Packing List on the outside of each package, detailing contents, placing it inside a water-proof sealed envelope so as to be protected against bad weather.

8.2. - THE VENDOR will label goods with permanent ink, on both sides, in the SPANISH or ENGLISH language, being SPANISH preferable, on each package, with clear printing, with the following information:

a) Name of the Purchaser
b) Contract Number
c) Destination
d) Name of product
e) Name of manufacturer and country or origin
f) Package number
g) Net and gross weight in kilograms
h) Measurements in centimeters
i) International Cautionary Symbols

8.3. - If goods must be stored or handled under special condition, THE VENDOR, will mark the pertinent instructions on each package or box, in the SPANISH or ENGLISH language, being SPANISH preferable.

8.4.- THE VENDOR assumes responsibility for every damage, loss or shortage suffered by the goods, attributable to defective outfitting, packaging, packing, protective system or labeling.

IX- AMOUNT AND QUALITY:

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9.1. - The amount of products to be acquired as per this Contract is listed in detail in Appendix No. 1 & No. 2, which form an integral part of same.

9.2. - Quality shall conform to the parameters, norms and/or manufacturer's specifications, in this case CE certification.

9.3- The goods delivered by THE VENDOR will be new and conform to the usual norms and be adapted to all effect for the object to which they are destined.

9.4. - THE VENDOR shall test and check the goods before packing them in order to ascertain that they correspond to Contract stipulations.

9.5.- THE VENDOR will totally answer for the quality of the goods, as well as for their raw materials or the materials used in their manufacture, their parts and components, and he will ensure that these shall be preserved for the length of their working life-spans.

9.6. - Quality is covered by manufacturer's quality certificates, and if not, by an internationally recognized Agency of prestige that has been chosen by BOTH PARTIES.

9.7. - THE PURCHASER reserves the right to refuse goods which are defective in quality, attributable to THE VENDOR.

9.9.- THE VENDOR may not carry out changes in the technical specifications without previous written consent of THE PURCHASER, in which case, these changes will be included in the document signed by BOTH PARTIES or their representatives, duly accredited, and which will be included as a supplement to this Contract.

9.10. - Non-compliance with the quality norms agreed to in this Contract will be the responsibility of THE VENDOR.

X- TRANSPORT:

10.1. - For transport of contracted goods, THE VENDOR will, as the first option, contract de services of a Cuban transport company or a foreign transport company that deals in traffic with Cuba.

10.2.- Expenses deriving from cargo operations, freight upon contracting the transport, expenses for handling of containers in the port of origin (terminal handling charges), hereinafter TCH, must be paid by THE VENDOR, who upon contracting the transport will be obliged to included said costs, indicating on the Bill of Lading the following: "TCH paid at origin".

XI- NOTIFICATION AND SHIPPING DOCUMENTS:

11.1. - THE VENDOR will be obliged to send to THE PURCHASER in Havana, via electronic means to be e-mail address: jorgito@gcatesa.sld.cu and the e-mail of the person that communicated you the purchase, or via FAX, within 72 hours calculated from the departure of the vessel or aircraft, everything related to availability and the loading of the goods, the shipping company or airline to be used, as well as all information related to the transfer of goods, using the following information:

1. Name of vessel or aircraft
2. Date of departure of vessel or aircraft
3. Name of sender
4. Shipping Port or Airport
5. Number of Bill of Lading or Airway Bill
6. Contract number
7. Name of Shipped Product
8. Total value of shipment

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9. Number of packages
10. Gross Weight in Kg
11. Lines and amounts shipped
12. Volume in cubic meters

11.2.- THE VENDOR, In order to speed up customs formalities for the importing of the goods, will send the following documents to THE PURCHASER, within 72 hours following the date of issuing the acknowledgement of shipment or airway bill, via FAX or E-mail copies of the documents indicated in the point 6.3 of this contract

11.3. - THE VENDOR, using a first-class messenger agency or express mail to Cuba, within the three (3) days following the date of issue of the shipment acknowledgement and within 24 business hours preceding the departure of the aircraft for air shipments, will send THE PURCHASER a complete set (1 original and 2 copies for shipments by sea and 1 copy for air shipments) of ALL documents required for payment appearing listed in point 6.3 of this contract.

11.4. - THE VENDOR shall assume the costs of all expenses incurred for THE PURCHASER as a result of the former's delay in delivering the documents related to the stipulations present in the preceding paragraph or because of supplying erroneous information on same.

XII- INSURANCE:

12.1. - THE PURCHASER will contract insurance for the goods with ESICUBA corresponding to the policy that has been signed with them, with coverage against all risks, also covering risks of strikes, wars and social upheavals. The goods will be insured for one hundred and ten percent (110%) of total value.

12.2. - THE VENDOR will be obliged to send the necessary documents or information no later than seven (7) days calculated from the shipment for transport by sea and within twenty-four (24) hours for transport by air, with the intent that goods may be insured in their totality.

12.3 THE VENDOR will contract insurance for the goods with a first order insurance company, being ESICUBA preferable corresponding to the current policy between that company and THE PURCHASER, with coverage against all risks, also covering risks of strikes, wars and social upheavals.

XIII- INSPECTION:

3.1.- The goods will be inspected in the factory, in factory warehouses or in the origin seaport/airport and this must be indicated by THE VENDOR to the PURCHASER and coordinated with supervisory entity. The inspectión will be carried out by the cuban agency CUBACONTROL S.A. or its agents and will be inspected the following parameters:

____ Quantity
___ Packaging
____ Quality
____ Weight

13.2.- THE VENDOR, at the request of and in the account of THE PURCHASER, will permit the carrying out of inspections at the points of origin and destination, by supervisory entities agreed to by BOTH PARTIES.

13.3. - Independently of the stipulations in the preceding paragraph, it is the obligation of THE VENDOR to inspect the goods which are to be delivered to PURCHASER.

13.4.- THE PURCHASER reserves the right to inspect and refuse goods, before shipment, to which effect THE VENDOR commits to facilitating the inspector

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of the former to make an inspection in the factories where the goods are manufactured and/or the warehouses where they are stored. Expenses deriving from this will be paid by THE PURCHASER.

13.5.- THE VENDOR is obliged to inform THE PURCHASER of the time to carry out an inspection of the goods, with thirty (30) days notice from the beginning of their manufacture and/or when they are available to be loaded for shipment.

13.6.- For the compliance with supervisions at the points of origin and/or destination, THE PURCHASER will designate CUBACONTROL S.A as representative, or other supervisory entity as designated by these.

13.7.- THE PURCHASER reserves the right to inspect the goods at the destination point at his own expense, and for this he can call on representatives of THE VENDOR to participate in said inspection. THE VENDOR will not be released of his obligations because of the absence of his representatives duly called upon to carry out inspections at the destination point.

13.8.- THE PURCHASER will lay a claim against THE VENDOR for any differences or deficiencies that result from the inspections, whenever these occur as defects that were present previous to the shipment.

13.9.- The fact that THE PURCHASER does not exercise his right to inspect the goods at the point of origin and subsequently does not refuse it, does not release THE VENDOR from his corresponding legal and contractual responsibilities, nor does it affect the right of THE PURCHASER to inspect the goods at the destination and to lay a claim on THE VENDOR for any differences or deficiencies so resulting.

13.1.- THE VENDOR, at the request of and in the account of THE PURCHASER, will permit the carrying out of inspections at the points of origin and destination, by supervisory entities agreed to by BOTH PARTIES.

13.2.- Independently of the stipulations in the preceding paragraph, it is the obligation of THE VENDOR to inspect the goods which are to be delivered to THE PURCHASER.

13.3.- THE PURCHASER reserves the right to inspect before shipment, to which effect THE VENDOR commits to facilitating the inspector of the former to make an inspection in the factories where the goods are manufactured and/or the warehouses where they are stored. Expenses deriving from this will be paid by THE PURCHASER.

13.4.- THE VENDOR is obliged to inform THE PURCHASER of the time to carry out an inspection of the goods, with thirty (30) days notice from the beginning of their manufacture and/or when they are available to be loaded for shipment.

13.5.- For the compliance with supervisions at the points of origin and/or destination, THE PURCHASER will designate CUBACONTROL S.A and INTERMAR S.A as representative, or other supervisory entity as designated by these.

13.6.- THE PURCHASER reserves the right to inspect the goods at the destination point at his own expense, and for this he can call on representatives of THE VENDOR to participate in said inspection. THE VENDOR will not be released of his obligations because of the absence of his representatives duly called upon to carry out inspections at the destination point.

13.7.- THE PURCHASER will lay a claim against THE VENDOR for any differences or deficiencies that result from the inspections, whenever these occur as defects that were present previous to the shipment.

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13.8.- The fact that THE PURCHASER does not exercise his right to inspect the goods at the point of origin and subsequently does not refuse it, does not release THE VENDOR from his corresponding legal and contractual responsibilities, nor does it affect the right of THE PURCHASER to inspect the goods at the destination and to lay a claim on THE VENDOR for any differences or deficiencies so resulting.

XIV- WARRANTY:

14.1 In the absence of any product specific warranty, VENDOR warrants to the Customer the good quality of any hardware Product, for a period of one year as from the date of Customer acceptance or first patient use, whichever occurs first, but in no event for more than fifteen (15) months from the date of dispatch, against defects which appear therein provided that the Product(s) had been subject to proper use and maintenance, and which arise solely from faulty materials or workmanship.

14.2 Any Product warranty is made on condition that VENDOR receives written notice of a defect during the warranty period and within ten (10) days of the discovery of the defect by the Customer, and, if so requested, the defective Product or parts have been returned to an address or location stipulated by VENDOR. Such defective parts shall become VENDOR property as soon as they have been replaced.

14.3 VENDOR obligations under any Product warranty shall be limited, at VENDOR option, to the repair or the replacement of the Products or a portion thereof, in which case replacements parts shall be new or equivalent to new in performance, or to a refund of a pro rata portion of the purchase price paid by the Customer.

14.4 VENDOR obligations under any Product warranty do not apply to any defects resulting from:

(a) improper or inadequate maintenance, configuration or calibration by the Customer or its agents;

(b) Customer or third party supplied software, interfaces or supplies;

(c) use, operation, modification or maintenance of the Products other than in accordance with Philips' applicable Product specifications and written instructions;

(d) abuse, negligence, accident, loss;

(e) damage in transit;

(f) improper site preparation;

(g) unauthorised maintenance or modifications to the Products, including any unauthorised attachment of hardware and software thereto;

(h) any damage to the Products or any medical or other stored data caused by an external source regardless of its nature, including but not limited to (i) hacking; or (ii) improper or incomplete application by the Customer of Philips' instructions on product security and/or (iii) viruses or similar software interference resulting from the connection of the Products to a network or use of removable devices.

14.5 VENDOR does not provide a warranty for any third party Products furnished to the Customer by Philips. However, in the event that Philips, pursuant to its license agreement or purchase agreement with such third party, is entitled to warranty and service remedies, Philips shall use reasonable efforts to extend to the Customer the third party warranty and service remedies for such Products.

XVI- FORCE MAJEURE:

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16.1.- Those causes exempt from responsibility are those arising after the perfection of the contract and which prevent its fulfillment as a result of events that are unforeseeable and inevitable for the parties.

16.2.- The party invoking these above-mentioned circumstances, must inform the other party, in writing and without delay, about the beginning and end of same and accredit the occurrence with a certified declaration by the Chamber of Commerce in the country where the occurrence took place.

XVII- CLAIMS:

17.1.- In the cases of differences in amounts, deficiencies in the quality of repairs and/or warranty, damages or any other kind of non-compliance of the clauses in this contract, THE PURCHASER is authorized to lay a claim by means of a simple letter, E-mail or FAX on THE VENDOR within one-hundred and eighty (180) days after the arrival at the destination PORT/AIRPORT.

17.2.- The date of admission of the claim shall be the postmark of the letter by the Post Office of the country of THE PURCHASER or the date of the acknowledgement of receipt of the message sent by E-mail or FAX, depending on the form being used, shall be considered to be the date of presentation.

17.3-The claim shall be presented with the following details:

a) Contract Number
b) Products that claim
c) Reasons for claimed.
d) Amount and quantity of the goods claimed
e) Terms of the contract is considered violated.
f) Date of delivery of the goods.
g) Application THE PURCHASER

17.4 -The claim shall be accompanied by certificates of oversight agencies and / or certifications recognized institutions that support the reasons for the claim.

17.5-THE SELLER shall respond within thirty (30) days from the date of receipt of such communication.

17.6 If necessary, the parties will sign a memorandum of understanding to carry out the claims, which should show the way in which to execute the claim.

XVIII- SUPPLEMENTS:

18.1.- Any amendment or supplement to this contract will be valid as long as it is made in writing and signed by the persons authorized to do so of BOTH PARTIES.

XIX- ARBITRATION:

19.1.- THE PARTIES will comply with this contract in good faith. Any discrepancy arising in its interpretation or execution, or in the agreements deriving from same, will be resolved by amicable negotiation.

19.2 - Dispute Resolution: Any dispute, controversy or claim arising out of or in connection with this Agreement, or the breach, termination or invalidity thereof shall be solely, exclusively and finally settled through arbitration under the Rules of Arbitration of the International Chamber of Commerce by three arbitrators appointed in accordance with the said rules. The place of arbitration shall be Madrid, Spain. The language to be used in the arbitration proceedings shall be English.

19.3.- This agreement shall be exclusively governed and in accordance with the laws of the Spain without regard to choice of law principles. The Vienna convention of international sales of goods shall not apply.

PHILIPS MEDICAL SYSTEMS NEDERLAND B.V. THE NETHERLANDS BEST PHILIPS MEDICAL SYSTEMS

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XXI- OTHER CONDITIONS:

21.1.- All expenses, including banking charges, taxes, customs duties and charges in the country of THE VENDOR related to this contract will be paid by THE VENDOR, and the similar charges in the country if the importer will be paid by THE PURCHASER.

21.2.- Expenses of amendments to letters of credit on request and originated by THE VENDOR will be paid by THE VENDOR as long as they are not the result of causes attributable to THE PURCHASER.

21.3.- The company MEDICUBA S.A. has legal capacity and own proprietorship having total legal and economic independence related to the Cuban state and/or any third party entities, and so it solely and exclusively responds with its own proprietorship for obligations contracted by virtue of this contract.

21.4.- THE PARTIES communicate to each other, reciprocally, all address changes, by certified letters with acknowledgement of receipt, FAX or E-mail. Until THE PARTIES have received notice of changes, communication sent to the address previously registered shall be valid for all legal effects.

21.5.- THE VENDOR is obliged to inform THE PURCHASER of any change in the principle shareholders or majorities in they entity, within thirty (30) days prior to the occurrence of such event. THE PURCHASER reserves the right to continue or not to continue the relationship with the new shareholder.

21.6.- It is expressly agreed that even in the case of liquidation of either of THE PARTIES, reparations for damages deriving from contractual non-compliance or frustration to whomever succeeds or in some form represents the capacity or proprietorship of THE PARTY in the occurrence of any of the situations described in this clause, can be demanded.

21.7 – Any other topics not covered in this agreement will be covered by the General Terms of Conditions of Sale of Philips Medical Systems Netherlands B.V. as included in the offices with reference JWVA-2012-07-03 (version 17) – see annex 1.

XXII- VALIDITY:

22.1.- This contract will become valid from date of its signing and will be considered to be valid until all the obligations stipulated therein are fulfilled.

IN THE BELIEF IN WHICH THE PARTIES sign this Contract, in the person of the representatives who have been duly authorized to do so, in two (2) copies in the English language, having the same tenor.

In Havana, Republic of Cuba, dated: Thursday September 27th 2012.

Fernando Martin Garcia

President

Javier Lozada

Proxy Holder (Attorney in Fact)

Philips Medical Systems Netherlands BV

Luis Oliveros

Vice president.

PHILIPS MEDICAL SYSTEMS NEDERLAND B.V. BEST PHILIPS MEDICAL SYSTEMS THE NETHERLANDS

12CATE205429IME

ANNEX 1
CONTRACT
No. 12CATE205429IME

Sres.

Philips Medical Systems Nederalands B.V.

Att. Sres. P. Smilde y H. Weernart

Havana, Julio 4 del 2012.

Ref.:Vuestra cotización JWVA-2012-07-03 (Version 17)
CIMEQ/INOR/AMEJEIRAS 2012 de Fecha Julio 3, 2012

Estimados Señores,

Nos complace hacerles llegar nuestra aceptación a los términos y condiciones de vuestra cotización de referencia por el monto de Euros 6.367.250 (Euros seis millones trescientos sesenta y siete mil doscientos cincuenta) incluyendo todas las opciones que, en señal de conformidad con la misma, se anexa a la presente carta debidamente firmada.

Dentro del plazo de 30 días corridos les enviaremos el contrato de compraventa basado en los términos y condiciones de vuestra cotización y la carta de crédito abierta a vuestro nombre a través de nuestro banco Financiero Internacional y su banco corresponsal de primera línea en Europa que deberá ser aprobado por Uds.

Sin otro particular, saludamos a Uds. muy atentamente.

GCATESA S.A.
Raul Fuentes
Presidente

mediCuba

PHILIPS MEDICAL SYSTEMS NEDERLAND B.V. BEST PHILIPS MEDICAL SYSTEMS THE NETHERLANDS

ANNEX 1
CONTRACT
No. 12CATE205429IME

0 Indice

Capt.	Cfg.	Descripción	Cant.	EUR
1		GEMINI TF 64 PET/CT CON ESTACION DE TRABAJO PINNACLE (FOB Rottordam - The Netherlands)	3	4,825,000
		Calibraciones NEMA en el sitio (La Habana)	3	75,000
		Total		4,900,000
		Descuento Final del Negocio Paquete		(477,750)
		Precio Total Final del Negocio Paquete		4,422,250
	Extra	Flete marítimo (CPT La Habana)	3	26,000
	Extra	4 años de garantía extendida CPT La Habana (partes y piezas solamente)	3	710,000
	Extra	4 años de garantía extendida CPT La Habana (tubos-RX solamente)	3	810,000
	Extra	Entrenamiento de 3 xMédico Nuclear (3 meses) Entrenamiento de 4 xFisicos Médicos (3 meses) Entrenamiento de 6 x Tecnólogos (1 mes) Entrenamiento de 6 x Ing. Biomédicos Hospital (10 días) Entrenamiento de 2 x Biomedicas del CNE (15 días)	1	500,000
	Extra	Entrenamiento del Software Pinacle RT (en el sitio La Habana, 1 semana)	1	15,000
	Extra	3 x Laptop Dell Latitude i7 con Windows 7 para Servicio Técnico	1	10,000
	Extra	3 x SONY UP-D77MD (en lugar de la impresora CODONICS Horizon)	1	Gratuito
ELEKTA Respiratory gating option NOT INcluded				
		Total NETT price including all options		6.292.250 EUR

This offer is subject to obtaining any of the requisite approvals or permissions under any of the applicable export control regulations and unless otherwise agreed in writing, the attached conditions of the sale apply.

Nota Importante:
- No incluye Image server with Mirror Image

PHILIPS MEDICAL SYSTEMS NEDERLAND B.V. BEST PHILIPS MEDICAL SYSTEMS THE NETHERLANDS

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Sres.

Philips Medical Systems Nederalands B.V.

Att. Sres. P. Smilde y H. Weemart

Havana, Julio 4 del 2012.

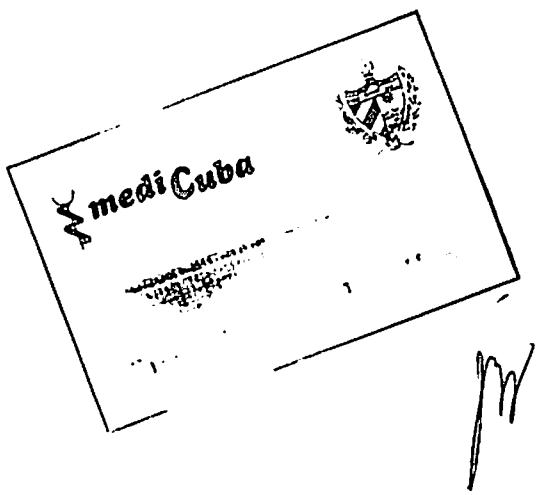
Ref.: Vuestra cotización JWVA-2012-07-03 (Version 17) de Fecha Julio 3, 2012 por 3 PET-CT TF64

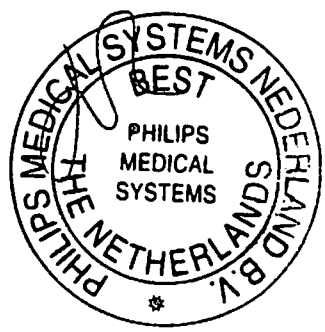
Estimados Señores,

Nos complace hacerles llegar nuestra aceptación a los términos y condiciones de vuestra cotización de referenciapor el monto de Euros 7.032.250 (Euros siete millones treinta y dos mil doscientos cincuenta) incluyendo todas las opciones que, en señal de conformidad con la misma, se anexa a la presente carta debidamente firmada.

Esta aceptación se realiza por cuenta y orden del Ministerio de Salud de la República Bolivariana de Venezuela a quien Uds. deberán consignar y exportar en forma directa los equipamientos objeto de esta cotización, siendo que dicha entidad de gobierno Venezolana será la titular de todos los derechos de dominio sobre los mismos.

Dentro del plazo de 30 días corridos les enviaremos el contrato de compraventa basado en los términos y condiciones de vuestra cotización y la carta de crédito abierta a vuestro nombre a través de





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nuestro banco Financiaro Internacional y su banco corresponsal de primera linea en Europaque deberá ser aprobado por Uds.

Sin otro particular, saludamos a Uds. muy atentamente.

GCATESA

Raul Fuentes

Presidente

PHILIPS MEDICAL SYSTEMS NEDERLAND B.V.
BEST
PHILIPS MEDICAL SYSTEMS
THE NETHERLANDS

0 Indice

Capt.	Cfg.	Descripción	Cant.	EUR
1		GEMINI TF 64 PET/CT CON ESTACION DE TRABAJO PINNACLE (FOB Rotterdam - The Netherlands)	3	4,825,000
		Calibraciones NEMA en el sitio (Caracas)	3	75,000
		Total		4,900,000
		Descuento Final del Negocio Paquete		(477,750)
		Precio Total Final del Negocio Paquete		4,422,250
	Extra	Flete marítimo (CPT Caracas)	3	25,000
	Extra	4 años de garantía extendida CPT Caracas (partes y piezas solamente)	3	710,000
	Extra	4 años de garantía extendida CPT Caracas (tubos-RX solamente)	3	810,000
	Extra	4 años de garanda extendida (Mano de obra Philips en Venezuela)	3	760,000
	Extra	Entrenamiento de 3 xMédico Nuclear (3 meses) Entrenamiento de 4 xFísicos Médicos (3 meses) Entrenamiento de 6 x Tecnólogos (1 mes) Entrenamiento de 6 x Ing. Biomédicos Hospital (10 días) Entrenamiento de 2 x Biomedicas del CNE (15 días)	1	500,000
	Extra	Entrenamiento del Software Pinacle RT (en el sitio Caracas 1 semana)	1	15,000
		Total including all options		7,032,250

This offer is subject to obtaining any of the requisite approvals or permissions under any of the applicable export control regulations and unless otherwise agreed in writing, the attached conditions of the sale apply.

Nota importante:

- No Incluye: Image server with Mirror Image
- Basados en experiencias pasadas, recomendamosampliamente incluir la garantía extendida de4 años de mano de obra Philips en Venezuela, especificamente por la sensibilidad y complejidad de de este tipo de equipamientos.
- De acuerdo al Export Control Regulations, actualmente asumimos que necesitamos aplicar por licencias formales de Export Control.
- Esta configuración ofertada (PET-CT Gemini TF64 ToF con Pinnacle) cumple con todas las especificaciones solicitadas en la licitación, e incluye todas las aplicaciones de cardio, neuro, y oncología solicitadas para SPECT.

In Havana, Republic of Cuba, date: September 27, 2012

Fernando Martin Garcia
President

Javier Lozada
Proxy Holder (Attorney in Fact)
Philips Medical Systems Nederland B.V.

Luis Oliveros
Vice president.

D.L.O.G
Indent Sales Manager
PMSN B.V.

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PHILIPS MEDICAL SYSTEMS NEDERLAND B.V. BEST PHILIPS MEDICAL SYSTEMS THE NETHERLANDS

ANNEX 2
CONTRACT
No. 12CATE205429IME

Included for the 3 systems with final end-user in Cuba:

- 4 years of extended warranty (including x-ray tubes) CPT La Habana (parts only, labor to be executed by Electromedicinas), total warranty = 5 years after installation & hand-over (ready for first patient use).
- Training of 3 x Médico Nuclear (3 meses) – timing & location to be confirmed by VENDOR
- Training of 4 x Físicos Médicos (3 meses) - timing & location to be confirmed by VENDOR
- Training of 6 x Tecnólogos (1 mes) - timing & location to be confirmed by VENDOR
- Training of 6 x Ing. Biomédicos Hospital (10 días) - timing & location to be confirmed by VENDOR
- Training of 2 x Biomedicas del CNE (15 dias) - timing & location to be confirmed by VENDOR
- Training on site of Software Pinacle RT (La Habana, 1 semana) - timing & location to be confirmed by VENDOR
- Service parts delivery: during warranty period, service parts will be ordered in the Netherlands via MCR EMEA parts order team, upon availability, delivery by air is estimated to take 7-10 days (subject to US export control regulations and only under US License), CPT Havana. Customs clearance time not included, and is the responsibility of Medicuba.
- Service labor: During first year standard factory warranty, first line support and installation will be executed by Electromedicinas Cuba, Tier 2 support to be provided by Philips Netherlands MCR EMEA. In case of complicated issues on site, which cannot be solved by helpdesk support, mutual agreed on-site support will be provided by Philips or Philips partner. On-site support will need to be planned and agreed between Vendor and Purchaser and is estimated to have a throughput time of approximately 3 weeks.

Included for the 3 systems with final end-user in Venezuela:

- 4 years of extended warranty (including x-ray tubes) CPT Caracas (parts only), total warranty = 5 years after installation & hand-over (ready for first patient use).
- 4 years of extended warranty (labor by Philips partner in Venezuela) = 5 years after installation & hand-over (ready for first patient use).
- Training of 3 x Médico Nuclear (3 meses) - timing & location to be confirmed by VENDOR

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- Training of 4 Físicos Médicos (3 meses) - timing & location to be confirmed by VENDOR
- Training of 6 x Tecnólogos (1 mes) - timing & location to be confirmed by VENDOR
- Training of 6 x Ing. Biomédicos Hospital (10 días) - timing & location to be confirmed by VENDOR
- Training of 2 x Biomedicas del CNE (15 dias) - timing & location to be confirmed by VENDOR
- Training on site of Software Pinacle RT (Caracas, 1 semana) - timing & location to be confirmed by VENDOR
- Service parts delivery: during warranty period, service parts will be ordered in the Netherlands via MCR EMEA parts order team, upon availability, delivery by air is estimated to take 7-10 days (subject to US export control regulations and only under US License), CPT Caracas. Customs clearance time not included, and is the responsibility of Medicuba.
- Service labor: During first year standard factory warranty, first line support and installation will be executed by Local Philips Licensed Service Partner, supported by the standard Philips Tier 2 and Tier 3 support structure. In case of complicated issues on site, which cannot be solved by our local Philips partner in Venezuela, mutual agreed on-site support will be provided by Philips. On-site expert support will need to be planned and agreed between Vendor and Purchaser and is estimated to have a throughput time of approximately 3 weeks.

In Havana, Republic of Cuba, date: September 27, 2012

Fernando Martin Garcia

President

Luis Oliveros

Vice president

Javier Lozada

Proxy holder (Attorney in Fact)

Philips Medical Systems Netherlands B.V.

Indent Sales Manager
PMSNBV.

PHILIPS MEDICAL SYSTEMS NEDERLAND B.V. BEST PHILIPS MEDICAL SYSTEMS THE NETHERLANDS

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Ministerio de Ciencia, Tecnología y Medio Ambiente
Centro Nacional de Seguridad Nuclear

CENTRO NACIONAL DE SEGURIDAD NUCLEAR

Calle 28 No. 504 entre 5ta y 7ma. Miramar. Habana. CP. 11 300. Cuba
Teléfono: 53 (7) 203 1935-37. Fax: 53 (7) 202-3166. E-mail: direccioncnsn@orasen.co.cu

CD00412

CNSN/-451
La Habana, 3 de Agosto de 2012.
"Año 54 de la Revolución"

Sr. Vincent Antonissen
Director, Business Development.
Philips

Asunto: Sobre el Marco Regulador Nuclear en la República de Cuba.

Estimado señor:

Esta Autoridad, el Centro Nacional de Seguridad Nuclear (CNSN), ha tenido información sobre la futura importación e instalación en Cuba de sistemas Hibridos TF64 PET/CT producidos por Philips. Considerando la necesidad e importancia de que la asimilación de esta nueva tecnología se realice cumpliendo lo establecido en las regulaciones vigentes en nuestro país, aprovecho la oportunidad para imponerlo sobre algunos particulares relativos al marco legal cubano al respecto.

En Cuba el Decreto-Ley Nro. 207 "Sobre el Uso de la Energía Nuclear", norma legal suprema sobre esta materia, dictada por el Presidente del Consejo de Estado y de Ministros, en fecha 14 de febrero del 2000, establece los aspectos fundamentales que rigen el uso de esta energía en nuestro país, entre estos aspectos se destacan los prescritos en los artículos siguientes:

Sobre el Ámbito de Aplicación:

ARTICULO 2. El presente Decreto-Ley se aplica a todas las entidades estatales, privadas, asociaciones económicas internacionales o empresas de capital totalmente extranjero, personas naturales o jurídicas, nacionales o extranjeras, radicadas o con representación en el territorio nacional que realicen en cualquier espacio en que la República de Cuba ejerza derechos de soberanía y jurisdicción, actividades relacionadas con el uso de la energía nuclear, las cuales incluyen:

b) diseño, fabricación, construcción. montaje. compra, importación, exportación, distribución. venta. préstamo. alquiler, recepción, emplazamiento, ubicación, puesta en servicio, posesión, uso, explotación, mantenimiento, reparación, transferencia, desmontaje, transportación, almacenamiento y evacuación de fuentes de radiaciones ionizantes, así como cualquier actividad donde intervengan éstas;

Sobre la Autoridad Reguladora

ARTICULO 4. El Ministerio de Ciencia, Tecnología y Medio Ambiente es el organismo encargado de dirigir, ejecutar y controlar la política del Estado y del Gobierno en relación con el uso de la energía nuclear y ejecuta la regulación y el control de la seguridad del uso de la energía nuclear y la contabilidad y control de los materiales nucleares a través del ***Centro Nacional de Seguridad Nuclear***

Sobre las Autorizaciones para el Uso de la Energía Nuclear

ARTICULO 9. Para la ejecución de actividades relacionadas con el uso de la energia nuclear ***se precisará de una autorización oficial*** *que será* ***expedida por el Centro Nacional de Seguridad Nuclear.***

ARTICULO 10. El Ministerio de Ciencia, Tecnologia y Medio Ambiente establece los requisitos y procedimientos necesarios para la solicitud, otorgamiento, modificación, renovación, suspensión o revocación de las autorizaciones a las que se refiere el artículo anterior.

Al amparo de estas facultades el Ministerio de Ciencia, Tecnologia y Medio Ambiente (CITMA) dicta las normas reglamentarias que complementan el referido Decreto Ley Nro. 207 y el Centro Nacional de Seguridad Nuclear dicta las normas técnicas y de procedimiento que detallan lo dispuesto en las normas reglamentarias.

En tal sentido la **Resolución Nro. 334/2011 del CITMA "Reglamento Sobre Notificación y Autorización de Prácticas y Actividades Asociadas al Empleo de Fuentes de Radiaciones Ionizantes"** establece los requisitos de la solicitud de Permisos y Licencias para desarrollar las actividades definidas en el Articulo 2 b) antes expuesto, incluyendo la documentación de apoyo a la solicitud que corresponda..

Consecuentemente, la práctica de Medicina Nuclear requiere la obtención de Licencias de Construcción, Operación o Cierre definitivo, en dependencia de la etapa en cuestión. Otros requisitos técnicos aplicables a los equipos, instalaciones y operaciones en la práctica de Medicina Nuclear se establecen en la Resolución Nro. 40/2011 del CNSN "Guia de Seguridad para la Práctica de Medicina Nuclear".

Todas las regulaciones referidas son públicas, han sido difundidas y son de conocimiento de las entidades que realizan prácticas asociadas al empleo de las radiaciones ionizantes en el pais, como los hospitales e instituciones de Salud Pública.

Es importante destacar que entidades como el Centro de Insvestigaciones Médico Quirúrgicas (CIMEQ), el Hospital Clínico Quirúrgico "Hermanos Ameijeiras" y el Instituto Nacional de Oncología y Radiobiología (INOR), que pretenden instalar equipos TF64 PET/CT producidos por Philips, poseen Licencias para desarrollar la Práctica de Medicina Nuclear acorde con la tecnología disponible y cuentan en su staff con Médicos, Físicos Médicos, Tecnólogos e Ingenieros electromédicos con Licencias Individuales otorgadas por el CNSN, para realizar la práctica de Medicina Nuclear.

Sepa usted que puede contactar con los especialitas de nuestra institución en caso que lo desee, a los fines de esclarecer lo que se requiera por esta Autoridad.

Respetuosamente,

p/o

Ing. Luisa Aniuska Betancourt Hernández.
Directora
CNSN