

U.O.C. INGEGNERIA CLINICA TEL. 0761 237818-816 FAX 0761 237803 luca.ronca@asl.vt.it giorgia.mindel@asl.vt.it



PROT. Nº 43794

VITERBO, 01/06/2017

A TUTTE LE DITTE INTERESSATE

Oggetto: Indagine di mercato. Servizio di manutenzione ed assistenza tecnica di tipo "full-risk" relativo ad apparecchiature elettromedicali di produzione Siemens per l'Azienda Sanitaria Locale di Viterbo.

Con riferimento al servizio di manutenzione indicato in oggetto, si informa che questa Azienda, con pubblicazione sul sito internet aziendale www.asl.vt.it – intende avviare un'indagine di mercato volta alla conoscenza di operatori tecnici in grado di effettuare il servizio di manutenzione ed assistenza tecnica di tipo "full-risk" relativo all'apparecchiatura elettromedicale Acceleratore Lineare "PRIMUS" di produzione Siemens, con le seguenti modalità:

- ✓ esecuzione delle manutenzioni preventive comprensive dei controlli di sicurezza elettrica secondo le norme CEI e secondo la periodicità e i protocolli indicati nel manuale delle apparecchiature (vedasi check-list allegate);
- ✓ esecuzione, almeno due volte all'anno, del controllo di qualità di ogni singola attrezzatura comprovato da un documento che ne accerti lo standard qualitativo della medesima;
- ✓ esecuzione di tutte le azioni conseguenti a eventuali avvisi di sicurezza e procedure di Field Maintenance Instructions in ambito di sicurezza e/o funzionalità emessi dal produttore;
- numero illimitato di chiamate per la manutenzione correttiva nonché tutte le operazioni necessarie al ripristino del funzionamento della apparecchiatura e relative componenti, in seguito a segnalazione di malfunzionamenti o rotture avvenute durante il normale utilizzo, esclusi i danni derivanti da incuria e/o uso impropri. Gli interventi di riparazione dovranno avvenire almeno entro le 8 ore lavorative dall'ora di segnalazione del guasto da parte dell'U.O. utilizzatrice dell'apparecchiatura.
 - Il singolo tempo di fermo macchina non potrà superare i 10gg. lavorativi complessivi consecutivi (comprensivi delle manutenzioni preventive, dei controlli di qualità e delle verifiche di sicurezza);
- ✓ dovranno essere previsti interventi su chiamata per assistenza applicativa clinica nella misura di almeno I giorno all'anno per apparecchiatura;
- ✓ fornitura, a titolo gratuito, dell'aggiornamento hardware e software per evitare problemi di obsolescenza, secondo le indicazioni del produttore;
- ✓ ogni necessaria assistenza, compresa la eventuale messa a disposizione di mezzi tecnici necessari, per la esecuzione congiunta con i responsabili della ASL di Viterbo (Servizio di Ingegneria Clinica e Fisica Sanitaria) alle prove di accettazione di cui all'art. 8 del D.Lgs. n. 187/2000 e relativo allegatoV;
- nel corso dell'esecuzione del servizio, deve essere svolto anche un servizio di teleassistenza tramite connessione remota via Wan per l'esecuzione di controllo proattivi, diagnosi remota dei guasti e riparazione di eventuali problemi del software, se prevista dal costruttore;
- ✓ tutti i ricambi saranno inclusi, così come saranno inclusi tutti gli eventuali materiali usurabili (filtri, batterie, lampade, parti non monouso, kit di manutenzione, cavi, eventuale materiale di calibrazione, etc...); le parti di ricambio dovranno essere originali e marchiate CE;
- ✓ sarà inclusa ogni spesa per il personale tecnico dedicato, che dovrà essere qualificato e formato specialisticamente (con idonea e comprovabile capacità tecnica e professionale), per operare sulle apparecchiature oggetto della presente indagine, al fine di garantire la massima affidabilità ed il



AZIENDA UNITÀ SANITARIA LOCALE

PARTITA IVA 01455570562

TA SANTANIA LOGALL

VITERBO 0°

VIA ENRICO FERMI, 15

01100 VITERBO

PEC prot.gen.asl.vt.it@legalmail.it

www.asl.vt.it

TEL. +39 0761 3391





mantenimento dei requisiti essenziali per quanto attiene le caratteristiche di sicurezza e di prestazione (secondo la direttiva CEE 93/42 e s.m.i);

sarà inclusa ogni spesa per l'aggiornamento al personale utilizzatore a al personale tecnico della ASL di Viterbo.

Gli operatori economici in grado di garantire almeno quanto sopra indicato sono invitati a darne comunicazione entro il giorno Venerdì 16 Giugno 2017 a mezzo fax al numero 0761/237803 oppure via e.mail agli indirizzi: luca.ronca@asl.vt.it e giorgia.mindel@asl.vt.it

Cordiali Saluti

Il Direttore U.O.C. Ingegneria Clinica Dott Ing. Luca Ronca

SIEWENS

PRIMUS Linear Accelerator

Maintenance Protocol System

PRHMUS Linear Acceleration Maintenance Projects

C	ustomer:		
A	ddress:		
F	ax / E-Mail:		
F	ax / E-Mail:		
			3
D	epartment:	Room:	The second secon
N	Naterial-No.:	Serial-No.:	A THE PROPERTY OF THE PARTY OF
C	ontract-No.:	Expire date:	
C	order-No.:	System - ID:	

The instructions T2-010.831.03.04.XX are required for this protocol

Evaluating the Condition of the System

The system has no deficiencies. *					
The system has slight deficiencies that have no effect on continued operation of the system. The deficiencies should be corrected preventively. *					
The system has serious deficiencies. For safety reasons, continued operation of the system is permitted only after successfully correcting the deficiencies.					
*) For imaging systems: The result of the image quality check show the reference values.	s no deviation from				
The evaluation was performed after completing all work steps.					
Signature:					
Date: Name:					
If required by country-specific regulations: The customer or a representative has taken note of the result of the evaluation of the system condition.					
Signature:					
Date: Name:					
Remarks:					

Remarks Regarding the Protocol

The chapter numbers refer to the chapters in the instruction, which is referenced on the cover page.

All pages have to have the serial number of the system and the date of maintenance in the page header.

The assignment n.a. (not applicable) indicates that the checkpoint or measured value is not used for this system.

On page 2 the completeness and the results of the maintenance work is confirmed.

Explanation of Abbreviations in the Protocol

11 10 2	型(gattagera) ((G)e)	Avaioncely	b), \$10-10 feet 1
SI	Safety Inspection	PMF	Preventive Maintenance, Operating Value Check, Function Check
SIE	Electrical Safety Inspection	Q	System Quality, Image Quality
SIM	Mechanical Safety Inspection	QIQ	Image Quality
PM	Preventive Maintenance	QSQ	System Quality Check
PMP	Periodic Preventive Mainte- nance	SW	Software Maintenance
РМА	Preventive Maintenance Adjustments	CSE	Customer Service Engineer

Measuring Equipment and Measuring Instruments Used

Measuring instruments and measuring devices (phantoms, MR coils, etc.) may not be entered in the table if they have already been entered in the mobile device.

មើរទីនេះបានទៅ.១៤១ ១១៤នូវតិ១ភេទ ស្រាក / ការការការិការបាត់ការការការប្រ	e production of the contract	Militar Resid

PM

Cleaned and inspected

5.4.40	KIUKI	stron Area and polenoid Assemblies		
	PM	Cleaned and inspected		
3.2.21		narge System Drawer		
	PM	Charge drawer inspected		
3.2.22	SF6 sys	SF6 pressure within range		
3.2.23		np Assembly		
ad a Sin a hearted	PM	Oil pump inspected, no leaks		
3.2.24	Cooler	,	,	
	PM	Cleaned and inspected		
3.2.25	+131/1-14	3 Primary Collimating System (if pres	ent)	
	PM	Inspected (if present)		
3.2,26		Console Cabinet (if installed)		
3 3 35	PM	Inside of CCC cleaned and inspected Console		
3.2.27	PM	Cleaned and inspected		
3.2.28	CC Noc			
	PM	Cleaned and inspected		
3.2.29	Contro	l Console Keyboard		
	PM	Cleaned and inspected		
3.2.30		l Console Monitor		
The The Thomas	PM	Cleaned and inspected		
3.2.31	PM	Console versions Batteries replaced		
3.4		ical Checks		
3.4.1	Ma H IV	odulator Assembly (if present) Voltage checked (if present)		
3.4.2		agnetron Filament Power Supply (if p	resent)	
27	PM	Operation verified (if present)		
3.4.3	536 PU	mp Stand Assembly		
	PM	Inspected		
3,4,4	537 B∈	nding Magnet Power Supply		
	PM	Operation verified (if present)		
3.4.5		enoid Power Supplies		
	PM	Operation verified (if present)		

				OK	not OK	n.a.
3.4.6	S38 Ele	ctromagnet Terminal Block (if present)				
	PM	Calibration checked (if present)				
3.4.7	Gantry	Bearing Lubrication				
	PM	Lubricated				
3.4.8	Bendin	g magnet and klystron power supplies rack				
	PM	Power supplies functional				
3.4.9	540B Va	acuum Power Supply Assembly				
	PM	Current and voltage normal				
3.4.10	Control	Console Cabinet (if installed)				
	PM	Ventilation checked				
3,4,11	Control	Console				
	PM	All modes and energies in use are operational				
	PM PM	Keyswitches are intact Current softpots downloaded as backup		H	\mathbb{H}	Н
	PM	Parameter sheet is available		H	H	H
	PM	Backup disks are available				
	PM	Interlock and error counters cleared				
3,5	Multi	Leaf Collimator				
3.5.1	58 MLC	- 30-MLC (if present)				
	Option	present: Yes: No:				
		Signature:	_			
	Date:	Name:				
3.5.1.1	Serup					
3.5.1.2	Leaf ca	libration				
	PM	Leaf calibration verified				
3.5.1.3	Exposu	re Field Accuracy				
	PM	Radiation to light field accuracy verified			_	

External Visual Check 3514 PM Cleaned and inspected Maintenance of this section was performed by: Signature: Date: Name: 58 NLC - 3D-MLC with HPC (if present) 3.5.2 No: Option present: Yes: Signature: Date: Name: Inspection, cleaning, and electrical connection checks 3.5.2.1 Cable connections verified PM PM Collimator cleaned and inspected Leaf track cleaned and inspected PM Electrical Checks 3.5.2.2 Power supply inspected and voltage verified PM Collimator head power supply inspected and voltage verified PM Calibration and Functional Checks 3.5.2.3 PM Radiation to light field accuracy verified PM Pot linearity verified Calibration and backlash checked PM PM X leaf light field range inspected PM X leaf reproducibility and overtravel checked System verification 3.5.2.4 Covers correctly installed PM **PMF** System tested Warning lights and door interlock tested SI 3.5.2.5 Completion Maintenance of this section was performed by: Signature:

Date:

Name:

3.5.3	82 MLC	C - OPTIFOCUS	(if present)		
		n present:	Yes:	No:	
			Signature:		
	Date:		Name:		
3.5.3.1	Setup		e		
3.5.3.2	inspec	tion and clear	ing		
	PM	Cable connec	ctions verified		
	PM		eaned and inspected		
	PM	Leaf track cle	eaned and inspected		
	Mainte	enance of this	section was perform	ed by:	
			Signature:		
	Date:		Name:		
3.6	BEAM	VIEW TI (if i	installed)		
3.6.1	Mirror		<u> </u>		
	PM	Cleaned and	inspected		
3.7	OPTIV	UE			
	PM	Check 2D gai	in calibration		
	PM	Check 3D M\	/CB gain calibration,	if applicable	
	PM		with compressed ai	r	
	PM		cables for wear		
	PM	Dead pixel II	nap evaluation		
3.8	Treati	ment table			
3.8.1	Genera	al functions			
	PM	Tested			
3.8.2	Z IV Ta	ble			
	PM	Cleaned and	inspected		
3.8.3	ZXT - ta	abie bearings			
	PM	Cleaned and	inspected		
3.8.4	550 TX	T - Table bear	=		
	PM	Cleaned and	inspected		

			OK .				
3.8.5	Tableto	pps -					
.8.5.1	Acrylic plates, treatment table						
	ΡM	Inspected (if present)					
.8.5.2	Carbon	fiber tabletop					
	PM	Inspected (if present)					
3.9	inspe	ction finalization					
3.9.1	System	verification					
	PM	Covers correctly installed					
	PMF	System tested in Treatment mode					
	SI	Motion Stop override functionality and light indicated	ion tes-				
	SI	Warning lights and door interlock tested					
3.9.2	Comple	etion					
		Discrepancy Log No problems					
		-					
	×						
	Mainte	enance of this section was performed by:					
		Signature:	_				
	Date:	Name:					
4	6-1/AC	nth Maintenance					
4.1	Gene	al Information					
4.1.2	Time e	stimation					

4.2.14

PM

PM

Gantry control

Inspected

Cleaned and inspected

Measured value:

Measured value:

4.4.11.4	Soleno	id current "SOLI"		
	PM	Voltages within range (if present)	
	N	leasured value:		
	N	leasured value:		
	Ν	leasured value:		
	Ν	leasured value:		
	Ν	leasured value:		
	Ν	Measured value:		
	Ν	Measured value:		
	Ν	Measured value:		
	Ν	Measured value:		
	Ν	Measured value:		
	Ν	Measured value:		
	Ν	Measured value:		
4.4.11.5	Core b	ias		
	PM	Voltage within range (if present)		
	Λ	Measured value:		
4.4.12	K2 aux	diliary interlock chassis assembly		
4.4.12.1	Klystro	on vacuum		
*	PM	Voltage normal (if present)		
	N	Measured value:		
4.4.12.2	Filame	ent voltage "FIL V"		
	PM	Voltages within range (if present	:)	
	Ν	Measured value:		
	Ν	Measured value:		
	Ν	Measured value:		

ОК

G31 Motor control PM Inspected Battery tested (if applicable) PM 4.4.15 Control Console All modes and energies in use are operational PM PM Keyswitches are intact PM Dose servo tested Parameter sheet is available PM Current softpots downloaded as backup PM Wulti Leaf Collimator 58 MLC - 3D-MLC (if present) 4.5.1 6-Month Inspection 4.5.1.1 4.5.1.2 4.5.2 58 MLC - 3D-MLC with HPC (if present) No: Option present: Yes: Signature: Name: Date: Inspection, cleaning, and electrical connection checks 4.5.2.1 PM Labels are intact PM Controller cleaned and inspected Cable connections verified PM PM Fuse operation verified PM Battery voltage checked PM Mylar film inspected Collimator mounting bolts inspected PM PM Collimator cleaned and inspected PM Leaf track cleaned and inspected Electrical Checks 4.5.2.2 Power supply inspected and voltage verified PM Collimator head power supply inspected and voltage verified PM PM Controller input voltage tested PM Controller terminal-to-ground voltage tested Protective grounding resistance tested PM 4.5.2.3 Mechanical Checks Collimator rotation inspected PM

PM

Digital display of collimator angle verified

PM PM PM PM PM PM	PM Pot linearity verified PM Calibration and backlash checked PM Y jaw light field range inspected PM X leaf light field range inspected PM Y jaw reproducibility and overtravel checked					
Motion						
PM	Motion stop tested					
	k Checks					
PM PM	Interlocks actuated when controller power is turned off Interlocks actuated by controller reset status					
	ion finalization					
PM	Covers correctly installed					
PMF SI	System tested Warning lights and door interlock tested	무무무				
Mainte	nance of this section was performed by:					
	Signature:					
Date:	Name:					
OPTIV	and the state of t					
PM	Inspect MCVB Geometry Cal Phantom					
PM	Inspect MVCB Image Quality Phantom					
PM	Bearing Alignment					
PM	Alignment correction					

4.6

4.10.1 System verification

23214111	VEHILGIOT	
PM	Covers correctly installed	
PM	System tested in Treatment mode	
SI	Motion Stop overide functionality and light indication tested	
SI	Warning lights and door interlock tested	

4.1	0.2	Completion

Discrepancy Log	No problems		
		4	

Maintenance of this section was performed by:

			Signature:	
	Date:		Name:	
4.11	interi	ock Checks		
4.11.1	interio	cks #15 and #24	- Mode (SW) and Wode (HW)	
	PM	Tested		
4.11.2	Interio	cks #21 and #22	- Hi Rate 1 and Hi Rate 2	
	PM	Tested		
4.11.3	interlo	ck #36 – Chamber	r High Voltage	
	PM	Tested		
4.11.4	interio	ck #37 – Gantry Li	imit Switch	
	PM	Tested		
4.11.5	interio	ck #39 Motion 5	Stop	
	PM	Tested		
4.11.8	Interio	ck #42 – Water Flo	ow	
	PM	Tested		
4.11.7	interlo	ck #47 - Bending	Magnet (HW)	
	PM	Tested		
4.11.8	Interio	cks #7 and #8 F	latness and Symmetry	
	PM	Tested		

	lio vanskivski		OK not n.a. OK
4.11.9	Interio	ck #53 – Monitor Sync (HW)	
	PM	Tested	
4.11.10	Interio	ck #54 – Dose Rate 2 (HW)	
	PIVI	Tested	
4.11.11		ck #55 – Interlock Circuits	
	PIM	Tested	
4.11.12		ck #94 pre-high rate	
	PM	Tested	
4.11.13		ck #98 – Dose Simulation	, — — —
	PM	Tested	
200	9-W/c	onth Meintenance	
5.1	Gene	ral Information	
5.2	Clean	ing & Electrical Connection	
5.2.1	Access	ory Holder	
5.2.1.1	H33 Ac	cessory Holder	
5.2.2	PM	Cleaned and inspected 40 Lower Defining Head	
and a first to the	PM	Cleaned, inspected, and lubricated (if present)	ппп
5,2.3		y Collimating System	
	PM	Cleaned and inspected (if due)	
	PM	Mode switches inspected (if due)	
	PM	Target area inspected (if applicable)	
5,2,3.1	Field L		
	PM	Bulb replaced	닐닐닐
	PM	Mirror cleaned	
5.2.3.2	PM	ssembly Cleaned and inspected	ппп
5.2.3.3		terconnect Assembly and Chambers	
3.2.3.3	PM	Cleaned and inspected	ппп
5.2.3.4		hielding	
at a language of the	PM	Inspected	ППП
5.2.3.5		ator rotation	
	PM PM	Collimator rotation range tested Collimator play tested	

ОК

6.2.4

6.2.5

6.2.6

PM

PM

PM

PM

G39 AFC Assembly

G38 ion Pump Assembly

G31/G32 Card Cage Assembly

Cleaned and inspected

Cleaned and inspected

Cleaned and inspected

Cleaned and inspected

6.3.10

H33 Accessory Holder

PM

Accessory codes are recognized

OK

not

n a

ОК

n.a.

Note that all the control of the con

ricipitation en la ligación con en contratación de la contratación de

Siemens Healthcare Headquarters Siemens Healthcare GmbH Henkestrasse 127 91052 Erlangen Germany Telephone: +49 9131 84-0 siemens.com/healthcare

siemens.com/healthcare