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PROT. N° 28760

VITERBO, 07/04/2017

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

✓ 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'eseuzione 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, presso strutture od organizzazioni di formazione riconosciute dal relativo costruttore, per operare sulle apparecchiature oggetto della presente indagine, al fine di garantire la VIA ENRICO FERMI, 15

AZIENDA UNITÀ SANITARIA LOCALE

01100 VITERBO

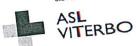
PEC prot.gen.asl.vt.it@legalmail.it

VITERBO

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PARTITA IVA 01455570562

www.asl.vt.it





massima affidabilità ed il mantenimento dei requisiti essenziali per quanto attiene le caratteristiche

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 ASI

Gli operatori economici in grado di garantire almeno quanto sopra indicato sono invitati a da Viterbo. comunicazione entro il giorno Venerdì 28 Aprile 2017 a mezzo fax al numero 0761/237 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

SIEMENS

PRIMUS Linear Accelerator

Customer

Maintenance Protocol System

PRAWIUS Linear Accepteration Walintenance Promotor

customer.	
Address:	
Fax / E-Mail:	
Fax / E-Mail:	
Department:	Room:
Material-No.:	Serial-No.:
Contract-No.:	Expire date:
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 tha ued operation of the system. The defi preventively. *		
The system has serious deficiencies. For operation of the system is permitted or recting the deficiencies.		
*) For imaging systems: The result of t the reference values.	the image quality check show	s no deviation from
The evaluation was performed after co	ompleting all work steps.	
	Signature:	
Date:	Name:	
If required by country-specific regulation. The customer or a representative has system condition.		e evaluation of the
	Signature:	V.
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

11.8:01 212	क्षित्वभावतराजी पुरिवेशकार विकास समिति । स्थापन	Albarty	e bo, from the re-
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
PMA	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.

Milera Mericala and expensional in Applicate and the	all the state of t	State Repair
,		
,		

- 1 PRIMUS General
- 1.1 Scope of Documents
- 1.1.1 Applicability restrictions
- 1.1.1.1 Sites with CTVision configuration
 - 1.4 Parts to be replaced during maintenance
 - 1.5 MLC replacement scheme
 - 1.5.1 58 MLC 3D-MLC / 58 MLC 3D-MLC with HPC
 - 1.5,2 82 MLC
 - 1.6 OPTIVUE/MVCB
 - 1.8 Abbreviations
 - 1.9 General Hints
 - 1.9.5 "Check all electrical connections ..."
 - 1.10 Grounding
 - 2 Safety Precautions
 - 2.1 General
 - 2.5 Mechanical damage
 - 2.10 SF6 gas
 - 2.11 Other risks of injuries
 - 3 3-Month Maintenance
 - 3.1 General Information
 - 3.1.1 Required parts
 - 3.1.2 Time estimation
 - 3.2 Cleaning & Electrical Connection Checks
 - 3.2.1 M31 Modulator Assembly (if present)
 - PM Cleaned and inspected (if present)
 - 3.2.2 S31 Power Distribution Panel Assembly
 - PM Cleaned and inspected

1 1 1 1 1	

			OK	not OK	n.a.
3.2.3	533/5	34 Card Cage Assembly			
	PM	Cleaned and inspected			
3.2.4	535 M	lagnetron Filament Power Supply (if present)			
	PM	Cleaned (if present)			
3.2.5	538 El	ectromagnetic Terminal Block Assembly (if present)			
	PM	Cleaned and inspected (if present)			
3.2.6		urrent Control Assembly			
	PM	Cleaned and inspected			
3.2.7		ectromagnet Power Supply (if present)			
my lang yay	PM	Cleaned and inspected (if present)		Ш	
3.2.8	544 PC	ower Supply (if present)			
3.2.9		Cleaned and inspected (if present)			
ad to have al	PM	Drive chain and gearbox inspected			П
3.2.10		wer Distribution			Ш
	PM	Contactors cleaned and inspected			П
5.2.11	S40A	Fimer Assembly			
	PM	Turn-on timer inspected			
3.2.12	540B \	acuum Power Supply Assembly			
	PM	Cleaned and inspected			
3.2.13	S4OC (Chamber High Voltage Power Supply Assembly			
	PM	Cleaned and inspected			
3.2.14		angle encoder and potentiometer			
,	PM	Inspected			
3.2.15		antry Shaft Encoder Assembly	-		
7050	PM	Cleaned and Inspected (If present)			
3.2.16	PM	ng Magnet and Klystron Power Supplies Rack Cleaned and inspected			
3.2.17		ccessory Holder (if present)			
2.44.17	PM	Cleaned, inspected, and lubricated (if present)			П
	PM	Accessories lock securely	H	H	
3.2.18	K2 Au	xiliary Interlock Chassis Assembly			
	PM	Cleaned and inspected			
3,2.19	K8 Pul	se Transformer/Tank Assembly			
	PM	Pulse tank cleaned and inspected			

						ОК	not OK	n.a.
3.4.5	S38 Ele	ctromagnet Term	iinal Block (if p	resent)				
	PM	Calibration check	ed (if present)					
3.4,7	Gantry	Bearing Lubricati	00					
	PM	Lubricated						
3,4.8	Bendin	g magnet and kly		upplies rack				
	PM	Power supplies fu	unctional					
3.4.9		acuum Power Sup						
	PM	Current and volta	_					
3,4,10		Console Cabinet						
	PM	Ventilation check	ced			Ш		
3,4,11		Console						
	PM PM	All modes and en Keyswitches are i		e operational		H	Н	H
	PM	Current softpots		backup		H	H	H
	PM	Parameter sheet		p.		H	П	H
	PM	Backup disks are	available					
	PM	Interlock and erro	or counters clea	red				
3.5	Multi	Leaf Collimato	Sy .					
3.5.1	58 MLC	- 30-MLC (if pres	ent)					
	Option	present:	Yes:	No:				
			Signature:		,			
	Date:		Name:					
3.5.1.1	Setup							
3.5.1.2		libration						
	PM	Leaf calibration v	erified	1		П	П	П
3.5.1.3	Exposu	re Field Accuracy	c					
	PM	Radiation to light	field accuracy	verified	u u			

Date:

Signature:

Name:

3.8.3

3.8.4

ZXT - table bearings

550 TXT - Table bearings

PM

PM

Cleaned and inspected

Cleaned and inspected

	- production of products to	Consistence (Consistence of the Consistence of the	OK not n.a. OK
3.8.5	Tableto	os ·	
.8.5.1	Acrylic p	lates, treatment table	
	ΡM	Inspected (if present)	
1.8.5.2	Carbon	fiber tabletop	
	PM	Inspected (if present)	
3.9	inspec	tion finalization	
3.9.1	System	verification	
		Covers correctly installed	
		System tested in Treatment mode	
		Motion Stop override functionality and light indication tested	
		Warning lights and door interlock tested	
3.9.2	Complei	don	
		Discrepancy Log No problems	
	Mainter	ance of this section was performed by:	
		Cignoturo	
		Signature:	
	Date:	Name:	
4	6-Wo	nth Maintenance	
4.1	Genera	il Information	
4.1.2	Time es	timation	

2 2 4 - 20 2 3 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	The second second second		OK not n.a. OK
4.2.15	Lasers	/ Patient Setup Devices	
	PM	Cleaned and inspected (if part of SIEMENS installation)	
4.2.16	Hand (Control Assembly	
	PM	Cleaned and inspected	
4.2.17		Control Overhead Suspension	
10.40	PM	Cleaned and inspected	
4.2.18	On Coc	oling System Cleaned and inspected	
	PM	Oil filter replaced (if due)	
4.2.19	H31/H4	43 primary collimating system & water lines	
	PM	Cleaned and inspected	
4.3	Electr	rical Setup	
4.3.1	Emerg	ency-off, -stop and Shunt Trip Push-buttons	
	SIE	Emergency Power Off circuits tested	
4.4	Electr	ical Checks	
4.4.1	541 Cu	irrent Control Assembly	
	PM	Calibration checked	
4.4.2		agnetron Filament Power Supply	
	PM	Operation verified	
4.4.3		tation drive assembly	— ·— ·
	PM PM	Limit switches tested Drive Chain inspected	
	PM	Gearbox inspected	
4.4.4	S36 Pu	imp Stand Assembly	
	PM	Inspected	
4.4,5	535 M	agnetron Filament Power Supply	
	PM	Operation verified (if present)	
4.4.6	G42 D	osimetry	
	PM	Offsets are in range	
4.4.7		nified G42 assembly	
	PM	Inspected (if present)	片片片
4.4.8	PM V7 RE	Voltage verified (if present) Driver Assembly (nRFD)	
7,7,0	PM	Operation verified	
		the state of the s	

			UK
4.4.9	Old RF	driver	
	PM	Operation verified (if present)	
4.4.10	K9 klys	stron filament power supply	
	PM	Power supply functional (if present)	
4.4.11	K2 au>	kiliary interiock chassis assembly	
4.4.71.1	Klystro	an vacuum	
	PM	Voltage normal (if present)	
	N	Measured value:	
4.4.11.2	Filame	ent voltage "FIL V"	
	PM	Voltages within range (if present)	
	٨	Measured value:	
	N	Measured value:	ar.
	N	Measured value:	
4.4.11.3	Filame	ant current "FIL I"	
	PM	Voltages within range (if present)	
	N	Measured value:	
	N	Measured value:	
	N	Measured value:	

4,4,11,4	Soleno	id current "SOLI"		
	PM	Voltages within range (if presen	nt)	
	N	leasured value:		
	N	leasured value:		
	N	leasured value:		
	N	leasured value:		
	N	leasured value:		
	Ν	leasured value:		
	Ν	leasured value:		
	Ν	leasured value:		
	Ν	leasured value:		
	N	Measured value:		
	Ν	Measured value:		
		Measured value:		
4.4.11.5	Core b			
	PM	Voltage within range (if presen	t)	
	V	Measured value:		
4.4.12	K2 aux	kiliary interiock chassis assembl	У	
4.4.12.1	Klystr	on vacuum		
,	PM	Voltage normal (if present)		
	N	Measured value:		
4.4.12.2	Filam	ent voltage "FIL V"		
	PM	Voltages within range (if prese	nt)	
	N	Measured value:		
	1	Measured value:		
	ſ	Measured value:		

n.a.

			OK not n.a. OK
	PM	Leaf track cleaned and inspected	
4.5.3.2	Clectric	tal Checks	
	PM	Power supply inspected and voltage verified	
	PM	Collimator head power supply inspected and voltage verified	
	PM	Controller input voltage tested	
	PM	Protective grounding resistance tested	
4.5.3.3	Wechai	nical Checks	
	PM	Collimator rotation inspected	
	PM	Digital display of collimator angle verified	
4.5.3.4	Calibra	tion and Functional Checks	
	PM	Upper jaw aperture and light field verified	
	PM	Radiation to light field accuracy verified	
	PM	Pot linearity verified	HHH
	PM	Calibration and backlash checked	
	PM PM	Y jaw light field range inspected X leaf light field range inspected	HHH
	PM	Y jaw reproducibility and overtravel checked	HHH
	PM	X leaf reproducibility and overtravel checked	HHH
4.5.3.5	Motion	stop	
	PM	Motion stop tested	
4.5.3.6	interio	ck Checks	
	PM	Interlocks actuated when controller power is turned off	
	PM	Interlocks actuated by controller reset status	
4.5.3.7	inspec	tion finalization	
	PM	Covers correctly installed	
	PMF	System tested	
	SI	Warning lights and door interlock tested	
	Mainte	enance of this section was performed by:	
		Signature:	
	Date:	Name:	
4.6	OPTIV	UE.	
	ΡM	Inspect MCVB Geometry Cal Phantom	
	PM	Inspect MVCB Image Quality Phantom	
	PM	Bearing Alignment	
	PM	Alignment correction	

SI

Warning lights and door interlock tested

a 10 2	Completion				OK not n.a. OK
719		Discrepancy Log	No problems		
		1			
	Maintonanc	e of this section was	nerformed by:		
	Mannenanc	e of this section was	s periorifica by.		•
		Signa	ture:		
	Date:	Name	:		
	interiock			A-1	
4.11.1		15 and #24 - Wod€	e (SW) and Mode	(HW)	
4.11.2	PM Test	ted 21 and #22 – Hi Ra	te 1 and Hi Rate	2	
7, 7 4, 2.	PM Tes				
4.11.3	interlock #3	6 – Chamber High	Voltage		
	PM Tes				
4.11.4	Interlock #3 PM Tes	१७ Gantry Limit S\ tad	witch		
4.11.5		ieu 39 – Motion Stop			
	PM Tes				
4.11.6	Interiock #4	12 – Water Flow			
	PM Tes		74 W 2 O		
4.11.7		17 – Bending Magn tod	et (HW)		
	PM Tes	icu			

PM

4.11.8 Interlocks #7 and #8 - Flatness and Symmetry

Tested

			OK
4.11.9		ck #53 – Monitor Sync (HW)	
	PM	Tested	
4.11.10	PM	ck #54 – Dose Rate 2 (HW) Tested	
4.11.11		ck #55 – Interlock Circuits	
TERRER S	PM	Tested	
4.11.12	Interio	ck #94 – pre-high rate	
	PM	Tested	
4.11.13	Interlo	ck #98 – Dose Simulation	
	PM	Tested	
£.,	SHAL	onth Maintenance	
5.1	Gene	ral Information	
5.2	Clean	ing & Electrical Connection	
5.2.1		ory Holder	
5.2.1.1		ccessary Holder	
5.2.2		Cleaned and inspected 40 Lower Defining Head	
	PM	Cleaned, inspected, and lubricated (if present)	
5.2.3	Primar	y Collimating System	
All All	PM	Cleaned and inspected (if due)	
	PM PM	Mode switches inspected (if due) Target area inspected (if applicable)	
5.2.3.1	Field L	ight	
	PM	Bulb replaced	
	PM	Mirror cleaned	
5.2.3.2		ssembly	
	PM	Cleaned and inspected	
5.2.3.3	G52 In	iterconnect Assembly and Chambers Cleaned and inspected	ппп
5.2.3.4		cleaned and inspected	
J.L. J.T	PM	Inspected	
5.2.3.5		nator rotation	
	PM PM	Collimator rotation range tested Collimator play tested	

			OK not n.a. OK
5.3	Electri	cal Checks and Adjustment	
5.3.1	Collima	tor Encoder	
	PM	Angle adjusted	
5.3.2	G42 Te	mperature and Pressure Compensation	
	PM	Inspected	
	PMA	Adjustment performed (if required)	
5.3.3	ODI		
	PM	Calibration verified	
	PM	Tested for mechanical tightness	
5.4	Multi	Leaf Collimator	
5.4.1	58 MLC	- 3D-MLC (if present)	*
5.4.2	58 MLC	- 3D-MLC with HPC (if present)	
	Option	present: Yes: No:	
		Signature:	
	Date:	Name:	
5.4.2.1	Inspect	tion, cleaning, and electrical connection checks	
	PM	Cable connections verified	
	PM	Collimator cleaned and inspected	
	PM	Leaf track cleaned and inspected	
5.4.2.2	Electric	al Checks	
	PM	Power supply inspected and voltage verified	
the second second	PM	Collimator head power supply inspected and voltage verified	
5.4.2.3		tion and Functional Checks	
	PM PM	Radiation to light field accuracy verified Pot linearity verified	HHH
	PM	Calibration and backlash checked	HHH
	PM	X leaf light field range inspected	
	PM	X leaf reproducibility and overtravel checked	
5.4.2.4	Inspeci	tion finalization	
	PM	Covers correctly installed	
	PMF	System tested	

5.6.2	Comple	tion			
		Discrepancy Log	No problems		
			ſ		
			,		
				- Alian Market	
	Mainter	nance of this section was	performed by:		
		Signat	ure:		
	Date:	Name	· :		
	1 1-1/1	onth Maintenan	And the second		
6.1	Genera	ai Information			
6.2	Cleani	ng & electrical conn	ection checks		
5.2.1	Non-Lyt	ron Pumpstand			
	PM PM	Cleaned and inspected Cartridge changed (if pr	esent)		
5.2.2	S36 Pun	np Stand Assembly			
	PIM PM	Water filter replaced Deionizer replaced			
5.2.3	K1 Pow	er Distribut i on			
	PM	Cleaned and inspected			
5.2.4	G39 AF	C Ass e mbly			
	PM	Cleaned and inspected			
5.2.5	G38 Ion	Pump Assembly			
	PM	Cleaned and inspected			
5,2,6		2 Card Cage Assembly			
	PM	Cleaned and inspected			

PM

Radiation to light field accuracy verified

			OK not n.a. OK
	PM	Pot linearity verified	
	PM	Calibration and backlash checked	
	PM	Y jaw light field range inspected	
	PM PM	X leaf light field range inspected Y jaw reproducibility and overtravel checked	HHH
	PM	X leaf reproducibility and overtravel checked	HHH
	PM	Motion stop tested	HHH
	PM	Interlocks actuated when controller power is turned off	
	PM	Interlocks actuated by controller reset status	
6.4.2.6		placement	
	PM	EPROMs and SRAMs replaced	
6.4.2.7	Inspect	ion finalization	
	PM	Covers correctly installed	
	PMF SI	System tested Warning lights and door interlock tested	
	31	warming lights and door interlock tested	
	Mainte	nance of this section was performed by:	
		Cimpatana	
		Signature:	
	Date:	Name:	
6.4.3		- OPTIFOCUS (if present)	
		present: Yes: No:	
	optioi	rest net	
		Signature:	
	Date:	Name:	
6.4.3.1	Inspeci	tion, cleaning, and electrical connection checks	
	PM	Labels are intact	
	PM	Controller cleaned and inspected	
	PM	Cable connections verified	
	PM PM	Fuse operation verified Battery voltage checked	片片片
	PM	Mylar film inspected	HHH
	PM	Collimator mounting bolts inspected	
	PM	Collimator cleaned and inspected	
	PM	Leaf track cleaned and inspected	
6.4.3.2	Electric	cal checks	
	PM	Power supply inspected and voltage verified	

	The state of the s		OK not n.a. OK
	PM PM	Inspect collision bumpers, if applicable Inspect the window shade	
6.5.2	36 Mor	nth	
	PM PM	Replace vertical ball screw belts Replace the Perkin Elmer power cable and trigger cables	
5.5.3	48 Mor	nth	
	PM	Replace Lambda Power Supply	
6.6	Treatr	ment table	
6.6.1	ZXTire	eatment table	
	PM PM	Cleaned and inspected Free movement verified	
6.6.2	ZXT ba	se plate checks	
5.6.2.1	Wheel	track wear	
	PM	Cleaned and inspected	
5.6.2.2	Wheel	parallelism check	
	PM	Checked	
5.6.2.3		witch check	
6.6.3	PM 550 Tv	Float switch checked T Table Maintenance	
0.0.0	PM	Cleaned, inspected, and lubricated	ппп
	PM	Float switch tested	
	PM	Inspect vertical push chain mounting	
6.6.4	550 Tx	T Vertical Brakes	
	PM	Inspected	
5.6.5	Carbor	n Fiber Tabletop	
7 7 7	PM	Inspected al functions	
6.6.6	PM	Tested	ппп
5.7	Prote	ctive Earth (PE) Ground	
	SIE	PE ground tested	
6.8	Inspe	ction finalization	
6.8.1	Systen	n verification	
	PM	Covers correctly installed	
	PM	System tested in Treatment mode Motion Stop overide functionality and light indication tested	HHH
	SI	Motion Stop overlide functionality and light mateation tested	

	SI Wa	OK not n.a. OK					
.8.2	Completio	n					
		Discrepancy Log	No problems				
	ž.						
	Maintenar	Maintenance of this section was performed by:					
		Signat	ure:				
	Date:	Name	:				

Petro and all All evolutives in a new propy the restaurance of successions of the property of the restaurance of the property of the property

President of the large in reading a final strategic and received

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Print No.: T2-010.832.03.04.02 | Replaces: T2-010.832.03.03.02 Doc. Gen. Date: 08.15 | Language: English © Siemens Healthcare GmbH, 2013

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