SISTEMA SANITARIO REGIONALE
ASL
VITERBO

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REGIONE LAZIO

PROT. N° 43842

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 Gamma Camera Computerizzata "E. Cam" 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 come meglio specificato nell'allegato;
- ✓ controlli di qualità delle immagini per una diagnosi sempre al massimo dell'accuratezza. Controllo dei parametri di qualità immagine e di quelli di misura, regolazione degli stessi in caso di deviazione degli standard qualitativi dichiarati dal costruttore mediante apposita strumentazione in grado di riallineare la matrice dei fotomoltiplicatori costituenti la testata detector;
- ✓ 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 **1 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 mantenimento dei requisiti essenziali per quanto attiene le caratteristiche di sicurezza e di prestazione (secondo la direttiva CEE 93/42 e s.m.i);

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

3 6-Month Maintenance

3.1 Detectors

3.1.1 Clean Dust from Detectors

PM Dust removed from detectors

3.1.2 Inspect Power Supply (For HD3, HD3C, and HD3CF detectors only)

PM Power Supply has been inspected and replaced if needed

3.2 Lubricate PHS

3.2.1 Front PHS Acme Screws

PM Front PHS acme screws lubricated

3.2.2 Docker Pedals

PM Docker pins/plate cleaned and lubricated

3.2.3 Lubricate Bronze Bearing/Shoulder Bolt

PM Bronze bearing/shoulder bolt lubricated

3.3 Cleaning/Inspecting the System

SIM Monitors, computers, gantry, and yokes cleaned and inspected

3.4 Cable Checks

SI All cables checked

3.5 Label Checks

SI All labels checked

3.6 Profile Option Checks

PM Profile checks completed

3.7 Condition of the System Checked

Q Condition of the system checked before returning to customer

4 12-Month Maintenance - PHS

4.1 Rear PHS

4.1.1 Check Up/Down Limit Switch Operation

SI Up/down limit switch is operating

4.1.2 Check Air/Gas Spring for Leakage

PMF Spring checked for leakage

4.1.3 Check Base Cover Does Not Contact Bolt Heads

SI Base cover clearance checked

4.1.4 Check Rollers for Damage

SI Rear PHS rollers checked for no obvious signs of wear

4.1.5 Check Wedge for Damage

SI Rear PHS wedge checked for no obvious signs of wear

4.1.6 Lubricate Linear Bearing Blocks

PM Rear PHS linear bearing blocks lubricated

4.2 Front PHS

4.2.1 Pallet Pad

Q Pallet pad inspected and cleaned

4.2.2 Acme Nut Inspection

PMF ACME back up nut inspected

PM Acme screws lubricated

4.2.3 Lubricate Linear Bearing Blocks

PM Front PHS linear bearing blocks lubricated

4.2.4 Lubricate Bronze Bearing/Shoulder Bolt

PM Bronze bearing/shoulder bolt lubricated

4.2.5 Check Pallet

Q PHS pallet checked

4.2.6 Verify PHS Alignment

PMA PHS alignment checked

4.2.7 Verify Brain Position and Latch Mechanism

Q Brain position latch mechanism cleaned and checked

4.2.8 Patient Positioning Aids and Phantoms

SIM Patient positioning aids and measurement phantoms and holders are in satisfactory condition without visible damage

4.2.9 Foot Pedals and Plungers

Q Foot pedals checked

PM Docker pins/plate cleaned and lubricated

4.2.10 Verify Pallet Release Switches

Q Pallet release switches checked

4.2.11 Check Pallet Arm Rests/Latch/Magnetic Switches

Q Pallet arm rest switches checked

4.2.12 Check End Caps

Q PHS end caps inspected

4.2.13 Verify PHS Storage Position

Q PHS storage position checked

4.2.14 Mammography Pallet (if pallet option is present)

Q Mammography pallet shows no obvious deformations

4.2.15 Pediatric Pallet (if pallet option is present)

Q Pediatric pallet shows no obvious deformations

5 12-Month Maintenance - Gantry

5.1 Gantry Checks and Lubrication

5.1.1 Verify Left/Right Emergency Stops

SIM Left and right emergency stops work correctly

5.1.2 Verify Remote Emergency Stop

SIM Remote emergency stop works correctly

5.1.3 Verify Hand Controller

SIE Hand controllers work correctly

PM Hand controllers replaced

5.1.4 Verify Caudal Tilt Switch/Clutches

PM Caudal tilt switch/clutches work properly with no obvious mechanical drag or noise

5.1.5 Verify Caudal Tilt Potentiometer position with PPM values

SI Caudal tilt potentiometer checked

5.1.6 Gantry Rotate and Cable Check

- **SI** Cables at motion points do not show wear
- **SI** Verified gantry rotate operation works and is clear of motion restriction and cable pinching
- **SIM** Rotate brake holds work properly
- **PM** Rotate ring greased

5.1.7 Take Up Reel

- **SIM** Take up reel inspected
- **PM** Take up reel replaced

5.1.8 Verify System Home Sequence

- **SIM** System home sequence completes and flags rest on the middle of the sensors

5.1.9 Reconfiguration (Dual Head Systems only)

- **SI** Verified Reconfigure stop points/segments/home
- **PM** Reconfigure cam lubricated

5.1.10 Radial Check

- **SIM** Radial alignment checked
- **SIM** Radial Ball Screw works well and is not deformed
- **SIE** Radial Brake LEDs (EBRBS) checked and functioning
- **PM** Ball screws lubricated
- **PM** Bevel gears lubricated

5.1.11 Lubricate Linear Bearing Blocks

- **PM** Linear bearing blocks lubricated

5.1.12 System Alignment Check

- **SIM** System Alignment checked

5.1.13 Collimator Cart Swivel Caster Inspection

- **SIM** Swivel Casters Inspected

5.1.14 Swivel Caster & Wheel Lubrication

- **PM** Swivel Casters Lubricated
- **PM** Caster Wheels Lubricated

5.1.15 Cart Check - High Energy Collimator

- **PMF** Cart with high energy collimator(s) checked

5.1.16 Verify Collimator Change Operation

PMF Collimator change operation and collimator cart checked

5.1.17 Inspect C-Frame(s) and Switches

PM C-frame(s), wear strips, and clips inspected

SIE C-frame/collimator cart switches work properly

5.1.18 C-Frame Shaft Weldment Check and Drive Assembly Lubrication

SI C-frame shaft weldment checked

PM C-frame drive assembly lubricated

5.1.19 Check C-Frame Drive Lockdown Screws

PM Checked C-frame lockdown screws

5.1.20 Gantry Left/Right (Dual Head Systems only)

SI Checked gantry rear wheels and plates

PM Rail track lubricated

PM Left/right drive screw lubricated

5.1.21 PPM Check

QIQ PPM Monitor settings checked

SI Sag on PPM knuckle checked

5.1.22 Cleaning/Inspecting the System

SIM Gantry and yokes cleaned and inspected

5.2 Load Bearing Bolt Checks

5.2.1 Frame to Base

SI Frame to Base Checked

5.2.2 Detector Bearing Cars

SI Detector Bearing Cars Checked

5.2.3 Ball Screw Bearing Housing

SI Ball Screw Bearing Housing Checked

5.2.4 Tub Shift Detector Clamp

SI Tub Shift Detector Clamp Checked

5.2.5 Top Clamp

SI Top Clamp Checked

5.2.6 Rail Casting

SI Rail Castings Checked

5.2.7 Tub Clutch Connection

SI Tub Clutch Connection Checked

5.2.8 Clutch Yoke Connection

SI Clutch Yoke Connection Checked

5.2.9 Front Upper Cam Followers

SI Front Upper Cam Followers Checked

5.2.10 Lower Casting

SI Lower Casting Checked

5.2.11 Collimator Clamp

SI Collimator Clamp Checked

5.2.12 Lower Rear Cam Follower

SI Lower Rear Cam Follower Checked

6 12-Month Maintenance - Tower and Detector

6.1 Tower

6.1.1 Check MEB Power Supplies: +5, +/- 12, +24 vdc

Q MEB voltages checked

6.1.2 Gantry UPS Checks

6.1.2.1 Gantry UPS Cleaning

PM Gantry UPS cleaned

6.1.2.2 Gantry UPS Replacement

Startup Date: ☐ . .

Date of Last Replacement: ☐ DD MMM YYYY

6.1.3 Clean Dust from Tower Cabinet

PM Tower cabinet dust removed

6.1.4 Run Camera and Gantry Diagnostics

Q Gantry Diagnostics checked

6.1.5 Verify Preserve Files are Backed Up

SW Preserve files checked

6.2 Acquisition e.soft/syngo MIWP Computer

6.2.1 Clean Dust from Computer

PM Computer dust removed

6.2.2 Backup SW Settings

SW SW settings backed up

6.2.3 Back up e.soft/syngo MI Applications Settings

SW e.soft Settings Backed Up

6.2.4 SRS Check (For systems with e.soft 3.5 and above)

SW SRS connection working

6.2.5 Auto Report Enabled Check (2008A software and above)

SW Auto Report is enabled

6.2.6 Run Error Checking on C: and D: Drive

SW Error checking on C: and D: drives performed successfully

6.2.7 Run Disk Defragmenter on C: and D: Drive

SW Disk Defragmenter on C: and D: drives performed successfully

6.2.8 Check Monitor Settings

QIQ Monitor settings checked

6.3 Acquisition ICON

6.3.1 Clean Dust from Computer

PM Computer dust removed

6.3.2 Run Diagnostics on the Hard Drive

SW Hard drive Diagnostics run successfully

6.3.3 Check Monitor Settings

QIQ Monitor settings checked

6.3.4 Re-Build Desktop (Hold Apple & Option when Booting)

SW Desktop rebuilt successfully

6.4 Processing ICON Computer

6.4.1 Clean Dust from Computer

PM Computer dust removed

6.4.2 Run Diagnostics on the Hard Drive

SW Hard drive Diagnostics run successfully

6.4.3 Check Monitor Settings

QIQ Monitor settings checked

6.4.4 Re-Build Desktop (Hold Apple & Option when Booting)

SW Desktop rebuilt successfully

6.5 Detectors

6.5.1 Check Fuse Holder

PM Fuse Holder Checked

6.5.2 Check all External Fans

PM External fans working properly

6.5.3 Clean Dust from Detectors

PM Dust removed from detectors

6.5.4 Inspect Detector Covers

Q Detector covers inspected

6.5.5 Inspect Power Supply (For HD3, HD3C, and HD3CF detectors only)

PM Power Supply has been inspected and replaced if needed

6.5.6 Detector Testing

6.5.6.1 View most recent QC performed

QIQ QC is up to date and within specification

6.5.6.2 10M intrinsic verification flood

QIQ Intrinsic Flood Performed and Within Spec

6.6 Imager/Printer

PM PM per manufacturer's instructions performed on printer

7 12-Month Maintenance - Options and Final Checks

7.1 Profile Option

Option present: Yes: ☐ No: ☐

Signature: _____

Date: Name:

PM Profile preliminary checks completed

Maintenance of this section was performed by:

Signature: _____

Date: Name:

7.2 Coincidence

Option present: Yes: ☐ No: ☐

Signature: _____

Date: Name:

7.2.1 Check Fan

PM Coincidence Module Fan Checked

7.2.2 Run Diagnostics

SW SNAC/detector Diagnostics executed successfully

Maintenance of this section was performed by:

Signature: _____

Date: Name:

7.3 e.cam Systems with Mobile Mounting Kit

Option present: Yes: ☐ No: ☐

Signature: _____

Date: Name:

7.3.1 Computer & Monitor Restraints

PMA Computer and monitor restraints checked and adjusted

7.3.2 Gantry, PHS, & Collimator Cart

PM Gantry, PHS & collimator cart restraints checked and secure

7.3.3 Release Pins

PMF Release pins are present and not damaged

Maintenance of this section was performed by:

Signature: _____

Date: Name:

7.4 Electrical Tests

7.4.1 Electrical Ground Tests

7.4.1.1 Gantry Boom Screw

SI Gantry: protective conductor resistance ≤ 300 mΩ

Measured value:

7.4.1.2 Measurement of the system leakage current

SIE System leakage current measured < 300 µA

Measured value:

7.4.1.3 Front PHS

SI Front PHS: protective conductor resistance ≤ 300 mΩ

Measured value:

7.4.1.4 Rear PHS

SI Rear PHS: protective conductor resistance ≤ 300 mΩ

Measured value:

7.4.1.5 Tower

SI Tower: protective conductor resistance ≤ 300 mΩ

Measured value:

7.4.1.6 Measurement of the ECG protective earth conductor resistance

SIE Conductor resistance measured ≤ to 300 mΩ

Measured value:

7.4.1.7 Measurement of the ECG leakage current

SIE Device leakage current measured < 1000 µA

Measured value:

7.4.1.8 Measurement of the patient leakage current

SIE Patient leakage current measured < 50 µA

Measured value:

7.5 Condition of the System Checked

SI No damage present on system or covers

Q Condition of the system checked before returning to customer

Maintenance of this section was performed by:

Signature: _____

Date: Name: