

Certification Test Report (21 CFR 1010.2c)

in version of 03.06.2009

Note: Report describes the status after manufacturing and voids when the system is deinstalled

Modell: Vfomex L240 SN: VTX 01 C0C04-1743 11

Test performed by: Wolfgang Sperner (RSC)

Identification Label (21 CFR 1010.3) Displays manufacturer, place and date of manufacturing, is permanently affixed and legible ok

Emission Limits (21 CFR 1020.40c) Leakage radiation measured at 5cm distance to touchable surface is less than 1µSv/h ok

Maximum Values @		U = 240 kV		1,33 mA	
Front	Rear	Left	Right	Top	Floor
<u><0,6</u> µSv/h	<u><0,5</u> µSv/h	<u><0,5</u> µSv/h	<u><0,5</u> µSv/h	<u><0,5</u> µSv/h	<u>—</u> µSv/h

Floor (21 CFR 1020.40c (2)) Permanent floor or no Room below system tested for emission limits ok

Apertures (21 CFR 1020.40c (3)) Sluices and apertures are sufficiently fixed, any body part cannot be inserted to reach the primary beam ok

Interlock (21 CFR 1020.40c (4)) Door equipped with two interlocks Independent function of interlocks checked ok

Post Interlock function (21 CFR 1020.40c (4)(iii)) Control need to restart X-Ray following interruption by any interlock ok

Independent Interlocks (21 CFR 1020.40c (4)(iv)) All interlocks have been independently checked (already checked above) ok

Ground Fault (21 CFR 1020.40c (5)) Constructively assured by electrical layout. ok

Key Control (21 CFR 1020.40c (6) (i))	Key control present	<u>ok</u>	<input type="checkbox"/> <u>ok</u>
	Key removable in OFF	<u>ok</u>	
	Key locked in ON	<u>ok</u>	
	Key removable in standby	<u>ok</u>	

Controls present (21 CFR 1020.40c (6) (ii)) Radiation can only be started by a designated X-RAY ON Control, X-RAY OFF Control present; ok

X-RAY Indicator (21 CFR 1020.40c (6) (iii))	Number of lamps	<u>3</u>	<input type="checkbox"/> <u>ok</u>
	Number of current indicator	<u>—</u>	
	Two means discernible from control	<u>ok</u>	
	Lamps visibly labelled X-RAY ON	<u>ok</u>	

Additional lamps need
(21 CFR 1020.40c (6) (iv))

At least one lamp seen	
from the door	ok
from the control	ok

ok

Additional Controls
and Indicators
(21 CFR 1020.40c (7) (i))

EMO inside cabinet present	ok
EMO inside cabinet labelled	ok
EMO inside cabinet works	ok

ok

(21 CFR 1020.40c (7) (ii)) No X-Ray ON control inside the cabinet

ok

(21 CFR 1020.40c (7) (iii)) Prewarning Signals inside the cabinet

Horn present	ok
Warning lamp present	ok
Horn active 10s prior to emission	ok
Warning lamp active 10s prior to emission	ok
Warning lamp failsafe checked	ok

ok

(21 CFR 1020.40c (7) (iv)) Warning lamp inside active during emission

ok

(21 CFR 1020.40c (7) (v)) Warning sign inside the cabinet

Number of present signs	4
Sign explains meaning of signals	ok
Signs explain location of EMO	ok
Visibility of signs checked	ok

ok

Warning label
(21 CFR 1020.40c (8)(i))

Label 'Caution: X-Rays Produced when energized'
present close to each X-ON Control

ok

Instructions
(21 CFR 1020.40c (9) (i))
(21 CFR 1020.40c (9) (ii))

Documentation includes:	
Operation manual	ok
Technical data	ok
Safety instructions	ok
Maintenance instructions	ok
Maintenance schedule	ok
Manufacturer's instructions	ok
Installation instructions	ok
Adjustment instructions	ok

ok

GE Sensing & Inspection Technologies certifies that this equipment was designed and manufactured pursuant to the requirements of the performance standard 21 CFR 1020.40, entitled 'Cabinet X-Ray Systems', in effect at the date of manufacture.

5.5.2011

Date


Signature RSO


Signature Production Leader

Certification Label
(21 CFR 1010.2)

Certification label was legibly affixed at the front
of the system.

ok

Boim Kunden!
Page 2/2