Applicability:

Test	Applicable:
1. Safety, Finishing, Start-up, Service and Remote Support Tests	☐
2. OTC (Vision C/Air) Tests	☐
3. FMTS (V) Tests	☐
4.1 Bucky Tests	☐
4.2 Wall Stand Tests	☐
4.3. Bucky Table Tests	☐
5. Portable/Mobile Positioner	☐
6. Integrated Position Tests (V, C and Air)	☐
7. U-Arm Tests	☐
8. Straight Arm Tests	☐
9. Imaging and X-ray Tests	☐
10. Advanced Function Tests	☐
11. Accessories Tests	☐
12. Specific Project Tests (AED retrofit system)	☐

1. Safety, Finishing, Start-up, Service and Remote Support Tests

Test SU. Safety, Finishing and Start-up Test Results

Tests	Result		
Test SU.1 Earthing measured impedance is <100 mΩ (SAT only)	P ☐	F ☐	N/A ☐
Test SU.2 Surfaces are smooth, clean and cold with no scratches or discolouration. Lights work comfortably bright. Cover gaps small and uniform. The buttons react to pressing.	P ☐	F ☐	N/A ☐
Test SU.3 The cable sleeves are intact, the cables are fastened, they do not cross sharp surfaces and cannot snag device motion or trip someone.	P ☐	F ☐	N/A ☐
Test SU.4 Device, safety and company/product labels present, intact and clearly visible. Correct device S/N visible in the console software. Check specific device requirements in VT-V10 Vision product labelling.	P ☐	F ☐	N/A ☐
Test SU.5 All components power up, applications are accessible, the tablet console and LEDs are on, user interfaces responsive are, the System state is on “Stand By”. The buttons on the stand respond. The language and metric system conform to the device location.	P ☐	F ☐	N/A ☐
Test SU.6 All components power down, no LEDs are active, the console shuts down. Only the backup power on the EP remains present (LEDs on the VXS). The stand cannot be moved easily.	P ☐	F ☐	N/A ☐

Test SU.7 Operator access is available. Avanse and Stand App auto-start within 30s. The system is unavailable to the Operator. The system can be accessed remotely with standard Admin access. The Service Shell loads automatically.	P ☐ F ☐	N/A ☐
Test SU.8 Activating the Emergency stop button on the mini console stops all movement of the device.	F ☐ P ☐	N/A ☐

Safety, Finishing and Start-up Notes:

3. FMTS (V) Test results

Tests	Result	
Test FM.1 The brakes release on all release handle contact, quietly. The motion is smooth and quiet over the full range. The cables bend without resistance. The brake holds when the handle is released. No rotation backlash.	P ☐ F ☐	N/A ☐
Test FM.2 The rotation brake release quietly, the motion is balanced and smooth. The brake holds position when the button is released. Mechanical indexing at the horizontal and vertical beam allows easy sliding in and out.	P ☐ F ☐	N/A ☐
Test FM.3 On the touchscreen Hand PA selection the stand shows Free position. When turned to WS bucky the console identifies Stand position (voice and on UI).	P ☐ F ☐	N/A ☐
Test FM.4 The touchscreen changes the exposure technique in < 2s. The battery never goes below 50% and the tablet does not loose connection.	P ☐ F ☐	N/A ☐
Test FM.5 By pressing the brake release button for the third axis, the tube goes slightly upwards or holds current position.	P ☐ F ☐	N/A ☐

FMTS Notes:

4. Detector Stand Test Results

4.1 Bucky Test results

Repeat the tests for every bucky on the system.

Tests	Result

Test BC.1 An Orange LED turns on when a grid is inserted and turns off when it's removed. Avanse shows a grid code consistent with the grid frame.	P ☐ F ☐	N/A ☐
Test BC.2 The bucky trolley moves smoothly and locks into place in the fully out and fully inserted positions.	P ☐ F ☐	N/A ☐
Test BC.3 The detector slides easily into the bucky trolley and comes out without resistance.	P ☐ F ☐	N/A ☐
Test BC.4 The detector rotates smoothly and locks into the portrait and landscape positions. Blue and green LEDs and the Avanse bucky indication show Portrait/Landscape indicators correctly.	P ☐ F ☐	N/A ☐

4.2 Wall Stand Test results

Test WS: WS Positioning and Safety

Tests	Result	
Test WS.1 The elevation brake releases quietly on the handle grip. Motion is smooth, balanced and quiet over full range. The cables bend without resistance. The brake engages when the handle is released and holds fast.	P ☐ F ☐	N/A ☐
Test WS.2 The tilt brake releases quietly, motion is smooth, balanced and quiet over full range. The cables bend without resistance. Moving into and out of 90° indexed positions is smooth. The brake holds the bucky with no backlash.	P ☐ F ☐	N/A ☐
Test WS.3 The system auto-positions smoothly and accurately, without stopping or errors, the status shows READY→MOVING→IDLE. When Move is released the system stops.	P ☐ F ☐	N/A ☐
Test WS.4 Motorised WS elevation and bucky tilt are smooth and quiet on press and stop when button is released. The bucky stops automatically in horizontal and vertical positions.	P ☐ F ☐	N/A ☐
Test WS.5 On emergency stop the WS stops immediately. It cannot be moved again until the EM stop is released.	P ☐ F ☐	N/A ☐

4.3 Bucky Table Test Results

Tests	Result	
Test BT.1 The table-top brake releases quietly, floating is smooth and quiet in full range. The brake holds and great force is needed to move the table top in any direction.	P ☐ F ☐	N/A ☐
Test BT.2 The bucky moves with no resistance, smoothly and quietly over the entire range and stays in position when released.	P ☐ F ☐	N/A ☐

Test BT.3 The table auto-positions smoothly and accurately, without stops or errors. When Move is released the table stops.	P ☐ F ☐	N/A ☐
Test BT.4 The table elevates on single/double click smoothly and quietly from top to bottom. It stops as soon as the footswitch is released.	P ☐ F ☐	N/A ☐
Test BT.5 On emergency stop, the table stops immediately. It cannot be moved again until the EM stop is released.	P ☐ F ☐	N/A ☐

<u>Bucky, Wall Stand and Bucky Table Notes:</u>

6. Integrated Position Test Results (V, C and Air)

Test IP.1 Auto-positioning and Accuracy WS

Tests	Result	
Test IP.1.1 On remote press, the stand auto-positions onto WS smoothly and accurately centred, without stopping or errors. When the remote is released the system stops. It carries on to final position when pressed again. In the final position the stand status is green (IDLE).	P ☐ F ☐	N/A ☐
Test IP.1.2 On SID increase, the system remains centred onto WS within 10mm.	P ☐ F ☐	N/A ☐
Test IP.1.3 The WS SID value on the collimator tape should be around 4cm less than the value shown on the tube-side console display .	P ☐ F ☐	N/A ☐
Test IP.1.4 On manual tube height adjustment the stand automatically adjusts the bucky height to match the beam height and stops when centred.	P ☐ F ☐	N/A ☐
Test IP.1.5 On manual WS height change, the OTC adjusts the tube height to match the beam height and stops when centred to WS bucky	P ☐ F ☐	N/A ☐
Test IP.1.6 The stand adjust the bucky height to match the manually inclined tube beam and stops when centred.	P ☐ F ☐	N/A ☐
Test IP.1.7 When pointing at an empty WS bucky, the stand status is RED. Exposure is not possible.	P ☐ F ☐	N/A ☐
Test IP.1.8 When the WS and beam are not in sync, the stand status is RED. Exposure is not possible.	P ☐ F ☐	N/A ☐
Test IP.1.9 The system positions the tube smoothly above the horizontal WS bucky programmed position.	P ☐ F ☐	N/A ☐

Test IP.2 Auto-positioning and Accuracy Bucky Table

Tests	Result		
Test IP.2.1 The system auto-positions into Table smoothly and accurately centred, without stopping or errors. In the final position the stand status is green (IDLE).	P ☐	F ☐	N/A ☐
Test IP.2.2 While moving the tube left/right, the beam remains centred onto table within 10mm.	P ☐	F ☐	N/A ☐
Test IP.2.3 Table SID value on the collimator tape should be around 4cm less than the value shown on the tube-side console display .	P ☐	F ☐	N/A ☐
Test IP.2.4 . On manual tube translation left/right the table automatically adjusts the bucky position to sync with the inclined beam.	P ☐	F ☐	N/A ☐
Test IP.2.5. On manual tube angle adjustment the table automatically adjusts the bucky position to sync with the beam.	P ☐	F ☐	N/A ☐
Test IP.2.6 When the table is elevated under the tube, the tube moves simultaneously with the table up and down.	P ☐	F ☐	N/A ☐
Test IP.2.7 When pointing at an empty table bucky, the stand status is RED. Exposure is not possible.	P ☐	F ☐	N/A ☐
Test IP.2.8 When the table bucky and beam are not in sync the stand status is RED. Exposure is not possible.	P ☐	F ☐	N/A ☐
Integrated Positioning Notes:			

9. Imaging and X-ray Test Results

IM.1 Console, Exam Entry, APR, System Status, Exposure

Tests	Result	
Test IM.1.1 The entered patient data appears on top of the screen, requested procedures are added. The system state on entry is on Stand by.	P ☐ F ☐	N/A ☐
Test IM.1.2 The status box exists for each detector. Portable detectors go offline when the battery is removed and return automatically when re-inserted.	P ☐ F ☐	N/A ☐
Test IM.1.3 Selecting a projection or patient size updates the exposure technique from APR within 2s. Smaller and paediatric size patients reduce the exposure settings.	P ☐ F ☐	N/A ☐
Test IM.1.4 (SAT Only) The worklist search shows the test exam and it loads correctly.	P ☐ F ☐	N/A ☐
Test IM.1.5 kV allows setting of 40 to 125/150, mA 10 to generator power x 1.2, e.g. 630 for 50kW. The generator allows preparation at max power of 100kV, the state goes into PREPARATION (Yellow).	P ☐ F ☐	N/A ☐

Imaging and X-ray Notes:

IM.2 Collimation

Tests	Result	
Test IM.2.1 When the light is turned on it turns off automatically after ~30s. The blades move smoothly with no resistance. When fully opened at 1m SID, the whole detector active area is covered. The cross-hairs are in the centre of the light field.	P ☐ F ☐	N/A ☐
Test IM.2.2 The system goes through PREPARATION into EXPOSURE (red) state. The acquired image appears on the screen. The lead markers are in the corners of the exposed area shown in the image.	P ☐ F ☐	N/A ☐
Test IM.2.3 The light field is slightly smaller than 20x20cm (95%) for both SID values.	P ☐ F ☐	N/A ☐
Test IM.2.4 The filters change manually or automatically.	P ☐ F ☐	N/A ☐
Test IM.2.5 The collimator rotates smoothly with a mechanical index when facing the front.	P ☐ F ☐	N/A ☐

IM.3 Exposure Accuracy, AEC, DAP, Detector Tests results

IM 3.1 kV Accuracy (SAT Only)

Test configuration:

- Free technique, the collimator pointing at the floor at 1m height, no detector, no filtration
- The X-ray instrument positioned in the center of the light field with collimator opening set to 10 x 10 cm

Focus	mA	mAs	kV_{target}	kV_{actual}	Tolerance [%]
SF	100	20	50		
SF	100	20	70		
SF	100	20	100		
SF	100	20	150		
LF	250	20	50		
LF	250	20	70		
LF	250	20	100		
LF	250	20	150		
SF	10	20	80		
SF	160	20	80		
LF	200	20	80		
LF	500	20	80		
Test 1: All exposures are without error. The values from the x-ray instrument are within ±10 % of the set values compared to the values returned by the generator					P ☐ F ☐ N/A ☐

kV, Exposure Time and mAs Accuracy and Dose Level (FAT Only)

The set doses are not the same for each generator. Pay attention to the focal spot (SF-small focus, LF – large focus). If the focal point doesn't match for the given values (kV_{target}, mAs_{target}, mA_{target}, ms_{target}), adjust them and write them in the table below. To obtain LF, it is best to adjust mA.

	SF	LF	
kV_{target}	60	80	
mAs_{target}	1.6	4	
mA_{target}	160	+/- 400	
ms_{target}	10	-/+ 10	
kV_{actual}			

Tolerance [%]			
All exposures without error. Values from the x-ray instrument within ±10 % of set values compared to the values returned by the generator.			P ☐ F ☐ N/A ☐
mAs_{actual}			
$Time_{actual}$ [ms]			
Both exposures without error. Time and mAs of each exposure in ±10 % of target.			P ☐ F ☐ N/A ☐
Dose [µGy]			
Tolerance [%]			
Draw a ROI box over the image. Compare the dose reading from the measurement instrument to the dose value indicated in the ROI box. The dose measurements (µGy) should be within 10% of each other.			P ☐ F ☐ N/A ☐

Note (Vision M only): Exposure doses: 1) 60kVp; 50mA; 5mAs; 10ms (SF/LF N/A)

IM 3.2 Dose Reproducibility (SAT Only)

Test configuration:

- Free technique, no detector, collimator into floor 1m SID to instrument
- X-ray instrument in the center of the light field, collimator opening 10 x 10 cm
- 1.5 mm CU additional filtration into the collimator
- Exposure technique: 77kV 200mA 10mAs

	Actual value	Tolerance [%]
Exposure 1 / Dose [µGy]		
Exposure 2 / Dose [µGy]		
Exposure 3 / Dose [µGy]		
Average Dose [µGy]		
Maximum tolerance + 10%		
Minimum tolerance – 10%		
All exposures are without error. The Dose value of each exposure is within ±10 % of the average measurement.		P ☐ F ☐ N/A ☐

IM 3.3 AEC (SAT Only)

Test configuration:

- Put a 25 mm Al filter under the collimator
- Place the X-ray instrument next to AEC field, no grid
- For the second test add another 1 mm Cu filter under the collimator

	kV	mA	Dose [µGy]	1. field [µGy]	2. field [µGy]	3. field [µGy]	4. field [µGy]	5. field [µGy]
1	70	160						
The same test with added 1 mm Cu under collimator.								
2	70	160						
The tolerance range is ≤10% between fields, within ±10% of the calibrated AEC value and the same values with the added Cu filter.							P ☐ F ☐ N/A ☐	

IM 3.4 DAP and Detector

Test configuration:

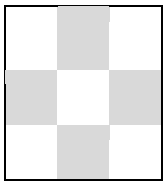
- Position the beam to point at the detector directly, set exposure values to 70kV, 5mAs, 1mm Cu filter, SID 100cm, no grid, the collimator opened to full size of the detector, the X-ray measuring instrument is positioned in the light field.

DAP

	kV	mA	mAs	1.measurement [mGycm^2]	2.measurement [mGycm^2]	3.measurement [mGycm^2]
2	70	200	20			
Test 1: The difference between 3 measurements is ≤20%					Test Evaluation	P ☐ F ☐

DETECTOR

- For this test, ensure that the tube and detector are perpendicular to each other, use a spirit level or digital protractor.
- If the PVI value in any ROI ≥50,000 you have overexposed the detector and have to repeat the test: check the filter, adjust exposure parameters to achieve lower dose.

Flatness - Draw 9 ROI boxes on the image	Max	Min	Mean	Max-Mean / Mean	Mean-Min / Mean
					
Test 2: (Max-Mean)/Mean <0.3, (Mean-Min/Mean) <0.3 **Note (Vision M Only):** Expose at: 70kVp; 5mAs.				P ☐ F ☐ N/A ☐	

Exposure Notes:

Test IM.4 Image Quality, Orientation, Processing, Annotations and Export Test Results

Tests	Result	
Test IM.4.1 On Hand PA exposure the system goes through preparation (yellow) then exposure (red), emitting a beep. The QA phantom image is displayed shortly after, processed using Extremities process group.	P ☐ F ☐	N/A ☐
Test IM.4.2 The highest detector resolution is clearly visible on the QA phantom image.	P ☐ F ☐	N/A ☐
Test IM.4.3 All 6 contrast phantom steps are visible on the QA phantom image.	P ☐ F ☐	N/A ☐
Test IM.4.4 The annotations list offers only “L” and “R”.	P ☐ F ☐	N/A ☐
Test IM.4.5 The top left of the QA phantom is shown on the top left of the displayed image.	P ☐ F ☐	N/A ☐
Test IM.4.6 Exam burning to CD completes without errors. The CD automatically opens on another PC and displays the exam correctly.	P ☐ F ☐	N/A ☐
Test IM.4.7 On close exam, images are sent to PACS without error and are accessible from the local archive.	P ☐ F ☐	N/A ☐
Test IM.4.8 (SAT Only) The image prints accurately with correct annotations.	P ☐ F ☐	N/A ☐

Imaging Notes:

10. Advanced Imaging Functions Tests Results

AD Long Anatomy Imaging

Tests	Result	
Test AD.1 Auto-stitching completes without error, the system positions and exposes in the correct order. Final long image is produced automatically and stitched correctly with continuous ruler.	P ☐ F ☐	N/A ☐

Test AD.2 The stitching tool stitches the manually positioned long anatomy images automatically and the ruler is continuous..	P ☐ F ☐	N/A ☐

<u>Advanced Imaging Function Notes:</u>

11. Accessories Test Results

Test AC.1 Mobile Table

Tests	Result	
Test AC.1.1 The table top floats smoothly in all directions when unlocked	P ☐ F ☐	N/A ☐
Test AC.1.2 The table top floats smoothly with a load of >130kg	P ☐ F ☐	N/A ☐

Test AC.2 Long Anatomy (Stitching) Platform Test Results

Tests	Result	
Test AC.2.1 The platform moves smoothly in all directions when unlocked. When locked the platform doesn`t move.	P ☐ F ☐	N/A ☐
Test AC.2.2 The platform doesn`t deform (or deform slightly) when force is applied on the plastic back. The adjustment of the ruler is easy.	P ☐ F ☐	N/A ☐
Test AC.2.3 The footrest works properly in both up and down positions.	P ☐ F ☐	N/A ☐
Test AC.2.4 The ruler markings are seen clearly in the image when exposed.	P ☐ F ☐	N/A ☐

12. Specific Project and Imaging Test Results

Test SP.1 AED Retro-fit System Tests Results

Perform tests IM.1.1 – IM1.3, IM4.1 – IM4.5, IM5.1 – IM5.2

Tests	Result	

Test SP.1.1 There are no scratches or discolouration on any surface. All surfaces are smooth and clean, with no sharp edges or other snag points. No surfaces are hot.	P ☐ F ☐	N/A ☐
Test SP.1.2 The system starts up normally, the detector connects and is ready for exposure.	P ☐ F ☐	N/A ☐
Test SP.1.3 The system goes into sleep and recovers without an error, the detector re-connects and can acquire an image.	P ☐ F ☐	N/A ☐
Test SP.1.4 The detector acquires the image.	P ☐ F ☐	N/A ☐

Product Acceptance Test type:	**FAT / SAT**
Test passed:	**YES / NO**
Tested By (Name/Signature):	
Date:	