

HT Vista – Installation Certification Protocol

This Qualification Protocol aims to establish documented evidence that the HT Vista is installed and operates in accordance with the Customer Education Requirements.

The highlight of this protocol is to accomplish and ensure optimal clinical usage with the HT Vista device.

It is the responsibility of the distributor to check and approve the Installation Qualification Protocol.

The scope covers three stages: pre-installation, installation and post-installation.

Reference documents:

1. Clinics profile
2. Pre-installation e-mail
3. Clinic registration
4. Education webinars- link
5. Set up protocol
6. Installation syllabus
7. Troubleshooting guide
8. Scans feedback format

Pre-installation:

- Choosing clinics: Clinic's profile
- Pre-installation e-mail
- Clinic registration- DB
- Educational webinars- Self Learning
 - The Unmet need
 - Validation Study
 - Clinical usage

- Excluded list
 - Extreme (edge) cases
 - Tumors on lower legs
 - Very big tumors
 - Mobile tumors
 - Capsulated tumor
 - Black fur patients
 - Black tumor
 - Results interpretation
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- In-clinic setup
 - Step by Step
 - Troubleshooting

Installation

- In clinic setup (protocol)
- Installation syllabus
- Hands-on training: 3 Scans on different models
- Hands-on training: real patient scans: must include 1 cutaneous, 1 subcutaneous

Post Installation

- 5 scans (per user) > HT Vista teams' feedback with HDI Scan Score** of >6

*User: Clinician in the clinic that has been trained and using the HT Vista

*HDI Scan Score: scan's quality score