



MICROBIAL SOLUTIONS

Pre-Installation Questionnaire:

Endosafe® nexgen-MCS™ Instrument with EndoScan-V™ Version 6

Name:

Date:

Organization:

Dear

Thank you for your recent purchase of the Endosafe® nexgen-MCS™ instrument and EndoScan-V™ version 6.0 and higher. Please review the following document and return to the Charles River Technician at least one week prior to your scheduled installation. Completing this document will ensure a smooth installation as there are a few items that need to be prepared ahead of time. Attached you will find our PC requirements. Please review and let us know if you have any questions. Enter your responses in the table below:

1. What is the Windows® Operating System of the computer EndoScan-V™ will be installed on?		
2. If you have .NET Framework Redistributable installed on the computer(s) were EndoScan-V™ will be installed, please list the version number.		
3. Does this computer require access to the internet/intranet along with being connected to an Endosafe® nexgen-MCS™ ?	Yes	No
4. The Endosafe® nexgen-MCS™ utilizes Ethernet or Wifi to connect to a network and can be configured with either an Static or DHCP IP address. Other options can be evaluated on request, but the data will always be accessible via EndoScan-V™ .		
5. Will you require the EndoScan-V™ Database to be installed locally on a PC or in a central location? (Please refer to IT Schematic attached for guidance on installation options)	Central/Server	Local PC
6. If you have purchased EndoScan-V™ Client Manager application, will you require a Charles River Technician to perform the install?	Yes	No
7. If you have purchased EndoScan-V™ Client Manager packages, will these be installed at the same time as the main EndoScan-V™ package?	Yes	No
8. Can you plan to have an IT admin Windows® account available at installation, either via an account that Charles River can use or by having a member of IT available throughout the installation? This will be required for both the PC and server if server installation is requested.	Yes	No
9. Do you utilize a local proxy server?	Yes	No

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10. If you are utilizing a central server, will you use a Static IP address?	Yes	No
11. Is this a multi-site installation? Note: If this is a multi-site installation, a VPN or Public IP address will be necessary for setup.	Yes	No
12. Have Windows® updates been performed regularly on the PC?	Yes	No
13. Is a printer connected to the PC? Note: If a printer is not connected or installed, it must be done prior to the installation of EndoScan-V™ version 6 in order to print EndoScan-V™ reports.	Yes	No
14. Does your laboratory have access to an Uninterruptable Power Supply?	Yes	No
15. Do you agree that you will have downloaded the software from the Charles River Customer Portal and have the files available on the PC(s) ready for install?	Yes	No
16. Does the Charles River Technician have permission to use a Charles River USB drive or an external hard drive? If the Charles River Technician does not have permission to use a Charles River USB drive or an external hard drive, please list the other solutions available that the customer's IT department can provide.	Yes	No
17. If necessary, does your Charles River Technician have permission to use Bomgar/ BeyondTrust to gain remote support if necessary?	Yes	No
18. Please confirm you have received the PC user requirements as attached with the IT Schematic.	Yes	No
19. Please confirm that both the Laboratory Manager and IT representative have read through the questionnaire. Laboratory Manager: _____ Email: _____ IT Representative: _____ Email: _____	Yes	No
20. Do you agree that a specific privilege group can be set up so that the IOPQs can be executed (a copy is available in the IOPQ documents or available upon request).	Yes	No
21. How many Endosafe® nexgen-MCS™ instruments will be connected to the software? (Up to three Endosafe® nexgen-MCS™ instruments can run from one PC)		
22. Please list the serial number(s) of the Endosafe® nexgen-MCS™ instrument(s). Note: Use the comment area to list serial numbers, if necessary.		
23. If you are utilizing exports in CSV or XML format, please confirm you have read the export document to note any changes.	Yes	No
24. Please list any employees that will need to be entered into the software as Users.		
Note: An EndoScan-V™ version 6 demo license is available to IT departments prior to installation in order to provide IT departments ample time to perform their own User Management and Backup and Restore procedures. A demo license may be requested up to thirty days prior to installation of the applications to be purchased.		
25. Comments/Concerns:		

Answer if installation will be remote:

1. Is your team comfortable with unpacking the Endosafe® nexgen-MCS™ instrument?	Yes	No
2. Is your team comfortable with the original Certificate of Calibration and proceeding with the software and instrument qualification only?	Yes	No
3. Does your team member responsible for the remote installation of the Endosafe® nexgen-MCS™ have experience using an Endosafe® nexgen-MCS™?	Yes	No
4. Which of the following would your site prefer: A: Charles River Technician to execute the EndoScan-V™ installation via a remote session B: Your IT team to install EndoScan-V™ by themselves with Charles River support	A	B
5. Is your IT team willing to execute and sign off the software IQ protocol with the remote support of a Charles River Technician?	Yes	No
6. Do you agree to execute the instrument qualification protocols on behalf of the Charles River Technician under remote supervision?	Yes	No
7. Once the instrument installation is complete, do you agree to send back any tools that were provided to you by the end of the following work week?	Yes	No
8. Have your designated personnel completed the remote training on the IOPQ process?	Yes	No
9. Are you comfortable with arranging a meeting to discuss the remote installation process and protocol execution? If yes, who should be involved? _____	Yes	No
10. What is your timeline to complete this installation?		
11. What is your timeline to complete this training?		
12. Did you receive the USB adaptor from Charles River?	Yes	No
13. Are you comfortable using Bomgar or Microsoft Teams for Charles River to engage in a remote session?	Yes	No

Prior to installation, we recommend obtaining the following accessories:

- Vortexer-for mixing sample dilutions
- Fixed, calibrated 25 µL pipettor
- Endotoxin-free pipette tips, we recommend using Eppendorf Biopur® 20-200 µL tips without a cotton filter
- Pyrogen free borosilicate glass or polystyrene plastic dilution tubes
- If sample dilution is required, it is recommended to use depyrogenated glass pipettes without a cotton filter in conjunction with a bulb or electronic pipettor

Installation and Qualification:

The installation and qualification will be performed by the Charles River Technician.

Following the purchase of our EndoScan-V™ software, you will receive information that provides you with either a postcard to download EndoScan-V™ or access to the Charles River Customer Portal to download EndoScan-V™. If the software is downloaded prior to the arrival of the Charles River Technician, please make sure all folders are stored on the PC in an accessible folder for the Charles River Technician. The download link will contain multiple files, please download them all.

NOTE: It is extremely important that all files are downloaded and placed into a folder on the desktop of the PC on which installation will take place.

The following protocols should be carefully reviewed:

- ES-VAL-ESV6
EndoScan-V™ Installation Protocol
- ES-VAL-nexgenPTSMCS001
Qualification Protocol- Installation of the Endosafe® Nexgen™ Instrument With Endoscan-V™ Version 6.0 or Higher
- ES-VAL-Cart001
Qualification Protocol – Communications of the Endoscan-V™ (Version 6.0.0 and Higher) With an Endosafe® Cartridge Instrument
- ES-VAL-Cart002
Qualification Protocol-Performance of the Endosafe® Cartridge Instruments With Endoscan-V™ Version 6.0 or Higher

Pre-requisites

The following pre-requisites are required for installation. Your Charles River Technician will install them prior to installing the EndoScan-V™ software.

- .NET Framework Redistributable Version Minimum of version 4.6.1 (if a higher version than 4.6.1 is already available on the computer, this will not appear in the list of required pre-requisites).
- Microbial Solutions Database (Custom PostgreSQL).
- Microsoft Visual C++ 2017 Redistributable Package Minimum of version 14.14.26405 (if a version higher than 14.14.26405 is already available on the computer, this will not appear in the list of required pre-requisites).

Documentation

The following documents should be reviewed prior to installation:

- SEENDO-ESV6CSV CART: **EndoScan-V™ version 6.0 CSV Export File Format for Cartridge Data**
- SEENDO-ESV6XMLCART: **EndoScan-V™ version 6.0 XML Export File Format for Cartridge Data**

PC System Requirements

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PC which meets all minimum requirements for the Windows® 7 operating system or Windows® 10 system.

Minimum hardware configuration:

- Intel Core i3 - 2.5 gigahertz (GHz) or faster
- 64-bit architecture
- 4 gigabyte (GB) RAM

Recommended hardware configuration:

- Intel Core i5 2.0 (GHz) or faster
- 64-bit architecture
- 8 gigabyte (GB) RAM

Hard drive minimum requirements:

- Minimum hard drive space for EndoScan-V™ Client installation – 200 MB
- Minimum hard drive space for EndoScan-V™ Services installation – 50 MB Minimum hard drive space for Microbial Solutions Database installation – 200 MB

Windows® Server System Requirements:

We support Server 2012, Server 2016, and Server 2019 (Server) using the GUI mode only.

Please note – Server Core is not supported.

Minimum hardware configuration:

- 1.4 GHz 64-bit processor
- Compatible with x64 instruction set
- 2 GB RAM
- 32 GB free of space for Server OS and 4 GB for Installation

Recommended hardware configuration:

- 2.0 GHz 64-bit processor
- Compatible with x 64 instruction set
- 8 GB RAM
- 60 GB free space for Server OS and 4 GB for Installation

Screen resolution requirements:

- Recommended resolution scaling is 100% for all supported resolutions.
- Resolution scaling set to 125% is only supported for the resolution of 1920 x 1080

Supported Languages:

The software supports English, French, German, Spanish, Italian, and Brazilian Portuguese.

- The installed OS language must be one of the 6 languages we support (English, French, German, Spanish, Italian and Brazilian Portuguese).
- The Display language can be the language of choice but if a Sino-Tibetan language (Korean/Japanese/Chinese) is chosen, the user must use English in the Windows® Format (Region and Language-> Format) settings.
- The Windows® Format (Region and Language -> Format) must be one of the 6 languages we support (English, French, German, Spanish, Italian, and Brazilian Portuguese).

Customer Training

Included in your purchase is one day of installation and one day of technician training (software and assay) if you have no other similar devices at your site. Additional training can be purchased/scheduled in consultation with your Charles River Account Manager and Charles River Technician.

How many technicians will need to be trained?			
Are you currently performing endotoxin testing in-house?	Yes	No	
If so, what type of assay do you currently run? Check all that apply.			
Turbidimetric	Endpoint	rFC (Other Recombinant)	
Chromogenic	Gel Clot	MAT	
Can the on-site training take place the day after the installation?	Yes	No	
When entering your site, will the Charles River Technician need to follow/perform specific training to be allowed on site?	Yes	No	
If yes, how many hours should we anticipate?			
When entering your site, will the Charles River Technician need specific documentation or specific Personal Protective Equipment (PPE)?	Yes	No	
Can an IT representative be present during the installation? If not, can a user with administrative privileges be present during the installation?	Yes	No	

Thank you in advance, and I look forward to working with you.

Laboratory Manager Sign

_____ Date: _____

IT Representative Sign

_____ Date: _____

Please note that if the Charles River Technician will not be able to complete the Installation and Training on site for the incongruences from what you agree upfront within this Pre-installation letter, you may be charged twice for the service.