Operating Manual

Secure Operating Manual for Magellan SW and Infinite F50 Reader Family

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WARNING: Carefully read and follow the instructions provided in this document before operating instrument and software.

Notice

Every effort has been made to avoid errors in text and diagrams; however, Tecan Austria GmbH assumes no responsibility for any errors, which may appear in this publication.

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We would appreciate any comments on this publication.

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Table of Contents

1 About this Manual

1.1 Scope of this Manual

This manual provides cybersecurity information for professional users of the microplate reader instruments Infinite F50, Infinite F50 Plus and Infinite F50 Robotic, as well as the Magellan V7.5 data analysis software.

This Secure Operating Manual applies to Magellan SW versions V7.5 and all subsequent versions, until a new edition of the manual is released.

For all released versions of this Secure Operating Manual please visit https://www.tecan.com/knowledge-portal.

For more information about the products listed above, please refer to the corresponding Instructions for Use (IFUs) which are provided with each product.

1.2 Definitions, Acronyms and Abbreviations

Abbreviations / Terms	Description
ASM	Application Software Manual
FAS	Field Application Scientist
FSE	Field Service Engineer
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
IAM	Identity Access Management
IFU	Instructions for Use
IoT	Internet of Things
LTSC	Long-Term Servicing Channel (Microsoft)
Maintained Software	Maintained software are software components for which Tecan will notify customers regarding known risks related to security and provide updates.
MFA	Multi-Factor Authentication
MQTT	Message Queuing Telemetry Transport
OS	Operating System
SBOM	Software Bill Of Materials
Supported Software	Supported software are software components from 3rd parties for which Tecan will notify customers regarding known risks related to security and the availability of compatible updates.
UMS	User Management System
VDR	Vulnerability Disclosure Report

2 General Information

Description	Information
Product Name	Instrument Infinite F50 / Infinite F50 Plus / Infinite F50 Robotic
Software System Name	Magellan
Software Application Name	Magellan
SBOM	Provided by Tecan upon request
Recommended Operating System	See Magellan IFU

2.1 Supported Software

Tecan will monitor the availability of recommended security updates for supported third-party software applicable to this system.

During the preventive maintenance visit, the Tecan Service Engineer will inform the customer of recommended software updates for their system.

Customers are responsible for regularly checking the homepages of third-party software suppliers, including those for operating systems and antivirus software, for recommended security updates. It is the responsibility of the customer to decide whether to download and apply these updates to their systems.

Back up Magellan data files before starting any updates.

Perform Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ) of Magellan software after every system modification.

For the compatibility of third-party software components and versions please check the Magellan Release Notes.

The following list contains software items categorized as supported software.

For a full overview of the software components and versions please consult the SBOM. The SBOM can be obtained on request from Tecan helpdesk.

- SAP Crystal Reports
- Microsoft .NET Framework
- Microsoft Visual C++
- Microsoft Visual C++ Redistributable

2.2 Maintained Software

Tecan will initiate software and security updates for the maintained software as needed.

Customers should regularly check the Magellan Release Notes on the Tecan homepage and review them for information on software and security updates:
https://www.tecan.com/knowledge-portal.

Updates to enhance the functionality of Magellan software are made available for ordering as software upgrade articles and can typically be installed by a professional user.

Firmware updates for the Instrument Infinite F50 typically become available as spare parts for the installation by a Tecan Field Service Engineer (FSE).

The following list contains all software items categorized as maintained software:

- Tecan Firmware package for Infinite F50 and Infinite F50 Plus as embedded software on the instrument
- Tecan Firmware package for Infinite F50 Robotic as embedded software on instrument
- Tecan Magellan software which is typically installed on the customer PC

2.3 End of Life

At the time of publishing this Secure Operating Manual no end-of-life date has been defined. Tecan will announce product phase-out information typically two years in advance at:
https://www.tecan.com/phaseouts

3 System Overview

This chapter and the system diagram describe all external interfaces or applications connected to the system, providing an overview of its integration and dependencies.

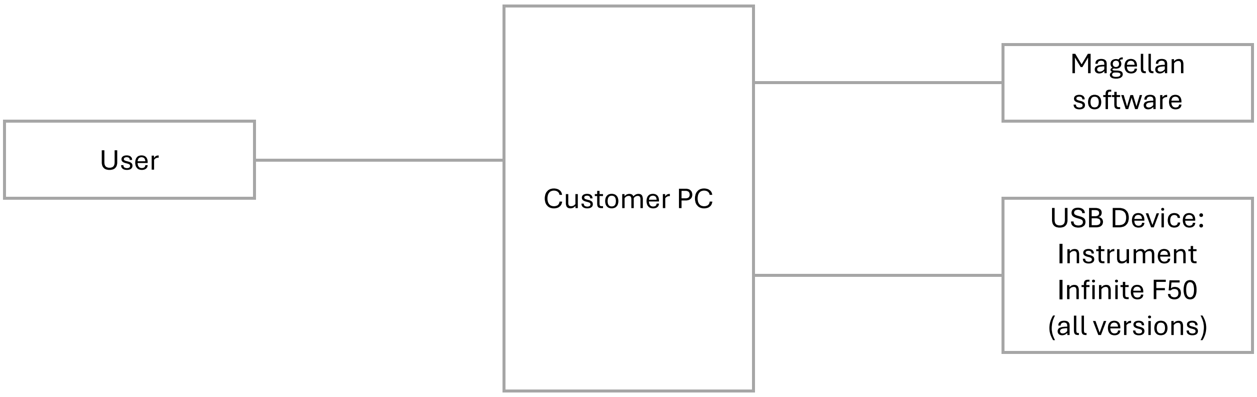

Fig.1: System diagram

Magellan software is used to control the reader and analyze data generated by measurements with any of the Tecan Infinite F50 absorbance microplate readers described above.

Magellan software does not generate/use/transmit or store patient related data – only sample IDs and the corresponding results.

Magellan software is designed to be operated on one computer; it is not intended to be integrated into a network.

For the system described above neither internet access nor access to a cloud-based system is required.

For enhanced cybersecurity and data protection, use the Tracker version of Magellan data analysis software in combination with the Infinite F50, Infinite F50 Plus, or Infinite F50 Robotic microplate reader.

- The Tracker version of Magellan SW provides comprehensive 21 CFR part 11-functionality, such as user administration, electronic records, electronic signatures and audit trail functionality.
- For more information on 21 CFR part 11 functionality, please refer to the chapters “Attach signature Wizard” and “Additional Features for Magellan Tracker” in the Magellan IFU.

3.1 Description of External Interfaces

Name	Protocol	Purpose
User	---	PC login with user password. Magellan login with user password.
Customer PC	USB	The customer PC is connected via a USB cable to the USB-port on the Instrument Infinite F50 (all versions)

4 User Access and Authentication

This chapter describes which user types and roles exist and what needs to be considered during operation.

Physical access control shall be in place as defined by local laboratory and facility regulations or GLP / GMP.

The System administrator of the customer is responsible for any changes made to the operating system of the customer computer. The System administrator typically belongs to the IT-department of the customer and has full Windows admin rights.

The System administrator shall create personalized user accounts for all operators of the device.

The Magellan administrator shall create personalized accounts for Magellan operators.

Summary of different roles and privileges are shown in the table below:

No.	User Group	User Sub-Group	Windows Account and Privileges	Magellan Account and Privileges	Service SW Access
1	Magellan Administrator	Administrator	“User” Read & execute	Full admin rights in Magellan	No
2	Magellan application specialist	Professional user	“User” Read & execute	Create and edit Magellan methods, no editing of signed methods	No
3	End user / Routine user (customer)	Operator	“User” Read & execute	“User” Execution of defined Magellan methods. Perform measurement and save results.	No
4	System administrator (belonging to the IT-department of the customer)	OS Administrator	“Admin” Full Windows admin rights	Optional	No
5	Tecan personnel	FSE	No Service SW is installed on the customer computer.	No	XInfiniTe-F50 Service SW is used on the laptop of the Tecan FSE.

5 System Setup and Configuration

5.1 Network Configuration

Magellan data analysis software is designed to be operated on one computer; it is not intended to be integrated into a network.

For the system described above neither internet access, nor access to a cloud-based system is required.

5.2 Anti-malware Software

Tecan recommends avoiding active scanning of hard drives or memory with anti-malware software while a measurement is in progress with Magellan software and the Infinite F50 reader family.

If a virus scan must be performed during a run, exclude (whitelist) the following directories and their subdirectories from the scan:

- C:\Program Files (x86)\Tecan
- C:\Program Files (x86)\Common Files\Tecan
- C:\ProgramData\Tecan

5.3 Decommissioning of the System

Proper decommissioning of the system is the responsibility of the professional user.

Tecan recommends the following actions when decommissioning the complete system:

- Utilize the Archive files-function in Magellan software to back up your data files.
- Activate the Windows uninstall routine as described in the chapter “Automatic Software Removal” in the Magellan IFU.

Before deleting these folders create a backup of your data:

- Delete C:\Users\Public\Documents\Tecan\Magellan Pro
- Delete C:\Users\Public\Documents\Tecan\Magellan
- Delete C:\Users\Public\Documents\Tecan\LogFiles\SystemAuditTrail
  This is a hidden folder that must be unhidden before it can be deleted.

6 System Operation and Maintenance

Please refer to the following checklist during system operation and maintenance:

- Customers should regularly review the Magellan Release Notes on the Tecan website for information about software and security updates: https://www.tecan.com/knowledge-portal.
- Customers should perform regular backups of their system to ensure that they can recover their data in the event of incidents, such as cyberattacks. For more information, please refer to the chapters “Cybersecurity Information” and “Archive files” in the Magellan IFU.
- Users shall always shut down the system and the running software properly.
- Disconnecting the power cord while the system is on, or closing the application software by shutting down the operating system may result in the system ending in a state like a power failure. For more information, please refer to the chapter “Power Failure” in the IFU for Infinite F50.
- Tecan recommends shutting down and restarting the system periodically to avoid performance problems.

7 Security Controls

The following security risks cannot be fully mitigated by the system described in this manual. Therefore, customers should implement the following security controls to reduce the risk of cyberattacks:

Risk	Mitigation
An attacker could attempt to gain physical access to the laboratory where the system – comprising the customer PC running Magellan SW and the Infinite F50 microplate reader – is located. The objective of such an attack is to compromise Magellan data files and make the system inoperable.	• A physical access control shall be in place as defined by local laboratory and facility regulations, or GLP / GMP. • Set up Windows access control and ensure system operators have the lowest suitable access rights. • Use the Tracker version of Magellan software, which supports 21 CFR part 11 functionality, to control access and enhance application security. • Utilize the archive feature in Magellan software to regularly back up data files.
An attacker could attempt to get Admin Access to Magellan software and modify user permissions.	• Minimize the risk of credential compromise by implementing unique local administrator passwords on all systems, separating and securing privileged accounts, and limiting broad permissions on file repositories. • Change the UMS admin password to a strong, secure password.
An attacker could attempt to gain system access by systematically trying multiple passwords.	• Implement a password policy that includes password strength, complexity rules, and update rules, and not to share passwords between different systems. • Enable email notifications to the Magellan Administrator when an account is locked due to multiple incorrect password attempts.
Reusing a password from another system can allow an attacker to gain access to Magellan software system, if the password is compromised.	• Implement a password policy that includes password strength, complexity rules, and update rules, and not to share passwords between different systems. • Enable email notifications to the Magellan Administrator when an account is locked due to multiple incorrect password attempts.
Attack through open internet connection.	• The Magellan software system operates independently of internet or cloud access. Therefore, the customer PC should remain disconnected from the internet.
An attacker could attempt to target data files exported from Magellan software to a Laboratory Information Management System (LIMS).	• It is the responsibility of the operating authority to protect data on LIMS server against attacks.

7.1 Open Vulnerabilities

For the open vulnerabilities and their corresponding risk control measures please refer to the Magellan Release Notes. If you require a Vulnerability Disclosure Report, please contact Tecan Helpdesk.

7.2 Contact in Case of a Security Incident

In case you experience a cybersecurity incident with these products, please report it to the Tecan Helpdesk. For contact information, visit https://www.tecan.com/support.

Tecan Customer Support

If you have any questions or need technical support for your Tecan product, please contact your local Tecan Customer Support team.

For contact information, visit http://www.tecan.com/customersupport.

Before contacting Tecan for product support, please have the following information ready for optimal technical assistance (refer to the instrument's name plate):

- Model name of your product
- Serial number (SN) of your product
- Software and software version (if applicable)
- Description of the problem and contact person
- Date and time when the problem occurred
- Steps that you have already taken to correct the problem
- Your contact information, including phone number and e-mail address