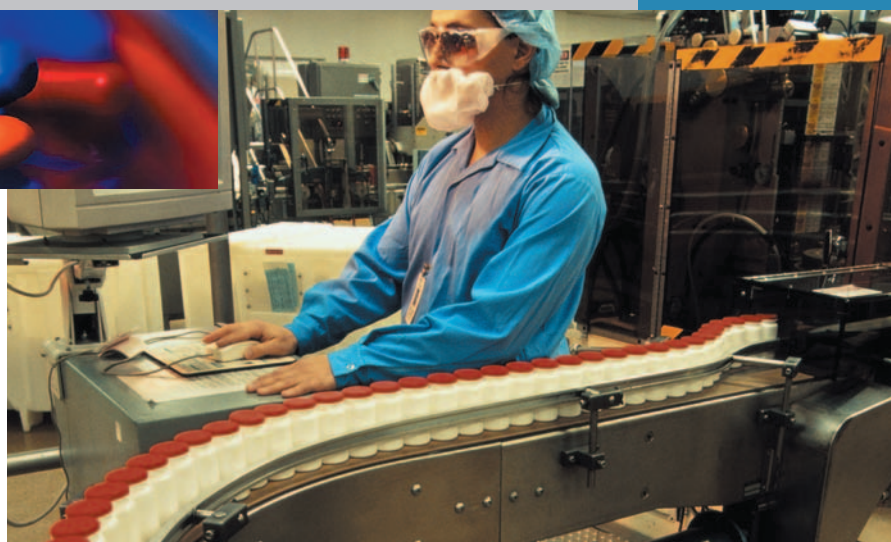


This upgrade kit permits customers to implement 21CFR Part 11 compliant software in existing Thermo Ramsey checkweighers. Existing users of Thermo Ramsey pharmaceutical checkweighers are able to enjoy the security of electronic audit trails, with the associated improvements in quality control, and potential operating savings. These kits allow compliance without the considerable additional investment in product replacement.

21CFR Part 11 Upgrade Kit

An economical solution for Ramsey Pharmaceutical Checkweigher 21CFR Part 11 compliance



Compliance with 21CFR Part 11 permits pharmaceutical companies to store and retrieve data electronically. It is a protocol that ensures data has security and is electronically signed so that there is complete traceability to the responsible person.

Thermo Electron Corporation offers a number of solutions for 21CFR Part 11 compliance including a full database management software package.

This upgrade kit allows existing Thermo customers to convert their pharmaceutical checkweighers to comply with the requirements of 21CFR Part 11 and features:

- Economic solution
- Hardware file storage
- Security software
- Audit trail data
- Simple field upgrade
- No external PC required

Data is stored on the integral hard disk and may be viewed from the checkweigher control panel. Data files are also exportable via a floppy disk for inclusion in the companies 21CFR Part 11 database system.

For security the regulations require each user to log onto the checkweigher. To do this the user must enter a unique user ID, which is controlled by the system administrator, and their password. These two elements form the Electronic Signature that provides the heart of the system security. Passwords are encrypted so that they cannot be read by any other person and can be changed by the user at any time. Passwords must be changed on a regular basis defined by the system administrator.

Electronic records consist of pre-determined sets of data that are stored within the system. These records will provide an audit trail of all activity carried out on the checkweigher.



Specifications and Features

User ID

The system administrator allocates user IDs on an individual basis and also determines the access level for each individual. A user ID will consist of a minimum of 7 characters and a maximum of 12 characters as defined within the regulation.

Passwords

Passwords are always selected by the user and are encrypted for security reasons. A password consists of a minimum of 6 characters and a maximum of 12 characters as defined within the regulation. Passwords will have a validity of 7 to 60 days (default 30 days) as defined by the system administrator. If the user does not change their password within the validity period then the user will be locked out of the checkweigher and will have to be re-admitted by the system administrator. The user may change their password at any time within the validity period.

Access Levels

Administrator

Has full access to all menus except FACTORY only (adding options).

Service

Reserved for maintenance personnel. Allows access to functions that stop production line.

Operator

Makes normal controls available, not allowing the use of functions that could have a potentially negative impact on the process.

Protected

When no user is logged in, the checkweigher is in protected mode. In this mode, no further changes to any variables are allowed until an operator logs in.

Audit Trail Records

Each record will consist of the following information:

- Date and Time (dd/mm/yyyy hh:mm:ss)
- User ID
- Event Description
- Variable Description
- New value of variable
- Old value of variable

Audit Trail Events

A record is generated for each of the following events:

- Reset alarms
- Clear Statistics
- Change product
- Copy product
- Dynamic calibration
- Static calibration
- Speed calibration
- Manual tare (re-zero)
- Change options

Audit Trail Records

Variable	Type	Field	Offset
Date and time	String	20+1	0
User ID	String	12+1	21
Variable/event descriptor	String	40+1	34
New value	String	20+1	75
Old value	String	20+1	96
Measure units	String	8+1	117
Terminator	String	2	126

Compatible Checkweighers

The following Ramsey checkweighers can be upgraded (for others please contact your nearest sales office):

- Ramsey AC9000 Rx
- Ramsey AC9000plus Rx
- Ramsey AC9 Rx
- Ramsey Sentron Pharma

Upgrade Kit

Two versions of the upgrade kit are available; one for use in North America, and the other for the rest of the world. Please contact your nearest sales office for order assistance.

Part No. 21CFR11 / UPG / USA

- Hard Drive
- Cables
- Mounting Kit
- Installation Instructions
- Software Upgrade Disk
- Software Installation Instructions
- Manual

Part No. 21CFR11 / UPG / EU

- Floppy Disk Drive
- Floppy Disk mounting kit
- Other items as 21CFR11/UPG/USA

Installation

The kits are designed for installation by a Thermo Weighing & Inspection field service representative. Installations typically take four hours to complete.

Training

Training is included with the upgrade kit installation.

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