The Ramsey AC9 Rx Checkweigher provides a superior quality assurance tool designed to GMP (Good Manufacturing Practice) standards. It offers customers the highest accuracy performance with the additional benefit of weighing speeds in excess of 550 ppm. Designed exclusively for the Pharmaceutical industry, it also offers the option of 21 CFR Part 11 compliance at the most economic price.

Ramsey AC9 Rx Checkweigher

High accuracy/speed dynamic weighing for the Pharmaceutical industry with 21 CFR Part 11 compliance option

The Ramsey AC9 Rx checkweigher provides the optimum solution for quality control of package contents within the pharmaceutical industry. The checkweigher provides the solution to meet the stringent FDA requirements for validated production by ensuring the accurate and repeatable dynamic measurement of content, leading to 100% inspection. The Ramsey AC9 Rx offers a wide range of production flexibility having the capability of inspecting a wide range of products including:

- Cartons
- Plastic and Glass Bottles
- Blister Packs
- Pouches
- Small Aerosols

High accuracy performance to better than ±50 mg (at 3 sigma) offers the capability of detecting the presence, or absence, of the lightweight but legally required descriptive pamphlet within cartoned products.

Ensuring product content is a key benefit of this checkweigher.

High operating speeds in excess of 500 ppm meet the requirements of modern high-speed production lines.

Full validation documentation is optionally available and assistance with FAT (Factory Acceptance Trials) is a crucial element of the support services offered by Thermo Electron Corporation.

Security of operation is a vital consideration within the pharmaceutical industry and options such as fail-safe reject mechanisms and reject validation are just some of the options available on the Ramsey AC9 Rx.

A full 21 CFR Part 11 compliant option is available to customers as they design new production lines to meet the modern FDA requirements for electronic data storage and traceability.

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Introduction

The use of inspection equipment within the pharmaceutical industry demands the highest standards of hygiene, performance, and reliability. The Ramsey AC9 Rx meets and exceeds these requirements and is uniquely designed for pharmaceutical applications.

The Ramsey AC9 Rx is a monoblock unit, constructed primarily of stainless steel and built to Good Manufacturing Practices (GMP) for the pharmaceutical industry.

The checkweigher is capable of weighing products from 2 g to 500 g at speeds up to 600 ppm dependant on the weight and size of the pack. Typical accuracies as low as ±10mg (one sigma) are possible dependant on pack size and speed.

The Ramsey AC9 Rx ensures brand protection and at the same time improves process efficiency.

Taut Band Weightable
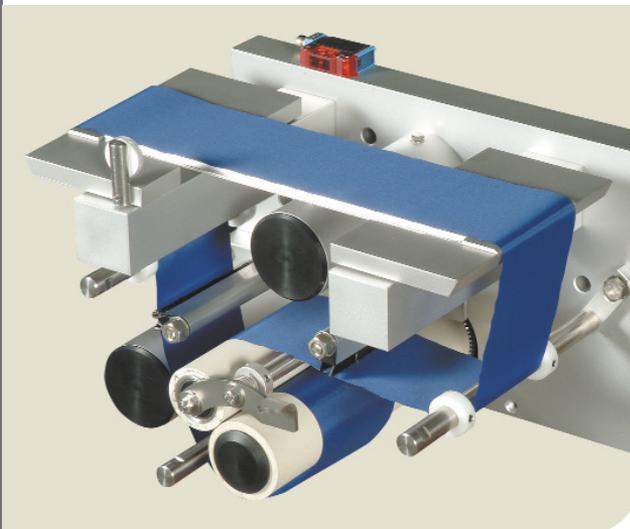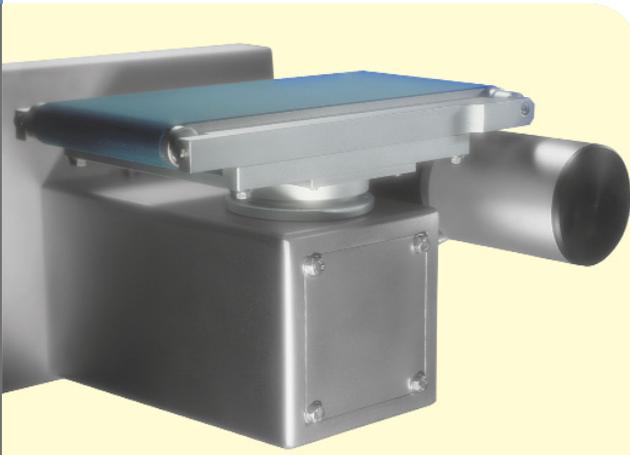
Slack Band Weightable

Weigh Station Features

In any checkweigher the performance will be determined by the design of the weigh station. The weighing area on the Ramsey AC9 Rx is totally enclosed with all pneumatics mounted inside the control cabinet. This ensures that weighing accuracy is not compromised by internally or externally generated drafts.

Performance is further enhanced by the use of a high performance loadcell and integrally mounted motors.

Two separate weigh stations are available to optimize the performance of the checkweigher for the particular pack weight and speed. For heavier packs (up to 500 g) and speeds up to 300 ppm a taut band, or powered weigh table, is employed. For lighter packages (up to 300 g) and for maximum operating speeds a slack band weighing system is used.

Automatic Reject Features and Options

A variety of automatic reject mechanisms are available to provide the optimum solution for each application. Air blast rejects are available for packs up to 200 g. A special pharmaceutical pusher is used for packs up to 500 g and a failsafe version is also available.

Plastic lockable reject bins can be provided for the secure handling of non-standard products.

Reject validation is available as an option to guarantee the most secure operation and can be operated in the accept stream or the reject stream. A consecutive rejects alarm indicates if there are more than "n" consecutive rejects.

Improving Process Efficiency

The advanced weighing controller within the Ramsey AC9 Rx unit allows customers to improve their process efficiencies and profitability. The extensive statistical graphic display information permits the line operator to instantly observe the process performance and make any necessary adjustments to ensure the highest line efficiency. Automatic servo feedback controls to the filler will ensure that the maximum efficiency is maintained during the fill process. A number of feedback options are available to suit specific fill operations.

Additional Inspection Options

The Ramsey AC9 Rx is intended to be the final quality checkpoint within the pharmaceutical packaging process and is therefore an ideal point to incorporate additional inspection functions. An open flap detector can be incorporated into the unit to ensure correct closure of cartons. This option offers additional quality checks with no requirement for additional line space.

Good Manufacturing Practices (GMP)

To ensure that the Ramsey AC9 Rx meets the exacting requirements of the pharmaceutical industry the design is based on GMP standards. Some of the unique features incorporated within the Ramsey AC9 Rx are:
- No operating parts above the product.
- Powered cantilevered conveyor belts.
- Sloping surfaces to ensure that powders fall to the floor.
- Hidden hinges and dust caps on all exposed surfaces ensure clean, clear operation conditions.
- Adjustable, telescopic mounting legs meet FDA requirements.
- Internally mounted air valve and regulator eliminate unwanted air currents.

Validation Option

The Ramsey AC9 Rx may be validated in compliance with the standard FDA rules. This ensures that the customer's cost of installation is minimized. The validation process consists of the following:

Project Plan

The project plan presents the Thermo organizational chart and the responsibility of supply.

Manufacturing Standards

The manufacturing procedures, material specifications, and supplier qualification are specified.

Test Procedures

A schedule of FAT tests is defined and the results of the tests are tabulated and certified.

Mechanical Drawings and Electrical Schematics

A complete bill of materials (BOM) is provided with a general layout drawing of the checkweigher. Spare parts lists are supplied with the electrical schematics of the machine.

Software

Flow charts of the software and source code (as appropriate) are documented. A procedure for software maintenance is also included in this section.

21 CFR Part 11 Option

This option provides full compliance with the requirements of 21 CFR Part 11 and includes the following 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:
- Date and Time (dd/mm/yyyy hh:mm:ss)
- User ID
- Event Description
- Variable Description
- New value of variable
- Old value of variable

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

After Market Services

A full range of aftermarket services are available to support the Ramsey AC9 Rx throughout its lifetime. These include commissioning and validation at the time of installation. A full range of operating and service training modules are available either on site, or at one of the Thermo worldwide training facilities.

To ensure maximum operational efficiency Thermo can offer on site maintenance contracts and a full spare parts service.
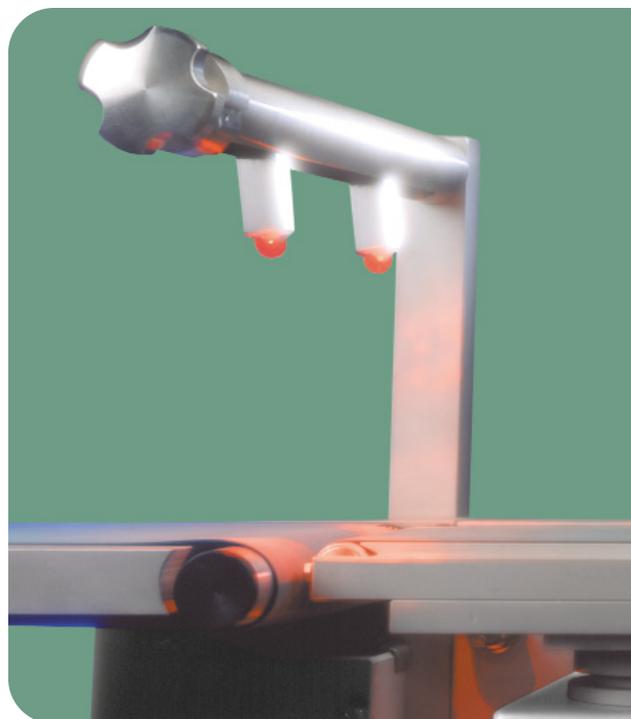
Open Flap Detector

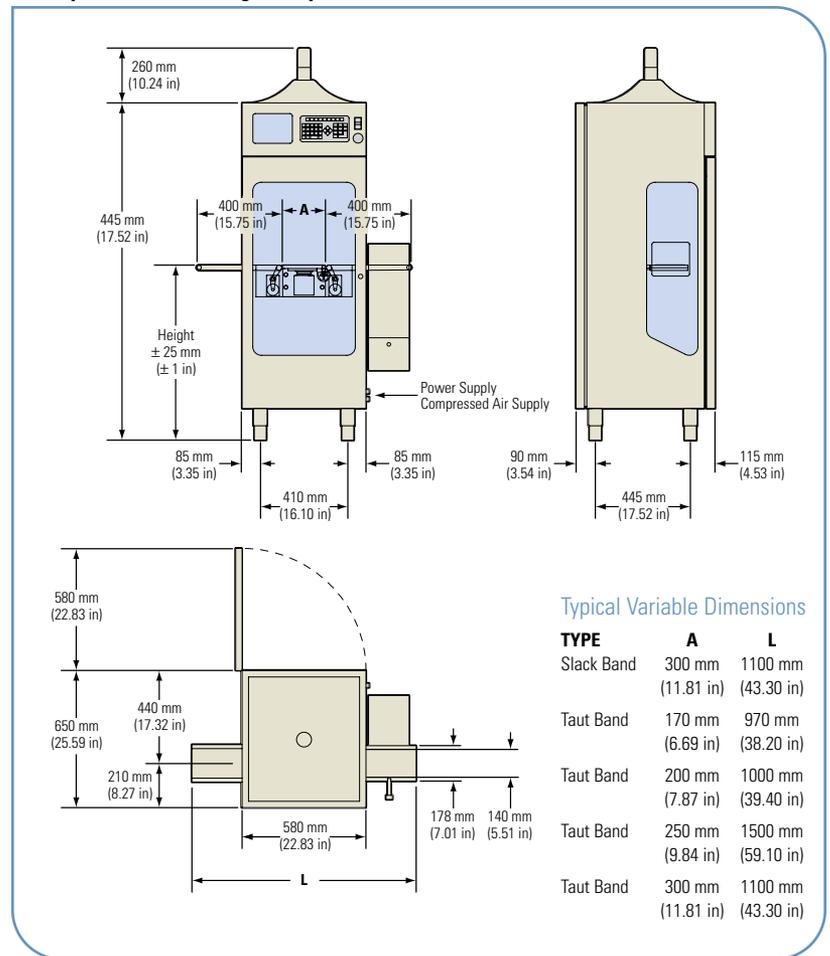## Ramsey AC9 Rx Checkweigher

Specification	
General Specifications	
Pack Rate	up to 600 ppm using slack band and 300 ppm with taut band
Accuracy	± 50mg (± 3 sigma)
Operating Temperature	-10°C to +50°C (+14°F to +122°F)
Relative Humidity	20% to 50% non-condensing
Weight Range	Slack Band: 2 g to 300 g (0.07 oz to 10.57 oz)
	Taut Band: 10 g to 500 g (0.35 oz to 17.62 oz)
Electrical Supply	115/230 VAC, 50/60 Hz, 15 amps
Air Supply	5.5 bar (80 psi)
Line Height	625 mm (24.6 in) to 1000 mm (39.4 in)

Options

- Printer with 42 characters per line for printing statistical data
- Lateral side belts for infeed and/or outfeed product transfers
- Scroll infeed for aerosol and bottle pitching
- Zone lights mounted on top of unit to indicate the last product weight category
- Air jet or pusher for rejected product
- Failsafe reject mechanism
- Lockable reject bin and reject validation
- Servo Feedback control of fillers
- Product memory expansion to 400 products
- Menus available in English, Italian, Spanish, French, Dutch and German
- Communications port: RS 232C/RS 422/RS 485
- SCADA protocols: Modbus, Ethernet (Modbus TCP/IP), Device Net, Profibus, Allan Bradley RIO
- 21 CFR Part 11 compliance

Ramsey AC9 Rx Checkweigher Physical Dimensions

260 mm (10.24 in)

445 mm (17.52 in)

400 mm (15.75 in) **A** 400 mm (15.75 in)

Height ± 25 mm (± 1 in)

Power Supply
Compressed Air Supply

85 mm (3.35 in) 85 mm (3.35 in)

410 mm (16.10 in)

90 mm (3.54 in) 115 mm (4.53 in)

445 mm (17.52 in)

580 mm (22.83 in)

650 mm (25.59 in)

440 mm (17.32 in)

210 mm (8.27 in)

580 mm (22.83 in)

178 mm (7.01 in) 140 mm (5.51 in)

L

Typical Variable Dimensions

TYPE	A	L
Slack Band	300 mm (11.81 in)	1100 mm (43.30 in)
Taut Band	170 mm (6.69 in)	970 mm (38.20 in)
Taut Band	200 mm (7.87 in)	1000 mm (39.40 in)
Taut Band	250 mm (9.84 in)	1500 mm (59.10 in)
Taut Band	300 mm (11.81 in)	1100 mm (43.30 in)

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