PRECISION

Technical Description

SP-4C Sample Weight Checker

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SP-4C Sample Weight Checker

Application

The SP-4C is an automatic benchtop balance that is used for checking the weight of samples of small objects such as tablets and capsules regularly taken from a production line. Each item in the sample is weighed and the unit then calculates statistical information and compares results with pre set limits. It provides accurate printed results eliminating the need for manual recording of weight data.

The operator simply loads the product into the SP-4C and sets the unit to run. It automatically weighs each item, up to the quantity required by the customer's particular testing regime, and prints the results on a printer.

Features

Detailed Sample Printouts

Each sample printout shows the product name, batch number, the time and date the sample was taken and which SP-4C unit it was taken on. It can also list the individual weights of the sample and show the mean weight, the SD and CV. Sample failures are clearly indicated on the printouts to alert the operator to drifts from the target weight.

Accumulated Results

The results of samples checked within a particular batch of product are accumulated and stored in the unit's memory until the batch is terminated. A batch summary can be printed at any time. This gives the weight results, the number of samples that have been taken and how many passed and failed. It can also display a basic histogram.

Product Methods and Limits Libraries

The SP-4C can store details of the name, code, target weight, type of product and the test method for up to 150 products in a product library. Each Product can be associated with a test method stored in the Method Library. The method details the sample size, interval, and what statistics are required.

The samples are compared to sets of limits stored in the unit's Limit Library. The Limit Library can store multiple sets of limit definitions. These can include standard British, European, or US Pharmacopoeia limits, or for an individualised testing regime you can create your own user-defined limits defining Upper and Lower A and B limits and the pass/fail criteria.

10 Operational Lines

The SP-4C can be used to monitor multiple production lines simultaneously. The operator is assigned a line number in the SP-4C for each of the production lines they are monitoring. There are ten lines available so ten production lines can be monitored at one time.

Adjustable Sample Size

The sample size can be pre-set to up 1000 tablets or capsules, so can easily be adjusted to suit your requirements.

Off-Line Samples

Most samples will be taken as standard so the results are stored and accumulated but the SP-4C does have the facility for 'off-line' samples. Off-Line samples are conducted in the same manner as other samples; however the results are not accumulated in the unit's memory.   Users may wish to use this facility during the configuration of a tablet press or capsule-filling machine.

Automatic Sample Prompt

When regular samples are required the SP-4C can be set to prompt the operator that a sample is due. When a sample becomes due an audible alarm is briefly activated accompanied by a message prompt on the instrument display.

Access Rights and Password Protection

The SP-4C can be configured to restrict access to authorised users only.

Description of Equipment

The SP-4C equipment consists of:

The SP-4C Weighing Unit

This consists of the balance, bowl feeder and bowl vibrator. The balance head is situated beneath a removable stainless steel chute assembly. The balance used is a CI top pan MK6 balance designed and manufactured in-house by CI. It is both robust and weighs items up to 2g in weight to an accuracy of +/- 0.5milligrams. The specially designed weigh pan is manufactured in 316 S/S. The bowl feeder is made from acetal. The weighing unit has an integrated polycarbonate draft shield.

The SP Benchtop Control Unit

The SP Benchtop control unit has a touch screen user interface to allow the operator to interact with the control program. The touch screen incorporates bowl vibrator control and alarm and status light indicators.

The SP control unit includes.

- Red alarm and green status indicators
- RJ-45 Ethernet connector
- USB port for printers
- Compressed Air inlet

A printer can be connected directly to the SP-4C controller via the USB port.

The unit can also be configured to work with a network printer (PCL compatible) via the network cable.

If required, printouts can also be transferred on to an USB memory card and copied to a PC. In this way reports are produced in HTML format but are similar in appearance to the standard printouts. The files can then be renamed and stored in folders. We supply an USB card reader with the unit.

Please note: A printer is not supplied.

Brief Description of Operation

The operator loads the sample into the bowl feeder and using the keyboard selects to run a sample. The bowl feeder is activated to feed the items one at a time onto the weigh pan. An optical detector is used to sense when an item drops onto the pan and the bowl feeder is halted whilst the item is weighed. Each weight appears on the display and the item is removed from the weigh pan pneumatically and placed into the collection pot and the bowl feeder activated to place the next item onto the pan for weighing.

Once the all the items required for the sample have been weighed an optional flush cycle will clear any remaining items from the bowl ready for the next sample.

Statistical Reports

The SADE SP sorter calculates statistical information during operation that can be viewed via the user interface. Each sample printout shows the product name, batch number, the time and date the sample was taken and which SP-4C unit it was taken on. It can also list the individual weights of the sample and show the mean weight, the SD and CV. The unit can be configured to show SAMPLE PASSED or SAMPLE FAILED clearly on the printouts.

The Batch Summary includes details such as the number of samples taken, the number passed or failed and the accumulated weight data.

Other reports can be printed including calibration history, Product and Method library details and system settings.

Operating System

Operating Software

The SP series checkweighers and sorters are controlled by the new sophisticated Ci-Matrix operating system which allows for multiple sampling modes and can calculate statistical data for samples and the batch. Sample and batch reports can printed directly on a local or network printer.

Data can be transferred to a PC for storage in randomly encrypted secure PDF file format using the optional SP Connect software.

Ci-Matrix has been designed using GAMP principles to facilitate validation for pharmaceutical use.

Sample Checkweighing

The SP-4C can be used to checkweigh samples of up to 1000 items to Pharmacopoeia or User defined limits, providing sample and batch reports including statistical analysis of the sample.

The SP-4C offers a flexible range of options for customising the sampling.

Configurable options available within sampling include:

- User configurable limits
- A and B Limits (Action and Alert)
- T1 T2 T 3 limits
- Maximum and minimum limits
- Nett weighing option for capsules
- Sample and batch alert/action criteria: Mean Weight Drift from Target, CV and individual weights
- Automatic sample and batch verdict option
- Routine sampling - samples to be performed following a specified time interval. The operator can be alerted when the sample is due.
- Initial sample of specified size. The initial sample must pass and its results are included in the batch.
- Quality control samples. Additional samples with the results being included in the batch statistics.
- Offline samples. Additional samples with the results omitted from batch statistics.
- Report printing options
    - automatically after each sample
    - on batch setup

        o   on batch termination
- Automatic sample prompt

Menu Structure

The menu driven operating system allows access to the following functions:

Configuration Settings	These settings relate to the system settings, security settings, user settings, calibration settings and external balance settings options.
Library Settings	The product, method and limits libraries can store details of more than 150 products
Utility Options	This functionality relates to the change password, set clock, calibration and shut down options.
Batch Menu	These are the batch set-up, and amend, view, start, pause
Sample Menu	These are the prompt, perform, delete, view, print

Balance Head & Calibration

CI MK6 Balance Head

The SP-4C incorporates a CI MK6 balance head, designed and manufactured by CI.
The MK6 balance head has a range of up to 2g provides an accuracy of +/- 0.5mg in suitable environmental conditions.

Auto Zero

The SP4-C has an automatic zero function that is performed at the beginning of each batch or sample.

Calibration

The SP-4C has been designed for easy and accurate calibration. The operator is guided through the calibration process and a record of the calibration can be printed. The system can be configured to prompt the operator to conduct calibration at regular intervals and calibration can be conducted using one or two calibration weights. The calibration status is included in the Batch report. If a calibration is due or a calibration check has failed the unit cannot be operated until a successful calibration has been achieved.
Access to the calibration settings and function can be restricted to authorised users.

A 1g and 500mg Calibration Weight are supplied with the unit.
An option to purchase a full set of UKAS certified calibration weights can be provided on request.

A calibration certificate is supplied with each unit.

Calibration Checks

The system allows a simple calibration check routine. The system can be configured to require a calibration check at pre set intervals or before the start of each batch.
Calibration checks are made using a single weight that is normally different to those used in calibration. A report of the calibration check can be printed. If the calibration check fails then the unit stops sorting and prompts the operator to conduct calibration.

Alarm Conditions

There are visible and audible alarms which are triggered by conditions including:
Zero Failure
Bowl time-out

Over-range

Specification

Material Specification

For GMP all contact parts are manufactured in acetal or 316 stainless steel. Non contact parts are made from acetal, polycarbonate, anodised aluminium and other appropriate materials. The collection pot is manufactured in polypropylene.

Technical Specification

Weight Range:	0 to 2.0g
Readability:	0.1mg
Reproducibility:	+/- 0.5mg to 3 SD depending on environmental conditions
Taring:	Automatic zero prior to each sample
Sample Size:	Up to 1000 tablets/capsules
Product and Method Library:	Details of 150 Products and 50 Methods can be stored
Operator Product Lines:	Up to 10 separate batches can be controlled at a time
Limits:	20 sets of limits can be stored, including standard European, British and US Pharmacopoeia limits for tablets and capsules as well as customer specific limits.

Options:

Support Documentation

CI can supply comprehensive Validation Support Documents with the SP-4C .The information contained in the documents represents a great saving in time and research for the customer.

Machine Technical Folder

The Machine Technical Folder includes machine specific documents such as technical specifications, dimensional drawings, circuit and wiring diagrams, parts list, material specification, machine build record, certificates of conformity, the Final Test Specification, Final Test Results and Calibration Certificate.

Validation Support DVD – Design and Functionality

This DVD has the generic design information for the model including full Functional Design Specifications, FAT specifications and results, for both the SP4C and the operating software together with up to date copies of the change control, software release notes and software revision history.

IQ /OQ Test Specification Template

This option provides the customer with an IQ/OQ test specification template to the CI standard. The document is in MS Word format that can be used as a basis for customer's own OQ.

Accessories & Spares Packs

Combined Accessories and Spares Pack

The combined Accessories and Spares Pack includes a spare balance head, balance pan, PCB board, SP-4C fan, Calibration weights (1g and 500mg F1 weights) with tweezers, a USB Memory card and reader, and various tools and fixings. The Accessories are supplied in a wallet, with a presentation case containing the Spares.

Accessories Pack

The Accessories Pack includes a spare balance pan, Calibration weights and tweezers, a USB Memory card and reader, and various tools and fixings.

UKAS Calibration Certificates

We can supply UKAS calibration certificates for the calibration weights supplied in the Accessories Pack.

Optional Data Output to a PC

SP Connect

SP Connect software allows communication between the SP-4C unit and PC applications using a standard RJ 45 connection.

SP Connect Server Licence

This optional software application allows data transfer from the SP-4C to a PC. It includes a client licence for 1 SP Instrument but can be used for multiple instruments when additional client licences are purchased.

- Automatically print enhanced colour reports on local or network printers
- Create pdf copies of reports for storage in designated files
- Export weight and statistical data into Excel files for further analysis or comparison with other results.

SP Connect Pdf report

See the separate SPConnect datasheet for details.

Network Operation Options

The SP-4C can interface with other external systems using the CI Matrix XML interface provided a suitable server application is provided.

For more information on the options available for interfacing CI's equipment with external systems please contact CI.

Installation and Training

Installation Requirements

In order to meet the performance criteria outlined above the equipment must be installed in an environment suitable for high accuracy weighing.

We will offer specific advice on this, but generally the SP-4C must be located on solid foundations. Air movement, mechanical vibration, temperature changes and humidity levels should be kept within reasonable levels.

Printer Requirements

The SP-4C can be connected to:

- An A4/Letter plain paper PCL3 compatible USB printer, or
- An Espon tally roll printer TM U220 Model M188B Power Supply Interface

A printer is not included as standard but if required please contact CI.

The SP-4C does not support HP printers designed for the home market that use Lightweight Imaging Device Interface Language (LIDIL).

Services Required

Description	
Supply voltage (Factory set)	220-240volts AC Single Phase
Frequency	50/60Hz
Power Consumption	120VA
Air Supply	Clean dry air 2-5 bar

Installation

The SP-4C is delivered to the customer's site by road or air freight. The supplied information is usually sufficient for the customer to install the machine. CI will also offer support via telephone and email to assist with installation if required.

If a customer would like a CI engineer to visit to conduct the installation and offer training then CI would be pleased to arrange this. A price for the installation and Training can be supplied on request.

On-site Training

During the installation, training is provided on:

> Optimum positioning of the Unit
> Operation Procedures
> Cleaning Procedures
> Routine Maintenance

The training is designed for operators and first line maintenance engineers.

SP-4C Training Certificates can be issued on request.

Installation to and training is usually carried out in one working day.

After Sales Support

We maintain a Customer Support Department and keep qualified personnel available for full technical support.

Service Contracts

CI offers a comprehensive Service Contract on all their equipment. Contract customers have priority of telephone support and engineers visits over our non-contract customers.