

# **PharmaSuite®**



## **OUTPUT WEIGHING**

RELEASE 8.4 FUNCTIONAL REQUIREMENT SPECIFICATION

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## Introduction

This document details the requirements of the functions implemented by the Output Weighing phases of PharmaSuite. The phases are executed as an Output Weighing operation in the Production Execution Client for EBR.

Each requirement is composed of a name and a unique identifier (e.g. Required number of sublots (SR0700.8.1)). If a requirement's meaning is for requirement grouping only, the identifier is appended by a plus sign (e.g. Process parameter (SR0700.8+)). For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier, [A1] (page 169).

The revision history (page 172) lists the changes made to the document with PharmaSuite 8.3 as the comparison baseline. Changes related to a requirement are marked as "Editorial", "Update", "New", or "Deleted", changes to the additional context information are marked as "Context information-related".

### **Typographical Conventions**

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

#### **Bold typeface**

Designates user interface texts, such as

- window and dialog titles
- menu functions
- panel, tab, and button names
- box labels
- object properties and their values (e.g. status).

Monospaced typeface

Designates code examples.

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## Recipe Structure for Output Weighing

This section provides an overview of weighing of produced material (Output Weighing). In addition, the yield and the prorate factor can be calculated, if a planned quantity has been defined for the output material.

In order to support different use cases, several Output Weighing operations can be modeled within one unit procedure in sequence or in parallel. This allows, e.g. to prepare containers or sublots and to weigh the produced material in a later separate step or to directly weigh the produced material without preparing any containers or sublots. For details, see "Use Cases" (page 13).

PharmaSuite also supports other weighing-related scenarios. For pre-dispensing for process orders (Dispense) and Inline Weighing before charging, see "Functional Requirement Specification Dispense and Inline Weighing" [A3] (page 169). For cost center-related dispensing, see "Functional Requirement Specification Workflow Phases" [A2] (page 169).

#### **Phases**

- For recent changes, see revision history (page 172).
  - An Output Weighing operation holds the phases specific to Output Weighing. A process parameter of the **Manage produced material** phase defines the operation mode of the operation: The **Flexible** mode allows to both prepare and weigh a container or sublots; the **Prepare only** mode only allows to prepare containers or sublots.
- ➤ NOTE: Output Weighing phases (RS) [1.0] (MR2) container handling in combination with the Identify container phase does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

The following phases are available for Output Weighing:

- Manage produced material (page 19)
  The Manage produced material phase (O Manage Produced Material) allows an operator to manage produced material on container and/or sublot level.
- Show GHS data (optional, see "Functional Requirement Specification Dispense and Inline Weighing" [A3] (page 169))

  The **Show GHS data** phase allows an operator to display the GHS data defined for the current material.

• '

Select scale (page 55)

The **Select scale** phase (O Select Scale) allows an operator to select a weighing method and an appropriate scale. Upon phase completion, the connected scale is initialized and zeroed.

Identify container (page 77) (optional)

The **Identify container** phase (O Identify Container) allows to identify an equipment entity (container) for the material to be produced and to bind this entity to the context in which it is being used. Appropriate equipment requirements can be defined in support of the fit-for-purpose checks during execution.

The usage of the **Identify container** phase during **Output Weighing** is optional. It can also be used during **Dispense**, but it must not be used during **Inline Weighing**.

■ Tare (page 103)

The **Tare** phase (O Tare) allows an operator to record the actual tare of a target container.

If an already prepared container or sublot has been identified, the phase sends the already known tare value to the connected scale and completes automatically.

Weigh (page 127)

The **Weigh** phase (O Weigh) allows an operator to record the actual weight of a target container or sublot and to print a label for it.

If the Output Weighing operation runs in the **Prepare only** mode, the **Weigh** phase completes automatically. In case no target container has been identified before with the **Identify container** phase, the **Weigh** phase creates a sublot in the **Prepared** status with zero quantity.

Release scale (page 155)

The **Release scale** phase (O Release Scale) checks whether the scale value returns back to zero after unloading.

The phases listed above support the concept of fall-through in order to handle unexpected issues that require the operator to rollback the current work with the **Return to material management** user-triggered exception. The **Show GHS data** phase supports fall-through without a specific user-triggered exception.

#### Weighing Methods

The following weighing methods are available:

- In Net weighing, first the tare weight of the target vessel is weighed. Then, the produced material is filled into the target vessel and weighed.
   Net weighing is available for Output Weighing operations that run in the Prepare only mode.
- In **Gross weighing**, first the filled source vessel is placed on the scale. Then, the tare of the source vessel is entered manually and the source vessel is weighed.

**Gross weighing** is neither available for Output Weighing operations that run in the **Prepare only** mode nor for container or sublot preparation in the **Flexible** operation mode.

■ In **Pallet weighing**, first the loaded pallet is placed on the scale. Then, the tare of the pallet and of one of the vessels it holds are entered manually, along with the number of vessels. Finally, the loaded pallet is weighed.

(**Pallet weighing** is based on the assumption that all vessels on a pallet have the same tare.)

**Pallet weighing** is neither available for Output Weighing operations that run in the **Prepare only** mode nor for container or sublot preparation in the **Flexible** operation mode.

Pallet weighing does not apply to the Identify container phase.

In **Quantity entry**, no physical scale is used at all. The quantity provided by external means has to be entered manually.

**Quantity entry** is available for Output Weighing operations that run in the **Prepare only** mode.

The **Tare** and **Release scale** phases are skipped in this weighing method.

#### **Equipment Management Integration**

Since PharmaSuite 8.1 (and Output Weighing phases (RS) [5.0]), equipment management is integrated into PharmaSuite and its phase building blocks. Equipment management covers containers (page 5), scales (page 6), and the handling of runtime properties during exceptional situations (page 6).

#### **Containers**

For recent changes, see revision history (page 172).

The system supports the management of target containers in the context of Output Weighing.

Containers are maintained based on the flexible S88 equipment management capability (see "Functional Requirement Specification Data Management" [A4] (page 169)). A container must be of the **Container** (**RS**) equipment type and a graph of the **Container Cleaning** (**RS**) purpose must be assigned to it.

Specific phases take care of container binding and automatic status graph transitions. In case a status transition fails, the phase requires to sign the **Status transition failed** system-triggered exception.

In addition, phases can write, read, or clear runtime properties of a container with the **Current Tare (RS)** or **Current Sublot (RS)** purposes. The **Tare** phase can read the container's runtime property of the **Reference Tare (RS)** purpose and uses the value for the optional tare value check.

For details, refer to the business logic section of the following phases:

- Manage produced material phase: Container management (SR0700.2.6) function (page 33)
- Tare phase: Container management (SR0720.2.10) function (page 112) and Check container tare (SR0720.2.13) function (page 112)
- Weigh phase: Container management (SR0730.2.10) function (page 138)

#### **Scales**

Scales are maintained based on the flexible S88 equipment management capability (see "Functional Requirement Specification Data Management" [A4] (page 169)). A scale must be of the **Scale** (**RS**) equipment type and graphs with the **Scale Test** (**RS**) and **Scale Calibration** (**RS**) purposes must be assigned to it.

Specific phases take care of scale binding, e.g. binding upon scale selection and unbinding after the weight has been recorded.

Upon selection of a scale with the **Select scale** phase, the system checks the scale's expiry status and, if necessary, automatically updates an expired status. If the status transition fails, the phase displays the **Expired trigger execution failed** error message and the scale can no longer be selected.

In addition, during preparation of a target container, the **Weigh** phase can be used to mark the used scale as currently loaded (runtime property of the scale with the **Current Load (RS)** purpose). This results in skipping the zeroing of the scale (with the **Select scale** and **Get weight** phases) and skipping its release check (in the **Release scale** phase) during subsequent process steps. In order to assure proper handling of loaded scales during execution, the operator has to confirm the current load (scan of container or sublot). If the current load cannot be confirmed, the **Select scale** phase does not allow to select an already loaded scale and the **Get weight** phase does not allow to skip zeroing. If a scale is used that is configured as manual scale, no automated scale communication takes place. During execution, all scale values have to be entered manually and a phase completion signature is automatically requested according to the system configuration.

For details, refer to the business logic section of the following phases:

- Manage produced material phase: Scale management (SR0700.2.7) function (page 34)
- Weigh phase: Scale management (SR0730.2.11) function (page 139)

#### Handling of Runtime Properties during Exceptional Situations

The Output Weighing phases provide specific exceptions that have an impact on the involved equipment objects. In general, the current status and/or context information is reset when such an exception is recorded, e.g. a **Return to material management** user-triggered exception.

For details, please refer to the sections "Equipment Management" of the Manage

**produced material** phase (page 32), the **Tare** phase (page 111), and the **Weigh** phase (page 138).

However, the value of a runtime property is never reset automatically by the system when an exception is recorded, because most likely this also requires further process steps on the shop floor. Runtime properties, in case they have to be reset manually as a consequence of such an exceptional situation, always need to be updated by a data administrator in Data Manager (or alternatively along with the execution of a respective clean-up-workflow on the shop floor, if enabled by project-specific phases).

The table below lists the exceptions and related runtime properties that may require a manual reset/update after an exception has been recorded:

| Phase                     | User-triggered exception                                |  |
|---------------------------|---|--|
| Manage Produced Material  | Annul prepared sublot (SR0700.3.1.3) (page 44)          |  |
| Phase (SR0700+) (page 19) | Container's property of the Current Tare (RS) purpose   |  |
|                           | Scale's property of the Current Load (RS) purpose       |  |
|                           | Replace weighed sublot (SR0700.3.1.4) (page 46)         |  |
|                           | Container's property of the Current Sublot (RS) purpose |  |
|                           | Container's property of the Current Tare (RS) purpose   |  |

#### Planned Quantity Modes and Application of a Prorate Factor

For Output Weighing, the system supports specific features related to several planned quantity modes and the application of a prorate factor in case a planned quantity has been defined.

#### **Planned Quantity Modes**

For a material output parameter of a phase, the following planned quantity modes can be defined:

- **As defined** requires a planned quantity and tolerances to be defined in the recipe. During execution, the planned quantity is based on the recipe definition and a prorate factor can be applied.
- **None** means that no planned quantity is relevant during execution. Any planned quantity defined in the recipe will be ignored.
  - During execution, the planned quantity is stated **N/A** and no planned quantity-related checks apply.
  - Subsequently, no yield and prorate factor can be calculated for the specific output material, because both calculations are based on a planned quantity.

#### Application of a Prorate Factor

The application of a prorate factor is used to automatically reduce the planned quantity of input and output materials of a current unit procedure, based on the yield calculation of produced output materials from one or more preceding unit procedures.

Yield and prorate factor for a produced material can only be calculated if a planned quantity was defined in the recipe for the related output material. The prorate factor is calculated as follows:

Prorate factor = Actual produced output quantity / Original planned output quantity (For details, see **Output Weighing done** (**SR0700.2.3**) business logic (page 30).)

The **Manage produced material** phase for Output Weighing provides the **Prorate factor** (**SR0700.8.6**) process parameter (page 35) to control the application of the prorate factor to output materials during execution. The process parameter can be configured via information flow, which means that the process parameter can be linked directly to a **prorate factor** output variable that provides the calculated prorate factor from a preceding unit procedure.

The following rules apply when a calculated prorate factor is applied during Output Weighing:

- The prorate factor is only applied to materials with the **As defined** a planned quantity mode.
  - It is not applied if the planned quantity mode of a material is **None**.
- Especially in case multiple Output Weighing operations are modeled in parallel for one output material (e.g. Prepare and Weigh, see use case "Multiple Output Material Parameters per Unit Procedure" (page 16)), the **Prorate factor** process parameter must be configured identically for each of the Output Weighing operations. The factor is only applied automatically once (see bullet below). However, due to the parallel structure, it is not determined which operation is started first during execution. Therefore the prorate factor has to be configured for both Output Weighing operations.
- The prorate factor is only applied automatically once per order step output material. This occurs during the first time a **Manage produced material** phase for this output material is activated. It is not applied automatically again in another Output Weighing operation for the same output material or in later instances of a phase, e.g. due to looping or rework scenarios (new unit procedure instance).
- The prorate factor can be overridden and a new factor can be applied to an output material with the **Override prorate factor** (**SR0700.3.1.1**) user-triggered exception (page 43). The exception is available as long as the **Done** option of the **Manage produced material** phase is not selected. As a result, the planned quantity of the output material is updated, which is used as the baseline for the yield calculation for the output material.

■ Note: In case two or more Output Weighing operations are modeled in parallel for one output material (e.g. Prepare and Weigh, see use case "Only One Output Material Parameter per Unit Procedure" (page 14)) and the prorate factor, in violation of this guideline, is not modeled for the first operation that becomes active, no automatic application of the prorate factor happens at this time. However, the prorate factor could already be set manually with the Override prorate factor (SR0700.3.1.1) user-triggered exception (page 43). In this case, the prorate factor is already set once and therefore is no longer applied automatically once other Output Weighing operations for the same output material become active.

## **Output Weighing Operation**

For recent changes, see revision history (page 172).

The typical structure of an Output Weighing operation includes all Output Weighing phases (page 3) in a graph with a loop and a completion-related branch controlled by transitions (page 11).

The usage of the **Identify container** phase and the **Show GHS data** phase is optional.

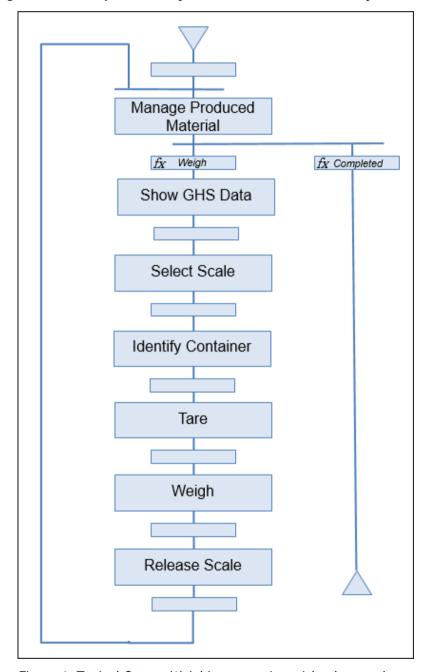


Figure 1: Typical Output Weighing operation with a loop and a completion-related branch

The behavior of the phases can be affected by exceptions and the applied weighing method (page 4).

#### **Transitions**

For recent changes, see revision history (page 172).

Transitions make use of the output variables of a phase to control the process.

The usage of the **Identify container** phase and the **Show GHS data** phase is optional.

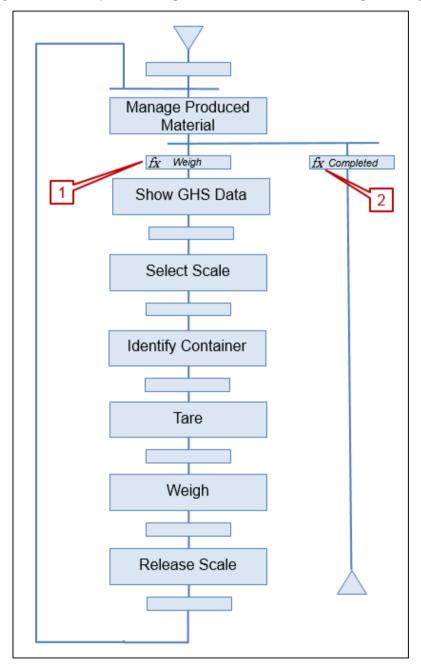


Figure 2: Transitions in a typical Output Weighing operation

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The transitions make use of specific data that is provided via information flow:

- **Result** output variable of the **Manage produced material** phase: WEIGH, COMPLETED
- 1. Weigh (Manager Produced Material » Select Scale)
  {Manage Produced Material}.{Result} == "WEIGH"
- 2. Completed (Manage Produced Material » End step)
  {Manage Produced Material}.{Result} == "COMPLETED"

#### **Exceptions**

- ➤ For recent changes, see revision history (page 172).

  Each phase provides a set of exceptions to record irregular circumstances.
- ➤ NOTE: Output Weighing phases (RS) [1.0] (MR2) exceptions marked with (\*) do not apply (see "Equipment Management Integration" (page 5)).

| Phase   | Exception   |
|---|---|
| Manage Produced Material<br>Phase (SR0700+) (page 19) | User-triggered exceptions: Override prorate factor (SR0700.3.1.1) (page 43) Identify manually (SR0700.3.1.2) (page 43) Annul prepared sublot (SR0700.3.1.3) (page 44) Replace weighed sublot (SR0700.3.1.4) (page 46)       |
|   | System-triggered exceptions: Violated number of sublots (SR0700.3.2.1) (page 39) Overweight check (SR0700.3.2.2) (page 40) Underweight check (SR0700.3.2.3) (page 40) (*) Status transition failed (SR0700.3.2.5) (page 41) |
| Show GHS Data Phase<br>(SR0380+)                      | See "Functional Requirement Specification Dispense and Inline Weighing" [A3] (page 169).  |
| Select Scale Phase<br>(SR0710+) (page 55)             | User-triggered exceptions: Return to material management (SR0710.3.1.1) (page 68) Select offline scale (SR0710.3.1.2) (page 69) (*) Confirm scale load manually (SR0710.3.1.3) (page 69)                                    |
| Identify Container Phase<br>(SR0750+) (page 77)       | User-triggered exceptions: Enter identifier manually (SR0750.3.1.1) (page 95) Unbind (SR0750.3.1.2) (page 96) Skip container identification (SR0750.3.1.3) (page 97) Return to material management (SR0750.3.1.4) (page 98) |
|   | System-triggered exceptions: Property value check (SR0750.3.2.1) (page 89) Container status check (SR0750.3.2.2) (page 91) Unforeseen resume (SR0750.3.2.4) (page 93) Status transition failed (SR0750.3.2.5) (page 94)     |

| Phase                                       | Exception  |
|---|--|
| Tare Phase (SR0720+) (page 103)             | User-triggered exceptions: Return to material management (SR0720.3.1.1) (page 119) Redo zero (SR0720.3.1.2) (page 120) Use offline tare (SR0720.3.1.3) (page 120)  |
|   | System-triggered exceptions: Failed tare check (SR0720.3.2.2) (page 117) Unforeseen resume (SR0720.3.2.1) (page 118)   |
| Weigh Phase (SR0730+)<br>(page 127)         | User-triggered exceptions: Return to material management (SR0730.3.1.1) (page 148) Enter weight manually (SR0730.3.1.2) (page 149) Override use-by date (SR0730.3.1.4) (page 150) System-triggered exceptions: (*) Status transition failed (SR0730.3.2.1) (page 146) Unforeseen resume (SR0730.3.2.2) (page 145) Out of tolerance (SR0730.3.2.3) (page 147) |
|   | Post-completion exceptions:<br>Reprint label (SR0730.3.3.1) (page 151)   |
| Release Scale Phase<br>(SR0740+) (page 155) | User-triggered exceptions: Enter scale value manually (SR0740.3.1.1) (page 164) System-triggered exceptions: Release was not successful (SR0740.3.2.1) (page 163) Unforeseen resume (SR0740.3.2.2) (page 163)  |

#### **Use Cases**

For recent changes, see revision history (page 172).

In order to support different use cases, several Output Weighing operations can be modeled within one unit procedure in sequence or in parallel. However, **not all use cases are supported at the same time**, which finally depends on the number of output materials to be produced within one unit procedure.

In general, the preparation of target sublots for the material to be produced requires that at least one source sublot of the input material has already been identified. However, if a target container that is managed within PharmaSuite has been identified for preparation, the preparation is no longer based on a target sublot, but on the identified container, and no restrictions apply any more regarding the identification of input material. In this case, the system supports the preparation of a container prior to any identification of a source sublot.

Aside from the definition of the overall planned quantity for an output material, PharmaSuite also supports Output Weighing against a pre-defined target weight for each sublot that is created during the Output Weighing process.

#### Only one output material parameter per unit procedure

In this case, only one MFC-related output material parameter is defined for a unit procedure.

Use case characteristics:

- One order step output during runtime
- PharmaSuite supports two different scenarios: Direct weighing (only one Output Weighing operation) and Preparation and weighing (two Output Weighing operations).

In both scenarios, the operations have to be configured to run in a specific operation mode (**Prepare only** or **Flexible**). The operation mode is defined with the **Operation mode** (**SR0700.8.12**) process parameter (page 35) of the **Manage produced material** phase.

Scenario: **Direct weighing** of sublots in one process step:

- One Output Weighing operation is modeled within one unit procedure.
- The operation runs in the **Flexible** operation mode.
- The phases are optimized to tare (except for **Quantity entry**) and directly weigh a sublot in the **Net**, **Gross**, **Quantity entry**, or **Pallet** weighing methods. Target container management is supported in the **Net**, **Gross**, and **Quantity entry** weighing methods.
- In addition, the system allows to first tare and prepare new containers or sublots and, in a later instance of the phase, identify and weigh an already prepared container or sublots, all within the same Output Weighing operation.
- The operation can only be completed without exceptions if the checks against the planned quantity and the final number of recorded containers/sublots have passed (see **Confirm by button** (**SR0700.2.5**) function (page 31)). In addition, no remaining containers or sublots in the **Prepared** status are allowed.

■ In case a planned quantity has been defined, upon completion of the phase, yield and prorate factor are calculated and made available for subsequent processing steps via information flow.

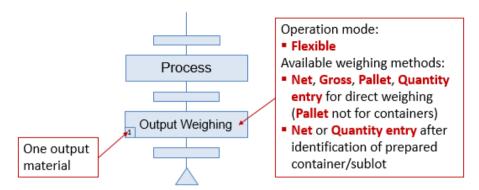


Figure 3: Scenario: Direct weighing of a container/sublots in one process step

Scenario: **Preparation and weighing** of sublots in two separate process steps:

- Two Output Weighing operations are modeled in sequence or in parallel.
- The MFC-relevant output material parameter must be defined only for one of the Output Weighing operations, which typically is the one used for weighing. All other Output Weighing operations run against the one unique order step output automatically.
- The first operation runs in the **Prepare only** operation mode. In this mode, the system only allows containers or sublots to be tared and prepared, but not to be weighed. The **Pallet** and **Gross** weighing methods are not available for the preparation of containers or sublots.
  - The operation can be completed without exceptions as soon as the required number of containers or sublots has been prepared. Yield and prorate factor are not calculated in the **Prepare only** mode.
- The second operation runs in the **Flexible** operation mode. In this mode, a previously prepared container or sublots can be identified and weighed. In addition, the system still allows to tare and prepare a new container or sublots or to tare and directly weigh a container or sublot.
  - The operation can only be completed without exceptions if all checks against the planned quantity and the final number of recorded containers/sublots have been passed (see **Confirm by button (SR0700.2.5)** function (page 31)). In addition, no remaining container or sublots in the **Prepared** status are allowed.
  - In case a planned quantity has been defined, upon completion of the phase, yield and prorate factor are calculated and made available for subsequent processing steps via information flow.

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In case two or more Output Weighing operations are modeled in parallel and they run in the same operation mode (**Prepare only** or **Flexible**), the same rules for completing the operation apply as for the first Output Weighing operation that runs in the same operation mode.

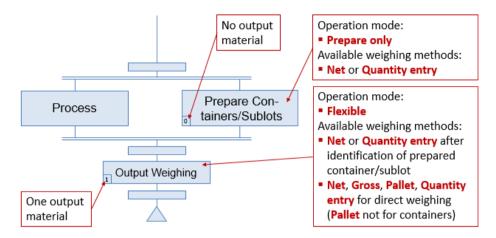


Figure 4: Scenario: Preparation and weighing of containers/sublots in two separate process steps (sequential)

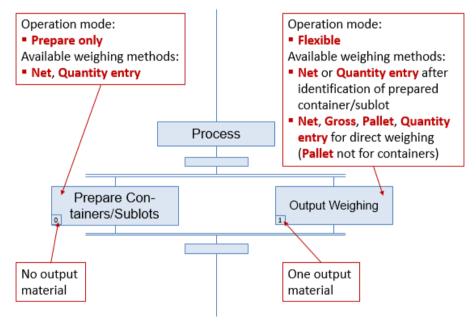


Figure 5: Scenario: Preparation and weighing of containers/sublots in two separate process steps (parallel)

#### Multiple output material parameters per unit procedure

In this case, two or more MFC-related output material parameters are defined for a unit procedure. Different material parameters can refer to the same material.

#### Use case characteristics:

- Multiple order step outputs during runtime
- PharmaSuite supports only one scenario: Direct weighing (only one Output Weighing operation per MFC-related output material).
  Important: This means that Output Weighing must not be split into two or more different Output Weighing operations per output material with the Prepare only and Flexible operation mode.

The operation mode is defined with the **Operation mode** (**SR0700.8.12**) process parameter (page 35) of the **Manage produced material** phase.

Scenario: **Direct weighing** of sublots in one process step (main scenario of this use case):

- One Output Weighing operation is modeled within the unit procedure per output material parameter.
- The operation runs in the **Flexible** operation mode.
- The phases are optimized to tare (except for **Quantity entry**) and directly weigh a sublot in the **Net**, **Gross**, **Quantity entry**, or **Pallet** weighing methods. Target container management is supported in the **Net**, **Gross**, and **Quantity entry** weighing methods.
- In addition, the system allows to first tare and prepare new containers or sublots and, in a later instance of the phase, identify and weigh an already prepared container or sublots, all within the same Output Weighing operation.
- The operation can only be completed without exceptions if the checks against the planned quantity and the final number of recorded containers/sublots have passed (see **Confirm by button (SR0700.2.5)** function (page 31)). In addition, no remaining containers or sublots in the **Prepared** status are allowed.

In case a planned quantity has been defined, upon completion of the phase, yield and prorate factor are calculated and made available for subsequent processing steps via information flow.

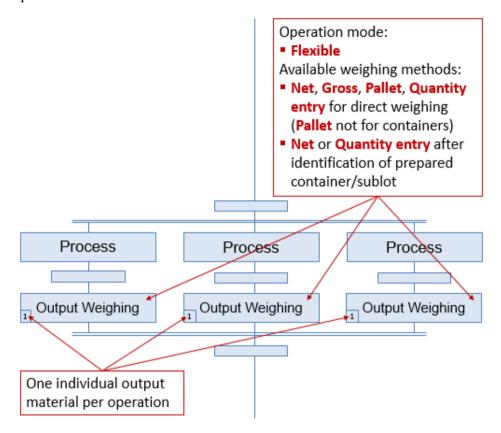


Figure 6: Scenario: Direct weighing of containers/sublots in one process step (multiple order step outputs)

# Manage Produced Material Phase (SR0700+)

The **Manage produced material** phase (O Manage Produced Material) allows an operator to manage produced material on container and/or sublot level.

Typically, it is the first step in an Output Weighing operation. It lists all containers or sublots that have already been prepared or weighed and is executed multiple times in order to support one of the following use cases:

- Weighing a container or sublot directly The operator completes the phase without any further action, followed by the subsequent weighing-related steps.
- Preparing a container or sublot Upon completion of the phase, the operator takes the subsequent weighing-related steps: either to tare a sublot and to print a label for the empty sublot or to identify and tare a target container.
- Weighing a prepared container or sublot This use case requires at least one prepared container or sublot with a known tare value in the list of containers or sublots. The container or sublot can be identified (scanned) by the operator.
  - Upon execution of the subsequent weighing-related steps, the tare value of the identified container or sublot is taken over automatically and its net weight can be recorded.
- Completing the current Output Weighing operation
  The operator explicitly declares that Output Weighing is **Done**, which means that all of the required containers or sublots have been prepared (**Prepare only** mode) or all produced materials have been weighed (**Flexible** mode).

  In this case, depending on the operation mode, certain checks apply (e.g. number of containers/sublots, planned quantity, no non-weighed containers/sublots left), calculations are triggered (yield, prorate factor), and, if configured, a phase

Upon phase completion, the system leaves the Output Weighing loop.

completion signature is requested.

Anomalies that occur during processing are covered by the phase exception handling (page 39) (e.g. annulling a prepared sublot, manual identification, violation of checks).

After completion the phase displays specific information about the material and batch to be produced in the Execution Window. In case a container or sublot has been identified, the phase also displays the container or sublot identifier.

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Details of the operator actions are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (page 26). In case the Output Weighing loop is completed, the sub-report and batch report contain an entire list of all the containers/sublots that hold the produced material, including their quantity information.

The Navigator displays the batch and material identifiers. In case a container or sublot has been identified, the container or sublot identifier is displayed instead.

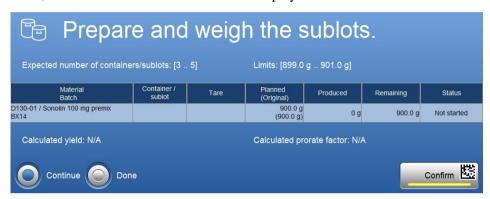


Figure 7: Manage produced material for sublots during execution (Continue)

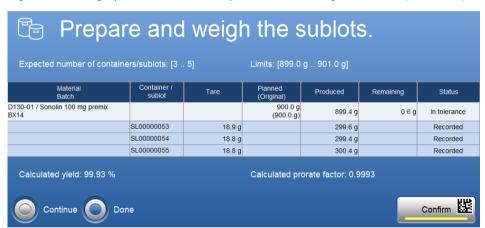


Figure 8: Manage produced material for sublots during execution (Done)

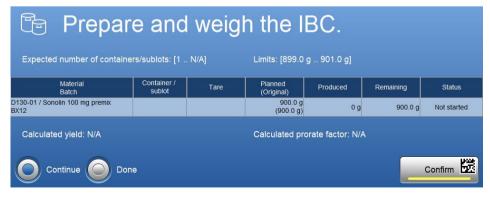


Figure 9: Manage produced material for container during execution (Continue)

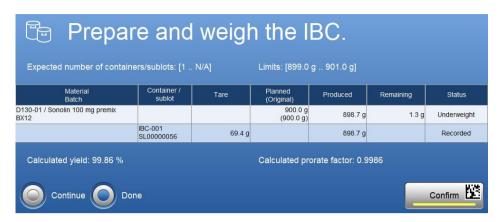


Figure 10: Manage produced material for container during execution (Done)

#### Layout

The phase provides individual layouts for its representation during execution (page 21), in the Navigator (page 25), and in the sub-report (page 26).

### Representation during Execution (SR0700.1+)

The representation during execution depends on the phase mode.

#### Preview mode (SR0700.1.1)

- 1. Phase-specific icon.
- <Instruction text>
   (taken from Instruction (SR0700.8.1) process parameter (page 34))
- 3. **Confirm** button (disabled).

#### Active mode (Continue) (SR0700.1.2)

- ➤ NOTE: O Manage produced material (RS) [1.0] (MR2) container-related UI texts do not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].
  - 1. Phase-specific icon.
  - 2. <Instruction text> (taken from **Instruction (SR0700.8.1)** process parameter (page 34))
  - 3. Expected number of containers/sublots: [<value> .. <value>] (taken from **Number of sublots (SR0700.8.2)** process parameter (page 35))
  - 4. Limits: [<lower limit> .. <upper limit>] (taken from material output parameter of the Weigh phase (SR0730.7.1) (page 140))

, ,

- Produced material and a list of its containers/sublots (Table of sublots (SR0700.1.4) (page 23))
   (material information taken from material output parameter of the Weigh phase (SR0730.7.1) (page 140))
- 6. Calculated yield: (empty, not defined yet)
- 7. Calculated prorate factor: (empty, not defined yet)
- 8. **Continue** option button and **Done** option button (**Continue** selected).
- 9. **Confirm** button.

#### Active mode (Done) (SR0700.1.3)

- ➤ NOTE: O Manage produced material (RS) [1.0] (MR2) container-related UI texts do not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].
  - 1. Phase-specific icon.
  - 2. <Instruction text> (taken from **Instruction (SR0700.8.1)** process parameter (page 34))
  - 3. Expected number of containers/sublots: [<value> .. <value>] (taken from **Number of sublots (SR0700.8.2)** process parameter (page 35))
  - 4. Limits: [<lower limit> .. <upper limit>]
    (taken from material output parameter of the Weigh phase (SR0730.7.1) (page 140))
  - Produced material and a list of its containers/sublots (Table of sublots (SR0700.1.4) (page 23))
     (material information taken from material output parameter of the Weigh phase (SR0730.7.1) (page 140))
  - 6. Calculated yield: <value>
  - 7. Calculated prorate factor: <value>
  - 8. **Continue** option button and **Done** option button (**Done** selected).
  - 9. **Confirm** button.
  - 10. Phase completion signature panel (only if a phase completion signature is assigned to the phase)

#### Table of sublots (SR0700.1.4)

- For recent changes, see revision history (page 172).
- ➤ NOTE: O Manage produced material (RS) [1.0] (MR2) container-related UI texts do not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

Data available per output material:

| Content  | UI text               | Comment  |
|--|-----------------------|--|
| Material identifier / short<br>description<br>Batch identifier | Material<br>Batch     |  |
| Container/sublot identifier(s)                                 | Container / sublot    | Sub-rows.  |
| Tare (containers/sublots)                                      | Tare                  |  |
| Planned and original quantities (material)                     | Planned<br>(Original) | Planned: Original quantity that might by updated by application of predecessor's prorate factor. |
|  |                       | Original: As originally defined in the recipe and calculated by order explosion.                 |
| Produced quantity (material)                                   | Produced              | Total of all produced sublots for the material item.   |
| Produced quantity (containers/sublots)                         | Produced              | Container/sublot-specific produced quantities.   |
| Remaining quantity (material)                                  | Remaining             | Difference between planned quantity and recorded quantity.                                       |
| Status (material)  | Status                | Not started: No containers/sublots have been prepared so far.                                    |
|  |                       | In process: At least one container/sublot has been weighed.                                      |
|  |                       | <b>Underweight:</b> Output Weighing has been completed below tolerance.                          |
|  |                       | In tolerance: Output Weighing has been completed within tolerance.                               |
|  |                       | Overweight: Output weighing has been completed above tolerance.                                  |
|  |                       | <b>Done:</b> Output Weighing has been completed with no planned quantity specified.              |

| Content                    | UI text | Comment   |
|----------------------------|---------|---|
| Status (container/sublots) | Status  | Prepared: Container has been prepared/Sublot has been created and tare recorded, but not yet weighed.   |
|                            |         | <b>Recorded:</b> Weight of container/sublot has been recorded.  |
|                            |         | Annulled: Prepared container/sublot has been annulled with Annul prepared sublot (SR0700.3.1.3) user-triggered exception (page 44). An annulled sublot remains in the table with its new status, an annulled container is removed from the table. |
|                            |         | Replaced: Weighed container/sublot has been replaced with Replace weighed sublot (SR0700.3.1.4) user-triggered exception (page 46).   |

#### Completed mode (Output Weighing in process) (SR0700.1.5)

- ➤ NOTE: O Manage produced material (RS) [1.0] (MR2) container-related UI texts do not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].
  - 1. Phase-specific icon.
  - 2. Details of material to be produced.
    - First line

| <material identifier=""></material> | <material short<="" th=""><th><planned quantity=""></planned></th></material> | <planned quantity=""></planned> |
|-------------------------------------|---|---------------------------------|
|                                     | description>  |                                 |

Second line

| <batch identifier=""></batch> | <container sublot<br="">identifier of prepared</container> |
|-------------------------------|--|
|                               | container/sublot (only if identified)>                     |

3. **Confirm** button (completed).

### Completed mode (Done) (SR0700.1.6)

- ➤ NOTE: O Manage produced material (RS) [1.0] (MR2) container-related UI texts do not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].
  - 1. Phase-specific icon.

- 2. <Instruction text> (taken from **Instruction (SR0700.8.1)** process parameter (page 34))
- 3. Expected number of containers/sublots: [<value> .. <value>] (taken from **Number of sublots** (**SR0700.8.2**) process parameter (page 35))
- 4. Limits: [<lower limit> .. <upper limit>]
  (taken from material output parameter of the Weigh phase (SR0730.7.1) (page 140))
- Produced material and a list of its containers/sublots (Table of sublots (SR0700.1.4) (page 23))
   (material information taken from material output parameter of the Weigh phase (SR0730.7.1) (page 140))
- 6. Calculated yield: <value> or N/A (if no planned quantity defined)
- 7. Calculated prorate factor: <value> or N/A (if no planned quantity defined)
- 8. **Continue** option button and **Done** option button (**Done** selected, both disabled).
- 9. **Confirm** button (completed).
- 10. Phase completion signature panel (only if a phase completion signature is assigned to the phase)

#### Representation in Navigator (SR0700.4+)

The Navigator provides the following details:

#### Phase column (Framework capability)

- <Phase name>
  - Example: Manage produced material

#### **Information column (SR0700.4.1)**

- ➤ NOTE: O Manage produced material (RS) [1.0] (MR2) container-related UI texts do not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].
  - N/A / <material identifier> or <Batch identifier> (if already known) / <material identifier> or <Container/sublot identifier>, if an already prepared container/sublot has been identified.

Example:

#### **Action column**

There are no actions available.

#### Representation in Sub-report (SR0700.5+)

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The sub-report contains the following information:

#### **Common sub-report elements (Framework capability)**

- <Start time>
- <Completion time>
- <Unit procedure> / / / phase>
- <Work center> / <station> / <device> <phase completion user>

#### **Sub-report elements (Continue) (SR0700.5.1)**

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related UI texts do not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

Output Weighing was still in process (**Done** option button not selected):

- Position: <number>
- Material: <identifier> / <short description>
- Batch: <identifier> (if already known)
- No container or sublot identified.
   or
   <Container/sublot identifier> container/sublot identified.

#### Sub-report elements (Done) (SR0700.5.2)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related UI texts do not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

Output Weighing was completed (Done option button selected):

- Position: <number>
- Material: <identifier> / <short description> (material information taken from material output parameter of the Weigh phase (SR0730.7.1) (page 140))

- Batch: <identifier>
- Planned and original quantities
- Produced and remaining quantities
- Status [of the material position]
- Expected number of containers/sublots: [<value> .. <value>] (taken from **Number of sublots** (**SR0700.8.2**) process parameter (page 35))
- Limits: [<lower limit> .. <upper limit>]
  (taken from material output parameter of the Weigh phase (SR0730.7.1) (page 140))
- Table of containers/sublots with the following columns from the (Table of sublots (SR0700.1.4) (page 23))
  - Container/sublot [identifier]
  - Tare
  - Produced [quantity of the sublot]
  - Status [of the sublot position]
- Calculated yield: <value>
- Calculated prorate factor: <value>
- <Phase completion signature> (only if a phase completion signature is assigned to the phase)

## Business Logic (SR0700.2+)

The phase implements the following business logic.

#### Main Path

Business logic related to the main path:

#### Display material grid (SR0700.2.1)

- ➤ NOTE: O Manage produced material (RS) [1.0] (MR2) container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].
  - Function: Display of material grid (Table of sublots (SR0700.1.4) (page 23))
  - Type: Main path
  - Trigger: Phase becomes active
  - Postcondition: Phase is active

Step Description Phase activation 10 Phase retrieves material information from the output material of the related unit procedure. In case a prorate factor is defined (see Prorate factor (SR0700.8.6) process 20 parameter (page 35)) and no prorate factor has been applied for the specific output material yet (in case of multiple Output Weighing operations for the same output material), the prorate factor is applied and the planned quantity is updated accordingly (= original quantity \* prorate factor). In case the prorate factor is an invalid value (not a scalar > 0), phase displays the Invalid prorate factor (SR0200.3.4.1) information message (page 47) and the new planned quantities are updated to zero. The prorate factor is automatically applied only once, when the first instance of the phase becomes active. It will never be applied automatically once again, not even not as part of a new instance of the unit procedure itself. (However, the prorate factor can be set manually with the Override prorate factor (SR0700.3.1.1) user-triggered exception (page 43).) 30 Phase updates the related container/sublot information, including tare, status of the container/sublot-related position, and produced quantity, if applicable. 40 In case a new produced quantity was recorded for a container/sublot, phase updates the produced and the remaining quantity of the output material position. 50 Phase listens to barcode scanning of an already prepared container/sublot. 60 In case the **Done** option button is selected, phase updates the status of the output material position.

#### Sublot barcode scan (SR0700.2.2)

- ➤ NOTE: O Manage produced material (RS) [1.0] (MR2) container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].
  - Function: Scan of container/sublot barcode
  - Type: Main path
  - Precondition: Prepared container/sublot is available. Phase's **Operation mode** is not set to **Prepare only**.
  - Trigger: Operator scans barcode
  - Postcondition: Phase is completed

| • |  |
|---|--|
| • |  |
| • |  |
| • |  |
| • |  |
|   |  |

| Step           | #  | Description   |  |
|----------------|----|---|--|
| Operator scans | 5  | Phase reads scanned data.   |  |
| barcode        |    | If phase operates in <b>Prepare only</b> mode (see <b>Operation mode (SR0700.8.12)</b> process parameter (page 35)), no container/sublot can be identified and phase displays the <b>Prepare only (SR0700.3.6.7)</b> error message (page 49).   |  |
|                | 10 | If barcode reading was technically successful, phase updates background<br>color of phase representation according to style sheet in order to confirm<br>the reading.   |  |
|                |    | If barcode reading was technically not successful, phase remains in listening mode.   |  |
|                |    | If barcode reading was not successful, phase displays the <b>Invalid barcode</b> (SR0700.3.6.1) error message (page 48).  |  |
|                | 30 | Phase performs business-related checks listed below.  |  |
|                | 40 | If one of the following checks is violated, phase displays an error message:  |  |
|                |    | 1. <b>Done</b> mode-related check Phase must not be in <b>Done</b> mode, <b>No sublot identification</b> (SR0700.3.6.8) error message (page 50).  |  |
|                |    | 2. Sublot-related check Sublot must exist, <b>Sublot does not exist (SR0700.3.6.3)</b> error message (page 50).   |  |
|                |    | 3. Container/sublot-related check Container/sublot must be prepared, Sublot is not prepared or cannot be replaced (SR0700.3.6.2) error message (page 49) or Container not prepared or recorded for this order step output (SR0700.3.6.10) error message (page 51).  |  |
|                |    | 4. Container/sublot-related check Container/sublots must be prepared for the current order step (CheckSublotProducedByOtherOSO_0 check), Sublot for different order step (SR0700.3.6.5) error message (page 50) or Container not prepared or recorded for this order step output (SR0700.3.6.10) error message (page 51). |  |
|                |    | 5. Sublot-related check Sublot must not be logically deleted (CheckSublotDeleted check), Sublot deleted (SR0700.3.6.6) error message (page 50).   |  |
|                | 50 | If all checks have passed successfully, the container/sublot is identified and its status is set to <b>Recording</b> .  |  |
|                | 60 | <b>Result (SR0700.9.1)</b> output variable (page 52) is set to WEIGH and phase is completed automatically.  |  |

## **Output Weighing done (SR0700.2.3)**

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

■ Function: Output Weighing is done

Type: Main path

Trigger: Operator selects **Done** option button

Postcondition: Status of the output material is set to a final state and calculations are triggered.

| Step                      | #  | Description  |  |  |
|---------------------------|----|--|--|--|
| Operators selects         | 10 | Phase updates the status of the output material position as follows:   |  |  |
| <b>Done</b> option button |    | In tolerance: produced quantity is within tolerances.  |  |  |
| Buccon                    |    | Overweight: produced quantity is greater than upper tolerance.   |  |  |
|                           |    | ■ Underweight: produced quantity is less than lower tolerance.   |  |  |
|                           |    | Done: no planned quantity is maintained.   |  |  |
|                           |    | Replaced containers/sublots are not taken into account.  |  |  |
|                           |    | The status is not updated if the phase operates in <b>Prepare only</b> mode (see <b>Operation mode (SR0700.8.12)</b> process parameter (page 35)).   |  |  |
|                           | 20 | If a planned quantity is maintained, phase calculates and displays   |  |  |
|                           |    | Yield = Actual quantity / Planned quantity<br>(The planned quantity that might be updated.)<br>and   |  |  |
|                           |    | Prorate factor = Actual quantity / Planned quantity (original)   |  |  |
|                           |    | Replaced containers/sublots are not taken into account.  |  |  |
|                           |    | The values are stored within the Yield (SR0700.9.2) output variable (page 53) and the Prorate factor (SR0700.9.3) output variable (page 53).   |  |  |
|                           |    | Yield and prorate factor are not calculated if the phase operates in <b>Prepare only</b> mode (see <b>Operation mode</b> (SR0700.8.12) process parameter (page 35)). In this case, phase displays "N/A".                               |  |  |
|                           | 30 | If a phase completion signature is assigned, the signature is only requested during execution if the <b>Done</b> option button is selected.  |  |  |
|                           | 40 | If the <b>Done</b> option button is selected, upon phase completion, all of the phase-specific data is available within the sub-report, see <b>Sub-report elements</b> ( <b>Done</b> ) ( <b>SR0700.5.2</b> ) representation (page 26). |  |  |

| Step                                    | #   | Description  |  |
|---|-----|--|--|
| Operator selects Continue option button | 100 | Phase updates the status of the output material position back to In process.   |  |
| Ducton                                  |     | Result of yield and prorate factor calculation is withdrawn. This includes the Yield (SR0700.9.2) output variable (page 53) and Prorate factor (SR0700.9.3) output variable (page 53). |  |
|   |     | Phase completion signature (if configured) is removed.   |  |

## Confirm by scan (SR0700.2.4)

Function: Confirm phase by use of barcode scan

Type: Main path

Precondition: **Continue** option button is selected

Trigger: Operator scans any scale

■ Postcondition: Phase is completed

| Step                 | #    | Description   |
|----------------------|------|---|
| Operator scans scale | 10   | If the <b>Continue</b> option button is selected, phase sets the <b>Result (SR0700.9.1)</b> output variable (page 52) to WEIGH.     |
|                      |      | Phase completion signature (if configured) is ignored.  |
|                      |      | Continue with step 20.2.  |
|                      | 20.1 | If the <b>Done</b> option button is selected, <b>Confirm by scan</b> is not supported and the phase is not completed automatically. |
|                      | 20.2 | Phase is completed automatically.   |

## Confirm by button (SR0700.2.5)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

■ Function: Confirm phase by use of button

■ Type: Main path

■ Trigger: Operator confirms phase

Postcondition: Phase is completed

• '

| Step                    | #    | Description  |  |  |
|-------------------------|------|--|--|--|
| Operator confirms phase | 10   | If the <b>Continue</b> option button is selected, phase sets the <b>Result (SR0700.9.1</b> ) output variable (page 52) to WEIGH.   |  |  |
|                         |      | Phase completion signature (if configured) is ignored.   |  |  |
|                         |      | Continue with step 50.   |  |  |
|                         | 20.1 | If the <b>Done</b> option button is selected, the following checks apply upon phase completion:  |  |  |
|                         |      | Unless all container/sublot weights are recorded, phase displays the<br>Weight of sublots missing (SR0700.3.6.4) error message (page 50).  |  |  |
|                         |      | The check is skipped if the phase operates in Prepare only mode (see<br>Operation mode (SR0700.8.12) process parameter (page 35)).   |  |  |
|                         | 20.2 | If the expected number of containers/sublots is violated (sublots in the Annulled or Replaced status are excluded), phase displays the Violated number of sublots (SR0700.3.2.1) system-triggered exception (page 39). |  |  |
|                         | 20.3 | ■ If the produced quantity is greater than the upper tolerance, phase displays the Overweight check (SR0700.3.2.2) system-triggered exception (page 40).   |  |  |
|                         |      | The check is skipped if the phase operates in Prepare only mode (see<br>Operation mode (SR0700.8.12) process parameter (page 35)).   |  |  |
|                         | 20.4 | ■ If the produced quantity is less than the lower tolerance, phase displays the Underweight check (SR0700.3.2.3) system-triggered exception (page 40).   |  |  |
|                         |      | The check is skipped if the phase operates in Prepare only mode (see<br>Operation mode (SR0700.8.12) process parameter (page 35)).   |  |  |
|                         | 30   | If the <b>Done</b> option button is selected, phase completion signature (if configured) becomes active.   |  |  |
|                         | 40   | If the <b>Done</b> option button is selected and all checks are passed successfully (or system-triggered exceptions are recorded), phase sets the <b>Result</b> (SR0700.9.1) output variable (page 52) to COMPLETED.   |  |  |
|                         | 50   | Phase is completed automatically.  |  |  |

# Weighing Method-specific Paths

There are no specifics available for any of the supported weighing methods.

# **Equipment Management**

Business logic related to equipment management:

## **Container management (SR0700.2.6)**

- ➤ NOTE: Does not apply to O Manage produced material (RS) [1.0] (MR2).
  - Function: Manage container
  - Type: Special handling of container binding, binding context, and graph transitions
  - Precondition: Container must be of the **Container** (**RS**) equipment type
  - Trigger: Empty or prepared target container has been identified during Output Weighing
  - Postcondition: Container life cycle is maintained

| a.   | ·<br>  |  |  |
|--|--|--|--|
| Step   | Description  |  |  |
| Case: Return to material management user-triggered exception was performed in a previous phase (after loop).                                     | In case container is not yet <b>Prepared</b> (not known in the context of the order step output):  Phase sends <b>CONT_EMPTY</b> trigger to the graph of the <b>Container</b> Cleaning (RS) purpose.  Phase resets binding context and unbinds container.  |  |  |
| Affected phases: Select scale (SR0710+) (page 55), Identify container (SR0750+) (page 77), Tare (SR0720+) (page 103), Weigh (SR0730+) (page 127) | In case container is already <b>Prepared</b> (i.e. it is still bound):  No trigger is performed.  No unbind is performed.  |  |  |
| Case: Annul prepared sublot (SR0700.3.1.3) user-triggered exception (page 44) was performed.   | <ul> <li>Phase does not only handle prepared sublots, but also prepared container.</li> <li>Phase does not clear container's property of the Current Tare (RS) purpose.</li> <li>Phase sends CONT_LOAD trigger to the graph of the Container Cleaning (RS) purpose.</li> <li>Phase resets binding context and unbinds container.</li> </ul>  |  |  |
| Case: Replace weighed sublot (SR0700.3.1.4) user-triggered exception (page 46) was performed.  | <ul> <li>Phase also handles replaced sublots that are associated with prepared containers.</li> <li>No action is performed on the container object.</li> <li>No bind/unbind is performed (container is already unbound after successful weighing, see Container management (SR0730.2.10) function (page 138) of the Weigh phase).</li> </ul> |  |  |

| Step | Description  |  |
|------|--|--|
|      | Phase does not clear container's properties of the Current Tare (RS) or<br>Current Sublot (RS) purposes. |  |
|      | No trigger is performed.   |  |

## Scale management (SR0700.2.7)

➤ Does not apply if the **Quantity entry** weighing method is used.

■ Function: Manage scales

Type: Special handling of scale binding and binding context

Precondition: Scale must be of the **Scale** (**RS**) equipment type

■ Postcondition: Scale life cycle is maintained

| Step                     | Description   |  |
|--------------------------|---|--|
| Case: Phase is activated | Phase resets binding context and unbinds the scale.   |  |
|                          | This also applies when the phase is activated after the Return to<br>material management user-triggered exception was performed in a<br>previous phase. |  |

## **Recipe Parameters**

The phase provides process parameters (page 34).

## Process Parameters (SR0700.8+)

The following process parameters define the behavior of the phase.

#### BASIC PARAMETERS

## **Instruction (SR0700.8.1)**

For recent changes, see revision history (page 172).

| Attribute | Туре      | Comment  |
|-----------|-----------|--|
| Column 1  | HTML text | Instruction text to be displayed. <b>Restriction:</b> Maximum length is 2000 characters (including HTML tags). |
| Column 2  | HTML text | Notused  |
| Column 3  | HTML text | Not used.  |

## Operation mode (SR0700.8.12)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

| Attribute | Туре        | Comment   |
|-----------|-------------|---|
| Mode      | Choice list | Defines the operation mode.  Flexible (default): Allows to prepare and to weigh containers or sublots.  Prepare only: Only allows to prepare containers or sublots. They can neither be identified nor weighed. |

#### Prorate factor (SR0700.8.6)

| Attribute | Туре | Comment  |
|-----------|------|--|
| Value     |      | Prorate factor to be applied. It is only applied once automatically, i.e. not in case of resume, reactivation, or within a loop. |

## Number of sublots (SR0700.8.2)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

| Attribute | Туре | Comment  |
|-----------|------|--|
| Minimum   | Long | Defines the minimum number of containers or sublots. |
| Maximum   | Long | Defines the maximum number of containers or sublots. |

#### CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### Number of sublots check (SR0700.8.4)

| Attribute       | Туре | Comment  |
|-----------------|------|--|
| Risk assessment |      | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low |

Attribute

Type

Comment

(mandatory comment), Medium,
Medium (mandatory comment), High,
High (mandatory comment).
Default setting: High.

Exception text

Text

Defines the exception description used
during exception handling and within
the batch record.
Maximum length is 250 characters.

See also **Violated number of sublots (SR0700.3.2.1)** system-triggered exception (page 39).

## **Confirm overweight (SR0700.8.7)**

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Overweight check (SR0700.3.2.2) system-triggered exception (page 40).

## Confirm underweight (SR0700.8.8)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment). |

| Attribute      | Туре | Comment  |
|----------------|------|--|
|                |      | Default setting: <b>High</b> .   |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters. |

See also Underweight check (SR0700.3.2.3) system-triggered exception (page 40).

## Status transition failed (SR0700.8.13)

## ➤ NOTE: Does not apply to O Manage produced material (RS) [1.0] (MR2).

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Status transition failed (SR0700.3.2.5) system-triggered exception (page 41).

## CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

## Override prorate factor (SR0700.8.9)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |

Attribute Type Comment

Exception text Text Defines the exception description used during exception handling and within the batch record.

Maximum length is 250 characters.

See also Override prorate factor (SR0700.3.1.1) user-triggered exception (page 43).

# Identify manually (SR0700.8.10)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Identify manually (SR0700.3.1.2) user-triggered exception (page 43).

## **Annul prepared sublot (SR0700.8.5)**

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Annul prepared sublot (SR0700.3.1.1) user-triggered exception (page 44).

#### Replace weighed sublot (SR0700.8.11)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Replace weighed sublot (SR0700.3.1.4) user-triggered exception (page 46).

## Exceptions (SR0700.3+)

The phase supports user-defined, user-triggered (page 42), system-triggered (page 39), and post-completion exceptions (page 47) and their configuration by means of process parameters (page 34).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

#### System-triggered Exceptions (SR0700.3.2+)

For recent changes, see revision history (page 172).

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

#### Violated number of sublots (SR0700.3.2.1)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

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After the exception has been recorded, the phase is automatically completed.

Representation of the exception:

<Exception text>

(taken from **Number of sublots check (SR0700.8.4)** process parameter (page 35))

Batch: <batch identifier>, material: <material identifier> Expected number of containers/sublots: [<value> .. <value>]

Actual value: <value>

Example:

Expected number of container/sublots violated.

Batch: BX123, material: D-9001-03

Expected number of containers/sublots: [15 .. 18]

Actual value: 19

#### Overweight check (SR0700.3.2.2)

After the exception has been recorded, the phase is automatically completed.

Representation of the exception:

<Exception text>

(taken from Confirm overweight (SR0700.8.7) process parameter (page 36))

Batch: <batch identifier>, material: <material identifier> Expected tolerances: [<lower limit> .. <upper limit>]

Actual value: <value>

Example:

Overweight situation.

Batch: BX123, material: D-9001-03 Expected tolerances: [100 kg .. 150 kg]

Actual value: 154 kg

#### Underweight check (SR0700.3.2.3)

After the exception has been recorded, the phase is automatically completed.

Representation of the exception:

<Exception text>

(taken from **Confirm underweight** (**SR0700.8.8**) process parameter (page 36))

Batch: <batch identifier>, material: <material identifier> Expected tolerances: [<lower limit> .. <upper limit>]

Actual value: <value>

Example:

Underweight situation.

Batch: BX123, material: D-9001-3

Expected tolerances: [100 kg .. 150 kg]

Actual value: 85 kg

#### Multiple exceptions (SR0700.3.2.4)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

#### Status transition failed (SR0700.3.2.5)

➤ NOTE: Does not apply to O Manage produced material (RS) [1.0] (MR2).

The **Status transition failed** exception is displayed automatically if a certain status transition could not be performed based on the given graph purpose and trigger.

The potential reasons for a failed status transition are:

- The graph of the required purpose is missing.
- The trigger is missing.
- Source status does not match.
- Condition cannot be fulfilled or is not unique (in case of multiple transition definitions per trigger).
- Error during condition evaluation.
- Error during action evaluation.

Representation of the exception:

**Exception dialog** 

- <Exception text> (taken from Status transition failed (SR0700.8.13) process parameter (page 37)) <the reason that applies>
  - List of potential reasons:
    - The graph of the required purpose is missing.
    - The trigger you are trying to perform is not contained in the graph.
    - Cannot find a transition for the current status.
    - Cannot find a fulfillable transition condition for the current status.
    - There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>.
    - Cannot evaluate the transition condition (<TR-ID>).

■ Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

#### **Exception Window**

#### <Exception text>

(taken from **Status transition failed (SR0700.8.13)** process parameter (page 37)) <reason>

Equipment: <equipment identifier> / <equipment short description>

Equipment type: t of equipment types> (if available)

Graph (ID): <graph display text> (<identifier>)

Purpose: <purpose>

Current status (key): <display text> (<key>) Failed trigger (key): <display text> (<key>)

#### Example:

Status transition failed.

Cannot find a transition for the current status.

Equipment: IBC0033

Equipment type: Container (RS)

Graph (ID): IBC Cleaning (IBCCleaning01)

Purpose: Container Cleaning (RS)

Current status (key): Blocked (BLOCKED)
Failed trigger (key): In use (IN\_USE)

#### Status transition failed - Logic (SR0700.3.2.5.1)

■ Trigger: The status transition could not be performed based on the given graph purpose and trigger.

■ Postcondition: Phase is active

| Step                                   | #  | Description                                     |
|--|----|---|
| Operator accepts exceptional situation | 10 | Phase shows exception description to be signed. |
| Operator signs exception               | 20 | Phase records exception.                        |

#### User-triggered Exceptions (SR0700.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

## Override prorate factor (SR0700.3.1.1)

The **Override prorate factor** exception allows an operator to override the prorate factor and apply a new prorate factor.

Representation of the exception:

■ Instruction:

Override the prorate factor with a new value.

Box for new prorate factor.

Confirm button.

Exception text

<Exception text>

(taken from **Override prorate factor** (**SR0700.8.9**) process parameter (page 37))

Original prorate factor: <value>

New prorate factor: <value>

**E**xample:

Prorate factor overridden and applied.

Original prorate factor 0.88 New prorate factor: 0.92

#### Override prorate factor - Logic (SR0700.3.1.1.1)

■ Trigger: Exception is selected

■ Precondition: **Continue** option button is selected

■ Postcondition: New prorate factor is applied and exception is recorded

| Step                        | #  | Description  |
|-----------------------------|----|--|
| Operator triggers exception | 10 | Phase displays Exception Window.   |
| Operator confirms exception | 20 | Phase applies new prorate factor, which means the planned quantity is updated (= original quantity * prorate factor), and records exception. |

## Identify manually (SR0700.3.1.2)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

The **Identify manually** exception allows an operator to identify a container/sublot manually.

The exception is disabled if the phase's **Operation mode** is set to **Prepare only**.

Representation during exception handling:

■ Instruction:

Enter the container or sublot you wish to identify.

Box for barcode input.

Confirm button.

Exception text:

<Exception text>

(taken from Identify manually (SR0700.8.10) process parameter (page 38))

Identified container/sublot: <container/sublot identifier>

Example:

Manual identification.

Identified container/sublot: SL00005678

#### **Identify manually - Logic (SR0700.3.1.2.1)**

Trigger: Exception is selected

Precondition: Phase's Operation mode is not set to Prepare only (see Operation mode (SR0700.8.12) process parameter (page 35)).

Postcondition: Phase is completed

| Step                        | #  | Description   |
|-----------------------------|----|---|
| Operator confirms exception | 10 | Phase performs checks as listed for the <b>Sublot barcode scan (SR0700.2.2)</b> function (page 28).   |
|                             | 20 | If all checks have passed successfully, phase records exception according to the <b>Identify manually (SR0700.8.10)</b> process parameter (page 38).  |
|                             | 25 | In case the identifier of a prepared container/sublot has been entered, but the container/sublot has already been identified at another client, phase displays the <b>Wrong container/sublot status (SR0700.3.6.9)</b> error message (page 51) when the operator signs the exception. |
|                             | 30 | Container/sublot is identified and phase is completed.  |

## Annul prepared sublot (SR0700.3.1.3)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

The **Annul prepared sublot** exception allows an operator to annul one or all of the already prepared containers/sublots.

#### Representation during exception handling:

#### Instruction:

Scan or type the container or sublot you wish to annul.

Box for barcode input.

List of prepared containers/sublots.

Single option button (default) and All option button.

Confirm button.

#### Exception text:

<Exception text>

(taken from **Annul prepared sublot** (**SR0700.8.5**) process parameter (page 38))

If one container/sublot was annulled:

<Material identifier> / <Material short description> / <Batch identifier> /

<Container/sublot identifier>

If all containers/sublots were annulled:

<Material identifier> / <Material short description> / <Batch identifier> /

<Container/sublot identifiers, comma-separated list>

Example (one sublot was annulled):

Container/sublot annulled.

D001-03 / Aqua purificata / BX123 / SL00001234

#### Annul prepared sublot - Logic (SR0700.3.1.3.1)

- Trigger: Exception is selected
- Precondition: Container/sublot must be in the **Prepared** status.
- Postcondition: Container/sublot is annulled and can no longer be identified for weighing as an output material container/sublot.

| Step   | #  | Description   |
|--|----|---|
| Operator selects Single option button and confirms exception | 10 | Phase checks if the container/sublot to be annulled is available in the list of prepared containers/sublots of this order step.  If not, phase displays the Sublot is not prepared or cannot be replaced (SR0700.3.6.2) error message (page 49) or the Container not prepared or recorded for this order step output (SR0700.3.6.10) error message (page 51). |
|  | 15 | In case a container/sublot is still displayed with its <b>Prepared</b> status, but the container/sublot has already been annulled or its weight has already been recorded at another client, phase displays the <b>Wrong container/sublot status</b> (SR0700.3.6.9) error message (page 51).  |
|  | 20 | If the check passes successfully, phase annuls the container/sublot and records the exception according to the <b>Annul prepared sublot (SR0700.8.5)</b> process parameter (page 38).   |

Step # Description

Operator selects All option button and confirms exception # Description

Phase does not allow to define a single container/sublot to be annulled. Upon confirmation, all remaining prepared container/sublots are annulled and phase records the exception according to the Annul prepared sublot (SR0700.8.5) process parameter (page 38).

#### Replace weighed sublot (SR0700.3.1.4)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

The **Replace weighed sublot** exception allows an operator to replace one of the already weighed container/sublots.

The exception is disabled if the phase's **Operation mode** is set to **Prepare only**.

Representation during exception handling:

■ Instruction:

Scan or type the container or sublot you wish to replace.

Box for barcode input.

List of recorded containers/sublots.

Confirm button.

Exception text:

<Exception text>

(taken from **Replace weighed sublot** (**SR0700.8.11**) process parameter (page 39))

<Material identifier> / <Material short description> / <Batch identifier> /

<Container/sublot identifier>

**E**xample:

Container/sublot replaced after weighing.
D001-03 / Aqua purificata / BX123 / SL00001234

#### Replace weighed sublot - Logic (SR0700.3.1.4.1)

- Trigger: Exception is selected
- Precondition: Phase's Operation mode is not set to Prepare only (see Operation mode (SR0700.8.12) process parameter (page 35)).
- Postcondition: Container/sublot is replaced and can no longer be identified as an intra material within the succeeding unit procedure.

| • |
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|   |

| Step                              | #  | Description   |
|-----------------------------------|----|---|
| Operator<br>confirms<br>exception | 10 | Phase checks if the container/sublot to be replaced is available in the list of recorded containers/sublots of this order step.  If not, phase displays the Sublot is not prepared or cannot be replaced (SR0700.3.6.2) error message (page 49) or the Container not prepared or recorded for this order step output (SR0700.3.6.10) error message (page 51). |
|                                   | 15 | In case a container/sublot is still displayed with its <b>Recorded</b> status, but the container/sublot has already been replaced at another client, phase displays the <b>Wrong container/sublot status</b> (SR0700.3.6.9) error message (page 51).  |
|                                   | 20 | If the check passes successfully, phase marks the sublot as replaced and updates the produced and remaining quantity of the output material position accordingly. Phase records the exception according to the <b>Replace weighed sublot (SR0700.8.11)</b> process parameter (page 39).   |

#### **Post-completion Exceptions**

There are no post-completion exceptions available.

## Information Messages (SR0700.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an  $\mathbf{OK}$  button.

The following information messages are available to inform the operator about how to proceed.

## **Invalid prorate factor (SR0700.3.4.1)**

| UI text                               | Comment   |
|---------------------------------------|---|
| The prorate factor has an             | Message pack: ow_ManProdMat <version></version> |
| invalid value ( <value>). The</value> | Message ID: OverrideProrateFactorInvalidValue   |
| related planned quantities            |   |
| have been set to zero.                |   |
| Apply a correct prorate               |   |
| factor manually.                      |   |

#### No sublot available to annul (SR0700.3.4.3)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

UI text Comment

There are no prepared containers or sublots available to annul.

Comment

Message pack: ow\_ManProdMat<version>
Message ID: noItemsToAnull\_InfoMsg

## Questions

There are no questions available.

#### **Decisions**

There are no decisions available.

## Error Messages (SR0700.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an  $\mathbf{OK}$  button.

The following error messages are available to inform the operator about error conditions.

#### Invalid barcode (SR0700.3.6.1)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

| UI text  | Comment   |
|--|---|
| The scanned barcode does not belong to a container or sublot.                      | Message pack: wd_UIMessage <version> Message ID: NoContainerOrSublotScanned_ErrorMsg  Applies if the scanned barcode presents neither a</version> |
|  | container nor a sublot.   |
| The barcode ( <barcode>) does not match the</barcode>                              | Message pack: clientfw_pec.BarcodeScannerSupport Message ID: no_matching_templates_1  |
| required barcode format. Please scan again or identify manually.                   | Applies if the scanned barcode starts with a sublot prefix, but is too short.   |
| The barcode ( <barcode>) does not contain all</barcode>                            | Message pack: clientfw_pec.BarcodeScannerSupport Message ID: not_enough_information_for_sublot  |
| information required to identify a sublot. Please scan again or identify manually. | Applies in case system is configured to require separate scans of sublot and batch at sublot identification.                                      |

| UI text | Comment   |
|---------|---|
| · ·     | Message pack: clientfw_pec.BarcodeScannerSupport Message ID: no_matching_templates_n Applies in case system is configured to require separate scans of sublot and batch at sublot identification. |

## **Sublot identifier missing (SR0700.3.6.11)**

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

| UI text                     | Comment   |
|-----------------------------|---|
| Please enter a container or | Message pack: ow_ManProdMat <version></version> |
| sublot ID.                  | Message ID: noDataForIdentification             |

## **Prepare only (SR0700.3.6.7)**

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

| UI text | Comment  |
|---------|--|
| _       | Message pack: ow_ManProdMat <version> Message ID: noIdentificationInPrepareOnly_ErrorMsg</version> |

## Sublot is not prepared or cannot be replaced (SR0700.3.6.2)

| UI text  | Comment  |
|--|--|
| Cannot proceed with the<br><sublot id=""> sublot, since its<br/>status (<status>) is<br/>unsuitable. For<br/>identification, the sublot<br/>needs to be in the <status><br/>status.</status></status></sublot> | Sublot must be in the <b>Prepared</b> status to be scanned for weighing. Sublot must be in the <b>Prepared</b> status to be annulled. Sublot must be in the <b>Recorded</b> status to be replaced. Message pack: srv_wd.checks Message ID: CheckSublotOutputStatus_0 |
| Cannot proceed with the<br><sublot id=""> sublot, since it<br/>has no status.</sublot>   | Message pack: srv_wd.checks Message ID: CheckSublotOutputStatus_1  |

, |

#### Sublot does not exist (SR0700.3.6.3)

| UI text  | Comment   |
|--|---|
| Cannot find a sublot to match the barcode ( <barcode>).</barcode>  | Identification by scanner:  Message pack: clientfw_pec.BarcodeScannerSupport  Message ID: no_sublot_found_1 |
| Cannot find the container or sublot ID. Please correct your input. | Manual identification:  Message pack: ow_ManProdMat <version> Message ID: sublotNotFound_ErrorMsg</version> |

## Weight of sublots missing (SR0700.3.6.4)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

| UI text | Comment   |
|---------|---|
|         | Check only applies if the <b>Done</b> option button is selected.  Message pack: ow_ManProdMat <version> Message ID: weightOfItemsMissing_ErrorMsg</version> |

## Sublot for different order step output (SR0700.3.6.5)

| UI text | Comment   |
|---------|---|
| ` '     | Message pack: srv_wd.checks Message ID: CheckSublotIsProducedForOSO_0 |

## Sublot deleted (SR0700.3.6.6)

| UI text                               | Comment  |
|---------------------------------------|--|
| · · · · · · · · · · · · · · · · · · · | Message pack: srv_wd.checks Message ID: CheckSublotDeleted_0 |

## No sublot identification (SR0700.3.6.8)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

| UI text  | Comment   |
|--|---|
| Cannot identify a container or sublot, since you have the Done option selected. Select Continue to proceed | Message pack: ow_ManProdMat <version> Message ID: noldentificationInDoneMode_ErrorMsg</version> |
| with identification.   |   |

## Container not prepared or recorded for this order step output (SR0700.3.6.10)

➤ NOTE: Does not apply to O Manage produced material (RS) [1.0] (MR2).

| UI text  | Comment  |
|--|--|
| Cannot proceed with the<br><container id=""> container,<br/>since it is not prepared for<br/>this order step output.</container> | Message pack: srv_wd.checks Message ID: CheckContainerIsPreparedForOSO |
| Cannot proceed with the<br><container id=""> container,<br/>since it is not recorded for<br/>this order step output.</container> | Message pack: srv_wd.checks Message ID: CheckContainerIsRecordedForOSO |

## Wrong container/sublot status (SR0700.3.6.9)

➤ NOTE: O Manage produced material (RS) [1.0] (MR2) - container-related functionality does not apply. Container management was introduced with PharmaSuite 8.1 and Output Weighing phases (RS) [5.0].

| UI text  | Comment   |
|--|---|
| Cannot identify the container/sublot, since its status has changed in the meantime. To continue processing, return to the Execution Window.          | Message pack: ow_ManProdMat <version> Message ID: setSublotOutputStatusRecording_ErrorMsg</version> |
| Cannot annul the container(s)/sublot(s), since its/their status has changed in the meantime. To continue processing, return to the Execution Window. | Message pack: ow_ManProdMat <version> Message ID: annulPreparedItems_ErrorMsg</version>             |

Cannot replace the container/sublot, since its status has changed in the meantime.

To continue processing, return to the Execution Window.

Canment

Message pack: ow\_ManProdMat<version>
Message ID: replaceRecordedSublot\_ErrorMsg

## Output Variables (SR0700.9+)

The following output variables are available to reference the phase's output.

## **Instance count (Framework capability)**

Data type: Long

Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.

The count variable of a phase that has not been executed provides 0 as output value.

#### **Start time (Framework capability)**

Data type: Timestamp

Usage: The output variable provides the start time of the phase.

## **Completion time (Framework capability)**

Data type: Timestamp

■ Usage: The output variable provides the completion time of the phase.

## **Identifier (Framework capability)**

Data type: String

■ Usage: The output variable provides the identifier of the phase.

## **Result (SR0700.9.1)**

Data type: String

■ Values: WEIGH, COMPLETED

- Usage: The output variable provides the result of the phase processing:
  - The value is WEIGH if there is output material for processing in the Output Weighing loop.
  - The value is COMPLETED if there is no material left for processing.

## Yield (SR0700.9.2)

- Data type: MeasuredValue
- Usage: The output variable provides the calculated yield as MeasuredValue object.

## Prorate factor (SR0700.9.3)

- Data type: MeasuredValue
- Usage: The output variable provides the calculated prorate factor as MeasuredValue object.

Rockwell Software PharmaSuite® 8.4 - Functional Requirement Specification Output Weighing

# Select Scale Phase (SR0710+)

The **Select scale** phase (O Select Scale) allows an operator to select a weighing method and an appropriate scale. Upon phase completion, the connected scale is initialized and zeroed.

It can provide to up to five scales for selection that are connected to a work center. If more scales are used that are dedicated to a specific work center, the respective phase capabilities need to be adapted.

In addition to pre-assigned scales, scales that are not assigned to this specific work center can also be used (shared scales).

The **Select scale** phase pre-selects the default weighing method defined with the material identified for processing, but also lets an operator switch manually to any other weighing method allowed in the material's parameters and supported for Output Weighing. The phase collects the tolerance and resolution data of all scales configured for a work center, matches it against the target load requirements of the identified material, and pre-selects the scale that is best suited to perform the task. It prevents scales that are not sufficiently tested or calibrated from being used. An operator can select another scale manually, provided it meets the tolerance and scale resolution requirements of the material to be processed. The operator confirms the scale to be used by scanning the barcode of the scale

If the **Quantity entry** weighing method is selected, no scale can be selected. Details of the selected scale and weighing method are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report. Anomalies that occur during processing are covered by the phase exception handling (e.g. using an offline scale).

After completion the phase displays the selected weighing method and scale, both in the Execution Window and in the Navigator.

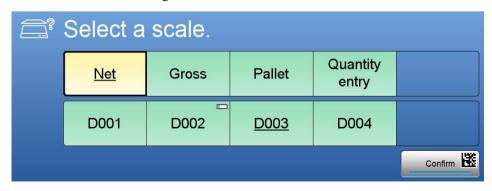


Figure 11: Select scale during execution

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## Layout

The phase provides individual layouts for its representation during execution (page 56), in the Navigator (page 58), and in the sub-report (page 58).

## Representation during Execution (SR0710.1+)

The representation during execution depends on the phase mode.

## Preview mode (SR0710.1.1)

- 1. Phase-specific icon.
- 2. <Instruction text> (taken from **Instruction (SR0710.8.1)** process parameter (page 66))
- 3. **Confirm** button (disabled).

#### **Active mode (SR0710.1.2)**

- 1. Phase-specific icon.
- 2. <Instruction text> (taken from **Instruction (SR0710.8.1)** process parameter (page 66))
- 3. List of weighing methods available for selection (taken from material output parameter of the Weigh phase (SR0730.7.1) (page 140))

In case a sublot with known tare has been identified (weighing of a prepared and loaded sublot), only the **Net weighing** and **Quantity entry** weighing methods are available for selection.

In case the prepared sublot does not have a known tare since the **Quantity entry** weighing method was used for the preparation, the **Quantity entry** weighing method is automatically selected and the phase is automatically completed.

| Content        | UI text | Comment  |
|----------------|---------|--|
| Net weighing   | Net     |  |
| Gross weighing | Gross   | Not available if the Operation mode of the Manage produced material phase is set to Prepare only (see Operation mode (SR0700.8.12) process parameter (page 35)). |

| Content         | UI text        | Comment  |
|-----------------|----------------|--|
| Pallet weighing | Pallet         | Not available if the Operation mode of the Manage produced material phase is set to Prepare only (see Operation mode (SR0700.8.12) process parameter (page 35)). |
| Quantity entry  | Quantity entry | If selected, cell background of scales is changed to gray. No scale can be selected.   |
| <empty></empty> |                |  |

4. List of scales available for selection, depends on work center data, scale-related weighing range, test status, and calibration status.

| Content             | UI text                        | Comment  |
|---------------------|--------------------------------|--|
| Connected scale (1) | <short description=""></short> | Phase displays scale identifier if short description is not available. |
| Connected scale (2) | <short description=""></short> | Phase displays scale identifier if short description is not available. |
|                     | •••                            |  |
| Connected scale (5) | <short description=""></short> | Phase displays scale identifier if short description is not available. |

#### LEGEND

Weight icon: scale is marked as loaded. (NOTE: Does not apply to O Select

scale (RS) [1.0] (MR2).)

Input box icon: scale is configured as manual scale

Underlined text: item was suggested by phase (best scale).

Yellow background: item is selected. Green background: item is selectable. Gray background: item is not selectable.

Red cross: Item is not usable due to missing scale test and/or calibration.

5. **Confirm** button.

## Completed mode (SR0710.1.3)

- 1. Phase-specific icon.
- 2. <Selected weighing method>
- 3. <Identifier of selected scale>
- 4. **Confirm** button (completed).

# Representation in Navigator (SR0710.4+)

The Navigator provides the following details:

#### Phase column (Framework capability)

- <Phase name>
  - Example: Select Scale

#### Information column (SR0710.4.1)

- <Selected weighing method> / <identifier of selected scale>
  - For the **Quantity entry** weighing method, phase displays no scale identifier.
    - Example:Net / QC7DCESQuantity entry

#### Action column

■ There are no actions available.

#### Representation in Sub-report (SR0710.5+)

The sub-report contains the following information:

#### **Common sub-report elements (Framework capability)**

- Start time>
- <Completion time>
- <Unit procedure> / < operation> / < phase>
- <Work center> / <station> / <device> <phase completion user>

#### **Sub-report elements (SR0710.5.1)**

- Position: <number>
- Method: <weighing method>
- Selected scale: <scale identifier>
  - For the **Quantity entry** weighing method, phase displays "N/A".
- Work center: <work center identifier>

# Business Logic (SR0710.2+)

The phase implements the following business logic.

#### Main Path

Business logic related to the main path:

## **Automated scale selection (SR0710.2.1)**

For recent changes, see revision history (page 172).

■ Function: Select scale automatically

■ Type: Main path

■ Trigger: Phase becomes active

■ Postcondition: Phase suggests scale

| Step             | #                                | Description  |
|------------------|----------------------------------|--|
| Phase activation | is of Ph rai are ba Th In "av 1. | Does not apply if the Quantity entry weighing method is the default weighing method.   |
|                  |                                  | If a planned quantity with its tolerances or a target weight with its tolerances is defined:   |
|                  |                                  | Phase suggests the most appropriate scale based on tolerances compared to ranges of available scales. In case both planned quantity and target weight are defined with their tolerances, the algorithm uses the smaller tolerance band.  The following algorithm is applied: In a first step, phase determines all (0-n) available scales and marks them as "available" in the <b>Active mode (SR0710.1.2)</b> layout (page 56). |
|                  |                                  | 1. Criterion 1: Maximum allowed tolerance band for weighing must be equal or greater than twice the scale resolution.  Example: target weight = 10g, lower tolerance = 8g, upper tolerance = 12g, tolerance band = 4g. Then, scales with a maximum resolution of 2g are considered.  |
|                  |                                  | 2. In case of multi-range scales, the system uses the lowest range when checking criterion 1 assuming it has the best resolution.  |
|                  |                                  | In a second step, phase determines the suggested (0-1) scale and marks it as "suggested" and initially as "selected" in the <b>Active mode (SR0710.1.2)</b> layout (page 56).  |
|                  |                                  | 3. Criterion 2: If multiple scales fulfill criterion 1, the scale with the coarsest resolution will be suggested.  |

| Step | #    | Description  |  |
|------|------|--|--|
|      | 10.2 | Does not apply if the Quantity entry weighing method is the default weighing method.   |  |
|      |      | If no planned quantity or target weight with tolerances is defined:  |  |
|      |      | Phase suggests the most appropriate scale with the coarsest resolution.  |  |
|      | 50   | Phase determines test and calibration statuses of all scales and also checks if test or calibration statuses are expired (simulation). |  |
|      | 60   | Phase marks not tested or not calibrated scales as "not ready" in the <b>Active</b> mode (SR0710.1.2) layout (page 56).                |  |
|      | 70   | Phase marks neither "suggested" nor "available" scales as "not available" in the Active mode (SR0710.1.2) layout (page 56).            |  |
|      | 80   | NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).   |  |
|      |      | Does not apply if the Quantity entry weighing method is the default<br>weighing method.  |  |
|      |      | In case a scale's property of the <b>Current Load (RS)</b> purpose is not empty, phase marks the scale as loaded.                      |  |

# **Automated WM selection (SR0710.2.2)**

■ Function: Select weighing method automatically

Type: Main path

■ Trigger: Phase becomes active

■ Postcondition: Phase suggests weighing method

| Step             | #  | Description  |
|------------------|----|--|
| Phase activation | 10 | Phase suggests appropriate weighing method based on the default weighing method of the related material parameter.  (Net removal weighing is not supported for Output Weighing.) |
|                  |    | In case a sublot with known tare has been identified (weighing of a prepared and loaded sublot), phase selects the <b>Net</b> weighing method.                                   |
|                  | 20 | Phase marks weighing method as "suggested" and "available" in the Active mode (SR0710.1.2) layout (page 56).   |
|                  | 25 | If <b>Quantity entry</b> is the default weighing method, the cell background of scales is changed to gray. No scale can be selected.   |

#### Manual scale selection (SR0710.2.3)

➤ Does not apply if the **Quantity entry** weighing method is used.

■ Function: Select scale manually

■ Type: Main path

■ Trigger: Operator selects scale manually.

Available scales are marked by **Automated scale selection** (**SR0710.2.1**) function (page 59).

■ Postcondition: Selected scale

| Step             | #  | Description  |
|------------------|----|--|
| Operator selects | 10 | Phase marks selected scale as selected in the Active mode (SR0710.1.2) |
| scale            |    | layout (page 56).  |

## Manual scale selection by scan (SR0710.2.4)

> Does not apply if the **Quantity entry** weighing method is used.

Function: Select scale manually by use of barcode scan

Type: Main path

■ Trigger: Operator scans scale
Available scales are marked by **Automated scale selection** (**SR0710.2.1**)
function (page 59). Phase also allows to scan shared scales that are not assigned to the current work center.

■ Postcondition: Selected scale

| Step                   | #  | Description   |  |
|------------------------|----|---|--|
| Operator scans 5 scale |    | Phase reads scanned data.   |  |
|                        | 10 | If barcode reading was technically successful, phase updates background<br>color of phase representation according to style sheet in order to confirm<br>the reading.   |  |
|                        |    | If barcode reading was technically not successful, phase remains in listening mode.   |  |
|                        | 12 | If, for the scale that has been marked as "selected", no barcode is maintained in the basic data of the scale equipment entity, phase displays the Inventory number missing (SR0710.3.6.4) error message (page 73). |  |

| Step                                 | #    | Description   |
|--------------------------------------|------|---|
|                                      |      | If the scanned barcode does not belong to a scale, phase displays the Barcode not valid (SR0710.3.6.1) error message (page 72).   |
|                                      | 15   | In case the Allow use of shared scales (SR0710.8.5) process parameter (page 66) is set to Yes and the barcode does not correspond to any of the suggested or available scales, phase adds the scanned scale to the list of scales, in addition to the already listed scales. The shared scale is selected.  If another shared scale is scanned, the new scale will replace the previous shared scale.  Another scan is necessary to trigger the Manual scale selection by scan (SR0710.2.4) function. |
|                                      | 15.1 | If the shared scale cannot be used for the material position (see checks of the Automated scale selection (SR0710.2.1) function (page 59)), phase displays the Scale is not suitable (SR0710.3.6.8) error message (page 73).  |
|                                      | 20   | In case the Allow use of shared scales (SR0710.8.5) process parameter (page 66) is set to No and the barcode does not correspond to any of the suggested or available scales, phase displays the Scale not listed (SR0710.3.6.6) error message (page 73).   |
|                                      | 30   | If barcode represents an available scale, phase marks new scale as selected in the Active mode (SR0710.1.2) layout (page 56).  Another scan is necessary to trigger Manual scale selection by scan (SR0710.2.4) again.  |
| Phase checks expiry status of graphs | 35   | If barcode represents the selected scale, the <b>Refresh expired equipment</b> status (SR0710.2.7) function (page 64) becomes active.   |
| Phase checks if                      | 36   | NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).  |
| scale is loaded                      |      | If the selected scale's property of the <b>Current Load (RS)</b> purpose is not empty, the <b>Confirm scale load (SR0710.2.8)</b> function (page 65) becomes active.  |
|                                      | 38   | The selected scale is bound and its binding context is set.   |
|                                      | 39   | NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).  If the scale's property of the Current Load (RS) purpose is not empty and the scale load has been confirmed successfully, zeroing is skipped and the phase  |
|                                      |      | is completed automatically.  If the scale's property of the <b>Current Load (RS)</b> purpose is empty, continue with step 40.   |

|   | • |
|---|---|
|   | • |
| ) | • |
|   | • |
|   | • |
|   |   |

| Step | #  | Description   |
|------|----|---|
|      | 40 | Phase zeros the scale and is completed automatically.  Zeroing is only executed if  the Zeroing option is selected in the equipment master data of the current scale and  the selected scale is not configured as manual scale. |
|      | 45 | If barcode represents a scale marked as "not ready", phase displays the Scale status error (SR0710.3.6.3) error message (page 72).  |
|      | 50 | If the phase tries to zero the scale, but zeroing fails, phase displays the Scale driver error (SR0710.3.6.7) error message (page 73).  |

# Manual WM selection (SR0710.2.5)

■ Function: Select weighing method manually

■ Type: Main path

■ Trigger: Operator selects weighing method manually

■ Postcondition: Selected weighing method

| Step                             | # | Description   |
|----------------------------------|---|---|
| Operator selects weighing method |   | Phase marks selected weighing method as selected in the <b>Active mode</b> (SR0710.1.2) layout (page 56).                             |
|                                  |   | If <b>Quantity entry</b> is the selected weighing method, the cell background of scales is changed to gray. No scale can be selected. |

# **Manual confirmation (SR0710.2.6)**

■ Function: Confirm phase manually

■ Type: Main path

■ Trigger: Operator confirms phase

Postcondition: Phase is completed

| Step                                       | #  | Description  |
|--|----|--|
| Operator confirms phase                    |    | If Quantity entry is the selected weighing method, continue with step 30.  If selected scale is marked as "not ready", phase displays the Scale status error (SR0710.3.6.3) error message (page 72). |
| Phase checks<br>expiry status of<br>graphs | 15 | The Refresh expired equipment status (SR0710.2.7) function (page 64) becomes active.   |

| Step                            | #  | Description  |
|---------------------------------|----|--|
| Phase checks if scale is loaded | 16 | NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).  If the selected scale's property of the Current Load (RS) purpose is not empty, the Confirm scale load (SR0710.2.8) function (page 65) becomes active.   |
|                                 | 18 | The selected scale is bound and its binding context is set.  |
|                                 | 19 | NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).  If the scale's property of the Current Load (RS) purpose is not empty and the  |
|                                 |    | scale load has been confirmed successfully, zeroing is skipped and the phase is completed automatically.  If the scale's property of the <b>Current Load (RS)</b> purpose is empty, continue with step 20.   |
|                                 | 20 | Phase zeros scale.  If scale cannot be zeroed, phase displays the Scale driver error (SR0710.3.6.7) error message (page 73).  If scale cannot be zeroed and scale is offline, phase displays the Scale communication issue (SR0710.3.5.1) question (page 71).  Zeroing is only executed if the Zeroing option is selected in the equipment master data of the current scale. |
|                                 | 30 | Phase is completed automatically.  |

# Refresh expired equipment status (SR0710.2.7)

Function: Refresh the expired statuses of an equipment entity

Type: Main path

■ Trigger: Equipment entity is identified successfully

■ Postcondition: Expired equipment graph statuses of entity are updated

| Step                                       | #  | Description  |
|--|----|--|
| Phase checks if graph statuses are expired | 10 | Phase checks in a loop for all equipment graphs assigned to the entity if the current status of equipment graph has expired.  If the status is <b>not expired</b> , phase checks the next equipment graph.  If the status is <b>expired</b> , phase performs the <b>Expired</b> ( <b>RS</b> ) equipment graph trigger and checks the next equipment graph. |

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| Step | #  | Description  |
|------|----|--|
|      | 20 | If the execution of any <b>Expired (RS)</b> equipment graph trigger fails, phase resets the status of the equipment entity to <b>Available</b> , updates the logbook accordingly (if maintained), and displays the <b>Expired trigger execution failed</b> (SR0710.3.6.9) error message (page 73). |
|      | 30 | If the execution of all Expired (RS) equipment graph trigger passed successfully, the phase continues with the Manual scale selection by scan (SR0710.2.4) function (page 61) or the Manual confirmation (SR0710.2.6) function (page 63).  |

# Confirm scale load (SR0710.2.8)

➤ NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).

■ Function: Confirm the scale load

■ Type: Main path

■ Trigger: Loaded scale is selected

■ Postcondition: Loaded scale can be used

| Step                            | #  | Description   |
|---------------------------------|----|---|
| Phase checks if scale is loaded | 10 | Phase displays the Confirm scale load (SR0710.3.4.1) information message (page 71).  If the information message is confirmed without scanning the scale's load, phase displays the Unsuccessful scan (SR0710.3.6.11) error message (page 75). |
|                                 | 20 | Phase checks the scanned container/sublot identifier against the scale's property of the <b>Current Load (RS)</b> purpose.  |
|                                 | 30 | If the check fails, phase displays the Current load does not match (SR0710.3.6.10) error message (page 74).  A different scale needs to be selected in order to proceed with weighing.  |
|                                 | 35 | If the check passes successfully, phase continues with the Manual scale selection by scan (SR0710.2.4) function (page 61) or the Manual confirmation (SR0710.2.6) function (page 63).   |

# **Weighing Method-specific Paths**

There are no specifics available for any of the supported weighing methods.

# **Recipe Parameters**

The phase provides process parameters (page 66).

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# Process Parameters (SR0710.8+)

The following process parameters define the behavior of the phase.

#### BASIC PARAMETERS

## **Instruction (SR0710.8.1)**

For recent changes, see revision history (page 172).

| Attribute | Туре      | Comment  |
|-----------|-----------|--|
| Column 1  | HTML text | Instruction text to be displayed. <b>Restriction:</b> Maximum length is 2000 characters (including HTML tags). |
| Column 2  | HTML text | Notused  |
| Column 3  | HTML text | Not used.  |

## Allow use of shared scales (SR0710.8.5)

➤ Does not apply if the **Quantity entry** weighing method is used.

| Attribute | Туре    | Comment   |
|-----------|---------|---|
| Enabled   | Boolean | Controls if it is allowed to use scales that are not assigned to the current work center. |

#### CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

#### **Return to material management (SR0710.8.2)**

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also **Return to material management (SR0710.3.1.1)** user-triggered exception (page 68).

## **Select offline scale (SR0710.8.3)**

➤ Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Select offline scale (SR0710.3.1.2) user-triggered exception (page 69).

# Confirm scale load manually (SR0710.8.6)

- ➤ NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).
- > Does not apply if the **Quantity entry** weighing method is used.

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Confirm scale load manually (SR0710.3.1.3) user-triggered exception (page 69).

## Exceptions (SR0710.3+)

The phase supports user-defined, user-triggered (page 68), system-triggered (page 68), and post-completion exceptions (page 71) and their configuration by means of process parameters (page 66).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

#### **System-triggered Exceptions**

There are no system-triggered exceptions available.

#### User-triggered Exceptions (SR0710.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### Return to material management (SR0710.3.1.1)

The **Return to material management** exception allows an operator to step out of the regular Output Weighing process and start a new run with processing the **Manage produced material** phase.

Representation during exception handling:

Instruction:

Return to material management.

Confirm button.

Exception text:

<Exception text>

(taken from **Return to material management** (**SR0710.8.2**) process parameter (page 66))

■ Back to material management.

#### Return to material management - Logic (SR0710.3.1.1.1)

Trigger: Exception is selected

■ Postcondition: N/A

| Step                        | #  | Description   |
|-----------------------------|----|---|
| Operator confirms exception | 10 | Phase records exception.  |
|                             | 20 | Phase is completed automatically and returns to Manage produced material (SR0700+) phase (page 19). |

#### Select offline scale (SR0710.3.1.2)

➤ Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

The **Select offline scale** exception allows an operator to select a scale even though it cannot communicate with the system.

Representation during exception handling:

Instruction:

Confirm the use and zeroing of the offline scale.

Confirm button.

Exception text:

<Exception text>

(taken from Select offline scale (SR0710.8.3) process parameter (page 67))

Offline scale selected.

#### **Select offline scale - Logic (SR0710.3.1.2.1)**

➤ Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

■ Trigger: Exception is selected

■ Postcondition: N/A

| Step                                 | #  | Description                    |
|--------------------------------------|----|--------------------------------|
| Operator confirms and adds exception | 10 | Phase records exception.       |
|                                      | 20 | Phase is ready for completion. |

#### Confirm scale load manually (SR0710.3.1.3)

- ➤ NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).
- ➤ Does not apply if the **Quantity entry** weighing method is used.

The **Confirm scale load manually** exception allows an operator to confirm the scale load (container/sublot) manually.

The exception is disabled if no loaded scale is selected.

Representation during exception handling:

Instruction:

Confirm the scale load manually.

Box for barcode input.

Confirm button.

Exception text:

<Exception text>

(taken from **Confirm scale load manually (SR0710.8.6)** process parameter (page 67))

Loaded scale: <scale identifier>

Confirmed scale load (container/sublot): <container/sublot identifier>

Example:

Load confirmed manually.

Loaded scale: Sc4711Floor

Confirmed scale load (container/sublot): C00005678

#### Confirm scale load manually - Logic (SR0710.3.1.3.1)

- > Does not apply if the **Quantity entry** weighing method is used.
  - Trigger: Exception is selected
  - Precondition: The scale's property of the Current Load (RS) purpose is not empty.
  - Postcondition: Phase is back in active mode (blocked status, i.e. no other weighing method or scale can be selected).

| Step                        | #  | Description   |
|-----------------------------|----|---|
| Operator confirms exception | 10 | Phase checks the entered container/sublot identifier against the scale's property of the Current Load (RS) purpose.   |
|                             | 20 | If the check fails, phase displays the Current load does not match (SR0710.3.6.10) error message (page 74). The exception cannot be signed and completed. A different scale needs to be selected in order to proceed with weighing. |
|                             | 30 | If the check passes successfully, the exception has to be signed.   |
| Operator signs exception    | 40 | Phase returns to active mode.  Weighing method or scale selection can no longer be changed.  Phase can be completed with the selected scale.  |

## **Post-completion Exceptions**

There are no post-completion exceptions available.

## Information Messages (SR0710.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an  $\mathbf{OK}$  button.

The following information messages are available to inform the operator about how to proceed.

#### Confirm scale load (SR0710.3.4.1)

## ➤ NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).

| UI text                    | Comment   |
|----------------------------|---|
|                            | Message pack: ScaleCurrentLoadChecker <version></version> |
| confirmed.                 | Message ID: ConfirmScalesCurrentLoad                      |
| Scan the load's barcode to |   |
| complete the scale         |   |
| selection.                 |   |

# Questions (SR0710.3.5+)

Questions are represented in a question dialog containing a message type-specific icon, the question, a **Yes** button, and a **No** button.

The following questions are available to request a decision from the operator how to proceed.

#### Scale communication issue (SR0710.3.5.1)

| UI text                    | Comment  |
|----------------------------|--|
| A communication error with | Message pack: wd_UIMessage <version></version> |
| the selected scale has     | Message ID: scalesCommunication_QuestionMsg    |
| occurred. The scale has    |  |
| been set to offline mode.  |  |
| Do you wish to reset it to |  |
| the online mode?           |  |

## **Decisions**

There are no decisions available.

# Error Messages (SR0710.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an  $\mathbf{OK}$  button.

The following error messages are available to inform the operator about error conditions.

## Barcode not valid (SR0710.3.6.1)

| UI text | Comment  |
|---------|--|
|         | Message pack: wd_SelectScale <version> Message ID: invalidBarcode_ErrorMsg</version> |

# Scale online error (SR0710.3.6.2)

| UI text | Comment   |
|---------|---|
|         | Message pack: wd_UIMessage <version> Message ID: scalesCommunication_ErrorMsg</version> |

## Scale status error (SR0710.3.6.3)

| UI text   | Comment   |
|---|---|
| The status of <scale> is unsuitable. The scale must be calibrated first.</scale>            | Message pack: wd_SelectScale <version> Message ID: scaleNotCalibrated_ErrorMsg</version>          |
| The status of <scale> is unsuitable. The scale must be tested first.</scale>                | Message pack: wd_SelectScale <version> Message ID: scaleNotTested_ErrorMsg</version>              |
| The status of <scale> is unsuitable. The scale must be calibrated and tested first.</scale> | Message pack: wd_SelectScale <version> Message ID: scaleNotTestedNotCalibrated_ErrorMsg</version> |

# **Inventory number missing (SR0710.3.6.4)**

| UI text | Comment   |
|---------|---|
|         | Message pack: wd_UIMessage <version> Message ID: inventoryNrScaleEmpty_ErrorMsg</version> |

# Scale not listed (SR0710.3.6.6)

| UI text | Comment  |
|---------|--|
|         | Message pack: wd_UIMessage <version> Message ID: noAvailableScalesScanned_ErrorMsg</version> |

# Scale driver error (SR0710.3.6.7)

| UI text   | Comment   |
|---|---|
| Cannot obtain a stable reading or a scale communication error has occurred. Please try again. | Message pack: srv_eqm.WDEquipmentService Message ID: zeroFailed |

## Scale is not suitable (SR0710.3.6.8)

| UI text                      | Comment  |
|------------------------------|--|
| You have selected a scale    | Message pack: ow_SelectScale <version></version> |
| that is not suitable for the | Message ID: notAllowedScalesScanned_ErrorMsg     |
| current material position.   |  |
| Please select another scale. |  |

# **Expired trigger execution failed (SR0710.3.6.9)**

| UI text   | Comment  |
|---|--|
| The <equipment identifier=""> entity is not suitable, since</equipment> | Message pack: pec_ExceptionMessage Message ID: cannotIdentifyExpiryTriggerFailure_ErrorMsg |
| the update of at least one expired status failed.                       | The <b>Details</b> button provides access to more graph-specific information:              |
|   | <the applies="" reason="" that=""></the>   |

UI text Comment Equipment: <equipment identifier> / <equipment short description> Equipment type: t of equipment types> (if available) Graph (ID): <graph display text> (<identifier>) Purpose: <purpose> Current status (key): <display text> (<key>) Failed trigger (key): <display text> (<key>) The potential reasons for a failed status transition are: The trigger you are trying to perform is not contained in the graph. Cannot find a transition for the current status. Cannot find a fulfillable transition condition for the current status. There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>. Cannot evaluate the transition condition (<TR-ID>). Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

#### **Current load does not match (SR0710.3.6.10)**

➤ NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).

| UI text   | Comment  |
|---|--|
| The scale's current load ( <scanned barcode="">) does not match the expected load (<current load="" property="" value="">). Cannot use the scale.</current></scanned> | Operator can still select a different scale, or the scale's master data needs to be corrected.  Message pack: ScaleCurrentLoadChecker <version> Message ID: CurrentLoadDoesNotMatch_ErrorMsg</version> |

## Unsuccessful scan (SR0710.3.6.11)

➤ NOTE: Does not apply to O Select scale (RS) [1.0] (MR2).

| UI text  | Comment   |
|--|---|
| You have not successfully scanned the load's barcode | Message pack: ScaleCurrentLoadChecker <version> Message ID: NothingScanned_ErrorMsg</version> |
| yet.   |   |
| Please re-confirm to scan a                          |   |
| suitable barcode, confirm                            |   |
| the load manually by                                 |   |
| exception, or select                                 |   |
| another scale.                                       |   |

## Output Variables (SR0710.9+)

The following output variables are available to reference the phase's output.

#### **Instance count (Framework capability)**

Data type: Long

■ Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.

The count variable of a phase that has not been executed provides 0 as output value.

#### **Start time (Framework capability)**

Data type: Timestamp

■ Usage: The output variable provides the start time of the phase.

#### **Completion time (Framework capability)**

Data type: Timestamp

■ Usage: The output variable provides the completion time of the phase.

#### **Identifier (Framework capability)**

Data type: String

■ Usage: The output variable provides the identifier of the phase.

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# Identify Container Phase (SR0750+)

The **Identify container** phase (O Identify Container) allows to identify an equipment entity (container) for the material to be produced and to bind this entity to the context in which it is being used. Appropriate equipment requirements can be defined in support of the fit-for-purpose checks during execution.

The phase can be used during **Output Weighing** and **Dispense**, but it must not be used during **Inline Weighing**.

Example use cases are:

- Verifying that a container meets requirements Containers used during processing must meet various requirements. Prior to being used, a container is checked against defined requirements (equipment class and additional properties). The ensuing results are documented in the entity's logbook.
- Exclusive usage of a container for processing an order In order to ensure the exclusive usage of a specific container, the entity is bound to a unit procedure. The binding itself is documented in the batch report and the entity's logbook.

The identified container, its equipment class, and the equipment property values are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (page 79).

Anomalies that occur during processing are covered by the phase exception handling (page 89) (e.g. requirements are not met).

After completion, the phase displays the identifier of the identified container, both in the Execution Window and in the Navigator.

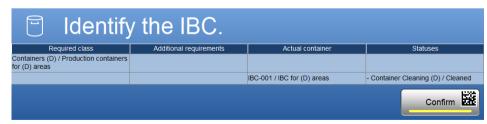


Figure 12: Identify container during execution

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#### Layout

The phase provides individual layouts for its representation during execution (page 78), in the Navigator (page 79), and in the sub-report (page 79).

#### Representation during Execution (SR0750.1+)

The representation during execution depends on the phase mode.

#### Preview mode (SR0750.1.1)

- 1. Phase-specific icon.
- <Instruction text>
   (taken from Instruction (SR0750.8.1) process parameter (page 85))
- 3. Table with list of equipment requirements required for identification (taken from **Equipment parameters** (**SR0750.6.1**) process input (page 84))
- 4. **Confirm** button (disabled).

#### **Active mode (SR0750.1.2)**

- 1. Phase-specific icon.
- 2. <Instruction text> (taken from **Instruction (SR0750.8.1)** process parameter (page 85))
- 3. Table with list of equipment requirements required for identification (taken from **Equipment parameters** (**SR0750.6.1**) process input (page 84))
  - Required class
  - Additional requirements [rule identifier / description or rule (if description is empty)]
     (This is related to properties, property values, and status graphs.)
  - Actual container (identified container)
  - Statuses (all actual statuses (available in the used FSM or graph) of the identified container)
- 4. **Confirm** button.

#### Completed mode (SR0750.1.3)

- 1. Phase-specific icon.
- <Instruction text>
   (taken from Instruction (SR0750.8.1) process parameter (page 85))
- 3. <Container identifier>
- 4. **Confirm** button (completed).

# Representation in Navigator (SR0750.4+)

The Navigator provides the following details:

#### Phase column (Framework capability)

- <Phase name>
  - Example: Identify container

## **Information column (SR0750.4.1)**

- <Identifier of identified equipment entity>
  - Example: 23478asUi

#### **Action column**

■ There are no actions available.

## Representation in Sub-report (SR0750.5+)

The sub-report contains the following information:

## **Common sub-report elements (Framework capability)**

- Start time>
- <Completion time>
- <Unit procedure> / < operation> / < phase>
- <Work center> / <station> / <device> <phase completion user>

#### **Sub-report elements (SR0750.5.1)**

- For recent changes, see revision history (page 172).
  - Position: <number>
  - Instruction text
  - Required equipment class (identifier and short description)
  - Identified container (identifier and short description)
  - Additional requirements [rule identifier / description or rule (if description is empty)]
  - Actual property names and values (for additional non-status property type-based requirements of the identified container) and all status values (available in the used FSM or graph) of the identified container (e.g. cleaning status)

For properties of the **Automation** type, the value is always N/A.

# Business Logic (SR0750.2+)

The phase implements the following business logic.

## Phase skipped (SR0750.2.6)

Function: Phase is skipped

Trigger: Certain conditions apply during phase activation

 Postcondition: Container identification is skipped and phase is completed automatically

| Step              | #  | Description   |
|-------------------|--|---|
| Phase performs 10 |  | Phase checks  |
| checks            | if the Gross weighing or Pallet weighing method has been selected in<br>the context of Dispense (see Select scale (SR0210+) phase in [A3] (page<br>169)), or |   |
|                   |  | if a <b>Keep target</b> situation (target not closed yet) exists in the context of Dispense, or             |
|                   |  | if, during Output Weighing, an already prepared sublot or container has<br>been identified for weighing, or |
|                   |  | if the Pallet weighing method has been selected in the context of Output<br>Weighing.                       |
|                   |  | If any of these conditions apply, phase skips container identification and is completed automatically.      |

## Identify and bind equipment entity (SR0750.2.1)

Function: Identify equipment entity

■ Trigger: Phase becomes active

Postcondition: Equipment entity is identified

| Step                   | #  | Description  |
|------------------------|----|--|
| Phase activation       | 10 | Phase displays its user interface according to the <b>Active mode (SR0750.1.2)</b> layout (page 78).   |
| Operator scans barcode | 20 | The Scan equipment entity barcode (SR0750.2.2) function (page 81) becomes active.  For manual identification, see Enter identifier manually (SR0750.3.1.1) user-triggered exception (page 95). |

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| Step                                    | #  | Description  |
|---|----|--|
| Phase performs identification checks    | 30 | The Identify equipment entity (SR0750.2.3) function (page 82) becomes active.  |
| Phase performs binding checks           | 40 | The <b>Bind equipment entity (SR0750.2.4)</b> function (page 82) becomes active.   |
| Operator confirms phase                 | 50 | If no equipment entity has been bound, phase displays the Nothing<br>identified (SR0750.3.6.5) error message (page 101). The phase cannot<br>be completed.                                       |
|   |    | If the checks have passed successfully and an equipment entity has been<br>bound, the operator confirms the identified and bound equipment entity.<br>Phase is completed.                        |
|   |    | If the Skip container identification (SR0750.3.1.3) user-triggered exception (page 97) has been signed, phase can be completed without having identified a container.                            |
| Phase runs in Automatic completion mode | 60 | In case the entity has been identified and bound without any exceptions and the Mode (SR0750.8.10) process parameter (page 85) is set to Automatic completion, phase is completed automatically. |

# Scan equipment entity barcode (SR0750.2.2)

■ Function: Scan an equipment entity barcode

■ Trigger: Operator scans barcode

■ Postcondition: Equipment entity barcode is scanned

| Step                     | #  | Description   |  |
|--------------------------|----|---|--|
| Operator scans barcode   | 10 | Phase reads scanned data.   |  |
| Phase performs<br>checks | 20 | If barcode reading was technically successful, phase updates background<br>color of phase representation according to style sheet in order to confirm<br>the reading.             |  |
|                          |    | If barcode reading was technically not successful, phase remains in listening mode.   |  |
|                          |    | If the required equipment entity is already in the <b>Identified</b> or <b>Bound</b> status, phase displays the <b>Already identified</b> (SR0750.3.6.2) error message (page 99). |  |
|                          |    | If barcode reading was not successful, phase displays the Cannot find entity (SR0750.3.6.1) error message (page 99).  |  |

| Step | # | Description   |  |
|------|---|---|--|
|      |   | If the checks have passed successfully, phase continues with Identify equipment entity (SR0750.2.3) function (page 82). |  |

# **Identify equipment entity (SR0750.2.3)**

■ Function: Identify a scanned equipment entity

■ Trigger: Equipment entity is scanned successfully

Postcondition: Equipment entity is identified

| Step  | #  | Description  |
|---|----|--|
| Phase checks<br>availability of<br>equipment entity | 10 | If the entity has already been identified or bound in the context of a different phase, the check fails and the phase displays the <b>Not available for usage</b> (SR0750.3.6.4) error message (page 101).   |
|   | 20 | If the phase has been resumed and the entity has already been identified in the context of this phase, the phase continues with the <b>Bind identified</b> equipment entity (SR0750.2.4) function (page 82).   |
|   | 30 | If the check passes successfully, phase changes the status of the equipment entity to <b>Identified</b> , updates the logbook accordingly (if maintained), and continues with the <b>Bind identified equipment entity (SR0750.2.4)</b> function (page 82). |

# Bind identified equipment entity (SR0750.2.4)

■ Function: Bind an identified equipment entity

■ Trigger: Equipment entity is identified successfully

■ Postcondition: Equipment entity is bound

| Step                                 | #  | Description   |  |
|--------------------------------------|----|---|--|
| Phase checks expiry status of graphs | 10 | The Refresh expired equipment status (SR0750.2.5) function (page 83) becomes active.  |  |
| Phase checks equipment type          | 20 | The check requires that the <b>Container (RS)</b> property type is assigned to the identified equipment entity.   |  |
|                                      |    | If the check fails, phase resets the status of the equipment entity to Available, updates the binding context and the logbook accordingly (if maintained), and displays the Wrong equipment type (SR0750.3.6.8) error message (page 100). |  |
|                                      |    | If the check passes successfully, phase continues with the next check.  |  |

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| Step  | #  | Description  |  |
|---|----|--|--|
| Phase checks<br>class<br>membership of<br>equipment entity                                    | 30 | <ul> <li>If the check fails, phase resets the status of the equipment entity to Available, updates the binding context and the logbook accordingly (if maintained), and displays the Not member of required class (SR0750.3.6.3) error message (page 101).</li> <li>If the check passes successfully, phase continues with the next check.</li> </ul>  |  |
| Phase checks if<br>class and entity<br>fulfill the<br>minimum<br>required status              | 40 | <ul> <li>Phase checks for the minimum class status and the minimum entity status required for equipment identification according to the Container status check (SR0750.8.5) process parameter (page 86). If the check fails, phase creates the Container status check (SR0750.3.2.2) system-triggered exception (page 91).</li> <li>If the check passes successfully, phase continues with the next check.</li> </ul>  |  |
| Phase checks if property values of equipment entity match and if flexible rules are fulfilled | 50 | <ul> <li>If the check fails, phase creates the Property value check (SR0750.3.2.1) system-triggered exception (page 89).</li> <li>If the check passes successfully or the exception is recorded,</li> <li>phase sets the status of the equipment entity to Bound and updates the binding context and the logbook accordingly (if maintained),</li> <li>phase sends the CONT_ID trigger to a status graph of the Container Cleaning (RS) purpose in order to trigger a status transition per status graph configuration, and</li> <li>the container will be available within the given weighing context (Output Weighing or Dispense).</li> </ul> |  |

# Refresh expired equipment status (SR0750.2.5)

- Function: Refresh the expired statuses of an equipment entity
- Trigger: Equipment entity is identified successfully
- Postcondition: Expired equipment graph statuses of entity are updated

| Step  | # | Description  |  |
|---|---|--|--|
| graph statuses current status of equipment graph has expired. |   | Phase checks in a loop for all equipment graphs assigned to the entity if the current status of equipment graph has expired.                   |  |
| are expired   |   | If the status is <b>not expired</b> , phase checks the next equipment graph.   |  |
|   |   | If the status is <b>expired</b> , phase performs the <b>Expired</b> ( <b>RS</b> ) equipment graph trigger and checks the next equipment graph. |  |

| Step | #  | Description   |
|------|----|---|
|      | 20 | If the execution of any Expired (RS) equipment graph trigger fails, phase resets the status of the equipment entity to Available, updates the binding context and the logbook accordingly (if maintained), and displays the Expired trigger execution failed (SR0750.3.6.9) error message (page 100). |
|      | 30 | If the execution of all <b>Expired (RS)</b> equipment graph trigger passed successfully, the phase continues with further checks of the <b>Bind identified equipment entity (SR0750.2.4)</b> function (page 82).  |

## **Recipe Parameters**

The phase provides equipment parameters as process inputs (page 84) and process parameters (page 85).

#### Process Inputs (SR0750.6+)

#### **Equipment parameters (SR0750.6.1)**

Equipment parameters allow to define equipment requirements as follows:

- by assigning an equipment class,
- by assigning a specific property type (check against existence),
- by setting specific property values (check against value, see **Technical Property Types and Editors** (**SR3071.8.7**+) in "Functional Requirement Specification Data Management" [A4] (page 169)),
- by defining a flexible rule, or
- by defining a conditional rule.

For properties of the following data types, the property values cannot be accessed within rules:

- Equipment type
- Flexible tag definition
- Ranges
- Room cleaning rules
- Scale configuration
- Work center assignment

For details about rules, see Expressions for Flexible Rules (SR3146.9.9.4.10) and Expressions for Conditional Rules (SR3146.9.9.4.12) in "Functional Requirement Specification Recipe and Workflow Management" [A5] (page 169).

# Process Parameters (SR0750.8+)

The following process parameters define the behavior of the phase.

#### BASIC PARAMETERS

## **Instruction (SR0750.8.1)**

For recent changes, see revision history (page 172).

| Attribute | Туре | Comment  |
|-----------|------|--|
| Text      |      | Instruction text to be displayed. <b>Restriction:</b> Maximum length is 2000 characters (including HTML tags). |

# Mode (SR0750.8.10)

| Attribute | Туре        | Comment  |
|-----------|-------------|--|
| Mode      | Choice list | Defines the processing mode.  Manual completion (default): Operator confirms phase manually.  Automatic completion: Phase is completed automatically after a container has been identified successfully. |

#### CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

# Property value check (SR0750.8.2)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Property value check (SR0750.3.2.1) system-triggered exception (page 89).

## **Container status check (SR0750.8.5)**

| Attribute             | Туре        | Comment   |
|-----------------------|-------------|---|
| Minimum class status  | Choice list | Defines the minimum class status required for equipment identification. Available settings: Verification, Approved. Default setting: Approved.  |
| Minimum entity status | Choice list | Defines the minimum entity status required for equipment identification. Available settings: Verification, Approved. Default setting: Approved.   |
| Risk assessment       | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text        | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Container status check (SR0750.3.2.2) system-triggered exception (page 91).

## **Unforeseen resume (SR0750.8.6)**

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |

| Attribute      | Туре | Comment  |
|----------------|------|--|
| Exception text |      | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters. |

See also Unforeseen resume (SR0750.3.2.4) system-triggered exception (page 93).

## **Status transition failed (SR0750.8.9)**

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Status transition failed (SR0750.3.2.5) system-triggered exception (page 94).

#### CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

# Enter identifier manually (SR0750.8.3)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |

Attribute Type Comment

Exception text Text Defines the exception description used during exception handling and within the batch record.

Maximum length is 250 characters.

See also Enter identifier manually (SR0750.3.1.1) user-triggered exception (page 95).

# **Unbind (SR0750.8.4)**

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Unbind (SR0750.3.1.2) user-triggered exception (page 96).

# Skip container identification (SR0750.8.8)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also **Skip container identification (SR0750.3.1.3)** user-triggered exception (page 97).

#### **Return to material management (SR0750.8.7)**

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also **Return to material management (SR0750.3.1.4)** user-triggered exception (page 98).

## Exceptions (SR0750.3+)

The phase supports user-defined, user-triggered (page 95), system-triggered (page 89), and post-completion exceptions (page 99) and their configuration by means of process parameters (page 85).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

#### System-triggered Exceptions (SR0750.3.2+)

For recent changes, see revision history (page 172).

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

#### Property value check (SR0750.3.2.1)

For each property that does not match, the exception lists the related rule identifier, the rule description (or the rule content, if the description is not maintained), the property

identifier, and the expected and actual values.

For each flexible rule that is not fulfilled, the exception lists the related rule identifier, the rule description (or the rule expression, if the description is not maintained), and the expected and actual values of the expression.

Representation of the exception:

#### Exception dialog

<Exception text>

(taken from **Property value check** (**SR0750.8.2**) process parameter (page 85)) Cannot identify the <Identifier of identified equipment entity> entity, since it does not meet the defined equipment requirements.

#### **Exception Window**

<Exception text>

(taken from **Property value check** (**SR0750.8.2**) process parameter (page 85)) Cannot identify the <Identifier of identified equipment entity> entity, since it does not meet the defined equipment requirements.

Rule: <identifier>

Description: <rule description> (or <rule content/expression>, if the description is not maintained)

For properties that do not match:

Equipment property: <identifier>

Expected value: <value>
Actual value: <value>

For rules that are not fulfilled:

Expected value: Yes Actual value: No

Example:

Equipment requirement violation

Cannot identify the AX67 entity, since it does not meet the defined equipment requirements.

Rule: Rule\_01

Description: Check of cleaning status Equipment property: Cleaning status

Expected value: Clean Actual value: To be cleaned

Rule: Rule 02

Description: Required volume range

Equipment property: Volume

Expected value: 150 - 2001

Actual value: 1001

Rule: Rule\_03

Description: Counter less or equal 5

Expected value: Yes Actual value: No

## Property value check - Logic (SR0750.3.2.1.1)

Trigger: Check has failed

Postcondition: Exception is recorded

| Step  | #    | Description   |
|---|------|---|
| Operator accepts exceptional situation                  | 1-10 | Phase shows exception description to be signed.   |
| Operator signs exception                                | 1-20 | <ul> <li>Phase records exception.</li> <li>Phase sets status of equipment entity to Bound and updates the binding context and the logbook accordingly (if maintained).</li> <li>Phase sends the CONT_ID trigger to a status graph of the Container Cleaning (RS) purpose in order to trigger a status transition per status graph configuration.</li> <li>The container will be available within the given weighing context (Output Weighing or Dispense).</li> </ul> |
| Operator does<br>not accept<br>exceptional<br>situation | 2-10 | Phase resets status of equipment entity to <b>Available</b> and updates the binding context and the logbook accordingly (if maintained).  |

## Container status check (SR0750.3.2.2)

The phase checks if the defined minimum statuses for the equipment class and entity are fulfilled according to the **Container status check** (**SR0750.8.5**) process parameter (page 86).

Representation of the exception:

#### Exception dialog

<Exception text> (taken from Container status check (SR0750.8.5) process parameter (page 86)) (Class status does not match:) Cannot identify the <entity identifier > equipment entity, since its required class (<class identifier>) is in the <status> status.

(Entity status does not match:)

Cannot identify the <identifier> equipment entity, since it is in the <status> status.

#### **Exception Window**

#### <Exception text>

(taken from **Container status check (SR0750.8.5**) process parameter (page 86)) (Class status does not match:)

Cannot identify the <entity identifier > equipment entity, since its required class (<class identifier>) is in the <status> status.

Required minimum status: <status>

(Entity status does not match:)

Cannot identify the <identifier> equipment entity, since it is in the <status> status. Required minimum status: <status>

#### Example:

Equipment status violation

Cannot identify the AX67 equipment entity, since its required class (CX14) is in the Verification status.

Required minimum status: Approved

Cannot identify the AX67 equipment entity, since it is in the Draft status. Required minimum status: Approved

#### Container status check - Logic (SR0750.3.2.2.1)

Trigger: Check has failed

■ Postcondition: Exception is recorded

| Step                                   | #    | Description  |
|--|------|--|
| Operator accepts exceptional situation | 1-10 | Phase shows exception description to be signed.  |
| Operator signs                         | 1-20 | Phase records exception.   |
| exception                              |      | Phase sets status of equipment entity to <b>Bound</b> and updates the binding context and the logbook accordingly (if maintained).                                     |
|  |      | Phase sends the CONT_ID trigger to a status graph of the Container<br>Cleaning (RS) purpose in order to trigger a status transition per status<br>graph configuration. |
|  |      | The container will be available within the given weighing context (Output Weighing or Dispense).   |

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| Step   | #    | Description  |
|--|------|--|
| Operator does not accept exceptional situation | 2-10 | Phase resets status of equipment entity to <b>Available</b> and updates the binding context and the logbook accordingly (if maintained). |

#### Multiple failed checks (SR0750.3.2.3)

For recent changes, see revision history (page 172).

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

After the exception has been recorded, the phase must be manually completed.

Representation in the message dialog:

- Several exceptions have occurred.
   For details refer to the Exception Window.
- 2. **Exception** button

Representation during exception handling:

Exception text:
 Concatenation of multiple exception texts>.

#### Unforeseen resume (SR0750.3.2.4)

Representation of the exception:

<Exception text>
(taken from **Unforeseen resume** (**SR0750.8.6**) process parameter (page 86))
The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.

Example:

A critical resume situation has occurred. Contact your supervisor before proceeding.

The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.

#### **Unforeseen resume - Logic (SR0750.3.2.4.1)**

- Trigger: Weighing process has been interrupted so that the system needs to be resumed
- Postcondition: Phase is back in active mode

| Step                        | #  | Description  |
|-----------------------------|----|--|
| Phase activation            | 10 | Phase displays the <b>Unforeseen resume</b> (SR0750.3.2.4) system-triggered exception. |
| Operator triggers exception | 20 | Phase records exception.   |

#### Status transition failed (SR0750.3.2.5)

The **Status transition failed** exception is displayed automatically if a certain status transition could not be performed based on the given graph purpose and trigger.

The potential reasons for a failed status transition are:

- The graph of the required purpose is missing.
- The trigger is missing.
- Source status does not match.
- Condition cannot be fulfilled or is not unique (in case of multiple transition definitions per trigger).
- Error during condition evaluation.
- Error during action evaluation.

Representation of the exception:

#### Exception dialog

- - List of potential reasons:
    - The graph of the required purpose is missing.
    - The trigger you are trying to perform is not contained in the graph.
    - Cannot find a transition for the current status.
    - Cannot find a fulfillable transition condition for the current status.
    - There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>.
    - Cannot evaluate the transition condition (<TR-ID>).
    - Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

#### **Exception Window**

#### <Exception text>

 $(taken\ from\ \textbf{Status}\ \textbf{transition}\ \textbf{failed}\ (\textbf{SR0750.8.9})\ process\ parameter\ (page\ 87))$ 

<reason>

Equipment: <equipment identifier> / <equipment short description>

Equipment type: st of equipment types> (if available)

Graph (ID): <graph display text> (<identifier>)

Purpose: <purpose>

Current status (key): <display text> (<key>) Failed trigger (key): <display text> (<key>)

#### Example:

Status transition failed.

Cannot find a transition for the current status.

Equipment: IBC0033

Equipment type: Container (RS)

Graph (ID): IBC Cleaning (IBCCleaning01)

Purpose: Container Cleaning (RS)

Current status (key): Blocked (BLOCKED)
Failed trigger (key): In use (IN\_USE)

#### Status transition failed - Logic (SR0750.3.2.5.1)

Trigger: The status transition could not be performed based on the given graph purpose and trigger.

■ Postcondition: Phase is active

| Step                                   | #  | Description                                     |
|--|----|---|
| Operator accepts exceptional situation | 10 | Phase shows exception description to be signed. |
| Operator signs exception               | 20 | Phase records exception.                        |

## User-triggered Exceptions (SR0750.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### **Enter identifier manually (SR0750.3.1.1)**

The **Enter identifier manually** exception allows an operator to enter the barcode of an equipment entity manually.

The exception is disabled, if the required equipment entity is already in the **Identified** or **Bound** status.

Representation during exception handling:

■ Instruction:

Identify by typing the container barcode.

Box for identifier input.

Confirm button.

Exception text:

<Exception text>

(taken from **Enter identifier manually** (**SR0750.8.3**) process parameter (page 87))

Manual entry: <barcode string>

Example:

Equipment entity barcode entered manually

Manual entry: 23478asUi

#### Enter identifier manually - Logic (SR0750.3.1.1.1)

Trigger: Exception is selected

■ Postcondition: Barcode string is entered manually

| Step                        | # | Description   |
|-----------------------------|---|---|
| Operator confirms exception |   | If entered barcode string does not match an equipment entity, phase displays the Cannot find entity (SR0750.3.6.1) error message (page 99).   |
| Operator signs exception    |   | If equipment entity can be identified as an existing entity and exception is signed, phase continues with Identify equipment entity (SR0750.2.3) function (page 82) (see also Identify and bind equipment entity (SR0750.2.1) function (page 80). |

#### **Unbind (SR0750.3.1.2)**

The **Unbind** exception allows an operator to revoke the identification of a container.

The exception is disabled, if the required container is not in the **Bound** status.

Representation during exception handling:

Instruction:

Confirm to unbind the container.

Confirm button.

Exception text:

<Exception text>

(taken from **Unbind** (**SR0750.8.4**) process parameter (page 88))

Unbound container: <Equipment entity identifier> / <Equipment entity short description>

Example:

Unbind during identification process Unbound container: 23478H / Hose 45 cm

## **Unbind - Logic (SR0750.3.1.2.1)**

Trigger: Exception is selected

■ Postcondition: Equipment entity is no longer bound

| Step                        | #  | Description   |
|-----------------------------|----|---|
| Operator confirms exception | 10 | Phase shows exception description to be signed according to <b>Unbind</b> (SR0750.8.4) process parameter (page 88).   |
| Operator signs exception    | 20 | Phase resets status of equipment entity to <b>Available</b> and updates the binding context and the logbook accordingly (Unbind) (if maintained).                   |
|                             |    | Phase sends the CONT_EMPTY trigger to a status graph of the Container Cleaning (RS) purpose in order to trigger a status transition per status graph configuration. |
|                             |    | The container will no longer be available within the given weighing context (Output Weighing or Dispense).  |

## Skip container identification (SR0750.3.1.3)

The **Skip container identification** exception allows an operator to skip the identification of a container.

The exception is disabled, if the required container is already in the **Identified** or **Bound** status.

Representation during exception handling:

■ Instruction:

Skip container identification.

Confirm button.

Exception text:

<Exception text>

(taken from **Skip container identification** (**SR0750.8.8**) process parameter (page 88))

No container identified.

Example:

Container identification has been skipped.

No container identified.

#### Skip container identification - Logic (SR0750.3.1.3.1)

Trigger: Exception is selected

■ Postcondition: Phase can be completed without container identification

| Step                        | #  | Description  |
|-----------------------------|----|--|
| Operator confirms exception |    | Phase shows exception description to be signed according to <b>Skip container identification (SR0750.8.8)</b> process parameter (page 88). |
| Operator signs exception    | 20 | Phase returns to the Execution Window and can be completed without having identified a container.  |

## Return to material management (SR0750.3.1.4)

The **Return to material management** exception allows an operator to step out of the regular Output Weighing process and start a new run with processing the **Manage produced material** phase.

In the context of Dispense operations, the exception allows the operator to start a new run with processing the **D Identify material** phase.

Representation during exception handling:

■ Instruction:

Return to material management.

Confirm button.

Exception text:

<Exception text>

(taken from **Return to material management** (**SR0750.8.7**) process parameter (page 89))

Example:

Back to material management.

#### Return to material management - Logic (SR0750.3.1.4.1)

Trigger: Exception is selected

■ Postcondition: N/A

| Step                        | #  | Description  |
|-----------------------------|----|--|
| Operator confirms exception | 10 | Phase records exception.   |
|                             | 20 | Phase is completed automatically and returns to the Manage produced material (SR0700+) phase (page 19) (Output Weighing context) or the Identify material (SR0200+) phase (Dispense context, [A3] (page 169)). |

## **Post-completion Exceptions**

There are no post-completion exceptions available.

## **Information Messages**

There are no information messages available.

## Questions

There are no questions available.

#### **Decisions**

There are no decisions available.

## Error Messages (SR0750.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an  $\mathbf{OK}$  button.

The following error messages are available to inform the operator about error conditions.

## Already identified (SR0750.3.6.2)

| UI text   | Comment   |
|---|---|
| Cannot identify the<br><scanned identifier=""><br/>container, since you have<br/>already identified a suitable<br/>container. To identify<br/>another container, unbind<br/>the <currently identified<br="">identifier&gt; container first.</currently></scanned> | Message pack: ow_IdentCont <version> Message ID: EqReqAlreadyIdent_ErrorMsg</version> |

## Cannot find entity (SR0750.3.6.1)

| UI text                  | Comment  |
|--------------------------|--|
| _                        | Message pack: ow_IdentCont <version> Message ID: EqNotExist_ErrorMsg</version> |
| available in the system. |  |

Expired trigger execution failed (SR0750.3.6.9)

| UI text   | Comment   |
|---|---|
| The <equipment identifier=""> entity is not suitable, since the update of at least one expired status failed.</equipment> | Message pack: pec_ExceptionMessage Message ID: cannotIdentifyExpiryTriggerFailure_ErrorMsg The Details button provides access to more graph-specific information:   |
|   | <pre><the applies="" reason="" that=""> Equipment: <equipment identifier=""> / <equipment description="" short=""> Equipment type: <list equipment="" of="" types=""> (if available) Graph (ID): <graph display="" text=""> (<identifier>) Purpose: <purpose> Current status (key): <display text=""> (<key>) Failed trigger (key): <display text=""> (<key>)</key></display></key></display></purpose></identifier></graph></list></equipment></equipment></the></pre> |
|   | The potential reasons for a failed status transition are:   |
|   | The trigger you are trying to perform is not contained in the graph.  |
|   | Cannot find a transition for the current status.  |
|   | Cannot find a fulfillable transition condition for the current status.  |
|   | There is more than one fulfillable transition<br>condition available for the current status: <tr-id;<br>TR-ID;&gt;.</tr-id;<br>   |
|   | Cannot evaluate the transition condition ( <tr-id>).</tr-id>  |
|   | Cannot evaluate the transition action ( <tr-action id="">) from the current status to the new status (<display (key)="" text="">).</display></tr-action>  |

# Wrong equipment type (SR0750.3.6.8)

| UI text  | Comment  |
|--|--|
| a suitable equipment entity. Please identify a | Message pack: ow_IdentCont <version> Message ID: WrongEquipmentType_ErrorMsg</version> |
| entity. Please identify a container.           |  |

## Not member of required class (SR0750.3.6.3)

| UI text | Comment  |
|---------|--|
|         | Message pack: eqm.Validation Message ID: eqmClassNotMatch_ErrorMsg |

## Not available for usage (SR0750.3.6.4)

| UI text   | Comment   |
|---|---|
| Cannot identify the <identifier> equipment entity, since it has already been identified or bound at</identifier>  | Message pack: fsm_S88EquipmentBinding Message ID: identifyNotAllowedOwnedByOther_ErrorMsg |
| the <identifier> work center for <workflow, order=""> (unit procedure: <identifier>, operation: <identifier>, phase: <identifier>).</identifier></identifier></identifier></workflow,></identifier> |   |

## Nothing identified (SR0750.3.6.5)

| UI text  | Comment   |
|--|---|
| You have to identify a container before you can confirm the phase. | Message pack: ow_IdentCont <version> Message ID: EqNotIdentified_ErrorMsg</version> |

## Output Variables (SR0750.9+)

The following output variables are available to reference the phase's output.

## **Instance count (Framework capability)**

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.

The count variable of a phase that has not been executed provides 0 as output value.

Start time (Framework capability)

Data type: Timestamp

■ Usage: The output variable provides the start time of the phase.

### **Completion time (Framework capability)**

Data type: Timestamp

Usage: The output variable provides the completion time of the phase.

#### **Identifier (Framework capability)**

Data type: String

Usage: The output variable provides the identifier of the phase.

## Container object (SR0750.9.1)

Data type: IMESS88Equipment

■ Usage: The output variable provides the complete object of the identified equipment entity. This is the output to use in subsequent phases for accessing data of the equipment object, such as changing its status or writing a property.

#### Container ID (SR0750.9.2)

Data type: String

Usage: The output variable provides the identifier of the identified equipment entity for displaying it as text.

#### **Container short description (SR0750.9.3)**

Data type: String

■ Usage: The output variable provides the short description of the identified equipment entity for displaying it as text.

# Tare Phase (SR0720+)

The **Tare** phase (O Tare) allows an operator to record the actual tare of a target container.

It precedes the Weigh phase and displays in real-time the tare weight of the container placed on the scale connected to the work center. Depending on the weighing method, scale availability, or scale configuration, taring happens automatically, manually with automatic scale communication, or offline by operator input only. The operator confirms the tare value by scanning the barcode of the scale.

Additionally, the phase is skipped, if the tare of the identified container or sublot is already known.

If the **Quantity entry** weighing method is selected, the phase is skipped.

Details of the tare value are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report.

Anomalies that occur during processing are covered by the phase exception handling (e.g. redo zero, using an offline tare).

After completion the phase displays the registered tare weight, both in the Execution Window and in the Navigator.



Figure 14: Tare during execution (Pallet weighing)



Figure 15: Tare during execution with a manual scale

#### Layout

The phase provides individual layouts for its representation during execution (page 104), in the Navigator (page 106), and in the sub-report (page 106).

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#### Representation during Execution (SR0720.1+)

The representation during execution depends on the phase mode.

#### Preview mode (SR0720.1.1)

- 1. Phase-specific icon.
- <Instruction text>
   (taken from Instruction (SR0720.8.1) process parameter (page 113))
- 3. **Confirm** button (disabled).

#### Active mode (automatic tare) (SR0720.1.2)

➤ Does not apply if scale is configured as manual scale.

This representation applies to **Net** weighing method. The tare type is **Automatic**. If a phase completion signature is assigned to the phase, the signature is ignored during execution.

- 1. Phase-specific icon.
- 2. <Instruction text> (taken from **Instruction** (**SR0720.8.1**) process parameter (page 113))
- 3. <Tare value>
- 4. **Confirm** button.

## Active mode (manual tare) (SR0720.1.3)

➤ Does not apply if scale is configured as manual scale.

This representation applies to **Gross** and **Pallet** weighing methods. The tare type is **Manual**, i.e. the tare value has been entered manually before it is automatically sent to the scale.

The recipe author must assign a phase completion signature to the phase in order to require the operator to sign the manual entry of tare values.

If a **Use offline tare** (**SR0720.3.1.3**) user-triggered exception (page 120) has been recorded, the input boxes are read-only.

- Phase-specific icon.
- <Instruction text>
   (taken from Instruction (SR0720.8.1) process parameter (page 113))
- 3. Container tare, input box.
- 4. Additionally for **Pallet** weighing:
  - 1. Number of containers on pallet, input box.
  - 2. Pallet tare, input box.

#### 5. **Confirm** button.

#### Active mode (manual scale) (SR0720.1.6)

This representation applies to all weighing methods if the selected scale is configured as manual scale. The tare type is **Offline**, i.e. the tare value is entered manually, but not sent to the scale.

If a phase completion signature is assigned to the phase, the signature is ignored during execution. Instead, a phase completion signature is added automatically according to the system configuration.

- 1. Phase-specific icon.
- 2. <Instruction text> (taken from **Instruction (SR0720.8.1)** process parameter (page 113))
- 3. Input box and **UoM** toggle button.
  - For **Net** weighing method.
  - The **UoM** toggle button provides all UoMs that are supported by the manual scale.
- 4. Container tare, input box and **UoM** toggle button.
  - For **Gross** and **Pallet** weighing methods.
  - The **UoM** toggle button provides all UoMs that are supported by the manual scale.
- 5. Additionally for **Pallet** weighing:
  - 1. Number of containers on pallet, input box.
  - 2. Pallet tare, input box and **UoM** toggle button.
    - The **UoM** toggle button provides all UoMs that are supported by the manual scale.
- 6. Phase completion signature panel
  - WD\_ES\_MANUAL\_SCALE access privilege.
- 7. **Confirm** button.

#### Completed mode (SR0720.1.4)

This representation applies to **Net** and **Gross** weighing methods.

- 1. Phase-specific icon.
- 2. Tare
- 3. <Tare value>

4. **Confirm** button (completed).

#### Completed mode (Pallet weighing) (SR0720.1.5)

- 1. Phase-specific icon.
- 2. Tare
- 3. <Number of containers> x <container tare>
- 4. <Pallet tare>
- 5. **Confirm** button (completed).

#### Representation in Navigator (SR0720.4+)

The Navigator provides the following details:

#### Phase column (Framework capability)

- <Phase name>
  - Example: Tare Scale

#### **Information column (SR0720.4.1)**

- <Total tare value>
  - Example: 10.0 g

#### **Action column**

■ There are no actions available.

#### Representation in Sub-report (SR0720.5+)

The sub-report contains the following information:

## **Common sub-report elements (Framework capability)**

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> <phase completion user>

## **Sub-report elements (SR0720.5.1)**

■ Position: <number>

■ For **Net** weighing and **Gross** weighing:

Tare: <Tare value>
Tare type: <tare type>

■ For **Pallet** weighing:

Container tare: <number of containers> x <container tare>

<Pallet tare>: <pallet tare>
Tare type: <tare type>

## Business Logic (SR0720.2+)

The phase implements the following business logic.

#### Main Path

Business logic related to the main path:

### Continuous read of scale (SR0720.2.1)

➤ Does not apply if scale is configured as manual scale.

■ Function: Continuous reading of scale value

Type: Main path

Trigger: Phase becomes active

■ Postcondition: N/A

| Step             | #  | Description  |
|------------------|----|--|
| Phase activation | 10 | Phase establishes communication to the scale.  If no communication can be established to the scale, phase displays the Scale online error (SR0720.3.6.1) error message (page 122). |
|                  | 20 | Phase continuously displays the scale value.   |

## Tare (manual scale) (SR0720.2.9)

➤ Applies only if scale is configured as manual scale.

Function: Taring with a scale that is configured as manual scale

Type: Main path

■ Trigger: Phase becomes active

■ Postcondition: N/A

| Step             | #  | Description   |
|------------------|----|---|
| Phase activation | 10 | Phase displays the <b>Active mode (manual scale) (SR0720.1.6)</b> layout (page 105).                      |
|                  | 20 | Operator enters current tare value manually, even in case of <b>Net</b> weighing.                         |
| Phase completion | 30 | Pre-defined phase completion signature is requested according to the WD_ES_MANUAL_SCALE access privilege. |
| signature        |    | Any other phase completion signature that has been assigned to the phase is ignored.                      |

## Confirm by scan (SR0720.2.2)

■ Function: Confirm phase by use of barcode scan

Type: Main path

■ Trigger: Operator scans scale

Postcondition: Phase is completed

| Step                 | #  | Description  |
|----------------------|----|--|
| Operator scans scale | 10 | If another scale than the selected scale was scanned, phase displays the Wrong scale (SR0720.3.6.2) error message (page 123).  |
|                      | 20 | If no stable tare value can be read, phase displays the Scale driver error (SR0720.3.6.4) error message (page 123).  For Gross weighing, see Weighing method - Gross (SR0720.2.4) function (page 109) and Weighing method - Gross (manual scale) (SR0720.2.11) function (page 110).  For Pallet weighing, see Weighing method - Pallet (SR0720.2.5) function (page 110) and Weighing method - Pallet (manual scale) (SR0720.2.12) function (page 111). |
|                      | 30 | Phase is completed automatically. In case the scale is configured as manual scale, the tare type is set to <b>Offline</b> .  |

## Confirm by button (SR0720.2.3)

■ Function: Confirm phase by use of button

■ Type: Main path

Trigger: Operator confirms phase

Postcondition: Phase is completed

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| Step                    | #  | Description  |
|-------------------------|----|--|
| Operator confirms phase | 10 | If no stable tare value can be read, phase displays the Scale driver error (SR0720.3.6.4) error message (page 123).  For Gross weighing, see Weighing method - Gross (SR0720.2.4) function (page 109) and Weighing method - Gross (manual scale) (SR0720.2.11) function (page 110).  For Pallet weighing, see Weighing method - Pallet (SR0720.2.5) function (page 110) and Weighing method - Pallet (manual scale) (SR0720.2.12) function (page 111). |
|                         | 20 | Phase is completed automatically. In case the scale is configured as manual scale, the tare type is set to <b>Offline</b> .  |

## Get tare value from prepared sublot (SR0720.2.8)

■ Function: Phase gets tare value automatically

Type: Main path

Trigger: Already prepared sublot has been identified within the **Manage** produced material (SR0700+) phase (page 19)

■ Postcondition: Phase is completed

| Step             | #  | Description  |
|------------------|----|--|
| Phase activation | 10 | Phase receives the tare value automatically, since it is already known for prepared sublots.   |
|                  | 20 | Only if the selected scale is not configured as manual scale: The tare value is sent to the scale, so that the scale reading reflects the actual net value.  Phase is completed automatically. |

## Weighing Method-specific Paths

Business logic related to weighing methods:

## Weighing method - Gross (SR0720.2.4)

- > Does not apply if scale is configured as manual scale.
  - Function: Use of **Gross/Gross removal**
  - Type: Special handling of weighing methods other than **Net** weighing
  - Trigger: Specific weighing method is selected
  - Postcondition: N/A

| Step  | Description  |
|---|--|
| Phase activation  | Phase displays Active mode (manual tare) (SR0720.1.3) layout (page 104).   |
| Use offline tare<br>(SR0720.3.1.3)<br>user-triggered exception<br>(page 120)  | If available, the tare value entered in the Active mode (manual tare) (SR0720.1.3) layout (page 104) is populated. |
| Operator scans scale or confirms phase (Confirm by scan (SR0720.2.2) function (page 108), Confirm by button (SR0720.2.3) function (page 108)) | The manually entered tare value is sent to the scale, so that the scale reading reflects the actual net value.     |

## Weighing method - Gross (manual scale) (SR0720.2.11)

■ Function: Use of **Gross/Gross removal**, scale is configured as manual scale

Type: Special handling of weighing methods other than **Net** weighing

■ Trigger: Specific weighing method is selected

■ Postcondition: N/A

| Step  | Description   |
|---|---|
| Phase activation  | Phase displays Active mode (manual scale) (SR0720.1.6) layout (page 105). |
| Operator scans scale or confirms phase (Confirm by scan (SR0720.2.2) function (page 108), Confirm by button (SR0720.2.3) function (page 108)) | Tare is recorded with the Offline tare type.                              |

## Weighing method - Pallet (SR0720.2.5)

➤ Does not apply if scale is configured as manual scale.

■ Function: Use of **Pallet** 

■ Type: Special handling of weighing methods other than **Net** weighing

Trigger: Specific weighing method is selected

■ Postcondition: N/A

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| Step  | Description   |
|---|---|
| Phase activation  | Phase updates representation according to the <b>Active mode (manual tare)</b> (SR0720.1.3) layout (page 104) for <b>Pallet</b> weighing. |
| Operator scans scale or confirms phase (Confirm by scan (SR0720.2.2) function (page 108), Confirm by button (SR0720.2.3) function (page 108)) | Phase checks the actual net weight loaded on the scale against the allowed upper tolerance.   |
|   | Tare is recorded and sent to the scale, so that the scale reading reflects the actual net value.  |
| Use offline tare<br>(SR0720.3.1.3)<br>user-triggered exception<br>(page 120)  | If available, the values entered in the Active mode (manual tare) (SR0720.1.3) layout (page 104) are populated.                           |

## Weighing method - Pallet (manual scale) (SR0720.2.12)

■ Function: Use of **Pallet**, scale is configuration as manual scale

Type: Special handling of weighing methods other than **Net** weighing

■ Trigger: Specific weighing method is selected

■ Postcondition: N/A

| Step  | Description  |
|---|--|
| Phase activation  | Phase updates representation according to the <b>Active mode (manual scale)</b> (SR0720.1.6) layout (page 105) for <b>Pallet</b> weighing. |
| Operator scans scale or confirms phase (Confirm by scan (SR0720.2.2) function (page 108), Confirm by button (SR0720.2.3) function (page 108)) | Phase checks the actual net weight loaded on the scale against the allowed upper tolerance.  |
|   | Tare is recorded with the <b>Offline</b> tare type.  |

## **Equipment Management**

Business logic related to equipment management:

## **Container management (SR0720.2.10)**

➤ NOTE: Does not apply to O Tare (RS) [1.0] (MR2).

■ Function: Manage container

■ Type: Special handling of container tare

■ Precondition: Container must be of the **Container** (**RS**) equipment type

 Trigger: Empty or prepared target container has been identified during Output Weighing

■ Postcondition: Data was retrieved from a container's property of the **Current Tare (RS)** purpose

| Step   | Description   |
|--|---|
| Case: Already prepared container has been identified with the Manage produced material (SR0700+) phase (page 19) | In deviation from the <b>Get tare value from prepared sublot (SR0720.2.8)</b> function (page 109), phase receives the tare value automatically from a prepared container's property of the <b>Current Tare (RS)</b> purpose.  Only if the selected scale is not configured as manual scale: The tare value is sent to the scale, so that the scale reading reflects the actual net value. |
| (1, 1, 2, 1, 1)  | Phase is completed automatically.   |
| Case: Phase activation with known target container in combination  | In deviation from the <b>Weighing method</b> - <b>Gross</b> ( <b>SR0720.2.4</b> ) function (page 109), phase receives the tare value automatically from a prepared container's property of the <b>Current Tare</b> ( <b>RS</b> ) purpose.   |
| with <b>Gross</b> weighing   | Only if the selected scale is not configured as manual scale: The tare value is sent to the scale, so that the scale reading reflects the actual net value.   |
|  | Phase is completed automatically.   |

## **Check container tare (SR0720.2.13)**

- For recent changes, see revision history (page 172).
- ➤ NOTE: Does not apply to O Tare (RS) [1.0] (MR2), [5.0], [5.1].
  - Function: Check container tare value against a reference value
  - Type: Specific business logic related to container management
  - Precondition: Tare check is enabled according to the Tare check configuration (SR0720.8.6) process parameter (page 114)
  - Trigger: Operator confirms phase
  - Postcondition: Specific business logic applies

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| Step   | Description  |
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| Phase completion  Case: In Net weighing, a target container has been selected and Tare check is enabled.  or  Case: In Gross weighing, a | The tare tolerances are calculated based on the tolerance values derived from Tare check tolerance definition (SR0720.8.7) process parameter (page 114) in the recipe and the resolution of the selected scale:  Lower tolerance = tolerance value (recipe) + scale resolution,  upper tolerance = tolerance value (recipe) - scale resolution  If the tolerance value (recipe) is provided as a percentage value, it is converted into an absolute value using the property of the Reference Tare (RS) purpose. |
| target container to be<br>weighed has been selected<br>and <b>Tare check</b> is  |  |
| enabled.   | In case the container's actual tare is not within the calculated limits of the container's property of the <b>Reference (RS)</b> purpose, phase creates the <b>Failed tare check (SR0720.3.2.2)</b> system-triggered exception (page 117).   |
| Phase completion  Case: No target container has been selected and Tare check is enabled.   | Phase creates the Failed tare check (SR0720.3.2.2) system-triggered exception (page 117) since no target container is available for which the tare check can be performed.   |

## **Recipe Parameters**

The phase provides process parameters (page 113).

## Process Parameters (SR0720.8+)

The following process parameters define the behavior of the phase.

## BASIC PARAMETERS

## **Instruction (SR0720.8.1)**

For recent changes, see revision history (page 172).

| Attribute | Туре      | Comment  |
|-----------|-----------|--|
| Column 1  | HTML text | Instruction text to be displayed. <b>Restriction:</b> Maximum length is 2000 characters (including HTML tags). |
| Column 2  | HTML text | Netured  |
| Column 3  | HTML text | Not used.  |

Tare check tolerance definition (SR0720.8.7)

For recent changes, see revision history (page 172).

| Attribute       | Туре          | Comment   |
|-----------------|---------------|---|
| Lower tolerance | MeasuredValue | Defines the lower tolerance as a percentage or absolute value including unit of measure for the tare check. |
| Upper tolerance | MeasuredValue | Defines the upper tolerance as a percentage or absolute value including unit of measure for the tare check. |

#### CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

## Tare check configuration (SR0720.8.6)

> For recent changes, see revision history (page 172).

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Enabled         | Flag        | Controls if a check is performed. If so, ensure that the Lower tolerance and Upper tolerance attributes of the Tare check tolerance definition process parameter (page 114) are set. If they are not set, 0 is used for the tolerance calculation. Default setting: No. |
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High.                         |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Failed tare check (SR0720.3.2.2) system-triggered exception (page 117).

## Unforeseen resume (SR0720.8.5)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Unforessen resume (SR0720.3.2.1) system-triggered exception (page 118).

#### CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

## **Redo zero (SR0720.8.2)**

➤ Does not apply if scale is configured as manual scale.

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Redo zero (SR0720.3.1.2) user-triggered exception (page 120).

## Return to material management (SR0720.8.3)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also **Return to material management (SR0720.3.1.1)** user-triggered exception (page 119).

## Use offline tare (SR0720.8.4)

> Does not apply if scale is configured as manual scale.

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also **Use offline tare (SR0720.3.1.3)** user-triggered exception (page 120).

### Exceptions (SR0720.3+)

The phase supports user-defined, user-triggered (page 119), system-triggered (page 117), and post-completion exceptions (page 121) and their configuration by means of process parameters (page 113).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

#### System-triggered Exceptions (SR0720.3.2+)

For recent changes, see revision history (page 172).

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

#### Failed tare check (SR0720.3.2.2)

For recent changes, see revision history (page 172).

The Failed tare check exception is displayed automatically if the check is enabled, but

- no container was not identified with the O Identify container (SR0750+) phase (page 77) or
- the container tare is out of the calculated limits or
- the limits cannot be calculated due to missing conversion factors or
- the container's property of the **Reference Tare (RS)** purpose is empty, or
- no property of the Reference Tare (RS) purpose has been assigned to the container.

Representation of the exception:

- <Exception text> (taken from **Tare check configuration (SR0720.8.6)** process parameter (page 114))
  - If no target container has been identified:

    The container tare is unknown, since no container has been identified yet.

    Please check the structure of your recipe.
  - If the actual tare does not match the reference tare:

    Tare: <actual tare>
    Reference tare: <reference tare> [<lower limit> .. <upper limit>]
  - Example:
    Actual tare value does not match the stored reference tare defined for the

container.

Check if the container is empty and all accessories have been dismounted.

Tare: 23 g

Reference tare: 25 g [24 g .. 25 g]

## Failed tare check - Logic (SR0720.3.2.2.1)

For recent changes, see revision history (page 172).

■ Trigger: Trigger: Check has failed

Precondition: Tare check is enabled (**Tare check configuration (SR0720.8.6**) process parameter (page 114))

Postcondition: Post-completion exception is recorded

| Step                                   | #  | Description   |
|--|----|---|
| Operator accepts exceptional situation | 10 | Phase shows exception description to be signed.   |
| Operator signs exception               | 20 | <ul> <li>Phase records exception.</li> <li>In the default configuration, the phase neither overwrites the reference tare in the container's property of the Reference Tare (RS) purpose with the actual tare nor updates the logbook accordingly (if maintained). See also Allow Override Reference Tare (SR0720.11.1) configuration key (page 125).</li> </ul> |

#### Unforeseen resume (SR0720.3.2.1)

Representation of the exception:

<Exception text>

(taken from **Unforeseen resume** (**SR0720.8.5**) process parameter (page 115)) The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.

Consider to replace the affected position.

Example:

A critical resume situation has occurred. Contact your supervisor before proceeding.

The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor. Consider to replace the affected position.

### Unforeseen resume - Logic (SR0720.3.2.1.1)

- Trigger: Output Weighing process has been interrupted so that the system needs to be resumed
- Postcondition: Phase is back in active mode

| Step                        | #  | Description  |
|-----------------------------|----|--|
| Phase activation            | 10 | Phase displays the <b>Unforeseen resume (SR0720.3.2.1)</b> system-triggered exception. |
| Operator triggers exception | 30 | Phase records exception.   |

#### User-triggered Exceptions (SR0720.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### Return to material management (SR0720.3.1.1)

The **Return to material management** exception allows an operator to step out of the regular Output Weighing process and start a new run with processing the **Manage produced material** phase.

Representation during exception handling:

Instruction:Return to material management.

Confirm button.

Exception text:<Exception text>

(taken from **Return to material management (SR0720.8.3)** process parameter (page 116))

Example: Back to material management.

## Return to material management - Logic (SR0720.3.1.1.1)

Trigger: Exception is selected

■ Postcondition: N/A

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| Step                        | #  | Description   |
|-----------------------------|----|---|
| Operator confirms exception | 10 | Phase records exception.  |
|                             | 20 | Phase is completed automatically and returns to Manage produced material (SR0700+) phase (page 19). |

#### Redo zero (SR0720.3.1.2)

> Does not apply if scale is configured as manual scale.

The **Redo zero** exception allows an operator to reset the scale to zero.

The exception is only enabled if the **Zeroing** option is selected in the equipment master data of the current scale.

Representation during exception handling:

Instruction:

Repeat zeroing.

Confirm button.

Exception text:

<Exception text>

(taken from **Redo zero** (**SR0720.8.2**) process parameter (page 115))

Example:Zeroing repeated.

#### Use offline tare (SR0720.3.1.3)

➤ Does not apply if scale is configured as manual scale.

The **Use offline tare** exception allows an operator to enter the offline tare value manually due to a broken scale connection.

Representation during exception handling:

Instruction:

Use the offline tare.

- Only for Net and Gross weighing methods: Input box for tare value.
- Only for **Pallet** weighing method:

Container tare, input box.

Number of containers on pallet, input box.

Pallet tare, input box.

Confirm button.

Exception text:

<Exception text>

(taken from Use offline tare (SR0720.8.4) process parameter (page 116))

Offline tare: <tare value>

Example:

Offline tare used.
Offline tare: 0.45 kg

## Use offline tare - Logic (SR0720.3.1.3.1)

> Does not apply if scale is configured as manual scale.

■ Trigger: Exception is selected

■ Postcondition: N/A

| Step                        | #  | Description   |
|-----------------------------|----|---|
| Operator triggers exception | 10 | Phase displays Exception Window.  |
|                             | 20 | For <b>Net</b> weighing, operator enters current offline tare value manually. For <b>Gross</b> weighing, see <b>Weighing method - Gross</b> ( <b>SR0720.2.4</b> ) function (page 109). For <b>Pallet</b> weighing, see <b>Weighing method - Pallet</b> ( <b>SR0720.2.5</b> ) function (page 110). |
| Operator confirms exception | 30 | Phase records exception. Tare value is read-only in the Execution Window. No tare value is communicated to/from scale. Tare type is Offline.  |

## **Post-completion Exceptions**

There are no post-completion exceptions available.

## **Information Messages**

There are no information messages available.

## Questions (SR0720.3.5+)

Questions are represented in a question dialog containing a message type-specific icon, the question, a **Yes** button, and a **No** button.

The following questions are available to request a decision from the operator how to proceed.

## Tare below valid range (SR0720.3.5.2)

| UI text   | Comment   |
|---|---|
| The current scale load is below the scale's valid range. Actual load: <scale (tare="" load="" weight)=""> Your scale load must range between <smallest -="" minimum="" permitted=""> and <highest -="" maximum="" permitted="" range=""></highest></smallest></scale> | This message is not displayed if at the same time the tare value triggers the display of the Tare equals zero (SR0720.3.5.1) question (page 122).  Message pack: wd_Tare <version> Message ID: tareBelowValidRange_ErrorMsg</version> |
| between <smallest<br>permitted - minimum&gt; and<br/><highest -<="" permitted="" range="" td=""><td></td></highest></smallest<br>   |   |

## Tare equals zero (SR0720.3.5.1)

| UI text                 | Comment                                   |
|-------------------------|---|
| The tare is 0.          | Message pack: wd_Tare <version></version> |
| Do you wish to proceed? | Message ID: nullTare_ErrorMsg             |

#### **Decisions**

There are no decisions available.

## Error Messages (SR0720.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an  $\mathbf{OK}$  button.

The following error messages are available to inform the operator about error conditions.

## Scale online error (SR0720.3.6.1)

| UI text | Comment   |
|---------|---|
|         | Message pack: wd_UIMessage <version> Message ID: scalesCommunication_ErrorMsg</version> |

## Wrong scale (SR0720.3.6.2)

| UI text  | Comment  |
|--|--|
| You have scanned another scale than selected. Scan the previously selected scale to proceed. | Message pack: wd_UIMessage <version> Message ID: WrongScale_ErrorMsg</version> |

## Negative tare (SR0720.3.6.3)

| UI text  | Comment   |
|--|---|
| Cannot proceed with the current negative tare. Make sure the scale is still correctly loaded with the tared container. If the scale is empty, repeat zeroing and tare again. | Message pack: wd_Tare <version> Message ID: negativeTare_ErrorMsg</version> |

## Scale driver error (SR0720.3.6.4)

| UI text                 | Comment                                   |
|-------------------------|---|
| Cannot obtain a stable  | Message pack: srv_eqm.WDEquipmentService  |
| reading or a scale      | Message ID: tareWeighedFailed             |
| communication error has | Message ID: errorDuringTareClear_ErrorMsg |
| occurred.               |   |
| Please try again.       |   |

## Tare above valid range (SR0720.3.6.5)

| UI text  | Comment                                      |
|--|--|
| Cannot tare, since the                               | Message pack: wd_Tare <version></version>    |
| current scale load is above                          | Message ID: scaleNotSuitableForTare_ErrorMsg |
| the scale's valid range,                             |  |
| which may have been                                  |  |
| determined by the required                           |  |
| scale resolution.                                    |  |
| Current scale load: <scale< td=""><td></td></scale<> |  |
| load (tare weight)>                                  |  |
| Your scale load must range                           |  |
| between <smallest< td=""><td></td></smallest<>       |  |
| permitted - minimum> and                             |  |

UI text Comment
<highest permitted range maximum>

## Output Variables (SR0720.9+)

The following output variables are available to reference the phase's output.

#### **Instance count (Framework capability)**

Data type: Long

■ Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.

The count variable of a phase that has not been executed provides 0 as output value.

#### **Start time (Framework capability)**

Data type: Timestamp

■ Usage: The output variable provides the start time of the phase.

#### **Completion time (Framework capability)**

Data type: Timestamp

■ Usage: The output variable provides the completion time of the phase.

#### **Identifier (Framework capability)**

Data type: String

■ Usage: The output variable provides the identifier of the phase.

## Configuration Keys (SR0720.11+)

For recent changes, see revision history (page 172).

The following configuration keys are available to configure the phase's behavior.

### Allow override reference tare (SR0720.11.1)

- For recent changes, see revision history (page 172).
  - Phase/OWTare/allowOverrideReferenceTare

■ **Type**: Boolean

■ Value: False

**Description**: The configuration applies to the **Failed tare check** system-triggered exception of the **O Tare** phase.

For details, see **Failed Tare Check** (**SR0720.3.2.2**) system-triggered exception (page 117).

If the value is set to **true** and the check fails, the operator first has to sign the exception then the phase overwrites the existing reference tare in the container's property of the **Reference Tare (RS)** purpose with the actual tare and updates the logbook accordingly (if maintained).

- **Evaluated**: When the **O Tare** phase is started in the Production Execution Client.
- **Range**: [False, True]

Rockwell Software PharmaSuite® 8.4 - Functional Requirement Specification Output Weighing

# Weigh Phase (SR0730+)

The **Weigh** phase (O Weigh) allows an operator to record the actual weight of a target container or sublot and to print a label for it. Additionally, an operator can prepare an empty container or sublot for weighing material in a later run of the Output Weighing loop.

It displays a scale control (not in **Prepare only** mode) with real-time interfacing to the selected scales and communicates all information between the scale and its operators. The scale control displays the actual value of the item that is being processed and the valid weighing range of the selected scale. The operator confirms a weighing value by scanning the barcode of the scale.

If a scale is used that is configured as manual scale or if the **Quantity entry** weighing method is used, the weighing range is displayed without a scale control. The phase requires a manual entry of the weighing value and for a manual scale its meaning (**Net scale value**).

If an empty target container has been identified or prepared, the **Weigh** phase supports the maintenance of the container's life cycle and sets the container's properties of the **Current Tare (RS)** and **Current Sublot (RS)** purposes.

In case of a loaded scale, it maintains the scale's property of the **Current Load (RS)** purpose.

Details of the weighing process are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report.

Anomalies that occur during processing are covered by the phase exception handling (e.g. overweight, underweight, reprint of labels).

After completion the phase displays the registered weight, both in the Execution Window and in the Navigator. Additionally, the Navigator displays a button that shows the identifier of the prepared or weighed sublot and provides access to the post-completion exception.

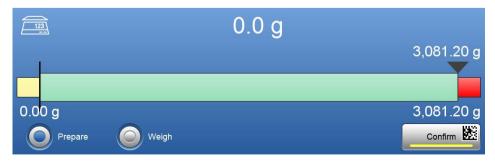


Figure 16: Weigh during execution (Prepare)

PSFRSOW-RM002E-EN-E, 1.0 127

300.6 g

3,081.20 g

0.00 g

3,081.20 g

Confirm Confirm

Figure 17: Weigh during execution (Weigh directly)

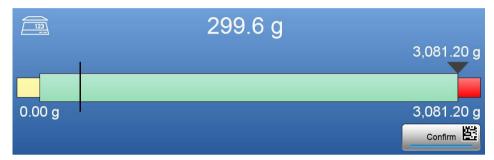


Figure 18: Weigh during execution (weighing of prepared sublots)



Figure 19: Weigh during execution (prepare only mode)

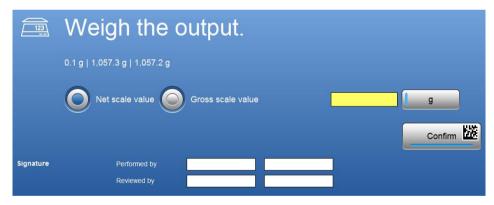


Figure 20: Weigh during execution with a manual scale



Figure 21: Weigh during execution (Weigh directly with Quantity entry)

#### Layout

The phase provides individual layouts for its representation during execution (page 129), in the Navigator (page 132), and in the sub-report (page 132).

#### Representation during Execution (SR0730.1+)

The representation during execution depends on the phase mode.

#### Preview mode (SR0730.1.1)

- 1. Phase-specific icon.
- <Instruction text>
   (taken from Instruction (SR0730.8.1) process parameter (page 140))
- 3. **Confirm** button (disabled).

#### **Active mode (SR0730.1.2)**

- For recent changes, see revision history (page 172).
  - 1. Phase-specific icon.
  - 2. <Scale value>
  - 3. Scale control with a tolerance band according to the valid scale range minus actual tare (linear scale mode).
    - Only if a target weight is defined: Scale control with target weight, actual, and tolerance values and marker for upper range of scale.
  - 4. **Prepare** option button (default) and **Weigh** option button.
    - Only for Pallet weighing and if a prepared sublot is weighed: No option buttons are displayed (Default is Weigh).
    - The phase is completed automatically, if the **Operation mode** of the **Manage** produced material phase is set to **Prepare only** (see **Operation mode** (**SR0700.8.12**) process parameter (page 35)).
  - 5. **Confirm** button.

#### Active mode (manual scale) (SR0730.1.6)

This representation applies to all weighing methods if the selected scale is configured as manual scale.

If a phase completion signature is assigned to the phase, the signature is ignored during execution. Instead, a phase completion signature is added automatically according to the system configuration.

1. Phase-specific icon.

2. <Instruction text> (taken from **Instruction (SR0730.8.1)** process parameter (page 140))

- 3. Tolerance values according to the valid scale range minus actual tare.
- 4. Net scale value option button and Gross scale value option button.
- 5. Input box and **UoM** toggle button.
  - The **UoM** toggle button provides all UoMs that are supported by the manual scale.
- 6. **Prepare** option button (default) and **Weigh** option button.
  - Only for Pallet weighing and if a prepared sublot is weighed: No option buttons are displayed (Default is Weigh).
  - The phase is completed automatically, if the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode** (**SR0700.8.12**) process parameter (page 35)).
- Phase completion signature panel
  - WD\_ES\_MANUAL\_SCALE access privilege.
- 8. **Confirm** button.

#### Active mode (Quantity entry) (SR0730.1.7)

For recent changes, see revision history (page 172).

This representation applies to the **Quantity entry** weighing method.

If a phase completion signature is assigned to the phase, the signature is ignored during execution. Instead, a phase completion signature is added automatically according to the system configuration.

- 1. Phase-specific icon.
- 2. <Instruction text> (taken from **Instruction (SR0730.8.1)** process parameter (page 140))
- 3. Input box for the quantity.
- 4. Input box for the unit of measure.
  - The unit of measure of the planned quantity and all convertible UoMs are allowed. The input box is pre-filled with the unit of measure of the planned quantity.
  - If the **Planned quantity mode** is set to **None**, the unit of measure of the material and all convertible UoMs are allowed. The input box is pre-filled with the unit of measure of the material.

- 5. **Prepare** option button (default) and **Weigh** option button.
  - The phase is completed automatically, if the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode** (**SR0700.8.12**) process parameter (page 35)).
- 6. Phase completion signature panel
  - WD\_ES\_QUANTITY\_ENTRY\_O access privilege.
- 7. **Confirm** button.

## Active mode (Prepare only) (SR0730.1.4)

Only in case the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode** (**SR0700.8.12**) process parameter (page 35)):

- 1. Phase-specific icon.
- 2. Weight
- 3. 0 < UoM of tare value >
  - <UoM of the planned quantity or material> if the Quantity entry weighing method is used.
- 4. **Confirm** button.

#### Completed mode (SR0730.1.3)

- 1. Phase-specific icon.
- 2. Weight
- 3. <Weighing value>
- 4. **Confirm** button (completed).

#### Completed mode (Prepare only) (SR0730.1.5)

Only in case the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode** (**SR0700.8.12**) process parameter (page 35)):

- 1. Phase-specific icon.
- Weight
- 3. 0 < UoM of tare value>
  - <UoM of the planned quantity or material> if the Quantity entry weighing method has been used.
- 4. **Confirm** button (completed).

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### Representation in Navigator (SR0730.4+)

The Navigator provides the following details:

#### Phase column (Framework capability)

- <Phase name>
  - Example: Weigh Material

#### Information column (SR0730.4.1)

- <Weighing value>
  - Example: 23.45 kg

#### Action column (SR0730.4.2)

- Sublot identifier>, reprints the sublot label.
  - Example: SL00001234
- Only for **Pallet** weighing with more than one sublot:
  - Sublots, provides reprint exceptions for each sublot label.

#### Representation in Sub-report (SR0730.5+)

The sub-report contains the following information:

#### **Common sub-report elements (Framework capability)**

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> <phase completion user>

### **Sub-report elements (SR0730.5.1)**

- Position: <number>
- Target sublot: <number>
- Actual quantity: <weighing value>
- Additionally if the scale is configured as manual scale:
  - Manual scale

- Net scale value entered (if applicable)
- Gross scale value entered (if applicable)
- Additionally for Pallet weighing:
  - <List of target sublot identifiers>

# Business Logic (SR0730.2+)

The phase implements the following business logic.

#### Main Path

Business logic related to the main path:

# Activate scale control (SR0730.2.1)

- For recent changes, see revision history (page 172).
- ➤ Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

See Weigh (Manual Scale) (SR0730.2.4) function (page 134), Weighing Method - Quantity Entry (SR0730.2.12) function (page 138).

■ Function: Activation of scale control

Type: Main path

■ Trigger: Phase becomes active

■ Postcondition: N/A

| Step             | #  | Description   |
|------------------|----|---|
| Phase activation | 10 | Phase establishes communication to scale.   |
|                  | 20 | <ul> <li>If no target weight is defined:         Phase displays scale control in linear mode.     </li> <li>If a target weight is defined:         Phase displays scale control with target weight and its lower and upper tolerances.         The actual tolerances are calculated based on the tolerance values derived from the recipe definition and the resolution of the scale:             Lower tolerance = tolerance value (recipe) + scale resolution,             upper tolerance = tolerance value (recipe) - scale resolution.     </li> </ul> |

#### Weigh (manual scale) (SR0730.2.4)

> Applies only if scale is configured as manual scale.

■ Function: Weighing with a scale that is configured as manual scale

Type: Main path

Trigger: Phase becomes active

■ Postcondition: N/A

| Step                             | #  | Description   |
|----------------------------------|----|---|
| Phase activation                 | 10 | Phase displays the <b>Active mode (manual scale) (SR0730.1.6)</b> layout (page 129).  |
|                                  |    | In case of <b>Net</b> weighing, the <b>Net scale value</b> option button is selected per default.                               |
|                                  |    | In case of <b>Gross</b> weighing or <b>Pallet</b> weighing, the <b>Gross scale value</b> option button is selected per default. |
|                                  | 20 | Operator enters current scale value manually.   |
| Phase<br>completion<br>signature | 30 | Pre-defined phase completion signature is requested according to the WD_ES_MANUAL_SCALE access privilege.                       |
|                                  |    | Any other phase completion signature that has been assigned to the phase is ignored.  |

# Prepare only mode (SR0730.2.8)

■ Function: Phase operates in **Prepare only** mode

Type: Main path

Precondition: Operation mode of the Manage produced material phase is set to Prepare only (see Operation mode (SR0700.8.12) process parameter (page 35)).

Trigger: Phase becomes active

Postcondition: Phase is completed

| Step             | #  | Description                       |
|------------------|----|-----------------------------------|
| Phase activation | 10 | Phase prints a label.             |
|                  | 20 | Phase is completed automatically. |

#### Confirm weight by scan (SR0730.2.2)

- For recent changes, see revision history (page 172).
- > Does not apply if the **Quantity entry** weighing method is used.

■ Function: Confirmation of weight by use of barcode scan

Type: Main path

Trigger: Operator confirms final weight that has been placed on the scale

■ Postcondition: N/A

| Step                 | #    | Description   |
|----------------------|------|---|
| Operator scans scale | 5    | Phase reads scanned data.   |
|                      | 10   | If barcode reading was technically successful, phase updates background<br>color of phase representation according to style sheet in order to confirm<br>the reading.   |
|                      |      | If barcode reading was technically not successful, phase remains in<br>listening mode.  |
|                      | 20   | If barcode does not correspond to the identifier of the selected scale, phase displays the <b>Wrong scale (SR0730.3.6.2)</b> error message (page 152).  |
|                      | 30   | Does not apply if scale is configured as manual scale.  |
|                      |      | If no communication can be established to the scale or any other scale driver-related error occurs, phase displays the Scale driver error (SR0730.3.6.3) error message (page 153).  |
|                      | 40   | Phase reads and records scale value.  |
|                      | 50.1 | If the weighing mode is active ( <b>Weigh</b> option button is selected or already prepared sublot is weighed) and the scale value is greater than zero, phase continues with the <b>Finalize target sublot</b> ( <b>SR0730.2.5</b> ) function (page 136).          |
|                      | 50.2 | If the preparation mode is active ( <b>Prepare</b> option button is selected or operation is used for <b>Prepare only</b> ) and the scale value is equal to zero, phase continues with the <b>Finalize target sublot</b> ( <b>SR0730.2.5</b> ) function (page 136). |
|                      | 50.3 | If the scale value does not correspond to the weighing or preparation mode of the phase, phase displays the <b>Weighing value not allowed (SR0730.3.6.6)</b> error message (page 153).  |
|                      | 50.4 | If a target weight is defined and the scale value is less than the lower tolerance or greater than the upper tolerance, phase creates the <b>Out of tolerance</b> (SR0730.3.2.3) system-triggered exception (page 147).   |
|                      | 50.5 | If a target weight is defined and the scale value is greater than lower tolerance and less than upper tolerance, phase continues with the Finalize target sublot (SR0730.2.5) function (page 136).  |

# Confirm weight by button (SR0730.2.3)

For recent changes, see revision history (page 172).

■ Function: Confirmation of weight by use of button

■ Type: Main path

■ Trigger: Operator confirms final weight that has been placed on the scale

■ Postcondition: N/A

| Step                     | #    | Description   |
|--------------------------|------|---|
| Operator confirms weight | 10   | Does not apply if the Quantity entry weighing method is the default weighing method.  |
|                          |      | If no communication can be established to the scale or any other scale driver-related error occurs, phase displays the <b>Scale driver error</b> (SR0240.3.6.3) error message.  |
|                          | 20   | Phase reads and records scale value.  |
|                          | 30.1 | If the weighing mode is active ( <b>Weigh</b> option button is selected or already prepared sublot is weighed) and the scale value is greater than zero, phase continues with the <b>Finalize target sublot</b> ( <b>SR0730.2.5</b> ) function (page 136).          |
|                          | 30.2 | If the preparation mode is active ( <b>Prepare</b> option button is selected or operation is used for <b>Prepare only</b> ) and the scale value is equal to zero, phase continues with the <b>Finalize target sublot</b> ( <b>SR0730.2.5</b> ) function (page 136). |
|                          | 30.3 | If the scale value does not correspond to the weighing or preparation mode of the phase, phase displays the <b>Weighing value not allowed (SR0730.3.6.6)</b> error message (page 153).  |
|                          | 30.4 | If a target weight is defined and the scale value is less than the lower tolerance or greater than the upper tolerance, phase creates the <b>Out of tolerance</b> (SR0730.3.2.3) system-triggered exception (page 147).   |
|                          | 30.5 | If a target weight is defined and the scale value is greater than lower tolerance and less than upper tolerance, phase continues with the <b>Finalize</b> target sublot (SR0730.2.5) function (page 136).   |

# $Finalize\ target\ sublot\ (SR0730.2.5)$

Function: Finalization of target sublot

Type: Main path

■ Trigger: Weight is confirmed

Postcondition: Phase is completed

|   | • |
|---|---|
|   | • |
| ) | • |
|   | • |
|   | • |

| Step                  | #  | Description   |
|-----------------------|----|---|
| Function finalization | 10 | For <b>Net</b> or <b>Gross</b> weighing, phase prints container label(s) with tare and net weight.  |
|                       |    | For Quantity entry, phase prints container label(s) with net weight.  |
|                       |    | For Pallet weighing, see Weighing method - Pallet (SR0730.2.7) function (page 137).   |
|                       | 20 | Phase calculates the use-by date for the target sublot based on the <b>Use-by</b> date (SR0730.8.2) process parameter (page 141).                       |
|                       | 30 | If the <b>Prepare</b> option button is selected, the status of the sublot position is set to <b>Prepared</b> .  |
|                       |    | If a phase completion signature is assigned to the phase, the signature is ignored during execution.  |
|                       |    | Phase is completed automatically.   |
|                       | 40 | If the <b>Weigh</b> option button is selected, the status of the sublot position is set to <b>Recorded</b> and the phase is completed automatically.    |
|                       |    | If a phase completion signature is assigned, the signature is requested and the phase is completed upon manual confirmation.                            |
|                       | 50 | In case no batch has been created for the output material yet, a new batch is created automatically and the batch status is set to <b>Quarantined</b> . |

# Weighing Method-specific Paths

Business logic related to weighing methods:

# Weighing method - Pallet (SR0730.2.7)

■ Function: Use of **Pallet** 

■ Type: Special handling of weighing methods other than **Net** weighing

Precondition: **Operation mode** of the **Manage produced material** phase is not set to **Prepare only** (see **Operation mode** (**SR0700.8.12**) process parameter (page 35)).

Sublot must not be identified.

Trigger: Specific weighing method is selected

■ Postcondition: N/A

| Step             | Description  |
|------------------|--|
| Phase activation | For <b>Pallet</b> weighing, the <b>Prepare</b> option button is not available. |

| Step  | Description  |
|---|--|
| Finalize target sublot (SR0730.2.5) function (page 136) | Phase prints a label for each sublot with number of containers (e.g.: 1/3, 2/3, 3/3), average tare, average net value per container, and total net weight of all containers. |
|   | Phase extends representation in the sub-report to the Sub-report elements (SR0730.5.1) layout (page 132).  |
|   | Phase adds the <b>Reprint label (SR0730.3.3.1)</b> post-completion exception (page 151) to the <b>Action column (SR0730.4.2)</b> in the Navigator (page 132).                |

#### Weighing method - Quantity entry (SR0730.2.12)

■ Function: Use of **Quantity entry** 

Type: Special handling of weighing methods other than **Net** weighing

Precondition: Operation mode of the Manage produced material phase is not set to Prepare only (see Operation mode (SR0700.8.12) process parameter (page 35)).

■ Trigger: Specific weighing method is selected

■ Postcondition: N/A

| Step             | Description   |
|------------------|---|
| Phase activation | Phase displays the Active mode (Quantity entry) (SR0230.1.7) layout (page 130).                               |
|                  | Operator enters current quantity manually.  |
|                  | Pre-defined phase completion signature is requested according to the WD_ES_QUANTITY_ENTRY_O access privilege. |
|                  | Any other phase completion signature that has been assigned to the phase is ignored.                          |

# **Equipment Management**

Business logic related to equipment management:

# Container management (SR0730.2.10)

➤ NOTE: Does not apply to O Weigh (RS) [1.0] (MR2).

Function: Manage container

■ Type: Special handling of sublot assignment and container status

Precondition: Container must be of the **Container** (**RS**) equipment type

- Trigger: Empty or prepared target container has been identified during Output Weighing
- Postcondition: Container's property of the **Current Sublot (RS)** and **Current Tare (RS)** purposes is maintained and container status is managed

| Step   | Description   |
|--|---|
| Case: An empty target container has been identified and the phase operates in the Prepare only mode or the Prepare option button has been selected (see Manage produced material (SR0700+) phase (page 19)). | <ul> <li>In deviation from the Prepare only mode (SR0730.2.8) function (page 134), phase does not create a sublot and does not print a label.</li> <li>In deviation from the Finalize target sublot (SR0730.2.5) function (page 136), phase set the status of the container position to Prepared.</li> <li>Phase writes a prepared container's property of the Current Tare (RS) purpose.</li> <li>No trigger is performed.</li> <li>No unbind is performed.</li> </ul> |
| Case: Weighing of a prepared target container.   | <ul> <li>Phase creates a sublot.</li> <li>Phase updates the prepare container's property of the Current Sublot (RS) purpose.</li> <li>Phase sends CONT_LOAD trigger to the graph of the Container Cleaning (RS) purpose.</li> <li>Phase resets binding context and unbinds container.</li> <li>Phase prints a label.</li> </ul>   |
| Case: An empty target container has been identified and is weight directly (without preparation).  | <ul> <li>Phase creates a sublot.</li> <li>Phase updates the prepared container's property of the Current Tare (RS) and Current Sublot (RS) purposes.</li> <li>Phase sends CONT_LOAD trigger to the graph of the Container Cleaning (RS) purpose.</li> <li>Phase resets binding context and unbinds container.</li> <li>Phase prints a label.</li> </ul>   |

# Scale management (SR0730.2.11)

- ➤ NOTE: Does not apply to O Weigh (RS) [1.0] (MR2).
- ➤ Does not apply if the **Quantity entry** weighing method is used.
  - Function: Manage scales
  - Type: Special handling of scale properties

• '

- Precondition: Scale must be of the **Scale** (**RS**) equipment type
- Postcondition: Scale properties are maintained

| Step                      | Description  |
|---------------------------|--|
| Case: Phase is completed. | Phase writes or clears the scale's runtime property of the Current Load (RS) purpose according to the Keep scale loaded (SR0730.8.5) process parameter (page 141).                     |
|                           | ■ In case of <b>Keep scale loaded</b> is set to <b>Yes</b> , the identifier of the prepared container or prepared sublot is written to the <b>Current Load (RS)</b> -related property. |
|                           | In case of Keep scale loaded is set to No, the Current Load (RS)-related<br>property is cleared.   |

# **Recipe Parameters**

The phase provides material output parameters as process outputs (page 140) and process parameters (page 140).

## Process Outputs (SR0730.7+)

#### Material output parameters (SR0730.7.1)

The default material output parameter is available to define which material can be managed during execution.

Quantity definitions of the material output parameter are populated to the **Table of materials** (**SR0700.1.4**) list (page 23) that is displayed during execution of the **Manage produced material** (**SR0700+**) phase (page 19). This includes the reflection of quantity-related calculations during order explosion.

## Process Parameters (SR0730.8+)

The following process parameters define the behavior of the phase.

#### **BASIC PARAMETERS**

#### Instruction (SR0730.8.1)

For recent changes, see revision history (page 172).

| Attribute | Туре      | Comment  |
|-----------|-----------|--|
| Column 1  | HTML text | Instruction text to be displayed. <b>Restriction:</b> Maximum length is 2000 characters (including HTML tags). |
| Column 2  | HTML text | Netured  |
| Column 3  | HTML text | Not used.  |

# **Use-by date (SR0730.8.2)**

| Attribute          | Туре    | Comment  |
|--------------------|---------|--|
| Use-by date [days] | Numeric | Defines the number of days allowed between the creation of an intra material sublot and its use in further processing steps. If the evaluation of the use-by date is required during further processing, the respective phase capabilities need to be adapted. |

# Keep scale loaded (SR0730.8.5)

➤ Does not apply if the **Quantity entry** weighing method is used.

| Attribute | Туре    | Comment  |
|-----------|---------|--|
| Enabled   | Boolean | Controls if the scale retains its "loaded" status during the subsequent process or if the "loaded" status is reset. While "loaded", the scale is not zeroed during scale selection and a release scale check is skipped. |

# CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

# Unforeseen resume (SR0730.8.10)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Unforeseen resume (SR0730.3.2.2) system-triggered exception (page 145).

#### **Status transition failed (SR0730.8.9)**

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also **Status transition failed (SR0730.3.2.1)** system-triggered exception (page 146).

# Tolerance check configuration (SR0730.8.11)

For recent changes, see revision history (page 172).

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Out of tolerance (SR0730.3.2.3) system-triggered exception (page 147).

#### CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

# Override use-by date (SR0730.8.3)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Override use-by date (SR0730.3.1.4) user-triggered exception (page 150).

# **Enter weight manually (SR0730.8.4)**

➤ Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Enter weight manually (SR0730.3.1.2) user-triggered exception (page 149).

# Return to material management (SR0730.8.6)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also **Return to material management (SR0730.3.1.1)** user-triggered exception (page 148).

#### CONFIGURATION OF POST-COMPLETION EXCEPTIONS

# Reprint label (SR0730.8.8)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also Reprint label (SR0730.3.3.1) post-completion exception (page 151).

# Exceptions (SR0730.3+)

The phase supports user-defined, user-triggered (page 148), system-triggered (page 145), and post-completion exceptions (page 151) and their configuration by means of process parameters (page 140).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

# System-triggered Exceptions (SR0730.3.2+)

For recent changes, see revision history (page 172).

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

#### Unforeseen resume (SR0730.3.2.2)

Representation of the exception:

<Exception text>

(taken from **Unforeseen resume** (**SR0730.8.10**) process parameter (page 141)) The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor. Consider to replace the affected position.

#### Example:

A critical resume situation has occurred. Contact your supervisor before proceeding.

The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor. Consider to replace the affected position.

# Unforeseen resume - Logic (SR0730.3.2.2.1)

- Trigger: Output Weighing process has been interrupted so that the system needs to be resumed
- Postcondition: Phase is back in active mode

| Step                        | #  | Description  |
|-----------------------------|----|--|
| Phase activation            | 10 | Phase displays the <b>Unforeseen resume (SR0730.3.2.2)</b> system-triggered exception. |
| Operator triggers exception | 30 | Phase records exception.   |

Status transition failed (SR0730.3.2.1)

➤ NOTE: Does not apply to O Weigh (RS) [1.0] (MR2).

The **Status transition failed** exception is displayed automatically if a certain status transition could not be performed based on the given graph purpose and trigger.

The potential reasons for a failed status transition are:

- The graph of the required purpose is missing.
- The trigger is missing.
- Source status does not match.
- Condition cannot be fulfilled or is not unique (in case of multiple transition definitions per trigger).
- Error during condition evaluation.
- Error during action evaluation.

Representation of the exception:

Exception dialog

- <Exception text> (taken from Status transition failed (SR0730.8.9) process parameter (page 142)) <the reason that applies>
  - List of potential reasons:
    - The graph of the required purpose is missing.
    - The trigger you are trying to perform is not contained in the graph.
    - Cannot find a transition for the current status.
    - Cannot find a fulfillable transition condition for the current status.
    - There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>.
    - Cannot evaluate the transition condition (<TR-ID>).
    - Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

# **Exception Window**

<Exception text>

(taken from **Status transition failed (SR0730.8.9)** process parameter (page 142)) <reason>

Equipment: <equipment identifier> / <equipment short description>

Equipment type: t of equipment types> (if available)

Graph (ID): <graph display text> (<identifier>)

Purpose: <purpose>

Current status (key): <display text> (<key>) Failed trigger (key): <display text> (<key>)

Example:

Status transition failed.

Cannot find a transition for the current status.

Equipment: IBC0033

Equipment type: Container (RS)

Graph (ID): IBC Cleaning (IBCCleaning01)

Purpose: Container Cleaning (RS)

Current status (key): Blocked (BLOCKED)
Failed trigger (key): In use (IN\_USE)

## Status transition failed - Logic (SR0730.3.2.1.1)

■ Trigger: The status transition could not be performed based on the given graph purpose and trigger.

■ Postcondition: Phase is active

| Step                                   | #  | Description                                     |
|--|----|---|
| Operator accepts exceptional situation | 10 | Phase shows exception description to be signed. |
| Operator signs exception               | 20 | Phase records exception.                        |

#### Out of tolerance (SR0730.3.2.3)

For recent changes, see revision history (page 172).

The **Out of tolerance** exception is displayed automatically if the confirmed weight is outside of the range defined by the target weight tolerances.

Representation of the exception:

<Exception text>

(taken from **Tolerance check configuration (SR0730.8.11)** process parameter (page 142))

Weighing result: Out of tolerance (according to the **Confirm weight by scan** (**SR0730.2.2**) function (page 134) or **Confirm weight by button** (**SR0730.2.3**) function (page 136))

Target weight: <target weight> [<lower limit> .. <upper limit>]

Actual quantity: <weighing value>

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•

**E**xample:

Tolerance check failed.

Weighing result: Out of tolerance

Target weight: 25.00 kg [24.50 kg .. 25.00 kg]

Actual quantity: 23.56 kg

#### Out of tolerance - Logic (SR0730.3.2.3.1)

For recent changes, see revision history (page 172).

■ Trigger: Exception is selected

■ Postcondition: N/A

| Step            | #  | Description              |
|-----------------|----|--------------------------|
| Operator        | 10 | Phase records exception. |
| confirms and    |    |                          |
| signs exception |    |                          |

#### User-triggered Exceptions (SR0730.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### Return to material management (SR0730.3.1.1)

The **Return to material management** exception allows an operator to step out of the regular Output Weighing process and start a new run with processing the **Manage produced material** phase.

Representation during exception handling:

■ Instruction:

Return to material management.

Confirm button.

Exception text:

<Exception text>

(taken from **Return to material management** (**SR0730.8.6**) process parameter (page 144))

Example:

Back to material identification.

#### Return to material management - Logic (SR0730.3.1.1.1)

Trigger: Exception is selected

■ Postcondition: N/A

| • |
|---|
| • |
| • |
| • |

| Step                        | #  | Description   |
|-----------------------------|----|---|
| Operator confirms exception | 10 | Phase records exception.  |
|                             | 20 | Phase is completed automatically and returns to Manage produced material (SR0700+) phase (page 19). |

## Enter weight manually (SR0730.3.1.2)

- For recent changes, see revision history (page 172).
- ➤ Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.
- ➤ Does not apply if, in the **Prepare only** mode, no sublot of ingoing material (order step input) has been identified yet.

The **Enter weight manually** exception allows an operator to enter the weighing value manually. It covers incidents when the communication to the selected scale is interrupted.

Representation during exception handling:

■ Instruction:

Enter the weight manually.

Confirm button.

Exception text:

<Exception text>

(taken from Enter weight manually (SR0730.8.4) process parameter (page 143))

Weight: <weighing value>

Example:

Weight entered manually.

Weight: 34.12 kg

#### Enter weight manually - Logic (SR0730.3.1.2.1)

- For recent changes, see revision history (page 172).
- ➤ Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.
- ➤ Does not apply if, in the **Prepare only** mode, no sublot of ingoing material (order step input) has been identified yet.

■ Trigger: Exception is selected

■ Postcondition: N/A

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 Step
 #
 Description

 Operator triggers exception
 10
 Phase displays Exception Window.

 20
 Operator enters current scale value manually. Phase performs checks at phase confirmation.

 Operator confirms
 30
 Phase records exception.

#### Override use-by date (SR0730.3.1.4)

- For recent changes, see revision history (page 172).
- ➤ Does not apply if, in the **Prepare only** mode, no sublot of ingoing material (order step input) has been identified yet.

The **Override use-by date** exception allows an operator to override the use-by date calculated from the period defined in the **Use-by date** (**SR0730.8.2**) process parameter (page 141).

Representation during exception handling:

■ Instruction:

Override.

Current use-by date <date>

New use-by date

Confirm button.

Exception text:

<Exception text>

(taken from Override use-by date (SR0730.8.3) process parameter (page 143))

Old use-by date: <date>
New use-by date: <date>

Example:

Use-by date overridden. Old use-by date: 12/4/2012 New use-by date: 12/4/2013

#### Override use-by date - Logic (SR0730.3.1.4.1)

- For recent changes, see revision history (page 172).
- ➤ Does not apply if, in the **Prepare only** mode, no sublot of ingoing material (order step input) has been identified yet.

Trigger: Exception is selected

■ Postcondition: N/A

exception

| • |
|---|
| • |
| • |
| • |
| • |

| Step                        | #  | Description                      |
|-----------------------------|----|----------------------------------|
| Operator triggers exception | 10 | Phase displays Exception Window. |
| Operator confirms exception | 20 | Phase records exception.         |

## Post-completion Exceptions (SR0730.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

## **Reprint label (SR0730.3.3.1)**

The **Reprint label** exception allows an operator to reprint a sublot label from the Navigator after the completion of the phase. For **Pallet** weighing with more than one sublot, the phase provides exceptions for each sublot label.

Representation during exception handling:

■ Instruction:

Reprint the sublot label.

<Sublot ID>.

Confirm button.

**Exception text:** 

<Exception text>

(taken from **Reprint label (SR0730.8.8)** process parameter (page 144)) <Sublot identifier> / <batch identifier> / <material identifier> / <material short

<Sublot identifier> / <batch identifier> / <material identifier> / <material short
description>

Example:

Label reprinted.

SL00001234 / BX123 / D001-03 / Aqua purificata

#### Reprint label - Logic (SR0730.3.3.1.1)

Trigger: Phase is completed, a label has been printed before

Postcondition: Label has been reprinted

| Step              | #  | Description                      |
|-------------------|----|----------------------------------|
| Operator triggers | 10 | Phase displays Exception Window. |
| action            |    |                                  |

 Step
 #
 Description

 Operator confirms exception
 20
 Phase reprints label.

# **Information Messages**

There are no information messages available.

# Questions

There are no questions available.

#### **Decisions**

There are no decisions available.

# Error Messages (SR0730.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an  $\mathbf{OK}$  button.

The following error messages are available to inform the operator about error conditions.

#### Scale online error (SR0730.3.6.1)

| UI text  | Comment   |
|--|---|
| A scale communication error has occurred at the <scale> scale.</scale> | Message pack: wd_UIMessage <version> Message ID: scalesCommunication_ErrorMsg</version> |

#### Wrong scale (SR0730.3.6.2)

| UI text                   | Comment  |
|---------------------------|--|
| You have scanned another  | Message pack: wd_UIMessage <version></version> |
| scale than selected. Scan | Message ID: WrongScale_ErrorMsg                |
| the previously selected   |  |
| scale to proceed.         |  |

# Scale driver error (SR0730.3.6.3)

| UI text | Comment   |
|---------|---|
|         | Message pack: srv_eqm.WDEquipmentService Message ID: weighFailed Message ID: nominalFailed_ErrorMsg |

# Gross outside scale range (SR0730.3.6.4)

| UI text   | Comment  |
|---|--|
| Cannot proceed, since the current scale load is outside the scale's valid range, which may have been determined by the required scale resolution. Current scale load: <value> Your scale load must range between <minimum value=""> and <maximum value="">.</maximum></minimum></value> | For multi-range scales: one lower range might be allowed, given its higher resolution, however, the final weight might require to switch to the next range with a lower resolution that no longer suffices.  Message pack: ow_Weigh Message ID: scaleNotSuitableForWeight_ErrorMsg |

# Weighing value not allowed (SR0730.3.6.6)

| UI text  | Comment   |
|--|---|
| The current weight is not compatible with the current mode of the phase. Preparation requires a 0 weight, whereas Weighing requires a weight greater than 0. | Message pack: ow_Weigh <version> Message ID: IllegalWeightForCurrentMode_ErrorMsg</version> |

# No ingoing material identified (SR0730.3.6.7)

| UI text | Comment  |
|---------|--|
| •       | Message pack: ow_Weigh <version> Message ID: NoOSIIdentifiedYet_ErrorMsg</version> |

# Output Variables (SR0730.9+)

The following output variables are available to reference the phase's output.

#### **Instance count (Framework capability)**

Data type: Long

■ Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.

The count variable of a phase that has not been executed provides 0 as output value.

#### **Start time (Framework capability)**

Data type: Timestamp

Usage: The output variable provides the start time of the phase.

## **Completion time (Framework capability)**

Data type: Timestamp

■ Usage: The output variable provides the completion time of the phase.

#### **Identifier (Framework capability)**

Data type: String

■ Usage: The output variable provides the identifier of the phase.

#### **Used scale (SR0730.9.1)**

➤ NOTE: Does not apply to O Weigh (RS) [1.0] (MR2).

Data type: IMESS88Equipment

Usage: The output variable provides the complete object of the used scale (equipment entity). This is the output to use in subsequent phases for accessing data of the equipment object (e.g. value of the runtime property of the Current Load (RS) purpose).

# Release Scale Phase (SR0740+)

The **Release scale** phase (O Release Scale) checks whether the scale value returns back to zero after unloading. The purpose of this phase is to ascertain that no loose material is left on the scale once the load with the recorded weight has been removed.

When the operator confirms the release of the scale, the phase sends a **delete tare** command to the scale.

For a manual scale, the operator enters the final scale value manually. No commands are sent to the scale.

During the calculation of the release result, tolerances are applied according to the resolution factor of the scale multiplied with the resolution defined for the lowest range of the scale that is about to be released.

The **Release scale** phase is skipped if the scale remains loaded.

If the **Quantity entry** weighing method is selected, the phase is skipped.

Details of the release process are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report.

Anomalies that occur during processing are covered by the phase exception handling (e.g. enter scale value manually, not successful release of the scale).

After completion it indicates as release status whether the check passed or failed, both in the Execution Window and in the Navigator.

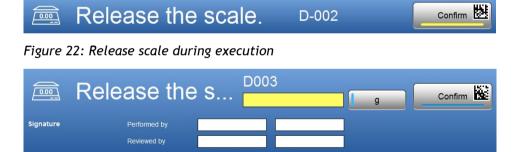


Figure 23: Release scale during execution with a manual scale

#### Layout

The phase provides individual layouts for its representation during execution (page 155), in the Navigator (page 157), and in the sub-report (page 157).

#### Representation during Execution (SR0740.1+)

The representation during execution depends on the phase mode.

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#### Preview mode (SR0740.1.1)

- 1. Phase-specific icon.
- 2. <Instruction text> (taken from **Instruction** (**SR0740.8.1**) process parameter (page 161))
- 3. Placeholder for selected scale
- 4. **Confirm** button (disabled).

# **Active mode (SR0740.1.2)**

- Phase-specific icon.
- <Instruction text>
   (taken from Instruction (SR0740.8.1) process parameter (page 161))
- 3. <Identifier of selected scale>
- 4. **Confirm** button.

#### Active mode (manual scale) (SR0740.1.4)

This representation applies to all weighing methods if the selected scale is configured as manual scale.

If a phase completion signature is assigned to the phase, the signature is ignored during execution. Instead, a phase completion signature is added automatically according to the system configuration.

- 1. Phase-specific icon.
- 2. <Instruction text> (taken from **Instruction (SR0740.8.1)** process parameter (page 161))
- 3. <Identifier of selected scale>
- 4. Input box and **UoM** toggle button.
  - The **UoM** toggle button provides all UoMs that are supported by the manual scale.
- 5. Phase completion signature panel
  - WD\_ES\_MANUAL\_SCALE access privilege
- 6. **Confirm** button.

#### Completed mode (SR0740.1.3)

- Phase-specific icon.
- 2. Release status

- 3. <"Check passed", "Check failed">
- 4. **Confirm** button (completed).

#### Representation in Navigator (SR0740.4+)

The Navigator provides the following details:

#### Phase column (Framework capability)

- <Phase name>
  - Example:Release Scale

#### **Information column (SR0740.4.1)**

- <Result: "Check passed", "Check failed">
  - Example: Check passed

#### **Action column**

■ There are no actions available.

#### Representation in Sub-report (SR0740.5+)

The sub-report contains the following information:

#### **Common sub-report elements (Framework capability)**

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> <phase completion user>

## **Sub-report elements (SR0740.5.1)**

- Position: <number>
- Release check: <"Check passed", "Check failed">
- Scale value: <scale value>

# Business Logic (SR0740.2+)

The phase implements the following business logic.

#### Main Path

Business logic related to the main path:

# Release by scan (SR0740.2.1)

■ Function: Release of scale by use of barcode scan

■ Type: Main path

 Trigger: Operator scans scale, scale has been released, target container has been removed

Postcondition: Phase is completed

| Step                 | #  | Description   |  |
|----------------------|----|---|--|
| Operator scans scale | 5  | Phase reads scanned data.   |  |
|                      | 10 | <ul> <li>If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading.</li> <li>If barcode reading was technically not successful, phase remains in listening mode.</li> </ul>          |  |
|                      | 20 | If barcode does not reflect barcode attribute of the selected scale, phase displays the <b>Wrong scale (SR0740.3.6.2)</b> error message (page 166).   |  |
|                      | 30 | Does not apply if scale is configured as manual scale.  If no communication can be established to the scale or any other scale driver-related error occurs, phase displays the Scale driver error (SR0740.3.6.3) error message (page 166).  |  |
|                      | 40 | <ul> <li>Does not apply if scale is configured as manual scale.</li> <li>Phase sends delete tare command to scale. This results in an expected scale display of zero (within defined tolerances).</li> </ul>  |  |
|                      | 45 | Phase reads and records scale value once. Phase runs the following check:  ABS (Current scale value) < Resolution factor(Scale) x Resolution (Scale) In case of multi-range scales, the scale resolution of the lowest range applies.   |  |
|                      | 50 | If scale value is not within the tolerances, phase creates the <b>Release was not successful (SR0740.3.2.1)</b> system-triggered exception (page 163). Otherwise continue with step 70.   |  |
|                      | 55 | If scale value is not within the tolerances, operator canceled exception dialog and thus did not record the <b>Release was not successful (SR0740.3.2.1)</b> system-triggered exception (page 163), phase does not read a new scale value, but keeps the scale value from the first time. |  |

| Step | #  | Description                       |
|------|----|-----------------------------------|
|      | 70 | Phase is completed automatically. |

# Release by button (SR0740.2.2)

Function: Release of scale by use of button

Type: Main path

Trigger: Operator confirms phase, scale has been released, target container has been removed

■ Postcondition: Phase is completed

| Step                    | #  | Description   |  |
|-------------------------|----|---|--|
| Operator confirms phase | 30 | Does not apply if scale is configured as manual scale.  If no communication can be established to the scale or any other scale driver-related error occurs, phase displays the Scale driver error (SR0740.3.6.3) error message (page 166).  |  |
|                         | 40 | <ul> <li>Does not apply if scale is configured as manual scale.</li> <li>Phase sends delete tare command to scale. This results in an expected scale display of zero (within defined tolerances).</li> </ul>  |  |
|                         | 45 | Phase reads and records scale value once.  Phase runs the following check:  ABS (Current scale value) < Resolution factor(Scale) x Resolution (Scale)   |  |
|                         | 50 | If scale value is not within the tolerances, phase creates the <b>Release was not successful (SR0740.3.2.1)</b> system-triggered exception (page 163). Otherwise continue with step 70.   |  |
|                         | 55 | If scale value is not within the tolerances, operator canceled exception dialog and thus did not record the <b>Release was not successful (SR0740.3.2.1)</b> system-triggered exception (page 163), phase does not read a new scale value, but keeps the scale value from the first time. |  |
|                         | 70 | Phase is completed automatically.   |  |

# Release (manual scale) (SR0740.2.4)

- > Applies only if scale is configured as manual scale.
  - Function: Release of a scale that is configured as manual scale
  - Type: Main path
  - Trigger: Phase becomes active, scale has been released, target has been removed

• ' •

#### ■ Postcondition: Phase is completed

| Step             | #  | Description   |
|------------------|----|---|
| Phase activation | 10 | Phase displays the <b>Active mode (manual scale) (SR0740.1.4)</b> layout (page 156).  |
|                  | 20 | Operator enters current scale value manually.   |
| Phase completion | 30 | Either manually with the Release by button (SR0740.2.2) function (page 159) or by scanning the scale barcode with the Release by scan (SR0740.2.1) function (page 158). |
| Phase completion | 40 | Pre-defined phase completion signature is requested according to the WD_ES_MANUAL_SCALE access privilege.   |
| signature        |    | Any other phase completion signature that has been assigned to the phase is ignored.  |

#### Scale loaded (SR0740.2.3)

➤ NOTE: Does not apply to O Release scale (RS) [1.0] (MR2).

Function: Scale is loaded

Type: Main path

■ Trigger: Phase becomes active

■ Postcondition: N/A

| Step   | #  | Description  |
|--|----|--|
| Used scale's property of the Current Load (RS) purpose is not empty. | 10 | Phase is skipped.  Release check result (SR0740.9.2) output variable (page 167) is set to SKIPPED. |

# **Weighing Method-specific Paths**

There are no specifics available for any of the supported weighing methods.

# **Recipe Parameters**

The phase provides process parameters (page 160).

# Process Parameters (SR0740.8+)

The following process parameters define the behavior of the phase.

#### BASIC PARAMETERS

# **Instruction (SR0740.8.1)**

For recent changes, see revision history (page 172).

| Attribute | Туре      | Comment  |
|-----------|-----------|--|
| Column 1  | HTML text | Instruction text to be displayed.  Restriction: Maximum length is 2000 characters (including HTML tags). |
| Column 2  | HTML text | Not used.  |
| Column 3  | HTML text | Not used.  |

#### CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

# Release check (SR0740.8.2)

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also **Release was not successful (SR0740.3.2.1)** system-triggered exception (page 163).

# **Unforeseen resume (SR0740.8.4)**

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, |

Attribute

Type

Comment

High (mandatory comment).
Default setting: High.

Exception text

Text

Defines the exception description used during exception handling and within the batch record.
Maximum length is 250 characters.

See also Unforeseen resume (SR0740.3.2.2) system-triggered exception (page 163).

#### CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

#### Enter scale value manually (SR0740.8.3)

> Does not apply if scale is configured as manual scale.

| Attribute       | Туре        | Comment   |
|-----------------|-------------|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.  Available settings: None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).  Default setting: High. |
| Exception text  | Text        | Defines the exception description used during exception handling and within the batch record.  Maximum length is 250 characters.  |

See also **Enter scale value manually (SR0740.3.1.1)** user-triggered exception (page 164).

# Exceptions (SR0740.3+)

The phase supports user-defined, user-triggered (page 164), system-triggered (page 163), and post-completion exceptions (page 165) and their configuration by means of process parameters (page 160).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

# System-triggered Exceptions (SR0740.3.2+)

For recent changes, see revision history (page 172).

A system-triggered exception is represented in a message dialog along with an Exception button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

#### Release was not successful (SR0740.3.2.1)

Representation of the exception:

<Exception text>

(taken from **Release check** (**SR0740.8.2**) process parameter (page 161))

Expected value between <lower value> and <upper value>.

Actual value: <scale value>

Example:

Release check performed.

Expected value between -0.02 kg and 0.02 kg.

Actual value: 0.04 kg

#### Release was not successful - Logic (SR0740.3.2.1.1)

- Trigger: Scale value is not within the release tolerances
- Postcondition: If no exception has been recorded, the already recorded value from the scale is no longer updated

| Step              | #  | Description              |
|-------------------|----|--------------------------|
| Operator triggers | 10 | Phase records exception. |
| exception         |    |                          |

#### Unforeseen resume (SR0740.3.2.2)

Representation of the exception:

<Exception text>

(taken from **Unforeseen resume** (**SR0740.8.4**) process parameter (page 161)) The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.

Consider to replace the affected position.

Example:

A critical resume situation has occurred. Contact your supervisor before proceeding.

The system has been resumed during weighing. It must be ensured that the

data recorded so far matches the physical situation on the shop floor. Consider to replace the affected position.

#### Unforeseen resume - Logic (SR0740.3.2.2.1)

- Trigger: Output Weighing process has been interrupted so that the system needs to be resumed
- Postcondition: Phase is back in active mode

| Step                        | #  | Description  |
|-----------------------------|----|--|
| Phase activation            | 10 | Phase displays the <b>Unforeseen resume (SR0740.3.2.2)</b> system-triggered exception. |
| Operator triggers exception | 30 | Phase records exception.   |

#### User-triggered Exceptions (SR0740.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### Enter scale value manually (SR0740.3.1.1)

> Does not apply if scale is configured as manual scale.

The **Enter scale value manually** exception allows an operator to enter the scale value of the unloaded scale manually.

Representation during exception handling:

■ Instruction:

Enter the scale value manually.

Confirm button.

**Exception text:** 

<Exception text>

(taken from **Enter scale value manually (SR0740.8.3**) process parameter (page 162))

Scale value: <entered value>

Example:

Scale value entered manually.

Scale value: 0.01 kg

## Enter scale value manually - Logic (SR0740.3.1.1.1)

➤ Does not apply if scale is configured as manual scale.

■ Trigger: Exception is selected

■ Postcondition: Scale value is not updated any more

| Step                              | #  | Description   |  |
|-----------------------------------|----|---|--|
| Operator triggers exception       | 10 | Phase displays Exception Window.  |  |
|                                   | 20 | Operator enters current scale value manually.   |  |
| Operator<br>confirms<br>exception | 30 | Phase records exception.  Phase performs checks as listed for the Release by scan (SR0740.2.1) function (page 158).  Phase is ready for completion. |  |

#### **Post-completion Exceptions**

There are no post-completion exceptions available.

# Information Messages

There are no information messages available.

# Questions

There are no questions available.

#### **Decisions**

There are no decisions available.

# Error Messages (SR0740.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an  $\mathbf{OK}$  button.

The following error messages are available to inform the operator about error conditions.

#### Scale online error (SR0740.3.6.1)

| UI text  | Comment   |
|--|---|
| A scale communication error has occurred at the <scale> scale.</scale> | Message pack: wd_UIMessage <version> Message ID: scalesCommunication_ErrorMsg</version> |

# Wrong scale (SR0740.3.6.2)

| UI text | Comment  |
|---------|--|
|         | Message pack: wd_UIMessage <version> Message ID: WrongScale_ErrorMsg</version> |

#### Scale driver error (SR0740.3.6.3)

| UI text   | Comment  |
|---|--|
| Cannot obtain a stable reading or a scale communication error has occurred. Please try again. | Message pack: srv_eqm.WDEquipmentService Message ID: errorDuringTareClear_ErrorMsg Message ID: weighFailed |

# Output Variables (SR0740.9+)

The following output variables are available to reference the phase's output.

#### **Instance count (Framework capability)**

Data type: Long

■ Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.

The count variable of a phase that has not been executed provides 0 as output value.

#### **Start time (Framework capability)**

Data type: Timestamp

■ Usage: The output variable provides the start time of the phase.

# **Completion time (Framework capability)**

Data type: Timestamp

■ Usage: The output variable provides the completion time of the phase.

# **Identifier (Framework capability)**

Data type: String

■ Usage: The output variable provides the identifier of the phase.

# Release check result (SR0740.9.2)

Data type: String

■ Values: PASSED, FAILED

- Usage: The output variable provides the result of the release check performed for the scale:
  - The value is PASSED if the current scale load is within the permitted tolerance band around zero and the check has thus passed successfully.
  - The value is FAILED if the check has failed.
  - The value is SKIPPED if the phase was skipped.

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# **Reference Documents**

The following documents are available from the Rockwell Automation Download Site.

| No. | Document Title  | Part Number             |
|-----|---|-------------------------|
| A1  | PharmaSuite Functional Requirement Specification Execution Framework            | PSFRSEF-RM004E-EN-E     |
| A2  | PharmaSuite Functional Requirement Specification Workflow Phases                | PSFRSWF-RM004E-EN-<br>E |
| A3  | PharmaSuite Functional Requirement Specification Dispense and Inline Weighing   | PSFRSDI-RM006E-EN-E     |
| A4  | PharmaSuite Functional Requirement Specification Data Management                | PSFRSDM-RM004E-EN-<br>E |
| A5  | PharmaSuite Functional Requirement Specification Recipe and Workflow Management | PSFRSRD-RM008E-EN-E     |

#### TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

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# **Document Information**

The document information covers various data related to the document.

#### **Approval**

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

| Name           | Role                |
|----------------|---------------------|
| Martin Dittmer | Product Manager     |
| Steffen Landes | Development Manager |
| Martin Irmisch | Test Manager        |

In addition, the electronic document approval via DMS is confirmed by a handwritten signature of all approvers in the Quality Document when the release is completed. The Quality Document summarizes the quality-related planning activities and results of a PharmaSuite release.

#### **Version Information**

| Object                               | Version                    |
|--------------------------------------|----------------------------|
| PharmaSuite                          | 8.4                        |
| O Manage produced material           | 5.2, 5.1, 5.0 MR1, 1.0 MR2 |
| O Select scale                       | 5.2, 5.1, 5.0 MR1, 1.0 MR2 |
| O Identify container                 | 5.2, 5.1, 5.0 MR1          |
| O Tare                               | 5.2, 5.1, 5.0 MR1, 1.0 MR2 |
| O Weigh                              | 5.2, 5.1, 5.0 MR1, 1.0 MR2 |
| O Release scale                      | 5.2, 5.1, 5.0 MR1, 1.0 MR2 |
| Functional Requirement Specification | 1.0                        |

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### **Revision History**

The following table describes the history of this document.

Changes related to the document:

| Object | Description | Document |
|--------|-------------|----------|
|        |             |          |

### Changes related to "Recipe Structure for Output Weighing" (page 3):

| Object                              | Description   | Document |
|-------------------------------------|---|----------|
| Phases (page 3)                     | Update<br>Show GHS Data phase added.  | 1.0      |
| Containers (page 5)                 | Update New purpose to check the tare value of a container against a reference value.  | 1.0      |
| Output Weighing Operation (page 10) | Update Show GHS Data phase added.   | 1.0      |
| Transitions (page 11)               | Update Show GHS Data phase added.   |          |
| Exceptions (page 12)                | Update Tare phase, Failed tare check: New system-triggered exception to check the tare value of a container against a reference value. Weigh phase, Out of tolerance: New system-triggered exception to check the scale value against the target weight. Show GHS Data phase added. | 1.0      |
| Use Cases (page 13)                 | Update PharmaSuite supports output weighing against a pre-defined target weight.  | 1.0      |

# Changes related to "Manage Produced Material Phase" (page 19):

| Object  | Description   | Document |
|---|---|----------|
| Table of Sublots (SR0700.1.4) (page 23)             | Editorial Clarification of the <b>Annulled</b> status, Status (container/sublots): An annulled sublot remains in the table with its new status, an annulled container is removed from the table. No change of code. | 1.0      |
| System-triggered Exceptions (SR0700.3.2+) (page 39) | Update The message dialog of a system-triggered exception no longer provides a Cancel button.   | 1.0      |

| Object                   | Description  | Document |
|--------------------------|--|----------|
| Instruction (SR0700.8.1) | Update   | 1.0      |
| (page 34)                | The maximum length of the Instruction process parameter is |          |
|                          | 2000 characters (including HTML tags). No change of code.  |          |

# Changes related to "Select Scale Phase" (page 55):

| Object   | Description  | Document |
|--|--|----------|
| Automated Scale Selection (SR0710.2.1) (page 59) | Update Step 10.1, 10.2: A target weight and its tolerances, if defined, are considered during automatic scale selection.           | 1.0      |
| Instruction (SR0710.8.1) (page 66)               | Update The maximum length of the <b>Instruction</b> process parameter is 2000 characters (including HTML tags). No change of code. | 1.0      |

### Changes related to "Identify Container Phase" (page 77):

| Object  | Description  | Document |
|---|--|----------|
| System-triggered Exceptions (SR0750.3.2+) (page 89) | Update The message dialog of a system-triggered exception no longer provides a Cancel button.  | 1.0      |
| Multiple Failed Checks (SR0750.3.2.3) (page 93)     | Update The message dialog of a combined system-triggered exception no longer provides a <b>Cancel</b> button.  | 1.0      |
| Sub-report Elements<br>(SR0750.5.1) (page 79)       | Update Sequence of report data updated: "Additional requirements" moved after "Identified container", "All status values" moved to "Actual property names", "Rule identifiers, property names" replaced by "Actual property names", "Rule identifiers and actual values" removed. No change of code. | 1.0      |
| Instruction (SR0750.8.1) (page 85)                  | Update The maximum length of the <b>Instruction</b> process parameter is 2000 characters (including HTML tags). No change of code.   |          |

### Changes related to "Tare Phase" (page 103):

| Object   | Description  | Document |
|--|--|----------|
| Check Container Tare<br>(SR0720.2.13) (page 112) | New Sew function to check the tare value of a container against a reference value. | 1.0      |

| Object  | Description   | Document |
|---|---|----------|
| System-triggered Exceptions (SR0720.3.2+) (page 117)          | Update The message dialog of a system-triggered exception no longer provides a Cancel button.                               | 1.0      |
| Failed Tare Check<br>(SR0720.3.2.2) (page 117)                | New New system-triggered exception to check the tare value of a container against a reference value.                        | 1.0      |
| Failed Tare Check - Logic (SR0720.3.2.2) (page 117)           | New New system-triggered exception to check the tare value of a container against a reference value.                        | 1.0      |
| Instruction (SR0720.8.1) (page 113)                           | Update The maximum length of the Instruction process parameter is 2000 characters (including HTML tags). No change of code. | 1.0      |
| Tare Check Configuration (SR0720.8.6) (page 114)              | New New process parameter to check the tare value of a container against a reference value.                                 | 1.0      |
| Tare Check Tolerance<br>Definition (SR0720.8.7) (page<br>114) | New New process parameter to check the tare value of a container against a reference value.                                 | 1.0      |
| Configuration Keys<br>(SR0720.11+) (page 124)                 | New grouping requirement for configuration keys.  | 1.0      |
| Allow Override Reference<br>Tare (SR0720.11.1) (page<br>125)  | New New configuration key to change the behavior of the Failed tare check system-triggered exception.                       | 1.0      |

# Changes related to "Weigh Phase" (page 127):

| Object  | Description   | Document |
|---|---|----------|
| Active Mode (SR0730.1.2) (page 129)                             | Update A target weight and its tolerances, if defined, are considered by the scale control.   | 1.0      |
| Active Mode (Quantity Entry) (SR0730.1.7) (page 130)            | Update The UoM toggle button is replaced by an input box. The WD_ES_QUANTITY_ENTRY_O access privilege replaces the WD_ES_QUANTITY_ENTRY access privilege. | 1.0      |
| System-triggered Exceptions (SR0730.3.2+) (page 145)            | Update The message dialog of a system-triggered exception no longer provides a Cancel button.   | 1.0      |
| Weighing Method - Quantity<br>Entry (SR0730.2.12) (page<br>138) | Update The WD_ES_QUANTITY_ENTRY_O access privilege replaces the WD_ES_QUANTITY_ENTRY access privilege.  | 1.0      |

| Object   | Description  | Document |
|--|--|----------|
| Activate Scale Control (SR0730.2.1) (page 133)               | Update A target weight and its tolerances, if defined, are considered by the scale control.  | 1.0      |
| Confirm Weight by Scan (SR0730.2.2) (page 134)               | Update A target weight, its tolerances, and the tolerance check are considered when the weight is confirmed.                         | 1.0      |
| Confirm Weight by Button (SR0730.2.3) (page 136)             | Update A target weight, its tolerances, and the tolerance check are considered when the weight is confirmed.                         | 1.0      |
| Enter Weight Manually (SR0730.3.1.2) (page 149)              | Update Does not apply if, in the <b>Prepare only</b> mode, no sublot of ingoing material has been identified yet. No change of code. | 1.0      |
| Enter Weight Manually - Logic (SR0730.3.1.2) (page 149)      | Update Does not apply if, in the <b>Prepare only</b> mode, no sublot of ingoing material has been identified yet. No change of code. | 1.0      |
| Override Use-by Date (SR0730.3.1.4) (page 150)               | Update Does not apply if, in the <b>Prepare only</b> mode, no sublot of ingoing material has been identified yet. No change of code. | 1.0      |
| Override Use-by Date - Logic (SR0730.3.1.4) (page 150)       | Update Does not apply if, in the <b>Prepare only</b> mode, no sublot of ingoing material has been identified yet. No change of code. | 1.0      |
| Out of Tolerance<br>(SR0730.3.2.3) (page 147)                | New New system-triggered exception to check the scale value against the target weight.   | 1.0      |
| Out of Tolerance - Logic (SR0730.3.2.3) (page 147)           | New New system-triggered exception to check the scale value against the target weight.   | 1.0      |
| Instruction (SR0730.8.1) (page 140)                          | Update The maximum length of the <b>Instruction</b> process parameter is 2000 characters (including HTML tags). No change of code.   | 1.0      |
| Tolerance Check<br>Configuration (SR0730.8.11)<br>(page 142) | New New process parameter to check the scale value against the target weight.  | 1.0      |

# Changes related to "Release Scale Phase" (page 155):

| Object   | Description  | Document |
|--|--|----------|
| System-triggered Exceptions (SR0740.3.2+) (page 163) | Update The message dialog of a system-triggered exception no longer provides a <b>Cancel</b> button. | 1.0      |

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| Object                              | Description   | Document |
|-------------------------------------|---|----------|
| Instruction (SR0740.8.1) (page 161) | Update The maximum length of the Instruction process parameter is 2000 characters (including HTML tags). No change of code. | 1.0      |

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