Oracle Health Sciences Empirica Signal

Vigibase Signal Management for Use with Oracle Empirica Signal Installation and Upgrade Instructions

Release 9.2.2

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Oracle Health Sciences Empirica Signal Vigibase Signal Management for Use with Oracle Empirica Signal Installation and Upgrade Instructions, Release 9.2.2

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Preface

This preface contains the following sections:

- Documentation accessibility
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Documentation accessibility

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1

Interactive Vigibase Signal Management installation overview

- • Introduction
  The Oracle Empirica Signal software is a web-based analysis environment for generating statistical scores for combinations of drugs and events in a drug safety database, and for detecting unexpected associations of drugs and events (signals).

- • About the installation process
  The installation process for interactive Vigibase Signal Management includes installing the Vigibase signal configuration on the Oracle Empirica Signal application server and enabling the Signal Management features.

- • Before you begin
  To perform the installation you need access to the Oracle Empirica Signal 9.x distribution media and required user names and passwords.

Introduction

The Oracle Empirica Signal software is a web-based analysis environment for generating statistical scores for combinations of drugs and events in a drug safety database, and for detecting unexpected associations of drugs and events (signals).

If your organization is licensed for Signal Management, users can employ the Signal Management feature in Oracle Empirica Signal on Vigibase data. The feature facilitates ongoing monitoring of safety signals by enabling users to perform statistical analyses on successive releases of the data.

A scripted form of Vigibase Signal Management was originally released in 2005. In scripted Vigibase Signal Management, quarterly refreshes are initiated by running shell scripts on the server. Scripted Vigibase Signal Management can be used with Oracle Empirica Signal versions 7.3.x and above.

Oracle Empirica Signal 9.x introduced a new Vigibase Signal Management that is interactive rather than scripted and Oracle Empirica Signal 9.0 enhanced interactive signal management introducing configurable alerts. Interactive Vigibase Signal Management can be installed with Oracle Empirica Signal 9.1.0.3 and above and requires Vigibase data 2018Q2 or later. If scripted Vigibase Signal Management was used previously, there is an optional conversion process to copy information from the old scripted Vigibase Signal Management into the new interactive Vigibase Signal Management.

About the installation process

The installation process for interactive Vigibase Signal Management includes installing the Vigibase signal configuration on the Oracle Empirica Signal application server and enabling the Signal Management features.

Perform these installation tasks:

- Install the interactive Vigibase signal configuration on the Oracle Empirica Signal application server.

- (Optional) For users of scripted Vigibase Signal Management, convert the scripted Vigibase Signal Management to the new interactive Vigibase Signal Management.

- Configure the Oracle Empirica Signal application to enable the Signal Management features.

Follow the instructions in Install and configure an interactive Vigibase signal configuration and (Recommended) Post install/upgrade to install.

Before you begin

To perform the installation you need access to the Oracle Empirica Signal 9.x distribution media and required user names and passwords.

To perform the installation, you need:

- Access to the Oracle Empirica Signal 9.x distribution media, which contains `Vigibase_Prep_3_0_0_x_xxx.zip`—A Zip archive file for interactive Vigibase Signal Management.

- The user name, password, and TNS name of the Oracle Empirica Signal database user account.

- The user name and password associated with a non-privileged user account on the Oracle Empirica Signal application server.

- The user name and password associated with an administrator account on the Oracle WebLogic Server Administration console.

- To convert an existing scripted Vigibase Signal Management to an interactive Vigibase Signal Management:

    – The password for the `Vigibase_SIGNAL_PREP` database account used by the scripted Vigibase Signal Management.

    – The ID of the scripted Vigibase signal configuration you are converting from. To find this ID, in Oracle Empirica Signal, in the left navigation pane, click **Settings**, then, in the Configure System section, select **Manage Signal Configurations**.

    – The ID of the interactive Vigibase signal configuration you are converting to. This ID appears at the end of the interactive Vigibase signal configuration installation. To find this ID, in the Oracle Empirica Signal application, after the installation of an interactive Vigibase signal configuration, in the left navigation pane, click **Settings**, then, in the Configure System section, select **Manage Signal Configurations**.

- Review the *Release Notes* available in the Oracle Help Center.

2

Install and configure an interactive Vigibase signal configuration

- **Install an interactive Vigibase signal configuration**
  Perform these steps using the non-privileged user account on the application server.

- **Enable Signal Management in the Oracle Empirica Signal application**
  You enable the **Signal Review** site option to turn on the Signal Management features in Oracle Empirica Signal.

- **Establish aliases for Vigibase data configurations**
  An interactive Vigibase signal configuration can use aliases for data configuration for 2D runs and 3D runs. If such aliases do not already exist, you can create them.

- **Edit the interactive Vigibase signal configuration**
  The interactive Vigibase signal configuration defines the behavior and content of the Signal Review page in the Oracle Empirica Signal application.

- **Make an interactive Vigibase signal configuration available for further configuration**
  To further configure the signal configuration, a user needs to access the configuration from the Signal Review page. If you are the owner of the signal configuration, then you have access.

- **Manage monitored drugs and signaling terms**
  You can use the interactive Signal Management feature in Oracle Empirica Signal to define the list of monitored products and signaling terms from the application user interface.

- **Validate the interactive Vigibase signal configuration**
  After you specify the list of monitored products and signaling terms for the interactive Vigibase signal configuration, you must validate the configuration to ensure that your changes are valid.

- **Refresh an interactive Vigibase signal configuration**
  You refresh an interactive Vigibase signal configuration to populate the data on the Signal Review page.

- **Make an interactive Vigibase signal configuration available to users**
  To make an interactive Vigibase signal configuration available to users, you must publish the configuration. Optionally, set the interactive Vigibase signal configuration as the default for login groups.

Install an interactive Vigibase signal configuration

Perform these steps using the non-privileged user account on the application server.

1. If it does not already exist on the Oracle Empirica Signal application server, create the following directory:

   `/u01/stage/projects`

2. Copy the `Vigibase_Prep_3_0_0_x_xxx.zip` file from the distribution media to:

/u01/stage/projects

3. Change your current directory to `/u01/stage/projects` as follows:

```
cd /u01/stage/projects/
```

4. Unpack the `Vigibase_Prep_3_0_0_x_xxx.zip` file into a temporary directory, for example:

```
$ unzip Vigibase_Prep_3_0_0_x_xxx.zip -d /u01/stage/projects/
```
The `Vigibase_ism_prep` subdirectory is created.

5. Navigate to the `Vigibase_ism_prep` subdirectory, for example:

```
$ cd /u01/stage/projects/Vigibase_ism_prep
```

6. Execute the following command to give execute permissions to all .sh files:

```
$ chmod u+x common/*.sh sigdet/*.sh site/*.sh
```

7. Navigate to `Vigibase_ism_prep/sigdet`, for example:

```
$ cd /u01/stage/projects/Vigibase_ism_prep/sigdet
```

8. Execute the following command to give write permissions to the database directory:

```
$ chmod u+w db
```

9. Execute the `main_install_sigmgt.sh` script to initiate the installation:

```
$ ./main_install_sigmgt.sh <signal database account name>@<TNS_name>
```
where `<signal database account name>` is the Oracle Empirica Signal database user account name; for example, *webvdme*, and `<TNS_name>` is the TNS name that the application server uses to access the database server.

A password prompt appears.

10. Enter `<password>`, where `<password>` is the Oracle Empirica Signal database user account password.

A second password prompt appears.

11. Reenter `<password>`.

> **Note:**
>
> If you enter the password incorrectly, an error such as this appears in the `install_sigmgmt.log` file: `Error returned from execution of "sqlplus /NOLOG @db/connect webvdme @db/fetch_next_config_id"`.

The database tables for the interactive Vigibase signal configuration are populated. The `install_sigmgmt.log` file is created in the `sigdet/sigmgt/install/log` subdirectory.

If the `Vigibase Signal Management` project already exists, error messages may appear, including the following:

```
ERROR at line 1:ORA-xxxxx: unique constraint (WEBVDME.UC_PROJECTS1)
violated
ERROR at line 1:ORA-xxxxx: table or view does not exist
```

```
ERROR at line 1:ORA-xxxxx: sequence does not exist
```

You can disregard these errors.

Enable Signal Management in the Oracle Empirica Signal application

You enable the **Signal Review** site option to turn on the Signal Management features in Oracle Empirica Signal.

For more information, see the *User Guide and Online Help*.

1. Log in to the Oracle Empirica Signal application as a superuser.

2. In the navigation pane on the left, click the **Settings** (⚙).

3. In the Administer System section, click **Set Site Options**.

4. From the **Show menu items** list, select **Signal Review**.

5. Optionally, select the following Signal Management options:

    • From the **Show menu items** list, select **Allow Free Text Signal Comments**. This allows users to enter free text comments when, on the Signal Review page, they filter a product-event combination or add a comment when reviewing a signal summary. Regardless of the setting of this option, users can select from a list of predefined comments.

    • In the **Notes for Signal Management Interactions Graph** text box, enter text to display at the bottom of the Interactions page for a product-event combination on the Signal Review page.

    • In the **Product-event combination comment length** text box, enter the maximum length of detailed comments for product-event combinations on the Signal Review page.

6. Click **Save**.

You must log out and log back in for the changes to take effect.

Establish aliases for Vigibase data configurations

An interactive Vigibase signal configuration can use aliases for data configuration for 2D runs and 3D runs. If such aliases do not already exist, you can create them.

To add or edit aliases, you must have the Manage Aliases user permission.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click **Settings** (⚙).

2. In the Configure System section, click **Manage Aliases**.

3. From the **Target Type** drop-down list, select **Configuration**.

4. Perform one of the following:

    • To add a new alias, click the **Add Alias** link.

- To edit an alias, click the alias' **Row Action menu** (⋮), and then click **Edit**. You can edit only aliases that you have created. However, if you have the Administer Users permission, you can edit aliases created by any user in your login group.

5. In the **Alias Name** field, enter an alias name.

6. From the **Target Type** drop-down list, select **Configuration**.

7. From the **Target** drop-down list, select the target.

   Select the most recent quarter for Target.

Alias Name	Target (example)
Latest Vigibase (S)	2020Q4: Vigibase (S)
Latest Vigibase (S + C)	2020Q4: Vigibase (S + C)

8. Click **OK**.

Edit the interactive Vigibase signal configuration

The interactive Vigibase signal configuration defines the behavior and content of the Signal Review page in the Oracle Empirica Signal application.

For example, the signal configuration specifies the data configurations and variables Oracle Empirica Signal uses for data mining runs. For more information, see the *User Guide and Online Help*.

Review the default settings of the interactive Vigibase signal configuration and change the settings as needed.

You must have the Manage Signal Configurations user permission to edit a signal configuration.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click **Settings** (⚙).

2. In the Configure System section, click **Manage Signal Configurations**.

3. Click the interactive Vigibase signal configuration's **Row Action menu** (⋮), and then click **Edit**.

4. On the Edit Signal Configurations page, edit the fields as needed.

   For more information, see the *User Guide and Online Help*.

5. Click **Save**.

   Oracle Empirica Signal validates the signal configuration. In case of any error or warning, a message appears at the top of the page.

Make an interactive Vigibase signal configuration available for further configuration

To further configure the signal configuration, a user needs to access the configuration from the Signal Review page. If you are the owner of the signal configuration, then you have access.

Follow the steps below to publish the configuration to a user with Manage Signal Configurations permission.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click **Settings** ( ).

2. In the Configure System section, click **Manage Signal Configurations**.

3. Click the interactive Vigibase signal configuration's **Row Action menu** ( ), and then click **Publish**.

4. Select **Publish to Users** to publish to individual users with Manage Signal Configurations permissions.

# Manage monitored drugs and signaling terms

You can use the interactive Signal Management feature in Oracle Empirica Signal to define the list of monitored products and signaling terms from the application user interface.

You can manage the products to monitor and the following signaling terms:

*   Designated medical events.

*   Custom terms.

*   Targeted medical events.

*   Listed events for a monitored product.

For more information about monitoring products and maintaining signaling terms, see Add or edit a product to monitor and Manage events and custom terms in the *User Guide and Online Help*.

To modify the list of monitored products and signaling terms:

*   The interactive Vigibase signal configuration must be selected for your user.

*   You must have the Manage Signaling Terms user permission.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Signal Review** icon ( ).

    The Products page appears.

2. If the interactive Vigibase signal configuration is not displayed in the **Signal Configuration** drop-down list, select it.

3. From the **Manage Reference Data** menu ( ), in the upper right corner, select **Add Product** or **Manage Custom Terms**.

4. To add or edit products, fill in the fields according to the table in Add or edit a product to monitor in the *User Guide and Online Help*. To manage signaling terms, see Add, edit, or delete a custom term in the *User Guide and Online Help*.

To manage events:

1. In the left navigation pane, click the **Signal Review** icon (📶).

2. To manage listed events or targeted medical events, click the product's **Row Action menu** (⋮) and select the appropriate command.
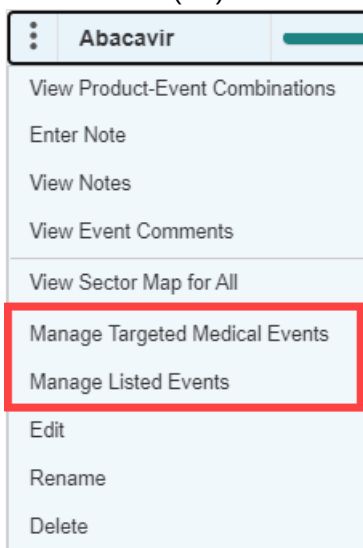
3. To manage designated medical events, click the **Manage Reference Data** menu (☰) in the upper right corner, and select **Manage Designated Medical Events**.

4. Follow the steps in Manage events and custom terms in the *User Guide and Online Help*.

Validate the interactive Vigibase signal configuration

After you specify the list of monitored products and signaling terms for the interactive Vigibase signal configuration, you must validate the configuration to ensure that your changes are valid.

During validation, Oracle Empirica Signal checks the signal configuration to ensure that:

• Referenced data configurations exist.

• Referenced data configurations are valid.

• Referenced variables exist in each data configuration and are of the correct type. For example, Oracle Empirica Signal checks whether event variables in the data configuration are of type *Event*.

• Variables referenced in custom term queries exist in each data configuration you referenced in the signal configuration.

For more information, see the *User Guide and Online Help*.

You must have the Manage Signal Configurations user permission to validate a signal configuration.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Settings** icon ( ).

2. In the Configure System section, click **Manage Signal Configurations**.

3. Click the signal configuration's **Row Action menu** ( ), and then click **Validate**.

4. On the Signal Configuration Validate page, review the list of findings.

5. Click **Continue**.

Refresh an interactive Vigibase signal configuration

You refresh an interactive Vigibase signal configuration to populate the data on the Signal Review page.

To initiate a refresh, you must have the Manage Signal Configuration and Create Data Mining Runs user permissions. For more information, see the *User Guide and Online Help*.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Settings** icon ( ).

2. In the Configure System section, click **Manage Signal Configurations**.

3. Click the interactive Vigibase signal configuration's **Row Action menu** ( ), and then click **Refresh**.

4. On the Refresh Signal Management page, specify when to perform the refresh:

   • **Run as soon as possible**—The refresh is executed immediately.

   • **Do not run until**—The refresh is executed on the date and time that you specify.

5. To receive an email notification when the refresh is complete:

   a. Select the **Email me when complete** check box.

   b. Enter one or more email addresses using a comma to separate each address.

      The email addresses associated with your Oracle Empirica Signal user name appear by default. To change these email addresses, contact your site administrator.

6. Click **Submit**.

   The Refresh Submitted page appears.

7. Click **Continue**.

   The Signal Management Refreshes page appears. The refresh is listed in the table.

   A refresh takes several hours to complete. After the status of the refresh changes to *Completed*, the contents of the Signal Review page are updated.

Make an interactive Vigibase signal configuration available to users

To make an interactive Vigibase signal configuration available to users, you must publish the configuration. Optionally, set the interactive Vigibase signal configuration as the default for login groups.

You must be a superuser to perform the following steps.

1. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Settings** icon (⚙).

2. In the Configure System section, click **Manage Signal Configurations**.

3. Click the interactive Vigibase signal configuration's **Row Action menu** (⋮), and then click **Publish**.

4. Select **Publish to Login Groups** to publish to each login group that will use Vigibase Signal Management (or to **All**).

Optionally, you can make a Vigibase signal configuration the default for each login group that will use it. Note that once the signal configuration is published to login groups, users will be able to select it on the Signal Review page even if it is not the default for their login group.

1. From the left navigation pane, click the **Settings** icon (⚙).

2. In the Manage Users section, click **Edit Login Groups**.

3. Perform the following for each login group to which you published the interactive Vigibase signal configuration:

    a. Click **Edit.**

    b. Select the interactive Vigibase signal configuration in the **Signal Management Configuration** drop-down list.

    c. Click **Save**.

    > ✎ **Note:**
    >
    > To access the Signal Review page and interactive Vigibase Signal Management, users must have at least the View Signal Management permission. Users who are currently logged in to Oracle Empirica Signal must log out and log back in.

4. Proceed to Post install/upgrade.

3

Upgrade Vigibase Signal Management

- Upgrade Vigibase signal configuration from 9.0 to 9.x
  The required upgrade for Vigibase signal management is done as part of the Oracle Empirica Signal 9.0 to 9.x upgrade.

Upgrade Vigibase signal configuration from 9.0 to 9.x

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4

(Recommended) Post install/upgrade

- Post install/upgrade
  After you have performed your first refresh on a signal management configuration, you can start taking advantage of the features introduced in Oracle Empirica Signal 9.0.

Post install/upgrade

After you have performed your first refresh on a signal management configuration, you can start taking advantage of the features introduced in Oracle Empirica Signal 9.0.

To define product property values, edit products, and add or edit alert types, you must have the Manage Signal Configurations, View Signal Management, and Manage Signaling Terms user permissions.

1. Define values for new product fields: **Complexity level**, **Organization**, and **Category**.

   a. Log in to the Oracle Empirica Signal application with Manage Signal Configurations permission.

   b. In the navigation pane on the left, click the **Settings** icon ( ).

   c. In the Configure System section, click **Manage Signal Configurations**.

   d. Click the interactive Vigibase signal configuration's **Row Action menu** ( ), and then click **Edit Product Fields**.

   e. Consult the *User Guide and Online Help* to see additional actions you can perform.

2. Assign values for product fields.

   a. Log in to the Oracle Empirica Signal application as a user with View Signal Management and Manage Signaling Terms permissions.

   b. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Signal Review** icon ( ).

   c. Click a product's **Row Action menu** ( ), and then click **Edit**.

   > ✎ **Note:**
   >
   > Complexity level, Birthdate, and Review period (if enabled) are product properties that can have alert calculation impact.

   d. For details, see the *User Guide and Online Help*.

3. Add/edit/activate alert types for the next refresh:

   a. Log in to the Oracle Empirica Signal application as a user with Manage Signal Configurations and View Signal Management permissions.

    b. In the Oracle Empirica Signal application, in the navigation pane on the left, click the **Settings** icon ( ).

    c. In the Configure System section, click **Manage Signal Configurations**.

    d. Click an interactive Vigibase signal configuration's **Row Action menu** ( ), and then click **Edit Alert Types**.

    e. You can:

        i. Add an alert type.

        ii. Edit an existing alert type, including designating an alert type as tracked or informational.

        iii. Activate or deactivate an alert type for the next refresh.

    f. For details, see the *User Guide and Online Help*.

4. You must refresh the Oracle Empirica Signal configuration to reflect all the changes made.

5

(Optional) Convert a scripted Vigibase configuration to interactive

- Convert a scripted Vigibase signal configuration to interactive
  Follow the steps in this topic only if you have scripted Vigibase Signal Management and want to convert to interactive Vigibase Signal Management. After the conversion, you must no longer use the scripted Vigibase signal configuration.

Convert a scripted Vigibase signal configuration to interactive

Follow the steps in this topic only if you have scripted Vigibase Signal Management and want to convert to interactive Vigibase Signal Management. After the conversion, you must no longer use the scripted Vigibase signal configuration.

The conversion will preserve:

- Monitored product list with product properties.
- Keep under review (KUR) events, which are referred to as Targeted Medical Events (TMEs) in interactive Signal Management.
- Listed (labeled) events.
- Designated medical events.
- Custom product and event terms.
- Reviewer assignments for product and product-event combinations.
- Custom comment types.
- Comment history (both public and private) for product-event combinations.
- Associated topics for product-event combinations.
- Drug notes.
- Custom views for the Product-Event Combinations page, including publication status.
- Configured alert types.
- Signal configuration properties including name, description, integrated topic workflow configuration and topic product field, default view, and properties for runs including the drug variable, event variables for 2D and 3D runs, stratification and subset variables, and the project for runs.

The conversion will not preserve:

- Customizations to Drug Overviews column labels, tooltips, or to associated views.
- Customizations to Product-Event Combinations column labels or tooltips.
- Information that distinguishes *Ongoing* from **NEW** alerts.
  Following the first refresh after conversion, all alerts appear as **NEW**. The Oracle Empirica Signal application makes the distinction between *Ongoing* and **NEW** for subsequent refreshes.

- KUR Only events.
  Interactive Vigibase Signal Management cannot limit the events monitored for a drug to only those that are in the Keep Under Review list. All events will be monitored.

- Any changes not yet processed in a refresh of your scripted Vigibase Signal Management. For example, drugs to add, rename, or delete; or changes to listed (labeled), designated medical, or KUR events.

To run a conversion, you will need the signal configuration ID of the existing scripted Vigibase Signal Management and the signal configuration ID of a freshly installed interactive Vigibase Signal Management.

When you are ready to initiate the conversion, verify that all Vigibase Signal Management users are logged out, and then unpublish the scripted Vigibase signal configuration as follows:

1. Log in to the Oracle Empirica Signal application as a superuser.

2. In the navigation pane on the left, click **Settings** ( ).

3. Click the scripted Vigibase signal configuration's **Row Action menu** ( ), and then click **Publish**.

4. Click **Remove** on each row under Publication Level.

   The text *This Signal Configuration is marked as Private* appears.

Perform these steps using the non-privileged user account on the aplications server.

1. Navigate to the vigibase_ism_prep/SSM_to_ISM_update directory, for example:

   ```
   $ cd /u01/stage/projects/vigibase_ism_prep/SSM_to_ISM_update
   ```

2. Execute the following command to give execute permissions to all .sh files:

   ```
   $ chmod u+x convert_SSM_to_ISM.sh
   ```

3. Execute the following command to give execute permissions to all .sh files:

   ```
   $ ./convert_SSM_to_ISM.sh <signal database account name> <TNS_name>
   <scripted Vigibase ID> <interactive Vigibase ID>
   ```

   For example:

   ```
   $ ./convert_SSM_to_ISM.sh WEBVDME ORCL 0 2
   ```

   A password prompt for VIGIBASE_SIGNAL_PREP appears.

4. Enter `<password>`, where `<password>` is the VIGIBASE_SIGNAL_PREP account password.

   A password prompt for the Oracle Empirica Signal database user account, such as WEBVDME, appears.

5. Enter `<password>`, where `<password>` is the Oracle Empirica Signal database user account password.

   When the conversion is done, the message, *Conversion for signal management objects completed*, appears.

   The `conversion.log` file is created.

The conversion sets the properties for the data configuration for 2D and 3D runs to relevant aliases. For example, if scripted Signal Management used the yyyyQn:

Vigibase (S) data configuration for 2D runs, then the conversion sets the 2D data configuration in the interactive signal configuration to Latest Vigibase (S). If scripted Signal Management used yyyyQn: Vigibase (S + C), then the conversion sets the interactive signal configuration to Latest Vigibase (S + C).

6
Change log

Date	Part number	Description
April 2023	F71145-01	- Updated version numbers and file names. - Modified files distributed with application. - Updated procedure for publishing the signal configuration to your login group. .
November 2021	F46289-01	9.2.0 release.
Mary 2021	F42416-01	Original version of this document (9.1.0.4 release).