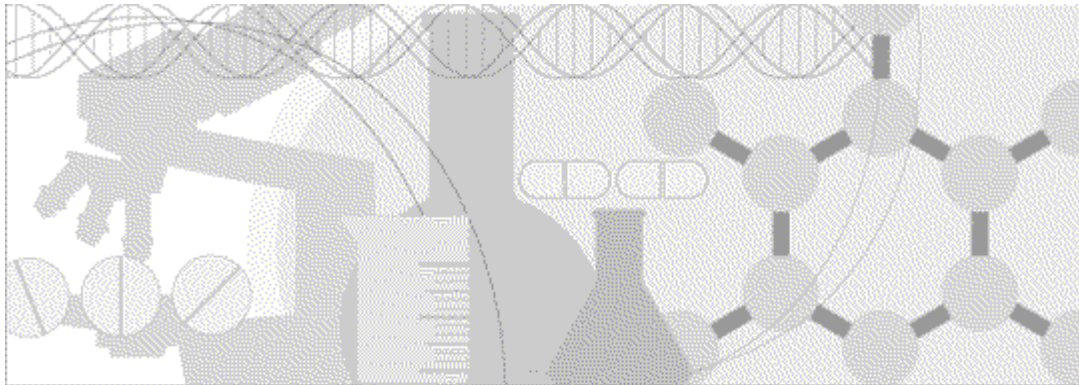


Installation Instructions

Oracle[®] Health Sciences Argus Mart Data and Argus Signal Management for Use with Empirica Signal 8.1



ORACLE[®]

Part number: E70267-01

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CHAPTER 1

Argus Mart data and Argus signal management installation overview

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About the installation process

The Empirica Signal application supports data from the Argus Mart application. Users access the data in Empirica Signal by using the Argus Mart data configurations. For example, users can reference the Argus Mart data configurations when creating data mining runs, queries, case series, and reports for ad hoc analyses.

Additionally, if your organization is licensed for Signal Management, users can employ the signal management feature in Empirica Signal on the data. The feature facilitates the ongoing monitoring of safety signals by enabling users to perform statistical analyses on successive updates of safety data. Users employ the feature by using the Argus Mart signal management configuration to populate the Signals tab. For more information, see the *User Guide*.

The installation process for the Argus Mart data configurations includes:

- Updating Argus Mart 8.0 (or higher) for use with Empirica Signal 8.1.
- Setting up the Argus data configurations on the Empirica Signal application server.

The installation process for the Argus Mart signal management configuration includes:

- Installing the Argus Mart signal management configuration on the Empirica Signal application server.
- Configuring the PL/SQL custom procedure to run from the Argus ETL hook.
- Configuring the Empirica Signal application to enable the signal management feature.

Before you begin

You need:

- An Argus Mart in which ETL has been run.
- Access to the Argus Mart 8.0 update for Empirica Signal 8.1 distribution media, which contains:
 - **Update_AM_8_0_for_Signal_8_1_0_0_xxx.zip**—A Zip archive file.
 - **Empirica_Signal_Argus_Installation.pdf**—This document in PDF format.
 - **Oracle Health Sciences Argus Mart Data Release Notes 8.0.pdf**.
 - **Argus_Prep_2_0_0_0_xxx.zip**—A Zip archive file. Optional for Argus Signal Management.
- The user name, password, and TNS name of the system, AM_MART_USER, and webvdme database user accounts.
- The user name and password associated with a non-privileged user account on the Empirica Signal application server.
- The MedDRA version used for each time period in the data.
- The user name and password associated with an administrator account on the Oracle WebLogic Server Administration console.

CHAPTER 2

Setting up the Argus Mart data configurations in Empirica Signal

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About the Argus Mart data configurations

You set up the following Argus Mart data configurations:

- ARGUS (S)
- ARGUS (S+C)
- Argus Spontaneous (S)
- Argus Spontaneous (S+C)

The data configurations provide access to the cases in the database tables that you can analyze using Empirica Signal. For example, the Argus Spontaneous (S+C) data configuration includes only spontaneous reports from Argus Mart, but both suspect and concomitant drug records for those cases.

Copying release notes to the /relnotes directory

Make the Argus Mart Data Release Notes available from the Contents tab in the *User Guide*.

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

- 1 On the distribution media, locate the **Oracle Health Sciences Argus Mart Data Release Notes 8.0.pdf** file.
- 2 Copy the file to the **<INSTALL_DIR>/relnotes** directory on the Empirica Signal application server, for example:

```
$ cp Oracle Health Sciences Argus Mart Data Release Notes 8.0.pdf
/u01/stage/Signal_Install/Signal/relnotes
```

If the file already exists in the directory, replace the file.

- 3 Redeploy the Empirica Signal WebLogic Server instance:
 - a In an Internet browser, navigate to the Oracle WebLogic Server Administration Console, for example:

```
https://<servername>:7002/console
```
 - b Log in using the administrator credentials provided to you by the system administrator.
 - c In the Domain Structure pane, click **Deployments**.
 - d In the Change Center pane, click **Lock & Edit**.
 - e In the Deployments table, select **Signal**.
 - f Click **Update**.
 - g Click **Finish**.
 - h In the Change Center pane, click **Activate Change**.

The deployment is updated.

Installing MedDRA accounts on the Empirica Signal database

Data from the Argus Mart application is timestamped. Therefore, you must create a MedDRA user account for each version of MedDRA used to code the data.

You create the user accounts using the **MedDRAxxx.zip** files provided by Oracle. **xxx** indicates the version of MedDRA. For example, the **MedDRA150.zip** file is for MedDRA version 15.0.

If a user account already exists on the database server for a given version of MedDRA, do not recreate the account.

For each MedDRA account that you need to create, perform these steps using the non-privileged user account on the application server.

- 1 Copy the **MedDRAxxx.zip** file from the distribution media to a temporary directory on the server.
- 2 Unpack the **MedDRAxxx.zip** file into a temporary directory, for example:


```
$ unzip MedDRAxxx.zip -d /u01/stage/
```

The **/MedDRAxxx** subdirectory is created.
- 3 Navigate to the **/MedDRAxxx** directory, for example:


```
$ cd /u01/stage/MedDRAxxx
```
- 4 Using a text editor, open the **Create_MedDRA.sql** file.
- 5 Locate the **DEFINE ORACLE_DBF_FILE** statement.
- 6 Edit the path in the **DEFINE ORACLE_DBF_FILE** statement to point to the location of the Oracle tablespace data files.

The path can point to any existing location on the application server. However, the Oracle tablespace data files are usually located in the **/oradata** subdirectory of the Oracle Database installation directory.

- 7 Optionally, change the password.
- 8 Save and close the file.
- 9 Execute the **Create_MedDRA.sql** script as the **system** user to create the **MEDDRAxxx** tablespace and user account, for example:

```
$ sqlplus system@<TNS_name> @Create_MedDRA.sql
```

A password prompt appears.

- 10 Type the **system** database account password, and press **Enter**.
- 11 Execute the **imp** command to populate the MedDRA tablespace you created in a previous step, for example:

```
$ imp userid=MEDDRAxxx@<TNS_name> file=MEDDRAxxx.dmp full=Y
Log=Imp_MEDDRAxxx.log
```

A password prompt appears.

- 12 Type a password for the **MEDDRAxxx** database account, and press **Enter**.

Updating Argus Mart 8.0 for use with Empirica Signal 8.1

For Argus Mart 8.0 and higher, perform these steps using the non-privileged user account on the application server.

- 1 Copy the **Update_AM_8_0_for_Signal_8_1_0_0_xxx.zip** file from the distribution media to a temporary directory on the server.
- 2 Unpack the **Update_AM_8_0_for_Signal_8_1_0_0_xxx.zip** file into a temporary directory, for example:

```
$ unzip Update_AM_8_0_for_SIGNAL_8_1_0_0_xxx.zip -d /u01/stage/
```

The **/UPDATE_AM_8_0_FOR_SIGNAL_8_1** subdirectory is created.

- 3 Navigate to the **/UPDATE_AM_8_0_FOR_SIGNAL_8_1** directory, for example:

```
$ cd /u01/stage/UPDATE_AM_8_0_FOR_SIGNAL_8_1
```

- 4 Using a text editor, open the **create_argus_spontaneous_configurations.sql** file.
- 5 Locate the following **WHERE** clause:

```
WHERE UPPER (report_type_ve) IN ('SPONTANEOUS','LITERATURE')
```

The **WHERE** clause describes the spontaneous reports from the Argus Mart database user account.

- 6 Modify the **WHERE** clause as needed.
- 7 Save and close the file.
- 8 Execute the **UPDATE_AM_8_0_FOR_SIGNAL_8_1.sql** script as the **am_mart_user**, for example:

```
$ sqlplus am_mart_user@<TNS_name> @UPDATE_AM_8_0_FOR_SIGNAL_8_1.sql
```

A password prompt appears.

- 9 Type the **am_mart_user** database account password, and press **Enter**.

Loading the Argus Mart data configurations into the Empirica Signal application

You load the following data configurations into Empirica Signal to enable users to work with data from the Argus Mart application:

- **ARGUS (S)**
- **ARGUS (S+C)**
- **Argus Spontaneous (S)**
- **Argus Spontaneous (S+C)**

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

- 1 Navigate to the `/u01/stage/UPDATE_AM_8_0_FOR_SIGNAL_8_1` directory, for example:

```
$ cd /u01/stage/UPDATE_AM_8_0_FOR_SIGNAL_8_1
```

- 2 Execute the `@init_configuration_account.sql` script as the **system** user and provide the Empirica Signal and Argus Mart database user accounts on the command line:

```
$ sqlplus system@<TNS_name> @init_configuration_account.sql webvdme  
AM_MART_USER
```

The script enables Empirica Signal to import the Argus Mart data configurations from the `am_mart_user` database user account without requiring Empirica Signal users to enter the database user account password.

A password prompt appears.

- 3 Type the **system** account password, and press **Enter**.
- 4 Log in to the Empirica Signal application as a user with the Manage Configurations user permission.
- 5 Click **Settings**.
- 6 Click **Manage Configurations**.
- 7 Click **Import Configurations**.
- 8 Below the list of database user accounts, click **Import Configurations from a Different Account**.
- 9 In the Oracle account field, type **AM_MART_USER**.
- 10 Specify a database group. For example, AM Mart.
- 11 Click **OK**.
- 12 Verify that the four Argus Mart data configurations are listed on the Manage Configurations page.

Specifying the version of MedDRA used for each time period in the Argus Mart data

You must specify the MedDRA version used for each time period in the data. A time period is a range of dates during which only one MedDRA version was used to code the data.

For example, suppose that the Argus Mart data includes the following rows:

Case ID	Start	Stop
100	01-01-2004	06-01-2004
200	06-01-2004	01-01-2005
300	01-01-2005	

Additionally, suppose that different versions of MedDRA were used to code the Argus Mart data:

- MedDRA version 6.1 was used until June 1, 2004.
- MedDRA version 7.0 was used between June 1, 2004 and January 1, 2005.
- MedDRA version 7.1 was used starting January 1, 2005.

You would specify the version of MedDRA used for each time period as described in this procedure.

- 1 In an Internet browser, navigate to the Empirica Signal login page.
- 2 Log in to the Empirica Signal application as a user with the Manage Configurations user permission.
- 3 Click **Settings**.
- 4 Click **Manage Configurations**.
- 5 Click the row menu for one of the Argus Mart data configurations, and select **Edit**.

The Modify Configuration page appears.

- 6 In the top table, click **Edit** in the far right column for the data configuration.

The Edit Configuration Details page appears.

- 7 In the **Event Hierarchy Version Table** field, click **Select/Edit Table**.

The Event Hierarchy Accounts for Configuration window appears.

- 8 To specify only one MedDRA version for all of the Argus Mart data, type the Empirica Signal database account name for the MedDRA version in the first row of the Hierarchy Account column, for example:

	Date	Hierarchy Account
ALL DATES	<input type="text"/>	MEDDRA61
	<input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>
	<input type="text"/>	<input type="text"/>

- 9 To specify a different MedDRA version for each time period in the Argus Mart data:
 - a In the first row of the **Date** column, type the last date of the earliest time period.
The date must be in *mm/dd/yyyy* format.

Note: Each date includes a time stamp of 12:00:00 a.m. unless you specify a time stamp. For example, if you specify that MedDRA version 6.1 was used until (<=) 06/01/2004 and MedDRA version 7.0 was used thereafter, then MedDRA 7.0 is applied to source data coded at 12:00:01 a.m. on June 1, 2004.

- b In the first row of the **Hierarchy Account** column, type the MedDRA account name.
- c Fill in one row for each time period in the Argus Mart data, for example:

Define Effective Dates for the Event Hierarchy Accounts

	Date	Hierarchy Account
DATE <=	06/01/2004	MEDDRA61
06/01/2004 < DATE <=	01/01/2005	MEDDRA70
01/01/2005 < DATE		MEDDRA71

Add additional empty rows upon saving

Save Cancel

If you need additional rows, you can select Add additional empty rows upon saving, and click Save.

For the last time period, type only the Oracle database account name for the MedDRA version.

- 10 Click **Save**.

Validating the Argus Mart data configurations

Validate the Argus Mart data configurations before you attempt to publish the configurations. For more information about the validation process, see the *User Guide*.

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

- 1 In the Empirica Signal application, click **Settings**.
- 2 Click **Manage Configurations**.
- 3 Click **Validate Configurations**.
- 4 Select the Argus Mart data configurations:
 - **ARGUS (S)**
 - **ARGUS (S+C)**
 - **Argus Spontaneous (S)**
 - **Argus Spontaneous (S+C)**
- 5 Click **Validate**.

After a few moments, a confirmation message appears.

- 6 Click **Continue**.

Publishing the Argus Mart data configurations

Publish the Argus Mart data configurations to the login groups and users that require access to the configurations.

- 1 Click **Settings**.
- 2 Click **Manage Configurations**.
- 3 Click **Select Rows**.
- 4 Select the Argus Mart data configurations:
 - **ARGUS (S)**
 - **ARGUS (S+C)**
 - **Argus Spontaneous (S)**
 - **Argus Spontaneous (S+C)**
- 5 Click **Publish**.
- 6 Set the group and individual permissions for the configuration.
- 7 Click **Save**.

A confirmation message appears.
- 8 Click **Continue**.

Attaching PL/SQL Custom Procedure to Argus ETL Hook

Argus Mart provides ETL Hooks for custom procedures that can be used to extend the existing behavior of the Argus Mart ETL. Follow the steps below to configure the **CUSTOM ROUTINE AFTER ETL** hook.

- 1 Log in to the Argus Safety application.
- 2 From the menu bar, click **Argus Console**.
The menu bar updates for Argus Console
- 3 From the new menu bar, click **System Configuration**.
- 4 Click **System Management** (Common Profile Switches).
On the left side of the screen, a list of all system-managed common profile switches appears.
- 5 Expand the Common Profile folder, and click **Argus Mart**.
The Modify Argus Mart page appears.
- 6 Navigate to the CUSTOM ROUTINE AFTER ETL hook, and enter:
`Empirica_Utils.Populate_smqmap_casescore`

For additional information about custom procedures with Argus Mart, see the *Argus Mart Extensibility Guide*.

CHAPTER 3

Installing and configuring the Argus Mart signal management configuration

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About the Argus Mart signal management configuration

The Argus Mart signal management configuration defines the behavior and content of the Signals tab in the Empirica Signal application. For example, the signal management configuration specifies the variables the application uses for data mining runs. For more information, see the *User Guide*.

When you install the Argus Mart signal management configuration, queries are created in the Argus Signal Mgmt project. Each query is a specification for retrieving a subset of cases from a data configuration in data mining runs.

Installing the Argus Mart signal management configuration

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

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

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

- 2 Copy the **Argus_Prep_2_0_0_0_xxx.zip** file from the distribution media to:

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

- 3 Unpack the **Argus_Prep_2_0_0_0_xxx.zip** file into a temporary directory, for example:

```
$ unzip Argus_Prep_2_0_0_0_xxx.zip -d /u01/stage/projects/
```

The **/argus_prep** subdirectory is created.

- 4 Navigate to the **/argus_prep/sigdet** directory, for example:

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

- 5 Execute the **main_install_sigmgmt.sh** script to initiate the installation:

```
$ main_install_sigmgmt.sh <signal database account name>@<TNS_name>
```

where *<signal database account name>* is the Empirica Signal database user account name, for example, **webvdme**, and *<TNS_name>* is the TNS name that the application server uses to access the *<db>* server.

A password prompt appears.

- 6 Type **<password>**, where **<password>** is the Empirica Signal database user account password.

A second password prompt appears.

- 7 Retype **<password>**.

The database tables for the Argus Mart signal management configuration are populated. The **install_sigmgmt.log** file is created in the **sigdet/sigmgmt/install/log** subdirectory.

Note: If you type 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".**

If the following error message appears, the **Argus Signal Mgmt** project already exists:

```
ERROR at line 1:
ORA-00001: unique constraint (WEBVDME.UC_PROJECTS1) violated
```

You can disregard the error.

Note: To create more than one Argus Signal Management configuration for Argus Mart, repeat step 5.

Enabling signal management in the Empirica Signal application

Enable the **Show "Signals" tab** site option to turn on the signal management features in Empirica Signal.

For more information, see the *User Guide*.

- 1 Log in to the Empirica Signal application as a superuser.
- 2 Click **Settings**.
- 3 Click **Set Site Options**.
- 4 Select **Show "Signals" tab**.
- 5 Optionally, set the following signal management options:
 - Allow Free Text Signal Comments
 - Notes for Signal Management Interactions Graph
 - Drug-event combination comment length
- 6 Click **Save**.

Editing the Argus Mart signal management configuration

Review the default settings of the Argus Mart signal management configuration and change the settings as needed.

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

- 1 In the Empirica Signal application, click **Settings**.

- 2 Click **Manage Signal Configurations**.

The Manage Signal Configurations page appears.

- 3 Click the row menu for the Argus Mart signal management configuration you created in the previous procedure, and then click **Edit**.

The Edit Signal Configuration page appears.

- 4 Fill in the fields.

For more information, see the *User Guide* by clicking the Help link on the page.

- 5 Click **Save**.

Empirica Signal validates the signal configuration. Warnings and errors are displayed at the top of the page.

Managing monitored drugs and signaling terms

The interactive signal management features in Empirica Signal enable you to define aspects of the Argus Mart signal management configuration such as:

- The drugs to monitor.
- Custom terms and designated medical events for the signal configuration.
- Targeted medical events and listed events for a monitored drug.

You must have the Manage Signaling Terms user permission to modify the list of monitored drugs and signaling terms.

- 1 In the Empirica Signal application, click **Signals**.

The Drug-Event Combinations page appears.

- 2 Click **Drug Overviews**.

The Drug Overviews page appears.

- 3 Edit the list of monitored drugs and signaling terms as needed.

For more information, see the *User Guide* by clicking the Help link on the page.

Validating the Argus Mart signal management configuration

After you specify the list of monitored drugs and signaling terms for the Argus Mart signal management configuration, you validate the configuration to ensure that your changes are valid.

During validation, Empirica Signal checks the signal management 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, 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 management configuration.

For more information, see the *User Guide*.

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

- 1 In the Empirica Signal application, click **Settings**.
- 2 In the Configure System section, click **Manage Signal Configurations**.
- 3 Click the row menu for the signal configuration, and then click **Validate**.

The Signal Configuration Validation page appears.

- 4 Review the list of findings.
- 5 Click **Continue**.

Refreshing the Argus Mart signal management configuration

Refresh the Argus Mart signal management configuration to update the data in the Empirica Signal Signals tab.

For more information, see the *User Guide*.

You must have the Manage Signal Configuration and Create Data Mining Runs user permissions to initiate a refresh.

- 1 In the Empirica Signal application, click **Settings**.
- 2 Click **Manage Signal Configurations**.
- 3 Click the row menu for the Argus Mart signal management configuration, and then click **Refresh**.
The Refresh Signal Management page appears.
- 4 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 Type one or more email addresses using a comma to separate each address.
The email addresses associated with your 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.

The time for the refresh to complete varies based on the size of your Argus Mart data. After the status of the refresh changes to Completed, the contents of the Signals tab is updated.

About the documentation

Where to find the product documentation

The product documentation is available from the following locations:

- **My Oracle Support** (<https://support.oracle.com>)—*Release Notes* and *Known Issues*.
- **Oracle Technology Network** (<http://www.oracle.com/technetwork/documentation/hsgbu-154445.html>)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

If the software is available for download, the complete documentation set is available from the Oracle Software Delivery Cloud (<https://edelivery.oracle.com>).

All documents may not be updated for every Empirica Signal release. Therefore, the version numbers for the documents in a release may differ.

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

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Documentation

Item	Description	Part number	Last updated
<i>Release Notes</i>	The <i>Release Notes</i> document provides descriptions of new features, enhancements, and bug fixes as well as system requirements.	E60410-01	8.1
<i>Known Issues</i>	The <i>Known Issues</i> document provides detailed information about the known issues in the release, along with workarounds, if available.	E70268-01	8.1
<i>User Guide and Online Help</i>	The <i>User Guide and Online Help</i> provides step-by-step instructions on how to use the Empirica Signal and Empirica Topics applications to perform statistical analyses of safety data.	E70269-01	8.1
<i>Installation and Upgrade Guide</i>	The <i>Installation and Upgrade Guide</i> document provides instructions on how to install and configure the environment for the Empirica Signal software.	E60411-01	8.1
<i>Secure Configuration Guide</i>	The <i>Secure Configuration Guide</i> provides guidance and recommendations on securely installing, configuring, and managing the Empirica Signal software and its system components.	E60408-01	8.1
<i>Topics API Guide</i>	The <i>Topics API Guide</i> describes how to integrate a proprietary application with Empirica Topics.	E77813-01	8.1
<i>Topics Reporting and Oracle Business Intelligence Configuration Guide</i>	The <i>Topics Reporting and Oracle Business Intelligence Configuration Guide</i> provides system requirements and configuration instructions for integrating OBIEE with the Empirica Signal application.	E60409-01	8.1
<i>Argus Mart Data and Argus Signal Management Installation Instructions</i>	The <i>Argus Mart Data and Argus Signal Management Installation Instructions</i> describe how to import proprietary data maintained in Argus Mart to Empirica Signal and how to install and configure Argus signal management.	E70267-01	8.1
<i>Argus Mart Data and Argus Signal Management Release Notes</i>	The <i>Argus Mart Data and Argus Signal Management Release Notes</i> describe new features, enhancements, and bug fixes to the Argus Mart data configurations for Empirica Signal. They also document the Argus Mart data tables available to Empirica Signal and the default signal management configuration.	E76553-01	8.1

Item	Description	Part number	Last updated
<i>Third Party Licenses and Notices</i>	The <i>Third Party Licenses and Notices</i> document includes licenses and notices for third party technology that may be included or distributed with the Empirica Signal software.	E78170-01	8.1
