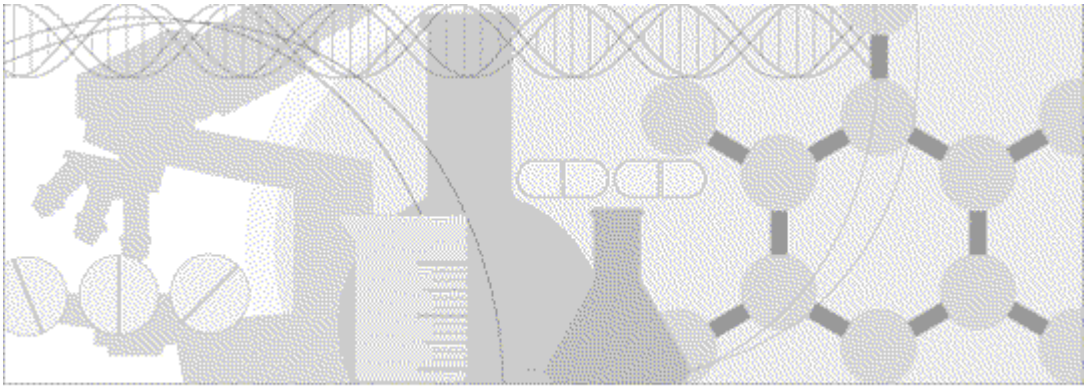
Specification for the Mortara E-Scribe Interface

Oracle® Health Sciences LabPas
Release 3.1



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Overview of this guide

The *Specification for the Mortara E-Scribe Interface* provides the information needed to set up jobs and import Mortara ECG files. The LabPas application uses the Mortara E-Scribe interface, as described in this guide, to import Mortara ECG results to the LabPas database.

This document includes a checklist that outlines the workflow, criteria for selecting orders to export, validation criteria for importing result files, and a detailed specification of the LabPas Mortara E-Scribe file formats.

Audience

This guide is for Oracle® Health Sciences LabPas users and outside lab system users who set up, configure, and monitor the import of data using the Mortara E-Scribe interface. This audience includes the LabPas administrator, study manager, or others who are assigned these tasks at your facility.

Documentation

All documentation is available from the Oracle Software Delivery Cloud (https://edelivery.oracle.com) and the Oracle Technology Network (http://www.oracle.com/technetwork/documentation).

All documents may not be updated for every LabPas release. Therefore, the version numbers for the documents in a release may differ. For a complete list of the documents in this LabPas release, their release version numbers, and part numbers, see the *Release Notes*.

Item	Description	Last updated
Release Notes	The *Release Notes* document presents information about new features, enhancements, and updates for the current release.	3.1
Known Issues	The *Known Issues* document presents information about known issues for the current release.	3.1
User Guide	The *User Guide* provides online access to all tasks you can perform from the LabPas application, as well as supporting concepts and reference information. You can access the *User Guide* from the Help button in the LabPas application.	3.1
Administration Guide	This guide provides a roadmap for configuring and setting up the LabPas application, setting up the LabPas Recruiting module, and viewing and printing reports. This guide contains step-by-step instructions and field definitions you can use to perform tasks such as setting up roles and permissions; setting up various aspects of a facility, such as instruments, samples, and vessels; and configuring the LabPas user interface and messaging.	3.1
Clinical Trial Design and Resource Management Guide	This guide provides a roadmap and step-by-step instructions for a variety of tasks, such as creating clinics, creating studies, planning clinic schedules, planning staff assignments, configuring and setting up the LabPas application, designing a clinical trial and recruitment, and viewing and printing reports and labels.	3.1
Recruiting User Guide	This guide provides step-by-step instructions for setting up and managing recruitment, including adding and contacting volunteers, scheduling, managing advertising campaigns, and performing other related operations. It also includes instructions for screening volunteers in a clinical trial.	3.1
Sample Management Guide	This guide provides step-by-step instructions for processing and tracking samples in the lab.	3.1
Clinical Data Entry Guide	This guide describes how to use the LabPas application to accomplish the typical tasks you would perform while gathering data during a clinical trial. It contains step-by-step instructions and field definitions you can use to perform data entry while capturing data about doses, samples, tests, adverse events, and other observations.	3.1

Item	Description	Last updated
Data Qualification Guide	This guide provides step-by-step instructions for reviewing data that is collected in LabPas CT studies.	3.1
Installation Guide	This guide provides step-by-step instructions for installing the LabPas application.	3.1
Secure Configuration Guide	This guide provides essential secure configuration considerations for the LabPas application.	3.1
Ad Hoc Reports Database Views Guide	This document provides details of the database views used in ad hoc reports. The descriptions include the details of each view as well as corresponding fields where you can verify data.	3.1
Specification for the HL7 Lab Data Interface	This document provides the information that is needed to set up jobs and exchange files automatically between LabPas facilities and the labs that process their samples.	3.1
Specification for the Mortara E-Scribe Interface	This document provides the information needed to set up jobs and import Mortara ECG files.	3.1
Third Party Licenses and Notices	This document includes licenses and notices for third party technology that may be included in or distributed with the LabPas software.	3.1

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CHAPTER 1

LabPas lab interface processing overview

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Setup of the LabPas and lab applications

General setup requirements

The LabPas application and the laboratory system must be configured to import Mortara ECG files using the Mortara E-Scribe interface:

- The LabPas application automatically sets up a default Mortara E-Scribe import directory. If you want to use a different base import directory, ask your LabPas administrator to set up a different directory structure.
- A system administrator configures the lab system to read and write from the base directory.

Within the LabPas application:

- A LabPas administrative user specifies the job schedule for importing Mortara ECG results.
- Each instance of the interface is configured on the Facility page, and it can be assigned to a clinical lab sample type during study setup. You can use multiple clinical labs for a single study.

Mortara E-Scribe setup requirements

Ensure the following actions are performed:

- Set the Test Code 2 value of the corresponding LabPas test to the Attribute Name value from the result XML (for example, R_PEAK).
- Set the Test Code 2 value of the test associated with the automatic (or machine) interpretation to **AUTO_INTERPRETATION**. This test should be set up as a Long Text test.
- Set the Panel Code 2 value for the Mortara ECG panel to **MORTARA**.

Checklist - Importing data using the LabPas Mortara E-Scribe interface

☑		Workflow step	Performed by	Where to get more information
❑	1	Configure system to allow the LabPas application read access to the Mortara E-Scribe import directories.	System administrator	***Setting up the lab import and export feature*** (in the *Installation Guide*).
❑	2	Enable the lab interfaces option in the sql.properties file.	System administrator	***Setting up the lab import and export feature*** (in the *Installation Guide*).
❑	3	Set up lab interfaces for each facility that imports Mortara results.	LabPas administrator	***Jobs*** (in the *Administration Guide*)

☑		Workflow step	Performed by	Where to get more information
❑	4	Monitor activity and troubleshoot as necessary.	LabPas administrator	Errors can be found in the Import Log.
❑	5	Review and approve lab results.	Principal investigator or delegate	***Reviewing results for a clinical event*** (in the *Clinical Trial Design and Resource Management Guide*)

Importing results from an external lab system

At configured intervals, the following actions automatically occur in the LabPas application:

1 A connection to the file import location (<*lab_interface_base_directory*>/<*lab_name*>/import/) is established. If a file connection cannot be made:

- An import error appears and is logged to the Import Log. The import function is terminated.
- The file is moved to an import error folder located in the import directory, (<*lab_interface_base_directory*>/<*lab_name*>/import/errors).

2 Each file is imported using the lab interface that was specified in the study setup

3 Each file is validated. For more information, see ***Import file validation*** (on page 5).

4 If a result already exists in the LabPas database, the database result value is overwritten with the new values. For more information, see the ***Import file validation*** (on page 5).

You can import Mortara ECG results manually, using the **IMPORT** button. Manual import jobs are used primarily for troubleshooting purposes.

Import file validation

Mortara ECG files are eligible for import if:

- The results it contains are not for a test that is part of a locked study, group, period, or visit.
- The Mortara interface is associated with its sample type and facility for the study.
- The file contains data for a single ECG.

Note: If sample logging is enabled, the sample that the result is associated with is logged.

If the file passes validation requirements, the LabPas application:

1 Matches the participant identifier (Screening Number, Subject Number or VRN) to the sample barcode. If the sample barcode and the participant identifier do not match a valid event associated to an ECG panel, the file is rejected.

2 Checks Numeric test results against numeric reference ranges configured in the LabPas application. Text and Long Text test results are not checked against a reference range.

Note: The LabPas application assumes that if a test is defined as Numeric, only numeric results will be found. If non-numeric values are likely to appear in the import results, the test should be set up as Text or Long Text, or the file will be rejected.

3 Checks the sample barcode for a maximum length of 20 characters. If the sample barcode is longer than 20 characters, the file is rejected.

4 Checks the machine interpretation for a maximum length of 2,000 characters. If the machine interpretation is longer than 2,000 characters, the file is rejected.

5 Stores all imported result values, LabPas reference ranges, and LabPas-generated alert codes associated with the sample.

The LabPas application schedules repeat tests and imports repeat test results. If a duplicate file with the same participant identifier and sample barcode is loaded, the import process checks the Acquisition Time value before proceeding:

- If the Acquisition Time is prior or equal to the time in the previously loaded file, the file is rejected.
- If the Acquisition Time is later than the time in the previously loaded file, all results are overwritten and an audit record is saved to the Change Log. Comments and clinical significance flags are not modified.
    - If an imported lab record has an Approval Status of Approved:
        - The Approval Status for the sample is set to Not Approved.
        - The Approval Date and Approved By fields are cleared.
        - An entry is recorded in the appropriate Change Log (SR or CT) with a source of Study Data Approval.
        - The comment for the audit record states that approved data has changed.

- If an imported lab record has a Monitor Review Status of Reviewed:
  - The Monitor Review Status for the sample is changed to Not Reviewed.
  - An entry is recorded in the appropriate Change Log (SR or CT) with a source of Study Data Approval.
  - The comment for the audit record states that reviewed data has changed.
- If an imported lab record is associated with a screening sample:
  - The Eligibility Review for the participant associated with the sample is set to Pending if the Eligibility Review was set to Completed.
  - An entry will be recorded in the Recruiting Change Log with a source of Study Participant Approval.
  - The comment for the audit record states that approved data has changed.

An audit trail of the import process is recorded in the Import Log, regardless of the import job outcome:

- If the import completes successfully, the imported file is deleted from the import location.
- If the file fails validation, it is moved to the import error directory.
- If the results cannot be imported due to system/connectivity issues, the file is not deleted and the system retries the import job.

CHAPTER 2

LabPas Mortara E-Scribe specification

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LabPas Mortara E-Scribe file format

Mortara files consist of the following segments:

- **ECG**— The ECG record is required and non-repeating. The ECG record contains the ACQUISITION_TIME value.
- **ACQUISITION_TIME**— The ACQUISITION_TIME record contains the date and time the ECG waveforms were recorded, in the yyyyMMddHHmmss format. It is a required, non-repeating element for Mortara files and is stored as both the Test Date and Test Time values.
- **DEMOGRAPHIC_FIELD**—The DEMOGRAPHIC_FIELD record contains the subject's demographic information. IDs 2 and 17 are required.
  - The DEMOGRAPHIC_FIELD ID="2" record contains the participant identifier (Subject Number, Screening Number, or VRN). The Screening No. and Subject No. values contain the Study ID prefix. This value is used in conjunction with the sample barcode to validate the file.
  - The DEMOGRAPHIC_FIELD ID="17" record contains the LabPas sample barcode value. The sample barcode must match an actual sample within the LabPas application.
- **STATEMENT**— The STATEMENT record contains the automatic interpretation statement, is required, and can repeat. Each repeated record has an incremented STATEMENT_NUMBER attribute.
- **TYPICAL_CYCLE**— The TYPICAL_CYCLE record contains the actual ECG information, is required and is non-repeating. Each TYPICAL_CYCLE attribute must match the Test Code 2 value for the appropriate ECG panel. The validated data is imported as the ECG result for the test.

The format is:

```
<ECG>
   <DEMOGRAPHIC_FIELD />
   <SITE />
   <SUBJECT />
   <SOURCE />
      <AUTOMATIC_INTERPRETATION>
         <STATEMENT />
      </AUTOMATIC_INTERPRETATION>
   <TYPICAL_CYCLE>
   </TYPICAL_CYCLE>
</ECG>
```

The following is a Mortara E-Scribe message using the XML format:

```
<ECG ACQUISITION_TIME="20050826163953" ROOM="" LOCATION="" COMMENT="OP"
AGE="59" AGE_UNITS="Y" HEIGHT="" HEIGHT_UNITS="I" WEIGHT="" WEIGHT_UNITS="L"
NUM_QRS="14" AVERAGE_RR="726" VENT_RATE="82" SEQUENCE_NUMBER="129">
   <DEMOGRAPHIC_FIELD ID="1" LABEL="LAST NAME" VALUE="SCOTT" UNITS=""/>
   <DEMOGRAPHIC_FIELD ID="7" LABEL="FIRST NAME" VALUE="MARTHA" UNITS=""/>
   <DEMOGRAPHIC_FIELD ID="2" LABEL="MR #" VALUE="210012" UNITS=""/>
   <DEMOGRAPHIC_FIELD ID="16" LABEL="DOB" VALUE="06/12/1946" UNITS=""/>
   <DEMOGRAPHIC_FIELD ID="3" LABEL="AGE" VALUE="59" UNITS="Y"/>
   <DEMOGRAPHIC_FIELD ID="4" LABEL="SEX" VALUE="Female" UNITS=""/>
   <DEMOGRAPHIC_FIELD ID="12" LABEL="ACCT #" VALUE="92500977167" UNITS=""/>
   <DEMOGRAPHIC_FIELD ID="17" LABEL="ROOM" VALUE="OP" UNITS=""/>
   <DEMOGRAPHIC_FIELD ID="19" LABEL="REF MD" VALUE="JMORGAN,ZMADDEL" UNITS=""/>
   <DEMOGRAPHIC_FIELD ID="22" LABEL="TECH" VALUE="DGH" UNITS=""/>
   <SITE ID="0"/>
   <SUBJECT LAST_NAME="SCOTT" FIRST_NAME="MARTHA" GENDER="Female" ID="210012"/>
   <SOURCE TYPE="RESTING" MANUFACTURER="Mortara Instrument, Inc."
   MANUFACTURER_ID="10" MODEL="el150/250" ID="0"
   TRANSMISSION_TIME="20050827095920"/>
      <AUTOMATIC_INTERPRETATION>
         <STATEMENT STATEMENT_NUMBER="1" TEXT="SINUS RHYTHM" REASON=""/>
         <STATEMENT STATEMENT_NUMBER="2" TEXT="NORMAL ECG" REASON=""/>
         <STATEMENT STATEMENT_NUMBER="3" TEXT="" REASON=""/>
         <STATEMENT STATEMENT_NUMBER="4" TEXT="Reviewed By Dr. Smith  9/6/2011
         2:38:51 PM" REASON=""/>
      </AUTOMATIC_INTERPRETATION>
   <TYPICAL_CYCLE R_PEAK="500" P_ONSET="-171" P_OFFSET="-64" Q_ONSET="-46"
   Q_OFFSET="48" T_OFFSET="310" P_DURATION="107" PR_DURATION="125"
   QRS_DURATION="94" QT="356" QTC="395" QTCB="417" QTCF="396" P_AXIS="42"
   QRS_AXIS="-16" T_AXIS="32" BITS="16" FORMAT="SIGNED" UNITS_PER_MV="400"
   DURATION="1200" SAMPLE_FREQ="1000" ENCODING="BASE64">
   | (Typical Cycle Channel info) |
   </TYPICAL_CYCLE>
   | (Channel info) |
</ECG>
```

LabPas Mortara E-Scribe import records

This section describes the fields in each segment of a Mortara E-Scribe message that is imported in the LabPas application.

A value of N/A in either column indicates that the LabPas application ignores data in that field. Unless stated otherwise, a value other than N/A in the LabPas field column indicates that the field is required.

ECG record

The ECG record is required and non-repeating.

Example:

```
<ECG ACQUISITION_TIME="20050826163953" ROOM="" LOCATION="" COMMENT="OP"
AGE="59" AGE_UNITS="Y" HEIGHT="" HEIGHT_UNITS="I" WEIGHT="" WEIGHT_UNITS="L"
NUM_QRS="14" AVERAGE_RR="726" VENT_RATE="82" SEQUENCE_NUMBER="129">
```

Attribute Name	Data
ACQUISITION_TIME	Date and time the ECG waveforms were recorded. yyyyMMddHHmmss format.
ACQUISITION_TIME_XML	N/A
ROOM	N/A
LOCATION	N/A
COMMENT	N/A
AGE	N/A
AGE_UNITS	N/A
HEIGHT	N/A
HEIGHT_UNITS	N/A
WEIGHT	N/A
WEIGHT_UNITS	N/A
NUM_QRS	N/A
AVERAGE_RR	N/A
VENT_RATE	N/A
TECHNICIAN	N/A
SYSTOLIC_BP	N/A
DIASTOLIC_BP	N/A
SEQUENCE_NUMBER	N/A

DEMOGRAPHIC_FIELD record

The DEMOGAPHIC_FIELD record is required and can repeat. This record is used to match to the correct ECG event in the LabPas database.

Example:

```
<DEMOGRAPHIC_FIELD ID="3" LABEL="AGE" VALUE="59" UNITS="Y"/>
```

Attribute Name	Data
ID	Field identifier: 1= Patient Last Name 2= Patient Id Number 3= Patient Age 4= Patient Gender (Male, Female, Unknown) 5= Patient Race ((blank), Caucasian, Black, Oriental, Hispanic, American Indian, Aleut, Hawaiian, Pacific Islander, Mongolian, Asian) 6= Medication ((blank), Digitalis, Beta blocker, Quinidine/Norpace, Diuretic, Calcium antagonist, Proc/Lido/Tocainide, Other antiarrhythmic, Psychotropic, Unknown) 7= Patient First Name 8= LCD Request 9= Patient Height 10= Patient Weight 11= Soc Sec Number 12= Patient Second Id 13= Patient Middle Name 14= Patient Location 15= Patient Room 16= Patient Birth Date (yyyyMMdd) 17= Comment 18= Reason Code 19= Referring Physician 20= Attending Physician

Attribute Name	Data
	21= Overreading Physician 22= Technician 23= Diagnosis 24= Note 1 25= Note 2 26= Order Number 27= Systolic Blood Pressure 28= Diastolic Blood Pressure 29= Requesting Physician 30= Accession Number 31= Admission ID
LABEL	N/A
VALUE	Field value. Only used when ID=2 or 17
UNITS	N/A

STATEMENT record

The STATEMENT record contains the automatic interpretation statement, is required, and can repeat. Each repeated record has an incremented STATEMENT_NUMBER attribute.

Example:

```
<STATEMENT STATEMENT_NUMBER="1" TEXT="SINUS RHYTHM" REASON=""/>
```

Attribute Name	Data
STATEMENT_NUMBER	VERITAS automatic interpretation statement number, starting with 1 as the first statement.
TEXT	Main body of the interpretation statements. For statements with more than one record, each statement is appended to the previous in the LabPas database to create one single statement string, separated by commas.
REASON	N/A

TYPICAL_CYCLE record

The TYPICAL_CYCLE record contains ECG test result information. It is required and non-repeating. For each field that the LabPas application parses, it expects the Attribute Name to match the Test Code 2 value for the appropriate ECG panel and uses the Data as the result for the test.

Example:

```
<TYPICAL_CYCLE R_PEAK="500" P_ONSET="-171" P_OFFSET="-64" Q_ONSET="-46"
```

```
Q_OFFSET="48" T_OFFSET="310" P_DURATION="107" PR_DURATION="125"
QRS_DURATION="94" QT="356" QTC="395" QTCB="417" QTCF="396" P_AXIS="42"
QRS_AXIS="-16" T_AXIS="32" BITS="16" FORMAT="SIGNED" UNITS_PER_MV="400"
DURATION="1200" SAMPLE_FREQ="1000" ENCODING="BASE64">
```

Attribute Name	Data
R_PEAK	Position of the R-peak as determined by VERITAS, expressed in milliseconds from the beginning of the typical cycle waveforms.
P_ONSET	Position of the P-onset as determined by VERITAS, expressed in milliseconds from the beginning of the typical cycle waveforms.
P_OFFSET	Position of the P-offset as determined by VERITAS expressed in milliseconds from the beginning of the typical cycle waveforms.
Q_ONSET	Position of the QRS-onset as determined by VERITAS, expressed in milliseconds from the beginning of the typical cycle waveforms.
Q_OFFSET	Position of the QRS-offset as determined by VERITAS, expressed in milliseconds from the beginning of the typical cycle waveforms.
T_OFFSET	Position of the T-offset as determined by VERITAS, expressed in milliseconds from the beginning of the typical cycle waveforms.
P_DURATION	Duration of the P-wave as determined by VERITAS, expressed in milliseconds.
PR_DURATION	Duration of the PR interval as determined by VERITAS, expressed in milliseconds.
QRS_DURATION	Duration of the QRS-wave as determined by VERITAS, expressed in milliseconds.
QT	Duration of the QT interval as determined by VERITAS, expressed in milliseconds.
QTC	Duration of the QT interval normalized to 60 BPM using the linear method: $QTc = QT + \frac{(1000 - RR)}{7}$
QTCB	Duration of the QT interval normalized to 60 BPM using the Bazett method: $QTcB\,[s] = \frac{QT[s]}{(RR[s])^{1/2}}$

Attribute Name	Data
QTCF	Duration of the QT interval normalized to 60 BPM using the Fridericia method: $QTcF = \frac{QT}{RR}^{1/3}$
P_AXIS	P axis as determined by VERITAS, expressed in degrees.
QRS_AXIS	QRS axis as determined by VERITAS, expressed in degrees.
T_AXIS	T axis as determined by VERITAS, expressed in degrees.
BITS	N/A
FORMAT	N/A
UNITS_PER_MV	N/A
DURATION	N/A
SAMPLE_FREQ	N/A
ENCODING	N/A