Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Machine to Machine HL7 SPL User Guide

Australian Unique Device Identification Database (AusUDID)

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Introduction

For the purpose of this document:

- Data Supplier refers to sponsors, manufacturers or agents
- UDI record refers to a UDI-DI and related data published as a record to the AusUDID
- We refers to the Therapeutic Goods Administration •
- You refers to you as a data supplier or Third Party Data Provider.

Australian Unique Device Identification (UDI) system

The Australian Government is strengthening patient safety by introducing the Australian Unique Device Identification (UDI) system.

The UDI system supports the identification of medical devices and other medical device reforms. It is designed to improve the effectiveness of the regulatory framework, including management of postmarket safety-related activities such as recalls.

The inability to effectively and efficiently track and trace medical devices that have been supplied to or implanted into patients has constrained timely clinical and regulatory action in a number of medical device safety crises. This includes hip implants, urogynaecological mesh and breast implants.

By introducing the UDI system, Australia joins a globally harmonised approach that enables more accurate identification of medical devices.

Managing data in the Australian UDI Database (AusUDID)

We established the AusUDID as the repository for UDI-DIs and related data in Australia. The AusUDID stores the UDI Device Identifier (UDI-DI) and related data for most medical devices and in vitro diagnostic (IVD) devices supplied in Australia.

Sponsors and manufacturers can use one of 4 methods to supply data to the AusUDID.



Figure 1: Submission methods in the Australian UDI Database

Purpose of this document

This user guide is part of a suite of documents that support the sponsors and manufacturers (or their Third Party Data Providers) who will supply data to the AusUDID via HL7 SPL.

We have created this suite of documents to help you:

- comply with UDI requirements
- understand the IT requirements of the AusUDID
- submit and verify UDI records in the AusUDID.

Machine to Machine HL7 SPL document suite

We have explained the suite of documents in the table below:

Document	Australian UDI Data Dictionary	User Guide	Implementation Specification	Code List	Sample HL7 XML Message
Purpose	Reference listing of all Australian UDI data elements including: data element names descriptions validation rules Grace Period rules permitted values other useful metadata.	 Overview of: UDI concepts AusUDID submission channels, roles and environments Data management rules M2M workflow API Management Portal Provisioning security credentials Testing scenarios – conformance. 	 Detailed instructions of: Versioning Creating UDI records Maintaining data Schema and data attribute specifications. 	Reference listing of codes and elements.	Series of sample HL7 XML messages for data submission and notifications (success and failure), including message annotations explaining the data attributes and intended purpose.
Audience	 Sponsors Manufacturers Agents Third Party Data Providers Regulatory teams Software development and support teams. 	 Sponsors Manufacturers Third Party Data Providers Agents Software development and support teams. 	Software development and support teams.	Software development and support teams.	Software development and support teams.
Assumed Knowledge	 UDI concepts Australian regulations. 	TBS Portal including access provisioning and/or understanding of Oauth 2.0 authentication framework.	HL7 SPL messaging protocols and system integration architecture patterns using XML schemas.	HL7 SPL messaging protocols and system integration architecture patterns using XML schemas.	HL7 SPL messaging protocols and system integration architecture patterns using XML schemas.

Getting started

To successfully submit UDI records via the HL7 SPL API, you should be familiar with the following prerequisites.

AusUDID data rules

UDI records submitted to the AusUDID using the HL7 SPL API are required to comply with data rules and permitted values. You can find the details on each Australian UDI data element, permitted values and other useful metadata in the <u>Australian UDI Data Dictionary</u>.

Testing of HL7 SPL submission

If you choose HL7 SPL to submit UDI records to the AusUDID, you must first complete testing in AusUDID Pre-Production environment.

Testing in the Pre-Production environment helps to identify data issues early and prevent submission of inaccurate or low quality data to the AusUDID Production environment.

Testing requirements are further described in Validating your HL7 SPL data submission.

Access controls

Submission of UDI records through the HL7 SPL API requires you to have the following elements in place:

- Access Token: The Access Token authorises the application to send requests to the AusUDID API
- Client ID and Secret: The Client ID and Secret combination identifies the Data Supplier organisation submitting the UDI record to the API
- **Subscription Key**: The Subscription Key identifies the Data Supplier organisation that the UDI record is submitted on behalf of. It is associated with the Data Supplier's TGA Business Services (TBS) account and is generated by a user within the TBS account.



The TBS user generating the Subscription Key must be assigned the TBS role of 'Submitter'.

XML Request Header

UDI records that you submit through the HL7 SPL channel must have 2 key values in the Request Header:

1. Access Token	Must be provided in the 'Authorization' field
2. Subscription Key	Must be provided in the 'Ocp-Apim-Subscription-Key' field.

Figure 2 illustrates the message flows between the Data Supplier and the AusUDID. It provides context to the remaining sections of this document.



Figure 2: Illustration of the message flows between Data Supplier and the AusUDID.

Roles and responsibilities

HL7 SPL submitters

UDI records can be submitted to the AusUDID using HL7 SPL by 4 types of submitters. These are:

- manufacturer submitters
- sponsor submitters
- Third Party Data Provider submitters
- agent submitters.

Manufacturer submitters

The manufacturer of a medical device is the person who is responsible for the following actions before the device is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations:

- design of the device
- production of the device
- packaging of the device
- labelling of the device.

If the above does not apply to a medical device, the manufacturer of the device is the person who, with a view to supplying the device under the person's name, does one or more of the following using ready-made products:

- assembles the device
- packages the device

- processes the device
- fully refurbishes the device
- labels the device
- assigns to the device its purpose by means of information supplied, by the person, on or in any one or more of the following:
 - o the labelling on the device
 - the instructions for using the device
 - o any advertising material relating to the device.

*However, a person is not the manufacturer of a medical device if:

- the person assembles or adapts the device for an individual patient; and
- the device has already been supplied by another person; and
- the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the following:
 - the labelling on the device
 - the instructions for using the device
 - o any advertising material relating to the device.

Sponsor submitters

A sponsor is a person or company who does one or more of the following:

- exports therapeutic goods from Australia
- imports therapeutic goods into Australia
- manufactures therapeutic goods for supply in Australia or elsewhere.

Third Party Data Provider submitters

A Third Party Data Provider is a person or company that curates and submits data on behalf of a sponsor or manufacturer.

Agent submitters

An agent is a person duly authorised in writing to act on behalf of the sponsor or manufacturer of the goods.

Terms of Use

Data Suppliers and Third Party Data Providers submitting UDI records to the AusUDID through the HL7 SPL channel must accept the Terms of Use before using HL7 SPL functionality in either the AusUDID Pre-Production or Production environments.

To do this you must:

- request a copy of the Terms of Use by contacting the UDI Support Team at UDI@health.gov.au
- acknowledge the Terms of Use by return email.

Sponsors and manufacturers

As a Data Supplier submitting UDI records to the AusUDID through the HL7 SPL channel directly from using your own IT system, you must:

- request a Client ID and Secret
- generate a Subscription Key.

As a Data Supplier submitting UDI records to the AusUDID through a Third Party Data Provider, you must:

- generate a Subscription Key
- give the Subscription Key to your Third Party Data Provider.

If you give the Subscription Key to a Third Party Data Provider, this allows them to submit UDI records to the AusUDID on your behalf. It does not grant them access to your TBS account.

If you wish to remove the Third Party Data Provider's ability to submit UDI records on your behalf, you can regenerate the Subscription Key. This will invalidate the existing Subscription Key previously provided to the Third Party Data Provider.

Sponsors and manufacturers are always responsible for the data supplied to the TGA, even if data is submitted via a Third Party Data Provider.

Third Party Data Providers

As a Third Party Data Provider submitting UDI records to the AusUDID through the HL7 SPL channel, you must:

- request a Client ID and Secret
- work with each organisation you are submitting UDI records on behalf of to obtain their Subscription Key. If supplying UDI records on behalf of multiple data suppliers, you will need to manage Subscription Keys for each.

If the Data Supplier regenerates the Subscription Key and does not provide you the new Subscription Key, you will be unable to submit UDI records to the AusUDID through the HL7 SPL channel on their behalf.

Key activities

Requesting a Client ID and Secret

To obtain a Client ID and Secret, you must contact the UDI Support Team at UDI@health.gov.au.

When you request the Client ID and Secret, you must provide:

- your organisation name
- contact details of your organisation's administrator:
 - o **name**
 - o position
 - o email

• phone number.

The UDI Support Team will create and provide your organisation's Client ID and Secret. You use the Client ID and Secret to generate the Access Token for your HL7 SPL message. The UDI Support Team does not general the Access Token.

Generating a Subscription Key

You can generate Subscription Keys in the UDI APIM Portal. You must have different keys for each of the AusUDID environments:

- AusUDID Pre-Production
- AusUDID Production.

URLs to each AusUDID environment:

AusUDID Pre-Production environment:	https://hpsp-pp-apim.developer.azure-api.net
AusUDID Production environment:	https://hpsp-prod-apim.developer.azure-api.net

As a sponsor or manufacturer, you can share your Subscription Key with multiple Third Party Data Providers. However, we recommend that you create a new API Subscription for every Third Party Data Provider. This allows you to revoke the access of one Third Party Data Provider without affecting other users of that Subscription Key.



Third Party Data Providers cannot generate Subscription Keys. As a Third Party Data Provider, you must work with the sponsor or manufacturer and request that they generate a Subscription Key and provide this to you.

See below the instructions for using the APIM Portal to generate a Subscription Key in both the AusUDID Pre-Production and Production environments.

Instruction	Pre-Production
Navigate to the relevant APIM Portal using the links provided above.	PRE-PROD
	Department of Health and Aged Care API Catalogue

Instruction	Pre-Production
Select 'Login with TGA' and login with your TBS credentials.	<image/> <image/> <image/> <form><form><text><text><text><text><text><text></text></text></text></text></text></text></form></form>
Once logged into the APIM Portal, click on the 'Products' tab in the navigation bar at the top right of the screen.	New AN Todats Reports And Signad Department of Health and Aged Care API Catalogue PRE-PROD Totaria

Instruction	Pre-Production
In the 'Products' page, click on the 'UDID PreProd' link.	Products P Search products Name Description UDID PreProd
You will be redirected to a page to name your subscription to the AusUDID HL7 SPL API. Enter a descriptive name that relates to the use of the key (for example Key for Acme Inc Third Party Data Provider). Click on 'Subscribe'.	TestSubscription
 You will be presented with the details of your newly created subscription: The 'Primary Key' is the Subscription Key The 'Secondary Key' also functions as a Subscription Key. This alternative key allows you to provide different keys to different systems or users, if you wish to do so. 	Subscriptions sescription details Product State Action Name TestSubscription Rename UDD PreProd Active Cancel Primary key Secondary key Secondary key

Instruction	Production
Navigate to the relevant APIM Portal using the links provided above.	Department of Health and Aged Care API Catalogue

Instruction	Production
Select 'Login with TGA' and login with your TBS credentials.	
TBS credentials.	<form><form><form><form><form><text><text><text><text><text><text></text></text></text></text></text></text></form></form></form></form></form>
Once logged into the APIM Portal, click on the 'Products' tab in the navigation bar at the top right of the screen.	Manual Commune Represent of Health and Aged Care API Catalogue
In the 'Products' page, click on the 'UDID Prod' link.	Products Search products Name Description Pharmaceutical Benefits Scheme • PU Pharmaceutical Benefits Scheme • PUBLIC UDID Prod TGA Aus UDID API

Instruction	Production
You will be redirected to a page to name your subscription to the AusUDID HL7 SPL API. Enter a descriptive name that relates to the use of the key (for example Key for Acme Inc Third Party Data Provider). Click on 'Subscribe'.	Your subscriptions Name Status UDI Prod Active Your new product subscription name Subscribe
You will be presented with the details of your newly created subscription:	Subscriptions
 The 'Primary Key' is the Subscription Key. The 'Secondary Key' also functions as a Subscription Key. This alternative key allows you to provide 	Subscription details Product Name UDI Prod Rename UDI Drod Stated on 11/20/024 UDI Prod UDI Prod Primary key xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
different keys to different systems or users, if you wish to do so.	



If you want to view the history of previously generated subscription keys, do so by following these steps:

- Select 'Profile' in the navigation bar
- Scroll to 'Subscriptions'
- Select 'Show'.

Revoking access to a Subscription Key

If you wish to revoke access via a Subscription Key (including if used by a Third Party Data Provider), you can do so by either:

- cancelling the subscription, or
- regenerating the Subscription Key.

Generating an Access Token

You can generate an Access Token by completing an OAuth 2.0 Client Credentials flow. To do this, you must have the Client ID and Secret.

Third Party Data Providers only need a single Client ID and Secret.

The Access Token can be used in conjunction with multiple Subscription Keys as the Subscription Key itself identifies the organisation which they are acting on behalf of.

Once you have the Client ID and Secret, you must send a POST request to the URL below to generate the Access Token.

URL to send a POST request for both AusUDID environments:

AusUDID Pre-Production and Production environment:	https://login.microsoftonline.com/4a3cd791-0600-4b56-9f17- befb124fbe03/oauth2/v2.0/token
Example POST request using c	url:



If the POST request is successful, you will receive a response that contains the JWL Bearer Token.

Note that the token expiry time in seconds is included in the response message. 3599 seconds is 1 hour.

```
{
    "token_type":"Bearer",
    "expires_in":3599,
    "ext_expires_in":3599,
    "access_token":"THE_ACCESS_TOKEN"
}
```

If the Client ID is incorrect, you will receive an error message like the one shown below:

```
{
   "error":"unauthorized_client",
   "error_description":"AADSTS700016: Application with identifier'YOUR-INCORRECT-
CLIENT-ID' was not found in the directory 'Department of Health'... ",
   "error_codes":[700016],
   "timestamp":"2023-11-09 02:57:06Z",
   "trace_id":"...",
   "correlation_id":"...",
   "error_uri":"https://login.microsoftonline.com/error?code=700016"
}
```

If the Secret is incorrect, you will receive an error message like the one shown below:

```
{
    "error":"invalid_client",
    "error_description":"AADSTS7000215: Invalid client secret provided. Ensure the se
cret being sent in the request is the client secret value, not the client secret ID
, for a secret added to app 'CLIENT-ID'...",
    "error_codes":[7000215],
    "timestamp":"2023-11-09 02:56:30Z",
    "trace_id":"...",
    "correlation_id":"...",
    "error_uri":"https://login.microsoftonline.com/error?code=7000215"
}
```



You add the generated Access Token to the Authorization Header of your HL7 SPL message, in the following format:

Authorization Bearer [YOUR_ACCESS_TOKEN]

Expired Access Token

If you receive a 'Unauthorized. Access token is missing or invalid' error message, this is because your Access Token has expired.

You must generate a new Access Token.

Submitting a UDI record through the API

Once you have the Access Token and Subscription Key, you can submit UDI records through the API using a HL7 SPL message.

You can use the HL7 SPL message to:

- create the initial UDI record
- update the UDI record
- correct the UDI record.



The HL7 SPL channel does not support submission of draft UDI records. It does support submission of 'unpublished' UDI records when the record has a future publish date.



Each message request equates to a single UDI record.

The Access Token can be reused for multiple messages until it expires. You do not need to generate Access Tokens for each individual UDI record or message.

You must include the Access Token in the Authorization header field and the Subscription Key in the Ocp-Apim-Subscription-Key header field.

The body of the request will be the HL7 SPL XML message.

Example post request using curl:

```
curl -v --location "https://hpsp-pp-apim.azure-api.net/pp/udid/api/v1/hl7" \
    --header "Content-Type: application/xml" \
    --header "Authorization: Bearer YOUR_ACCESS_TOKEN" \
    --header "Ocp-Apim-Subscription-Key: YOUR_SUBSCRIPTION_KEY" \
    --data-binary "@hl7_message.xml"
```



The above curl command assumes that you have a file called hI7_message.xml in the directory you are running the command from. The contents of this XML file will be sent as the request body.

The AusUDID response below is what you will receive when the submission is successful.

In this example, the Primary DI is TEST123456.

The response below shows a failed submission.

In this example, the error is because of the 'Brand Name' field is longer than 80 characters.



Failed submissions are not retained in the AusUDID or kept as drafts.

If the UDI record's publish date in the HL7 document is today or in the past, the UDI record will be published immediately. If the UDI record publish date is in the future, it will be created as an 'unpublished UDI record' which will automatically publish when the scheduled date is reached. Once the UDI record is published, the UDI record's 'Grace Period' will commence.



The Grace Period is a set time frame that begins once you have published your initial version of the UDI record. During this time frame, you can make any needed changes to any data element. The purpose of the Grace Period is to allow you fix errors in the UDI record due to data entry errors or technical issues.

The length of the Grace Period is subject to change as we introduce UDI and the AusUDID. You can find the current length of the Grace Period on the UDI Hub, or when updating or correcting a UDI record.

UDI records that are in the Grace Period are visible to public users. Only UDI records that are submitted without an ARTG are not shown to public users.

Once the UDI record is out of the Grace Period, it will be subject to the UDI Trigger Data Elements rules. This means that changes to those data fields defined as UDI Trigger Data Elements will require a new UDI record, per the rules defined in the Australian UDI Data Dictionary. If you need to correct the UDI record due to an error, you can do so by sending a HL7 request using the correction

message type code, or by prefiling a correction request through the AusUDID online portal which will treat the next update you submit via the HL7 channel as a correction.

Verifying UDI record submission

Once you have successfully published a UDI record, you can view your UDI record online in the AusUDID portal. To do so, you must log into the AusUDID with your web browser.

Once logged in, select 'My UDI Records' to see the UDI records created by your organisation.

Sample Postman Collection

We have included a sample Postman Collection as part of the HL7 SPL suite of documents.

After importing the collection into Postman, you must select the collection name and then select the 'Variables' tab.

You must enter your Client ID and Secret into both the 'Initial Values' and 'Current Values' columns. The 'TenantID' value will be 4a3cd791-0600-4b56-9f17-befb124fbe03

You must ensure you select 'Save' to save your changes.

ace	New Import	M2M Sample Colle	ction 🗧 POST Subi	nit UDI Record 🔹 🕂 👓	0	No Environment
- -	000	M2M Sample Colle	ection		r Share v Fork	0 🕨 Run 🖺 Save
M2M Sample Collection		Overview Author These variables are Q Filter variable	e specific to this co	equest Script Tests Va	riables • Runs	
		Varia	able	Initial value	Current value	
			tld			
		Clien	tld tSecret			
		Client client client	tld tSecret ntld			

Figure 2: Image of Postman Collection - Highlighting the 'Variables' tab, values columns and 'Save' button.

Once you have saved your changes, you must select the 'Authorization' tab. You must scroll down and select the 'Get New Access Token' button. You must select 'Proceed' and 'Use Token'. This Access Token will now be automatically included on all requests in the Authorization Header. A new Access Token will need to be requested when the current Access Token expires.

Token Name	accessToken	
Grant Type	Client Credentials	~
Access Token URL ③	https://login.microsoftonline.c	com/{{t
Client ID (i)	{(clientId))	
Client Secret ④	{{clientSecret}}	
Scope (1)	{{clientId}}/.default	
Client Authentication ④	Send as Basic Auth header	~
> Advanced		
🚯 Clear cookies 🚯		
Get New Access Token		

Figure 3: Image of new Access Token configuration screen

You must then select the 'Submit UDI Record' button and then select the 'Headers' tab. You must change the 'Ocp-Apim-Subscription-Key' value to the Subscription Key that you generated in the APIM. You can now select the 'Body' tab and fill out the request payload with the UDI HL7 SPL XML message.

 M2M Sample Collection POST Submit UDI Record POST ~ https://hpsp.apim.azure-api.net/acc/udid/api/v1/hl7 Params Authorization Headers (11) Body ● Pre-request Script Tests Settings Headers © 10 hidden Key Ocp-Apim-Subscription-Key Key Value 	000	M2M Sample Collection / Submit UDI Record		
Params Authorization Headers (1) Body • Pre-request Script Tests Settings Key Key Value Value	M2M Sample Collection POST Submit UDI Record	POST v https://hpsp spim.azure-api.net/acc/udid/api/v1/hl7		
Key Value Ocp-Apim-Subscription-Key Key Value		Params Authorization Headers (11) Body • Pre-request Script Tests Headers	Settings	
Ocp-Apim-Subscription-Key Mail Key Value		Кеу	Value	
Key Value		Ccp-Apim-Subscription-Key		
		Кеу	Value	

Figure 4: Image of Postman Collection - Highlighted 'Submit UDI Record' button, 'Headers' button and value column.

Validating your HL7 SPL data submission

Before you can connect software to the AusUDID, you will need to ensure your software has successfully transmitted the HL7 SPL message.

This testing will occur in the AusUDID Pre-Production environment.

You must advise us that the Pre-Production testing of your HL7 SPL messages have occurred before submitting data through the AusUDID Production API.

This testing is to confirm:

- Correct transmission of the HL7 SPL message
- Compatibility with the AusUDID messaging services and platform •
- Integrity of the UDI record(s) •
- Acceptable system performance and load management .
- Correct detection and management of errors.

Stage 1 – Simple message validation

Stage 1 assesses your ability to successfully send transactions and manage any submission issues using a simple set of UDI records.

You must run a set of HL7 SPL transactions that:

- Verifies both successful and unsuccessful transactions and creation of UDI records
- Represents the breadth of devices that the Data Supplier organisation supplies in Australia •
- Includes varying device characteristics, for example, UDI records with and without Direct • Marking DIs, Package DIs, or varying clinical characteristics.

Your initial dataset should be limited to 30 UDI records and should only be new UDI records.

During Stage 1, we recommend you create UDI records with today's publish date.

Stage 2 – Advanced message validation

Stage 2 increases the complexity and scale of testing. This stage focuses on more complex UDI records and includes Corrections to UDI records.

You must only commence Stage 2 once you have completed Stage 1 successfully.

Your dataset for Stage 2 should be limited to 100 UDI records and should include both new and corrected UDI records.

Stage 3 – Data volume validation

Stage 3 increases the scale of testing. This stage focuses on large volumes of UDI records.

You must only commence Stage 3 once you have completed Stages 1 and 2.

You are not limited to a set number of UDI records for Stage 3.

Stage 4 – Complex data scenarios

Stage 4 includes specific testing scenarios.

Test scenario	Test description	Record changes or updates	Success criteria
Scenario 1	Submit a new UDI record with today's publish date	None.	UDI record is submitted to AusUDID as a published UDI record.

Test scenario	Test description	Record changes or updates	Success criteria
Scenario 1.1	Update the newly submitted UDI record during the Grace Period.	We suggest you update the following data element(s): • Brand Name • For Single Use • Latex Information.	UDI record is updated correctly.
Scenario 2	Submit a new UDI record with a future publish date.	None.	UDI record is submitted to AusUDID as an unpublished UDI record.
Scenario 2.2	Update the newly submitted UDI record.	Change the UDI record publish date to today's date.	UDI record is updated correctly. UDI record displays as published.
Scenario 3	Submit a new UDI record with today's publish date. UDI record must include a package hierarchy.	None.	UDI record is submitted to AusUDID as a published UDI record. UDI record displays package hierarchy correctly.
Scenario 3.3	Update the newly submitted UDI record after the Grace Period.	 We suggest you update the following data element(s): Sponsor commercial distribution end date Storage and handling information Clinically relevant size information. 	UDI record is updated correctly.

Completing testing

Once you advise us by emailing <u>UDI@health.gov.au</u> that you have successfully completed all 4 stages of AusUDID testing, you can submit data through the AusUDID Production API.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Reforms Taskforce	Month Year
V1.1	Revisions for multiple sponsor and other editorial changes	Devices Reforms Taskforce	March 2025

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