

## Electronic Instructions for Use

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### 1.0 **PURPOSE**

This work instruction defines the steps for publishing electronic instructions for use (e-IFU) to the St Jude Medical e-labeling website for distribution to customers.

### 2.0 **REFERENCES**

#### 2.1 **Applicable Documents**

Number	Title
86931	Regulatory Country Requirements
88067	eIFU Upload Worksheet

#### 2.2 **External References**

Number	Title
N/A	N/A

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### 3.0 RESPONSIBILITIES

Function or Title	Responsibility
Technical Publications	Uploads and reviews eIFUs. Removes eIFUs from the website when required. The technical writer is responsible for uploading US and OUS English manuals after they have been production released. The localization coordinator is responsible for uploading translated manuals after they have been production released.
Regulatory Affairs	Reviews and publishes eIFUs

### 4.0 DEFINITIONS

Term	Definition
Content Manager (CM)	Uploads PDFs to the eIFU website and enters associated metadata.
Content Reviewer	Reviews the uploaded PDF and metadata for completeness and accuracy. This must be someone other than the Content Manager.
DMR	Device Master Record
DTP	Desktop Publisher
eIFU	Electronic Instructions for Use. IFUs provided to customers via the internet, CD, thumb drive, or onscreen help.
IFU	Instructions for use
Informatica	Data management tool used for uploading and storing data before publishing to the eIFU site.
LC	Localization Coordinator
Manuals.sjm.com medical.abbott/manuals	External websites for publishing PDFs of released and approved manuals
PDF	Portable document format
PLM	Product Lifecycle Management (document control system)
Publishing approver	Publishes the manual to eIFU website
RA	Regulatory Affairs
Regulatory Affairs Approver	Reviews the uploaded content to ensure that the manual has been approved by the relevant regulatory authorities.
Sitecore	Web content management software. The eIFU website runs on Sitecore.
TCE	TeamCenter Engineering

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Term	Definition
TP	Technical Publications
TW	Technical Writer
ZFIN	Finished good material type

### 5.0 FLOW CHART

N/A

### 6.0 INSTRUCTIONS

IFUs may be delivered in electronic format on a website, on portable data storage medium, or as onscreen help.

#### 6.1 Before eIFU Upload

Step	Action	Role
1	Before starting an eIFU upload, verify that: <ul style="list-style-type: none"> <li>- the IFU is released in a PLM system.</li> <li>- Regulatory approval was received or that no approval is needed.</li> </ul>	TW/LC, RA
2	Get input from a cross-functional team to determine whether publication of the eIFU requires synchronization with other product- or business-related activities, such as new/updated labels, new/updated product, software releases, regulatory approval etc. <ul style="list-style-type: none"> <li>- Record product- or business-related activities for synchronization in Section 2.0 of the eIFU Upload Worksheet (88067).</li> </ul>	TP, RA, Project Management, Marketing, Systems Engineering, Manufacturing Engineering, Software Engineering, Labeling, Quality, others as needed
3	Record the new eIFU information in Section 1.0 of the eIFU Upload Worksheet (88067).	TW/LC
4	Determine if a current/predicate eIFU is posted on the public website. <ul style="list-style-type: none"> <li>- Record the current/predicate eIFU information in Section 1.0 of the eIFU Upload Worksheet (88067).</li> </ul>	TW/LC
5	If a current/predicate eIFU is posted on the public website, identify ALL of the countries where it is currently available. <ul style="list-style-type: none"> <li>- Record the countries where the current/predicate IFU is posted on the public website in Section 3.0 in the eIFU Upload Worksheet (88067).</li> </ul>	TW/LC
6	Determine where the current/predicate eIFU can be removed from the public website and be replaced with the new eIFU. <i>Pay special</i>	RA

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Step	Action	Role
	<p><i>attention to countries that lag behind in regulatory approvals, such as Canada and Australia.</i></p> <ul style="list-style-type: none"> <li>- For countries where the new eIFU replaces the current/predicate eIFU, check the Remove box for the current/predicate eIFU and the Add box for the new eIFU in Section 3.0 on the eIFU Upload Checklist (88067). When a specific language is removed from ALL countries where it is currently posted an end date will be entered in Section 1.0 of the eIFU Upload Checklist (88067). The end date of the current/predicate eIFU must align with the begin date of the new eIFU.</li> <li>- For countries where the current/predicate eIFU will stay on the public website, do not check the Remove box for the current/predicate eIFU or the Add box for the new eIFU in Section 3.0 on the eIFU Upload Checklist (88067). The languages specific to countries that keep the current/predicate eIFU on the public website will not have an end date entered in Section 1.0 of the eIFU Upload Checklist (88067).</li> </ul>	
7		
8	Upload a copy of the completed eIFU Upload Checklist to the Tech Pubs Sharepoint site.	TW/LC
9	Forward a copy of the eIFU Upload Worksheet to Operations and Labeling.	TW/LC

### 6.2 Create or Update an eIFU

Step	Action	Role
1	<p>Create a new IFU or update an existing one.</p> <p>If an e-IFU exists on the website, upload any updates to it that are released in the PLM system.</p>	TW, LC, or DTP
2	<p>Create the e-IFU PDF according to normal practice.</p> <p>The same PDF is used for print and eIFU except for the MRI Procedure Manual. MRI Procedure Manual eIFU versions are A4 or US letter.</p> <p>For the initial view, the e-IFU PDF document file must use the single-page page-layout setting, the Fit Page magnification setting, and the Bookmarks Panel and Page navigation pane.</p>	TW or DTP

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### 6.2 Create or Update an eIFU

Step	Action	Role
	For single-language IFUs, bookmark according to normal division practice. For multilingual IFUs, bookmark the start page of each language with the name of the language	
3	Create the change request in the PLM system. Indicate in the change request description that Manufacturing Engineering will be responsible for maintaining traceability of the IFU in the Device Master Record. For example, by associating the IFU/eIFU with the appropriate BOM on a subsequent CR.	TW, LC, or DTP
4	Obtain IFU/eIFU approval in the PLM system.	TW, LC, or DTP

### 6.3 Upload an eIFU

Step	Action	Role
1	Log into Informatica. <a href="http://prod.informaticamdm.sjm.com:9080/bdd/login.jsf?bdd_name=ProducteIFU&amp;antiloop=1466699755362">http://prod.informaticamdm.sjm.com:9080/bdd/login.jsf?bdd_name=ProducteIFU&amp;antiloop=1466699755362</a> Login Name: sjm\ <network id&gt;<br=""></network> Password: <network password>	CM
2	To create a new record, go to the Data tab and choose Product (eIFU) > New product (eIFU). To find an existing record, go to the Data and select the Search tab.	
3	Upload the e-IFU PDF to the e-labeling website and enter the requested metadata. <b>Note: If this version replaces a version that is already on the website with a different part number, update the older version to change the Effective End Date. Process that update through the review and publish process.</b> <b>If this version replaces a lower revision of the same part number, do not create a new record. Find the existing record, replace the old PDF, and update the metadata as appropriate for the new revision.</b>	CM
4	Assign a Content Reviewer by choosing More Actions -> Assign Tasks.	CM

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### 6.3 Upload an eIFU

Step	Action	Role
	<ul style="list-style-type: none"> <li>Use the Comments box in the Assign Task dialog box or a follow up email to provide the Content Reviewer with any relevant information not included in the notification from Informatica.</li> </ul> <p>For example, if an eIFU is being superseded, alert the Content Reviewer that there is a pair of records to be reviewed. Provide the eIFU identification numbers of both.</p> <p>Informatica alerts the reviewer that a task has been assigned.</p>	

### 6.4 Content Review an eIFU

Role: Content Reviewer		
Step	Action	
1	Log into Informatica. <a href="http://prod.informaticamdmsjm.com:9080/bdd/login.jsf?bdd_name=ProducteIFU&amp;antiloop=1466699755362">http://prod.informaticamdmsjm.com:9080/bdd/login.jsf?bdd_name=ProducteIFU&amp;antiloop=1466699755362</a> Login Name: sjm\ <network id&gt;<br=""></network> Password: <network password>	
2	Review the work of the Content Manager, validating that the file and associated data are correct. Pay special attention to the following: <ul style="list-style-type: none"> <li>Manual title</li> <li>Countries</li> <li>Languages</li> <li>Model numbers</li> <li>Model names</li> <li>Does this version replace a previous one? If so, is the previous version being updated to reflect the new Effective End Date?</li> <li>Practice area</li> <li>Product type</li> <li>Product family</li> <li>PDF: Title and models in the PDF match the metadata</li> </ul>	
3	If the content is correct, approve the content and assign an RA Approver by choosing More Actions -> Assign Tasks. Informatica alerts the approver that a task has been assigned. <ul style="list-style-type: none"> <li>Use the Comments box in the Assign Task dialog box or a follow up email to provide the RA Approver with any relevant information not included in the notification from Informatica.</li> </ul>	

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### 6.4 Content Review an eIFU

Role: Content Reviewer	
Step	Action
	<p>For example, if an eIFU is being superseded, alert the reviewer that there is a pair of records to be reviewed. Provide the eIFU identification numbers of both.</p> <p>If the content is not correct, assign a Content Manager by choosing More Actions -&gt; Assign Tasks. Informatica alerts the Content Manager that a task has been assigned.</p> <ul style="list-style-type: none"> <li>Use the Comments box in the Assign Task dialog box or a follow up email to explain why the record is being returned.</li> </ul>
4	<p>Save the PDF of the approval form with a filename containing the document's artwork number and revision level, as well as the two-letter language abbreviation(s) (For example: ARTLAXxxxxxxa.pdf; ARTEN40002801a.pdf).</p> <p>If a form (or forms) already exists with this name, append a number to distinguish the versions. (For example: ARTLAXxxxxxxa_2.pdf; ARTEN40002801a_2.pdf).</p>
5	<p>Sign the PDF of the approval form electronically.</p> <p>It is also acceptable to print the approval form, sign it manually, scan it, and upload it to the SharePoint site.</p>
6	<p>Place the signed form on the SharePoint site  <a href="http://team2.sjm.com/crmcollab/org2/IT/VePostMrktXferSite/RA/EIFU/Forms/AllItems.aspx">http://team2.sjm.com/crmcollab/org2/IT/VePostMrktXferSite/RA/EIFU/Forms/AllItems.aspx</a></p>
7	<p>Assign an RA Approver by choosing More Actions -&gt; Assign Tasks. Informatica alerts the approver that a task has been assigned.</p>

### 6.5 Regulatory Affairs Approve an eIFU

Role: RA Approver	
Step	Action
1	<p>Log into Informatica.  <a href="http://prod.informaticamdmsjm.com:9080/bdd/login.jsf?bdd_name=ProducteIFU&amp;antiloop=1466699755362">http://prod.informaticamdmsjm.com:9080/bdd/login.jsf?bdd_name=ProducteIFU&amp;antiloop=1466699755362</a>            Login Name: sjm\<network id&gt;<br=""></network>           Password: &lt;network password&gt;</p>
2	<p>Review the content, validating that the e-IFU is planned for use in the countries specified by the Content Manager and that the content is approved there.</p>
3	<p>If the content is correct, approve the content and assign a Publishing Approver by choosing More Actions -&gt; Assign Tasks. (This is, typically, the same person who did the RA approval. Informatica alerts the publisher that a task has been assigned.</p>

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### 6.5 Regulatory Affairs Approve an eIFU

Role: RA Approver	
Step	Action
	If the content is not correct, assign a Content Manager by choosing More Actions -> Assign Tasks. Informatica alerts the reviewer that a task has been assigned. Use the Comments box in the Assign Task dialog box or a follow up email to explain why the record is being returned.
4	Save the approval form as a PDF, with a filename containing the artwork number and rev level of the document and "RA" to indicate that it is the Regulatory Affairs approval form (For example: ARTLAXxxxxxxa_RA.pdf; ARTEN40002801a_RA.pdf) on the SharePoint site <a href="http://team2.sjm.com/crmcollab/org2/IT/VePostMrktXferSite/RA/EIFU/Forms/AllItems.aspx">http://team2.sjm.com/crmcollab/org2/IT/VePostMrktXferSite/RA/EIFU/Forms/AllItems.aspx</a> If a form (or forms) already exists with this name, append a number to distinguish the versions. (For example: ARTLAXxxxxxxa_RA_2.pdf; ARTEN40002801a_RA_2.pdf).
5	Sign the PDF of the approval form electronically.
6	Place the signed form on the SharePoint site <a href="http://team2.sjm.com/crmcollab/org2/IT/VePostMrktXferSite/RA/EIFU/Forms/AllItems.aspx">http://team2.sjm.com/crmcollab/org2/IT/VePostMrktXferSite/RA/EIFU/Forms/AllItems.aspx</a>

### 6.6 Publish an eIFU

Role: Publishing Approver	
Step	Action
1	Log into Informatica. <a href="http://prod.informaticamd.sjm.com:9080/bdd/login.jsf?bdd_name=ProducteIFU&amp;antiloop=1466699755362">http://prod.informaticamd.sjm.com:9080/bdd/login.jsf?bdd_name=ProducteIFU&amp;antiloop=1466699755362</a> Login Name: sjm\ <network id&gt;<br=""></network> Password: <network password>
2	Publish the content to the public website.

### 6.7 Remove a Paper IFU from the Package

Role: Technical Publications	
Step	Action
1	Obtain agreement with Operations and/or R&D, Regulatory Affairs, Packaging Engineering and other groups as required before removing paper IFUs from the product package.
2	Coordinate with the manufacturing engineer for the project to ensure traceability of the IFU.



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### 7.0 APPENDIXES

The following appendixes are included in this document: Informatica Fields

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**APPENDIX 1: INFORMATICA FIELDS**

Field	Definition	Advice/Notes
eIFU Identification	The artwork number for the IFU.	This is the number used to search for the record in Informatica.
Division	The legacy division to which the IFU belongs.	Informatica for eIFU was designed when we still had multiple divisions.
SAP Part Number	The part number of the IFU.	This number cannot be typed. It is selected from SAP. If a part number is not in SAP, the IFU cannot be uploaded in Informatica.
SAP Description	The description for the SAP part number.	This description cannot be typed. It is selected from SAP. If a part number is not in SAP, the IFU cannot be uploaded in Informatica.
Revision Reason	The reason for this revision of the IFU.	This is not a required field, but it could be useful to know what makes this version of the IFU different from previous versions. Enter a short description.
eIFU Effective Begin Date	Date after which PDF appears in searches.	Enter today's date unless you know that the effective date should be further in the future. <b>Note: Make sure that you leave enough time for other processes to complete.</b> For example, RA needs to see the IFU on the website before they release for shipment, so using the ship date as the Begin Date means that the block won't be lifted until after the planned ship date.
eIFU Effective End Date	Date after which the PDF cannot be found by searching on the site. It is still linked as a previous version.	Leave blank unless you are superseding this PDF with a more recent version. If this version is being superseded, make sure that the Effective Begin Date of the new version is the same as the Effective End Date of the superseded version. To remove a PDF from the site, manipulate Effective Begin Date and/or End Date

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Field	Definition	Advice/Notes
Retention End Date	Date after which all traces of manual are removed from the site.	Leave blank (defaults to 100 years).
Active Version	Indicates whether or not this is the latest version on the site. Yes if it is. No if it is not.	This field may or may not be reliable, depending on whether an older version has been kept alive for a limited set of countries.
Change Request Number	The Change Request/Engineering Change Order number.	This is an optional field.
Revision Number	The rev level of the IFU artwork number.	Make sure that the letter you enter here matches the PDF.
Revision Type	Identifies whether or not the change was made for safety reasons. Choices are blank or Safety.	Safety-related revisions will be very rare and most likely associated with a field action. Verify with RA before choosing Safety.
<b>Title &amp; Products Tab</b>		
Title	The title of the IFU.	English: Use what's on the manual cover if it will fit. Translations: Use English (because there is an issue with displaying accent marks).
Reorder/Model Description(s) & Number(s)	Provides the keywords for searches on site.	Choose zFINs. Click Add on each page. <b>Important:</b> Choose an SAP part number for every model number and name listed in the manual. If the model name/number is not included in this field, it will not be searchable on the website.
<b>Upload PDF Tab</b>		
PDF to Upload	The PDF to be displayed on the website.	MUST come from the PLM system.
<b>Languages &amp; Countries Tab</b>		
Language Name	The language of the IFU.	Language and country are linked.

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Field	Definition	Advice/Notes
Country Name	The countries for which the IFU will be displayed on the website.	Choose the language of the IFU first, then the countries where the IFU is to be displayed. <b>Important:</b> Check the list of countries with the RA Approver before completing the upload.
<b>Hierarchy Tab</b>		
Practice Area (Segment)		The choices for these fields depend on the legacy product division selected.  These entries are taken from the web product catalog, which is maintained by Digital Marketing.  Choose as many hierarchies as required to cover all of the products in the IFU.
Product Type (Category)		
Sub-Type (Family)		
<b>Version Control Tab</b>		
Previous Versions	Lists the superseded versions of this IFU.	When uploading an IFU that has a previous version on the site, remember to also set the Effective End Date for the superseded version (unless it will be used for countries that don't have approval for the new version).  If the superseded version will continue to be used in some countries, remove the rest of the countries listed for the IFU.
Superseding Versions	Lists the newer versions of this IFU	
<b>Preview Content Tab</b>		
Displays all of the metadata for the IFU.		
<b>Review Content Tab</b>		
Allows the Content Reviewer to sign off on the eIFU.		Select the checkboxes, click Apply, then Print/Preview Approval.
<b>Approve Regulatory Tab</b>		
Allows the RA Approver to sign off on the eIFU.		Select the checkboxes, click Apply, then Print/Preview Approval.

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Field	Definition	Advice/Notes
<b>Publish Approval Tab</b>		
Publishes the eIFU.	Select the checkbox, then click Apply and Publish.	