

Technical Publications Content Development

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1.0 **PURPOSE**

This document defines the instructions and standards used to develop and maintain technical publication content and corresponding localized content. Examples of technical publication content created by TP include IFUs, Operator Manuals, Quick Reference Guides, Patient Manuals, Physician Manuals, User Manuals, etc. To simplify the information within this work instruction, “IFU” is used to represent all forms of technical publication content.

Advertising and promotional materials, Bills of Materials, manufacturing and distribution center procedures, and product and package labels are not included in the scope of this document.

2.0 **REFERENCES**

2.1 **Applicable Documents**

Number	Title
87728	Instructions for Use Responsibilities Matrix
87778	Instructions for Use Requirements Matrix

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Number	Title
94-2442	NMD Template: Product Labelling Specifications
87253	Product Descriptor Reference Document
87254	Product Descriptor Translation Request Form

2.2 External References

Number	Title
NA	NA

3.0 RESPONSIBILITIES

Function or Title	Responsibility
Technical Publications	Owns this WI and is responsible for ensuring that it is maintained and followed.

4.0 DEFINITIONS

Term	Definition
3PR	Third-Party Review; independent review of localized content
AIT	Author-it (content management/desktop publishing software)
CAT	Cardiovascular Ablation Technology
CIB	Change Implementation Board
CMS	Content Management System
CoC	Certificate of conformance; a certification in writing that localized content is a complete and accurate representation of the English-language content
CRM	Cardiac Rhythm Management
DTP	Desktop Publishing Specialist; processes localized content for draft and final output, and performs graphic design services
eIFU	Electronic Instructions for Use
FMEA	Failure Mode and Effect Analysis
FMECA	Failure Mode and Effect Criticality Analysis
ICR	In-country review; the process of reviewing localized content by an Abbott employee living in-country where the language is the primary language spoken, a native speaker of the language, and a subject-matter expert in the information being reviewed. If an Abbott employee is not available then the reviewer must fit the criteria and can be a distributor, physician, clinician, etc.

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Term	Definition
IFU	Instructions for Use
LC	Localization Coordinator; coordinator of localization projects
LSP	Language Service Provider; primary resource for translated content; provides translation, localization, and voice recording services
MT	Multi-lingual translation (multiple languages included in a single IFU)
NM	Neuromodulation
PDP	Product Development Process
PLM	Product Lifecycle Management
PR	Purchase Requisition
RFQ	Request for Quote
SME	Subject Matter Expert
SMS	Short message service; a text messaging service component of most telephone, World Wide Web, and mobile telephony systems
SW Dev	Software Development
TOC	Table of Contents
TP	Technical Publications

5.0 **FLOW CHART**

NA

6.0 **INSTRUCTIONS**

6.1 **English Content Creation**

Role: Technical Writer	
Step	Action
1	Identify project scope, including number of IFUs, timelines, and deliverables.
2	Identify SMEs and CIB team.

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6.1 English Content Creation

Role: Technical Writer	
Step	Action
3	<p>Collect content inputs, including intended users, predicate IFUs, marketing specifications, customer requirements, system requirements, product requirements, design verification and validation testing reports, device or system compatibility analysis, regulatory submission strategies, Failure Mode and Effect Analysis (FMEA) or Failure Mode and Effect Criticality Analysis (FMECA), and hazard analysis and risk management reports.</p> <p>Refer to the Instructions for Use Responsibilities Matrix to determine functional SMEs for content elements.</p>
4	<p>If making modifications to a predicate IFU, interchangeability is determined at the part level. Functional representatives for interchangeability determination are identified in the material assessment and change notice work instruction.</p> <p>Based on this evaluation, obtain a new part number or revise the existing part number.</p> <ul style="list-style-type: none"> • In the legacy CAT and NM Quality Systems, create part numbers as described in the create and maintain part objects work instruction. • In the legacy CRM Quality System, part numbers are obtained through an automated process within the PLM system. <p>NOTE: Notify Purchasing/Supply Chain of upcoming changes to legacy IFU parts, so that they may manage inventory appropriately.</p> <p>NOTE: If creating or revising content using a predicate IFU, the source content must come from the PLM system.</p> <p>NOTE: If creating country-specific IFUs, you must pull a new part number and a new artwork number from the PLM system. The description of the part number and artwork number must indicate the country for which the part and artwork are being created. For example, if you are creating a manual for Canada, the description of the part number and artwork number description must include Canada (e.g., Canada, CA, or CAN as part of the description).</p>
5	<p>Determine format limitations based on package size, distribution plan (HTML, eIFU, paper IFU, or patient IFU), and sterilization methodology, and create content in the appropriate template format.</p> <ul style="list-style-type: none"> • Patient-facing materials may require larger font size, greater use of illustrations, and simplified content. • Paper IFUs packaged in terminally-sterilized product configurations may need to adhere to strict page count limitations. • Paper IFUs must meet Packaging Engineering dimensional requirements.
6	<p>Compile content inputs and formatting requirements and create an English draft.</p> <p>NOTE: Maintained working files are controlled in TP directories. Directory structure is based on product hierarchy, and each working folder has subfolders for CO, History, Work in Process (WIP), and Resources. Save IFUs using standard naming conventions.</p>

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6.1 English Content Creation

Role: Technical Writer	
Step	Action
7	Ensure that the product identification (product name, product descriptor, and additional text) conforms to the proper format (see 6.1.1) and that the product descriptor and additional text elements are present in the CMS.
8	<p>Review the English draft against the Instructions for Use Requirements Matrix. You must consult this document when creating or revising any IFU to ensure all applicable content is addressed in the respective IFU. If required content elements are missing, create missing content with help from functional owners identified in the Instructions for Use Responsibility Matrix.</p> <p>NOTE: If you are creating or editing a list of compatible components and accessories in an IFU for a product or system based on any type of requirements, ensure that the compatibility list is complete and accurate by checking it against applicable documentation, such as the compatibility section of a project plan or a Systems Compatibility Matrix Analysis report. Refer to the Instructions for Use Responsibility Matrix to determine the functional SME that will provide the appropriate reference documentation.</p>
9	<p>Review the IFU against the labels to confirm that:</p> <ul style="list-style-type: none"> • All symbols used on the label and their definitions are present in the IFU or symbols glossary (100158316). If there are symbols missing from the IFU or symbols glossary, update the IFU and symbols glossary as appropriate. • The product identification elements (trade name, product descriptor, and additional descriptor) align. Work with the label designer to align the IFU and label as necessary.
10	<p>Send the draft IFU to SMEs and applicable CIB members for review.</p> <p>NOTE: For IFUs that consolidate content across multiple projects, include at least one SME from each additional project to serve as an additional CIB member on the CO. Consult with the program manager to select the correct cross-project SME or SMEs, and consider adding the rationale for including non-project CIB members to your CO justification.</p>
11	Incorporate any required changes identified in draft review. Repeat iterative reviews as needed.
12	Submit English content for approval on CO.
13	<p>If localization is required, prepare English content for handoff to localization coordinator. Handoff typically includes:</p> <ul style="list-style-type: none"> • Source files • Redlines • Predicate files • Print specification document • Output requirements (multi-lingual, single language, bundled [specific languages grouped together, not all languages for the project] format/output size, eIFU upload requirements, or zlsdmanual-mediated supplemental language identification requirements.)

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6.1.1 Product Identification Elements (Trade Name, Product Descriptor, and Additional Text)

Do not include the trade name or trademarked terms in the product descriptor. Do not include measurements in the product descriptor. Trademarked terms and measurements are allowed in the additional text element.

Step	Action	Role
1	<p>When space allows on the IFU cover, place the product identification elements on separate lines as shown below. When space is limited, the elements may be placed in-line.</p> <p>Preferred format:</p> <ul style="list-style-type: none"> Trade name (line 1); not all products have a trade name Product descriptor (line 2); all products have a product descriptor Additional text (line 3); not all products have additional text 	Writer
2	<p>To promote consistency between the IFU and product label:</p> <ul style="list-style-type: none"> CMS-based IFUs: Maintain the product descriptor and additional text elements as separate objects. Embed these objects in the IFU cover object, at the beginning of the language section of a multi-language IFU, in the symbols definition section of the IFU (when applicable), and in the product descriptor reference document. Traditional-file based IFUs: Identify the product descriptor and additional text elements with a character style named Product Descriptor on the cover of all IFUs, at the beginning of the language section of a multi-language IFU, in the symbols definition section of the IFU (when appropriate), and in the product descriptor reference document. 	<p>Writer (when English IFU requires a new product descriptor or additional text element)</p> <p>LC (when label string request requires a new product descriptor or additional text element)</p>

6.2 Localization of English Content

Step	Action	Role
1	Identify project scope, including the type of content being localized, timeline, and deliverables.	LC
2	Obtain cost center and project number information for localization expenses from program manager or requestor of localization work.	LC
3	Set up project folders as required, based on project scope and deliverables. Working files are maintained on controlled TP directories.	LC

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6.2 Localization of English Content

Step	Action	Role
4	<p>Receive and review English content handoff deliverables, resolve any questions with the writer, project team, or requestor as needed. Place the deliverables in the proper project location.</p> <p>For label strings: Review CMS for product descriptor and additional text elements. Create product descriptor and additional text elements in CMS if necessary.</p>	LC
5	<p>For IFUs: Obtain a new part number or revise the existing part number.</p> <ul style="list-style-type: none"> • In the legacy CAT and NM Quality Systems, create part numbers as described in the create and maintain part objects work instruction. • In the legacy CRM Quality System, part numbers are obtained through an automated process within the EDM. <p>For label strings, software strings, voice recordings, and SMS content: N/A</p>	DTP
6	<p>For IFUs: Create the part number list for the project. Place the part number list in the proper project location.</p> <p>For label strings, software strings, voice recordings, and SMS content: N/A</p>	DTP
7	<p>For IFUs: Create specification document. Use English specification document as a template. Forward to another DTP for review. Place the specification document in the proper project location.</p> <p>For label strings, software strings, voice recordings, and SMS content: N/A</p>	DTP

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6.2 Localization of English Content

Step	Action	Role
8	<p>Prepare RFQ. Suggested communication includes:</p> <p>Priority:</p> <ul style="list-style-type: none"> This is a high priority project. Please respond with your quickest delivery schedule. This is a normal priority project. <p>Target Languages:</p> <ul style="list-style-type: none"> [book name] – [languages] <p>Hand-off: Please find files with your company name in this email. If the file is not found with this email please check our Large File Transfer utility. Each ZIP file contains:</p> <ul style="list-style-type: none"> [Specify contents] <p>Review:</p> <ul style="list-style-type: none"> Specify in-country review, third party review, etc. <p>[Add specific instructions for the review]</p> <p>Quote: [Add specific instructions for the quote]</p> <p>Deliverables:</p> <ul style="list-style-type: none"> Certificate <p>[Add specific instructions for the deliverables]</p> <p>Delivery Schedule: Please confirm the final delivery date with the quote. [Add required delivery schedule]</p> <p>Notes: [Add additional notes]</p> <p>Place the RFQ in the proper project location.</p>	LC
9	Send RFQ to LSP.	LC
10	Analyze RFQ and content for localization.	LSP
11	Receive and review quote from LSP, resolve any questions with the LSP, project team, or requestor as needed. Place the quote in the proper project location.	LC
12	Create purchase requisition (PR) and forward to the responsible party for approval. Place the PR in the proper project location.	LC
13	Submit the signed/approved PR for processing (creation of PO). Place the PO in the proper project location.	LC
14	Receive approval for the purchase requisition and notify the LSP to begin the project. Place the signed PR or electronic approval in the proper project location.	LC
15	Localize the content. Edit and proofread the localized content.	LSP

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6.2 Localization of English Content

Step	Action	Role
16	<p>Review and finalize the localized content.</p> <p>For additional information:</p> <ul style="list-style-type: none"> • See 6.2.1 for CMS-based IFUs • See 6.2.2 for traditional-file-based IFUs • See 6.2.3 for label strings • See 6.2.4 for software strings • See 6.2.5 for voice recordings • See 6.2.6 for SMS content 	See section referenced

6.2.1 Review and Finalize Localized Content: CMS-Based IFUs

Step	Action	Role
1	<p>Receive draft localization from LSP.</p> <p>As needed, request draft PDF and review of draft localization by DTP.</p> <p>Place the draft localization in the proper project location.</p>	LC
2	<p>As needed, create and review draft PDF localization.</p> <ul style="list-style-type: none"> • Identify English content in draft localization. • Notify LC of any English content in the draft localization. <p>Place the draft PDF localization in the proper project location.</p>	DTP
3	<p>Deliver additional English content to LSP to include in the project.</p> <p>Deliver draft PDF to LSP for optional use during linguistic review.</p> <p>Place the additional English content in the proper project location.</p>	LC
4	<p>Perform linguistic review. Review by 3PR preferred, can use ICR if necessary.</p>	3PR or ICR (managed by LSP)
5	<p>Deliver final localization.</p>	LSP
6	<p>Receive final localization and CoC from LSP. Review CoC for accuracy. Place final localization and CoC in the proper project folder.</p> <p>Request final PDF and review of final localization by DTP.</p>	LC
7	<p>Create and review final PDF localization.</p> <ul style="list-style-type: none"> • Identify formatting and other issues • Correct issues <p>Forward to second DTP for review of final localization.</p>	DTP
8	<p>Perform second DTP review of final PDF localization.</p> <ul style="list-style-type: none"> • Identify formatting and other issues • Notify first DTP of any issues • Forward to LC for review of final localization 	DTP

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6.2.1 Review and Finalize Localized Content: CMS-Based IFUs

Step	Action	Role
9	Perform LC final review of localization.	LC
10	Notify DTP of any changes. Repeat review steps as necessary. If no changes, notify DTP that final PDF is ready for upload to the CO.	LC

6.2.2 Review and Finalize Localized Content: Traditional-File-Based IFUs

Step	Action	Role
1	Perform linguistic review. Review by 3PR preferred, can use ICR if necessary.	3PR or ICR (managed by LSP)
2	Deliver final localization.	LSP
3	Receive final localization and CoC from LSP. Review CoC for accuracy. Place final localization and CoC in the proper project folder. Request final PDF and review of final localization by DTP.	LC
4	Create and review final PDF localization. <ul style="list-style-type: none"> Identify formatting and other issues Correct issues Forward to second DTP for review of final localization.	DTP
5	Perform second DTP review of final PDF localization. <ul style="list-style-type: none"> Identify formatting and other issues Notify first DTP of any issues Forward to LC for review of final localization 	DTP
6	Perform LC final review of localization.	LC
7	Notify DTP of any changes. Repeat review steps as necessary. If no changes, notify DTP that final PDF is ready for upload to the CO.	LC

6.2.3 Review and Finalize Localized Content: Label Strings

Step	Action	Role
1	Perform linguistic review. Review by ICR preferred, can use 3PR if necessary.	ICR or 3PR (managed by LSP)
2	Deliver final localization.	LSP
3	Receive final localization from LSP. Review CoC for accuracy. Place final localization and CoC in the proper project folder. Deliver final localization to requestor.	LC
4	Add product descriptor and additional text elements to the Product Descriptor Reference Document. Release updates quarterly.	LC

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6.2.4 Review and Finalize Localized Content: Software Strings

Step	Action	Role
1	Receive localization from LSP. Place the localization in the proper project location. Deliver localization to requestor for incorporation into software.	LC
2	Receive screen captures and navigation script from requestor for linguistic contextual testing. <ul style="list-style-type: none"> Review can be performed by on-site reviewers with live software or by remote reviewers with screen captures Both review methods must provide a method for recording comments regarding format, linguistic issues, etc. 	LC
3	Make arrangements for on-site or remote linguistic contextual testing.	LC
4	Perform linguistic contextual testing. Return comments upon completion of testing. Review by ICR preferred, can use 3PR if necessary. If no changes needed, localization is complete.	ICR or 3PR (managed by LSP)
5	Review comments from ICR. Update localization. Deliver updated localization to LC.	LSP
6	Deliver localization to SW Dev. Place the updated localization in the proper project location. Deliver updated localization to requestor for incorporation into software. Repeat review steps as necessary. If no changes needed, localization is complete. Request CoC from LSP.	LC
7	Deliver CoC to SW Dev. If needed, deliver linguistic contextual testing report to SW Dev.	LC

6.2.5 Review and Finalize Localized Content: Voice Recordings

Step	Action	Role
1	Identify voice talent. Send sample recordings for selection by reviewer.	LSP
2	Perform linguistic review of localization (written script and call workflow file). Review by ICR preferred, can use 3PR if necessary.	ICR or 3PR (managed by LSP)
3	Initiate voice recording of localization (written script).	LSP
4	Perform linguistic review of localization (recorded script). Review by ICR preferred but can use 3PR if necessary.	ICR or 3PR (managed by LSP)
5	Deliver final localization (written script, recorded script, and call workflow file) to LC.	LSP

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6.2.5 Review and Finalize Localized Content: Voice Recordings

Step	Action	Role
6	Receive final localization and CoC from LSP. Review CoC for accuracy. Place final localization and CoC in the proper project folder. Deliver final localization and CoC to requestor.	LC


6.2.6 Review and Finalize Localized Content: SMS Content

Step	Action	Role
1	Receive localization from LSP. Place the localization in the proper project location. Deliver localization to requestor for incorporation into software.	LC
2	Communicate with LSP on timing of linguistic contextual review of SMS messages sent directly to reviewer (mobile phone).	LC
3	Perform linguistic contextual review. Return comments upon completion of review. Review by ICR preferred, can use 3PR if necessary. Deliver updated localization to LC. Repeat review steps as necessary. If no changes needed, localization is complete.	ICR or 3PR (managed by LSP)
4	Deliver CoC to requestor. If needed, deliver linguistic contextual review report to SW Dev.	LC

6.3 Barcode Creation


The following subsections cover creating a barcode for IFUs. Code 128 bar code creation is the preferred method. Code 39 bar code creation, which is the method that NM uses as part of its legacy procedures, is an alternate means to create a bar code.

6.3.1 Barcode Creation (Code 39), Font-Based

Role: Technical Writer or DTP	
Step	Action
1	Type the barcode number, include an asterisk "*" before and after the number: Example: *1001313128*
2	Select the barcode number including the asterisk before and after the number: <ul style="list-style-type: none"> Font = CarolinaBar-B39-25F2 Font size = 12 pt <p>The asterisks do not show in the final barcode. Example: </p>

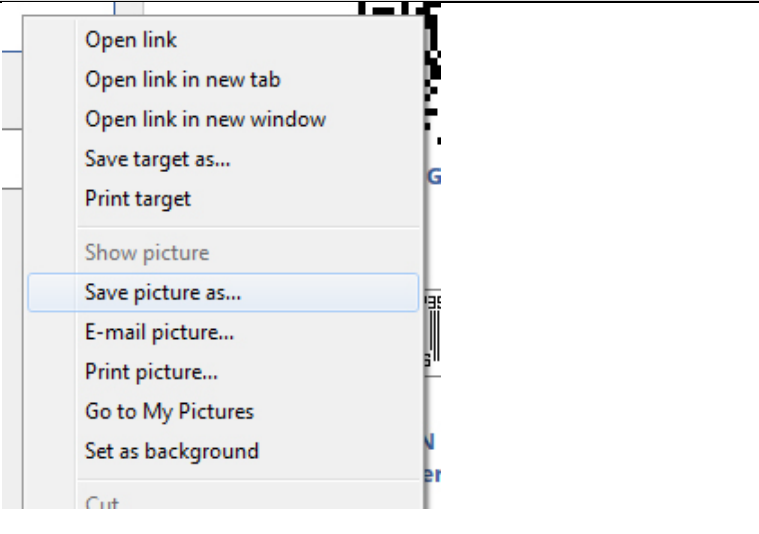
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6.3.2 Barcode Creation (Code 128), Graphic-Based

Role: Technical Writer or DTP	
Step	Action
1	To generate a graphic-based barcode navigate to http://bar-code-generator.net/code128.php .
2	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Complete the form with following required settings:</p> <ul style="list-style-type: none"> • Symbology: Code 128 • File type: PNG – Portable Network Graphics • DPI: 300 • Thickness: 35 • Scale: 2 • Rotation: No rotation • Font: Arial ttf 20 • Starts with: Auto • Data: Type barcode number </div> <div style="width: 50%;"> <p>Code 128</p> <p><i>Configurations</i></p> <hr/> <p>Symbology <input type="text" value="Code 128"/></p> <p>File type <input type="text" value="PNG - Portable Network Graphics"/></p> <p>DPI <input type="text" value="300"/></p> <p>Thickness <input type="text" value="35"/></p> <p>Scale <input type="text" value="2"/></p> <p>Rotation <input type="text" value="No rotation"/></p> <p>Font <input type="text" value="Arial.ttf"/> <input type="text" value="20"/></p> <p>Starts with <input type="text" value="Auto"/></p> <p>Data <input type="text" value="600016760"/> <input type="button" value="Generate"/></p> <p><i>Output</i></p> <hr/>  <p>600016760</p> </div> </div>
3	Click the Generate button.
4	Ensure that the screen updates to show the new barcode with the correct barcode number.

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6.3.2 Barcode Creation (Code 128), Graphic-Based
Role: Technical Writer or DTP

Step	Action
5	Right-click the barcode, and select "Save picture as..." from the drop-down menu. 
6	In the Save Picture window that opens, choose the correct designated location on the network, rename the file using the barcode number as the file name, and click Save to save the barcode.