A Software Tool for Development of High Quality Device Instruction and Training

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ABSTRACT

User manuals aid the user on how to properly use a device and understand its purpose and functions. However, many devices are not used correctly because of the lack of adequate instruction. This project aims to resolve this problem by creating a tool that helps manufacturers prepare a more effective, organized, and comprehensive training for device users. We maintain that a tool to assist manufacturers with creation of a manual and other educational tool would be helpful to speed up the approval process and to increase the likelihood of safe and effective use of an approved or cleared device as well as market success. To our knowledge, no integrated software tool for this purpose is available.

OBJECTIVES

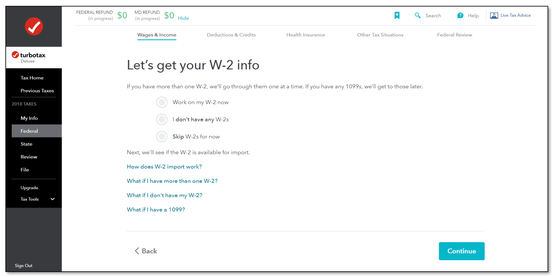
- To create a software tool that helps medical device manufacturers write a more comprehensive and organized device instruction manual

MATERIALS

- eP2 Dynamic Controller Operator's Manual
- InnoSight Diagnostic Ultrasound System User Manual
- OMRON Blood Pressure Monitor Instruction Manual
- HP Arbitrary Waveform Generator User Manual
- ADMET Mechanical Testing Device
- TurboTax® tax preparation software

METHODS

- Analyzed the contents of each of the listed user manuals and identified the elements that are generally present and commonly omitted
- Ran a test on the ADMET Mechanical Testing Device using the instructions provided on the eP2 Dynamic Controller Operator's Manual and was unable to complete the test
- Examine questionnaire style and page layout used by the TurboTax® software as seen in the photo below



- Created a flowchart of required information and generated questions that would prompt the interviewee to respond based on their medical device type and its features
- Designed questionnaire prototype for the software tool to prepare the needed resources like external links and interface layout
- Designed an optional instruction manual template that manufacturers can modify to appropriately present their answers to the questionnaire software

RESULTS

- This software will assist the manufacturer with creating the proper information for inclusion in the manual, present a place for each item, and recommend additional learning aids when appropriate.
- The flowchart outline will provide the manufacturers a sense of completion when they refer to it. They will see their progress as they continue to answer questions.
- The software will also provide the manufacturer with the inclusion of supporting items like diagrams and photos, footnotes, and warnings.
- After using this software tool to write a device user manual, users will be presented information to remind them of certain warnings and other important details which prevents them from overlooking these important details when using the device.

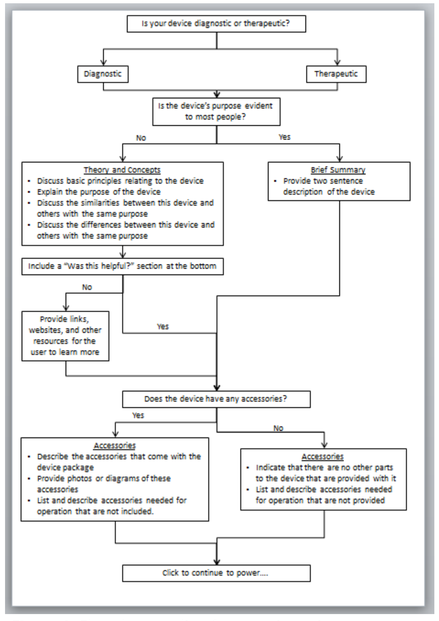


Figure 1. Flowchart outline for questionnaire contents

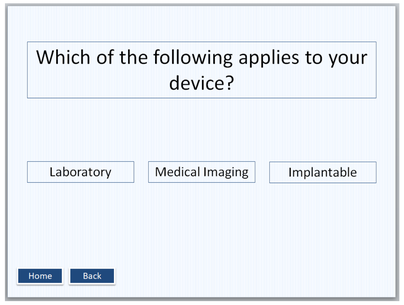


Figure 2. Interactive questionnaire to gather information from manufacturer about medical device.

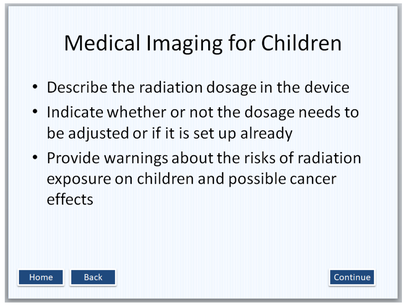


Figure 3. Guidance on creation of content after user answers questions that indicate the device's purpose to be for imaging on pediatric patients

CONCLUSION

- This software tool is useful for medical device manufacturers because it sets up a foundation for a device user manual by asking the manufacturer the necessary information to be included and suggesting the use of additional learning aids when appropriate.

FUTURE WORK

- Complete and refine the tool to be useful for more approved medical devices on the market
- Test the tool on volunteer test manufacturers and receive comments on adjustments to make

ACKNOWLEDGEMENTS

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