

Text for Project Homepage:

Welcome to the FDA [Medical](#) Device Labeling Study website! We appreciate you taking the time to help us with this important project by providing your valued opinion on abbreviated medical device labeling's. In order to participate in the study, you will need your username and password, which we sent to you either by U.S. mail or email. Please enter this information below.

USERNAME: _____
PASSWORD: _____

Please enter the Case ID and password that you received. Passwords are CASE SENSITIVE, so please type carefully.

<PLACE AT BOTTOM OF SCREEN, SEPARATE FROM TEXT, IN DIFFERENT FONT:>
[OMB Approved No. XXXXXXXXXXXX Expires xx/xx/xxxx](#)

SURVEY SCREEN 1

Welcome to the Food and Drug Administration's (FDA's) Medical Device Labeling Survey! The purpose of this project is to examine what information needs to be provided with medical devices, and how that information should be organized. We are asking health care professionals to provide their opinion about an example medical device label created for this survey. The project findings will provide evidence to inform the FDA's regulatory approach to standardizing device labeling.

The survey will take approximately 30 minutes. To thank you for your time, you will be paid [FILL] for completing the survey. Your participation in this research will be kept private to the fullest extent allowed by law. Your participation in this research is also voluntary. Refusal to participate will involve no penalty, and you may discontinue participation at any time. There are no direct benefits to you for completing the survey.

If you have any questions about the study, please contact 1-800-334-8571, x26902. If you have any questions about your rights as a study participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

Thank you for participating in this important study!

SURVEY SCREEN 2

Please be sure to review and print the [example](#) medical device abbreviated labeling prior to [beginning the](#) questionnaire. To access the [example abbreviated](#) labeling, please click [<here>](#).

When you are ready to begin taking your survey, please click on the other box. This will bring you to the FDA survey.

- Always use the 'Logoff' button to exit the survey. You may stop the survey at any time and resume where you left off.
- To resume the survey you will need to re-enter your username and password. If you do not complete your survey in one session, the responses that you have previously

entered can be viewed by someone else if they gain access to your username and password, so please keep this information secure.

- This survey is best viewed with Google Chrome. It may also be viewed in Firefox or Internet Explorer V. 8.0 or higher.

NAVIGATION INSTRUCTIONS

- Do NOT use your browser's 'Back' and 'Forward' buttons to navigate through the survey questions.
- After you enter or select your answer, click on the 'Next' button below the question to continue to the next question.
- To go back to the previous question, click on the 'Previous' button below the question.
- You may stop the survey at any time and resume where you left off. To re-enter and resume the survey you will need to navigate to the web site address provided to you by RTI and re-enter your login credentials.
- Once you submit your survey you will not be able to access it again.

- 0.** Please review the example medical device abbreviated labeling. You will be unable to provide informed answers without reviewing the example abbreviated labeling. Have you reviewed the example abbreviated labeling?

- ₁ YES
₂ NO

[IF 2, DISPLAY SOFT EDIT TEXT: Please review the example medical device abbreviated labeling. You will be unable to provide informed answers without reviewing the example abbreviated labeling. The abbreviated labeling can be accessed from the study's main webpage.]

First, we'd like to ask some questions about you. For the following questions please choose the best answer.

- 1.** Which of the following best describes the place where you perform most of your work?

- ₁ Ambulatory surgical center
₂ Clinic or doctor's office
₃ Home health
₄ In-patient care facility
₅ Outpatient diagnostic facility (lab or medical imaging center)
₆ Outpatient treatment facility (dialysis, infusion therapy, cancer)
₇ Other, specify: _____

2. During a typical week of practice how many hours of direct patient care do you provide?
By direct patient care we mean seeing patients, reviewing tests, preparing for and performing procedures, or providing other related patient care services.

- ₁ None
- ₂ 1-15 hours
- ₃ 16-25 hours
- ₄ 26-40 hours
- ₅ More than 40 hours
- ₆ Don't know

3. Which of the following best describes your occupation?

- ₁ Physician
- ₂ Nurse practitioner or physician assistant
- ₃ Registered nurse
- ₄ Licensed practical nurse
- ₅ Therapist
- ₆ Lab technologist or technician
- ₇ Other, specify: _____

If Q3 = 1 (Physician) go to Q5, otherwise continue.

4. Which of the following best describes your main area of practice?

- ₁ Acute care facility
- ₂ Clinic
- ₃ Education/academic
- ₄ Home care
- ₅ Rehabilitation or chronic care
- ₆ Surgical
- ₇ Other, specify: _____

Go to Q6

5. Which of the following best describes your main area of practice?

- ₁ Academic
- ₂ Acute care facility
- ₃ Public health

- 4 Private or group practice
- 5 Rehabilitation or chronic care
- 6 Surgical
- 7 Other, specify: _____

Go to Q8

6.How many years have you been practicing health care since completing your training?

[PLEASE ENTER ONLY WHOLE NUMBERS. IF NECESSARY, ROUND UP TO THE NEAREST WHOLE NUMBER.]

_____ YEARS <ALLOW UP TO TWO DIGITS; SOFT EDIT CHECK IF 60+>

7.What is your gender?

- 1 Male
- 2 Female

Go to Q10

8.How many years have you been practicing since completing your residency or fellowship?

[PLEASE ENTER ONLY WHOLE NUMBERS. IF NECESSARY, ROUND UP TO THE NEAREST WHOLE NUMBER.]

_____ YEARS <ALLOW UP TO TWO DIGITS; SOFT EDIT CHECK IF 60+>

9.What is your gender?

- 1 Male
- 2 Female

If Q3 = 1 or 2 (Physician, Nurse Practitioner, or Physician Assistant) continue, else go to Q11.

10. In the last month, about how many times did you **prescribe** the use of an infusion pump?

- ₁ 0
- ₂ 1-2 times
- ₃ 3-5 times
- ₄ 6-10 times
- ₅ 11 or more times

11. In the last month, about how many times did you **use** an infusion pump with a patient?

- ₁ 0
- ₂ 1-2 times
- ₃ 3-5 times
- ₄ 6-10 times
- ₅ 11 or more times

Defining the Document and Device

In the remainder of the survey we are going to ask questions about the “Tohamadi Large Volume Infusion Pump” document. Please click here [INSERT LINK] to see this document. Please note this short type of document is NOT intended to include all the information needed for the use of a medical device. We are using an infusion pump as an example of a commonly used medical device.

[RESPONDENT WILL RANDOMLY RECEIVE ONE OF THE THREE FOLLOWING RESPONSE OPTION ARRANGEMENTS:]

12_1. In your opinion, which of the following best describes the document?

- ₁ Device or instrument labeling
- ₂ User or operator guide
- ₃ Instructions for use
- ₄ Quick guide
- ₅ Reference guide
- ₆ Something else, specify: _____.

12_2. In your opinion, which of the following best describes the document?

- ₁ Quick guide
- ₂ Reference guide
- ₃ Device or instrument labeling
- ₄ User or operator guide
- ₅ Instructions for use
- ₆ Something else, specify: _____.

12_3. In your opinion, which of the following best describes the document?

- ₁ Instructions for use
- ₂ Reference guide
- ₃ Quick guide
- ₄ Device or instrument labeling
- ₅ User or operator guide
- ₆ Something else, specify: _____.

13.How often would you refer to a document such as our Tohamadi Infusion Pump example when...

	All of the Time	Most of the Time	Some of the Time	Rarely	Never	Not Appli cable
a. Unpacking the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
b. Setting up the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
c. Using the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
d. Prescribing the use of the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
e. Selecting the proper device for a patient?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
f. Storing the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
g. Disposing of products used with the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
h. A patient has an adverse event?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆
i. A warning or error message appears?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅	<input type="checkbox"/> ₆

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j. An alarm on the device sounds?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
k. Troubleshooting?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6
l. Looking for risks?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

14. How likely is it that you would refer to a *diagram* of a medical device, such as the one on the front page of the Tohamadi Infusion Pump document, when...

	Very Likely	Likely	Unlikely	Very Unlikely	Not Applicable
a. Unpacking the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
b. Setting up the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
c. Using the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
d. Prescribing the use of the device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
e. Selecting the proper device for the patient?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
f. A warning or error message appears?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
g. An alarm on the device sounds?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

The following series of questions is about how the document is *organized*.

15. Please look at the headings in the <link>document</link>, for example **Description** and **Uses**. How easy or difficult are these headings to understand?

- ₁ Very easy
- ₂ Somewhat easy
- ₃ Somewhat difficult
- ₄ Very difficult

QUESTION 16 HAS BEEN DELETED AND IS INTENTIONALLY MISSING.

17. Are you satisfied with the way the information is ordered?

- ₁ Yes
- ₂ No
- ₃ Don't know

If Q17 = 1 or DK Go to Q18, otherwise continue

17a. Please indicate the order in which the information should appear. Please order from 1 (first) to 10 (last).

- Description
- Uses
- Contraindications
- Risks
- Instructions for use
- Warnings and precautions
- Cleaning the pump
- Compatible accessories
- Common alarms
- Troubleshooting

18. If you believe there is a **better term** for any of the current headings in the document please indicate below.

₁ No change to headings needed.

[DO NOT ALLOW SELECTION OF 1- NO CHANGE AND ANY OTHER RESPONSE.]

The heading in this list should be	Replaced with (please specify)
<input type="checkbox"/> ₂ Description	_____
<input type="checkbox"/> ₃ Uses	_____
<input type="checkbox"/> ₄ Contraindications	_____
<input type="checkbox"/> ₅ Risks	_____
<input type="checkbox"/> ₆ Instructions For Use	_____
<input type="checkbox"/> ₇ Warnings and Precautions	_____
<input type="checkbox"/> ₈ Cleaning the Pump	_____
<input type="checkbox"/> ₉ Compatible Accessories	_____
<input type="checkbox"/> ₁₀ Common Alarms	_____
<input type="checkbox"/> ₁₁ Troubleshooting	_____

Evaluating the Content

The next series of questions is about the **content** of the document.

19. Which of the following sections should be added? Please keep in mind that this type of document is to be used for quick reference only.

₁ Fine as is. No additions are needed.

[DO NOT ALLOW THE SELECTION OF 1- FINE AS IS AND ANY OTHER RESPONSE.]

	Add to Document
a. Adverse Effects	<input type="checkbox"/> ₁
b. Battery Type	<input type="checkbox"/> ₁
c. Boxed Warnings	<input type="checkbox"/> ₁
d. Compatibility	<input type="checkbox"/> ₁
e. Additional Diagram	<input type="checkbox"/> ₁
f. Disposal of Accessories	<input type="checkbox"/> ₁
g. Electronic Interference	<input type="checkbox"/> ₁
h. Expiration Date	<input type="checkbox"/> ₁
i. Frequently Asked Questions (FAQs)	<input type="checkbox"/> ₁
j. How Supplied	<input type="checkbox"/> ₁
k. Maintenance	<input type="checkbox"/> ₁
l. Patient/Special Populations	<input type="checkbox"/> ₁
m. Storage	<input type="checkbox"/> ₁
n. Table of Contents	<input type="checkbox"/> ₁
o. Use Environment	<input type="checkbox"/> ₁
p. Other, specify: _____	<input type="checkbox"/> ₁

20. Thinking about medical devices **in general**, how useful is it to have the following sections included in an **abbreviated** document?

	Very Useful	Useful	Somewhat Useful	Not Useful at All
a. Description?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
b. Uses?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
c. Contraindications?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
d. Risks?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
e. Instructions for Use?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
f. Warnings and Precautions?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
g. Cleaning a Device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
h. Compatible Accessories?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
i. Common Alarms?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
j. Troubleshooting?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄

Format of the Document

The next series of questions is about the *format* of the document.

21. In this type of abbreviated document do you think that words such as “not” or “only” should appear in bold-face type in **some** instances, **all** instances, or are the instructions easy enough to understand without special emphasis? *Choose one.*

- ₁ In *some* instances
- ₂ In *all* instances
- ₃ Special emphasis is not necessary

If Q21 = 2, 3 go to Q22, otherwise continue.

21a. In what instances should words such as “not” or “only” appear in bold-face type?

- 22.** How would you like the information under each heading presented: in a bulleted list, numbered list, in paragraph form, or some other way? Please review the examples of the four formats and choose one format for each heading. If you prefer the information be provided in some other way please specify.

22a Instructions for Use?

Bulleted List	Plain List
<ul style="list-style-type: none"> • Verify you have the custom tubing and the pole clamp. • Connect the pump to the charger. Mount the charger on an IV pole. • Connect the charger to the power cord and into a standard AC outlet. • Open the door and thread infusion catheter through pump mechanism. Close the door. • Connect the infusion set to the medication bag. Mount the bag on the IV pole. • Prime the primer line. • Connect the infusion set to the patient. • Press the START button once. You will hear 4 beeps and the display screen will light up. The pump is now ready to use. 	<p>Verify you have the custom tubing and the pole clamp.</p> <p>Connect the pump to the charger. Mount the charger on an IV pole.</p> <p>Connect the charger to the power cord and into a standard AC outlet.</p> <p>Open the door and thread infusion catheter through pump mechanism. Close the door.</p> <p>Connect the infusion set to the medication bag. Mount the bag on the IV pole.</p> <p>Prime the primer line.</p> <p>Connect the infusion set to the patient.</p> <p>Press the START button once. You will hear 4 beeps and the display screen will light up.</p> <p>The pump is now ready to use.</p>
Numbered List	Paragraph Form
<ol style="list-style-type: none"> 1. Verify you have the custom tubing and the pole clamp. 2. Connect the pump to the charger. Mount the charger on an IV pole. 3. Connect the charger to the power cord and into a standard AC outlet. 4. Open the door and thread infusion catheter through pump mechanism. Close the door. 5. Connect the infusion set to the medication bag. Mount the bag on the IV pole. 6. Prime the primer line. 7. Connect the infusion set to the patient. 8. Press the START button once. You will hear 4 beeps and the display screen will light up. 9. The pump is now ready to use. 	<p>Verify you have the custom tubing and the pole clamp. Connect the pump to the charger. Mount the charger on an IV pole. Connect the charger to the power cord and into a standard AC outlet.</p> <p>Open the door and thread infusion catheter through pump mechanism. Close the door. Connect the infusion set to the medication bag. Mount the bag on the IV pole. Prime the primer line. Connect the infusion set to the patient.</p> <p>Press the START button once. You will hear 4 beeps and the display screen will light up. The pump is now ready to use.</p>

- ₁ Bulleted List
- ₂ Plain List
- ₃ Numbered List
- ₄ Paragraph Form
- ₅ Some Other Way

[IF 22a= 5, CONTINUE; ELSE, SKIP TO 22b]

22aSpec
Please specify: _____



22b Warnings and Precautions?

Bulleted List	Plain List
<ul style="list-style-type: none"> • This pump has not been tested for administration of infusion to pregnant women. • Use only accessories designed for this system. • Do not reuse tubing or other disposables. • Do not use in the presence of flammable anesthetics. 	<p>This pump has not been tested for administration of infusion to pregnant women.</p> <p>Use only accessories designed for this system.</p> <p>Do not reuse tubing or other disposables.</p> <p>Do not use in the presence of flammable anesthetics.</p>
Numbered List	Paragraph Form
<ol style="list-style-type: none"> 1. This pump has not been tested for administration of infusion to pregnant women. 2. Use only accessories designed for this system. 3. Do not reuse tubing or other disposables. 4. Do not use in the presence of flammable anesthetics. 	<p>This pump has not been tested for administration of infusion to pregnant women. Use only accessories designed for this system. Do not reuse tubing or other disposables. Do not use in the presence of flammable anesthetics.</p>

- ₁ Bulleted List
- ₂ Plain List
- ₃ Numbered List
- ₄ Paragraph Form
- ₅ Some Other Way

[IF 22b= 5, CONTINUE; ELSE, SKIP TO 23]

22bSpec
Please specify: _____

23. In this example we use several symbols, such as  and . In general, how useful are symbols?

- ₁ Very useful
- ₂ Somewhat useful
- ₃ Not very useful
- ₄ Not useful at all

24.Where do you think you would typically look for information on how to contact the manufacturer's customer service?

- _1 On the first page
- _2 On the last page
- _3 In the troubleshooting section
- _4 By the device name and model number

25.An abbreviated document such as this would include the following disclaimer:

"These instructions do not include all the information needed for the safe and effective use of this pump. See the full device labeling for more complete information on the use of this device."

Where do you think is the best location for the disclaimer?

- _1 Top of the first page
- _2 Bottom of the first page
- _3 Top of the last page
- _4 Bottom of the last page

[RESPONDENT WILL RANDOMLY RECEIVE ONE OF THE TWO FOLLOWING RESPONSE OPTION ARRANGEMENTS:]

26_1 A table of contents should be included in a document like this...

- _1 Always
- _2 If 5 or more pages
- _3 If 3 or more pages
- _4 Never
- _5 Don't know

26_2. A table of contents should be included in a document like this...

- _1 Never
- _2 If 3 or more pages
- _3 If 5 or more pages
- _4 Always
- _5 Don't know

Completeness of the Information

The next series of questions focuses on the completeness of the information.

27. Based on this example document, how confident are you that you would be able to respond to the following situations...?

	Very Confident	Somewhat Confident	Not Very Confident	Not At All Confident
a. The infusion pump's low-battery alarm sounded?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
b. An accessory didn't fit properly?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
c. The screen went blank?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
d. You wanted to dispose of the accessories?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
e. You needed to contact the pump's manufacturer?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
f. You needed to set up the pump?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄

28. Do you think an abbreviated document such as our example should indicate whether or not you can...

	Yes	No	Don't Know
a. Dispose of it in your regular trash?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
b. Disable features designed to facilitate safe operation?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
c. Clean it with a disinfectant?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
d. Replace parts of this pump yourself?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃

29. An abbreviated document such as this includes a variety of information. Thinking about medical devices **in general**, do you think an abbreviated document should specifically include information about whether a medical device can be used...

	Yes	No	Don't Know	REFUSE
a. With rechargeable batteries?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
b. With over-the-counter batteries?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
c. With replacement parts from a similar device?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
d. Near equipment that emits high-energy radio frequencies?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
e. With any size tubing?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
f. Near flammable gasses?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
g. Without a prescription?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
h. In the presence of an MRI?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
i. In the home?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
j. With patients under the age of 12?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
k. With patients who have specific health conditions?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇
l. With pregnant patients?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₋₇

The last question focuses on where you would want to find this type of information when using a medical device.

30. If you were caring for a patient and you needed to access this document where would you want to obtain it? (Select up to 3 options from the lists below.)

In Hard Copy Form

- ₁ With or on the device
- ₂ In a central location in your office or hospital

In Electronic Form

- ₃ On the device's computer memory, displayed on its screen
- ₄ On the manufacturer's or distributor's website
- ₅ On the FDA's website
- ₆ On your hospital's or office's internal website
- ₇ On a mobile device like a smart phone

- ₈ Other
- ₉ No preference for either hard copy or electronic formats

[ALLOW UP TO 3 RESPONSES. EDIT CHECK: DO NOT ALLOW A COMBINATION OF 9-NO PREFERENCE AND ANY OTHER]

[IF 8-OTHER WAS SELECTED, CONTINUE; ELSE, SKIP TO 31.]

30Spec:

Please specify where else you would want to obtain this information:

31. Thank you for completing the survey! As outlined earlier, your participation in this research will be kept private to the extent provided by law. Your name and contact information will be separated from the data so it will not be linked with the responses you provided.

Please provide us with your name and the mailing address where you would like to receive your check.

- a. Name: _____
- b. Address: _____
- c. Address1: _____

- d. City: _____
- e. State: _____
- f. Zip: _____
- g. Phone number: _____

PROGRAMMER: ADD SOFT EDIT CHECK IF ANY FIELDS ARE BLANK: "You have left your contact information blank. If you do not provide complete contact information, we cannot guarantee that your incentive payment will reach you."

- 32.** You should receive your check at the address you specified in approximately 1-2 weeks. Thank you again for your participation in this important study. If you have any further questions, you may contact us at 1-800-334-8571 x26902.

[END]