



# TRANSPORT2

## Overview of Evaluations

Veronica T. Rowe, PhD, OTR/L



## Standardization Committee

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- Standardization and ongoing checks of fidelity
  - Veronica Rowe PhD, OTR/L – raters & evaluations
    - (central adjudicator for FM-UE)
  - Stacy Fritz PT, PhD – trainers and CIMT
  - Steve Wolf PT, PhD



## TRANSPORT2 Endpoints

- **Primary Endpoint:** Fugl-Meyer Upper-Extremity (FM-UE) scale - a measure of motor impairment
- **Secondary Endpoints:** Wolf Motor Function Test (WMFT) time score, a measure of functional motor activity; Stroke-Impact-Scale (SIS) hand subscale, an assessment of patient-centered quality of life.

Table: Schedule of Evaluations

Event	Baseline 1/screening visit Day -14 to -10	Baseline 2/randomization visit Day 0	Intervention (10 sessions)	First Assessment Day 15	Second Assessment Day 45	Final Assessment Day 105
FM-UE Scale	X	X		X	X	X
WMFT		X		X	X	X
SIS		X		X	X	X

The FM-UE may be repeated multiple times (if there is a difference of  $\geq 2$  in the first two UE-FM assessments). A stable baseline is required based on inclusion criteria. See inclusion criteria 5.1.



**If the Fugl-Meyer upper extremity score was not stable between two visits....**

Please bring the subject back 2 weeks (12 $\pm$ 2 days) later to repeat the FM-UE score; the subject can be recruited if the two baseline assessments are  $\leq 2$  points difference, indicating stable motor impairment. You can bring the subject back no more than 3 times. (i.e., 4 visits in total). Minimal FMA score that is acceptable is  $\leq 54$  (out of 66).

## Fugl-Meyer – Upper Extremity (FM-UE)

Fugl-Meyer AR, Jaasko L, Leynam I, Olsson S, Steglind S. The post-stroke hemiplegic patient. Scand J Rehabil Med 1975; 7: 13-31.

- Based on Brunnstrom's observations that there is a regular order of motor function recovery among stroke patients.
- Recovery of motor function takes place in stages:
  1. Reflexes re-occur.
  2. Stereotyped volitional movements can be initiated within flexor and extensor synergies.
  3. Movements can be performed with little or no synergy dependence.
  4. Reflexes are normalized.



# FM-UE Video

- [You Tube video](#)
- <https://www.youtube.com/watch?v=B70qDf13LyA>



## Wolf Motor Function Task (WMFT)

- Assesses changes in impairment of UE for mild to moderate stroke
  - 15 timed measures (mean)
  - 2 strength measures



Wolf SL, Catlin PA, Ellis M, Archer AL, Morgan B, Piacentino A. Assessing Wolf motor function test as outcome measure for research in patients after stroke. *Stroke*. Jul 2001;32(7):1635-1639.

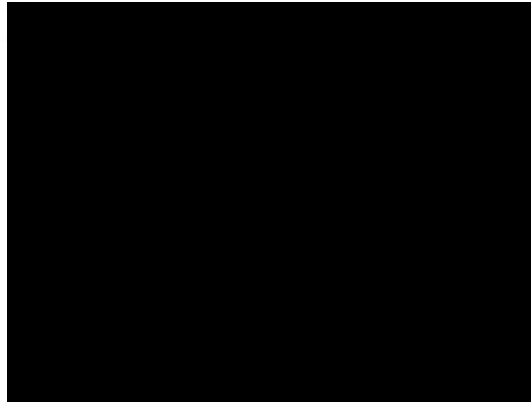
Full instructions found in supplementary material: Duff, S.V., He, J., Nelsen, M.A., Lane, C.J., Rowe, V.T., Wolf, S.L., Dromerick, A.W., Winstein, C.J. Inter-rater reliability of the Wolf motor function test – Functional Ability Scale: Why it matters. *Neurorehabil Neural Repair*. Jun 2015;29(5):436-443.



## WMFT video

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- [WMFT on You Tube](#)
  - <https://www.youtube.com/watch?v=SIJk88Nd-ZM>



## Stroke Impact Scale (SIS), version 3.0

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Duncan, P.W., D. Wallace, S.M. Lai, D. Johnson, S. Embretson, L.J. Laster (1999) The Stroke Impact Scale Version 2.0. Evaluation of reliability, validity, and sensitivity to change. *Stroke* 30, 2131-2140.

### [SIS Website](#)

<http://www.kumc.edu/school-of-medicine/preventive-medicine-and-public-health/research-and-community-engagement/stroke-impact-scale.html>



## Stroke Impact Scale (SIS), version 3.0

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### **Domains:**

Strength  
Hand Function  
Mobility  
ADLs  
Emotion  
Memory  
Communication  
Social Participation



## Stroke Impact Scale, v.3.0 example

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**The following questions are about your ability to use your hand that was MOST AFFECTED by your stroke.**

<b>7. In the past 2 weeks, how difficult was it to use your hand that was most affected by your stroke to...</b>	<b>Not difficult at all</b>	<b>A little difficult</b>	<b>Somewhat difficult</b>	<b>Very difficult</b>	<b>Could not do at all</b>
a. Carry heavy objects (e.g. bag of groceries)?	5	4	3	2	1
b. Turn a doorknob?	5	4	3	2	1
c. Open a can or jar?	5	4	3	2	1
d. Tie a shoe lace?	5	4	3	2	1
e. Pick up a dime?	5	4	3	2	1





# TRANSPORT2

## Raters and Assessments

Veronica T. Rowe, PhD, OTR/L



## What's in the BOX???



- TRANSPORT2 MOP – Evaluations
- Fugl-Meyer – Upper Extremity
  - Fugl-Meyer – UE Videos
    - Instructional video, Video 1, Video 2
  - FM-UE Data Collection Form
  - MOP Appendix – FM-UE Instructions for Administration (v.7 from BlueCloud – adapted for TRANSPORT2)
  - MOP Appendix – FM-UE items to be utilized
  - MOP Appendix – FM-UE Standardization of Ratings Form
- Wolf Motor Function Test
  - WMFT Videos
    - Instructional video, Video 1, Video 2
  - WMFT Data Collection Form
  - MOP Appendix – WMFT Instructions for Administration Adapted for TRANSPORT2
  - MOP Appendix – WMFT items to be utilized
  - MOP Appendix – WMFT Standardization of Ratings Form
- Stroke Impact Scale
  - SIS Video
    - Instructional video
  - MOP Appendix – SIS Data collection Form – PatientInstrument (copyright)
  - MOP Appendix – SIS Instructions for Administration
  - MOP Appendix – SIS Ratings Scales in Large Print
  - MOP Appendix – SIS Standardization of Ratings Form



## Manual of Procedures (MOP) for TRANSPORT2 Outcome Assessments

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### STUDY OVERVIEW

[Purpose of Manual of Procedures](#)  
[Description of Study Intervention and Study Design](#)  
[Endpoints](#)

### EVALUATIONS OF MOVEMENT AND FUNCTION

[GENERAL OPERATING PROCEDURES FOR EVALUATIONS](#)  
[Standardization Committee](#)  
[Start-Up Phase](#)  
[Masking of Personnel](#)  
[Procedure for Evaluations](#)  
[Procedure for Initial Standardization and Ongoing Checks of Fidelity for Administration of Evaluations](#)  
[Submitting Video Records](#)  
[Rating Video Records](#)  
[Results of Standardization Rating](#)  
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[Fugl-Meyer Upper Extremity \(FM-UE\)](#)  
[Wolf Motor Function Test \(WMFT\)](#)  
[Stroke Impact Scale \(SIS\) Version 3.0](#)

### Appendix contents

[1. FM-UE Instructions for Administration](#)  
[2. FM-UE Data Collection Form \(CRF\)](#)  
[3. FM-UE Standardization of Ratings Form](#)  
[4. FM-UE items to be utilized](#)  
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[9. SIS Instructions for Administration](#)  
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[13. SIS Standardization of ratings form](#)

### FM-UE References

### WMFT References

### SIS References



## Procedures for Evaluations

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1. Prior to the in-person training workshop, each rater will all obtain part of their initial standardization with certification for the FM-UE via [www.bluecloud.com](http://www.bluecloud.com) (login and access will be provided to therapists at each site). Each rater will also review written and video example material on the FM-UE, WMFT, and SIS.
2. During the in-person training workshop, verbal, live, and video demonstrations of the FM-UE, WMFT, and SIS will be delivered along with questions and answers. Raters will also be allowed to practice administration of all assessments and given feedback on their performance.



## Procedures for Evaluations

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3. Each site will submit pictures of FM-UE and WMFT items to be used during the evaluations for approval from the Standardization Committee member in charge of raters and evaluations.
4. After the in-person training workshop, each rater will return to their respective site to continue practicing administration of the outcome measures. Each rater will then upload video recordings of FM-UE, WMFT, and SIS being administered with a pilot participant, along with a self-report of the rater's administration on the standardized rating form for each assessment to the TRANSPORT2 website or a HIPAA compliant storage site, such as BOX.
5. Initial standardization to occur with a score of 90% criterion of conformity to trial-wide standardized procedures prior to enrollment of TRANSPORT2 participants.
6. Video of every FM-UE and WMFT assessed on randomized participants are to be uploaded to WebDCU.



## Procedures for Evaluations

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7. Continued fidelity checks for each rater will be as follows:
  1. Video submission of baseline FM-UE, WMFT, and SIS for every 4th participant enrolled of each rater for ongoing fidelity checks.
  2. In addition, each rater will obtain re-certification after each 4th participant enrolled via [www.bluecloud.com](http://www.bluecloud.com) on the FM-UE.
  3. A member of the Standardization Committee will make a site visit to ensure the adherence of the standards and fidelity for the FM-UE. On average, each site will have at least one visit during the study period unless there is an additional issue with the site.
  4. Occasional random requests (no set timing) for checks of fidelity.
8. Additional initial standardizations and subsequent ongoing checks of fidelity are added with changes in personnel as needed.





## Fugl-Meyer – Upper Extremity (FM-UE)

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- Unilateral tasks and movements.
- Tasks ordered according to presumed stages of recovery.
- Patient performs single- or multi-joint movements and maintains position in another joint, to reach and control a starting position, to grasp objects and hold them against resistance.
- Co-ordination and speed for the upper limb measured by finger-to-nose test (dysmetria, tremor, speed)
- Each side evaluated separately.



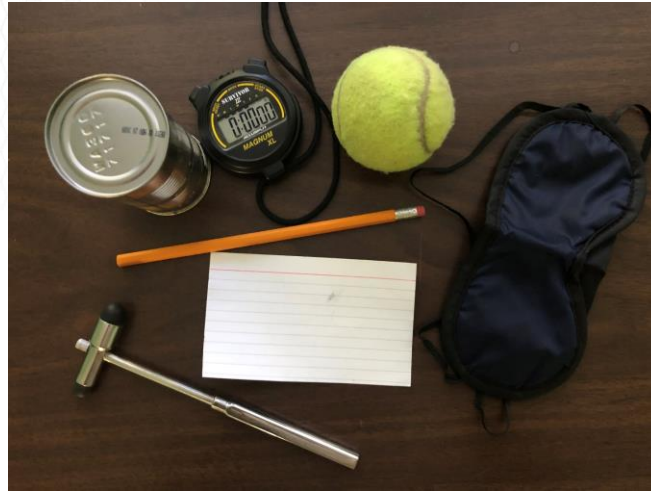
## FM-UE Scoring

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- Cumulative numerical score (out of 66).
- Most tasks 3 point ordinal scale (except reflex activities which are dichotomous):
  - 0 = No function
  - 1 = Partial function
  - 2 = Perfect function



## FM-UE Materials Needed



## FM-UE protocol for TRANSPORT2

Fugl-Meyer AR, Jaasko L, Leynam I, Olsson S, Steglind S. The post-stroke hemiplegic patient. Scand J Rehabil Med 1975; 7: 13-31.

*Some specific interpretations:*

- \*Participant seated in chair without armrests
- \*Flexor synergy – note the order on the score sheet: 1. Shldr retraction 2. Shldr elevation, etc.
- \*Extensor synergy – forearm pronation can only be scored a 2 when there is full elbow extension AND shoulder add/IR in items 9 (add/IR of shoulder) and 10 (extension of elbow)
- \*Dorsiflex wrist - 0=can't dorsiflex wrist to 15°, 1=can dorsiflex at least 15° but not against resistance
- \*Thumb adduction – paper pulled in direction away from participant
- \*Pincer grasp – pencil presented in vertical manner and pulled in direction away from participant (vertically)
- \*Grasp a cylinder – small can approximately 4.5 cm diameter, grasped between thumb and index finger, pulled in an upward direction
- \*Spherical grasp – present tennis ball on open palm to subject's finger tips, pulled in an anti-palmar direction, all fingers must be on the ball
- \*Coordination/Speed – begin timing when subject's hand leaves knee and stop timing when hand reaches nose for 5<sup>th</sup> time
  - Tremor – oscillations during trajectory from start to end point, which may or many not increase as subject approaches target
  - Dysmetria – error in endpoint destination
    - 0=pronounced or unsystematic (random error occurs)
    - 1=light and systematic (same error of size and direction)
    - 2=none (index finger tip or MCP lands in area 1 cm squared to tip of nose)
- Speed – timed and compared to less affected side
  - 0= ≥6 seconds slower
  - 1= between 2-5 seconds slower
  - 2= less than 2 seconds slower



## FM-UE protocol for TRANSPORT2

- TRANSPORT2 will follow all the WRITTEN instructions for administration of the FM-UE available from BlueCloud (created by Steve Cramer), EXCEPT for the following:
  - Raters will not stretch or perform ROM on the participants during testing, nor will they instruct the participants in stretching or ROM. The participant may independently perform self ROM and stretching unprompted.
  - Raters will not provide physical support to the participants during any of the tasks.



## FM-UE protocol for TRANSPORT2

Table 1. Support may be given during certain tasks.

Task	Assist to starting position?	Support during task?	Where is support given?
Reflexes	yes	yes	Anywhere on arm
Shoulder Retraction Elevation Abduction External Rotation Elbow flexion Forearm supination			
Shoulder Add/IR Elbow Extension Forearm Pronation		Should not assist; rapidly; will be manual	Humerus and forearm
Hand to L/S Shoulder Flexion 0-90 Elbow 90 – pro -supination	Yes – <i>Shldr</i>	No	Stretch arm into position
Shoulder Abduction 0-90 Shoulder Flexion 90-180 Elbow 0 – pro -supination			Stretch arm into position
Wrist Elbow 90 wrist stability Elbow 90 flex/extension Elbow 0 wrist stability Elbow 0 flex/extension Elbow 0 circumduction			Proximal forearm to support elbow to 90 or 0. Caution not to affect synergistic movement, start position or active movement during task.
Hand Fingers grasp/extension Grasps A-E	Yes	Yes	Proximal forearm to support elbow to 90.
Coordination Tremor Dysmetria Speed	No	No	



# FM-UE Video

- Videorecording considerations –
  - Verbalize observations of reflex testing, especially if it is difficult to capture on video
  - Verbalize any observations, especially if you think they may not be adequately captured on the video. For example – whether or not the participant was able to hold an object against a tug.
  - Do NOT verbalize your score of any task on the video.
  - Video angle from front for all movements, except for the following (these three movements should have video evidence from a posterior position):
    - Shoulder girdle retraction
    - Shoulder girdle elevation
    - Hand to lumbar spine



## Fugl-Meyer – Upper Extremity (FM-UE)

- **FM-UE Instructions for Administration**
- **FM-UE Items to be Utilized**
- **FM-UE Data Collection Form (CRF\*)**
- **FM-UE Standardization of Ratings Form**

**\*CRF not finalized yet**



## Wolf Motor Function Task (WMFT)

### General Instructions

- Both upper extremities are to be tested. Less affected first, then more affected
- Encourage participants to do the best they can with the non-affected side as the comparison of both sides is key to scoring.
- For each of the 17 tasks, verbal and demonstrative instructions shall be provided.
- For all timed tasks, participants shall be instructed to perform the tasks as quickly as possible.
- Participants shall not practice the task before being tested.
- The tester shall cue the start of the timed tasks by saying, "Ready! Set! Go!!"



## WMFT General Instructions, cont.

- Start time must be coincident with "Go!" The stop time must be coincident with the event defined in the instructions.
- Verbal encouragement may be given to Participants during a task attempt to maintain motivation or attention.
- If objects are dropped on the floor during a task attempt, the tester shall quickly return the object to the starting position without interruption of the timing process.
- Participants are allowed up to 2 minutes to complete each task.
- Record grip strength in **kilograms**
- Record weight to box in **pounds**



## WMFT General Instructions, cont.

- Essential Elements vs. Desirable Elements
  - Essential Elements- Specific elements that must be accomplished in order for the task to be deemed “complete”.
  - Desirable Elements- Other qualitative elements that should be included in the task but are not necessary for completion.
  - Presence of both the Desirable Elements and the Essential Elements define “correct” completion of a task. If the Participant completes the Essential and Desired Elements of a task, the timed score is reported on the CRF with an indication of “Desired elements completed”.
  - If the Participant is unable to complete the Desirable Elements within all valid trial opportunities, but performed all Essential Elements on the last trial, the task was completed and thus a timed score shall be recorded with an indication of “Essential Elements only completed”.
  - If the Participant is unable to complete the Essential Elements of a task, a 120 is assigned for the timed score.
- The Evaluator shall comment for the video re: deviations from the desired movement elements



## WMFT Materials



## WMFT task example from updated instructions 5.8.12

### 3. Extend elbow (to the side)

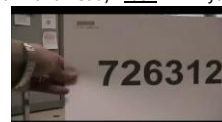
SET UP	TASK	VERBAL INSTRUCTIONS
<p><u>Starting Position:</u></p> <ul style="list-style-type: none"> <li>Chair Position (Side).</li> <li>Hips against back of chair.</li> <li>Table surface shall be lightly dusted with baby/talcum powder.</li> <li>Hand not being tested in lap.</li> <li>Shoulder of test arm abducted with forearm resting flat on table in a pronated position. Palmar surface of hand need not be flat on table.</li> <li>Forearm being tested is resting on, adjacent and parallel to front edge of table; elbow at 14-cm line.</li> <li>Filming Position (Side-Facing).</li> </ul>	<p><u>Task description:</u></p> <p>Participant attempts to reach across the 40-cm. line on template by extending the elbow (to the side). Elbow can be lifted off the table during the task. This may be the only way shorter subjects can reach 40-cm. line. Shoulders should be kept level to prevent leaning with the trunk. Some external rotation at the shoulder is necessary to carry out this movement, but the examiner should prevent too much of this movement.</p> <p><u>Timing Procedure:</u></p> <p>Starts on the word "Go" and ends when any part of the thumb crosses the line.</p> <p><u>Measure:</u></p> <p>The time elapsed from the starting point to the time any part of the thumb initially crosses the line.</p>	<p><u>Verbal Instructions while demonstrating slowly:</u></p> <ul style="list-style-type: none"> <li>"Slide your hand across the table by moving your hand away from your body and straighten your elbow to its fullest extent; like this. Your thumb should cross this line (point to the 40-cm line). You can raise your elbow from the table if you like but your hand should remain in contact with the table. Also, please keep your shoulders level and just move your arm; just like this (demonstrate). Do not lean over; keep your body as straight as possible. Do this as quickly as you can."</li> <li>(Note: the Participant should <u>slide</u> his/her hand across the table. Repeat the task if the hand is lifted off of the table.)</li> </ul> <p><u>Verbal instructions while demonstrating quickly:</u></p> <ul style="list-style-type: none"> <li>"Straighten your elbow as fast as you can. Slide your hand across the table so your thumb crosses this line (point to 40cm line)"</li> <li>"Do you have any questions?"</li> <li>"Ready...Set...Go!"</li> </ul> <p><u>Desirable Element:</u></p> <ul style="list-style-type: none"> <li>Hand maintains contact with table as sliding</li> </ul> <p><u>Essential Element:</u></p> <ul style="list-style-type: none"> <li>Part of thumb crosses 40 cm line</li> </ul> <p><u>Repeat once if:</u></p> <ul style="list-style-type: none"> <li>Thumb does not cross the 40 cm line</li> <li>Hand loses contact with table</li> </ul>



## WMFT video

### Videorecording considerations –

- For each session, film the participant number before beginning the test.
- Camera height and position should allow a field of view that includes maximal clarity of the task end position on the template. Additionally, one of the following filming positions should be used when videotaping each task.
  - Filming position (Side-Facing)** – View of the whole body while participant's side being tested is placed next to the desk: The camera should be placed approximately 3 feet in front of and to the opposite side of the participant being tested (camera on participant's left side if right arm being tested) and in line with the back edge of the desk. The camera view should include the participant's entire body so that the full movement of the hand from the lap to the table can be seen. Tasks: 1. Forearm to table, 2. Forearm to box, 3. Extend elbow, 4. Extend elbow with weight
  - Filming position (Side-Side)** – View of the whole body while participant is facing the desk: The camera should be placed approximately 3 feet to the side of the participant and on the same side being tested (camera on participant's left side if left arm being tested) and in line with the back edge of the desk. The camera view should include the participant's entire body. Tasks: 5. Hand to table, 6. Hand to box, 7. Weight to box, 8. Reach and retrieve
  - Filming position (Side-Close)** - Profile of Expanded View of Limb Being Tested. Camera in same position as Side-Side, but the camera view should be zoomed in to focus on fine motor skills. The view should include the participant's entire upper extremity. Tasks: 9. Lift can, 10. Lift pencil, 11. Lift paperclip, 12. Stack checkers, 13. Flip cards, 14. Grip Strength, 15. Turning key in lock, 16. Fold towel
  - Filming Position (Front)** - Front View: The camera should be placed approximately 3 feet in front of the desk and the camera view should include the participant's upper body (trunk and head). Task: 17. Lift basket



## Wolf Motor Function Test (WMFT)

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- **WMFT Instructions for Administration**
- **WMFT items to be utilized**
- **WMFT Data Collection Form (CRF\*)**
- **WMFT Standardization of Ratings Form**

**\*CRF not finalized yet**



## Stroke Impact Scale (SIS), version 3.0

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Duncan, P.W., D. Wallace, S.M. Lai, D. Johnson, S. Embretson, L.J. Laster (1999) The Stroke Impact Scale Version 2.0. Evaluation of reliability, validity, and sensitivity to change. *Stroke* 30, 2131-2140.

[SIS Website](http://www.kumc.edu/school-of-medicine/preventive-medicine-and-public-health/research-and-community-engagement/stroke-impact-scale.html)

<http://www.kumc.edu/school-of-medicine/preventive-medicine-and-public-health/research-and-community-engagement/stroke-impact-scale.html>





## Stroke Impact Scale (SIS), version 3.0

- Based on feedback from patients and their caregivers
- Measures aspects of stroke recovery
- Health related quality of life questionnaire
- Assesses changes in impairments, disabilities, and handicaps following a stroke
- Interviewer-administered questionnaire
- Repeated administration with at least 1 month in between



## Stroke Impact Scale, v.3.0 example

**The following questions are about your ability to use your hand that was MOST AFFECTED by your stroke.**

<b>7. In the past 2 weeks, how difficult was it to use your hand that was most affected by your stroke to...</b>	<b>Not difficult at all</b>	<b>A little difficult</b>	<b>Somewhat difficult</b>	<b>Very difficult</b>	<b>Could not do at all</b>
a. Carry heavy objects (e.g. bag of groceries)?	5	4	3	2	1
b. Turn a doorknob?	5	4	3	2	1
c. Open a can or jar?	5	4	3	2	1
d. Tie a shoe lace?	5	4	3	2	1
e. Pick up a dime?	5	4	3	2	1



## SIS rating scale in large print example

**7. The following questions are about your ability to use your hand that was MOST AFFECTED by your stroke.**

**1 = Could not do at all**

**2 = Very difficult**

**3 = Somewhat difficult**

**4 = A little difficult**

**5 = Not difficult at all**



### 9. Stroke Recovery

**On a scale of 0 to 100, with 100 representing full recovery and 0 representing no recovery, how much have you recovered from your stroke?**

\_\_\_\_\_ 100 Full Recovery  
 \_\_\_\_\_  
 \_\_\_\_\_ 90  
 \_\_\_\_\_  
 \_\_\_\_\_ 80  
 \_\_\_\_\_  
 \_\_\_\_\_ 70  
 \_\_\_\_\_  
 \_\_\_\_\_ 60  
 \_\_\_\_\_  
 \_\_\_\_\_ 50  
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 \_\_\_\_\_ 40  
 \_\_\_\_\_  
 \_\_\_\_\_ 30  
 \_\_\_\_\_  
 \_\_\_\_\_ 20  
 \_\_\_\_\_  
 \_\_\_\_\_ 10  
 \_\_\_\_\_  
 \_\_\_\_\_ 0 No Recovery



## Stroke Impact Scale (SIS), version 3.0

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- **SIS Instructions for Administration**
- **SIS Patient Instrument**
- **SIS Data Collection Form (CRF\*)**
- **SIS Rating Scales in Large Print**
- **SIS Standardization of ratings form**

**\*CRF not finalized yet**



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