User Manual:
Instructions for targeted Box and Blocks Test (tBBT)

Tool Reference

RST Reference Number: RST24NO02.01

Date of Publication: 07/11/2024

Recommended Citation: U.S. Food and Drug Administration. (2024). *Targeted Box and Blocks Test (tBBT)* (RST24NO02.01). https://cdrh-rst.fda.gov/targeted-box-and-blocks-test-tbbt

For more information

Catalog of Regulatory Science Tools to Help Assess New Medical Devices

Disclaimer

About the Catalog of Regulatory Science Tools

The enclosed tool is part of the Catalog of Regulatory Science Tools, which provides a peer-reviewed resource for stakeholders to use where standards and qualified Medical Device Development Tools (MDDTs) do not yet exist. These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed. These tools use the most innovative science to support medical device development and patient access to safe and effective medical devices. If you are considering using a tool from this catalog in your marketing submissions, note that these tools have not been qualified as Medical Device Development Tools and the FDA has not evaluated the suitability of these tools within any specific context of use. You may request feedback or meetings for medical device submissions as part of the Q-Submission Program.

For more information about the Catalog of Regulatory Science Tools, email OSEL_CDRH@fda.hhs.gov.

General information

The targeted Box and Blocks Test (tBBT) is a performance-based clinical outcome assessment tool that elicits ecologically representative actions including movement initiation, grasp, transport, and controlled release of objects during an upper limb task.

Equipment needed

- Stopwatch
- Table of standard height between 71 – 81 cm (28 – 32 in)
- Chair
- tBBT inserts (see Appendix for detailed drawing of inserts)
- Box and Blocks Test box (wooden box with dimensions 53.7 cm x 25.4 cm x 8.5 cm with 15.2 cm tall partition placed in the middle of the box)
- 9 wooden blocks (2.5 cm x 2.5 cm x 2.5 cm) numbered 1 – 9
- Paper underneath the inserts with target spaces labeled as shown in Figure 1

Set-up

- Place a sheet of white paper on each side of the box.
- Place inserts inside the test box on each side of the partition. Use a marker to label the target spaces according to Figure 1.
- Place one block inside each of the target holes on the side of the participant's testing hand. For ease of task explanation, each row can consist of a single-color block (see Figure 1). However, this is not a requirement.
- Place the box 5 cm from the edge of the table closest to the subject
- Ask participant to sit/stand in a comfortable position at the table
- Align the center of the box with the participant's body midline

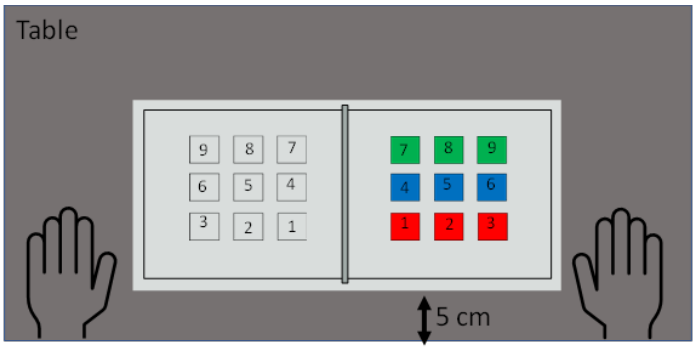

Figure 1: Initial block placement and order selection, and final block placement after transport for testing of the right hand. The box is oriented in this figure as it would be oriented in front of the participant.

See Figure 1 for a pictorial representation of the test set-up.

Overview of test administration (see page 3 for detailed administrator script)

- Participants will be instructed to transport one block at a time, placing the blocks in the mirrored position on the opposite side of the partition. The blocks on the right side of Figure 1 are numbered in the order the participants should pick them up. The left side of Figure 1 shows the location of the mirrored position for each block.
- Prior to testing, the participant is permitted (but not required) to practice by transporting up to the first two rows of blocks (i.e. blocks 1 – 6).
- The participant will be instructed to place their hands on the sides of the box before testing begins.
- The participant's score will be the time it takes to transport all 9 blocks. Each participant should complete three (3) trials, where a trial constitutes the attempted transport of all 9 blocks.
- The number of unsuccessful transports will also be tracked for each trial. **An unsuccessful transport is any block that is not within the target space, leaning against the target grid, or any block that was dropped during the task** (Figure 2).
    - A transport is deemed successful if the block is placed within designated space in the target grid. The block must be placed flat in the target space (see Figure 2)

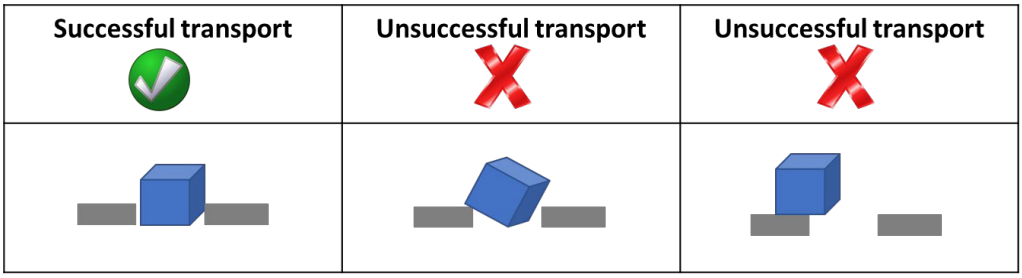

Figure 2: Depiction of the final placement of a block for successful and unsuccessful transports.

Reasons to stop and retest

- The participant consistently drops the block over the partition and/or nudges it into the target hole.
- The participant forgets the order of transport and does not place the blocks in their mirrored position.

Administrator script for tBBT

The following *"italized and highlighted text"* should be read to the participant, with statements in **[bold and brackets]** indicating actions that can be taken by the test administer to improve instruction clarity. The test administrator can choose whether the participant performs the task first in seated or standing position. The instructions that follow are the same for both positions.

"In this task, you will have to grasp and transport 9 blocks as quickly as you can from one side of the box to the opposite side, placing the blocks within the holes of the target grid. When I say, 'Go', you will start by picking up the block in the lower corner closest to the partition, transporting it over the partition, and placing it in its mirrored position on the opposite side."
[test administrator points to the target hole closest to the partition in the first row on the testing hand side then points to the target hole closest to the partition in the first row on the non-testing side]

"Continue to transport all blocks in this row, placing them in their mirrored position on the opposite side of the partition. Let me show you."
[test administrator should transport the first row of blocks in the same direction the participant should move the blocks. Put all blocks back in the proper starting position after this demonstration].

"Once you complete a row, move to the row above, again starting with the block closest to the partition and working your way across the row."
"A transport is deemed successful as long as the block is placed fully within the target hole, like this."

[test administrator should pick up a block and place it fully within the target space]

"If the block is leaning against the target space **[DEMO]** *or the block is sitting on top of the insert* **[DEMO]**, *these would count as unsuccessful transports."*
[test administrator should take the same block as demonstrate the situations pictured in Figure 2, respectively]

"You should attempt to control the release of the block into the target hole. You should not make any adjustments to the block once you have released it on the opposite side of the partition. Particularly, you should not drop the block over the partition and nudge the block until it falls into the correct target hole."

[test administrator should pick up a block and drop it when they are about 2" above the target space, and then push the block into the target space]

"When moving these blocks, make sure to pass over the divider without touching it. However, if you do come into contact with the divider, you should continue the task. If you drop a block for any reason, leave the block and continue on to the next block."

"Do you have any questions?"

[Test administrator should answer any questions. Note: if the participant drops any block, instruct them to continue the task. A dropped block will count as an unsuccessful transport and be noted in the final scoring sheet.]

"We will now practice the task by transporting up to the first two rows with your [right/left] *hand/prosthesis. Please place your hands on the sides of the box. When it is time to start, I will say "Ready…go".*

[Initiate the practice trial, making sure that the participant is selecting the blocks in the correct order and accurately placing them in the correct target hole. If the participant has any issues, clarify the instructions. Once the participant has completed the practice trial, return the blocks to their original positions. If the participant has significant issues completing the practice trials, the test administrator can make a decision to forego testing at this time.]

"We will now start the actual test. The instructions are the same. Work as quickly and as accurately as you can. Please start with your hands on the sides of the box. Ready…go."

[Start the timer when you say 'Go'. Stop the timer when the participant releases the 9th block on the non-testing side of the partition. Record the time. Multiple trials of the task can be repeated in this position (seated/standing) as needed. Once 3 acceptable trials in the current position is reached, instruct the participant to perform the task in the other position.]

Appendix

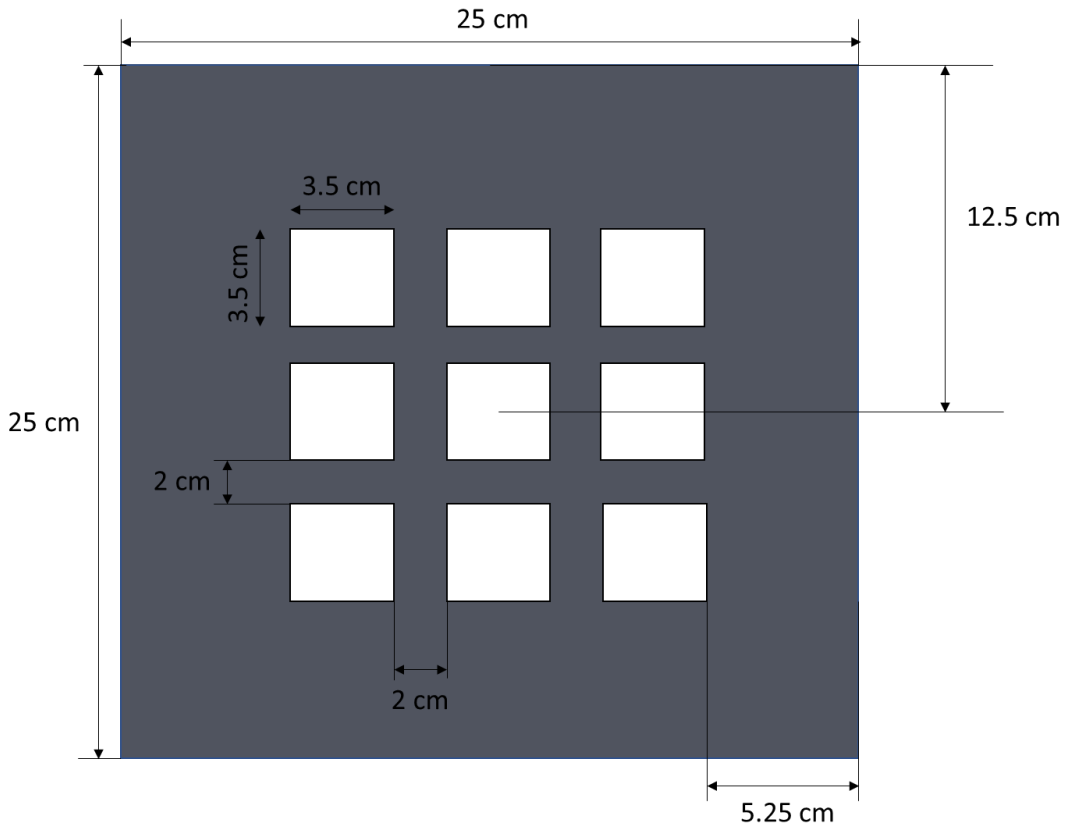

Figure A1: Detailed drawing of insert dimensions. The recommended material for the inserts is polyethylene plastic. This material comes in a standard thickness of approximately 0.635 cm (0.25 inches).