Usability Management File - Assess		
Document Number	Document Title	Revision No.
UMF-SB20-001	**Instructions for Use - Assess**	**002**

<u>Effective Date:</u> *See eQMS for list of approval and effective date.*

BrainCheck

BrainCheck Assess®
Instructions for Use (IFU)

Warning: *BrainCheck Assess is an FDA Class II Medical Device. The device should be interpreted only by qualified healthcare professionals. The device is not intended to be used as a stand-alone diagnostic device. The device is not intended to identify the presence or absence of clinical diagnosis. BrainCheck Screen, BrainCheck Plan and screeners are not regulated devices, but may be used alongside BrainCheck Assess to support clinical decision making in evaluating cognitive status.*

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BrainCheck, INC.

All questions or concerns about BrainCheck products should be forwarded to:

BrainCheck, INC.
3000 E Cesar Chavez Street, Suite 300
Austin, TX 78702
USA

Tel: 888.416.0004
Email: Support@BrainCheck.com
Website: https://braincheck.com/
Website Support: https://braincheck.com/about/#contact
BrainCheck Assess Login: https://provider.braincheck.com/login

IMPORTANT: Do not change or modify any component of BrainCheck Assess, unless expressly approved by BrainCheck INC.

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INTRODUCTION

This overview was written for people who are considering administering BrainCheck Assess as a **computerized cognitive assessment aid** in clinical work up for cognitive function. Every person is unique and medical needs differ, even people with the same condition and the same Report scores.

The first part of this overview discusses cognitive impairment and BrainCheck Assess. It is based on common questions that people have about their condition, this particular option for **computerized cognitive assessment aid** in clinical work up for cognitive function, and BrainCheck Assess.

The second part of this overview explains how to use the device.

Throughout the overview, definitions of medical or electronic terms are provided in a shaded box with a definition.

> **Computerized Cognitive Assessment Aid.** The computerized cognitive assessment aid is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The computerized cognitive assessment aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical diagnoses. The computerized cognitive assessment aid is not intended as a stand-alone or adjunctive diagnostic device. **-21 CFR 882.1470 (a)**

ABOUT COGNITIVE ABILITY

Cognitive ability is defined as a general mental capability involving reasoning, problem solving, planning, abstract thinking, complex idea comprehension, and learning from experience. An individual's cognitive ability provides the foundation for innovative capabilities. Such cognitive abilities include intelligence, attention, memory ability, and even pattern recognition. Cognitive ability refers to the functioning usually considered to be from a person's brain domain. In general, the higher an individual's cognitive abilities, the more able that person is to develop innovations and implement innovations from other sources.[1]

[1]*M. Mayfield, in Encyclopedia of Creativity (Second Edition), 2011*

ABOUT COGNITIVE IMPAIRMENT AND FUNCTION

There are many factors that could impact people' cognitive functioning, intellectual functioning, and health literacy, including a primary illness, other comorbid medical conditions, previous brain injuries, and demographic factors such as age and educational attainment.[2]

[2]*Kristy L. Engel, Kristin K. Kuntz, in Psychosocial Aspects of Chronic Kidney Disease, 2021*

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Most people experience cognitive impairment, at some point, when there is a stimulus impacting cognitive function. The normal process of aging, substance ingestion, lack of sleep, and other adverse events may cause temporary cognitive impairment. Normal cognitive function returning within a reasonable time period of cognitive impairment is normal.

Chronic cognitive impairment is very different. Individuals with chronic cognitive impairment may also feel cognitive impairment when there is no obvious reason or may have impairment that does not go away after several months. A Test Administrator should independently evaluate the overall conditions to determine if chronic cognitive impairment is present.

> **CHRONIC.** Something that persists or lasts for more than 3 months. Chronic cognitive impairment does not go away with the passage of time. Cognitive decline over time may also be an indicator of chronic cognitive impairment.

Chronic cognitive impairment can be **intractable**, which is the medical term meaning that it is hard to treat.

THE BRAINCHECK PLATFORM

BrainCheck Assess works as a computerized cognitive assessment aid for a prescribing clinician or Test Administrator, to use as an element in a clinical cognitive work up. BrainCheck Assess is a prescription medical device requiring a health care provider to administer and interpret the device results. BrainCheck Assess is capable of measuring correctness of responses in cognitive domains via the digitization of clinically validated paper-pencil administered tests. It is also capable of measuring accurate response times, which was not available in the traditional paper-pencil administered tests. The cognitive domains measured are:

- Memory (Immediate and Delayed Recognition)
- Attention (Trails A)
- Mental Flexibility (Trails B)
- Executive Function (Stroop and Digit Symbol Substitution)
- Processing Speed (Digit Symbol Substitution)

The Report is generated by measuring the score against a normative database of similar candidates. Cutoff levels are pre-established based on demographic criteria and results of normative data. The Report is capable of calculating the score, percentiles, and likelihood of impairment.

INTENDED USE/PURPOSE

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BrainCheck Assess is intended (appropriate) for certain *usage conditions*:
1) Computerized Cognitive Assessment Aid.
2) Measurement of likelihood for cognitive impairment, function and/or ability.
3) Brain domain assessment.

BrainCheck Assess may not be right for everyone. The intended use/purpose of this device are as follows: BrainCheck Assess is intended to be used as a prescribed Class II (special controls) medical device. It is a computerized cognitive assessment that helps healthcare providers evaluate a person's cognitive function by way of delivering a battery of game-like tests. The associated report is intended to be interpreted by a qualified healthcare provider to provide results of a Test Taker's performance. The Assessment is not intended to be used as a stand-alone diagnostic to identify the presence or absence of clinical diagnoses or any specific disease or condition. The Assessment should not be used as a substitute for an independent review or diagnosis of any disease or condition by a qualified health provider.

INTENDED PERFORMANCE

BrainCheck Assess is a computerized cognitive assessment that helps healthcare providers evaluate a Test Taker's cognitive function by way of delivering a battery of game-like tests. The administration and test taking are streamline, intuitive and efficient once a workflow is established.

CONTRAINDICATIONS

BrainCheck Assess is contraindicated (not appropriate) for certain *administration conditions*:
- Testing Areas with Network interference.
- Testing Areas with Internet interference.
- Testing Areas with Environmental disturbances.
- Test Takers that are illiterate in English and/or Spanish.
- Test Takers that are under age 18.

BrainCheck Assess is contraindicated (not appropriate) for *person use* who is:
- Unable to operate the system due to:
  - Extraordinary cognitive impairment.
  - Paralysis of the arms, forearms or hands.
  - Disabilities causing tremors, shaking, or uncontrollable movements of the arms, forearms or hands.
  - Vision impairment.
  - Sensitive to light.

CONTRAINDICATIONS are situations in which the device should not be used because the risk of use clearly outweighs any possible benefit. Contraindications are determined

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by medical experts, clinical studies, and/or the Food & Drug Administration (FDA).

WARNINGS

Warnings are statements about the safety of BrainCheck Assess that should be taken very seriously. If these warnings are not followed, it may be possible that the device could contribute to an inadequate clinical work-up of cognitive function. The following are some warnings for BrainCheck Assess:

- The device does not identify the presence or absence of clinical diagnosis.
- The device is not a stand-alone diagnostic.
- The safety and effectiveness has not been established for children ages 0-9.

Warning: BrainCheck Assess is an FDA Class II Medical Device. The device should be interpreted only by qualified healthcare professionals. The device is not intended to be used as a stand-alone diagnostic device. The device is not intended to identify the presence or absence of clinical diagnosis. BrainCheck Screen, BrainCheck Plan and screeners are not regulated devices, but may be used alongside BrainCheck Assess to support clinical decision making in evaluating cognitive status.

PRECAUTIONS

Precautions are instructions about the device that should follow to avoid corruption to BrainCheck Assess, so that it will have correct functionality. During administration:

- Do not have the mobile device plugged into a power source at time of Assess administration.
- Use only BrainCheck approved Browsers, Operating Systems, and Devices.
- Ensure mobile devices are set to Do Not Disturb during Assess administration.

RESIDUAL RISK & SIDE EFFECTS

Residual risk, or side effects, are risks associated with the use of this or any other BrainCheck Product.

Foreseeable *residual risk* associated with BrainCheck Assess are:

- Test Administrator
  - Clinical output of computerized cognitive assessment results in false positive/negative clinical work-up.
  - No clinical output from computerized cognitive assessment aid.
  - Skewed imitations or results due to usage and usability errors.
  - Inconvenience.

- Test Taker

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- ○ Visual Fatigue from straining to take the assessment.
- ○ Anxiety waiting for results of Cognitive Assessment.
- ○ Unauthorized access to personal data.
- ○ Inconvenience.
- ○ Retesting.

Known *residual risk* associated with BrainCheck Assess are:
- Inconveniences and frustration from accessibility issues.
- Potentially inaccurate results due to retesting from Assess results not saving.
- Potentially inaccurate results due to inconvenience from Assess freeze and/or runs slow before, during or after administration.
- Inconveniences and/or potentially inaccurate results from system outage in BrainCheck Assess services or support.
- Data Security Threats.

There are no known or foreseeable adverse events or side effects associated with taking or administering Assess. Please contact the ordering Test administrator or BrainCheck Support, immediately, if experiencing any adverse events associated with the device.

USER SPECIFICATIONS
User Characteristics:
- Education Level: Any
- Technical Expertise: The ability to use the basic functionality of a desktop computer or a mobile device.
- Age Range: 13+ (Guardian consent is required for minors under age 18).
- Sex: Any

Hardware limitations (e.g., signal timing requirements):
- The desktop clients require at least 4 GB of RAM.
- The mobile client requires the mobile device's Operating System (OS) to be updated to the latest manufacturers version, i.e. System Updates are enabled.
- For remote testing, a consistent internet connection of at least 10 mbps.

Training
- No specific training is required, users can execute tasks according to prompted instructions or by following the Instructions for Use (IFU).

INSTALLATION
BrainCheck Assess is available via direct integration within the electronic health record and / or through the BrainCheck clinical application.

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PREPARATION FOR USE

In order to ensure best results from the mobile device used to administer Assess:

- Ensure the device is charged.
- Ensure the display brightness is set to >20%. >50% brightness is recommended.
- Ensure the device is clean and smudge free.
- Ensure that device notification, reminders, alerts and alarms are silenced or turned off.
- Ensure that device internet and network connectivity is established.
- Ensure that the test taker is established in the BrainCheck system prior to administration.

REQUIREMENTS FOR SPECIAL FACILITIES, OR SPECIAL TRAINING, OR PARTICULAR QUALIFICATIONS OF THE DEVICE USER

The only requirement for the test administrator is that Assess be administered by prescription. There are no specific requirements for facilities, training, and/or qualifications.

SPECIAL SYSTEM STORAGE AND/OR HANDLING

Test Administrator must be a prescribing clinician or under the orders of a prescribing clinician.

SYSTEM AVAILABILITY & APPROPRIATE USE

In order to utilize services from BrainCheck, Inc. a Test Administrator must be a client of BrainCheck. To become a client of BrainCheck, contact BrainCheck's team. Upon successful onboarding to BrainCheck and receiving appropriate training and documentation (such as this Instructions for Use document) a Test Administrator can begin prescribing BrainCheck products for individuals and interpreting the results. Ongoing use of the BrainCheck platform will require the customer account to be in good standing with BrainCheck.

ACCESS TO TESTING PLATFORM

BrainCheck Assess will be available on the Administrator's Electronic Medical Record (EMR) and/or Electronic Health Records (EHR), and through BrainCheck's clinical application. Logging in through the EMR/EHR will allow access to the integrated BrainCheck Assess functionality for both prescription and review of BrainCheck products such as BrainCheck Assess.

ADDING TEST TAKER(S)

Test takers are automatically added through the EMR/EHR integration in response to an order from a Test Administrator. No further steps are required to add a Test Taker into the BrainCheck system.

For non-integrated customers, Test Takers can be added using the intuitive clinical application via the add a patient workflow.

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ASSESS ADMINISTRATION

BrainCheck Assess should be taken in a quiet, distraction-free environment. It takes approximately 10-15 minutes to complete. During Assess, the test administrator can explain the directions and objectives to the test taker, as well as, assist the person with practice test portions. Once Assess begins, it is important that the test taker complete each assessment on their own, unaided by the test administrator.

Prior to Assess initiation, ensure the test taker:
- Has no visual impairment. Test takers should wear glasses or contact lenses, if needed.
- Can hold the testing device with comfort, keeping the device stable.
- Is in a well lit, distraction free environment.

The test administrator is required to make an entry for the 'Reason for Testing' Section. Based on the Reason for Testing, the test administrator may be prompted to enter more information and/or answer further questions.

Once Reason for Testing is complete, the Test Administrator will be prompted to notice Device and Security data prior to clicking "Begin" to proceed to test taker instructions. The device should be handed off to the test taker at this point in time to observe a brief instruction.

REMOTE ADMINISTRATION

> ***Remote Administration*** simply enables the Test Administrator to remotely administer a BrainCheck Assessment versus in-clinic. It continues to be a prescription device. BrainCheck access is controlled by the Test Administrator. The data and results are not viewed by the Test Taker, but rather intended to be interpreted by the Test Administrator.

BrainCheck can be administered remotely through BrainCheck's creation of a one-time-use access code.

Once an access code has been assigned for the Test Taker, a set of instructions will be sent to the test taker via email or SMS. These instructions will aid the test taker on how to access Assess.

TAKING ASSESS

Instruction shall inform the Test Taker to complete short games to assess the test taker's cognitive ability. It should take the test taker approximately 10 to 15 minutes to complete. Each game will start with a practice test. The Test Taker must respond as quickly and accurately as possible for best results.

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The test taker will be prompted to click "Begin Test" prior to starting the first practice test for Immediate Recognition:

1. **Immediate Recognition** - The Test Taker will be shown a brief set of instructions and then be prompted to click "Understood" when ready to take the cognitive assessment. Test Taker will see a set of ten (10) words. Each word will appear on the screen one (1) at a time for three (3) seconds. Test Taker will be prompted to remember these words. Words will begin to appear after clicking "Understood". After the ten (10) words are shown, Test Taker will then be shown a series of twenty (20) words with the option to indicate if those words were among the ten (10) previously shown. Test Taker will be asked if the word displayed is a word previously asked to remember. Test Taker will be prompted to respond "Yes" or "No" to each word shown.
   - Immediate Recognition has no time limit and no timeout functionality.
   - Recognition is scored based on accuracy.

2. **Trail Making** - Consists of two (2) separate, similar cognitive assessments:
   - **Trails A** - Test Taker will be shown a series of twenty five (25) dots. Tap the dots in numerical order (i.e. 1 - 2 - 3) until all the dots have been selected. During the practice, dots will illuminate red if incorrectly selected and will fill with dark purple if correctly selected. Once complete, Test Taker will be prompted to take the practice test again or take the cognitive assessment. After clicking "Take Test", Test Taker will be instructed to be quick and accurate and then prompted to click "Understood". The cognitive assessment will start after a 3 second countdown. Completing Trails A will initiate Trails B instructions.
     - Trails A will timeout after 30 seconds of no action.
     - Trails A is scored based on the reaction time.

   - **Trails B** - Test Taker will be shown a series of twenty four (24) dots labeled as numeric 1-12 and alphabetic A-L. Tap the dots in number-letter order (i.e. 1 - A - 2 - B - 3 - C) until all the number-letter dots have been selected. During the practice, dots will illuminate red if incorrectly selected and will fill with dark purple if correctly selected. Once complete, Test Taker will be prompted to take the practice test again or take the cognitive assessment. After clicking "Take Test", Test Taker will be instructed to be quick and accurate and then prompted to click "Understood". The cognitive assessment will start after a 3 second countdown.
     - Trails B will be skipped if Trails A times out.
     - Trails B will timeout after 30 seconds of no action.
     - Trails B is scored based on reaction time.

3. **Stroop** - Practice test will initiate. Test takers will be instructed to find and select the boxed word in the list of words provided. A green Check mark will illuminate if the correct word is selected. A red X mark will illuminate if the incorrect word is selected. Once

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complete, Test Taker will be prompted to take the practice test again or take the cognitive assessment. After clicking "Take Test", Test Taker will be instructed to be quick and accurate and then prompted to click "Understood". The cognitive assessment will start after a 3 second countdown.

- Stroop will timeout after 30 seconds of no action.
- Stroop is scored based on the reaction time.

4. **Digit Symbol Substitution** - Practice test will initiate. First, look at the symbol. Match the symbol to its number. Tap the corresponding number. A green Check mark will illuminate if the correct symbol is selected. A red X mark will illuminate if the incorrect symbol is selected. Once complete, Test Taker will be prompted to take the practice test again or take the cognitive assessment. After clicking "Take Test", Test Taker will be instructed to be quick and accurate and then prompted to click "Understood". The cognitive assessment will start after a 3 second countdown.
   - There is no timeout functionality other than the 60 second time interval.
   - DSS is scored based on the reaction time.

5. **Delayed Recognition** - Assessment will start immediately after completing the Digit Symbol Substitution. Test Taker will then be instructed to select the words shown from the Immediate Recognition assessment and displayed a series of twenty (20) words. Ten (10) words will be from the original to remember from Immediate Recognition. Distractor words will be added that were not a part of the original ten (10) words. Test Taker will be prompted to respond "Yes" or "No" to each word shown.
   - Delayed Recognition has no time limit and no timeout functionality.
   - Recognition is scored based on accuracy.

Once the final assessment is complete, Test Taker will be notified that Assess is complete. Test Taker will be requested to return the device to the Test Administrator. The Test Administrator will click "Done" and be prompted to re-enter the account password to complete the BrainCheck Assess and return to the main screen.

RESULTS AND REPORT INTERPRETATION

Once the test taker completes BrainCheck Assess, a Report will be generated by the BrainCheck system and sent to the provider's EMR/EHR. The Report provides scoring of the Test Taker's performance on BrainCheck Assess. The Report is intended to enable Health Care Providers to independently review the basis for the recommendations presented within the report. The Report must not be relied on primarily as a stand-alone clinical recommendation and must be used in combination with the Health Care Providers own judgment on making clinical decisions for individual people. The Report may be used as supplemental documentation to a clinical decision, review, and/or workup for a measurement of cognitive

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function, ability, or impairment. The Report must not be used as a stand-alone tool for diagnosis.

The Test Administrator may view/manage the Report on their EMR/EHR. Explaining results of the Report may be done using the following supplemental information:

Trails A: Test Takers with impairment may struggle with processing speed, reaction time, paying attention, visual search.
Clinical correlates to consider:
- Difficulty or avoidance of busy places
- Changes to mobility
- Difficulty with driving

Trails B: Test Takers with impairment may struggle with sequencing, working memory and set shifting, which is the ability to quickly shift between tasks.
Clinical correlates to consider:
- Navigating familiar places
- Difficulty with driving
- Paying bills correctly
- Managing medications

Digit Symbol Substitution: Test Takers with impairment may struggle with paying attention for longer periods, reading, and basic arithmetic.
Clinical correlates to consider:
- Depression
- Anxiety
- Poor sleep
- Substance use
- Driving

Stroop: Test Takers with impairment may struggle with following instructions and making decisions. Impairment on this test typically indicates frontal lobe changes.
Clinical correlates to consider:
- Personality changes or socially inappropriate behavior
- Apathy
- Poor judgment
- Social withdrawal
- Poor diet

Immediate Recognition: Test Takers with impairment may struggle with repeating themselves or asking the same question repeatedly, forgetting what they were going to do or where they placed something.

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Clinical correlates to consider:
- Losing objects
- Getting lost in familiar places
- Forgetting to turn off the stove
- Medication compliance

Delayed Recognition: Test Taker's with impairment may struggle with repeating themselves, forgetting the content of a conversation and relying on a calendar or alarm for reminders.
Clinical correlates to consider:
- Not knowing current events
- Forgetting appointments
- Medication compliance
    - Forgetting why they went somewhere or where they are going

CEASING OF USE OF BRAINCHECK PRODUCTS
1. For people there is no software to uninstall.
2. For Test Administrator users, contact BrainCheck Support for cancellation and removal of EMR/EHR connectivity and / or access to the clinical application.

DEVICE TROUBLESHOOTING & CONTACT INFORMATION
If adverse events are experienced while using the device, please report them to the ordering clincianand/or BrainCheck Inc:

BrainCheck, INC.
3000 E Cesar Chavez Street, Suite 300
Austin, TX 78702, USA
Tel: 888.416.0004
Email: Support@BrainCheck.com

If issues are experienced with BrainCheck Assess the following methods of troubleshooting may resolve the issue prior to contacting support:

For software freezing, Assess results not displaying or saving, slow downs/lags, and other inconveniences, attempt the following:
1. Exit the EMR/EHR, wait 5 seconds and attempt to relaunch Assess on the EMR/EHR.
2. Ensure the device is prepared as described in this instruction.
3. Ensure device internet connectivity. Speedtest may be executed using free software such as https://speed.cloudflare.com/.

If troubleshooting does not resolve the issue, contact BrainCheck Support at Support@BrainCheck.com .

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UMF-SB20-001 (DOC-252) Ver. 2

Approved By:

(CO-72) Update IFU Disclaimers/Warnings

Description

This change order has been initiated to update the Disclaimers and Warning statement on Medical Device IFUs and SOP037 to be consistent with, "Warning: BrainCheck Assess is an FDA Class II Medical Device. The device should be interpreted only by qualified healthcare professionals. The device is not intended to be used as a stand-alone diagnostic device. The device is not intended to identify the presence or absence of clinical diagnosis. BrainCheck Screen, BrainCheck Plan and screeners are not regulated devices, but may be used alongside BrainCheck Assess to support clinical decision making in evaluating cognitive status." UMF-SB20-001 add BrainCheck Assess Login Link on page 2/15. Result Interpretation Section for Stroop and DSST description were corrected in UMF-SB20-001. All documents in this CO were rebranded with new BrainCheck Logo.

Justification

AUDIT-1 was initiated as follow-up to verification of effectiveness in CAPA-5. Refer to Audit-1 for further details.

Assigned To:	Initiated By:	Priority:	Impact:
Ted Ramlawi	Ted Ramlawi	High	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Ted Ramlawi	October 9, 2024 5:27 PM CDT	CO-72	2	Published
Ted Ramlawi	March 29, 2024 9:20 AM CDT	CO-42	1	Superseded
Ted Ramlawi	October 26, 2023 9:47 AM CDT	CO-25	0	Superseded