

ImPACT[®]



VERSION 4

Administration and Interpretation Manual

Copyright © 2022 by ImPACT Applications, Inc
www.concussionmanagement.com
All Rights Reserved

Table of Contents

Intended Use.....	3
Warnings and Cautions.....	3
Chapter 1 - ImpACT Version 4 Neurocognitive Test Battery	4
Overview	4
What Is a Concussion?	4
When Is a Head Injury More Than a Concussion?	4
What Symptoms Are Often Associated with a Concussion?.....	4
What Is Neurocognitive Assessment and Why Use It?.....	5
Rationale for the Development of ImpACT Version 4	5
Chapter 2 - Administration and Scoring of ImpACT Version 4.....	7
What is ImpACT Version 4?	7
Ages	7
Qualifications for Administration and Interpretation	7
Administration Time	7
Technical Requirements.....	7
Test Environment	7
General Guidelines for Test Administration	8
Order of Administration	8
Instructions for Starting a New Test or Reviewing Test Records from the Customer Center	8
Neurocognitive Test Modules Descriptions, Administration Instructions, and Scoring	9
ImpACT Version 4 Post Concussion Symptom Inventory.....	12
Scoring	12
The Derived Scores for ImpACT Version 4	14
Reliable Change Index Score	17
ImpACT Version 4 Invalidity Indicators.....	20
Chapter 3 - Development and Standardization	21

Content Development	21
Alpha testing of items and development of the test modules from early versions ImpACT.....	21
Description of the Standardization Sample for ImpACT Version 4.....	21
Chapter 4 - Statistical Properties of ImpACT Version 4	23
Reliability Data for ImpACT.....	23
Validity, and sensitivity and specificity of ImpACT	25
Construct and concurrent validity of ImpACT and ImpACT Version 4	26
Summary.....	28
Chapter 5 - Interpretation.....	29
General Guidelines for Interpretation.....	29
ImpACT Clinical Report	29
The Composite Indices.....	31
Post-Concussion Symptoms Scale (PCSS)	33
Graphic Display of Neurocognitive Composite and Total Symptom Scores	34
Summary.....	34
Appendix A. References.....	35

Intended Use

ImPACT Version 4 is a medical device intended for use as a computer-based neurocognitive test battery to aid in the assessment and management of concussion. ImPACT Version 4 is a neurocognitive test battery that provides healthcare professionals with objective measure of neurocognitive functioning as an assessment aid and in the management of concussion in individuals ages 12-80.

Warnings and Cautions

ImPACT Version 4 is not intended to provide a diagnosis or decision about the test taker. The results should be interpreted only by qualified healthcare professionals.

ImPACT Version 4 does not identify the presence or absence of a clinical diagnosis.

ImPACT Version 4 cannot be used as a stand-alone diagnostic for concussion.

The device is not intended to be used as a stand-alone assessment for making determinations regarding return to activity.

Caution should be exercised when using this test to assess individuals that have been diagnosed with or are currently experiencing other confounding conditions including but not limited to the following: insomnia, post-traumatic stress disorder (PTSD), depression, attention deficit hyperactivity disorder (ADHD), memory impairment, vision impairment corrected outside normal limits, dementia, delirium, prescription and non-prescription medication, some nutritional supplements, as well as other neurological and psychiatric disorders in which impaired cognitive function may be present and a variety of other psychological states (e.g., fatigue and stress).

The safety and effectiveness of ImPACT Version 4 for individuals under the age of 12 years and over the age of 80 years has not been established.

The reliability and validity of the ImPACT Version 4 results in individuals with color blindness has not been established.

The reliability and validity of the ImPACT Version 4 results in individuals with a reading level below the sixth grade has not been established.

Baseline testing performed in an unsupervised manner may include a higher possibility for distraction than baseline testing performed in a supervised manner, which requires clinical judgment when interpreting results.

ImPACT Version 4 is intended to be used by medical professionals qualified to interpret the results of a concussion assessment examination and aid in the management of concussion.

Caution: US Federal Law restricts this device to use by, or on the order of a licensed healthcare professional.

Contact the ImPACT Applications Support Team for product or training support, to submit a complaint or report if the use of the device contributed to a serious injury, or to obtain a free printed copy of this manual.

Web: www.impacttest.com/contact

Tel: 1-877-646-7991

Email: support@impacttest.com



Manufacturer
ImPACT Applications, Inc.
2140 Norcor Ave., Ste 115
Coralville, IA 52241 USA

Australian Sponsor
ACRA Regulatory Services Pty Ltd
7/ 84 Poinciana Avenue,
Tewantin QLD Australia 4565

New Zealand Sponsor
ACRA Regulatory Services LTD
182 Teasdale Street,
Te Awamutu, 3800, New Zealand



Advena Ltd. Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

UDI: 00864127000349



Medical Device

Chapter 1 - ImPACT Version 4 Neurocognitive Test Battery

Overview

Interest in evaluating individuals to determine their neurocognitive status has evolved significantly throughout the years. With this interest comes an increasing demand for a computerized neurocognitive battery that is practical, cost effective, and efficient for healthcare professionals to use with large numbers of athletes and individuals. ImPACT Version 4 is designed to meet these demands while maintaining high standards for reliability, validity, sensitivity, and specificity. This manual is designed to describe, educate, and fully support the use of ImPACT Version 4 in clinical and research settings.

This manual has been formatted to accomplish several goals. First and foremost, this manual is structured to provide necessary background information regarding the role of neurocognitive assessment in the evaluation of an individual. The information presented in the following chapters assumes a basic level of knowledge regarding the medical treatment of concussion related injuries. In addition to presenting background information regarding concussion, this manual also presents general information that is designed to help the user get the most out of this tool. As emphasized throughout the manual, ImPACT Version 4 is a sophisticated tool developed from years of research. ImPACT Version 4 is not structured to provide diagnostic information and the diagnosis of concussion should always be made by a health care professional who has the requisite training and is authorized to manage concussion in his/her State, Province or country.

What Is a Concussion?

A concussion is a disturbance in brain function following either a blow to the head or as a result of the violent movement of the head. Existing research suggests that concussion is more of a metabolic rather than anatomic injury to the brain. In other words, following concussion there is a temporary disruption of energy utilization in the brain that does not appear to produce permanent injury in the majority of cases. However, research also suggests repeated injury, particularly during the recovery period, may result in more severe and, in some rare cases, life-threatening injury. It is important to emphasize the underlying pathophysiology of concussion is still being investigated and the definition of the injury continues to develop and evolve.

Because a concussion is currently thought to be primarily a metabolic rather than structural injury, traditional neurodiagnostic techniques (e.g., CT scan, MRI) are often normal following concussive insult; however, these techniques can be invaluable in ruling out more serious difficulties (e.g., cerebral bleed, skull fracture) that also may occur with head trauma.

When Is a Head Injury More Than a Concussion?

Most individuals recover relatively quickly from concussion (generally within two to three weeks). However, healthcare professionals need to be aware of the warning signs of severe injury. Any penetrating injury to the skull signifies a more severe head injury and should be treated as such. Any loss of consciousness requires a prompt and complete medical evaluation. Although headache is common following concussion, a severe headache that increases in intensity should be treated as a medical emergency. A pronounced decline in mental status in the minutes to hours following injury also is a cause for emergency care. Finally, sensory or motor loss in the limbs may indicate spinal injury or a subdural or epidural hematoma and should also be evaluated immediately. As noted throughout this manual, decisions regarding whether or not a concussion has or has not occurred, and the management of that injury always should be made by a qualified healthcare professional and should not be based on neurocognitive test results alone.

What Symptoms Are Often Associated with a Concussion?

Identifying a concussion can be difficult under the best of circumstances. There may be no direct trauma to the head and the individual is often not rendered unconscious. The individual may be unaware that he or she has been injured immediately after the incident and may not show any obvious signs of concussion such as

imbalance, confusion, or obvious amnesia. To complicate this situation, an individual may intentionally minimize or hide symptoms in an attempt to prevent being removed from the game or not lose time at work, thereby creating the potential for additional injury. Finally, individuals may have different symptoms following a concussive injury depending on the biomechanical forces involved and the individual's injury history. Signs (observed by others) and symptoms (reported by the person) differ from person to person and therefore an individualized approach to evaluation is necessary.

Some signs and symptoms that are frequently associated with a concussion include:

- Headache or a sensation of pressure in the head
- Nausea with or without vomiting
- Confusion or disorientation to time, place
- Retrograde amnesia (loss of memory for events preceding injury)
- Posttraumatic amnesia (difficulty with formation of new memory)
- Feeling mentally slowed down
- Feeling mentally “foggy” or “groggy”
- Dizziness
- Disruption of balance
- Sensitivity to light (photosensitivity)
- Sensitivity to noise (phonosensitivity)
- Visual blurriness, fuzziness, or difficulty tracking
- Short-term memory difficulties
- Concentration problems
- Motor clumsiness (stumbling, slowed movement)

What Is Neurocognitive Assessment and Why Use It?

Neurocognitive assessment is a performance-based method to assess the many aspects of cognitive functioning. Included in this assessment are measurements of reaction time, processing speed and memory. A neurocognitive assessment is used to examine normal cognitive function and differentiate the cognitive consequences of traumatic brain injury, brain disease, and mental illness. Neurocognitive assessment may be used to aid clinicians and researchers in formulating diagnostic impressions, assessment of treatment response, and prediction of functional potential and functional recovery. Recent advances in neurocognitive assessment include computerized presentation of many of the tasks traditionally presented in paper and pencil format.

Computer-based neurocognitive testing has become the principle component of concussion evaluation. International expert meetings on the topic of concussion in sports explicitly endorsed neuropsychological testing as the “cornerstone” of concussion management (McCrorry, Meeuwisse, Dvorak, et al 2016). Many pediatricians who currently manage concussions report using neurocognitive testing as part of their evaluation. While most of the attention in diagnosing and treating concussions has been focused on younger individuals, the highest combined incidence of TBI-related emergency department (ED) visits, hospitalizations, and deaths actually occurs in older adults (Taylor, Bell, Breiding, Xu, 2017; Gardner, Dams-O'Connor, 2018). Given the large number of reported concussions and the notion that there is significant underreporting of concussions that actually occur, there is an increasing need for high-quality, empirically validated tools to aid healthcare professionals in their identification and treatment of head injury.

Rationale for the Development of ImPACT Version 4

Because a concussion is primarily a pathophysiological event rather than a structural event, and because traditional imaging tests are of little value in identifying the injury, there is a need to identify the neurocognitive changes associated with a concussion. ImPACT Version 4 is designed to provide relevant information regarding cognitive and clinical symptoms in individuals suspected of having sustained a Traumatic Brain Injury (TBI). This information, combined with other relevant clinical data and objective test information, can be used to help identify a concussion and manage recovery from an injury. This approach to clinical management of a concussed individual is a reliable and valid method for determining when an individual is sufficiently recovered from a concussion to return to daily activity.

The most common and effective way to use ImPACT Version 4 is to establish baseline performance in an individual prior to participation in an activity. A baseline test can either be supervised by a trained proctor following established standard administration procedures or taken remotely after the test taker reviews a set of instructions and watches a video of testing conditions and requirements (See Chapter 2 for a complete description.) After a suspected concussion, an individual should be

reevaluated by a trained healthcare professional. The individual's performance on the post-injury evaluation is compared with his/her performance on the baseline evaluation. Any discrepancies in the results, along with other medical, behavioral, and psychological information should be used by the healthcare provider to make a determination about the individual's concussion status and to serve as a guide for future treatment strategy.

Comparison of ImPACT to ImPACT Version 4

In developing the revision of ImPACT, special emphasis was placed on preserving much of what has made the test the most widely used tool for assessing and managing patients with a concussion. The primary changes were as follows:

1. New normative data by age and gender
New normative data collected and stratified by age and gender. A complete description of the procedures used to collect the data and the description of the standardization sample can be found in Chapter 3.
2. Normative data for both mouse and trackpad administrations
Earlier versions of ImPACT required the use of a computer mouse when performing the test. Over time, the computer mouse became less common and use of a trackpad became more common. New normative data is presented separately for users that use a trackpad and those that use a computer mouse.
3. Revised Invalidity Indicators
Invalidity Indicator cut-offs have been recalculated using data from the new normative dataset.
4. Expansion of the normative age range from 12-59 to 12-80
There is increasing evidence that TBI is the leading cause of hospitalization in individuals in the 60+ age range. As the population ages and people are working longer and staying active longer there is an increased risk of concussion in individuals 60 years and older. For that reason, we collected normative data that will enable ImPACT Version 4 to be used from ages 60 to 80 years 11 months.
5. An additional factor structure allowing for a two factor (speed and memory) interpretation of the test data
Research has shown that in addition to the 4 composite scores historically been used to describe ImPACT test results, a Two-Factor Score can also provide a valid approach to interpreting the data.
6. New validity and reliability data
New validity and reliability data were calculated as part of the renorming process. This includes data for the 60-80-year age range.
7. A revised clinical report design
The clinical report has undergone redesign to make it simpler to use and explain. This includes the elimination of the Cognitive Efficiency Index which was omitted due to dearth of independent clinical and research support for this index.

All of these changes were made with the end user in mind so that ImPACT Version 4 remains easy to use and a valid tool to aid healthcare providers in evaluating and managing patients suspected of having a concussion.

Chapter 2 - Administration and Scoring of ImPACT Version 4

What is ImPACT Version 4?

ImPACT Version 4 is a computerized neurocognitive test battery used to assess Sequencing/Attention, Word Memory, Visual Memory and Reaction Time. When used to obtain baseline neurocognitive functioning, it can be individually self-administered or administered to a group supervised by a trained proctor. However, when used for a post-injury evaluation, ImPACT Version 4 should be supervised and interpreted by a trained healthcare professional.

Ages

ImPACT Version 4 is designed to be administered to test takers ages 12 years 0 months to 80 years 11 months of age.

Qualifications for Administration and Interpretation

The results of ImPACT Version 4 have been specifically developed for professional use. Post-injury testing should always be supervised by properly trained and licensed healthcare providers with specific knowledge and experience in interpreting neurocognitive test results. For more information on the qualifications necessary for administering and interpreting ImPACT Version 4 testing or access to online training tools, please visit www.impacttest.com.

Administration Time

In general, test administration can be completed within 20 minutes. A variety of factors can contribute to differences in administration time such as the age of the individual being tested, their speed in responding, their attention and focus on the task or other psychological or behavioral factors.

Technical Requirements

ImPACT Version 4 is designed to be administered on any laptop or desktop computer that has a color monitor and a pointing device such as mouse or trackpad. The test is delivered as a web application thus it requires a modern web browser and a reliable Internet connection.

The full set of current computer requirements are available in the Quick Reference Guide, which can be accessed inside the ImPACT Applications' Customer Center, under the 'Resources' tab on the left.

Test Environment

Specific requirements regarding test environment should be followed to prevent distractions and interruptions. Administration is guided by the software and assumes sixth grade reading level. Test takers' performance can be affected by distraction or engaging in other activities while attempting to take the test. Therefore, we recommend the following:

1. The physical environment should be quiet and free of noise.
2. All mobile phones, music players, and other electronic devices should be turned off.
3. The test taker should not be engaging in another activity or conversing with others.
4. Seating arrangements should allow the test taker to sit comfortably with at least 1 seat between test takers when being administered in a group setting.
5. Ideally, the test should be administered in an area limiting glare on the screen. Testing outdoors in direct sunlight is not recommended due potential issues with glare.

Note: It is recommended that test takers are well-rested and do not complete testing immediately after vigorous exercise as this may affect test results.

General Guidelines for Test Administration

Test directions for ImPACT Version 4 are embedded within the test battery making the test easy to administer. Nevertheless, to help with the understanding of the administration process, the following section provides general guidelines as well as specific instructions for administering the test battery. It is important that examiners become familiar with the instructions in this section in order to maintain standard procedure and yield valid interpretation.

It should be noted that these general guidelines, as well as test taking conditions described above, apply whether the test is administered in a directly supervised setting or remotely.

Providers are offered free and fee-based online content at www.impacttest.com to enhance their knowledge and skills interpreting ImPACT Version 4 test results. Additionally, test takers performing a remote baseline test are provided with a brief video and a set of instructions outlining proper test taking environment.

Order of Administration

Each administration of ImPACT Version 4 is fixed and follows a set sequence. The order of administration is as follows:

1. Demographics > 2. Symptom Scale > 3. Word Memory > 4. Design Memory > 5. X's and O's > 6. Symbol Match > 7. Color Match > 8. Three Letters > 9. Word Memory Delayed Recall > 10. Design Memory Delayed Recall

Instructions for Starting a New Test or Reviewing Test Records from the Customer Center

ImPACT Customer Center Login Screen

Enter the Username (Email) and Password that was provided to you by ImPACT Applications, Inc. Your Username and Password should be kept secure at all times and should NOT be shared with test takers as this would allow them to have access to other test takers' records.

Navigating Selection Menu in Customer Center

Start New Test: Selecting "Start New Test" proceeds to the next screen for test-type selection.

First time test takers: Select the organization with which to associate this test by choosing it from the organization drop-down.

Previously tested individuals: Type the first few characters of their last name. Matches will be displayed in a drop-down list. Select the appropriate individual from the list.

Select the type of test: For pre-injury evaluations, select the "Baseline" test option. Following injury or when a concussion is suspected, select one of the "Post-injury" test options.

Basic Test Instructions: Ensure all technical requirements are fulfilled and the environment is quiet and free of distractions (see Technical Requirements and Test Environment sections of the manual for more information).

Once you select the test type, a new browser window will open, and it will begin the administration of the test battery.

Neurocognitive Test Modules Descriptions, Administration Instructions, and Scoring

Word Memory – Module 1

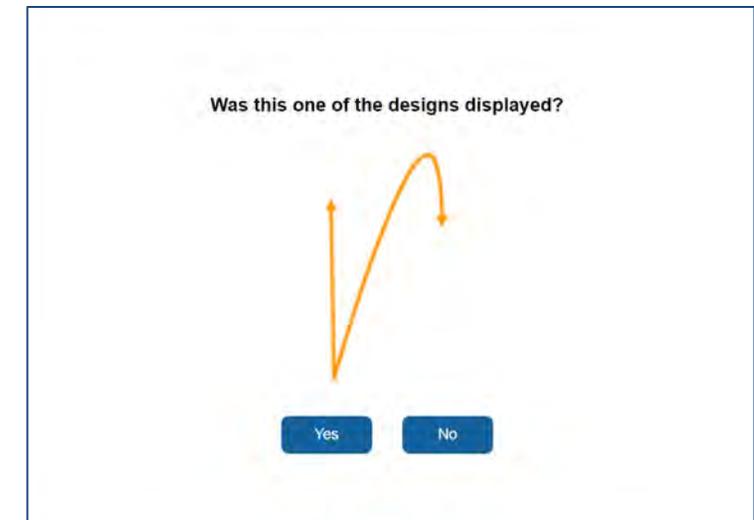
- Evaluates attentional processes and verbal recognition memory
- Utilizes a word discrimination paradigm
 - Presents 12 target words twice for 750 milliseconds to facilitate learning the list.
 - Tests recall via the presentation of the 24-word list.
 - The words are chosen from the same semantic category as the target word.
 - There are five different forms of the word list to minimize practice effects from one administration to the next.
 - Twelve target words were selected for inclusion in each of the five word lists.
 - Twelve related but not identical words make up each of the administrations. Non-target words are included to create a challenge situation.
 - For example, if the target word is SMALL, the non-target word might be BIG.
 - To respond to each question, the test taker clicks the “yes” or “no” buttons.
- Individual scores are provided for both correct “yes” and “no” responses. In addition, a total percent correct score is provided.



Delay Condition: Following the administration of all other test modules (approximately 20 minutes), the test taker is again tested for recall via the same method described above. The same scores that are described above are provided for the delay condition.

Design Memory – Module 2

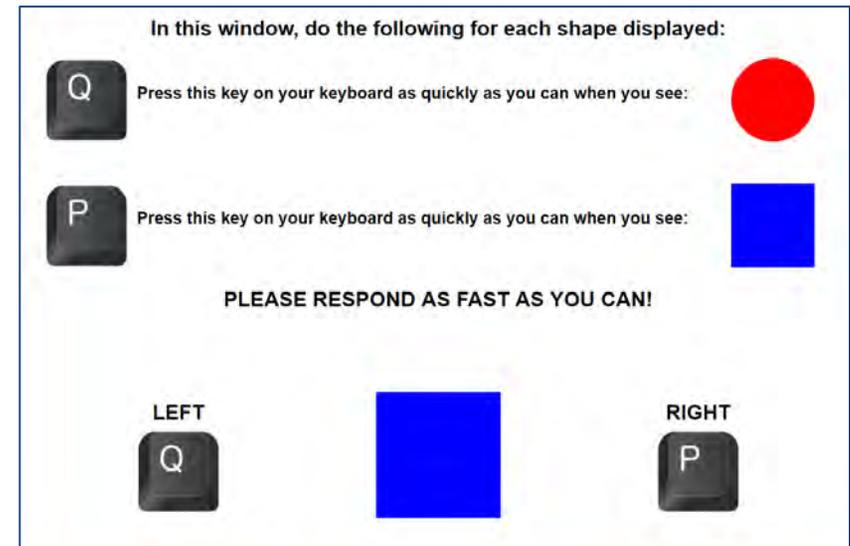
- Evaluates attentional processes and visual recognition memory
- Utilizes a design discrimination paradigm
 - Tests recall of 24-designs
 - Comprised of 12 target designs and 12 non-target designs (target designs rotated in space).
 - Presents 12 target designs twice for 750 milliseconds to facilitate learning the list.
 - The test taker responds by mouse-clicking the “yes” or “no” buttons.
 - Individual scores are provided for both correct “yes” and “no” responses.
 - In addition, a total percent correct score is provided.
- Test stimuli were selected to be relatively difficult to encode verbally.
- Designs were “assigned” to one of the five administrations randomly.



Delay Condition: Following the administration of all other test modules (approximately 20 minutes), the test taker is again tested for recall via the same method described above. The same scores that are described above are provided for the delay condition.

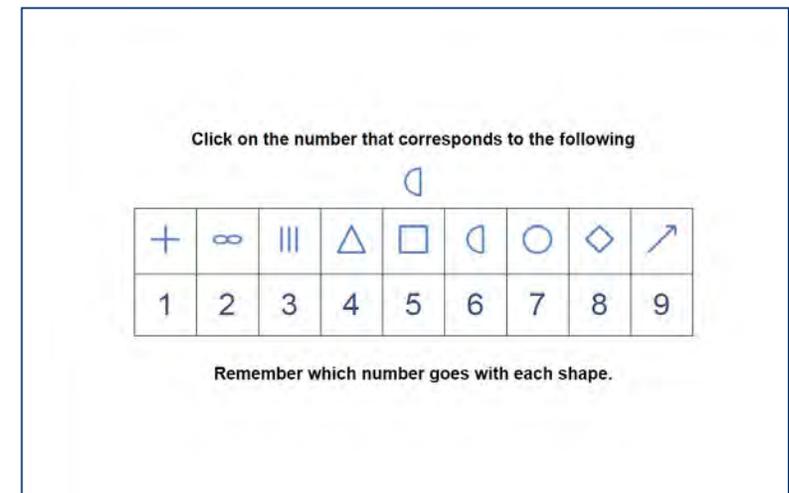
X's and O's – Module 3

- Measures visual working memory and visual processing/visual motor speed
- Includes a distracter task to interfere with memory rehearsal
- The distracter is a choice reaction time test and performance on this measure is incorporated into other aspects of ImPACT (e.g., visual motor processing speed and reaction time).
- The test taker practices the distracter task prior to presentation of the memory task.
- During this task, the test taker is asked to perform a specific action if a blue square is presented or if a red circle is presented.
- Once the test taker has completed this task, the memory task is presented.
 - Memory task: a random assortment of X's and O's is displayed for 1.5 seconds
 - For each trial: three of the X's or O's are illuminated in YELLOW (the test taker has to remember the location of the illuminated objects).
 - Immediately after the presentation of the 3 X's or O's, the distracter task re-appears on the screen.
 - Following the distracter task, the memory screen (X's and O's) re-appears and the test taker is asked to click on the previously illuminated X's and O's.
 - Scores are provided for correct identification of the X's and O's (memory), reaction time for the distracter task, and the number of errors on the distracter task.
- For each administration of ImPACT, the test taker completes 4 trials.



Symbol Match–Module 4

- Evaluates visual processing speed, learning, and memory
 - Presents a screen that displays common symbols (triangle, square, arrow, etc.).
 - Directly under each symbol is a number button from 1 to 9
 - Below this grid, a symbol is presented.
 - The test taker is required to click the matching number as quickly as possible and to remember the symbol/number of pairings.
 - Correct performance is reinforced through the illumination of a correctly clicked number in **GREEN**. Incorrect performance illuminates the number button in **RED**.
 - Following the completion of 27 trials, the symbols disappear from the top grid.
 - The symbols reappear below the grid and the test taker is asked to recall the correct symbol/number pairing by clicking the appropriate number button.
- This module provides an average reaction time score and a score for the memory condition.



Color Match-Module 5

- Represents a choice reaction time task and measures impulse control/response inhibition
 - First, the test taker is required to respond by clicking a red, blue or green button as they are presented on the screen. This procedure is completed to assure that subsequent trials would not be affected by color blindness.
 - Next, Word names are displayed on the screen in the same color as the word (e.g. **RED**), or in a different color (**GREEN** or **BLUE**)
 - The test taker is instructed to click in the box as quickly as possible only if the word name is presented in the matching color.
- In addition to providing a reaction time score, this task also provides an error score.



Three Letters - Module 6

- Measures working memory and visual-motor response speed
- First, the test taker is allowed to practice a distracter task that consists of 25 numbered buttons on a 5x5 grid.
 - The test taker is instructed to click as quickly as possible on the numbered buttons in backward order starting with 25.
 - The position of the numbers on the grid are randomized after each trial to minimize practice effects.
 - The test taker is then presented with three consonants displayed on the screen.
 - Immediately following display of the three letters, the numbered grid re-appears, and the test taker is again instructed to click the numbered buttons in backward order.
 - After 18 seconds, the numbered grid disappears, and the test taker is asked to recall the three letters by typing them on the keyboard.
 - This task yields a memory score (total number of correctly identified letters), and a score for the average number of correctly clicked numbers per trial from the distracter test.
- Five trials of this task are presented for each administration of the test.

Click each of these buttons in BACKWARD ORDER.

Start with 25 and count down to 1 AS FAST AS YOU CAN

If you make a mistake, use the 'Go Back' button to clear the buttons you have already clicked, one at a time.

<< Go Back

5	9	7	15	11
25	3	12	14	17
19	22	21	2	24
20	1	4	16	8
23	6	13	18	10

ImPACT Version 4 Post Concussion Symptom Inventory

The symptom section is designed to obtain information helpful in identifying whether the test taker is experiencing symptoms characteristic of a concussion. The administrator may read the questions to the test taker but the administrator should never provide the test taker with answers to the questions.

Click "OK" to start the section. As you move through each screen of the section, select "Continue" to move to the next screen or "Back" to go to a previous screen to make changes. All questions must be answered before continuing to the next screen.

The symptoms are:

- Headache
- Trouble Falling Asleep
- Nausea
- Sleeping More than Usual
- Vomiting
- Sleeping Less than Usual
- Balance Problems
- Drowsiness
- Dizziness
- Sensitivity to Light
- Sensitivity to Noise
- Irritability
- Feeling Mentally Foggy
- Sadness
- Difficulty Concentrating
- Nervousness
- Difficulty Remembering
- Feeling More Emotional
- Visual Problems
- Numbness or Tingling
- Feeling Slowed Down
- Fatigue

Scoring

All tests are automatically scored within the software. In addition to scores that are provided for each module, composite scores, a symptom score, measures of efficiency, validity, and a Reliable Change Index (RCI) score are all calculated. Each of these are discussed below.

Module Scores

Each module has a set of scores that are unique to that module. Scores were designed to reflect speed of performance or accuracy, which are the two primary components measured by the test. Each of the modules and the associated scores are presented below.

Word Memory	
Hits (immediate)	Number of correctly identified words (out of 12)
Correct distracters (immediate)	The number of correctly identified distracter items (out of 12)
Learning percent correct	$((\text{Hits} + \text{correct distracters})/24) \times 100$.
Hits (delay)	Number of correctly identified words (out of 12)
Correct distracters (delay)	Number of correctly identified distracter items (out of 12)
Delayed memory percent correct	Delay hits + correct distracter delay items (out of 12)
Total percent correct	Average percent correct (learning percent correct + delayed percent correct/2)

Design Memory	
Hits (immediate)	Number of correctly identified designs (out of 12)
Correct distracters (immediate)	Number of correctly identified incorrect distracter items (out of 12)
Learning percent correct	$((\text{Hits} + \text{correct distracters})/24) \times 100$
Hits (delay)	Number of correctly identified designs (out of 12)
Correct distracters (delay)	Number of correctly identified distracter designs (out of 12)
Delayed memory percent correct	Delay hits + correct distracter items (out of 12)
Total percent correct	Average percent correct $((\text{learning percent correct} + \text{delayed percent correct})/2)$

X's and O's	
Total correct (memory)	Measures the number of correctly identified items (total possible correct =12)
Total correct (interference)	This score provides a measure of the number of correct responses on the interference test
Average correct RT (interference)	Measures the average reaction time for correct responses on the interference (distracter) test
Total incorrect (interference)	Measures the number of errors on the distracter test
Total incorrect RT (interference)	Provides an index of the reaction time for incorrect responses on the interference test

Symbol match	
Total correct (visible)	Provides the number of correct matches out of 27 when the symbol number pairings are visible
Total correct RT (visible)	The average reaction time for the 27 matches
Total correct (hidden)	This represents the number of items correctly recalled when symbol number pairings are hidden
Total correct RT (hidden)	The average reaction time for recall of the memory items

Color Match	
Total correct	Number of correct matches
Average correct RT	Average reaction time for correct matches
Total commissions	Number of incorrect for color/word matches
Average commissions RT	Average reaction time for commissions

Three Letters	
Total sequence correct.	Total number of letter sequences correct (out of 5)
Total letters correct	Total letters correct (out of 15)
Percent of total letters correct	Percent letters correctly identified
Average time to first click	Time to initiation of first click of mouse
Average counted	The average number of numbers clicked, regardless of errors
Average counted correctly	The average number of numbers clicked that are in correct sequence

The Derived Scores for ImPACT Version 4

In addition to the individual subtest scores, Composite Scores were developed by combining specific subtest scores that were selected by the test authors *a priori*. Composite scores were derived logically rather than through factor analysis and were designed to provide summary level information to facilitate interpretation of test taker performance by the healthcare provider. The Composite Scores provide a summary score that represents unweighted average raw scores for the component subtests. Scores are expressed as percentiles for each input device (computer mouse and trackpad) separately relative to individuals of their own age group and sex. Separate normative data was calculated for the computer mouse (n=38,095) and trackpad (n=33,720). Percentile ranks were created by using a standard computer software conversion program and any resulting irregularities were identified and smoothed manually. It should be noted that no trackpad normative data was collected for individuals aged 60-80. Thus, when testing individuals in this age group, the test should only be administered on a laptop or desktop with a computer mouse. There are four Composite Scores, also referred to as Core Composite Scores, (Verbal Memory Composite, Visual Memory Composite, Visual Motor Speed Composite, and Reaction Time), and two supplemental scores, Impulse Control Composite, and Total Symptom Score.

New to ImPACT Version 4 is the option to obtain a Two-Factor Score in addition to the existing Composite Scores. Both the Composite Scores (Schatz, Pardini, Lovell, Collins, Podell, 2006; Schatz & Sandel, 2013) and the Two-Factor Scores (Schatz & Maerlender, 2013; Gerrard, Iverson, Atkins, et al 2017) have been validated in prior independent research.

Verbal Memory Composite

Evaluates attentional processes, learning, and memory within the verbal domain

This composite score represents the average performance on:

- Word Memory (Module 1) Total Percent Correct
- Symbol Match (Module 4) Total Correct Hidden/9*100
- Three Letters (Module 6) Percent Total Letters Correct

EXAMPLE

Word Memory Total Percent Correct =	98%
Symbol Match (Total Correct Hidden)/9*100 = 6/9*100 =	66.7%
Three Letters Percent Total Letters Correct =	80%
<hr/>	
Total Divided by 3=	244.7/3 = 82

Verbal Memory Composite Score= 82

WORD MEMORY

Hits (Immediate)
 Correct Distractors (immed.)
 Learning percent correct
 Hits (delay)
 Correct distractors (delay)
 Delayed memory pct. correct
 Total percent correct

Baseline	Post Injury 1
12	11
12	7
100%	75%
11	8
12	6
96%	58%
98%	66.5%

SYMBOL MATCH

Total correct (visible)
 Avg. correct RT (visible)
 Total correct (hidden)
 Avg. correct RT (hidden)

27	27
1.52	1.85
6	4
1.94	2.79

THREE LETTERS

Total sequence correct
 Total letters correct
 Pct. of total letters correct
 Avg. time to first click
 Avg. counted
 Avg. counted correctly

3	1
12	9
80%	60%
2.26	3.15
12.8	9.6
12.8	9.6

Visual Memory Composite

Evaluates visual attention and scanning, learning, and memory
This score in its current form is comprised of the average of:

- Design Memory (module 2) Total Percent Correct
- X's and O's (module 3) (Total Correct Memory)/12*100

EXAMPLE

Design Memory Total Percent Correct =	90 %
X's and O's (Total Correct Memory)/12= 8/12*100	66.7%
<hr/>	
Total Divided by 2 = 156.7/2 =	78

Visual Memory Composite Score= 78

Visual Motor Speed Composite

Evaluates visual processing, learning and memory, and visual-motor response speed.
This score is comprised of the average of following scores:

- Total Number Correct/4 during Interference of X's and O's (module 3).
- Average Counted Correctly*3 from Countdown Phase of Three Letters (module 6).

EXAMPLE

Total Number Correct/4 during Interference of X's and O's=	109/4 = 27.25
Average Counted Correctly x 3 from Countdown Phase of Three Letters =	12.8 x 3 = 38.40
<hr/>	
Total Divided by 2 =	65.65/2 = 32.83

Visual Motor Speed Composite Score= 32.83

DESIGN MEMORY

Hits (Immediate)
Correct distractors (immediate)
Learning percent correct
Hits (delay)
Correct distractors (delay)
Delayed memory pct. correct
Total percent correct

12	10
10	5
92%	63%
12	4
9	7
88%	46%
90%	54.5%

X'S AND O'S

Total correct (memory)
Total correct (interference)
Avg. correct RT (interference)
Total correct (interference)
Avg. incorrect RT (interference)

8	5
109	67
0.55	1.17
3	3
0.43	1.04

X'S AND O'S

Total correct (memory)
Total correct (interference)
Avg. correct RT (interference)
Total correct (interference)
Avg. incorrect RT (interference)

8	5
109	67
0.55	1.17
3	3
0.43	1.04

THREE LETTERS

Total sequence correct
Total letters correct
Pct. of total letters correct
Avg. time to first click
Avg. counted
Avg. counted correctly

3	1
12	9
80%	60%
2.26	3.15
12.8	9.6
12.8	9.6

Reaction Time Composite

Evaluates average response speed.

This score is comprised of the average of the following scores:

- Average Correct RT of Interference Stage of X's and O's (module 3).
- Symbol Match (module 4) Average Correct RT Visible/3.
- Color Match (module 5) Average Correct RT.

EXAMPLE

Average Correct RT of Interference Stage of X's and O's =	0.55
Symbol Match Average Correct RT Visible/3 =	1.52/3 = 0.51
Color Match Average Correct RT =	0.76
<hr/>	
Total Divided by 3 =	1.82/3= 0.61

Reaction Time Composite Score= 0.61

Impulse Control Composite

While not one of the core composites for ImpACT scoring, this composite provides a measure of errors on testing and is useful in determining test validity. This score indicates the sum of errors committed during different phases of the test, and while clinical decisions should not be based on this composite, its inclusion may help in the interpretation of other composites.

Scores above 30 should be viewed as invalid.

This score is obtained by adding:

- Total Incorrect on the Interference Phase of X's and O's (module 3).
- Color Match Total Commissions (module 5).

EXAMPLE

Total Incorrect on the Interference Phase of X's and O's =	3
Color Match Total Commissions =	0
Total=	3

Impulse Control Composite Score= 3

Total Symptom Score

This score presents summary information regarding the individual's self-reported symptom data. A higher score reflects a higher symptom total.

X'S AND O'S

Total correct (memory)	8	5
Total correct (interference)	109	67
Avg. correct RT (interference)	0.55	1.17
Total correct (interference)	3	3
Avg. incorrect RT (interference)	0.43	1.04

8	5
109	67
0.55	1.17
3	3
0.43	1.04

SYMBOL MATCH

Total correct (visible)	27	27
Avg. correct RT (visible)	1.52	1.85
Total correct (hidden)	6	4
Avg. correct RT (hidden)	1.94	2.79

27	27
1.52	1.85
6	4
1.94	2.79

COLOR MATCH

Total correct	9	9
Avg. correct RT	0.76	1.58
Total commissions	0	1
Avg. commissions RT	0	1.31

9	9
0.76	1.58
0	1
0	1.31

X'S AND O'S

Total correct (memory)	8	5
Total correct (interference)	109	67
Avg. correct RT (interference)	0.55	1.17
Total correct (interference)	3	3
Avg. incorrect RT (interference)	0.43	1.04

8	5
109	67
0.55	1.17
3	3
0.43	1.04

COLOR MATCH

Total correct	9	9
Avg. correct RT	0.76	1.58
Total commissions	0	1
Avg. commissions RT	0	1.31

9	9
0.76	1.58
0	1
0	1.31

Two-Factor Score

A new scoring approach, called a Two-Factor Score comprised of a Memory component and a Speed component was independently developed and validated for ImPACT (Schatz and Maerlander, 2013) and, will be provided as an additional option to the existing Composite Scores approach provided in the predicate device. The Two-Factor Scores are calculated as Z-scores (subtracting the user's score from the group mean and dividing by the standard deviation: $(X - \text{Mean})/SD$) and are presented as percentile ranks. The Two Factor Score is calculated using the raw score mean and standard deviation (based on age and gender) as described below.

Speed Composite

The Speed Composite is comprised of the Motor Speed and Reaction Time and is calculated by converting the Motor Speed composite score into a Z-score by subtracting the age- and gender-appropriate mean from the test-taker's raw score and dividing by the standard deviation. Similarly, the Reaction Time composite score is also converted into a Z-score, and the Speed Composite is calculated by subtracting the Motor Speed and Reaction Time Z-scores and dividing by 2.

Memory Composite

The Memory Composite is comprised of the Visual Memory and Verbal Memory and is calculated by converting the Verbal Memory composite score into a Z-score by subtracting the age- and gender-appropriate mean from the test-taker's raw score and dividing by the standard deviation. Similarly, the Visual Memory composite score is also converted into a Z-score, and the Memory Composite is calculated by summing the Verbal Memory and Visual Memory Z-scores, and dividing by 2.

The Two-Factor Score (speed and memory) provides an additional summary score approach for interpretation of the test data. Research has shown that in addition to the existing four Composite Scores that have historically been used to describe the ImPACT test results, a Two-Factor Score can also provide a valid approach to interpreting the data. In addition, this research has shown that the two-factor structure has improved test-retest reliability with no loss of sensitivity/specificity and may improve understanding and interpretability of ImPACT test results. This increased reliability is likely a result of more items included in each factor, thus possibly reducing error.

Over the years there has been some debate as to the most parsimonious explanation of the constructs underlying ImPACT. As described in the device labeling, the authors of the test used an a priori, logical method of assigning subtests to 4 Composite Scores (i.e., Visual Memory, Verbal Memory, Reaction Time and Processing Speed). Subsequent research has generally supported that structure; however, there appears to be evidence for shared variance among Processing Speed and Reaction Time scores as well as Verbal Memory and Visual Memory scores. Given those findings, it made sense to offer a two-factor interpretive solution as an additional method of interpreting test results. The valid clinical association of providing a Two-Factor Score is supported in published literature by Schatz and Maerlander (2013), and Gerrard, Iverson, Atkins (2017).

Reliable Change Index Score

In addition to the presentation of both raw and percentile-based scores, the software also calculates RCI scores that provide information about the magnitude of change from baseline testing performance to post-injury. If a particular score is significantly different from the baseline score obtained by the test taker, the scores are printed in red on the Clinical Report. Some variation and test score change over repeated administrations is to be expected. The issue for healthcare professionals is to determine when this change is significant and clinically meaningful. ImPACT Version 4 provides Reliable Change Index Scores (RCI's) for each Module, Composite and Two-Factor Score. The reliable change methodology allows the clinician to reduce the adverse impact of measurement error on test interpretation. To represent clinically significant improvement, the change score must be statistically reliable. However, the converse is not true; a statistically reliable change does not necessarily guarantee a clinically meaningful change. It is also important to emphasize that an RCI score is not synonymous with a diagnosis.

Calculating the RCI for ImPACT Version 4 remains the same as the previous versions of ImPACT, even when an individual takes a baseline test using a computer mouse and is retested with a post injury test using a track pad device. (or vice-versa). There are only two conditions where an RCI cannot be calculated:

- a) When a potentially invalid Baseline Test ("Baseline ++") is included on a report;
- b) When test results with "mixed norms" (tests prior to version 3.8.0 released on 26-Jan-2019 and tests version 3.8.0 or newer) are included on a report.

The Reliable Change Index (RCI) method for interpreting change on neurocognitive tests is a well-accepted method for determining change. This method relies heavily on the standard error of the difference score. The standard error of the difference (S_{diff}) can be used to create a confidence interval (i.e., a prediction interval in the statistical literature) for a test-retest difference score. Essentially, this confidence interval represents the probable range of measurement error for the distribution of difference scores.

RCI scores were calculated to provide an index of change from baseline to post-injury. RCI scores were calculated by an independent professional statistician based on methodology described in detail by Iverson et al. (2003) and Jacobson & Truax, (1991) to assess whether a change among repeated assessments was reliable and meaningful. The RCI provides an estimate of the probability that a given difference between a test taker's scores would not be obtained as a result of measurement error (Iverson, Sawyer, McCracken, Kozora, 2001). This allows clinicians to reduce any effects of measurement error, usually in the form of practice effects (Iverson, Brooks, Collins, Lovell, 2006), inattentiveness or fatigue.

Given two assessment scores (Time 1 and Time 2), calculation of RCIs involves the use of the standard error of difference (S_{diff}), which is used to create a confidence interval around the two baseline assessment scores. The formula for S_{diff} is provided below.

1. $SEM_1 = SD\sqrt{1-r_{12}}$ Standard deviation from time 1 multiplied by the square root of 1 minus the test-retest coefficient.
2. $SEM_2 = SD\sqrt{1-r_{12}}$ Standard deviation from time 2 multiplied by the square root of 1 minus the test-retest coefficient.
3. $S_{diff} = \sqrt{SEM_1^2 + SEM_2^2}$ Square root of the sum of the squared SEMs for each testing occasion.
4. Reliable Change Confidence Intervals: The S_{diff} is multiplied by the following z-scores: ± 1.04 (70% CI), ± 1.28 (80% CI), ± 1.64 (90% CI) and ± 1.96 (95% CI)

The values used for the RCI calculation were obtained from the study by Iverson, Lovell and Collins (2005). A description of this study follows.

Participants

The first sample was comprised of 56 adolescents and young adults who completed the ImPACT test twice for the purpose of a test-retest study. There were 29 males and 27 females. Their average age was 17.6 years ($SD=1.7$, range=15–22). Approximately 64% were in high school and 36% were in university. The average retest interval was 5.8 days (median=7, $SD=3.0$, range=1–13). Approximately 29% were retested within 3 days, 43% within 4 days, 82% within 7 days, and 95% within 11 days.

The second sample was comprised of 41 amateur athletes who sustained a sports-related concussion.

All athletes completed ImPACT at the beginning of the season. All were retested within 72 hours of their concussions (mean=1.3, median=1, $SD=0.7$ days). This sample was 90% male. Their average age was 16.8 years (median=16, $SD=2.4$, range=13–22).

Approximately 71% were in high school and 29% were in university. The vast majority of athletes were football players (88%), with small numbers of athletes in other sports such as hockey, soccer, basketball, and wrestling.

Most athletes had sufficient information to classify the severity of their concussions using the American Academy of Neurology Concussion Grading System.

Approximately 54% had Grade I Concussions, 22% had Grade II Concussions, and 7% had Grade III Concussions. Missing data prevented the confident classification of 17% (i.e., 7 athletes).

Design

The first set of analyses were based on the healthy young people tested twice. Relative position across the two distributions was examined with a Pearson correlation.

Level of performance within subjects was examined with dependent t-tests. Reliable change estimates were derived from a modification of the method proposed by Jacobson and Truax (1991).

Results

The descriptive statistics, standard errors of measurement (SEMs), standard errors of difference (S_{diff}), and reliable change confidence intervals are presented in the Table below.

The Pearson test-retest correlation coefficients for the composite scores were as follows:

- Verbal Memory = .70,
- Visual Memory = .67,
- Reaction Time = .79,
- Processing Speed = .86,
- Post-concussion Scale = .65.

These coefficients are used in the calculation of the RCI, which are referred to as r₁₂ test-retest coefficients.

The Mean and SD by composite with the calculated S_{diff} is presented in the Table 1.

The reliable change difference scores associated with the two confidence intervals were applied to the original data. If the distributions of difference scores were perfectly normal, then one would expect to see 10% in each tail for the 0.80 confidence interval and 5% in each tail for the 0.90 confidence interval. As seen in Table 4, the percentages of subjects that would be classified as reliably improved or declined was reasonably close to what would be predicted from the theoretical normal distribution.

The number of scores that reliably declined for each subject was computed. A decline was defined as reliably lower Verbal or Visual Memory, slower processing speed or reaction time, or greater symptoms at retest versus baseline (80% confidence interval). The percentages of subjects showing declines across the five composite scores are as follows: no declines = 63.0%, one decline = 39.3%, two declines = 1.8%, 3 declines = 0%, and 4 declines = 1.8%.

It should be noted that adjustments of 2 points were made to the ImPACT Processing Speed composite score to account for practice effects. It was not necessary to adjust the other composite scores because practice effects were not identified. ImPACT was designed to reduce practice effects through randomization of stimuli presentation. This was an essential design feature because the battery is intended to be used repeatedly, over short intervals.

The reliable change methodology allows the clinician to reduce the adverse effect of measurement error on test interpretation. Clinically significant improvement can only be identified using this approach if the change score is statistically reliable. However, a statistically reliable change does not guarantee a clinically meaningful change. For that reason, we recommend that change scores found to be significant should be areas the clinician focus attention on for further investigation. We do not suggest that statistically significant changes are synonymous with clinically significant events.

Table 1. Adapted from Table 1 from Iverson 2003

Composite	M (SD)		p	SEM ₁	SEM ₂	S _{diff}	Confidence intervals	
	Time 1	Time 2					0.80	0.90
Verbal Memory	88.68 (9.50)	88.84 (8.09)	0.86	5.20	4.43	6.83	8.75	11.21
Visual Memory	78.70 (13.39)	77.48 (12.67)	0.40	7.69	7.28	10.59	13.55	17.37
Reaction Time	0.543 (0.087)	0.536 (0.063)	0.34	0.03	0.03	00.5	0.06	0.08
Processing Speed	40.54 (7.64)	42.24 (7.06)	0.00	2.64	2.64	3.89	4.98	6.38
Post-concussion Scale	5.23 (6.75)	5.79 (10.07)	0.59	5.96	5.96	7.17	9.18	11.76

Note. SEM: standard error of measurement; S_{diff}: Standard error of difference

Table 2. Adopted from Table 2 from Iverson 2003

Composite	0.80 confidence interval		0.90 confidence interval	
	Declined (%)	Improved (%)	Declined (%)	Improved (%)
Verbal Memory	10.7	16.1	5.4	8.9
Visual Memory	10.7	8.9	5.4	3.6
Reaction Time	8.9	14.3	5.4	7.1
Processing Speed	7.1	8.9	3.6	5.4
Post-concussion Scale	12.5	7.1	10.7	3.6

Note. The confidence intervals for the Processing Speed composite were adjusted for a 2-point practice effect.

ImPACT Version 4 Invalidity Indicators

ImPACT Version 4 provides a validity index designed to aid in identifying invalid baseline examinations. Validity cut-offs were calculated by identifying the point at which 5% of the test-takers fell below the sum total of all of the indicators, based on their age, gender, and input device. See Table 3.

If any of these criteria are reached for a given baseline test, the ImPACT Version 4 report will automatically print a sentence that identifies the test results as being “invalid”. If this is the case, the test administrator is encouraged to repeat the baseline exam, only after discussing the test results with the individual and identifying the reasons for the invalid test (e.g. difficulty understanding one or more of the modules, not taking the test seriously, etc.).

Invalidity Calculation	Age		
	12 - 13	14 - 59	60-80
Impulse Control Composite Score	> 30	> 30	> 30
Word Memory Learning Percent Correct	< 69	< 69	< 69
Design Memory Learning Percent Correct	< 45 Male <50 Female	< 50	< 45
Three Letters Total Letters Correct	< 7	< 8	Not Calculated

What are the Most Common Causes of Test Invalidity during Baseline?

- Failure to properly read directions due to a reading disability or carelessness.
- Attention deficit disorder and/or hyperactivity (ADD or ADHD).
- Excessive fatigue (e.g. completion of testing after vigorous exercise).
- “Horseplay” which can occur when individuals are not properly supervised or are placed too close together in a room.
- Left-right confusion which often is evidenced by scores about 20 on the Impulse Control composite and is usually the result of the reversal of left and right on the X’s and O’s distracter task
- Intentional poor performance to attempt to set a low baseline standard.
- Other neurological and psychological disorders in which impaired cognitive function is commonly present.

Intentional poor performance on a baseline test

Intentional poor performance on baseline testing is a topic that garners attention from time to time. Practically speaking, it is not different than any of the other above-listed causes of invalidity of a Baseline test. There has been no consensus on the frequency of occurrence of this phenomenon, or mechanisms for identifying individuals who engage in this practice. Version 4 contains validity indices that can be used to identify atypically low scores. If a test taker is suspected to intentionally underperform on the test, the proctor should use that opportunity to educate the test taker about the importance of performing to the best of his or her ability and repeat the test.

Chapter 3 - Development and Standardization

Content Development

ImPACT Version 4 is a computer-based neurocognitive testing platform created to measure aspects of attentional processes, immediate and delayed memory, visuo-spatial processes, impulse control, and visual motor speed in individuals ages 12 years 0 months to 80 years 11 months. As noted throughout this manual, ImPACT Version 4 is designed to serve as a neurocognitive test battery that complements other types of assessment (e.g., balance, visuo-spatial) and clinical information (behavioral, psychological, etc.) gathered as part of the comprehensive evaluation of an individual suspected of having a concussion. The content for the various modules was selected with these specific goals in mind:

- The tasks have been shown in past research to be sensitive to the effects of a concussion.
- The tasks had to be challenging and assess the major areas of neurocognition.
- The tasks needed to provide an efficient means of assessing neurocognitive status.
- The tasks must produce reliable results for individuals across age and time periods so that change metrics are interpretable.
- The tasks had to be compatible with a laptop or desktop computer.
- The test must allow individual and group administration.

Alpha testing of items and development of the test modules from early versions ImPACT

Early item development was conducted from 1994-1996 based on the need to assess the relevant neurocognitive domains that are often affected by concussion. The assessment was based on the author's prior experience in administering and interpreting traditional "paper and pencil" tests in professional and amateur athletes. Items were initially selected based on measuring the key domains of memory and processing speed. Within these broad domains, specific subtests were created that measured word memory; X's and O's (spatial memory); symbol match (memory for symbols and reaction time); three letter memory (verbal memory and motor speed) and color match (reaction time). See Chapter 2 for a complete description of the subtests. After this data was consolidated and evaluated, several items were eliminated from further consideration, some items were modified based on field tester recommendations, and others were retained in their original form. For example, the alpha version of ImPACT included a sequential memory task that was dropped because it did not provide unique information.

Alpha testing was completed in one Midwestern University and four high schools in the Midwest. From 1996-2000, this initial version of the test was utilized as a research tool in ten universities and eight high schools in the Midwest and in select high schools in Maine and Oregon. Subsequent research did not reveal any geographic difference between groups (Lovell et al., 2003). Items were reviewed again using the aforementioned criteria and once selected, the remaining items were piloted in the Detroit metropolitan area. A final review of the items was conducted with data on the ease of administration, the individual's ability to understand and complete the task, the performance differences between individuals who were concussed versus those who were not (sensitivity and specificity). This final version was published as the Desktop version of ImPACT.

The Desktop version was in use for approximately 5 years until an online version of the test was developed and validated. The items from the online version of the test formed the basis of ImPACT Version 4 as no new items were added or deleted.

Description of the Standardization Sample for ImPACT Version 4

Different procedures were used to obtain the standardization sample for ImPACT Version 4 for ages 12-59 and ages 60-80. The total standardization sample consisted of 72,369 individuals who completed baseline ImPACT testing. There were nearly the same number of males (36,854; 50.9%) and females (35,515; 49.1%) in the sample. The specific age and gender breakdown are presented in Table 4.

For the 12-59 sample, de-identified data of 71,815 subjects were selected from our test database. Subjects were selected based on age and gender and type of input

device they used to complete the test (i.e., computer mouse versus trackpad), spoke English as a primary language, completed a baseline test in English, and were from the United States of America. Further, in order to ensure subjects were not experiencing post-concussion symptoms or chronic effects of neurological disorders, all subjects reported as not having sustained a concussion in the 6 months prior to testing and had no other neurological issues that would affect performance (e.g., history of epilepsy, meningitis, brain surgery or other neurological disease). In addition, all subjects had no self-reported diagnosis of Attention Deficit Hyperactivity Disorder or Learning Disorder. The stratification of the sample was implemented to assure inclusion of adequate cell sizes across gender and age. Age bands were constructed based on logical developmental inflection points (e.g., 1-year bands at younger ages, larger bands at older ages). All normative cases had a valid score on the test and did not trigger any of the built-in validity indicators. For a complete breakdown of the sample, please see Table 4.

The normative sample age 60-80 was collected from 8 different sites across the United States, including universities and private medical practices. Data collection took place between 2017 and 2020. All sites were IRB approved with oversight from Advarra IRB services. All subjects had to meet the following inclusion criteria to be eligible:

- 1) Age: 60-80
- 2) Primary English speaking or fluent in English.
- 3) Currently does not reside in a skilled nursing facility.
- 4) Currently not suffering from a concussion or being treated for a concussion.
- 5) No known physical, neurological, behavioral or psychological impairment that would affect their ability to perform the test.
- 6) Hearing or vision impairments that have not been corrected within normal limits.
- 7) A score of 24 or greater on the Mini-Mental State Examination (MMSE).
- 8) Signed IRB approved consent form.

Normative cases were collected by testers who underwent training to administer testing. Testers consisted of neuropsychologists, psychologists, physicians, graduate students and other trained healthcare professionals. All testing was completed in a supervised setting. It should be noted that all 60-80-year-old subjects were administered the test on a laptop or desktop computer with a computer mouse thus, there is no normative data for this age range on the computer trackpad as an input device. All data was uploaded onto a secure HIPAA compliant server and all data was de-identified for analysis.

Table 4. Age and Gender Breakdown for ImPACT Normative Sample

Age Group	Mouse Input		Trackpad Input	
	Males	Females	Males	Females
12	2000	2000	2000	2000
13	2000	2000	2000	2000
14	2000	2000	2000	2000
15	2000	2000	2000	2000
16	2000	2000	2000	2000
17	2000	2000	2000	2000
18	2000	2000	2000	2000
19-22	2000	2000	2000	2000
23-29	1500	1500	800	300
30-39	1200	700	300	100
40-49	500	275	130	90
50-59	250	170		
60-69	84	200	N/A	N/A
70-80	90	180	N/A	N/A
Total	19624	19025	17230	16490

Chapter 4 - Statistical Properties of ImPACT Version 4

This chapter includes technical and psychometric information on ImPACT Version 4, including details on the reliability of the modules, and the various forms of validity evidence that have been established. All data presented here are for the current online version of ImPACT. In addition, there is substantial reliability and validity data presented on the company website at www.impacttest.com.

Reliability Data for ImPACT

Over the years, there have been a sizeable body of literature that has documented the reliability of ImPACT. In general, ImPACT has been found to be highly reliable across time. As the items of the test and the six modules have not changed, this literature is relevant to ImPACT Version 4.

Test-retest reliability

Multiple studies have evaluated the reliability of ImPACT across two time intervals. In a study of collegiate athletes by Schatz (2010) the reliability of the ImPACT test battery over time was investigated. The author studied 95 athletes completing baseline cognitive testing at two time periods, approximately 2 years apart. No participant sustained a concussion between assessments. All athletes completed the ImPACT test battery; dependent measures were the composite scores and total symptom scale score. Intraclass correlation coefficient estimates for visual memory (.65), processing speed (.74), and reaction time (.68) composite scores reflected stability over the 2-year period, with the greatest variability occurring in verbal memory (.46) and symptom scale (.43) scores. Using RCIs and regression-based methods, only a small percentage of participants' scores showed reliable or "significant" change on the composite scores (0%-6%), or symptom scale scores (5%-10%). These results suggest that college athletes' cognitive performance at baseline remains considerably stable over a 2-year period.

In a follow up study, Schatz and Ferris (2013) evaluated the reliability of the ImPACT test battery over a shorter time span. Two ImPACT tests were administered with 4 weeks between assessments. Participants had not previously completed ImPACT and had no history of concussion. Pearson's correlation coefficients (r) and intra-class correlation coefficients (ICCs) were as follows:

Verbal Memory = .66/.79 (r/ICC), Visual Memory = .43/.60, Visual Motor Speed = .78/.88, Reaction Time = .63/.77, and Total Symptoms = .75/.81. Dependent sample t-tests revealed significant improvement on only Visual Motor Speed Composite Scores. Reliable Change Indices showed a significant number of participants fell outside 80% and 95% confidence intervals for only Visual Motor Speed scores (but no other indices), whereas all scores were within 80% and 95% confidence intervals using regression-based measures. Results suggest that repeated exposure to the ImPACT test may result in significant improvements in the physical mechanics of how college students interact with the test (e.g., performance on Visual Motor Speed), but repeated exposure across 1 month does not result in practice effects in memory performance or reaction time.

Variable	Interval Between Assessments						
	30 days Schatz (2013) n=25	30 days Cole (2013) n=44	0-45 days Nakayama (2014) n=85	0-50 days Nakayama (2014) n=85	45-50 Nakayama (2014) n=85	1 year Elbin (2011) n=369	2 years Schatz (2010) n=95
Verbal Memory							
ICC	0.79	0.6	0.76	0.65	0.69	0.62	0.46
r	0.66	0.61	-	-	-	0.45	0.3
Visual Memory							
ICC	0.6	0.5	0.72	0.6	0.69	0.7	0.65
r	0.43	0.49	-	-	-	0.55	0.49
Visual Motor Speed							
ICC	0.88	0.83	0.87	0.85	0.88	0.82	0.74
r	0.78	0.86	-	-	-	0.74	0.6
Reaction Time							
ICC	0.77	0.53	0.67	0.71	0.81	0.71	0.68
r	0.63	0.53	-	-	-	0.62	0.52

Most recently, (Nakayama et al.) in a 2014 study of 85 college age students, concluded that ImPACT is a reliable neurocognitive test battery at 45 and 50 days after the baseline assessment. These findings support those of other reliability studies that have reported acceptable intraclass correlation coefficients (ICCs) across 30-day to 1-

year testing intervals, and they support the utility of the ImpACT's use in a multidisciplinary approach to concussion management. Other research has produced similar findings. A summary of the findings is presented in Table 5.

As part of the research to establish the reliability of ImpACT Version 4 we calculated test-retest reliability on a sample of test-takers ages 12-21. This age group was selected because these are the ages where retesting is likely done on a regular basis as part of the test taker's participation in organized group activities such as sports teams or a school. Test takers were 300 individuals from the standardization sample who completed two baseline assessments using a mouse input and 150 individuals who completed two baseline assessments using a trackpad input. Test-takers that utilized a computer mouse were 166 males (55.3%, mean age 16.2, SD=2.2 years) and 134 females (44.7%, mean age 15.7, SD=2.3 years). Test-takers that utilized a track pad were 74 males (49.3%, mean age 16.1, SD=2.2 years) and 76 females (50.7%, mean age 15.8, SD=2.2 years). All test-takers completed an initial baseline assessment, and a second baseline with a between test interval ranging of 7 to 14 days (mean=10.1 days, SD=2.4 days). Test-retest reliability was calculated using intra-class correlation coefficients (ICCs) for the ImpACT Composite Scores as well as Two Factor Scores.

Using RCIs, only a small percentage of participants' scores showed reliable or "significant" change on the composite scores (0%-3%), or factor scores (1%-3%). These results suggest that test-takers cognitive performance at baseline remains considerably stable over a 2-week period, for both mouse and trackpad input (Table 6).

Table 6. Test-retest reliability coefficients for mouse and trackpad as input devices, ages 12-21

Test Module	MOUSE (N=300)					TRACKPAD (N=150)				
	ICC	ΔRCI 90% CI	90% CI	ΔRCI 95% CI	95% CI	ICC	ΔRCI 90% CI	90% CI	ΔRCI 95% CI	95% CI
Memory Factor	.61	1.48	90%	1.76	96%	.69	1.39	89%	1.66	92%
Verbal Memory	.50	22	90%	26	95%	.43	22	92%	26	95%
Visual Memory	.57	24	90%	28	94%	.72	22	90%	26	94%
Speed Factor	.80	1.14	88%	1.36	96%	.74	1.45	89%	1.73	92%
Visual Motor Speed	.91	6.9	90%	8.2	94%	.87	6.9	87%	8.3	92%
Reaction Time	.63	.16	92%	.19	95%	.59	.17	93%	.24	95%

A second set of participants ages 60-80 (mean age of 68.18, SD=5.1 years) completed two ImpACT assessments across an average range of 30 days (mean=16.04 days, S.D. = 8.65 days). The sample consisted of a total of 93 individuals (64.5% females, 35.5% males). Intraclass Correlations (ICCs) were calculated to examine test-retest reliability for the component tests across the time periods (See Table 7).

Table 7. Test-retest reliability coefficients for ages 60-80 (N=93)

Test Module	ICC	ΔRCI 90% CI	90% CI	ΔRCI 95% CI	95% CI
Memory Factor	.86	.99	88%	1.18	95%
Verbal Memory	.88	18	91%	22	98%
Visual Memory	.73	20	91%	24	94%
Speed Factor	.85	.85	92%	1.18	95%
Visual Motor Speed	.91	6.3	91%	7.5	94%
Reaction Time	.65	.53	95%	.63	97%

Using RCIs, only a small percentage of participants' scores showed reliable or "significant" change on the composite scores (0%-1%), or factor scores (0%-2%). These results suggest that test-takers cognitive performance at baseline remains considerably stable over a one-month period (Table 7).

Validity, and sensitivity and specificity of ImPACT

Several studies have been completed that evaluate the validity of ImPACT. Studies include sensitivity, specificity and aspects of validity. As noted above, because, ImPACT Version 4 contains the same items and modules as ImPACT, these studies are relevant and provide validity evidence for ImPACT Version 4.

Sensitivity and specificity

In 2006, Schatz and Pardini studied 138 high school athletes (72 concussed and 66 non-concussed) selected from a larger sample of 1,500 individuals. Non-concussed athletes self-reported no history of diagnosed concussion on their health questionnaire. All athletes from both groups self-reported no significant medical problems on their health questionnaire and all subjects from both groups successfully completed a baseline evaluation prior to participation.

A MANOVA on all ImPACT subscales and Composites found significant differences found on Verbal Memory, Visual Memory, Reaction Time, Processing Speed and Symptom scale with concussed athletes performing significantly worse on all variables than their matched controls. When considering classification accuracy, 82.4 % of concussed group were correctly identified as were 89.4% of non-concussed group.

A 2007 study (Broglio et al., 2007) found lower levels of sensitivity and specificity, but also discovered values that were superior to comparable tests, concluding that a battery of tests was ideal. ImPACT and HeadMinder Concussion Resolution Index (Erlanger, Feldman, & Kutner. (1999). were the most sensitive to concussion (79.2 and 78.6%, respectively). These tests were followed by self-reported symptoms (68.0%), the postural control evaluation (61.9%), and a brief pencil-and-paper assessment of neurocognitive function (43.5%). When the complete battery was assessed, sensitivity exceeded 90%. These findings supported previous recommendations that sports-related concussion should be approached through a multifaceted assessment with components focusing on distinct aspects of the athlete's function.

In a 2012 study, Schatz and Sandel examined the sensitivity of ImPACT in matched samples of symptomatic concussed high school athletes and matched controls who were not concussed. They reviewed the cases of 81 athletes observed to sustain a concussion and who had completed the ImPACT test within 3 days of injury. Data were compared with an independent sample of 81 athletes who completed preseason baseline cognitive assessments using ImPACT and who were matched (with concussed athletes) on the basis of sex, age, sport, concussion history, absence of attention deficit hyperactivity disorder (ADHD) and learning disability.

The authors determined that data from ImPACT yielded 91.4% sensitivity and 69.1% specificity. For asymptomatic athletes suspected of hiding their concussion, data from ImPACT yielded 94.6% sensitivity and 97.3% specificity."

A summary of the studies described above are and additional supporting research is presented in Table 8.

Table 8 – Summary of study results supporting sensitivity and specificity of ImPACT

Study	Sample	Analysis Performed	Summary of Results
Schatz, Pardini (2006)	N= 138	ANOVA for between group differences on age/education MANOVA on ImPACT subscales and composites Stepwise Discriminant Function Analysis Chi square on gender, handedness, diagnosed Hx of LD or Special Ed.	ANOVA: No significant findings MANOVA: Significant effects of concussion group on Verbal Memory [$F(1,136) = 32.4; p = .001$], Visual Memory [$F(1, 136) = 34.9; p = .001$], reaction time [$F(1, 136) = 43.6; p = .001$], Processing Speed [$F(1, 136) = 61.1; p = .001$], and symptom scale scores [$F(1, 136) = 39.6; p = .001$], Stepwise DFA: concussed performing worse than controls 82.4 % of concussed group were correctly identified as were 89.4% of non-concussed group Chi Square: Males found to be more likely in concussion group.
Thoma, Cook	N = 87	MANOVA on days since most recent	MANOVA: Number of days was significant on Visual Memory Composite and Reaction Time Composite.

(2015)		concussion and total number of concussions ANOVA on Visual Memory Composite	The overall main effect of Days was significant ($F(5,69)=3.11, p=0.01$; partial $\epsilon^2=0.198$) and there were significant univariate effects for Days on Visual Memory Composite score (VMC; $F(1,73)=10.89, p=0.004$; partial $\epsilon^2=0.133$) and Reaction Time Composite score (RTC; $F(1,73)=6.12, p=0.02$; partial $\epsilon^2=0.079$). ANOVA: Significant main effect for Group for Visual Memory Composite. VMC ($F(1,72)=7.59, p=0.007$; partial $\epsilon^2=0.095$), and higher scores associated with longer time since concussion. Significant main effect for group for the Reaction time composite ($F(1,74)=7.74, p=0.007$; partial $\epsilon^2=0.095$), and Days ($F(1,74)=4.43, p=0.04$; partial $\epsilon^2=0.058$)
Schatz & Sandel (2012)	N=81	Symptomatic and Asymptomatic MANOVA on ImPACT subscales Stepwise Discriminant Function Analysis Chi square on between group differences for sex and concussion Hx	- Symptomatic MANOVA: Significant differences were found on all ImPACT scales and composites between concussed and controls. Cognitive performance ($F[20,302] = 558.6; P = .001$; partial $\eta^2 = .97$). Symptoms ($F[1,162]=141.5; P = .001$; Partial $\eta^2 = .47$). Asymptomatic- MANOVA: Significant differences were found on all ImPACT scales and composites between concussed and controls: Cognitive performance ($F[7,67] = 2048; P = .001$; partial $\eta^2 = .99$). - Stepwise DFA: 91.4 % of concussed group and 69.1 of control group were correctly classified - Stepwise DFA: 94.6% of asymptomatic concussed group and 97.3% of control group were correctly classified - Symptomatic- Chi square: no significant findings
Broglio, Macciocchi (2007)	N=75	Correct Classification	Correct Classification: 65.2% of athletes were identified correctly using just cognitive variables. Correct classification increases to 79.2% when symptom inventory included.

Incremental validity of ImPACT compared with self-reported symptoms

In a 2006 study, van Kampen, Lovell, Pardini, Collins, & Fu assessed the added value of neuropsychological testing (ImPACT) relative to symptom self-report in a group of 122 concussed and 72 non-concussed high school and collegiate athletes who had completed the ImPACT test battery. Both male and female athletes were included. This study found that the addition of ImPACT resulted in an increase in sensitivity of 19% relative to symptom monitoring alone. 93% percent of the concussed athlete group was correctly identified as being concussed in this study. In contrast, symptom data alone correctly classified only 64 percent of the sample. This study highlighted the frequent “disconnect” between self-reported symptoms and more objective neuropsychological test results. In addition, this study found that although none (0 percent) of the control group had both abnormal ImPACT neurocognitive performance and elevated symptoms relative to baseline (determined by RCI scores, relative to baseline test results). In contrast, 93 percent of the concussed group had either poorer ImPACT test scores or elevated symptoms.

Construct and concurrent validity of ImPACT and ImPACT Version 4

One of the first studies to look at the construct validity of ImPACT was completed by Iverson, Lovell and Collins (2005) who administered ImPACT to the Symbol Digits Modalities Test (Smith, 1982). A sample of 72 athletes randomly selected from a larger sample were administered both scales. All athletes had successfully completed an ImPACT baseline test prior to participation and at a later time were determined to have suffered a concussion by a physician or an ATC. Correlational analysis, t-tests and Principle Components Factor Analysis were completed. The SDMT was found to correlate .70 with Processing Speed and -.60 with Reaction Time. Pairwise T-tests revealed strongest relationships were between SDMT and Processing Speed and Reaction Time versus Verbal, or Visual Memory or Total Symptoms. The PCFA confirmed a three-factor solution of Speed/Reaction Time Memory and Total Symptoms as the solution best fitting the data.

Schatz and Putz (2006) studied 30 college student volunteers who were administered the Trail Making Test A & B (TMT) and the Digit Symbol subtest of the Wechsler Adult Intelligence Scale-Revised (WAIS-R). These researchers found that Reaction time was significantly correlated with Trails A-B (.61, .44 respectively) and Digit Symbol from the WAIS (.46). Digit Symbol was also significantly correlated with ImPACT Processing Speed Index -.51

In the most extensive independent study published to date, Maerlender (2010) examined the correlations of ImpACT with a traditional comprehensive test battery. These authors' test battery was comprised of tests of verbal (California Verbal Learning Test [CVLT]) and visual memory (Brief Visuospatial Test-Revised [BVM-T-R™]); cognitive speed (Trail Making Tests- A and B, Verbal Fluency, Delis-Kaplan Executive Function System [DKEFS] Color Word Memory); reaction time (Conners Continuous Performance Test [CPT]) and working memory (Paced Auditory Serial Addition Test [PASAT]). They concluded that "the present study demonstrates that cognitive domains represented by ImpACT have good construct validity with standard neuropsychological tests that are sensitive to cognitive functions associated with mild TBI". They highlighted that ImpACT is best used as a screening tool along with other neuropsychological tests.

Allen and Gfeller (2011) compared ImpACT to a standard "paper and pencil" test battery. In this study, 100 neurologically intact college students completed ImpACT and a more traditional test battery that was previously used throughout the National Football League (NFL). Tests were administered in counter balanced order. A factor analysis was completed and correlations between the two batteries were presented. The authors found significant overlap between the batteries' assessed constructs, but noted slightly different factor structures for them.

Table 9 Summary of study results supporting construct validity of ImpACT

Study	Sample	Analysis	Results
Iverson, Lovell (2005)	N=72.	Comparison to the Symbol Digit Modalities Test (SDMT) Correlational analysis, t-tests Principle Components Factor Analysis	SDMT correlated with: Processing Speed ($r=.70, p<.01$), Reaction Time $r=-0.60, p=0.01$; Verbal Memory $r=.46, p<.01$; Visual Memory $r=.37, p<.01$ Pairwise T-tests revealed strongest relationships between SDMT and Processing Speed ($t = 2.69, p < .01$), and Reaction Time ($t = 2.24, p < .05$). The PCFA confirms a three-factor solution of Speed/Reaction Time Memory and Total Symptoms: (1) <i>Speed/Reaction Time</i> : SDMT .87, Processing Speed Composite .85, and Reaction Time Composite -.76; (2) <i>Memory</i> : Verbal Memory Composite .87 and Visual Memory Composite .80; (3) <i>Total symptoms</i> .93
Maerlender (2010)	N=54.	Correlational analysis relating ImpACT Composites and Neuropsychological domains	Overall ImpACT was shown to have good convergent and discriminant validity. Significant correlations were found between traditional pencil and paper neuropsychological testing domains and all ImpACT domain (composite) scores except for the Impulse Control factor. ImpACT composites correlated with the experimental neuropsychological measures, Processing Speed and Reaction Time measures were inter-correlated; the experimental Working Memory task was related to three of the five ImpACT composites, as well as NP Working Memory.
Schatz & Putz (2006)	N=30	Correlational analysis relating ImpACT Composites to Trail Making A-B, D-2 test and Digit Symbol from WAIS-R	ImpACT Reaction time was significantly correlated with Trails A ($r=.64, p<.05$), Trails B ($r=.44, p<.01$), and Digit Symbol from the WAIS ($p=.46, p<.01$). Digit Symbol was also significantly correlated with ImpACT Processing Speed Index $r=-.51, p<.004$.
Allen & Gfeller (2011)	N=100	Correlational analysis with ImpACT and NFL Battery (HVL-T-R, BVM-T-R, Trail Making Test A-B, COWA and Symbol Search and Digit Span Forward and Backward from the WAIS-III	Significant correlations were obtained between many of the ImpACT composite scores and components of the NFL battery. Correlations tended to be in the .3 to .45 range and likely could have been suppressed by a restricted range in the sample.

For ages 60-80, to determine whether ImpACT Version 4 correlates significantly with a widely utilized and previously validated instrument of Memory and Motor Speed, select subtests of the HVL-T, BVM-T-R, SDMT, and ImpACT were administered within the same session. The sample was composed of 71 individuals between the ages of 60 and 80 (mean age of 67.27 years, S.D. 4.92 years) with 63.4% females and 36.6% males. All measures were administered by Neuropsychologists who were trained in test administration as part of the study to collect data for the normative dataset described in section 2

Table 10. Concurrent validation for ages 60-80 (N=71).

Test	Verbal Memory		Visual Memory		Motor Speed		Reaction Time		Memory		Speed	
	r	p	r	p	r	p	r	p	r	p	r	p
HVLT T Score	.45	.001	.37	.002	.19	.12	-.03	.79	.49	.001	.13	.29
HVLT T Score Delayed	.53	.001	.39	.001	.23	.06	-.12	.31	.57	.001	.22	.07
BVMT-R Total Score	.57	.001	.51	.001	.41	.001	-.23	.05	.62	.001	.35	.003
BVMT-R Delayed	.38	.001	.41	.001	.30	.012	-.09	.44	.44	.001	.21	.09
SDMT Correct	.34	.004	.43	.001	.63	.001	-.37	.001	.39	.004	.45	.001
SDMT Memory Correct	.38	.001	.35	.003	.37	.002	-.14	.24	.43	.001	.26	.03
SDMT Memory Error	-.38	.001	-.34	.004	-.37	.002	.14	.23	-.43	.001	-.26	.03

ImpACT Verbal and Visual Memory Composite scores correlate with both the HVLT and BVMT-R, as well as the SDMT Memory Sub-scales (significant at $P < .001$) which represent measures of verbal and visual memory. ImpACT Motor Speed and Reaction Time Composite Score both correlate with the SDMT Total Correct Subscales, which represents a measure of psychomotor coding speed. These correlations provide validity support to the claim that ImpACT is a measure of Verbal and Visual Memory and psychomotor speed.

Summary

The evidence presented in this chapter provides substantial support for the reliability and validity of ImpACT Version 4. The results obtained from this tool have been found to be stable over time and to be consistent with what one would expect from a test of memory and reaction time. Additional research is being conducted to augment these findings and support the conclusions that have been drawn.

Increased variability in the elderly population in measures of reaction time, memory and fluid intelligence has been consistently found in early research (Hale, Myerson, Smith, and Poon 1988; Morse 1993). ImpACT Version 4 likewise shows increased variability in the Verbal Memory and Reaction Time composites. As a result, increased caution should be exercised when interpreting scores for these composites in this age group as poor performance may be attributed to a number of factors not related to TBI such as other health conditions (i.e., age related cognitive decline, Parkinson's, etc.) or medications taken by the individual. As always, results from ImpACT testing should be viewed in combination with other medical and behavioral information before making a diagnosis or determining a course of treatment.

Chapter 5 - Interpretation

General Guidelines for Interpretation

Interpreting ImPACT Version 4 requires the judgment and expertise of a trained healthcare professional with specific knowledge of interpreting neurocognitive test results. ImPACT Version 4 results should be considered along with other data gathered from multiple sources, including other test data. It is important to emphasize that ImPACT Version 4 is not a diagnostic instrument; it does not provide the clinician with diagnostic decisions. Any test or product that claims to make diagnostic decisions through a “yes-no” or “red light-green light” decision-making process is overly simplistic and may miss subtle difficulties that can expose the individual to further injury.

ImPACT Version 4 does not yield one summary score, but rather a series of scores. Not every test taker will demonstrate impairment on all indices. The performance of the test taker depends on a number of different factors (e.g., past medical history). The interpretation of a test taker’s performance on ImPACT should follow a multi-level path of analysis in which the Composite scores or Two-Factor Scores represent the first level of analysis and are followed by a more thorough analysis of the neurocognitive module scores that contribute to those Composite or Two-Factor Scores. Although ImPACT Version 4 provides significant information about the individual’s neurocognitive functioning, a more complex evaluation of neuropsychological functioning may be warranted. That evaluation should always be conducted by a qualified healthcare professional.

ImPACT Clinical Report

The ImPACT Version 4 Clinical Report provides the healthcare professional with valuable information. The report allows for tracking recovery following an injury by using a side-by-side comparison of multiple assessments and baseline scores. Practitioners can administer the test multiple times over a short period of time to evaluate changes in symptoms and cognitive status across a number of different neurocognitive domains. New to the report for ImPACT Version 4 is the ability to select and print Two-Factor Score in addition to the Composite Scores depending on how you would prefer to interpret the summary data. An example is provided below.

As with prior versions of ImPACT, the report for ImPACT Version 4 provides detailed information about the individual’s performance on a specified series of tasks administered in a standard fashion. The data are automatically scored, and each test taker’s performance is compared with his or her own age group and for the input device (mouse versus trackpad) by the software. The report saves practitioners time and eliminates the possibility of human error when deriving test scores. Furthermore, the report can be accessed easily through ImPACT Applications’ Customer Center and shared with appropriate personnel through secure email.

Interpreting the ImPACT Version 4 Clinical Report

ImPACT Version 4 is a neurocognitive test battery that provides much information about the extent of individual’s injury and their progress toward recovery from that injury. Recovery from concussion cannot be accurately tracked through the evaluation of overly simplistic reaction time tests or through tests that are not structured to detect subtle memory dysfunction. The tracking of recovery following injury requires the analysis of test performance across a variety of different neurocognitive domains. The ImPACT Version 4 Clinical Report is designed to provide information concerning the individual’s current neurocognitive functioning and his or her medical and developmental history.

ImPACT Clinical Report Sections

Page 1: Demographic Information

- Background Information and Native Language
- Education and Special Needs
- Concussion and Sport Background
- Relevant Medical Information

Page 2: ImPACT Composite Scores

- Verbal Memory Composite, Visual Memory Composite, Visual Motor Speed Composite, Reaction Time Composite, Impulse Control Composite, Total Symptom Score, Two-Factor Scores

Page 3: Test Battery Modules

- Word Memory, Design Memory, X's and O's, Symbol Match, Color Match, Three Letters

Page 4: Post-Concussion Symptom Scale

- Individual Symptom Scores

Page 5: Graphic Representation of Composite Scores and Symptoms

- Graphs depicting: Verbal Memory, Visual Memory, Visual Motor Speed, and Reaction Time Composite Scores, Total Symptom Score



ImPACT Clinical Report

Sample Sam

Name	Sample Sam	ImPACT Passport ID	K9LH-BPBZ-L9E3
Date of birth	01/01/2000	Gender	Male
Organization	School 1,2, 3		
Native Country/Region	US		
Native Language	English		
Second Language			
Years of education completed (excluding kindergarten)	13	Repeated one or more years of school	No
Received speech therapy	No	Diagnosed learning disability	No
Attended special education class	No	Diagnosed with ADD/ADHD	No
Current sport	Wrestling		
Primary position/event/class			
Current level of participation			
Years of experience at this level	2		

CONCUSSION HISTORY

Number of times diagnosed with a concussion (excluding current injury)	2	Treatment for:	
Number of concussions resulting in:		- Headaches by physician	Yes
- Loss of consciousness	1	- Migraine headaches by physician	Yes
- Confusion	1	- Epilepsy/seizures	No
- Difficulty remembering events that occurred immediately after injury	0	- Brain surgery	No
- Difficulty remembering events that occurred	0	- Meningitis	No
Total games missed as a result of all concussions combined	10	- Substance or alcohol abuse	No
		- Psychiatric condition (depression/anxiety)	No
		Diagnosed with dyslexia	No
		Diagnosed with autism	No
		Strenuous exercise in the last 3 hours	No

Background information and native language

All of the information regarding date of birth, age, and pertinent physical information should be entered. In addition, the individual always should be questioned about his or her fluency in other languages because this may affect test results.

Education, special needs

Years completed may be recorded along with any history of learning disabilities (LD) or ADD/ADHD, or any other defined special education diagnosis, whether individual was enrolled in special education classes. Please note if he/she attended any special education classes even if they are not currently enrolled.

Sport and concussion background

The test taker may record the sport they are currently playing or planning to play in the near future. This part of the report allows for the careful tracking of injury and recovery, and documents important markers of injury severity and concussion severity.

Other background information that may affect the outcome of the clinical report

Certain pre-existing medical problems may affect recovery from concussion and should be recorded.

Exam type, date tested, last concussion, and exam language

This section should be referenced to determine if a baseline test is available for comparison, including the date of the post injury test relative to the date of concussion. In the event multiple post-injury tests are available, the scores in the following section should be examined for change in performance and reported symptoms. To ensure the most accurate results, it should be determined whether the exam was administered in the test taker's preferred spoken language.

Exam Type	Baseline	Post-Injury 1
Age When Tested	19	20
Date Tested	04/09/2019	08/10/2020
Concussion Date		08/10/2020
Exam Language	English	English
Test Version	3.8.0	4.0.0
Pointing Device	Mouse	Trackpad

The Composite Indices

Composite scores

This section provides information on each of the composites calculated from the individual test modules. When interpreting change in scores from baseline to post-injury, look for scores in **bold RED** type, indicating that this score exceeds the RCI when compared to the baseline score. Percentile scores, if available, are listed in small type.

COMPOSITE SCORES

	A		B			
Memory composite (verbal)	82	49%	57	<1%		
Memory composite (visual)	78	60%	48	2%		
Visual motor speed composite	32.83	32%	22.78	<1%		
Reaction time composite	0.61	46%	1.12	<1%		
Impulse control composite	3		4			
Total Symptom Score	0		38			

A indicates old normative data set, B indicates new normative data set.

TWO-FACTOR SCORES

Memory	-2.75	-2.75		
Speed	-2.62	-2.62		

Hours slept and medication

This section indicates whether the individual is experiencing a sleep disturbance and if they are currently taking medication that may affect their recovery from the concussion.

Hours slept last night	8	7.5
Medication(s)		

Test modules

This section provides the details of the individual's performance on each of the six test modules. Included here are the multiple calculations made on each module. The typical interpretive strategy compares the individual's post-test performance to their baseline performance and looks for significant change that is indicated in Red. Performance on the individual modules should be considered only after evaluating the individual's performance on the composites.

WORD MEMORY

	Baseline	Post injury 1
Hits (immediate)	12	12
Correct distractors (immediate)	12	12
Learning percent correct	100%	100%
Hits (delay)	12	10
Correct distractors (delay)	12	9
Delayed memory percent correct	100%	79%
Total percent correct	100%	89.5%

DESIGN MEMORY

Total correct (memory)	7	9
Total correct (interference)	115	100
Average correct RT (interference)	0.51	0.7
Total incorrect (interference)	1	0
Average incorrect RT (interference)	0.65	0

SYMBOL MATCH

Total correct (visible)	27	27
Avg. correct RT (visible)	2.78	2.48
Total correct (hidden)	9	5
Average correct RT (hidden)	1.41	2.84

COLOR MATCH

Total correct	9	9
Average correct RT	0.8	1.21
Total commissions	0	0
Average commissions RT	0	0

THREE LETTERS

Total sequence correct	5	5
Total letters correct	15	15
Percent of total letters correct	100%	100%
Average time to first click	2.78	3.61
Average counted	11.4	8.2
Average counted correctly	11.2	8.2

Post-Concussion Symptoms Scale (PCSS)

This section describes the symptoms and the level of endorsement of those symptoms by the individual. The higher the level of reported symptoms, the more likely it is that the reported symptoms interfere with the individual's performance. When there are repeated post injury evaluations, the individual's reported change in symptoms should be carefully considered along with his or her performance on the testing tasks.

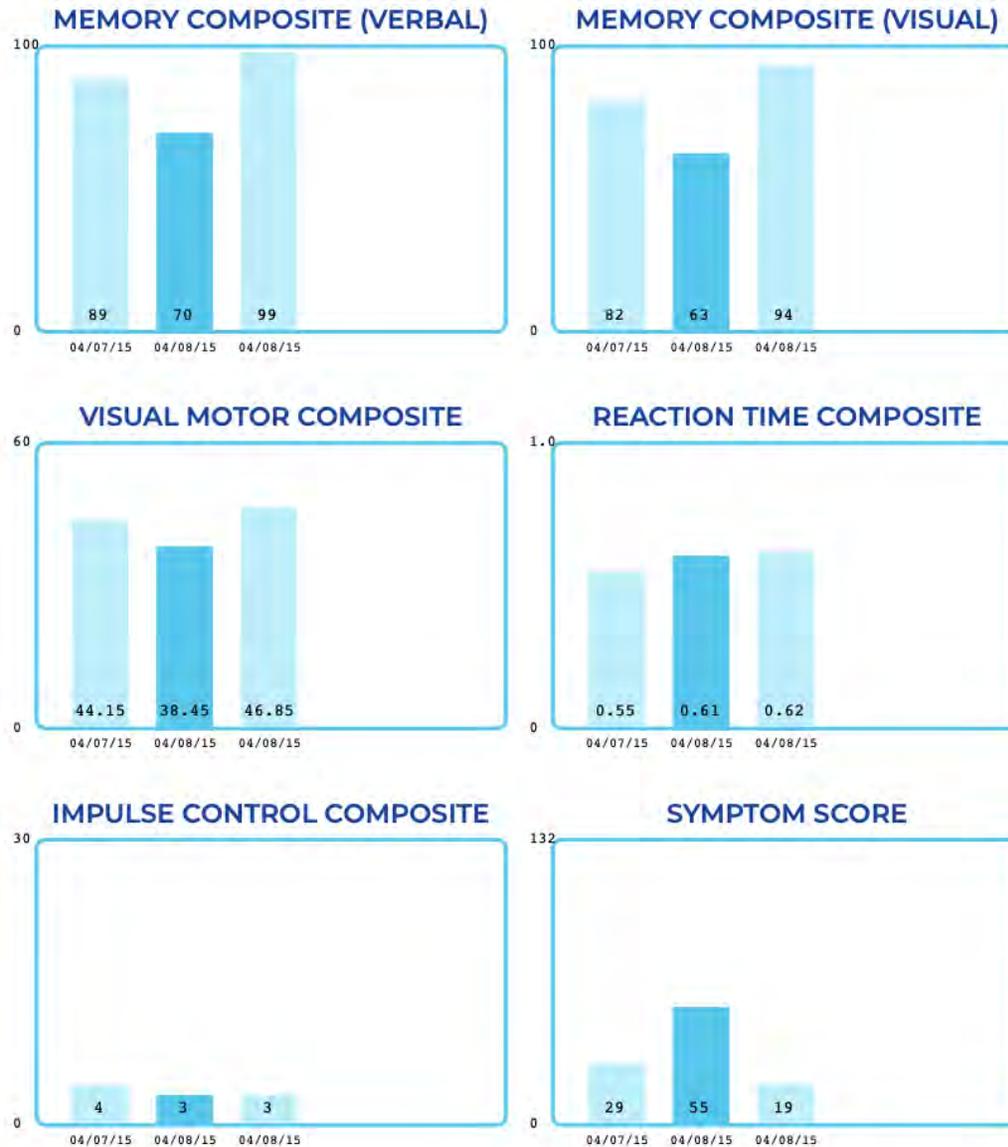
POST-CONCUSSION SYMPTOMS	Baseline	Post-Injury
Headache	0	3
Nausea	0	1
Vomiting	0	0
Balance problems	0	0
Dizziness	0	2
Fatigue	0	4
Trouble falling asleep	0	2
Sleeping more than usual	0	0
Sleeping less than usual	0	3
Drowsiness	0	2
Sensitivity to light	0	2
Sensitivity to noise	0	3
Irritability	0	2
Sadness	0	0
Nervousness	0	2
Feeling more emotional	0	2
Numbness or tingling	0	0
Feeling slowed down	0	2
Feeling mentally foggy	0	2
Difficulty concentrating	0	3
Difficulty remembering	0	2
Visual problems	0	1
Total Symptom Score	0	36

Graphic Display of Neurocognitive Composite and Total Symptom Scores



ImPACT Clinical Report

Sample Sam



Summary

Interpretation of ImPACT Version 4 should be conducted only by a trained healthcare professional who has experience in assessing individuals with suspected concussion. The results should be considered in concert with all available medical and clinical data along with other observational, psychological, and behavioral data and other test data when making a decision about the individual's neurocognitive status and appropriate course of treatment.

Appendix A. References

- Allen BJ, Gfeller JD. The immediate post-concussion assessment and cognitive testing battery and traditional neuropsychological measures: A construct and concurrent validity study. *Brain Inj.* 2011;25(2):179-191
- Aubry et al. Summary and agreement statement of the First International Conference on Concussion in Sport, Vienna 2001. Recommendations for the improvement of safety and health of athletes who may suffer concussive injuries. *Br J Sports Med.* 2002 Feb;36(1):6-10.
- Bell, D.R., Guskiewicz, K.M., Clark, M.A., Padua, D.A. (2003). Balance Error Scoring Symptom Test (BEST). Chapel Hill, NC.
- Benedict, R.H. (1997). Brief Visuospatial Memory Test-Revised (BVRT-R™). Odessa, FL: Psychological Assessment Resources.
- Broglio, S.P., Macciocchi, S.N., Ferrara, M.S. (2007). Sensitivity of the concussion assessment battery. *Neurosurgery*, 60(6):1057-1058.
- Delis, D.C., Kaplan, E., and Kramer, J.H. (2001). Delis-Kaplan Executive System™ (D-KEFS). San Antonio, TX: Pearson.
- Dishion, Kim, Hanjoe, Stormshak, O'Neill (2014). A Brief Measure of Peer Affiliation and Social Acceptance (PASA): Validity in an Ethnically Diverse Sample of Early Adolescents. *J Clin Child Adolesc Psychol.* 43(4):601-1.
- Erlanger, D., Feldman, D., & Kutner, K. (1999). Concussion Resolution Index. New York: HeadMinder, Inc.
- Green, P., (2003, revised 2005) Medical Symptom Validity Test (MSVT). Edmonton, Canada, Green's Publishing.
- Gardner, R. C., Dams-O'Connor, K., Morrissey, M. R., & Manley, G. T. (2018). Geriatric Traumatic Brain Injury: Epidemiology, Outcomes, Knowledge Gaps, and Future Directions. *Journal of neurotrauma*, 35(7), 889-906. <https://doi.org/10.1089/neu.2017.5371>
- Gerrard PB, Iverson GL, Atkins JE, et al. Factor Structure of ImPACT® in Adolescent Student Athletes. *Arch Clin Neuropsychol.* 2017;32(1):117-122. doi:10.1093/arclin/acw097
- Hale, S., Myerson, J., Smith, G. A., & Poon, L W (1988). Age, variability, and speed: Between-subjects diversity. *Psychology and Aging*, 3, 407-410
- Iverson GL, Lovell MR, Collins MW. Interpreting change on ImPACT following sport concussion. *Clin Neuropsychol.* 2003;17(4):460-467.
- Iverson GL, Lovell MR, Collins MW (2005). Validity of ImPACT for Measuring Processing Speed Following Sports-Related Concussion, *Journal of Clinical and Experimental Neuropsychology*, 27:6, 683-689
- Iverson GL, Brooks BL, Collins MW, Lovell MR (2006). Tracking neuropsychological recovery following concussion in sport. *Brain Inj.* 20(3):245-252.
- Iverson, G.L., Sawyer, DC, McCracken, LM, & Kozora, E. (2001). Assessing depression in systemic lupus erythematosus: Determining reliable change. *Lupus*, 10 (4), 266-271.
- Jacobson, Traux. Clinical Significance: A Statistical Approach to Defining Meaningful Change in Psychotherapy Research. *J. of Consult. and Clin. Psy.* 1991. 59 (1), 12-19
- Van Kampen DA, Lovell MR, Pardini JE, Collins MW, Fu FH. The "value added" of neurocognitive testing after sports-related concussion. *Am J Sports Med.* 2006;34 (10):1630-1635.
- Kontos, A.P., Elbin, R.J., Covassin, T., Larson, E. (2010). Exploring differences in neurocognitive concussion testing in African American and White athletes. *Archives of Clinical Neuropsychology*, 25(8), 734-744.
- Lau, B.C., Collins, M.W., Lovell, M.R. (2011). Sensitivity and specificity of subacute computerized neurocognitive testing and symptom evaluation in predicting outcomes after sports-related concussion. *Am J Sports Med*, 39(6):1209-1216.
- Lovell MR, Collins MW, Iverson GL, et al. Recovery from mild concussion in high school athletes. *J Neurosurg.* 2003;98(2):296-301.
- Lovell M, Collins M, Bradley J. Return to play following sports-related concussion. *Clin Sports Med.* 2004 Jul;23(3):421-41, ix.
- Maerlender A, Flashman L, Kessler A, et al. Discriminant construct validity of ImPACT: A companion study. *Clin Neuropsychol.* 2013;27(2):290-299.
- McCrory P, Meeuwisse W, Dvorak J, et al. Consensus statement on concussion in sport—the 5th international conference on concussion in sport held in Berlin, October 2016. *British Journal of Sports Medicine* 2017;51:838-847
- Morse, C. (1993). Does Variability Increase With Age?: An Archival Study of Cognitive Measures. *Psychology and Aging*, Vol. 8. No. 2.156-164
- Nakayama Y, Covassin T, Schatz P, Nogle S, Kovan J. Examination of the Test-Retest Reliability of a Computerized Neurocog. Test Battery. *Am J Sports Med.* 2014
- Schatz P. Long-term test-retest reliability of baseline cognitive assessments using ImPACT. *Am J Sports Med.* 2010;38(1):47-53.
- Schatz P, Maerlender A. A two-factor theory for concussion assessment using ImPACT: memory and speed. *Arch Clin Neuropsychol.* 2013;28(8):791-797. doi:10.1093/arclin/act077
- Schatz, P., & Sandel, N. (2013). Sensitivity and specificity of the online version of ImPACT in high school and collegiate athletes. *Am J Sports Med*, 41(2):321-6.
- Schatz P, Ferris CS. One-month test-retest reliability of the ImPACT test battery. *Arch Clin Neuropsychol.* 2013.
- Taylor CA, Bell JM, Breiding MJ, Xu L. Traumatic Brain Injury-Related Emergency Department Visits, Hospitalizations, and Deaths - United States, 2007 and 2013. *MMWR Surveill Summ.* 2017;66(9):1-16. Published 2017 Mar 17. doi:10.15585/mmwr.ss6609a1
- Trahan, D.E. & Larraabee, G.J. (1996). Continuous Visual Memory Test-Revised (CVMT-R™). Odessa, FL: Psychological Assessment Resources.
- Zuckerman, SL, Lee, YM, Odom, MJ, Solomon, GS, Sills, AK. *Journal of Neurosurgery-Pediatrics*, 2013, 12(2), 103-109.