Optical Diagnostic Systems, LLC

CRAINscan

Training Guideline

reddot CE

1. Product Applications

- **Crainscan is designed for rapid and reliable detection of intracerebral hemorrhages of patients with traumatic brain injuries.**

- **A rapid detection of intracerebral hematomas drastically improves the chance of survival.**

- **The rapid and reliable diagnosis enables the caretakers to advice immediate action, hence no waste of time.**

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1. Product Applications

- **Crainscan is the first choice for instant and reliable detection of hematomas at the site of accident or in the emergency care/trauma centers.**

- **Repeated detections for recognizing delayed intracranial hemorrhages can be safely done in the intensive and critical care units at the patients bedside.**

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1. Product Applications

In summary, Crainscan is the key diagnostic tool in:

- **Accidents and emergency/trauma centers**
- **Intensive care, critical care and neuro care centers**
- **Remote/Small sized hospitals, especially if not equipped with CT's**
- **Ambulance services, military, firearms, police emergency care staffs and sports**

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2. Detection Principle

The principle behind crainscan is the measurement of the optical density of tissue.

The device contains a laser source and a neighboring photo-receiver which are both pressed simultaneously to the patient's head.

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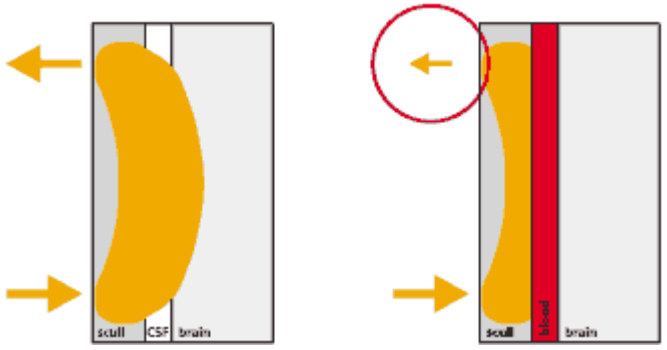
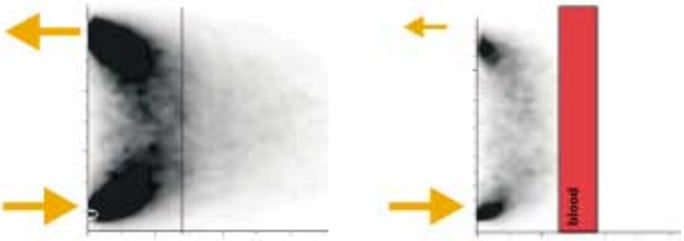
2. Detection Principle

Near infrared light travels from the laser source through the bony skull and the uppermost layers of the brain to the photo-receiver. The light depth is 3 cms.



Schematic drawing

If the light path is obstructed by a hemorrhage, only a fraction of the irradiated light reaches the photo-receiver.



CT Scan

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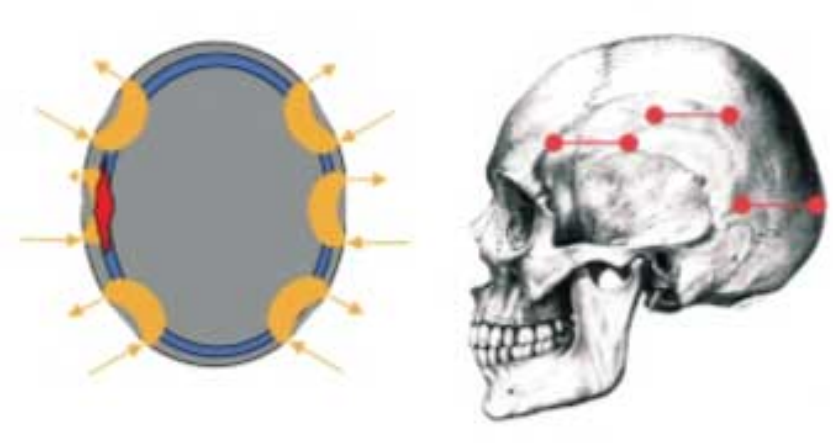
2. Detection Principle



Symmetric Measurements

Since intracranial pathologies proximate to the calotte, it can occur in different places; three measurements - frontal, temporoparietal and occipital - have to be carried out on each side, i.e. six in total.

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2. Detection Principle

Results Clinical Study: Patients with EDH, SDH and superficially intracranial hematomas

Clinical trials for CE-mark approval (58 patients):

- **Sensitivity 100% (all 16 patients with hemorrhages where detected)**
- **Specificity 98% (only 1 patient of 42 patients with no hemorrhages was diagnosed to have a hemorrhage)**

Additional clinical studies:

Used in emergency vehicle, measurement time max. 2 minutes, 140 patients diagnosed (total study 200 patients, finished in 2003).

- **All patients with sub-, epidural and superficially intracranial hematomas where identified.**

Uni-Klinik Mainz intends to do a further study in ICU's.

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3. Product features

Crainscan is a portable optical detection device for the diagnosis of

- **epidural**
- **subdural**
- **superficially intracerebral hemorrhages**

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3. Product features

Important features of Crainscan and its uses are:

- **non-invasive**
- **fast measurement**
- **portable**
- **battery powered**
- **repeatedly usable**
- **harmless**

4. How to operate Crainscan

Very Important:

Please take your time to read through the product manual thoroughly.

4. How to operate Crainscan

Taking a measurement:

Important to know

Press optodes for laser source and photo receiver simultaneously on the patients head (detection points).

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4. How to operate Crainscan

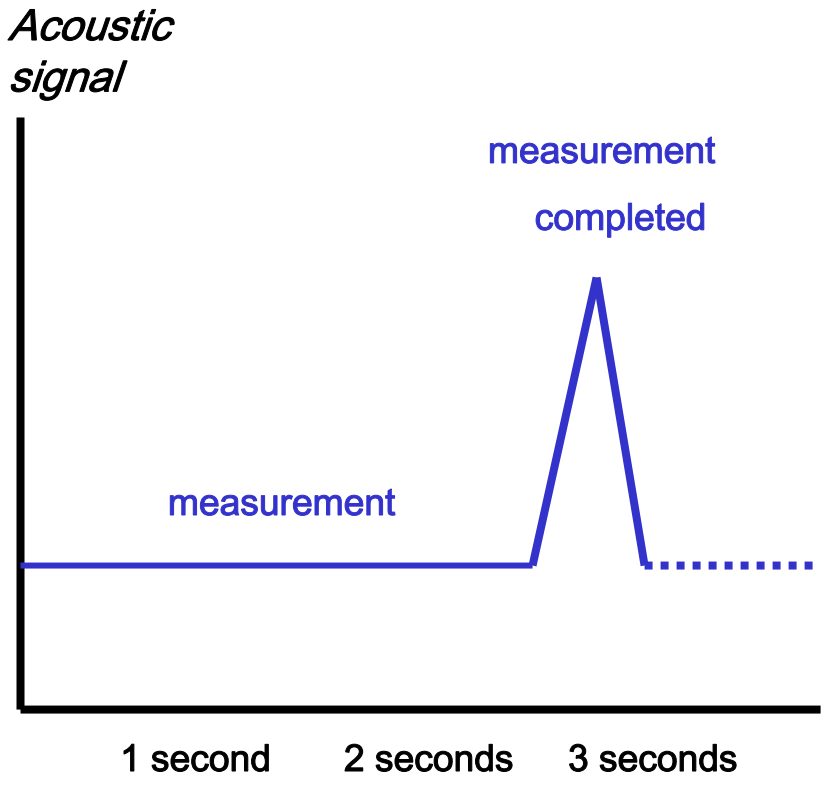
Take a measurement:

Important to know

The measurement is indicated by an acoustic signal.

While pressing the optodes for the laser source and the photo receiver simultaneously, there is a continuous acoustic signal for 2 to 3 seconds. During this time the measurement is taken.

When you hear a peak of the acoustic signal the measurement is finished.



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4. How to operate Crainscan

Take a measurement:

Target the same detection points

It is important to take exact symmetrically opposite measurements on the detection points – right/left frontal, right/left temporoparietal, right/left occipital.

Readings will be incorrect if the measurements are not symmetrically opposite

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4. How to operate Crainscan

Take a measurement:

Keep the device horizontal

During the measurement, keep the device always horizontal, otherwise the detection results may be not correct.

4. How to operate Crainscan

Take a measurement:

Close contact to skin

By taking a measurement at patients with long hair, try to get the optodes of the laser source and the photo receiver as close as possible in contact with the patients skin. Otherwise the measurement results may not be correct.

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4. How to operate Crainscan

Take a measurement:

Important to know – detection cycle

The detection process should always be

1. Measurement: Frontal right
2. Measurement: Frontal left
3. Measurement: Temporoparietal right
4. Measurement: Temporoparietal left
5. Measurement: Occipital right
6. Measurement: Occipital left

By following the sequence it is easer to meet the detection results more accurately.

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4. How to operate Crainscan

Take a measurement:

Values

After taking a detection, you receive a value for optical density.

The values differ from person to person as all human beings are anatomically different. But in an individual person, their right and left sides are anatomically identical, ie the bone structure, muscle thickness etc.

A low optical density is shown by a low value, a high optical density is shown by a higher value

4. How to operate Crainscan

Take a measurement:

Measurement: Frontal right

After finalizing the frontal right measurement, store the absolute value with the press of the frontal right button. This value will be displayed on the panel.

Typically this value is between 7.00 and 9.50, depending on the patient.

4. How to operate Crainscan

Take a measurement:

Measurement: Frontal left

After finalizing the frontal left measurement, store the absolute value with the frontal left button. This value will be displayed in the table format on the display.

Typically this value is between 7.00 and 9.50, depending on the patient

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4. How to operate Crainscan

Take a measurement:

Measurement: Temporoparietal right

After finalizing the temporoparietal right measurement, store the absolute value with the temporoparietal right button. This value will be displayed on the panel.

Typically this value is between 7.00 and 9.50, depending on the patient

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4. How to operate Crainscan

Take a measurement:

Measurement: Temporoparietal left

After finalizing the temporoparietal left measurement, store the absolute value with the temporoparietal left button. This value will be displayed on the panel.

Typically this value is between 7.00 and 9.50, depending on the patient

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4. How to operate Crainscan

Take a measurement:

Measurement: Occipital right

After finalizing the occipital right measurement, store the absolute value with the occipital right button. This value will be displayed on the panel

Typically this value is between 7.00 and 9.50, depending on the patient

4. How to operate Crainscan

Take a measurement:

Measurement: Occipital left

After finalizing the occipital left measurement, store the absolute value with the occipital left button. This value will be displayed on the panel.

Typically this value is between 7.00 and 9.50, depending on the patient

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4. How to operate Crainscan

Take a measurement:

Differences:

The device automatically calculates the difference between the symmetrically opposite readings in the “nine-column table” for:

- frontal right/frontal left
- temporoparietal right/ temporoparietal left
- occipital right/occipital left

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4. How to operate Crainscan

Take a measurement:

Differences:

If the difference in one or more values > than 0.45 (in any symmetrically opposite readings), then it can be definitely assumed to be hematoma.

In order to be very sure, the complete detection cycle should be repeated again.

If the difference is still > than 0.45 it can be concluded, that there is definitely a hematoma.

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4. How to operate Crainscan

Take a measurement:

Where is the hemorrhage

Example:

If the absolute optical density value for the measurement at the frontal right is 7.5

and if the absolute optical density value for the measurement at the frontal left is 8.60

the difference is 1.10, also higher than 0.45.

Therefore it can be assumed that there is a hematoma. Since the light from the Crainscan (near infra-red) is absorbed by the blood (hematoma), the higher value side, i.e. frontal left has a bleeding, since less light is received back by the device, which leads to a higher optical density.

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4. How to operate Crainscan

Take a measurement:

Typical values for differences

If the measurement is done properly the typical difference for patients with no hematoma is in the range of 0.00 to 0.15. If it is higher than 0.15 but lower than 0.45, the measurement was not done properly. But such a difference is still okay and indicating that there is no hematoma.

For patients who show a hematoma, the difference value is typically 1.0 and higher, if the measurement was done correctly.

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4. How to operate Crainscan

Take a measurement:

Restrictions for using the device

Exclusion for the device are:

- Hematomas on both sides (for example frontal right and frontal left)
- Deep intracranial hematomas

  But usually these patients have other indications or are already in bad condition, showing that there is an urgent need for immediate action.

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4. How to operate Crainscan

Take a measurement:

General

It is not hard to use the device properly. Normally, you will learn how to use it within a couple of hours.

Practice on your colleague, your husband, your wife, your boss and most conveniently, on yourself.

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5. Recharging the device

The display shows the charging status of the internal battery.

If the device is heavily used, the battery lasts at least 20 hours.

In stand-by mode, the battery can last at least one year.

If the battery indicator displays low charge, place the device in the charging station and wait until the battery is completely recharged.

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6. Further Questions

If you have further questions, please contact Optical Diagnostic Systems, LLC.