

Technical Service Manual

STIMPOD™
NMS410/450 CE 0120

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Cautions

Federal (US) law restricts this device to sale by or on the order of a physician.

Indications for use:

This product is a nerve stimulation device designed to be used by an anaesthetist during

- General Anaesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes (not supplied) (NMS450).
- Regional Anaesthesia for the purpose of
 - Nerve mapping using the non-invasive Nerve Mapping Probe (supplied).
 - Nerve locating using invasive electrodes/needles (not supplied).

Warnings:

- Read the entire User Manual before attempting to use the device.
- Use of cables or accessories other than those supplied with the STIMPOD may result in serious injury.
- Maintenance on this device may only be performed by the manufacturer or persons explicitly authorized by the manufacturer.
- Do not use the STIMPOD in close proximity to equipment that produces strong electromagnetic fields, such as high frequency surgical equipment. The cable leads could act as antennae and dangerous currents could be induced as a result.
- Do not apply the STIMPOD to patients with implanted electrical devices, such as cardiac pacemakers, without first consulting with an appropriate medical specialist.
- The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- The patient should avoid contact with metallic objects that are grounded, produce an electrical conductive connection with other equipment and/or enable capacitive coupling.
- The cables should be positioned in such a way that they do not contact either the patient or other cables.
- Simultaneous connection of a patient to high frequency surgical ME equipment and the STIMPOD may result in burns and possible damage to the stimulator.
- Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy ME equipment may produce instability in the stimulator output.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

Cautions:

- Prior to changing the batteries be sure to switch off the device and remove all the cables.
- Remove elements which may adversely affect the connection between the electrodes and the skin, e.g., dirt, hair, oil.
- Ensure that ECG electrodes are not damaged or dried out.
- Large current densities associated with failing ECG electrodes may cause superficial burns.
- The Stimpod is designed to be compatible with a standard ECG electrode, however, for high currents the use of a dedicated NMBA

electrode such as the Xavant XT45008 (-NA) is recommended.

- Electrodes that have current densities exceeding $2\text{mA}/\text{cm}^2$ may require special attention of the operator.
- This product must be stored at $0 - 50^\circ\text{C}$.
- This product must be transported in the carry case provided.
- This product and all the accessories have been certified latex free.
- Inspect all parts for any damage or manipulation. Never use any damaged or manipulated part!
- If an electrically conductive surface of the Stimpod device or its cables are exposed, such electrically conductive surface may shock a person handling it. Do not use such a device or accessory, please contact the manufacturer for repair.
- The refractory period delay is set at a default value to prevent the user from repeating stimulation while the nerve synapse is recovering from effects of the previous stimulation. A refractory period of less than 12 seconds in TOF mode is not advisable as measurements might not represent the effect of blocking agents on the neuromuscular junction.

Warranty:

- The Stimpod (device only) carries a 24 Month Warranty against defects, provided that the device was used in accordance with the operating instructions.
- The cables included in the Stimpod Kit carry a 6 Month Warranty against defects, provided that they were used in accordance with the operating instructions.
- The Stimpod enclosure should not be opened under any circumstances. Opening the unit will void the warranty.

1. Performance test for the StimPod NMS410/450

Before operating and using the device a performance test must be carried out by the user at the site of use in compliance with § 5 MPBetreibV.

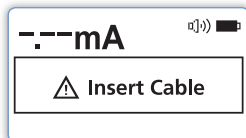
1.1 Performance tests at the site of use

- Insert the batteries and switch on the device.

The following screen should appear on the display.



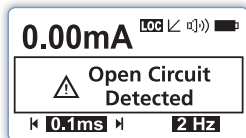
followed by



1.1.1. Nerve Locating Mode

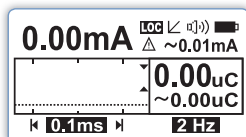
- Insert the Nerve Locating Cable.

The following screen should appear on the display.

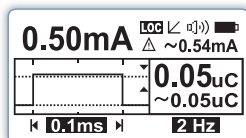


- The LED should flash RED and no audible feedback should be heard.
- Short-circuit the needle connector and the ECG connector.

The following screen should appear on the display.



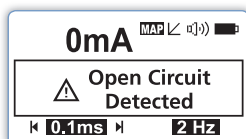
- The LED should flash GREEN and if sound is enabled in the menu a beep should be heard each time a stimulus is delivered.
- Stimulus should occur at the set frequency. (1,2 or 5Hz).
- Use the adjusting wheel and slowly increase the current to 5.00mA.
- Monitor that the stimulating waveform, measured and displayed in the diagnostic window is square and the top part of the wave touches the dotted line, which represents the current setting as shown below.



1.1.2. Combined Nerve Mapping/Nerve Locating Mode

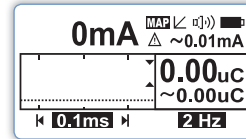
- Insert the Combined Nerve Mapping/ Nerve Locating Cable.

The following screen should appear on the display.



- The LED should flash RED and no audible feedback should be heard.

- Short-circuit the Nerve Mapping probe and the ECG connector.
The following screen should appear on the display.



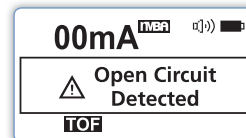
- The LED should flash GREEN and if sound is enabled in the menu a beep should be heard each time a stimulus is delivered.
- Stimulus should occur at the set frequency. (1,2 or 5 Hz).
- Use the adjusting wheel and slowly increase the current to 20mA.
- Monitor that the stimulating waveform, measured and displayed in the diagnostic window is square and that the top part of the square wave touches the dotted line, which represents the current setting.

In order to test the Nerve Locating connection and device functionality follow the instructions in 1.1.1.

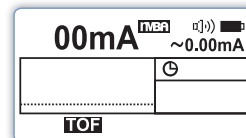
1.1.3. Neuromuscular Blocking Agent Mode (NMBA Mode) (NMS450 only)

- Insert the NMBA Cable.

The following screen should appear on the display.



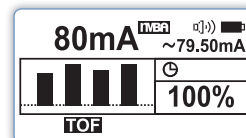
- Ensure that the device is in 'TOF' mode.
- Short-circuit the red and black electrode connectors.



- Use the adjusting wheel and increase the current to 80mA.
- Press the 'play/pause' button while shaking the accelerometer.

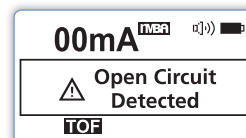
The NMS450 should respond as follows:

- The LED should flash GREEN in accordance with the four stimulations.
- Each stimulation should be accompanied by an audible 'beep'.
- In 'Diagnostic window' four bars of different heights should indicate that the accelerometer detected movement.
- Monitor the actual current delivered to ensure that the warning sign does not appear.



- Separate the red and black electrode connectors to cause an open circuit between them.
- Press the 'play/pause' button.

The following screen should appear on the display.



- The LED should flash RED and no audible feedback should be heard.

If the STIMPOD malfunctions in any of these performance tests, it should be checked by qualified staff proficient in the testing of electronic medical devices in accordance with the Test Instructions for the safety checks (STK).

2. Test instructions for the safety checks (STK)

Section 6 of the MPBetreibV specifies that safety checks should be performed by the user.

The safety check should be performed by qualified staff (§ 6, para 4 MPBetreibV) in accordance with the following test instructions.

- Print the Report Template (Appendix A).

2.1 Measuring Equipment

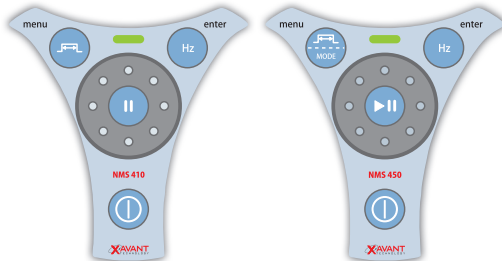
The following measuring and testing equipment is required:

- Storage Oscilloscope
- 20 kOhm measuring resistor
- 4,5kOhm measuring resistor
- 4 x AAA batteries

2.2 Checking the external condition of the device

(Check the following and tick the corresponding check box in the Report Template.)

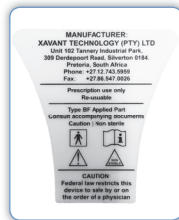
- Check that the housing/ connectors and cables are intact and clean (Soap and water, applied with a damp cloth is suitable to clean and disinfect the STIMPOD. It is imperative that no moisture penetrates the STIMPOD. Any commercially available methanol-free disinfectant in an ethyl alcohol base can be used for disinfection.)
- Check that the keypad is legible.



- Check that the label on the battery cover is legible (Previous versions might vary).
- Switch unit on and verify that the display is working.
- Connect a locate cable and verify that the current can be increased using the keypad dial.
- Verify that the pulse width can be changed using 'pulse width' button on the keypad.
- Verify that the frequency can be changed using the 'frequency' button on the keypad.
- Verify that the menu can be accessed using the 'menu' button.
- Connect a locate cable. Verify that the pause button operated when pressed.
- Check that the enclosure, screen, keypad is clean.
- Check that the Claw operates correctly.
- Inspect the keypad to ensure that it is even and flat on the front cover.



CE Version



North America Version

2.3 Performance Testing

- Carry out performance test according to 1.1 and 1.2.

2.4 Checking and measuring the Stimpod Output

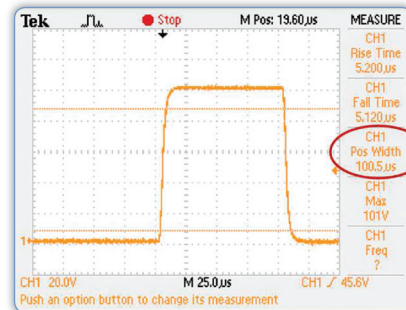
2.4.1. Pulse Width test (Locate mode, Locating cable)

Scope settings are as follow:

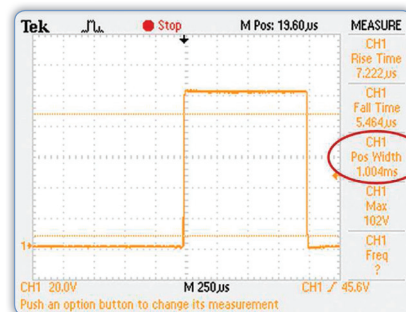
- Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- Probe**
 - 10X
- Horizontal Setting**
 - 25µs/Div
- Vertical Setting**
 - 20V/Div



- Insert the Locate Cable.
- Connect a 20KΩ load.
- Adjust the Current to 5mA.
- Adjust the Frequency to 5Hz.
- Adjust the **Pulse Width** to 0.1ms.¹



- Record the Pulse Width on the Report Template.
- Adjust the **Pulse Width** to 1ms.¹



- Record the **Pulse Width** on the Report Template.

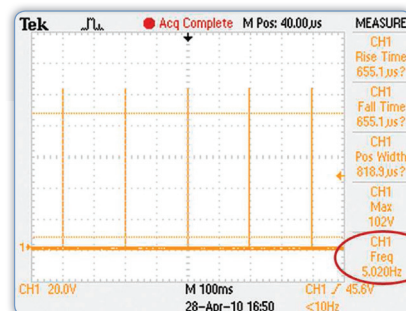
2.4.2 Frequency test (Locate mode. Insert Locating cable)

Scope settings are as follow:

- Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- Probe**
 - 10X
- Horizontal Setting**
 - 100ms/Div
- Vertical Setting**
 - 20V/Div



- Connect a 20KΩ load.
- Adjust the Current to 5mA.
- Adjust **Frequency** to 5Hz.
- Adjust the Pulse Width to 0.1ms.



Record the **Frequency** on the Report Template.

¹ 0.1ms option and 1.0ms option must be selected in the SETUP MENU PULSE WIDTH.

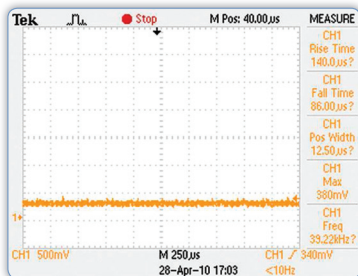
2.4.3 Stimulus current test (Locate Mode, Insert Locating cable)

Scope settings are as follow:

- **Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- **Probe**
 - 10X
- **Horizontal Setting**
 - 250µs/Div
- **Vertical Setting**
 - 500mV/Div



- Connect a 20KΩ load across the needle and the ECG clip connector.
- Adjust the Frequency to 5Hz.
- Adjust the Pulse Width at 1ms.
- Adjust the **Current** to 0mA.



- Check that there is no stimulating pulse.
- If a pulse is present:
 - Record the **Voltage** on the Report Template.
 - Calculate the current: $\text{Current} = \frac{\text{Voltage}}{20\,000\Omega}$
- Record the **Current** on the Report Template.

Scope settings are as follow:

- **Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- **Probe**
 - 10X
- **Horizontal Setting**
 - 250µs/Div
- **Vertical Setting**
 - 20V/Div

- Connect a 20KΩ load.
- Adjust the Frequency to 5Hz.
- Adjust the Pulse Width at 1ms.
- Adjust the **Current** to 5mA.



- Record the **Voltage** on the Report Template.
- Calculate the current: $\text{Current} = \frac{\text{Voltage}}{20\,000\Omega}$
- Record the **Current** on the Report Template.
- Record the **Rise Time** on the Report Template.
- Record the **Fall Time** on the Report Template.

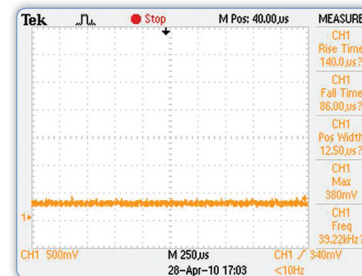
2.4.4 Stimulus current test (Locate Mode, Insert Map/Locating cable)

Scope settings are as follow:

- **Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- **Probe**
 - 10X
- **Horizontal Setting**
 - 250µs/Div
- **Vertical Setting**
 - 500mV/Div



- Connect a 20KΩ load across the needle and the ECG clip connector.
- Adjust the Frequency to 5Hz.
- Adjust the Pulse Width at 1ms.
- Adjust the **Current** to 0mA.



- Check that there is no stimulating pulse.
- If a pulse is present:
 - Record the **Voltage** on the Report Template.
 - Calculate the current: $\text{Current} = \frac{\text{Voltage}}{20\,000\Omega}$
- Record the **Current** on the Report Template.

Scope settings are as follow:

- **Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- **Probe**
 - 10X
- **Horizontal Setting**
 - 250µs/Div
- **Vertical Setting**
 - 20V/Div

- Connect a 20KΩ load.
- Adjust the Frequency to 5Hz.
- Adjust the Pulse Width at 1ms.
- Adjust the **Current** to 5mA.



- Record the **Voltage** on the Report Template.
- Calculate the current: $\text{Current} = \frac{\text{Voltage}}{20\,000\Omega}$
- Record the **Current** on the Report Template.
- Record the **Rise Time** on the Report Template.
- Record the **Fall Time** on the Report Template.

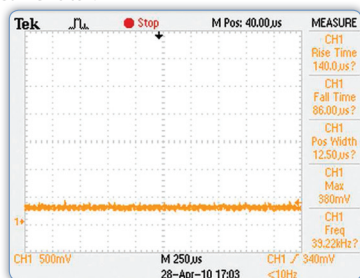
2.4.5 Stimulus current test (Mapping Mode, Insert Map/Locating cable)

Scope settings are as follow:

- **Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- **Probe**
 - 10X
- **Horizontal Setting**
 - 250µs/Div
- **Vertical Setting**
 - 500mV/Div



- Connect a 20KΩ load across the Mapping Probe and ECG connector.
- Adjust the Frequency to 5Hz.
- Adjust the Pulse Width at 1ms.
- Adjust the **Current** to 0mA.

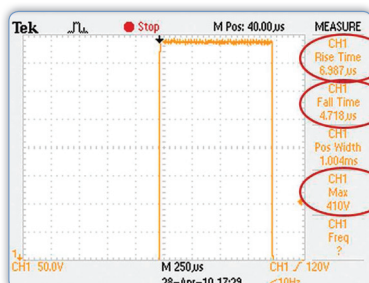


- Check that there is no stimulating pulse.
- If a pulse is present:
 - Record the **Voltage** on the *Report Template*.
 - Calculate the current: $\text{Current} = \frac{\text{Voltage}}{20\,000\Omega}$
- Record the **Current** on the *Report Template*.

Scope settings are as follow:

- **Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- **Probe**
 - 10X
- **Horizontal Setting**
 - 250µs/Div
- **Vertical Setting**
 - 50V/Div

- Connect a 20KΩ load.
- Adjust the Frequency to 5Hz.
- Adjust the Pulse Width at 1ms.
- Adjust the **Current** to 5mA.



- Record the **Voltage** on the *Report Template*.
- Calculate the current: $\text{Current} = \frac{\text{Voltage}}{20\,000\Omega}$
- Record the **Current** on the *Report Template*.
- Record the **Rise Time** on the *Report Template*.
- Record the **Fall Time** on the *Report Template*.

2.4.6 Stimulus current test (NMBA Mode, Insert NMBA cable)

Stimpod settings are as follow:

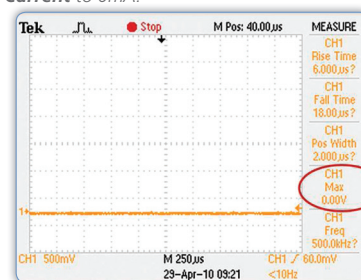
- Make sure the mode of operation is TWI.
- Frequency set at 5Hz.

Scope settings are as follow:

- **Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- **Probe**
 - 10X
- **Horizontal Setting**
 - 250µs/Div
- **Vertical Setting**
 - 500mV/Div



- Connect a 4.5KΩ load across the two ECG connectors.
- Adjust the Frequency to 5Hz.
- Adjust the **Current** to 0mA.

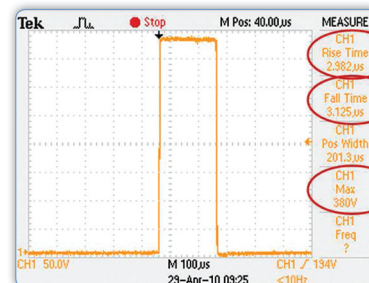


- Check that there is no stimulating pulse.
- If a pulse is present:
 - Record the **Voltage** on the *Report Template*.
 - Calculate the current: $\text{Current} = \frac{\text{Voltage}}{4\,500\Omega}$
- Record the **Current** on the *Report Template*.

Scope settings are as follow:

- **Channel 1 settings**
 - Coupling DC
 - Probe 10X voltage
 - Invert off
- **Probe**
 - 10X
- **Horizontal Setting**
 - 100µs/Div
- **Vertical Setting**
 - 50V/Div

- Connect a 4.5KΩ load.
- Adjust the **Current** to 80mA.



- Record the **Voltage** on the *Report Template*.
- Calculate the current: $\text{Current} = \frac{\text{Voltage}}{4\,500\Omega}$
- Record the **Current** on the *Report Template*.
- Record the **Rise Time** on the *Report Template*.
- Record the **Fall Time** on the *Report Template*.

2.4.7 Default Settings

Ensure that the device is reset to the following default settings after testing:

- Reset **Pulse Width** options to 0.1ms and 0.3ms.

3. Replacing the electrode cable.

A faulty electrode cable can be easily replaced on site with a new one.
The polarized connector prevents the wrong connection of the electrode cable.

4. Repair address

Should the STIMPOD fail any of the safety checks, it may only be repaired by the manufacturer or by an organisation expressly authorised by the manufacturer.

Manufacturer

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Web: www.xavant.com

Appendix A: Report Template

Checking external condition of the device (Refer to paragraph 2.2)											Pass	Fail
Check that the housing/ connectors and cables are intact and clean.											☐	☐
Check that the keypad is legible.											☐	☐
Check that the battery cover is legible.											☐	☐
Switch unit on and verify that the display is working.											☐	☐
Connect a locate cable and verify that the current can be increased using the keypad dial.											☐	☐
Verify that the pulse width can be changed using the 'pulse width' button on the keypad.											☐	☐
Verify that the frequency can be changed using the 'frequency' button on the keypad.											☐	☐
Verify that the menu can be accessed using the 'menu' button.											☐	☐
Connect a locate cable. Verify that the pause button operated when pressed.											☐	☐
Check that the enclosure, screen and keypad is clean.											☐	☐
Check that the Claw operates correctly.											☐	☐
Inspect the keypad to ensure that it is even and flat on the front cover.											☐	☐

Performance Testing (Refer to paragraph 2.3)											Pass	Fail
Carry out performance test according to 1.1 and 1.2											☐	☐

Connect a 20kΩ load and set the current to 5mA and frequency to 5Hz (Refer to paragraph 2.4.1) Pulse width test (Locate mode, Locate cable)						Connect a 20kΩ load and set the current to 5mA and frequency to 5Hz (Refer to paragraph 2.4.2) Frequency test (Locate mode, Locate cable)							
Expected values			Variance		5%		Expected values			Variance		5%	
Setting (ms)	Measured (ms)		Min (ms)	Max (ms)	Pass	Fail	Setting (Hz)	Measured (Hz)		Min (Hz)	Max (Hz)	Pass	Fail
0.1			0.095	0.105	☐	☐	5			4.750	5.250	☐	☐
1.0			0.950	1.050	☐	☐						☐	☐

Connect a 20kΩ load and set the pulse width of 1.0ms (Refer to paragraph 2.4.3)													
Locate Cable (Locate Mode)													
Stimulus Current/Rising/Falling Edges													
Expected values			Variance		5%		Expected values			Variance		5%	
Setting (mA)	Measured (V)	Calculated (mA)	Min (mA)	Max (mA)	Pass	Fail	Setting (mA)	Measured (μs)		Min (μs)	Max (μs)	Pass	Fail
0.00			0.000	0.000	☐	☐							
5.00			4.750	5.250	☐	☐							

Connect a 20kΩ load and set the pulse width of 1.0ms (Refer to paragraph 2.4.4)													
Map/Locate Cable (Locate Mode)													
Stimulus Current/Rising/Falling Edges													
Expected values			Variance		5%		Expected values			Variance		5%	
Setting (mA)	Measured (V)	Calculated (mA)	Min (mA)	Max (mA)	Pass	Fail	Setting (mA)	Measured (μs)		Min (μs)	Max (μs)	Pass	Fail
0.00			0.000	0.000	☐	☐							
5.00			4.750	5.250	☐	☐							

Connect a 20kΩ load and set the pulse width of 1.0ms (Refer to paragraph 2.4.5)													
Map/Locate Cable (Mapping Mode)													
Stimulus Current/Rising/Falling Edges													
Expected values			Variance		5%		Expected values			Variance		5%	
Setting (mA)	Measured (V)	Calculated (mA)	Min (mA)	Max (mA)	Pass	Fail	Setting (mA)	Measured (μs)		Min (μs)	Max (μs)	Pass	Fail
0.00			0.000	0.000	☐	☐							
20.00			19.000	21.000	☐	☐							

Connect a 4.5kΩ load (Refer to paragraph 2.4.6)													
NMBA Cable (NMBA Mode)													
Stimulus Current/Rising/Falling Edges													
Expected values			Variance		5%		Expected values			Variance		5%	
Setting (mA)	Measured (V)	Calculated (mA)	Min (mA)	Max (mA)	Pass	Fail	Setting (mA)	Measured (μs)		Min (μs)	Max (μs)	Pass	Fail
0.00			0.000	0.000	☐	☐							
80.00			76.000	84.000	☐	☐							

Default Settings (Refer to paragraph 2.4.7)											Pass	Fail
Reset pulse width options to 0.1ms and 0.3ms.											☐	☐