CCi-MOBILE Research Interface
for Cochlear Implant and Hearing-Aid Research
Software Patch – Compliance Notification System

In the latest release of the CCi-MOBILE software suite, new features were added to existing functionality to communicate to the user when stimulation parameters (clinical levels/current levels) generated from custom signal processing are out of safe operating limits. Additionally, these safety features were migrated from traditional MATLAB script (.m) to protected scripts (.p files). These features help ensure researchers maintain the safety of cochlear implant users.

New Updates to Existing Programs

- 'AudioFileProcessor.m'
- 'RealtimeStimulator.m'
- 'RealtimeStimulatorScript.m'
- 'Stream.m'
- 'timing_check.p' (protected)

- 'check_map.p' (protected)
- 'field_check.p' (protected)

New Programs

- 'safety_check.p' (protected)
- 'stimuli_check.p' (protected)

Processing Pipeline

Run commands from:
- AudioFileProcessor.m
- RealtimeStimulator.m
- RealtimeStimulatorScript.m

During initialization (initialize_ACE.m or initialize_ACE_interger_ppf.m):
1. Load the subject MAP file (.m) – **'load_map.m'**
2. Initiates a three step process to check subject MAP to ensure all fields are valid, all parameters are within safety limits, and stimulation characteristics are feasible – **'check_map.p'**
3. Check to ensure all of the individual fields of the MAP are specified and/or default (e.g., stimulation rate, implant type, pulse width, etc.) – **'field_check.p'**
4. Check to ensure user-defined stimulation parameters produce a feasible stimulation configuration the operating specifications of the Standard Rate Protocol and/or High Rate Protocol from Cochlear Corp. – **'timing_check.p'**
5. **NEW!** Check to ensure the user-defined stimulation parameters are compliant per the implant type (i.e., individual current levels on each electrode do not exceed charge limits specified by Cochlear Corp.) – **'safety_check.p'**
6. Check the maximum comfort levels and minimum threshold levels of each electrodes in the subject MAP are between 0 CU and 255 CU -- **'level_check.p'**

Signal processing (ACE_process.m, ACE_Processing_Realtime.m, or custom signal processing scripts)
1. Run the signal processing strategy (frame-by-frame processing) – **'ACE_Process.m'** (default)
2. **NEW!** Check the stimuli generated from the signal processing strategy to ensure all clinical levels generated are within compliance charge limits specified by Cochlear Corp. – **'stimuli_check.p'**
3. Initialize the board (CCi-MOBILE) by sending null frames and initiate communication routines – **'initializeBoard.m'**
4. Create the output buffer – **'create_output_buffer.m'**
5. Fill the buffer frame by frame – Various programs depending on implementation
   a. Real-time operation: **'RealtimeStimulator.m'** within the function 'button_start_Callback'
   b. Real-time operation: **'RealtimeStimulatorScript.m'**
   c. Offline operation: **'Stream.m'**

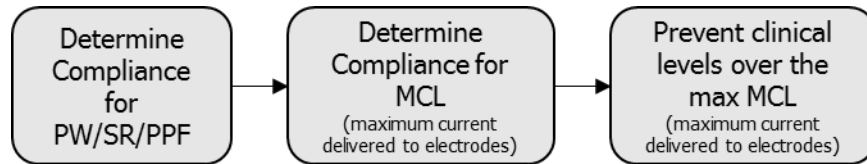## SAFETY/COMPLIANCE (3-STEP) PROTOCOL

Figure 0. Three step process to ensure all user-specified parameters produce safe stimulation to cochlear implant users.

I.   ADJUSTING STIMULATION PARAMETERS – **'timing_check.p'** and embedded function 'check_timing_parameters'

Description: This safety check ensures the specified pulse width is greater than 25 us and less than 400 us. When these limits are either not met or exceeded, the pulse width is adjusted to automatically to meet timing criteria according to Equation 1. Additionally, warning dialogs are prompted to notify the user of these automatic adjustments shown in Figures 1-2.

1. **Stimulation Protocol:** This safety check also mimics the 'Standard Rate Protocol' and the 'High Rate Protocol' from Cochlear Corp Equation 1 describes the relationship between the pulse width, number of selected channels for stimulation (N_{max}), and the stimulation rate as it relates to the total stimulation rate. When the pulse width specified exceeds the limit (PW_{max}), the pulse width is automatically set the maximum allowable limit (PW_{max}). If the pulse width is adjusted, the user is notified with a warning dialog box as shown in Figure 3.

$$PW_{max} = \frac{1e6}{StimulationRate * N_{max}} - IPG + SG + AG \qquad (1)$$

PW_{max}	Maximum pulse width (PW)	IPG	Inter-phase-gap, 8us
SG	Stimulation gap (0) – Reserved	AG	Additional gap (1us)
N_{max}	'n-maxima' or number of stimulation channels per stimulation cycle		
$StimulationRate$	Stimulation rate (pulses per second per channel – ppspch)		

NOTE: CCi-MOBILE does not support 'High Rate Protocol'.

To prevent CCi-MOBILE from operating in 'High Rate Protocol' (i.e., total stimulation rate has exceeded 14,400 pulses per second), the stimulation rate is reduced in order to meet with compliance of 14,400 pulses per second. If the stimulation rate is adjusted, the user is notified with a warning dialog box and an in-screen display of the decrement in stimulation rate as shown in Figure 4.

2. **Criteria for Pulses per Frame:** The operating conditions for the number of pulses per frame requires the number of pulses to be an integer value (i.e., integer pulses per frame). If a non-integer pulse per frame is specified, the user is notified via the Command Window.

    ```
    Non-integer pulses per frame detected, data may be lost.
    ```

3. **Protocol for Stimulation Mode:** To ensure CCi-MOBILE is operating in its only stimulation mode supported (MP1+2), the pulse width is checked again using Equation 2. If the pulse width specified (and/or adjusted previously) exceeds this value, the pulse width is adjusted to the maximum pulse width allowed per Equation 2 and the user is notified using a dialog box shown in Figure 5.

$$PW_{max} = 0.5 * \frac{1e6}{StimulationRate*N_{max}} - IPG + 11 \qquad (2)$$

PW_{max}	Maximum pulse width (PW)	IPG	Inter-phase-gap, 8us
N_{max}	'n-maxima' or number of stimulation channels per stimulation cycle		
$StimulationRate$	Stimulation rate (pulses per second per channel – ppspch)		

4. **Warning Notification System (examples):** If any changes have been made to the user-specified parameters (pulse width, stimulation rate, and/or, pulses per frame, the user is notified through the Command Window.

```
Pulse Width has been adjusted to: 35 us
Rate has been adjusted to: 889 pps
```
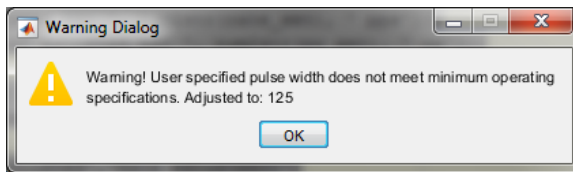

Figure 1 (left). Warning dialog display when the pulse width specified is less than 25us. **Figure 2 (right).** Warning dialog display when the pulse width specified is greater than 400us.
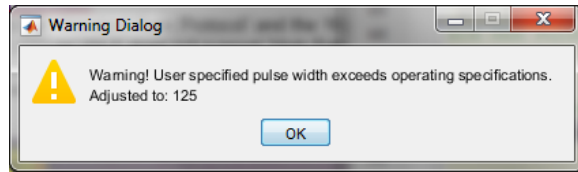

Figure 3 (left). Warning dialog display when the pulse width specified has been adjusted to meet operating specifications. **Figure 4 (right).** Warning dialog display when the stimulation rate has been decremented to meet the total stimulation rate allowed.
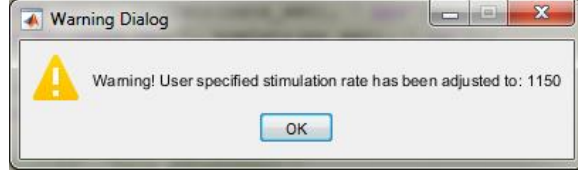

Figure 5. Warning dialog display when the pulse width specified has been adjusted to meet operating specifications.

II. ADJUSTING MAP MCL/THR PARAMETERS – 'level_check.p'

Description: Each implant (Cochlear Corp.) has varying compliance limits with respect to charge that is dependent on the pulse width and the clinical level. In order to stay within these limits, the Equation 3 is used to determine the maximum 'safe' clinical limit that is compliant with Cochlear Corp.

$$CL_{max} = A - B \times \log_{10}(PW) \qquad (3)$$

CL_{max} (CI24RE)	Maximum clinical level or clinical unit (CL)	A	519.8
PW (CI24RE)	Pulse width	B	127.7

The general process to maintain the safety for the CI user is to check if the maximum comfort level (MCL, 'C-Level') specified in the MAP is greater than the maximum clinical level allowed on the electrode (CL_{max}). If the specified clinical level exceeds the maximum clinical level allowed, the software suite prompts the user (researcher) to allow automatic adjustment with compliance

or to terminate processing to adjust the MCL manually (see Figure 6). Selecting 'Yes', allows the CCi-MOBILE to automatically adjust the MCL to the maximum allowable clinical level as shown below and notifies these changes through the Command Window. Selecting 'No' will terminate the processing and no stimulation will be sent to the board/coil. Additionally, the user will be prompted of termination through the Command Window. If the user closes this window without a selection, the process will terminate as it is out of compliance (see Figure 8).

```
Channel 1 : MCL(1) = 250 -> Corrected to 188.
Channel 2 : MCL(2) = 250 -> Corrected to 188.
Channel 3 : MCL(3) = 250 -> Corrected to 188.
Channel 4 : MCL(4) = 250 -> Corrected to 188.
Channel 5 : MCL(5) = 250 -> Corrected to 188.
Channel 6 : MCL(6) = 250 -> Corrected to 188.
Channel 7 : MCL(7) = 250 -> Corrected to 188.
Channel 8 : MCL(8) = 250 -> Corrected to 188.
Channel 9 : MCL(9) = 250 -> Corrected to 188.
Channel 10 : MCL(10) = 250 -> Corrected to 188.
Channel 11 : MCL(11) = 250 -> Corrected to 188.
Channel 12 : MCL(12) = 250 -> Corrected to 188.
Channel 13 : MCL(13) = 250 -> Corrected to 188.
Channel 14 : MCL(14) = 250 -> Corrected to 188.
Channel 15 : MCL(15) = 250 -> Corrected to 188.
Channel 16 : MCL(16) = 250 -> Corrected to 188.
Channel 17 : MCL(17) = 250 -> Corrected to 188.
Channel 18 : MCL(18) = 250 -> Corrected to 188.
Channel 19 : MCL(19) = 250 -> Corrected to 188.
Channel 20 : MCL(20) = 250 -> Corrected to 188.
Channel 21 : MCL(21) = 250 -> Corrected to 188.
Channel 22 : MCL(22) = 250 -> Corrected to 188.
```

1. **Warning Notification System (examples):** If any of the specified parameters are out of compliance, the user will be requested to make a selection.
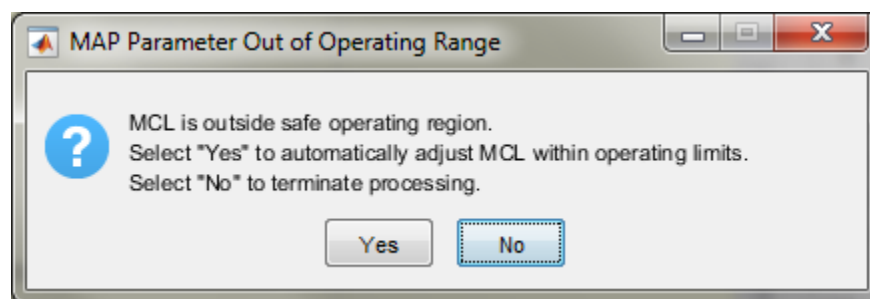

Figure 6. Dialog box notification system within the CCi-MOBILE software suite when an MCL has been detected to be outside of the operating specifications. The user is prompted to allow the software to adjust the MCL ('Yes') or to terminate the process ('No').
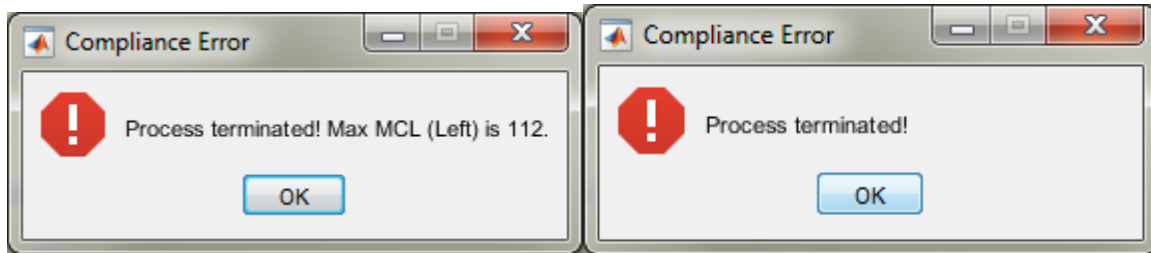
Figure 7 (left). Error dialog box to notify user of the maximum MCL for the particular ear. **Figure 8 (right).** Error dialog box if no action is taken by the user (researcher) to adjust the MCL within compliance limits.

III. ADJUSTING STIMULI – 'stimuli_check.p'

Description: The maximum clinical level is set using Equation 3. If the clinical levels per electrodes exceed the maximum clinical level <u>post-processing</u> (ACE or custom signal processing strategy) before sending the stimulation to the board, the user will be notified of the compliance issue and the clinical levels are decremented to the maximum allowable clinical level to prevent over-stimulation to the cochlear implant user. See the error dialog boxes for each ear in Figures 9-10. The board will produce safe clinical levels that do not exceed the maximum allowable amount of current.
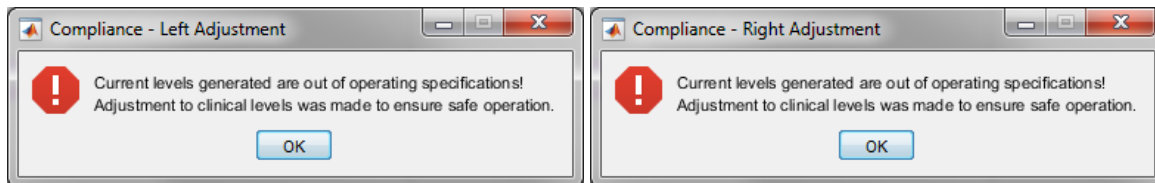

Figure 9-10. Out of compliance dialog box for stimulation levels adjusted automatically for the left (left) and the right (right) stimuli.