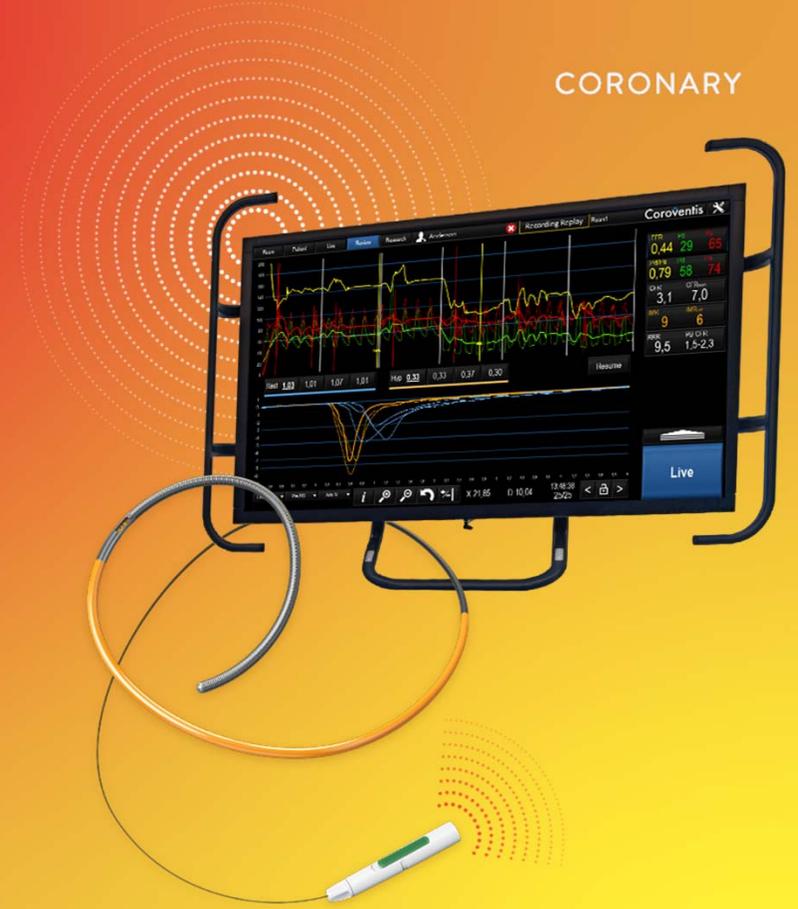




CORONARY

PROCEDURE GUIDE

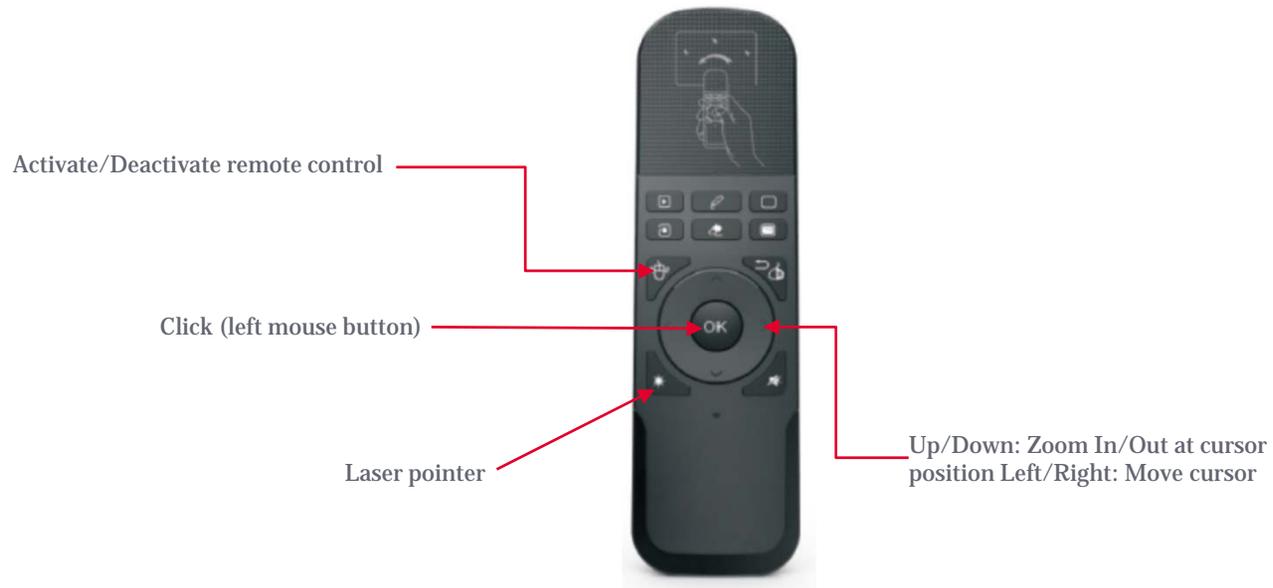
Coroventis CoroFlow[†] System



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Air Mouse Remote Control

Tilt mouse with small movements to move cursor on PC screen



Caution: Always refer to CoroFlow¹ IFU for full safety information and handling instructions.

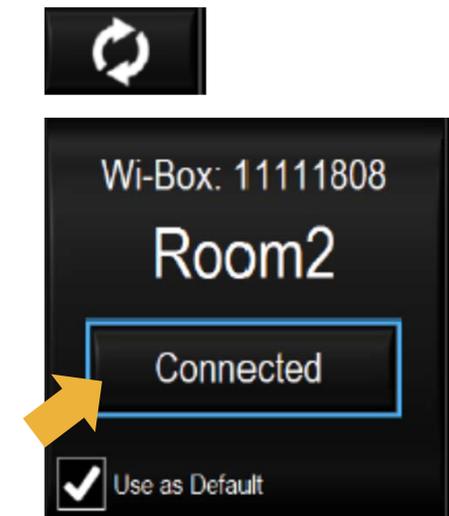
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1. Select Room

1. Click Room Menu, Wi-boxes in radio range are displayed
 2. Click Refresh Icon if needed
 3. Select Room/AO Source by clicking Connect
- Click Set as Default to automatically connect to this AO-Source next time
 - Click and enter a unique room name to simplify connection



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2. Register New Patient - Manually

1. Click Patient menu
2. Click New
3. Enter patient info
4. Optionally enter baseline characteristics and treatment info
5. Click + New Measurement

The screenshot displays a software interface for patient registration. On the left, a 'Patient' menu is open, showing options: 'New', 'Open', 'Edit', a refresh icon, and a trash icon. A yellow arrow points to the 'New' button. The main area shows a table of patients with columns for 'Patient Name', 'Patient ID', and 'Study'. The table lists several patients, including AERTS L, Anderson, Black, Carlson, CHAJURY Z, CoroFlow, Davies M, De Clerk, DE COCK L, Jansen, LEEMANS M, Lindson, Lindstrom, LORIS A, Rulberg, Wilson, and Wolf. A yellow arrow points to the '+New Measurement' button at the bottom right of the form.

Patient Name	Patient ID	Study
AERTS L	650740774-2121	FAME3
Anderson	852312-2122	FAME3
Carlson	128740774-2121	PREDICT
CHAJURY Z		
CoroFlow		
Davies M	PAT005	
De Clerk	123456789	CORAL T-TIME
DE COCK L		CORAL
Jansen		
LEEMANS M		
Lindson	1234567	CORAL
Lindstrom	652312-2123	FAME3
LORIS A		
Rulberg	220424234-2123	ORBITA
Wilson	123456789-2122	FAME3
Wolf	003456789	COURAGE

The form on the right is titled 'Patient/Study Info' and has tabs for 'General Info', 'Baseline Characteristics', and 'Treatment'. The 'General Info' tab is active, showing fields for 'Patient name (Required)' (filled with 'Huges Amy Mrs'), 'Patient ID' (filled with 'PAT007'), 'Age', and 'Gender' (filled with 'F'). There is also a 'Comment' field, a 'Physician' field, a 'Study' field, a 'Subject ID' field, and a 'Dicorn Study UID' field. At the bottom, there are two buttons: '+New Measurement' (blue) and 'Cancel' (red). A yellow arrow points to the '+New Measurement' button.

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2. Register New Patient – Dicom Worklist

1. Click Patient menu
2. Click New
3. Click Connect icon
4. Select scheduled patient and click Select
5. Optionally enter baseline characteristics and treatment info
6. Click New Measurement

Patient/Study Info

General Info Baseline Characteristics Treatment

Patient name (Required)
Huges Amy Mrs

Patient ID PAT007 Age Gender F

Comment

Physician

Study

Subject ID

Dicom Study UID
1.2.826.0.1.3680043.11.109

+New Measurement Cancel

Select patient to register Date: 2017-05-08

Patient name	Patient ID	Gender	Study date
Bowen William Dr	PAT004		20170508
Thomas Sarah Miss	PAT008		20170508
Thomas Sarah Miss	PAT008		20170509
Thomas Sarah Miss	PAT008		20170511
Bowen William Dr	41	F	20170510
No Name	PAT004		20170509
No Name	PAT004		20170510

Select Refresh Cancel

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3. Zero AO

1. Open AO transducer to Air
2. Place mouse over the AO field – the Zero AO button is visible
3. Click ZERO AO
4. Close AO transducer.



Caution: Always refer to CoroFlow¹ IFU for full safety information and handling instructions.

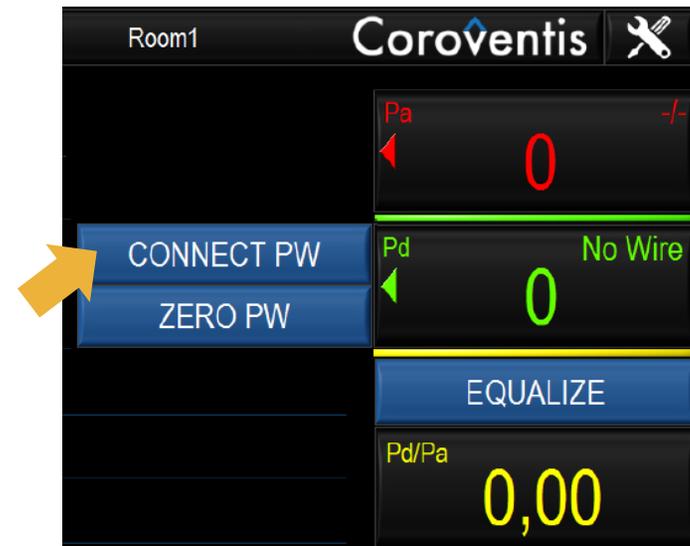
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4. Connect PW

1. Place packaging coil on a flat surface and flush with saline
2. Place mouse over the PW field – the CONNECT PW button is visible
3. Click CONNECT PW
4. Turn ON PressureWire™ X Guidewire transmitter



Connect: Turn Wire OFF then ON

Cancel

Note: Order is important, FIRST Click 'Connect PW' in CoroFlow, then turn ON PressureWire. If PW was turned on too early, turn PW OFF then ON again.

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5. Equalize Pressures

1. Advance PressureWire™ Guidewire until the sensor element is just outside of the guide catheter.
2. Flush guide
3. Click EQUALIZE
4. Pd /Pa value should equal 1.00
5. Advance PressureWire™ distally



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6. Select Measurement Mode

- Click Mode Selector to select measurement mode:
 - FFR
 - RFR
 - AbsFlow
 - CFR and IMR
 - IMR
 - Temperature
 - dP/dt & Tau



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FFR: Record

1. Click Rec to record
2. Measure FFR at maximum hyperemia.
3. Click Marker [M] to place marker
4. Optionally add marker info
5. Click Stop to end recording and the Review window is opened.



Set Marker

Add Marker Info

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FFR: Review

- Validate cursor position
- Set case annotation
- Optionally add Pd/Pa cursor
- Optionally right-click on graph to add/edit marker
- Optionally Lock recording
- Click Live to return to live view

Caution: Always confirm valid cursor positions



Caution: Always refer to CoroFlow¹ IFU for full safety information and handling instructions.

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FFR: Pullback

- Click Pullback to record a Pullback
- Scale is maximized and Pressure filter is set to 1 beat
- Click Stop to Review Pullback recording



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FFR: Review Pullback

- FFR and Pd/Pa cursors are placed automatically at Min and Max Pd/Pa
- Validate cursor positions
- Set case Annotation
- Optionally Lock recording
- Click Live to return to live view

Caution: Always confirm valid cursor positions



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RFR: Quick Measure

- Confirm correct proximal pressure Equalization with overlapping pressure waveforms
- Select RFR Mode
- Advance distal to lesion
- Click RFR button to start
- System captures next 5 heart beats automatically

Caution: Always confirm correct Equalization



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RFR: Review Quick Measure

- Confirm valid waveforms and marker positions
- Set case annotation
- Optionally Lock recording
- Click Live to return to live view

Caution: Always confirm valid pressure tracings and marker positions



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RFR: Record Pullback

- Confirm correct proximal pressure Equalization with overlapping pressure waveforms
- Select RFR mode
- Place wire distal in vessel
- Click Pullback
- Scale is maximized and averaging is set to 1 beat
- Slowly pull back wire to guide
- Click Stop to review pullback recording



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RFR: Review Pullback

- Validate cursor positions and waveform quality
- Set case annotation
- Optionally Lock recording
- Click Live to return to live view

Caution: Always confirm valid pressure tracings and marker positions



Caution: Always refer to CoroFlow¹ IFU for full safety information and handling instructions.

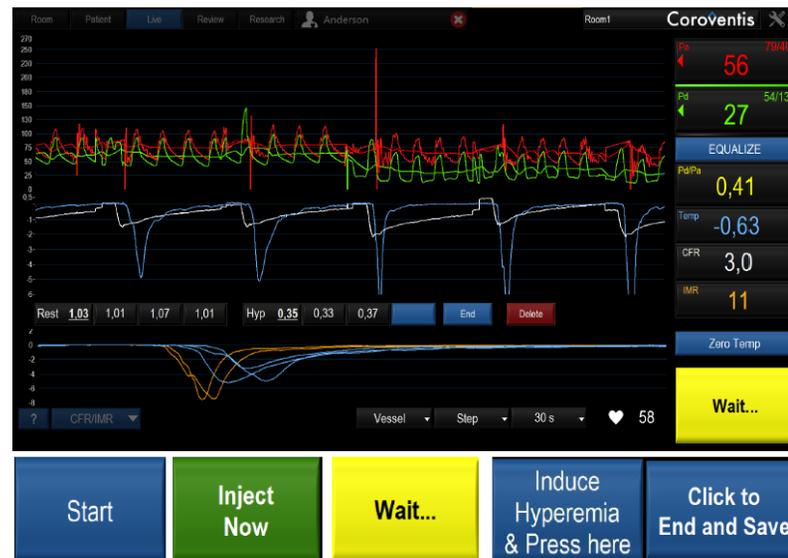
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Record CFR and IMR

- Advance wire distally
- Flush guide with saline
- Click Start
- Vigorously inject 3 cc and close the injection port on manifold to monitor pressure
- Inject again when prompted
- Repeat 3 times at rest and 3 times at max hyperemia
- Click Press to End and Save



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Review CFR and IMR

- Validate cursor position
- Set case Annotation
- Optionally add Pd/Pa cursor
- Optionally click on T_{mn} value to erase it
- Optionally Lock recording
- Click Resume to resume recording of the same case
- Click Live to return to live view
- Note: If T_{mn} variability is too high the average T_{mn} is highlighted in yellow

Caution: Always confirm valid cursor positions



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Record IMR

- Advance wire distally
- Induce hyperemia
- Flush guide with saline
- Click Start
- Vigorously inject 3 cc
- Close valve, wait
- Inject again when prompted
- Repeat 3 times at max hyperemia
- Click Press to End and Save



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Review IMR

- Validate cursor position
- Set case Annotation
- Optionally click on T_{mn} value to erase it
- Optionally Lock recording
- Click Live to return to Live view
- Note: If T_{mn} variability is high the average T_{mn} is highlighted in yellow

Caution: Always confirm valid cursor positions



Caution: Always refer to CoroFlow¹ IFU for full safety information and handling instructions.

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Export Recording

1. Open Review screen
2. Click on Options bar to show recording list
3. Click Export
4. Select Export format:
 - Raw waveform, Excel CSV
 - Result summary, Excel CSV
 - Max & Min values, Excel CSV
 - Screenshot, PNG image
 - CoroFlow[†] data set
 - DICOM
5. Click Export



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Change Graph Scales/Sweep Rate

Y-scale:

- Click on graph
 - Use arrows to set max/min
- or
- Click Autoscale

X-scale/Sweep rate:

- Click Sweep rate button
- Select 10/30/60/120 seconds



Sweep Rate

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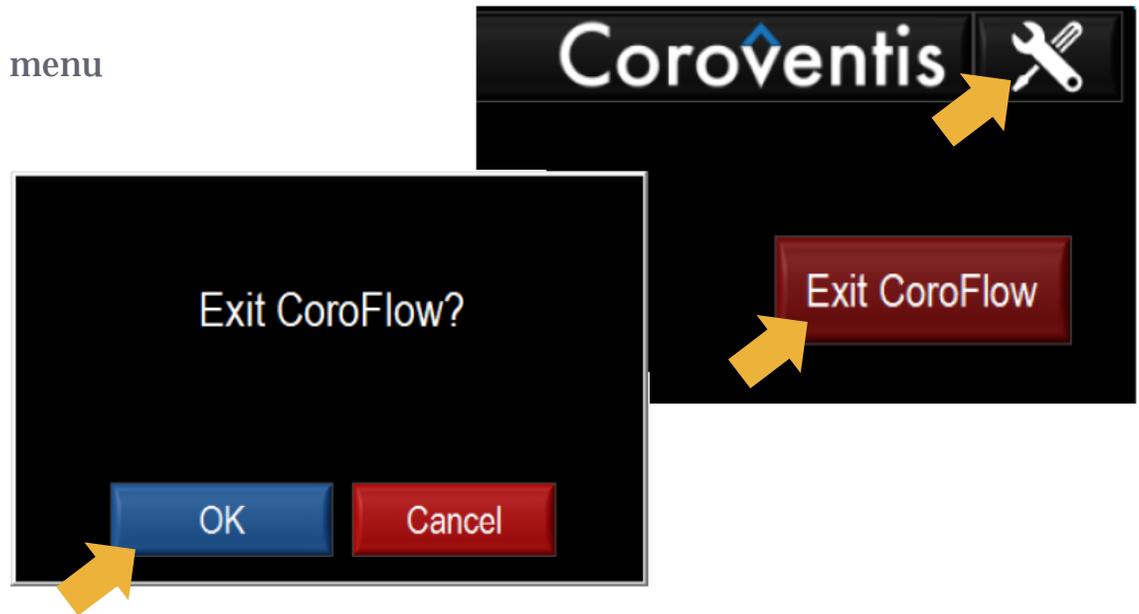
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Shut Down Coroflow[†]

- Click on tools icon to open settings menu
- Click Exit CoroFlow[†]
- Click OK



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Troubleshooting

Problem Description (AO Source)	Solution
AO source (Wi Box) not found. Basic	<ol style="list-style-type: none">1. Verify that Wi Box is powered with green light and within ~5 m from CoroHub[†]2. Ensure CoroHub[†] is connected to USB port on PC3. Click on the Room Menu in CoroFlow[†]4. Click Refresh
AO source (Wi Box) not found. Advanced	<ol style="list-style-type: none">1. Ensure CoroHub[†] is connected to USB port on PC2. Open Settings Menu, Click CoroHub[†] Tab3. Click Reconnect CoroHub[†]4. Verify that PW Receiver and AO Receiver are detected and in Acquisition or Tracking mode5. If modules are not detected - Re-connect CoroHub[†] and click Reset CoroHub[†]6. If modules are still not detected - restart CoroFlow[†] PC

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Troubleshooting (Continued)

Problem Description (CFR/IMR)

Cause/Solution

Error Message:

Error
Slow Inject
0,65s

- Injection too slow (>0.6 s)
- Use smaller (5 ml) syringe and max 3 ml injection bolus
- Draw saline from reservoir and inject with a vigorous motion
- Make certain each injection is ended abruptly

Error Message:

Error
Timeout

- Temperature did not return to baseline within time limit (8 s)
- Zero temperature and retry

Error Message:

Error
Low Amp

- Temperature did not reach minimum limit during injection (1°C)
- Flush guide with fresh room temperature saline before injecting
- Verify guide engagement
- Zero temperature and repeat injection

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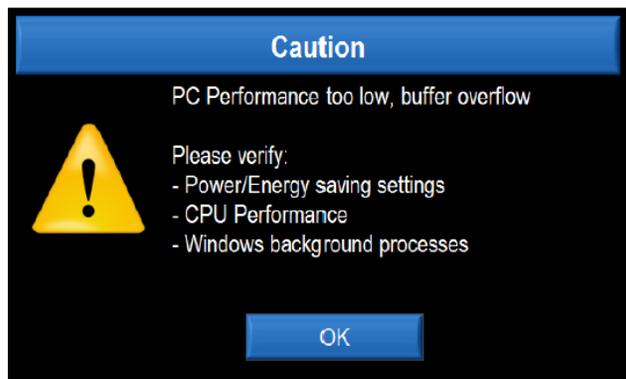
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Troubleshooting (Continued)

Problem Description (General)

Error Message:



Cause/Solution

CPU Performance is too low to handle incoming data stream, CoroFlow[†] is buffering too much data

Probable Cause/Solution:

1. PC is running on battery which may cause Windows to reduce CPU performance. Change Energy saving scheme to High Performance (Windows Control Panel) or plug into mains power
2. PC CPU has too low performance to run application. Upgrade to high performance PC
3. Windows is performing resource consuming tasks in the background, such as Windows Update. Reschedule updates to occur when PC is not being used with CoroFlow[†]

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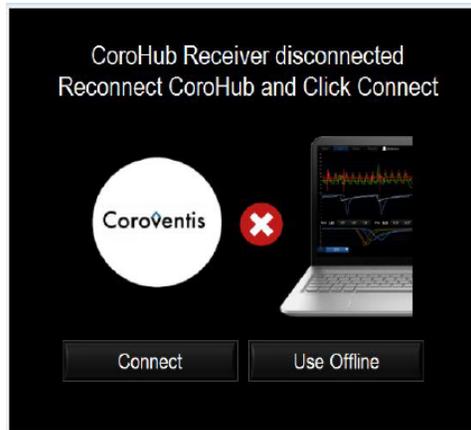
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Troubleshooting (Continued)

Problem Description

Error Message:



Cause/Solution

- CoroHub[†] has been disconnected
- Reconnect CoroHub[†] and click “Connect”
- Alternatively click “Use Offline” to use CoroFlow[†] only for offline review/demo

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Troubleshooting (Continued)

Problem Description

Error Message:



Cause/Solution

- CoroHub[†] is not detected
- Connect CoroHub[†] and click “Retry”
- Alternatively click “Use Offline” to use CoroFlow[†] only for offline review/demo

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