

# NEW TECHNOLOGY FOR CARDIAC CHARACTERIZATION

# **COROVENTIS COROFLOW CARDIOVASCULAR SYSTEM**

Coroventis CoroFlow Cardiovascular System is an advanced platform for assessment of coronary physiology.

Designed to communicate with Abbott Vascular's wireless PressureWire<sup>®</sup> X, CoroFlow is easy to use for daily clinical practice at the same time as it provides powerful tools for advanced physiologic research.





### **OVERVIEW**

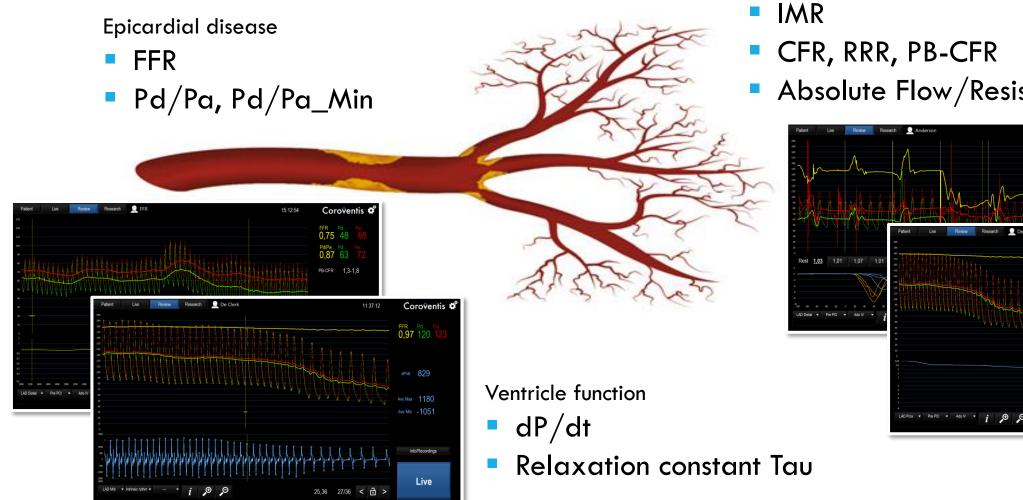
CoroFlow provides an unmatched number of hemodynamic parameters, covering both epicardial disease states as well as unique tools for assessment of the micro-circulation, providing the means for a near Complete Cardiac Characterization.

- FFR (Fractional Flow Reserve), Pd/Pa at rest
- Absolute coronary flow (L/min)
- Absolute Microvascular Resistance (mmHg/L/min)
- IMR & Corrected IMR (Index of Microvascular Resistance)
- CFR & Normalized CFR (Coronary Flow Reserve)
- PB-CFR (Pressure bounded CFR)
- RRR (Resistive Reserve Ratio)
- Intravascular temperature
- Intra-coronary/ventricular dP/dt
- Diastolic relaxation constant Tau
- Systolic/diastolic/end-diastolic pressures and ratios
- Channel phase synchronization
- DICOM Worklist



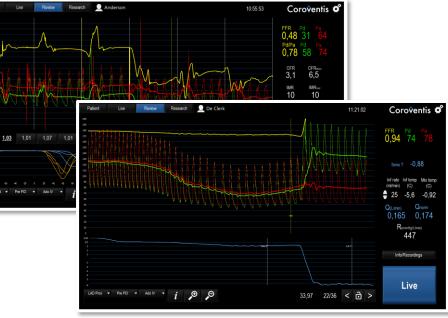


# **CARDIAC CHARACTERIZATION**



Micro-vascular disease

Absolute Flow/Resistance

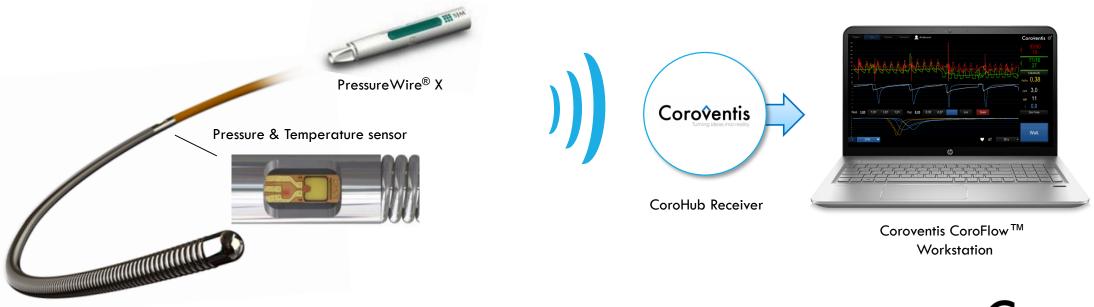


Coroventis

Turning ideas into reality

### TECHNOLOGY

- Abbott Vascular's PressureWire<sup>®</sup> X measures intra-coronary pressure and temperatures which are broadcasted using secure frequency hopping radio technology
- Coroventis CoroFlow<sup>™</sup> receives the transmitted pressure and temperature wirelessly from PressureWire<sup>®</sup> X and calculates pressure and flow parameters using thermo-dilution techniques



Coroventis Turning ideas into reality

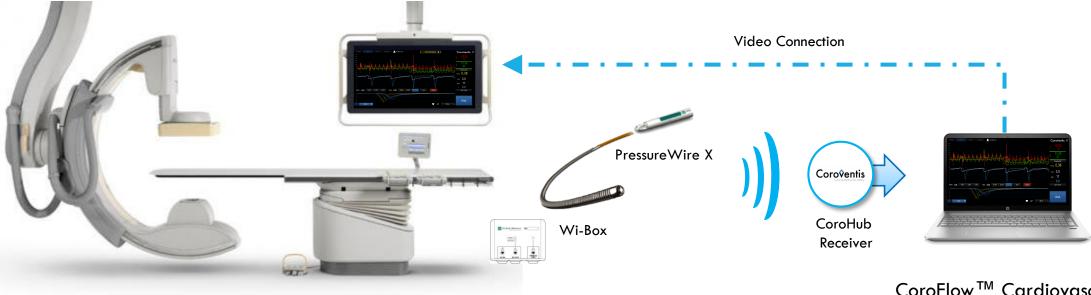
# DATA MANAGEMENT

CoroFlow is designed to handle large number of subjects and facilities effective and secure data management both for regular practice as well as in single or multi-center research projects.

- Local or distributed network/cloud database
- Unlimited number of remote review stations
- Unlimited number of subjects and recordings (based on network storage capacity)
- Adaptive database filtering and automated bulk extraction and export of key study parameters
- Up to 2 hours uninterrupted recording time per recording
- Extensive case annotation and configurable event markers
- Multiple data export formats



# WIRELESS LAB INTEGRATION



CoroFlow<sup>™</sup> Cardiovascular Research system

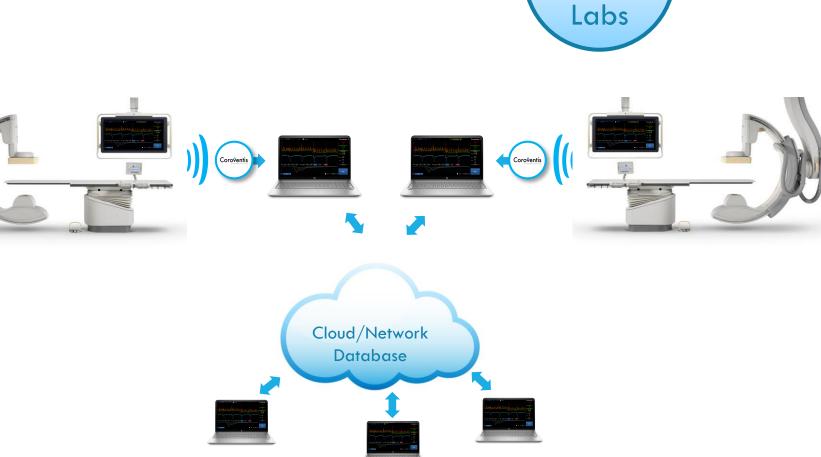
Windows<sup>®</sup> 7,8,10

- Wireless communication with pressure sources in the lab (PressureWire/Wi-Box)
- Optional boom monitor display
- Network connectivity for data storage and DICOM Worklist retrieval

Laptop/Server/Surface Pad



# **CLOUD DATA MANAGEMENT**



One or

**Multiple** 



# AUTOMATED KEY DATA EXTRACTION

### Measurements



### Automated Data Indexing

FFR	Pd	Pa		
Pd/Pa	Pd	Pa		
CFR	CFRNorm	PBCFR	50	
IMR	IMR Corr		FR FR	
BRI	RRR			
TMN1	TMN2	TMN3	10	
Pre	Post		13	
LAD	RCA	LCX		
Prox	Mid	Dist		
Gender	Age	ID		
•••				

### Study Level Data Filtering/Anonymization Export to Excel/Matlab

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13 FAME, GET			Nils	Danden		2016-08-25		COROVEER	LAD Distal Pos					
14 FAME, GET			Nils	Danden		2017-01-24		COROVEER	LAD Distal Pre		nine			1
15 FAME, GEI			Nils	Danden			16:44:41 C		LAD Distal Pre					*
16 FAME, GEI			Nils	Danden		2017-01-24		COROVCER	LAD Distal Pre					
17 FAME, GET			Nils	Danden			17:04:28 C		LAD Distal Pre					
18 FAME, GEI			Nils	Danden		2017-01-24		COROVEER	LAD Distal Pre					
19 FAME2		2	53 Nils		A PI54N871		13:14:12 C		LAD Prox Pos		1			
20 FAME2	1		53 Nils	Daniele	A PIS4N871			COROVFFR	LAD Prox Pos					
21 FAME2	1	12	53 Nils	Daniele	A PISAN871	2017-03-14		COROV AbsFlow	LAD Prox Pos			25	NaN	Nat
22 FAME2	1	12	53 Nils	Daniele	A PISAN871	2017-03-14	13:18:16 C	COROV dP/dt	LAD Prox Pos					
23 FAME, CO	RA #5	98323	52 Dox	Demore	cordings	2016-04-05	11:56:15 C	COROV AbsFlow	LAD Prox Pre	PCI Saline	This is a d	x 25	412	
24 FAME, CO	RA #5	98323	52 Dox	Demore	cordings	2016-05-02	11:42:41 C	COROV FFR	LAD Prox Pre	PCI	This is a c	omment		
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25 FAME, CO	RA #5	98323	52 Dox	Demore	cordings	2016-05-03	10:23:02 C	COROVFER	LAD Prox Pre	PCI	This is a c	omment		
27 FAME, CO	RA #5	98323	52 Dox	Demore	cordings	2016-09-01	10:38:21 C	COROVEER	LAD Distal Pre	drug Nitro IC				
28 FAME	#24	6456456	56 Carl	J Cox		2016-05-19	13:23:08 C	COROVFER	LAD Prox Res	ting RegalC				
29 FAME	#24	6456456	56 Carl	J Cox		2016-05-19	13:25:11 C	COROV CFR	LAD Prox Res	ting RegaIC				
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31 FAME	#24	6456456	56 Carl	J Cox		2016-05-19	13:42:19 C	COROV dP/dt	LAD Prox Res	ting RegalC				
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### **TECHNICAL SPECIFICATIONS**

Index	Definition	<u>References</u>
FFR, Fractional Flow Reserve	Pd/Pa at maximum hyperemia	FFR 1
Tmn, Transit Mean Time (s)	Inversely proportional to coronary blood flow. Point of balance of dilution curve from start of injection	CFR 1
	until temperature has returned to baseline	
CFR, Coronary Flow Reserve	Tmn_Rest/Tmn_Hyp	CFR 1
CFR_Norm, CFR normalized for epicardial disease	CFR/FFR	CFR 5
PB-CFR, Pressure bounded CFR	Upper boundary = $\Delta P_Hyp/\Delta P_Rest$ Lower boundary = $\sqrt{(\Delta P_Hyp/\Delta P_Rest)}$	PB-CFR 1
IMR, Index of Microvascular Resistance	Tmn_Hyp x Pd_Hyp	IMR 1
IMR_Corr, IMR corrected for influence from collateral supply	Two modes: Wedge: Pa_Hyp x Tmn_Hyp x [(Pd – PW) / (Pa – PW)]_Hyp Yong: Pa_Hyp x Tmn_Hyp x [1.34*Pd_Hyp/Pa_Hyp-0.32]	IMR 6
BRI, Baseline resistance index. Microvascular Resistance at	Two modes:	IMR 11
rest, corrected for collateral supply.	Wedge: Pa_Rest x Tmn_Rest x [(Pd - PW)/(Pa - PW)]_Rest	IMR 6
	Yong: Pa_Rest x Tmn_Rest x [1.34*Pd_Rest/Pa_Rest-0.32]	
RRR, Resistance Reserve Ratio	BRI/IMR	IMR 11
Q, Absolute Flow (L/min)	Q = 1.08 x T_inf/T_Mix x Inf_rate	ABS 1
Q_Norm, Normalized flow (L/min)	Q/FFR	ABS 4
R, Absolute Resistance (mmHg*min/L)	Pd/Q	ABS 4
Wot, Wash out time (s)	Time for temperature to return to baseline after bolus injection	Novel
Wor, Wash out ratio (s)	Wot_Rest/Wot_Hyp	Novel
Tau, Diastolic Relaxation constant (s)	Time for distal pressure to fall from point of dP/dt_Min to a preset point. Three modes:	Ταυ 1
	1/2 Time from P[dP/dt_min] to P[dP/dt_min]/2	Adapted.
	1/e Time from P[dP/dt_min] to P[dP/dt_min]/e	
	Diastolic/e Time from P[dP/dt_min] to [P[dP/dt_min]-P[Diastole]]/e	
dP/dt Max/Min	Max/Min dP/dt, with averaging	

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#### FFR, Fractional Flow Reserve

1. Measurement of Fractional Flow Reserve to Assess the Functional Severity of Coronary-Artery Stenoses, Nico H.J. Pijls et al, N Engl J Med 1996; 334:1703-1708 June 27, 1996DOI: 10.1056/NEJM199606273342604

#### Absolute Flow, Resistance and local hypothermia

- 1. Direct volumetric blood flow measurement in coronary arteries by thermodilution. Aarnoudse W et al. J Am Coll Cardiol. 2007 Dec 11;50(24):2294-304. PubMed PMID: 18068038.
- 2. Continuous infusion thermodilution for assessment of coronary flow: theoretical background and in vitro validation. van't Veer M et al. Med Eng Phys. 2009 Jul;31(6):688-94. doi: 10.1016/j.medengphy.2009.01.006. PubMed PMID: 19237308.
- 3. Absolute coronary blood flow measurement and microvascular resistance in ST-elevation myocardial infarction in the acute and subacute phase. Wijnbergen I et al. Cardiovasc Revasc Med. 2016 Mar;17(2):81-7. doi: 10.1016/j.carrev.2015.12.013. PubMed PMID: 26905054.
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- 2. Coronary Thermodilution to Assess Flow Reserve. Validation in Humans. Nico H.J. Pijls et al. Circulation. 2002;105:2482-2486 Originally published May 6, 2002
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- 5. Pressure-derived measurement of coronary flow reserve. MacCarthy et al. J Am Coll Cardiol. 2005 Jan 18;45(2):216-20.

### IMR, BRI, RRR, Indices of Microcirculatory Resistance

- 1. Novel index for invasively assessing the coronary microcirculation. Fearon et al. Circulation. 2003;107:3129-3132. Originally published July 1, 2003
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- 9. Review: Invasive Coronary Microcirculation Assessment, Current Status of Index of Microcirculatory Resistance. Yuhei Kobayashi et al. Circ J 2014; 78:1021 1028
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- 11. Vasodilatory capacity of the coronary microcirculation is preserved in selected patients with NSTEMI. Layland et al Circ Cardiovasc Interv. 2013 Jun;6(3):231-6.



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### PB-CFR, Pressure-Bounded CFR

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- 3. Coronary Artery disease: physiology and prognosis. Colin Berry et al. European Heart Journal (2017) 0, 1–3

#### Tau, Diastolic Relaxation constant

1. Assessment of diastolic function: suggested methods and future considerations. | Mirsky, Circulation. 1984;69:836-841, doi: 10.1161/01.CIR.69.4.836



# SYSTEM COMPONENTS



CoroFlow Workstation Software License One for each cathlab



CoroHub Receiver & Gyro Air Remote control One for each cathlab

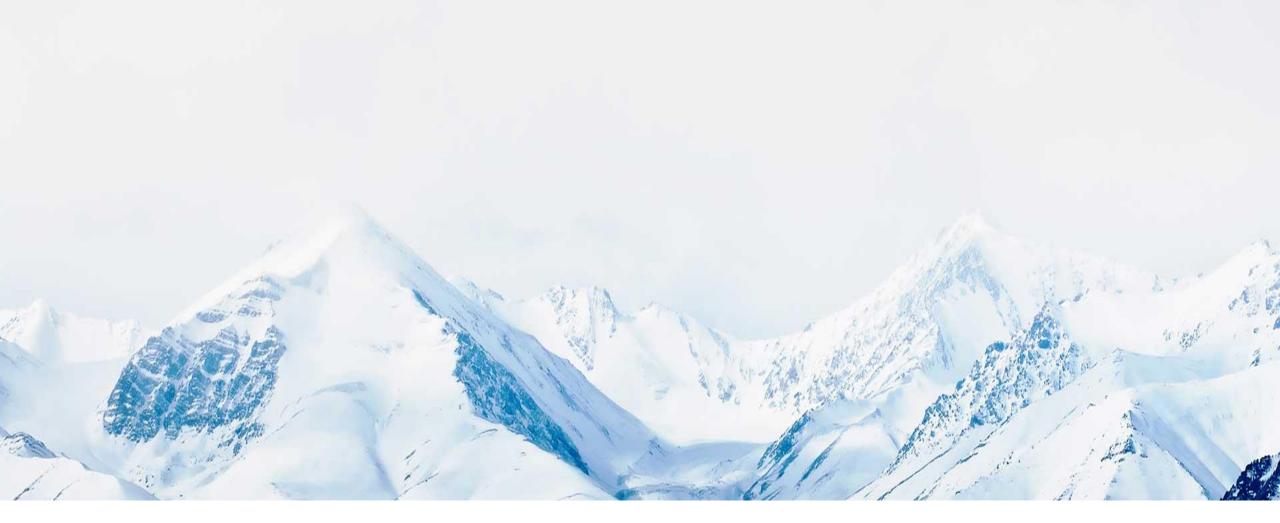


CoroFlow Review App License Unlimited number of installs



Workstation PC One for each cathlab. Existing hospital provided PC can be used or optionally provided by Coroventis





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**Class 1 Medical Device**