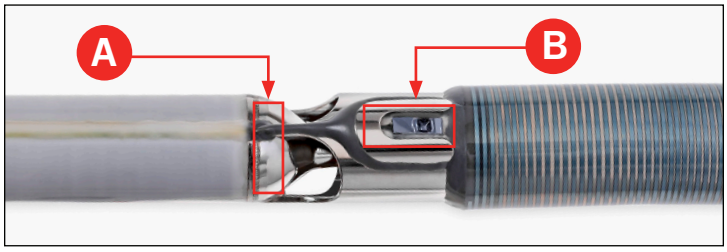
Optimized Device Performance Guidance

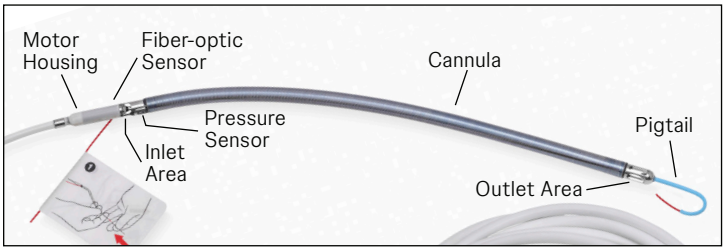
Understanding Impella RP Flex™ with SmartAssist™ Sensor Location and Impact on Metrics

Impella RP Flex with SmartAssist pump sensor location and explanations are detailed below and the information can also be found in the product IFU*.



(A) The **fiber-optic sensor** is located at the proximal end of the inlet area. This sensor is used as an input to the pulmonary artery placement signal and the central venous placement signal during catheter operation.

(B) The **differential pressure (dP) sensor** measures the pressure difference between the inside and outside of the cannula. The pressure value is used for calculating displayed flow and as an input to the pulmonary artery placement signal and the central venous placement signal during catheter operation. The differential pressure sensor is a flexible membrane integrated into the cannula. One side of the sensor is exposed to the blood pressure on the outside of the inlet area and the other side is exposed to the pressure of the blood on the inside of the cannula. The sensor generates an electrical signal proportional to the difference between the pressure outside the inlet area and the pressure inside the cannula.



NOTE: *Avoid manual compression of the inlet, outlet, or sensor areas of the cannula assembly.*

Sensor measurements may be impacted by malfunction or by physical contact with the sensor and therefore contact should be avoided; this includes manual compression during implant, contact with concomitant lines or devices, contact with patient anatomy, or thrombus in the inlet.

**Sensor location and explanation located on page 3.4 of product IFU. Placement Screen Display explanation located on page 4.8 of product IFU.*

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert and/or Impella RP Flex with SmartAssist IFU 10003286. April 2026.

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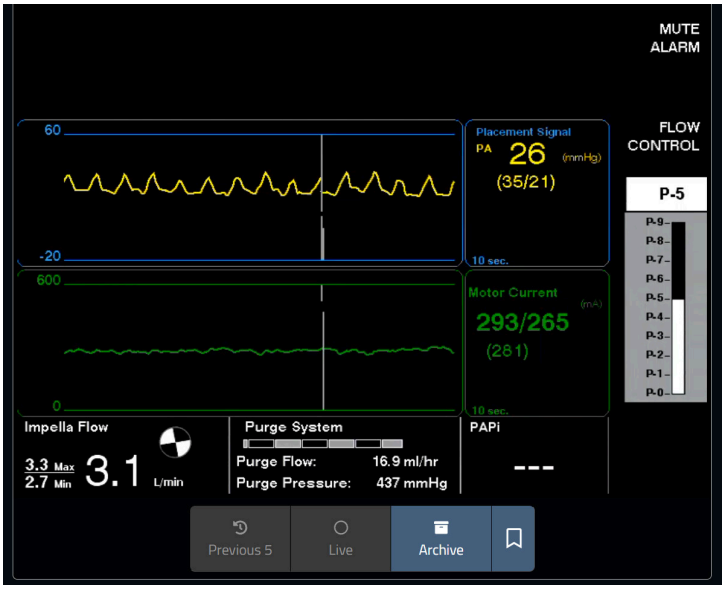
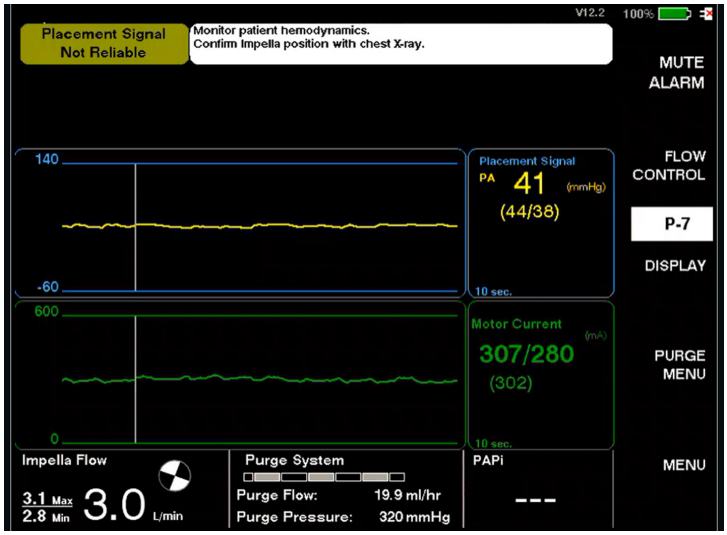
Pulmonary Artery Placement Signal Waveform (Non-diagnostic information for the user) Signal derived from optical and differential pressure sensors.

Motor Current (Ensures pump function) Energy intake of the pump varying with motor speed and pressure difference. Motor current is NOT used in the calculation for Impella flow.

AIC Impella Flow (Non-diagnostic information for the user) The differential pressure sensor is used to calculate Impella flow.



If there is a problem with the Impella Catheter sensor signal, the following **Placement Signal Not Reliable** banners may appear.



Optical Sensor Affected

- Placement Signal Not Reliable banner issued
- Calculated flow text still available
- The circular catheter operation icon rotates when the pump is running

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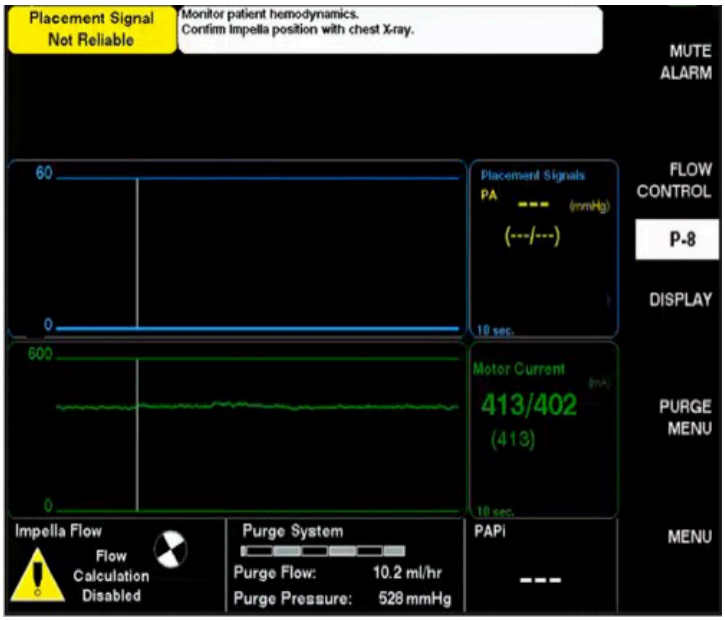
DP Sensor Affected

- Placement Signal Not Reliable banner issued
- PA placement signal and impella flow rate are disabled
- Because the displayed flows are derived from the differential pressure sensor not the motor current, flows will no longer be displayed

While AIC metrics are not displayed, pump function is not necessarily impacted (see Motor Current), the circular catheter operation icon rotates when the pump is running.

NOTE: *The pump metrics are for informational purposes only. Do not use for diagnostic purposes or patient monitoring. Independently verify all parameters are displayed with a cleared or approved diagnostic device.*



Differential Pressure Sensor and Effects on Flow Calculation

The differential pressure sensor is used to calculate Impella flow. Sensor signal may drift and become inaccurate due to sensor malfunction. Sensor accuracy can also be impacted by physical contact with the sensor and therefore contact should be avoided; this includes handling during insertion, presence of thrombus in the inlet, contact with concomitant lines or devices, or contact with patient anatomy.

Table 5.4 P-Level Flow Rates should be relied on over the AIC displayed flow. However, displayed Impella flow and pump metrics should still be monitored and trended for monitoring pump performance and identifying sudden changes. An abrupt change in flow or abrupt discrepancy from the IFU may indicate a need to reassess pump positioning and performance, patient conditions, and clinical hemodynamics. Monitor patient hemodynamics using cleared or approved diagnostic devices, and monitor Impella positioning with imaging. Monitor the motor current waveform and the circular catheter operation icon to monitor pump function. The circular catheter operation icon rotates when the Impella RP Flex with SmartAssist System Catheter is running.

When the differential pressure sensor signal exceeds the operating range for the sensor, a Placement Signal Not Reliable alarm will occur, the controller will no longer calculate the PA Placement Signal, the Central Venous Placement Signal, or the Impella flow rate, and the controller will display a yellow triangular caution icon with the message “Flow Calculation Disabled.” When this occurs, refer to Table 5.4 P-Level Flow Rates, and monitor the motor current waveform and the circular catheter operation icon to monitor pump function. Continue to monitor patient hemodynamics using cleared or approved diagnostic devices and continue to monitor Impella positioning with imaging.

NOTE: *Placement Signal Not Reliable alarm may not occur in all instances of sensor drift*

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IFU flow table should be relied on over the AIC displayed flow. However, displayed Impella flow and pump metrics should still be monitored and trended for monitoring pump performance and identifying sudden changes. An abrupt change in flow or abrupt discrepancy from the IFU may indicate a need to reassess pump positioning and performance, patient conditions, and clinical hemodynamics.

Flow rate is increased approximately 10% with every additional performance level, but depends on preload and afterload and can vary due to suction or incorrect positioning. Flow rate may be reduced if thrombus is present in the inlet of the Impella catheter.

Displayed Impella flow is the calculated flow rate based on current performance level and the pressure signals measured from the differential pressure sensor. Select the lowest performance level that will enable you to achieve flow rate necessary for patient support.

Table 5.4 P-Level Flow Rates

P-Level	*Flow Rate (L/min)
P-0	0.0
P-1	0.0-0.9
P-2	0.0-1.3
P-3	0.0-1.8
P-4	0.7-2.3
P-5	1.3-2.6
P-6	2.0-3.0
P-7	2.7-3.4
P-8	3.2-3.7
P-9	3.7-4.2

*Flow rate depends on preload and afterload and can vary due to suction or incorrect positioning.

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