

WARNING

Before using EXCOR® Pediatric VAD with Stationary Driving Unit Ikus, read the Instructions for Use carefully.

Changes in the startup procedure

In distinction to former software versions, in the new software version 3.41 the pump size and the cannulae size has to be chosen. The new menu is shown in Figure 1 below.

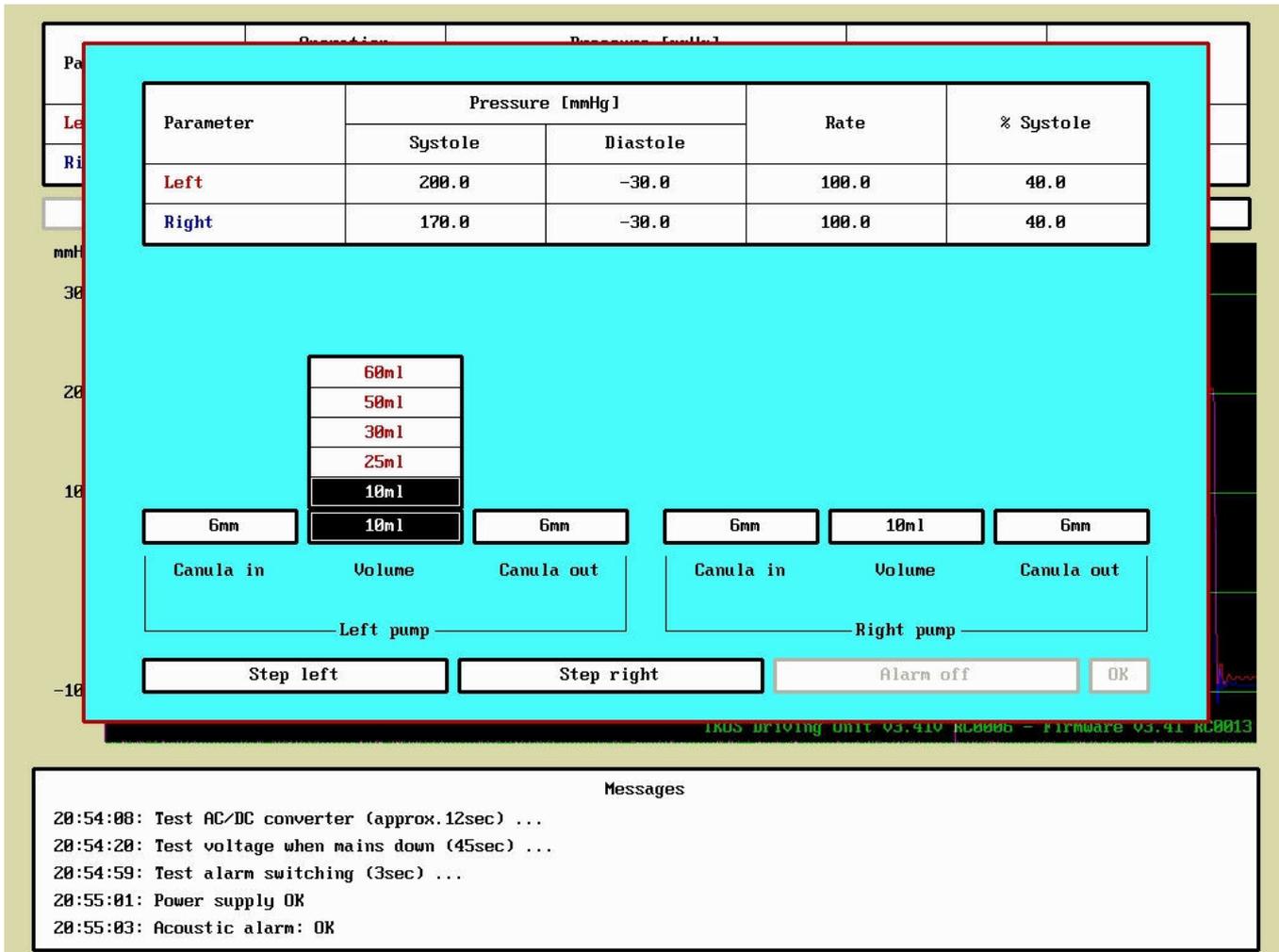


Figure 1: Pump size and single step mode

ADVICE

Follow the numbered instructions exactly in their sequential order.

INSTRUCTION

1. Choose first the size of the **right blood pump**.
2. Choose the size of the **left blood pump**.
3. Choose the size of the **inflow cannula** of the **left pump**.
4. Choose the size of the **outflow cannula** of the **left pump**.
5. Choose the size of the **inflow cannula** of the **right pump**.
6. Choose the size of the **outflow cannula** of the **right pump**.

If after the selecting the blood pump and cannula size all digits of the chosen values are displayed in black, the pump-cannula combination recommended by Berlin Heart has been selected. In case one or more values are displayed in red the pump-cannula combination is not the most favorable option for each individual case. Check whether a blood pump combination that is not recommended has been selected for the patient. The final decision on the combination of blood pumps and cannulas is to be reached by the implanting surgeon, in consultation with Berlin Heart, Inc. Clinical Affair.

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Changes in the operating mode

In distinction to former software versions, in the new software version 3.41 it is possible, that the values of rate and %systole shown in the parameter table change from black to red during operation (see figure 2).

Parameter	Operation	Pressure [mmHg]		Rate	% Systole
	Normal	Systole	Diastole		
Left	L	200.0	-30.0	100.0	60.0
Right	R	170.0	-30.0	100.0	40.0

Figure 2: Rate and %systole are displayed in red

Red marked values displayed on the laptop: The parameter combinations (pump rate, % systole, systolic and diastolic pressure) selected for the pump-cannula combination selected can lead to incomplete filling and emptying of the blood pump(s).

Observe the filling behavior of the blood pump(s)!

In biventricular mode: The lower value of both pump rates (corresponding to the pump sizes used) must also be considered. The higher of the 2 pump rates should be disregarded.

The upper threshold for the pump rate, for recommended blood pump cannula combinations is displayed in table 1.

Cannulation		Blood pump					
∅ Inflow cannula	∅ Outflow cannula	10 ml	25 ml	30 ml	50 ml	60 ml	80 ml
5 mm	5 mm	130 bpm					
6 mm	5 mm	130 bpm					
6 mm	6 mm	130 bpm	80 bpm	65 bpm			
9 mm	6 mm		100 bpm	90 bpm			
9 mm	9 mm		130 bpm	130 bpm	130 bpm	105 bpm	80 bpm
12 mm	9 mm				130 bpm	105 bpm	80 bpm
12 mm	12 mm				130 bpm	125 bpm	95 bpm
16 mm	12 mm						100 bpm

Table 1: Pump-cannula combinations

Relative systolic duration: The relative systolic duration is adjustable in the range of 20% to 70%. The upper and lower threshold (20-30% and 60-70%) are marked in red on the laptop. With values above and below these thresholds, it cannot be guaranteed that the activated pressure parameters are achievable for each single case.

The final decision on the combination of blood pumps and cannulas is to be reached by the implanting surgeon, in consultation with Berlin Heart, Inc Clinical Affairs