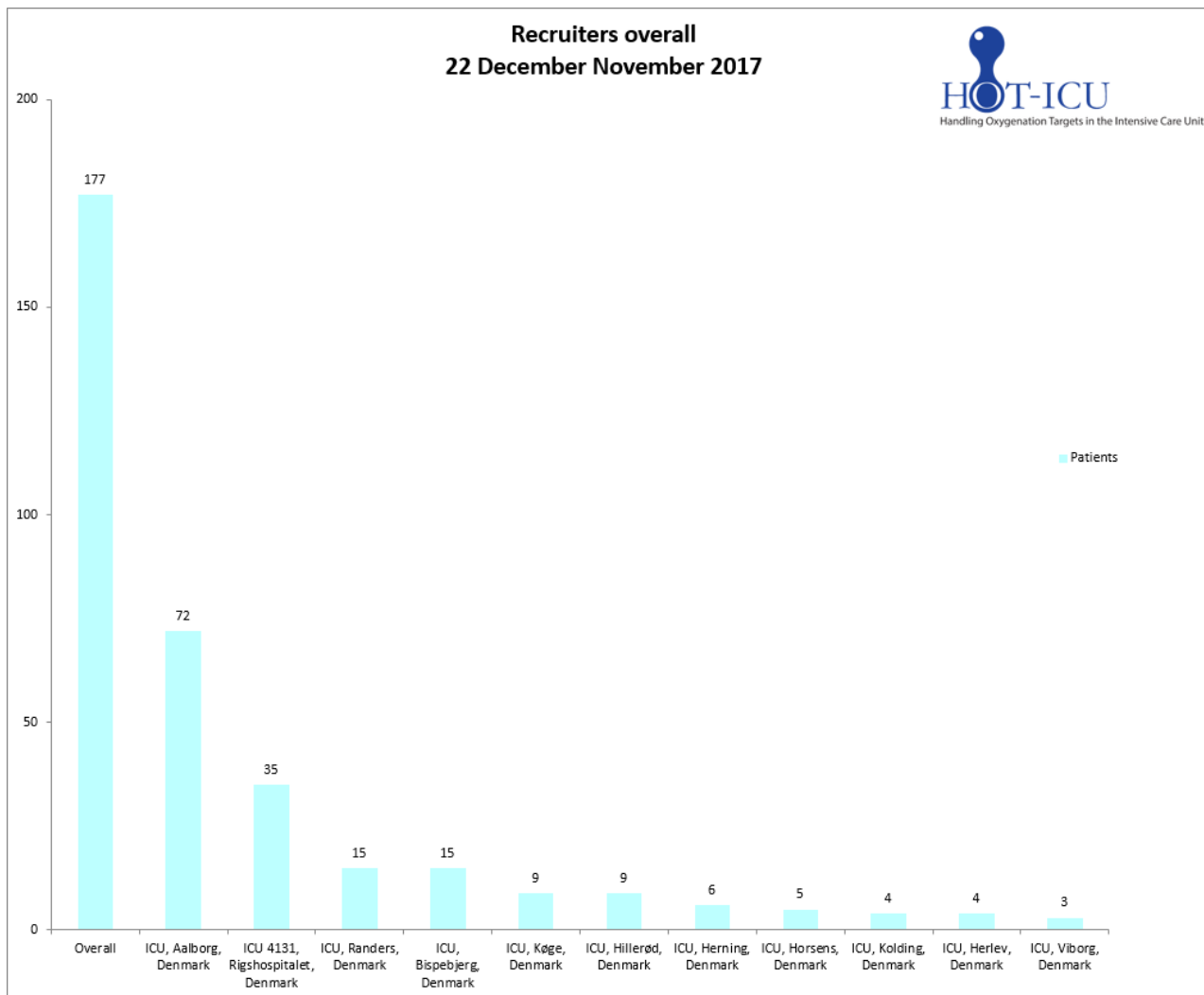




## Place in Site Master File #13f

### HOT-ICU newsletter – December 2017

Thank you very much for your great engagement in the HOT-ICU trial.



#### Status

During the last month, the ICUs at Herning, Viborg and Horsens has successfully joined the HOT-ICU trial. Welcome to you all.

We are actively recruiting at eleven sites now and have randomised 177 patients in total. Our first non-Danish site in Basel, Switzerland is ready to start and the first randomisation is expected any time. Two additional Danish sites and the first sites in Norway and in the Netherlands are expected to start inclusion in January.

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**A few things to highlight:**

1. Regarding registration of PaO<sub>2</sub> values in the eCRF: If two arterial blood gas analyses with identical **highest** PaO<sub>2</sub> measurements exist within the same 12-hour interval, then the **highest** FiO<sub>2</sub> of the two shall be registered. Similarly, If two arterial blood gas analyses with identical **lowest** PaO<sub>2</sub> measurements exist within the same 12-hour interval use the **lowest** FiO<sub>2</sub> of the two.
2. We are experiencing a significant amount of protocol violations. Please ensure that the specific notifications of any “major protocol violations” are handled to secure adherence to the protocol and to limit future protocol violation at your site.

If you have any questions, do not hesitate to send an e-mail to [hot-icu@cric.nu](mailto:hot-icu@cric.nu) or to contact the HOT-ICU hotline (+45 2118 2543). Please **leave a message and your phone number if the call is not answered** and we will call you back as soon as possible.

Please archive this newsletter in your site master file.

The next newsletter will be due January 2018.

**We wish you all a merry Christmas and a happy New Year**

**Our highest wish for 2018 is high inclusion rates at every site**

**Bodil and Olav**