

INTELLiVENT^{ASV}

Intelligent Ventilation

Reduce
complexity –
more time and
safety for your
patient



Fully closed-loop ventilation solution

**HAMILTON[®]
MEDICAL**

Efficiency through innovation

Reduce complexity – more time and safety for your patient

As the world population is growing and people are getting older and sicker, the number of ventilated patients in ICUs is increasing¹. The estimated cost for intensive care and mechanical ventilation is expected to increase from 16 billion in 2003 to 60 billion by 2020². The clinical impact will be significant: an increased number of older patients will lead to a greater workload, while ICUs will be facing a lack of specialist staff³.

INTELLiVENT®-ASV is the solution

HAMILTON MEDICAL's INTELLiVENT®-ASV is the world's first complete closed-loop ventilation solution that offers automated adjustment of oxygenation and ventilation. Today, conventional mechanical ventilation still requires a lot of expertise and manual adjustment of ventilator settings. This can be challenging and stressful as a respiratory expert can't be at the bedside all the time. INTELLiVENT®-ASV guides you when making complex decisions, even if there is no respiratory expert available. What makes INTELLiVENT®-ASV revolutionary is that it does more than just give recommendations: it also adjusts ventilation settings automatically.

INTELLiVENT®-ASV automatically applies comprehensive lung-protective strategies, reduces the risk of operator errors and encourages early weaning. It continuously adapts to patient conditions and reacts in case of sudden changes. A unique Ventilation Cockpit gives you evidence-based guidance in complex decision-making and visualizes complex information in an intuitive way. INTELLiVENT®-ASV provides transparency of what the device is doing by using standardized therapy concepts: ARDSnet, OpenLung concept and permissive hypercapnia.

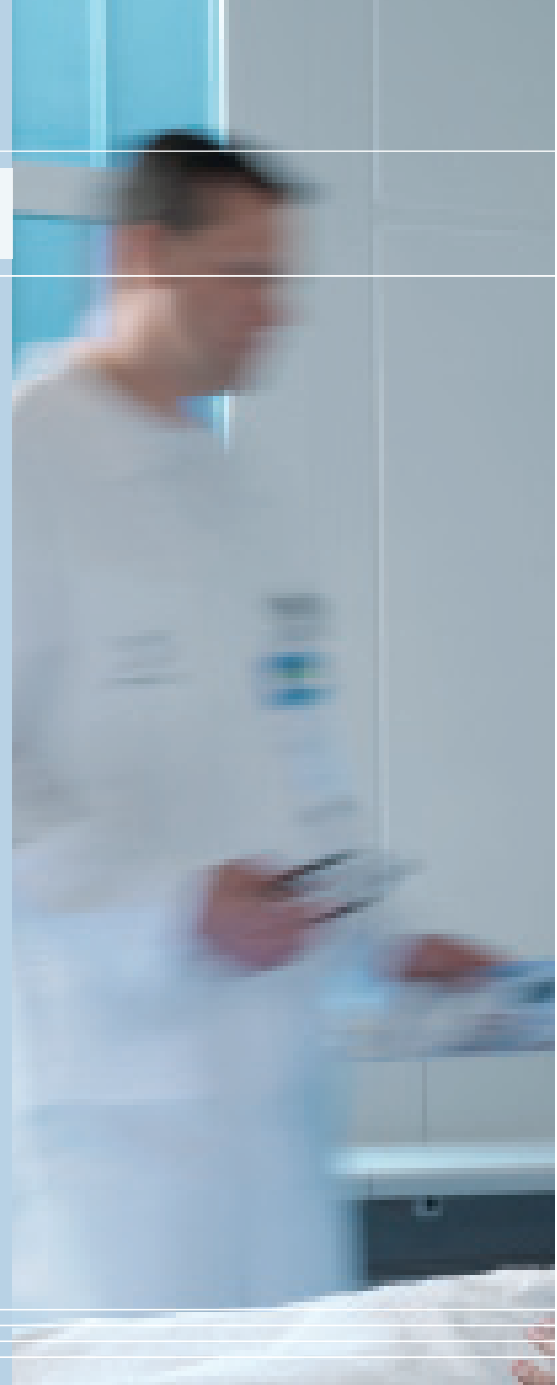
You can trust proven technology

INTELLiVENT®-ASV is based on ASV® technology from HAMILTON MEDICAL. ASV® (Adaptive Support Ventilation) provides major improvements compared to conventional ventilation modes. ASV® was the first step on the way to INTELLiVENT®-ASV, the world's first fully closed-loop solution.

¹ U.S. Census Bureau, Systems Support Division, Last Revised: July 14, 2009

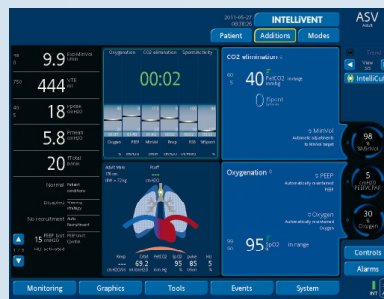
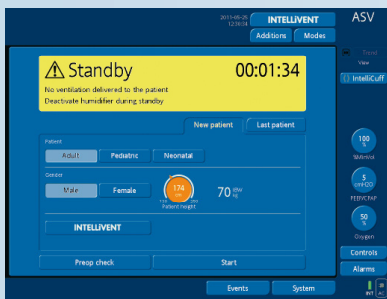
² Zilberberg M et al. BMC Health Services Research 2008;8:242

³ Prospects: The 2008 Revision. Committee on Quality of Healthcare in America. To Err is Human. Institute of Medicine, 1999. Angus D. JAMA 2000, Martin GS. CCM 2006, Poncet MC. AJRCCM 2007, Embriaco N. AJRCCM2007



Easy to use

Before you start INTELLiVENT®-ASV, you set your patient's height and gender. An initial classification of the patient's condition helps to achieve faster adaptation, but is not mandatory. Then, just press "Start".



INTELlVENT®-ASV:

- Based on proven technology (SpO₂ and etCO₂)
- In accordance with clinical standards
- Uses well-accepted protocols (eg. ARDSnet)
- Offers manual and automatic flexibility

Ease of use

Understand all important information at a glance

INTELLiVENT®-ASV reduces complexity by graphically displaying the patient's status, current treatment decisions made by the algorithms, and the required support in a single window. It provides transparency by implementing and supporting protocolized care so you can always be sure that INTELLiVENT®-ASV is making the right decision.

You need only three controllers

With INTELLiVENT®-ASV's automation capabilities, ventilation and oxygenation of the patient are controlled by automatically setting of Minute Ventilation, PEEP and FiO₂. A set of complex algorithms work together to enable INTELLiVENT®-ASV to completely close the loop on mechanical ventilation covering all phases of ventilation from intubation to extubation.

You are always in the driver's seat

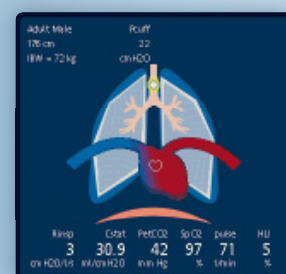
INTELLiVENT®-ASV lets you override the settings or switch individual settings back to manual mode at any time, managed by the clinical operator. The INTELLiVENT window allows a variety of adjustments to the behavior of the automatic ventilation, optimizing ventilation for a wide range of patients in different clinical situations.



Control of %MinVol, PEEP, and Oxygen can each be set to manual or automatic control according to the clinicians preference 1. Different patient conditions 2 allow tailoring the automatic control behavior to different clinical situations. Quick weaning 3 is used to ventilate patients ready to be weaned from the ventilator. An automatic recruitment maneuver 4 can be performed on patients to improve oxygenation. An upper PEEP limit 5 can be set for safety. Heart Lung Interaction Index 6 can be used to limit automatic PEEP setting. Target range for etCO₂ 7 or SpO₂ 8 can be shifted if clinical conditions require this.

HLI Panel and Dynamic lung

INTELLiVENT®-ASV provides a unique, intuitive and efficient way to monitor the patient's Heart-Lung Interaction, lung compliance and resistance, tidal volume, cuff pressure and patient activity.



How the controllers work

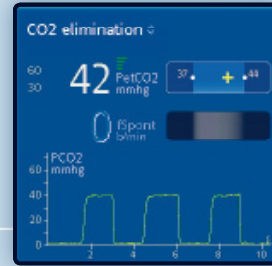


Manual mode is indicated by a solid blue circle. In manual mode, the operator manages the ventilation manually.



Ventilation Cockpit

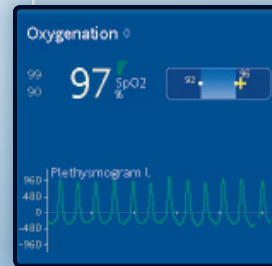
The configurable Ventilation Cockpit is designed to guide you when making decisions by visualizing complex information in an intuitive way and allows you to configure your patient's monitored data the way you want. Choose any setting for manual or automatic ventilation, select from various layouts to display a combination of Intelligent Panels in the Ventilation Cockpit, including Dynamic Heart-Lung Interaction (HLI), Vent Status, and INTELLiVENT®-ASV target graphics, plus traditional waveforms.



Ventilation Horizon
 Gives detailed information about the ventilation status and CO₂ elimination. The Horizon displays the physiological input (CO₂) versus the treatment target in automatic mode.

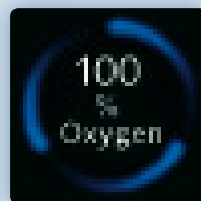


Three control parameters
 Automatic controllers are available for %MinVol, PEEP and Oxygenation. With INTELLiVENT®-ASV, you can choose between manual and automatic adjustment. Automatic mode is indicated by a pulsing circle. At any time, you can override the settings or switch individual settings back to manual.

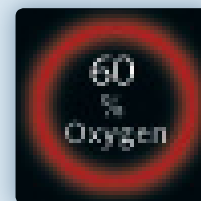


The Oxygenation Horizon
 Is very similar to the ventilation horizon: it provides detailed information about the oxygenation status based on the major physiological input (SpO₂) and displays the assessment of signal quality for SpO₂.

Automatic mode is indicated by a pulsing circle. In automatic mode, a circle rotating clockwise indicates that INTELLiVENT®-ASV is managing the patient and is increasing the treatment.



A circle rotating counterclockwise indicates that INTELLiVENT®-ASV is decreasing the treatment. Treatment changes are indicated by faster rotation of the circle.



A solid red circle indicates that no sensor value is present and no automatic management takes place.

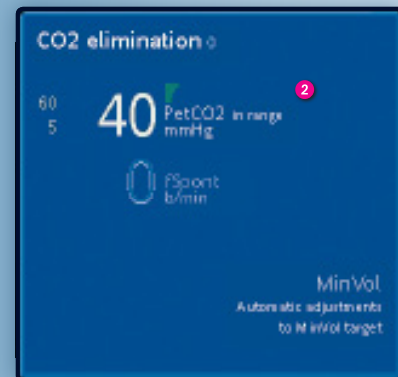
Ventilation with INTELLiVENT®-ASV

How does INTELLiVENT®-ASV determine ventilation settings?

Ventilation therapy is controlled mainly by lung status, etCO₂ value and spontaneous breathing rate. Breath-by-breath etCO₂ and spontaneous efforts are measured to adjust minute ventilation. The INTELLiVENT®-ASV algorithms then determine the tidal volume and rate according to the lung physiology.

In the **Ventilation Horizon**, you can see the current etCO₂ level, the capnogram, the target range for etCO₂, and, in case of a spontaneously breathing patient, the target range for the spontaneous breathing rate. The **Ventilation Map** and the **Ventilation Guide** displays more detailed information on the automatic management of the ventilation and gives access to the **Trend function**, reviewing the automatic management of %MinVol performed previously for the last 1, 3, 12, 24 or 96 hours.

During passive ventilation, INTELLiVENT®-ASV keeps etCO₂ in an appropriate range via adaptation of minute ventilation by automatically setting %MinVol. In active patients INTELLiVENT®-ASV adjusts %MinVol automatically to keep the patients breathing rate in an acceptable range. INTELLiVENT®-ASV detects the patients condition automatically and switches smoothly from passive to spontaneous ventilation mode.



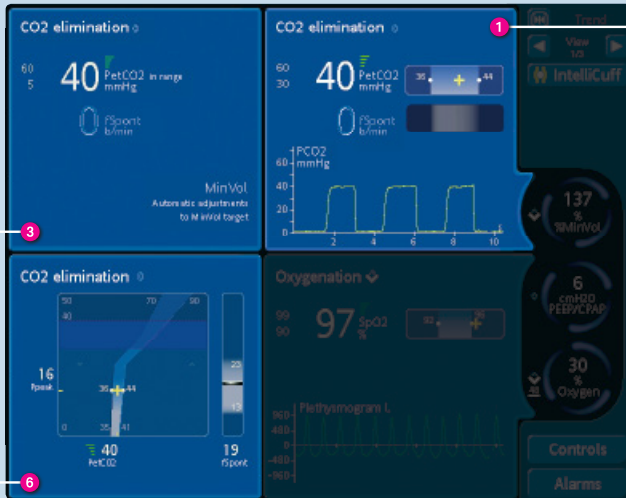
The Ventilation Guide



The Ventilation Map

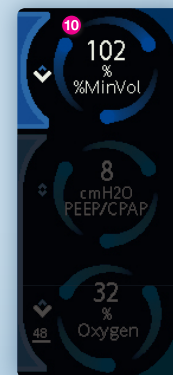
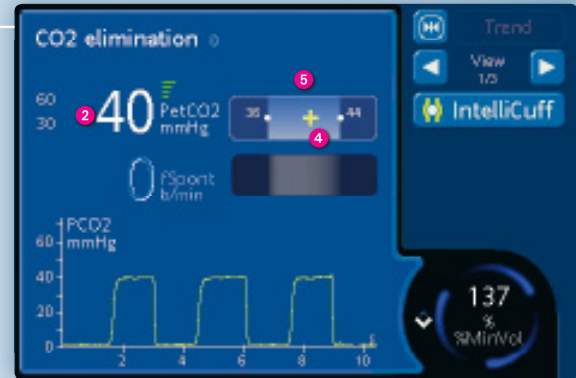
¹ Hickling Respir Care Clin N Am 2002 Jun;8(2) Review

² Hickling et al. Int Care Med 1990; 16: 372



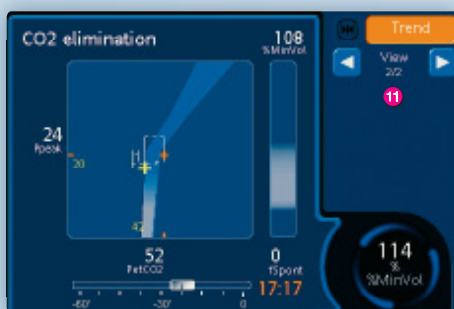
Ventilation Horizon, Map and Guide

The Ventilation Horizon 1 displays the physiologic input. It shows the current etCO₂ level 2. The user is notified if the etCO₂ value is within the acceptable range using text in the Ventilation Guide 3 and the yellow cross in the Ventilation Horizon 4. The acceptable 5 range is broader in cases where a patient's condition is more severe and higher pressures are needed, in order to avoid unsafe pressures. This concept of tolerating higher arterial and endtidal CO₂ in patients needing more aggressive treatment is described in the literature^{1,2} as 'Permissive Hypercapnia'. The Ventilation Map 6 displays more detailed information on the automatic management of the ventilation. The reliability indicator for PetCO₂ 7 gives the user a quick visual status about the signal quality of the input data. In an active patient, the current breathing rate per minute (fSpont) and the target range are visualized in the Spont status graph 8.



Ventilation Horizon: how INTELLiVENT[®]-ASV adjusts %MinVol

If PetCO₂ 2 is too low, INTELLiVENT[®]-ASV will automatically decrease %MinVol 9. If PetCO₂ is too high, %MinVol will be increased 10.



Improve patient assessment with the Trend function 11

INTELLiVENT[®]-ASV protocolizes therapy, so you always know what changes have occurred for the patient and ventilator settings. Just refer to the trend function to the current status of your patient, their developments in the last 24 hours, and whether they are currently on track.

Oxygenation with INTELLiVENT®-ASV

INTELLiVENT®-ASV's oxygenation therapy follows state-of-the-art clinical evidence.

Oxygenation therapy is controlled mainly by lung status and pulse oximetry, FiO_2 and PEEP are adjusted automatically to keep the SpO_2 within an acceptable range.

For increasing oxygen therapy, INTELLiVENT®-ASV follows the well established ARDSnet protocol as well as an estimated hemodynamic stability HLI-index to titrate PEEP in relation to inspiratory oxygen concentration. When applying decreasing therapy, the Open Lung Protocol principles are employed and FiO_2 is decreased first while PEEP is reduced later, thus keeping the lung open.

Severe septic ARDS patients often require high PEEP values and are often hemodynamically unstable. Increased pressures and volumes can further deteriorate their circulation. INTELLiVENT®-ASV limits the maximum applied PEEP level to coincide with the hemodynamic status of the patient based on the HLI index. The HLI index is the Heart-Lung Interaction calculated by an automated analysis of the pulse oximetry waveforms and the well-known pulse pressure variations. This index is used to determine if the patient's circulation can withstand higher ventilation pressures.¹⁻⁴

Controlling Ventilation and Oxygenation using non-invasive sensors

INTELLiVENT®-ASV relies on noninvasive sensors for SpO_2 using pulse oximetry and CO_2 concentration in the exhaled air for endtidal CO_2 ($etCO_2$).

INTELLiVENT®-ASV uses proprietary algorithms to analyse signals from multiple pulse oximetry sensors as well as the main stream capnometer to produce filtered artifact-free SpO_2 and $etCO_2$ values respectively. These values are robust enough to adjust Oxygen and PEEP and also give you an $etCO_2$ value close to $PaCO_2$. A newly developed reliability indicator for SpO_2 provides a quick visual status about the signal quality so the user can verify that INTELLiVENT®-ASV is getting the best input data.

¹ Feissel et al. Int Care Med 2007;33:993

² Demory et al. Int Care Med 2010;36 Supl 2: S337, 1002

³ Novotni et al. Int Care Med 2010;36 Supl 2: S350, 1054

⁴ Novotni et al. Int Care Med 2010;36 Supl 2: S351, 1057



The Oxygenation Guide



The Oxygenation Map

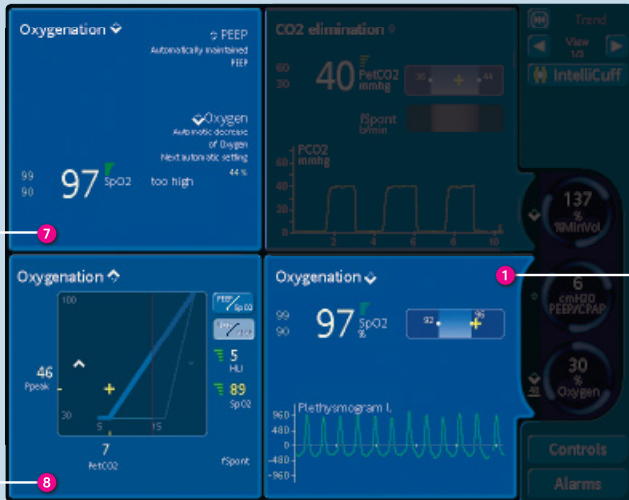
Noninvasive sensors
INTELLiVENT®-ASV relies on non-invasive sensors for SpO_2 using pulse oximetry and end-tidal CO_2 ($etCO_2$) for CO_2 .



Pulse oximetry



Capnography



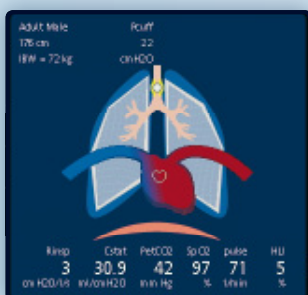
The Horizon, Map and Guide for Oxygenation/PEEP

The Oxygenation Horizon 1 structure is very similar to the ventilation horizon. The input SpO_2 2 is displayed together with the acceptable range 3 which is targeted by the oxygenation controller. Below the plethysmogram waveform produced by the pulse oximeter is displayed 4. In this example oxygenation is above the target range, causing the Oxygen concentration to be decreased as indicated by the text 5 and the white arrow pointing downward 6 in the Oxygenation guide window 7. The Oxygenation map 8 displays more detailed information on the automatic management of the oxygenation using two different maps displaying the PEEP/Oxygen correlation based on ARDSnet used by INTELLiVENT-ASV's algorithm 9 and the SpO_2 target range dependency on PEEP. In both maps the current values for PEEP and Oxygen respectively PEEP and SpO_2 are displayed.



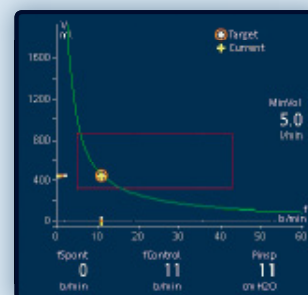
How INTELLiVENT[®]-ASV adjusts FiO_2

In case the SpO_2 10 is too low: INTELLiVENT[®]-ASV will automatically increase FiO_2 and/or PEEP 11. If SpO_2 is too high, FiO_2 and/or PEEP will be reduced.



The HLI Index

The Heart-Lung Interaction index is used to determine if the patient's cardiovascular system can withstand higher ventilation pressures.



Understanding changes in the patient and how INTELLiVENT[®]-ASV reacts

The INTELLiVENT[®]-ASV target graphics screen shows how the adaptive lung controller moves towards its targets. It shows both the target and actual parameters for tidal volume, frequency, pressure, and minute ventilation.

Improved patient outcome and safety

INTELLiVENT®-ASV can help reduce the burden of routine tasks in mechanical ventilation and reduce false positive alarms, giving you more time and providing increased safety for your patients. And most importantly, it has the potential to reduce the patient's time on the ventilator up to 50%.¹

Increased safety of operation with INTELLiVENT®-ASV

With the Ventilation Cockpit panel, you get an intuitive visualization of the most important parameters and settings related to patient-ventilator dependency.

Guidance in complex decision making

INTELLiVENT®-ASV provides 24/7 optimized ventilation to the patient. No matter how many ventilated patients or respiratory specialists your hospital may have, INTELLiVENT®-ASV ensures optimized protocolized care at all times.

Provide patient-centered care with fewer resources

Unlike conventional modes, which require you to set many parameters manually, INTELLiVENT®-ASV removes the need for routine adjustments by responding to the patient's needs at all times.

Studies show that INTELLiVENT®-ASV

- ventilates virtually all intubated patients – whether active or passive, and regardless of their lung disease¹
- requires less user interaction, adapts to the patient's breathing activity more frequently, and causes fewer alarms²
- works with an accuracy comparable to experienced clinicians³
- adapts to changes in the patient's lung mechanics over time⁴
- increases time of ventilation in the optimal zone significantly without any manual intervention compared to conventional ventilation⁵

¹ Arnal JM et al. Int Care Med 2004;30:84.

² Petter AH et al. Anesth Analg 2003;97:1743-50.

³ Iotti GA et al. Int. Care Med 2010; 36:1371-9

⁴ Arnal JM et al. Int Care Med 2006;32: 120.

⁵ Arnal JM et al., Am. J. Respir. Crit. Care Med., May 2010; 181: A3004.

⁶ Lellouche F et al., Am. J. Respir. Crit. Care Med. 2010;181:A6035.

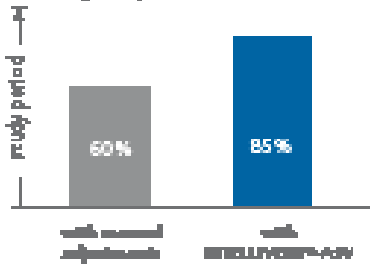


Optimal ventilation with INTELLiVENT®-ASV

In a clinical study, patients with changing lung conditions spend more time within optimal ventilation conditions using automatic INTELLiVENT®-ASV than patients in the manually controlled group with conventional ventilation⁵.



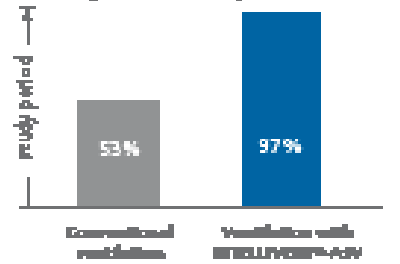
Percentage of optimal ventilation



Safer ventilation with INTELLiVENT®-ASV

Another study with INTELLiVENT®-ASV provided more stable ventilation within an optimal range with fewer user interactions. It was concluded that INTELLiVENT®-ASV can be safer than conventional ventilation⁶.

Percentage of rescue and optimal ventilation



For further information about INTELLiVENT®-ASV,
please contact:

INTELLiVENT 

HAMILTON MEDICAL AG
Via Crusch 8
CH-7402 Bonaduz
Switzerland

 (+41) 81 660 60 10
 (+41) 81 660 60 20

www.hamilton-medical.com



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