



PLIEGO DE PRESCRIPCIONES TÉCNICAS QUE HA DE REGIR EN LA CONTRATACIÓN DEL SUMINISTRO, IMPLANTACIÓN Y PUESTA EN MARCHA DE UN SISTEMA INTEGRAL DE INFORMACIÓN CLÍNICA Y TELEMONITORIZACIÓN DE ALTA DENSIDAD DE DATOS PARA INVESTIGACIÓN CLÍNICA PEDIÁTRICA DESTINADO A LA NUEVA UNIDAD PARA EL AVANCE DE LA INVESTIGACIÓN CLÍNICA EN NIÑOS Y ADOLESCENTES DE LA FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS, A ADJUDICAR POR PROCEDIMIENTO ABIERTO CON PLURALIDAD DE CRITERIOS PARA EL PROYECTO UICC24/00044, FINANCIADO POR EL PLAN DE RECUPERACIÓN, TRANSFORMACIÓN Y RESILIENCIA – FONDOS NEXT GENERATION EU*.

EXPEDIENTE 009/22026

Las prescripciones técnicas previstas en el presente pliego tienen por objeto definir las características funcionales y técnicas mínimas que deberá cumplir la solución ofertada. Tendrán carácter obligatorio aquellos requisitos que se identifiquen expresamente como mínimos o esenciales. Las referencias a prestaciones, capacidades o funcionalidades adicionales deberán interpretarse conforme a lo previsto, en su caso, en los criterios de adjudicación del PCAP, sin que puedan entenderse como exigencias mínimas salvo indicación expresa en contrario.

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1. ANTECEDENTES

La FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS (FIBHNJS) es una entidad que tiene como finalidad la gestión de programas y proyectos de investigación clínica y otras actividades conexas en el campo de la biomedicina. Entre sus fines se encuentra la promoción y coordinación de programas de investigación científica aplicada a la Biomedicina y a las Ciencias de la Salud, actividades que se realizan en el Hospital Infantil Universitario Niño Jesús (HIUNJ) de Madrid y que contribuyen a la promoción y protección de la salud de la población y al progreso del Sistema Sanitario de la Comunidad de Madrid.

El HIUNJ, a través de su Fundación, ha impulsado el proyecto UICC24/00044, financiado con cargo a los fondos europeos NextGenerationEU que financian las actuaciones del Mecanismo para la Recuperación y Resiliencia (MRR) y promovido por el Ministerio de Ciencia, Innovación y Universidades y el Instituto de Salud Carlos III, que publicó resolución de concesión de ayudas para el desarrollo de Unidades de Investigación Clínica, correspondiente al expediente UICC24/00044: "Unidad para el avance de la Investigación Clínica en niños y adolescentes" (UICEC), cuyo beneficiario es la FIBHNJS.

En el marco de este proyecto, la telemedicina y la monitorización clínica avanzada constituyen herramientas estratégicas para facilitar el desarrollo de investigación clínica descentralizada y promover un acceso más equitativo de los pacientes a los estudios clínicos. El HIUNJ, como hospital monográfico pediátrico de tercer nivel, atiende patologías complejas, pacientes crónicos y pacientes candidatos a ensayos clínicos y terapias avanzadas, por lo que la implantación de sistemas de telemonitorización y monitorización clínica avanzada permitirá optimizar la recogida de datos de investigación, reducir desplazamientos asociados a la participación en estudios clínicos y mejorar la coordinación entre los distintos entornos en los que se desarrollan las actividades de investigación. Asimismo, la implementación de sistemas de información clínica de alta densidad de datos posibilitará la captura, almacenamiento y análisis de grandes volúmenes de información procedente de dispositivos médicos y sistemas de monitorización, permitiendo su explotación avanzada con fines de investigación y facilitando, en su caso, el desarrollo futuro de herramientas de análisis avanzado, incluidos modelos basados en inteligencia artificial.

Este sistema de monitorización resulta especialmente relevante en el contexto de la nueva UICEC, ya que permitirá mejorar la recogida estructurada de datos clínicos, la monitorización remota de pacientes incluidos en ensayos clínicos y el seguimiento de pacientes complejos tanto en ámbito tanto en entorno hospitalario como, en su caso, domiciliario. Dentro de los objetivos del proyecto se contempla la implantación de soluciones de telemonitorización para diferentes entornos de monitorización y seguimiento clínico, incluyendo hospitalización, cuidados intensivos, urgencias, hospitalización domiciliaria, pacientes crónicos complejos y oncología pediátrica, así como la creación de una infraestructura de datos de alta densidad con capacidad de integración, explotación y análisis avanzado de la información clínica generada.

La solución requerida deberá permitir la adquisición, integración y explotación clínica de datos multiparamétricos en tiempo real, incluyendo capacidades de monitorización de alta

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densidad, almacenamiento continuo y análisis avanzado de señales clínicas procedentes de múltiples dispositivos biomédicos. Se considera especialmente relevante la capacidad del sistema para integrar información clínica procedente de monitores y dispositivos biomédicos heterogéneos con frecuencias elevadas de adquisición de datos, según el tipo de dispositivo y frecuencia de adquisición configurada, permitiendo la transmisión, representación gráfica, almacenamiento histórico y explotación analítica avanzada de los parámetros monitorizados. Asimismo, se valora la disponibilidad de funcionalidades orientadas a monitorización remota avanzada, análisis estadístico automatizado de variables clínicas y soporte a entornos de telemedicina y cuidados críticos, incluyendo la posibilidad de desarrollo futuro de herramientas de apoyo a la decisión clínica, análisis predictivo, identificación precoz de eventos clínicos y explotación avanzada de datos longitudinales en entornos de investigación biomédica pediátrica.

La infraestructura objeto del contrato requiere un elevado grado de interoperabilidad funcional, resultando especialmente relevante la experiencia previa en entornos de cuidados críticos y/o complejos pediátricos, hospitalización domiciliaria y monitorización multiparamétrica. La integración efectiva entre equipamiento biomédico, sistemas de monitorización continua, almacenamiento estructurado y herramientas de explotación clínica y analítica es un elemento nuclear del proyecto. En este sentido, se considera necesaria la disponibilidad de una plataforma que disponga de experiencia previa acreditada y validación en entornos clínicos reales, que permita la integración nativa de monitorización de alta densidad, representación gráfica avanzada, almacenamiento histórico continuo, telemonitorización y análisis estadístico automatizado, minimizando riesgos de integración, adaptación y validación tecnológica.

La investigación biomédica asociada al proyecto requiere, además, continuidad metodológica en el tratamiento y explotación de datos clínicos de alta complejidad. La alteración de los flujos de trabajo, algoritmos de explotación de datos o arquitecturas tecnológicas previamente validadas podría comprometer la trazabilidad científica de los resultados obtenidos, así como generar riesgos de incompatibilidad técnica, pérdida de continuidad metodológica y retrasos en la ejecución de las actuaciones financiadas dentro del proyecto UICC24/00044.

El proyecto se desarrollará garantizando el cumplimiento de la normativa vigente en materia de protección de datos personales y seguridad de la información, incluyendo el Reglamento (UE) 2016/679 (RGPD), la Ley Orgánica 3/2018 de Protección de Datos Personales y garantía de los derechos digitales, así como las recomendaciones y marcos normativos aplicables a proyectos de telemedicina y sistemas de información sanitaria.

La FIBHNJS no dispone actualmente de medios técnicos, infraestructuras tecnológicas ni recursos humanos especializados suficientes para el desarrollo, implantación e integración de una infraestructura de estas características, resultando necesario acudir a contratación externa especializada para garantizar la correcta ejecución del proyecto, la adecuada interoperabilidad con los sistemas clínicos y tecnológicos existentes y la continuidad funcional y metodológica de los procesos de investigación clínica asociados.

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2. OBJETO DEL CONTRATO

El objeto del presente pliego es describir y definir las condiciones técnicas necesarias para la contratación del suministro, implantación, instalación, configuración, integración y puesta en funcionamiento de un sistema integral de información clínica y telemonitorización de alta densidad de datos para investigación clínica pediátrica, destinado a la UICEC de la FIBHNJS. Esta solución tendrá la capacidad de gestionar simultáneamente 20 puestos de monitorización/camas, que cubrirían un total de 20 pacientes en camas de hospitalización y domicilio.

La solución deberá disponer de una arquitectura modular, escalable y basada en estándares que permita su continuidad de uso durante su vida útil, evitando dependencias tecnológicas cerradas o configuraciones que puedan comprometer su evolución, interoperabilidad o utilización futura. Asimismo, deberá facilitar, desde el punto de vista técnico, futuras ampliaciones, integraciones o incorporación de nuevos dispositivos, siempre que resulten compatibles con la arquitectura implantada y con los requisitos técnicos y normativos aplicables.

El contrato se configura como un proyecto integral, incluyendo todas las actuaciones necesarias para la completa puesta en funcionamiento de la solución, así como los trabajos de instalación, integración tecnológica, configuración, validación funcional, formación y soporte técnico necesarios para garantizar su correcta operatividad.

3. LOCALIZACIÓN

La instalación estará situada en el HIUNJ.

Situación: espacios, áreas funcionales, puestos de monitorización y recursos vinculados a la actividad de la UICEC, definidos por la dirección de la FIBHNJS, incluyendo aquellos entornos necesarios para el desarrollo de actividades de investigación clínica, ensayos clínicos, monitorización y seguimiento de participantes en estudios clínicos.

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4. CARACTERÍSTICAS TÉCNICAS GENERALES DE LA SOLUCIÓN.

Arquitectura, interoperabilidad y escalabilidad

La solución deberá disponer de capacidad de integración multimarca con equipamiento biomédico heterogéneo permitiendo la interoperabilidad con dispositivos de distintos fabricantes, a pie de cama, recibiendo información cada pocos segundos, utilizando para ello los puertos y protocolos de comunicación oficiales de cada equipo y evitando dependencias tecnológicas asociadas a entornos cerrados o propietarios, integrándose con los dispositivos médicos actualmente en uso en las camas/puestos de monitorización.

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Con el fin de dar a conocer los dispositivos médicos en uso, será obligatorio una visita técnica a las instalaciones para identificar in situ sus modelos, versiones y puertos de comunicación disponibles.

La integración se realizará siempre que existan puertos, protocolos oficiales de comunicación o mecanismos técnicamente documentados que permitan dicha integración y siempre que resulte compatible con la normativa técnica, sanitaria, de seguridad y de certificación aplicable.

La solución deberá disponer de una arquitectura modular, escalable y basada en estándares que permita, desde el punto de vista técnico, la eventual incorporación futura de nuevos dispositivos médicos, puestos de monitorización, módulos o funcionalidades compatibles. Esta capacidad de evolución no implicará la obligación del adjudicatario de ejecutar sin coste adicional integraciones, ampliaciones, desarrollos o prestaciones no incluidas expresamente en el objeto, precio y alcance inicial del contrato, si no que pretenden asegurar la continuidad del uso de los equipos.

Con carácter previo a la propuesta de adjudicación definitiva, el órgano de contratación podrá requerir al licitador mejor clasificado para que realice una demostración técnica de la solución ofertada, limitada a la comprobación de la compatibilidad e integración con los dispositivos expresamente incluidos en el alcance inicial del contrato.

La demostración se realizará conforme al protocolo previsto en el Anexo 1. Protocolo de prueba de interoperabilidad del PPT, debiendo documentarse mediante informe técnico o acta de validación. En caso de que la demostración evidencie el incumplimiento de requisitos mínimos del PPT, se procederá en los términos previstos en el PCAP.

Asimismo, deberá ser plenamente compatible con la infraestructura tecnológica y los requerimientos de la red corporativa del HIUNJ, adaptándose a los requerimientos técnicos, de conectividad, seguridad e integración definidos por los servicios informáticos del centro.

La solución deberá disponer de capacidad de integración con el sistema de información HCIS.

La solución deberá acreditar, mediante documentación técnica suficiente, que cumple los requisitos de interoperabilidad, seguridad, almacenamiento, explotación de datos y validación funcional exigidos en el presente pliego, sin perjuicio de la solvencia técnica que se exija en el PCAP.

La solución deberá permitir el intercambio seguro de información con otros sistemas y plataformas de información sanitaria mediante mecanismos documentados de interoperabilidad. No se exige como requisito inicial la integración directa con los sistemas corporativos del Hospital, salvo en aquellos extremos expresamente definidos en este pliego, sin perjuicio de que la solución deba disponer de una arquitectura que permita futuras integraciones, siempre que estas sean técnicamente viables.

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El sistema deberá permitir, desde terminales autorizados ubicados en cualquier punto habilitado, la visualización integrada de la información clínica en tiempo real.

La información generada por el sistema se almacenará en infraestructuras autorizadas por la FIBHNJS y/o el HIUNJ, que deberán garantizar la seguridad, confidencialidad, integridad, disponibilidad y trazabilidad de los datos de investigación, de conformidad con los requisitos técnicos, organizativos y normativos aplicables.

La arquitectura de la solución deberá ser escalable, modular y evolutiva, de forma que permita la continuidad de uso de la solución implantada y su adaptación técnica a futuras necesidades del proyecto, evitando que la prestación quede obsoleta por limitaciones de diseño, incompatibilidades técnicas o dependencia de entornos cerrados.

La exigencia de escalabilidad no implica la obligación del adjudicatario de ejecutar, sin coste adicional, ampliaciones, integraciones, desarrollos o prestaciones no incluidas expresamente en el alcance inicial del contrato, sin perjuicio de la obligación de entregar una solución técnicamente preparada para permitir dichas evoluciones.

Condiciones técnicas de la ejecución

Las empresas licitadoras serán responsables del conocimiento de las instalaciones previamente a la formulación de las ofertas, así como de la comprobación de su estado e idoneidad para cumplir con todas las exigencias que figuran en el proyecto y presente pliego de prescripciones técnicas, a cuyo efecto será obligatorio para la admisión de las empresas interesadas, la aportación, en el sobre 1, del certificado de visita obligatoria de las instalaciones por cada licitador a realizar antes de la presentación de ofertas.

Visita a las instalaciones.

Será obligatorio para la admisión de las empresas interesadas, la aportación, en el sobre 1, del certificado de visita obligatoria de las instalaciones por cada licitador a realizar antes de la presentación de ofertas. Se publicará en el Portal de Contratación Pública de la Comunidad de Madrid la hora y fecha de la visita.

Los licitadores que estén interesados podrán solicitar su interés al correo fibhnjs@salud.madrid.org en el plazo máximo de 7 días desde la publicación de la licitación.

Capacidades de monitorización y explotación de datos

El sistema de información clínica deberá gestionar información clínica de alta densidad utilizando tecnología Big Data, basada en los principios de volumen, velocidad, variedad, veracidad y valor.

La solución deberá permitir la transmisión, adquisición, integración y explotación clínica de datos multiparamétricos en tiempo real, incluyendo capacidades de monitorización de alta

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densidad, almacenamiento continuo y análisis avanzado de señales clínicas procedentes de múltiples dispositivos biomédicos.

Los datos clínicos serán accesibles para los profesionales autorizados en tiempo real y diferido desde las Unidades de Control Hospitalario (UCH), puestos de control o accesos remotos habilitados por la solución.

Se considera especialmente relevante la capacidad del sistema para integrar información clínica procedente de monitores y dispositivos biomédicos heterogéneos con frecuencias elevadas de adquisición de datos, según el tipo de dispositivo y frecuencia de adquisición configurada, permitiendo la transmisión, representación gráfica, almacenamiento histórico y explotación analítica avanzada de los parámetros monitorizados.

La solución deberá disponer de funcionalidades orientadas a monitorización remota avanzada, análisis estadístico automatizado de variables clínicas y soporte a entornos de telemedicina y monitorización clínica compleja, incluyendo la posibilidad de desarrollo futuro de herramientas de apoyo a la decisión clínica, análisis predictivo e identificación precoz de eventos clínicos.

Funcionalidades generales

La solución deberá permitir la adquisición, integración y explotación clínica de datos multiparamétricos en tiempo real, incluyendo, al menos, las siguientes funcionalidades:

A. Gestión y explotación de la información clínica

- La información registrada deberá almacenarse de forma histórica y procesarse mediante tablas resumen que faciliten la detección y el acceso a los periodos que requieran análisis con fines de investigación.
- El sistema de información clínica deberá ser único tanto para pacientes hospitalarios como para pacientes domiciliarios.
- El sistema deberá elaborar automáticamente un resumen de la evolución de cada parámetro monitorizado mediante indicadores estadísticos, estructurando la información mediante indicadores descriptivos e inferenciales adaptados al tipo de variable monitorizada.
- Explotación clínica e investigadora de los datos.
- Representación gráfica avanzada de la información clínica.

B. Captura e integración de información

- La captura de datos de los dispositivos médicos conectados al paciente se realizará a pie de cama mediante un dispositivo independiente de los dispositivos médicos existentes y capaz de transmitir la información a través de un único puerto Ethernet.
- Integración multimarca con dispositivos biomédicos heterogéneos. El sistema utilizará información procedente de equipos de monitorización, análisis y tratamiento de rango hospitalario de distintos fabricantes de prestigio y con tecnología de última generación.
- Interoperabilidad con sistemas de información clínica y plataformas sanitarias/

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corporativas.

- Compatibilidad con la infraestructura tecnológica y la red corporativa del Hospital.

C. Telemonitorización

- Capacidad telemédica, de forma que el sistema pueda utilizarse con pacientes independientemente de su ubicación física, especialmente en el ámbito domiciliario.
- Telemonitorización y acceso remoto seguro a la información clínica desde terminales autorizados.

D. Capacidades clínicas y de investigación

- Capacidad de registro de estudios gasométricos.
- Capacidad de registro de resultados de laboratorio.
- Capacidad de facilitar al personal investigador debidamente autorizado el acceso estructurado a la información contenida en la base de datos para el desarrollo de actividades de investigación clínica.

E. Características generales de la solución:

- Compatibilidad con la infraestructura tecnológica y la red corporativa del Hospital.
- Escalabilidad futura mediante incorporación de nuevos dispositivos y funcionalidades.

Alcance del proyecto

El adjudicatario deberá garantizar la integración de los dispositivos, puestos de monitorización y elementos incluidos expresamente en el alcance inicial del contrato.

Esta capacidad de evolución y escalabilidad constituye una característica técnica de la solución ofertada, orientada a evitar su obsolescencia funcional y garantizar su continuidad de uso, sin que suponga la inclusión automática de prestaciones futuras no previstas en el objeto, precio y alcance inicial del contrato.

Continuidad tecnológica y no obsolescencia funcional

La solución ofertada deberá estar diseñada de forma que permita su continuidad de uso durante su vida útil, evitando configuraciones cerradas, dependencias tecnológicas injustificadas o limitaciones de arquitectura que impidan su evolución razonable.

A tal efecto, el licitador deberá acreditar que la solución:

- a) No se encuentra en situación de fin de vida, fin de comercialización o fin de soporte técnico por parte del fabricante o proveedor tecnológico.
- b) Dispone de una arquitectura modular y escalable que permita la incorporación futura de nuevos dispositivos, puestos de monitorización, usuarios, módulos o funcionalidades compatibles.

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c) Permite la exportación, consulta y conservación estructurada de los datos generados, evitando la pérdida de información o la dependencia exclusiva de formatos no interoperables.

d) Utiliza mecanismos documentados de interoperabilidad, conectividad y gestión de datos que permitan su evolución técnica.

e) Permite mantener la operatividad de la solución implantada sin necesidad de sustituir íntegramente la arquitectura inicial ante ampliaciones razonables del sistema.

La finalidad de esta exigencia es garantizar que la inversión financiada permita disponer de una solución útil, operativa y técnicamente evolucionable, sin que la misma quede obsoleta o limitada a corto plazo.”

5. INFRAESTRUCTURA TECNOLÓGICA

La solución incluirá la infraestructura tecnológica necesaria para el almacenamiento, procesamiento, integración y explotación de los datos clínicos generados por el sistema de información clínica y telemonitorización.

El suministro comprenderá un servidor destinado a la infraestructura de monitorización clínica, telemonitorización y explotación de datos, cuyas características mínimas serán:

- Procesador Intel Xeon de última generación o equivalente.
- Memoria RAM mínima de 64 GB, ampliable.
- Controladora RAID hardware empresarial incluida.
- Sistema de almacenamiento redundado mediante tecnología RAID.
- Capacidad mínima instalada de 4 TB mediante unidades SSD empresariales o tecnología equivalente.
- Adaptadores de red Ethernet multipuerto para integración con la infraestructura tecnológica del Hospital.
- Fuentes de alimentación redundantes.
- Herramientas de administración, monitorización y gestión remota del servidor.
- Compatibilidad con los requerimientos técnicos, de conectividad y seguridad definidos por los servicios informáticos del Hospital.

El suministro incluirá los servicios de configuración, integración, puesta en marcha y soporte técnico necesarios para la correcta implantación de la infraestructura tecnológica.

Podrán ofertarse soluciones equivalentes o superiores a las características indicadas, siempre que se acredite que cumplen los requisitos funcionales y de rendimiento exigidos para la infraestructura objeto del contrato.

La información generada por el sistema será almacenada en infraestructuras autorizadas, bajo un modelo de gestión compartida que garantice la seguridad, trazabilidad y adecuada gestión de los datos de investigación.

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El soporte técnico de puesta en marcha, configuración e integración de la infraestructura tecnológica deberá estar incluido en la adquisición.

6. REQUISITOS DE INTEGRACIÓN E INTEROPERABILIDAD

La solución deberá permitir la integración multimarca con equipamiento biomédico heterogéneo, evitando dependencias tecnológicas asociadas a entornos cerrados o propietarios.

Durante la ejecución del contrato, el adjudicatario deberá realizar la integración de los dispositivos y elementos expresamente definidos en el alcance inicial del contrato, siempre que los fabricantes faciliten los protocolos de comunicación necesarios y que la integración sea compatible con la normativa técnica, sanitaria y de certificación aplicable.

La solución deberá contar, además, con una arquitectura escalable que permita futuras integraciones o ampliaciones, sin que ello implique la obligación del adjudicatario de ejecutar prestaciones adicionales no incluidas en el precio y alcance inicial del contrato.

7. FUNCIONALIDADES DEL SISTEMA

El sistema incluirá desde parámetros básicos hasta parámetros complejos o específicos, pudiendo incorporarse parámetros adicionales según las necesidades del proyecto.

Funcionalidades mínimas:

- Monitorización integrada en tiempo real: monitor individual, multipaciente y monitorización de dispositivos asociados.
- Monitorización en tiempo diferido: evolución gráfica diaria, evolución en tablas y evolución gráfica mensual.
- Visualización gráfica avanzada de parámetros clínicos.
- Hoja de enfermería electrónica.
- Hoja respiratoria.
- Hojas de análisis clínicos.
- Monitorización continua o intermitente, con posibilidad de ampliación para visualización de múltiples pacientes.
- Captura de eventos.
- Almacenamiento histórico estructurado de la información clínica.
- Gestión y explotación analítica de datos clínicos.
- Acceso remoto seguro a la información clínica.
- Exportación y consulta de datos para actividades de investigación clínica y docencia.
- Gestión de usuarios y perfiles de acceso.
- Acceso a información clínica para investigación y docencia.

8. SERVICIOS DE IMPLANTACIÓN

La empresa adjudicataria realizará:

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- Instalación del concentrador de comunicaciones.
- Configuración de drivers para conexión de dispositivos médicos.
- Conexión a la red hospitalaria.
- Cableado y etiquetado.
- Configuración del servidor.
- Instalación de la solución de información clínica y telemonitorización.
- Integración con los sistemas de información y plataformas tecnológicas del Hospital.
- Configuración de puestos de control.
- Generación inicial de usuarios y contraseñas.
- Configuración y validación de la interoperabilidad con los dispositivos biomédicos conectados.
- Formación de uso de la aplicación.
- Formación sobre conectividad y cableado.
- Pruebas de funcionamiento y validación.
- Puesta en marcha de la solución en los entornos definidos por el proyecto.

9. PRUEBAS DE ACEPTACIÓN

Con carácter previo a la aceptación definitiva de la solución, la empresa adjudicataria realizará las pruebas necesarias para verificar el correcto funcionamiento de todos los elementos suministrados e implantados.

Las pruebas de aceptación incluirán, al menos:

- Verificación de la correcta instalación de la infraestructura y componentes suministrados.
- Validación de las comunicaciones y conectividad con la red corporativa del Hospital.
- Verificación de la integración con los dispositivos biomédicos conectados.
- Verificación del acceso remoto y funcionamiento de los puestos de control.
- Validación funcional de la plataforma de información clínica y telemonitorización.
- Comprobación del correcto almacenamiento y acceso a la información clínica generada.
- Resolución de incidencias detectadas durante el proceso de validación.
- Aceptación final de la solución por parte de la FIBHNJS.

La aceptación definitiva de la solución estará condicionada a la correcta integración y operatividad de todos los elementos suministrados, de forma que no se comprometa el calendario previsto de implantación y puesta en funcionamiento de la Unidad.

Las pruebas de aceptación deberán documentarse mediante informe o acta de validación, en el que se reflejen las pruebas realizadas, resultados obtenidos, incidencias detectadas, medidas correctoras aplicadas y conformidad final de la FIBHNJS.

La recepción de la solución quedará condicionada a la superación satisfactoria de las pruebas de aceptación y a la entrega de la documentación técnica y funcional exigida en el presente pliego.

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10. SERVICIOS DE SOPORTE Y GARANTÍA

La solución incluirá el soporte técnico de implantación, configuración, integración, validación y puesta en marcha necesario para garantizar su correcta operatividad inicial.

Asimismo, el adjudicatario deberá garantizar durante el periodo de garantía establecido en el contrato (1 año) la correcta operatividad de los elementos suministrados e implantados, incluyendo la corrección de defectos, errores o incidencias imputables a la solución suministrada o a su implantación inicial.

La garantía comprenderá la reparación o sustitución de los elementos defectuosos. Asimismo, durante el periodo de garantía quedarán incluidos los sistemas de interconexión, hardware, software y accesorios de la solución necesarios para garantizar su correcta operatividad.

Las actualizaciones, parches o correcciones solo se entenderán incluidas cuando sean necesarias para garantizar la seguridad o correcta operatividad de la solución implantada durante el periodo de garantía.

La garantía técnica de la solución comprende la aplicación de las versiones de software requeridas para su normal operatividad y estabilidad operativa. La compatibilidad del hardware frente a estas actualizaciones operativas queda cubierta por el adjudicatario bajo los términos de la garantía técnica contratada, sin que proceda la reclamación de costes adicionales.

La solución deberá incorporar mecanismos de seguridad que permitan protegerla frente a vulnerabilidades, accesos no autorizados o posibles ataques cibernéticos, garantizando en todo momento la integridad, disponibilidad y confidencialidad de los datos tratados.

Las actuaciones anteriores no constituyen una prestación autónoma de mantenimiento recurrente, mantenimiento evolutivo ni funcionamiento ordinario de la entidad, sino obligaciones vinculadas a la adquisición inicial, implantación, puesta en marcha y garantía de la solución contratada.

La integración de nuevos dispositivos, funcionalidades, módulos o desarrollos no incluidos en el alcance inicial del contrato no se entenderá comprendida en la garantía, sin perjuicio de la capacidad de escalabilidad técnica de la solución ofertada.

Durante el periodo de garantía, el adjudicatario deberá realizar las actuaciones correctivas, parches o ajustes técnicos que resulten necesarios para garantizar la seguridad, estabilidad y correcta operatividad de la solución implantada, cuando estén vinculados a defectos, errores o incidencias imputables a la solución suministrada o a su implantación inicial.

Estas actuaciones tendrán por finalidad preservar la continuidad de uso y evitar la obsolescencia funcional prematura de la solución implantada, sin constituir una prestación autónoma de mantenimiento recurrente, mantenimiento evolutivo o funcionamiento ordinario.

11. FORMACIÓN

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La empresa adjudicataria impartirá la formación necesaria al personal sanitario, investigador y técnico designado por la FIBHNJS para garantizar el correcto uso y explotación de la solución implantada.

La formación incluirá, al menos:

- Manejo y utilización de la plataforma.
- Uso clínico y funcional de la solución.
- Gestión de usuarios y perfiles de acceso.
- Configuración básica, conectividad y cableado.
- Resolución básica de incidencias.
- Procedimientos de acceso remoto.
- Actualizaciones y nuevas funcionalidades.
- Buenas prácticas de utilización y explotación de la información clínica.

La formación deberá realizarse con carácter previo a la puesta en marcha definitiva de la solución y se impartirá en castellano.

12. PLAZO DE EJECUCIÓN

La solución deberá estar completamente suministrada, instalada, configurada, integrada y operativa dentro del plazo establecido en el contrato.

La ejecución comprenderá, al menos:

- Suministro de la infraestructura tecnológica y componentes asociados.
- Instalación y configuración de la solución.
- Integración con los sistemas y dispositivos definidos en el proyecto.
- Validación técnica y funcional.
- Formación inicial avanzada y transferencia de conocimiento para la utilización de la solución.
- Realización de las pruebas de aceptación.
- Puesta en marcha definitiva de la solución.

La planificación de los trabajos deberá garantizar la disponibilidad operativa de la solución dentro de los plazos previstos para la puesta en funcionamiento de la UICEC, incluyendo las actividades de instalación, integración, validación técnica, transferencia de conocimiento y pruebas de aceptación necesarias para su correcta utilización.

13. PROTECCIÓN DE DATOS Y SEGURIDAD

La ejecución del contrato podrá implicar el acceso por parte del adjudicatario a información o datos personales exclusivamente en la medida necesaria para la implantación, configuración, integración, validación, puesta en marcha, soporte técnico inicial y garantía de la solución.

El adjudicatario no podrá utilizar la información o los datos a los que acceda para fines propios, ni comunicarlos a terceros, salvo autorización expresa y por escrito de la entidad responsable

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del tratamiento y en los términos legalmente procedentes.

La solución deberá garantizar la gestión de usuarios, perfiles de acceso, autenticación, trazabilidad de accesos y operaciones, confidencialidad, integridad, disponibilidad y conservación de la información, conforme a la normativa de protección de datos y seguridad de la información aplicable.

La solución deberá garantizar el cumplimiento de la normativa vigente en materia de protección de datos personales, seguridad de la información y sistemas de información sanitaria.

En particular, deberá cumplir con:

- Reglamento (UE) 2016/679 (RGPD).
- Ley Orgánica 3/2018 de Protección de Datos Personales.
- Normativa aplicable a sistemas de información sanitaria y seguridad de la información.
- La información clínica generada permanecerá bajo control y gestión del HIUNJ de la FIBHNJS, garantizando su confidencialidad, integridad, disponibilidad y trazabilidad.

14. FINANCIACIÓN

La presente contratación se realiza en el marco del proyecto UICC24/00044 “Unidad para el avance de la Investigación Clínica en niños y adolescentes”, cuyo beneficiario es la FIBHNJS. Proyecto financiado por:

- Instituto de Salud Carlos III (ISCIII).
- Fondos NextGenerationEU.
- Plan de Recuperación, Transformación y Resiliencia.

15. DOCUMENTACIÓN TÉCNICA A PRESENTAR POR EL LICITADOR

Los licitadores deberán aportar la documentación técnica necesaria para acreditar el cumplimiento de las especificaciones técnicas mínimas exigidas en el presente pliego.

A tal efecto, deberán presentar, al menos:

- Memoria técnica descriptiva de la solución ofertada.
- Documentación técnica suficiente para acreditar el cumplimiento de las especificaciones técnicas mínimas exigidas.
- Descripción de la arquitectura tecnológica propuesta.
- Descripción de las capacidades de integración, interoperabilidad y telemonitorización.
- Plan de implantación y puesta en marcha.
- Relación de licencias incluidas en la oferta.
- Características de la infraestructura tecnológica ofertada.
- Cualquier otra documentación necesaria para acreditar el cumplimiento de los requisitos establecidos en el presente pliego.

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16. DOCUMENTACIÓN A ENTREGAR CON LA SOLUCIÓN

Con la puesta en marcha de la solución, la empresa adjudicataria deberá entregar:

- Manuales de usuario en castellano.
- Manuales técnicos de administración y mantenimiento, al menos en castellano o acompañados de la documentación necesaria en castellano para su correcta utilización por la FIBHNJS.
- Documentación de configuración e instalación.
- Relación de licencias suministradas.
- Documentación de la infraestructura tecnológica implantada.
- Certificado de realización de las pruebas de aceptación.
- Documentación acreditativa de formación impartida.



ANEXO 1. Protocolo de prueba de interoperabilidad.

Objeto: el presente protocolo tiene por objeto verificar el cumplimiento del requisito mínimo de interoperabilidad exigido en el Pliego de Prescripciones Técnicas.

Prueba técnica: demostración, en la pantalla de visualización de la aplicación del sistema o en la base de datos donde se guardan los parámetros, que los valores recogidos de los dispositivos coinciden en tiempo real con los que aparecen en la aplicación o con los que se almacenan en la base de datos.

La demostración se realizará para los siguientes dispositivos:

- Monitores IntelliVue MX de Philips.
- Ventiladores mecánicos Servo-i y Servo-u de Getinge.
- Bombas de infusión de Fresenius Kabi.

Fabricante	Modelo
Philips	IntelliVue MX500 o MX850
Getinge	Servo-i y Servo-u
Fresenius Kabi	Agilia SP

Se incorporan como apéndices al presente protocolo las fichas técnicas de los dispositivos utilizados para la realización de la prueba de interoperabilidad:

- Apéndice A del Anexo 1. Ficha técnica del monitor multiparamétrico Philips IntelliVue MX500.
- Apéndice B del Anexo 1. Ficha técnica del monitor multiparamétrico Philips IntelliVue MX850.
- Apéndice C del Anexo 1. Ficha técnica del ventilador mecánico Getinge Servo-i.
- Apéndice D del Anexo 1. Ficha técnica del ventilador mecánico Getinge Servo-u.
- Apéndice E del Anexo 1. Ficha técnica de la bomba de infusión Fresenius Kabi Agilia® SP MC / Agilia® SP MC WiFi.



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Apéndice A del Anexo 1. Ficha técnica del monitor multiparamétrico Philips IntelliVue MX500.



IntelliVue MX500 Patient Monitor

Philips 866064 Technical Data Sheet

Release M.04

The IntelliVue MX500 Patient Monitor offers a flexible and modular monitoring solution, designed to suit a broad spectrum of needs. The monitor can be connected to the Philips Multi-Measurement Module family with its extensions, plug-in measurement modules, and the IntelliVue Gas Analyzers to extend its functionality with plug-and-play convenience. Dedicated configurations are available for the anesthesia, intensive, cardiac, neonatal and general care environments.

Features

- Intuitive user interface.
- Easy-to-read, easy-to-use touchscreen.
- Simple menu hierarchy gives fast access to all basic monitoring tasks.
- Screen layouts are easily adjustable, allowing flexible display of measurement information.
- Previous/Next Screen function provides access to the most recently used screens including the last three modified screens.
- Temperature, height, and weight can be configured either in metric or imperial units. Pressure measurements can be displayed in kPa or mmHg. Gases can be displayed in kPa or mmHg.
- Patient data management with tabular and graphic trends, and high-resolution trends to track changes with beat-to-beat resolution.
- Drug, ventilation, hemodynamic, and oxygenation calculations.
- User or case-specific profiles enable rapid case turnover. Patented automatic alarm limits help clinicians provide care more efficiently.

- Alarm Advisor provides feedback on recurring and continuous alarm limit violations, helping clinicians to adapt alarm limits more specifically for individual patients.
- Event Surveillance including Neonatal Event Review (NER) for automatic detection of patient status deterioration.
- Guardian Early Warning Scoring (EWS) calculates a score based on vital signs to help recognize early signs of deterioration in patients.
- Tympanic Temperature measurement¹. In-Ear SpotCheck thermometer, delivers accurate temperature readings in less than two seconds.
- Bed-to-bed overview provides clinicians with an overview of all the patient beds in their care.
- Choice of input devices: Touchscreen, remote control, trackball, mouse, keyboard, or barcode reader.
- Capable of functioning in a wireless infrastructure.
- Electronic Strip Recording.
- Graphical measurement window shows which measurements are being measured by which device, making it easier to resolve measurement label conflicts.
- The Timers application enables notifications to be set when a specific time period has expired.
- Additional independent display capability using IntelliVue XDS Remote Display.
- Bedside information access using the IntelliVue XDS Clinical Workstation.

¹ Requires Option J13 - MIB/RS232 (2 ports) interface, or J40 - Advanced System Interface

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- XDS Database (option X40) enables the collection and storage of vital signs information (numeric data only – no waves), for example, heart rate, pressure, etc. on an external SQL database.
- The monitor can be configured to automatically vary the screen brightness to the ambient light conditions. The range within which this adaption is made is configurable.
- Support for pre-configured remote applications hosted on Citrix®¹ XenApp® or standard IT web servers.
- Integrated carrying handle.

Indications for Use

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitor is intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment.

The monitor is additionally intended for use in transport situations within hospital environments, and is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.

Rx only: U.S. Federal Law restricts this device to sale by or on the order of a physician.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI ECT1).

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients. The transcutaneous gas measurement (tcGas) with the M1018A plug-in module is restricted to neonatal patients only.

The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.

The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

The IntelliVue NMT Module is intended to be used as an objective neuromuscular transmission monitor, using accelerometry for measuring the muscle contraction following an electrical stimulation of a peripheral nerve. The NMT Module is intended to be used with adult and pediatric patients.

Modularity

The monitor's functionality can be extended by connecting Philips Multi-Measurement Modules (with extensions), and gas analyzers, with plug-and-play convenience.

The monitor is available as a standalone or networked solution.

The monitor's modular design allows new capabilities to be added in the future as monitoring requirements change. This upgradability provides the security of knowing that the monitor can be enhanced and updated as practices and technologies advance, protecting long-term investments.

Main Components

Monitor

The monitor has a color 12-inch LCD TFT display with a wide viewing angle, providing high-resolution waveform and data presentation. The monitor integrates the display and the processing unit into one device. One external display² – providing an adaptive duplicate image of the primary display – can be connected to a built-in DVI-I port.

Remote Display

IntelliVue XDS Remote Display allows the remote display of an IntelliVue Patient Monitor³ on a PC connected to the same network. It can be configured to allow remote operation of the patient monitor. It is intended to be used as an additional independent display for viewing and operation by clinicians and nurses.

User Interface

The color graphical user interface is designed for fast and intuitive operation, and ensures clinicians quickly feel at ease using the monitor.

- Configurable SmartKeys with intuitive icons allow monitoring tasks to be performed quickly and easily, directly on the monitor screen.
- Waves and numerics are color-coded, colors are customizable.
- The monitor displays up to six waves simultaneously. For 10-electrode lead ECG monitoring, it can display 12 real-time ECG waves, with a rhythm strip and all ST values.
- Flexible screen layout allows optimal use of the available display space, for example, waves can be overlapped or wave size can adjust dynamically depending on the number of waves configured for the space.
- The Basic Help provides on-screen operating help, explaining INOP and alarm messages.

Touchscreen Operation

The monitor is supplied with a resistive touchscreen display.

1. Citrix®, Citrix Receiver™, XenApp®, and ICA® (Independent Computing Architecture) are trademarks of Citrix Systems, Inc. and/or one or more of its subsidiaries, and may be registered in the United States Patent and Trademark Office and in other countries.

2. Requires Option J15 – Adaptive Secondary Display

3. Requires Option X00 – XDS Connectivity to be installed on either the patient monitor, or on a PC running the IntelliVue XDS Solution with an activated license



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Remote Control (865244)

The IntelliVue Remote Control 865244 provides direct access to five hardkeys, a navigation knob, and a numeric keypad which can also be used for alphanumeric entry. The hardkeys include "Silence", "Alarms Off / Pause Alarms", "Back Key", "MainScreen", and a "SmartKeys" key that displays a block of configurable smart keys. The remote control is connected to the monitor via USB interface or SRR interface (wireless) and used for remote operation of the monitor.



Remote Alarm Device¹ (866406)

When connected to a patient monitor, the Remote Alarm Device 866406 provides audible and visual indicators of alarms, in addition to the indicators at the monitor.



Input Devices

Supported input devices include the following USB-compatible, off-the-shelf computer accessories:

- **Mouse:** Any specified USB mouse or trackball may be used for data entry.
- **Computer Keyboard:** A USB-compatible off-the-shelf keyboard can be connected to the monitor for data entry.
- **Barcode Reader:** A USB barcode reader in 'keyboard emulation mode' can be used via a USB connection.
- **Simulated Keyboard:** If alpha or numeric data entry is required, for example to enter patient demographics, a pop-up, on-screen keyboard will automatically appear on the screen.

Input devices can be used individually or in combination.

X1 Multi-Measurement Module (M3001A/M3001AL)

The X1 Multi-Measurement Module can be connected directly to the rear of the monitor. It can also be placed in patient vicinity connecting it to the monitor via cable.



It sends measurement waves and numerics to the monitor and generates alarms and INOPs.

The X1 can simultaneously monitor ECG (using 3-, 5-, 6-, or 10-electrode lead sets, including arrhythmia and ST monitoring), respiration, oxygen saturation of arterial blood (SpO₂), noninvasive blood pressure (NBP), and either invasive pressure or temperature. Diagnostic 10-electrode lead capability is optionally available. The X1 stores trend data, patient demographic information and measurement settings and transfers it to a connected IntelliVue Patient Monitor.

¹ Requires Option J23 - Remote Device Interface

² Choice of Philips FAST SpO₂, Masimo SET SpO₂, Nellcor Oximax SpO₂ or Masimo rainbow SET SpO₂ (including certain Masimo rainbow parameters).

X2 Multi-Measurement Module (M3002A)

The X2 can be used:

- As a stand-alone patient monitor.
- As a Multi-Measurement Module for the IntelliVue family of patient monitors.



It can also be placed in patient vicinity connecting it to the monitor via cable. It sends measurement waves and numerics to the monitor and generates alarms and INOPs.

The X2 can simultaneously monitor ECG (using 3-, 5-, 6-, or 10-electrode lead sets, including arrhythmia and ST monitoring), respiration, oxygen saturation of arterial blood (SpO₂), noninvasive blood pressure (NBP), and either invasive pressure and temperature, or CO₂. The X2 stores trend data, patient demographic information and measurement settings.

Combining its role as a Multi-Measurement Module with that of stand-alone monitor, the X2 is particularly suited to transport situations. When the X2 is disconnected from the host monitor, it continues to monitor the patient as a stand-alone monitor running on battery power, eliminating the need for a separate transport monitor.

When the X2 is reconnected to a host monitor, it resumes its role as a Multi-Measurement Module, uploading trend data, patient demographic information and measurement settings, and allowing fully continuous monitoring. The X2 can operate using battery power for over three hours with basic monitoring configuration to let you safely and easily monitor patients during in-hospital transfer.



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X3 Patient Monitor/Multi-Measurement Module (867030)

- The X3 can be used:
- As a stand-alone patient monitor.
 - As a Multi-Measurement Module for the IntelliVue family of patient monitors.



The X3 can also be connected directly to the rear of the monitor.

It can also be placed in patient vicinity connecting it to the monitor via cable. It sends measurement waves and numerics to the monitor and generates alarms and INOPs.

The X3 can simultaneously monitor ECG (using 3-, 5-, 6-, or 10-electrode lead sets, including arrhythmia and ST monitoring), respiration, oxygen saturation of arterial blood (SpO₂¹), noninvasive blood pressure (NBP), two invasive pressures, temperature, and CO₂. The X3 stores trend data, patient demographic information and measurement settings.

Combining its role as Multi-Measurement Module with that of stand-alone monitor, the X3 is particularly suited to transport situations. When the X3 is disconnected from the host monitor, it continues to monitor the patient as a stand-alone monitor running on battery power, eliminating the need for a separate transport monitor.

When the X3 is reconnected to a host monitor, it resumes its role as a Multi-Measurement Module, uploading trend data, patient demographic information and measurement settings, and allowing fully continuous monitoring.

The X3 can operate using battery power for over five hours with basic monitoring configuration to let you safely and easily monitor patients during in-hospital transfer. During in-hospital transport the X3 can power the Measurement Extensions (867039, 867040, and 867041) without requiring the use of the IntelliVue Battery Extension (865297).

MMX Multi-Measurement Module (867036)

The MMX Multi-Measurement Module can be connected directly to the rear of the monitor. It can also be placed in patient vicinity connecting it to the monitor via cable.



It sends measurement waves and numerics to the monitor and generates alarms and INOPs.

The MMX can simultaneously monitor ECG (using 3-, 5-, 6-, or 10-electrode lead sets, including arrhythmia and ST monitoring), respiration, oxygen saturation of arterial blood (SpO₂¹), noninvasive blood pressure (NBP), two invasive pressures, temperature, and CO₂. Diagnostic 10-electrode lead capability is optionally available.

The MMX stores trend data, patient demographic information and measurement settings and transfers it to a connected IntelliVue Patient Monitor.

1. Choice of Philips FAST SpO₂, Masimo SET SpO₂, Nellcor Oximax SpO₂ or Masimo rainbow SET SpO₂ (including certain Masimo rainbow parameters)

Measurement Extensions

The following Measurement Extensions can be slotted onto an X1, X2, X3, or MMX:

- The **867039 Hemodynamic extension**: Adds temperature, two pressures, and optionally cardiac output/PiCCO.
- The **867040 Capnography extension**: Adds mainstream/sidestream capnography, and optionally temperature, two pressures, and cardiac output/PiCCO².
- The **867041 Microstream® CO₂ extension**: Adds Microstream capnography, and optionally temperature, two pressures, and cardiac output/PiCCO⁴.
- The **M3012A Hemodynamic extension**: Adds temperature, pressure, an additional pressure or a temperature and optionally cardiac output/PiCCO.
- The **M3014A Capnography extension**: Adds mainstream or sidestream capnography, and optionally one pressure plus either a pressure or a temperature and cardiac output/PiCCO.
- The **M3015A Microstream CO₂ extension**: Adds Microstream CO₂, and optionally either pressure or temperature.
- The **M3015B Microstream CO₂ extension**: Adds Microstream CO₂, and two pressures and a temperature.

Integrated Module Slots

The MX500 has three integrated module slots for use with plug-in modules.

Plug-in modules

The following individual plug-in measurement modules are available:

- M1006B Invasive Blood Pressure
- M1011A Intravascular Oxygen Saturation (SO₂)
- M1012A Cardiac Output/Continuous Cardiac Output
- M1014A Spirometry
- M1020B SpO₂
- M1027B Electroencephalograph (EEG/aEEG)
- M1029A Temperature
- M1034B Bispectral Index (BIS™)⁵
- 865383 Neuromuscular Transmission (NMT)
- 866173 G7m Gas Analyzer
- 867191 SpO₂ (Masimo rainbow SET)
- 867192 SpO₂ (Masimo SET)

Additional plug-in modules available are:

- M1116C Thermal Array Recorder
- 865115 IntelliBridge EC10

Supported Device Interfaces

Supported Device Interfaces are:

- IntelliBridge EC10 Module/EC10 Interface Board
- RS232 Data Export

2. PiCCO is not available for the 867040 Capnography extension in the USA and territories relying on FDA market clearance

3. Microstream is a registered trademark of Orion Systems Ltd

4. PiCCO is not available for the 867041 Microstream CO₂ extension in the USA and territories relying on FDA market clearance

5. Bispectral Index and BIS are registered trademarks of Covidien AG and/or its affiliates



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IntelliVue Gas Analyzers

The G7m Gas Analyzer module measures the five most commonly used anesthetic gases, as well as N₂O and CO₂. It also provides inspiration and expiration values for display on IntelliVue Patient Monitors and the values required for MAC calculation in the IntelliVue Patient Monitors.

The IntelliVue G7m features automatic agent identification and mixed-agent measurement capability.

Advanced O₂ technology based on paramagnetic measurements is included with the G7m.

The TcG10¹ measures the transcutaneous O₂ and CO₂ partial pressure in neonates, pediatrics and adults.

Mounting

The standard mounting options enable flexible, space saving placement of the monitor for an ergonomic work space.

Applications for Specific Care Settings

Anesthesia Features

- The **IntelliVue G7m Gas Analyzer module** measures the five most commonly used anesthetic gases, as well as N₂O and CO₂.
- The **BIS Module** assesses the level of consciousness in the OR, providing a measure of the effect of anesthetic agents.
- The **IntelliBridge EC10 Module / EC10 Interface Board** provides external-device interface capability to external devices at the bedside which have a serial RS232 and/or LAN output.
- The **EEG Module** determines coma prognosis and extent of cerebral insult. CSA information can be either permanently displayed on specially designed screens or viewed in a separate window. Burst Suppression Ratio (BSR) indicates the amount of time within an interval spent in the suppressed state.
- The **Spirometry Module** provides airway pressure, volume, and flow measurements to monitor changes in respiratory status.
- The **NMT Module** together with the NMT Patient Cable offers automatic measurements of muscle response to electrical stimuli delivered via electrodes placed over a peripheral nerve. This enables the evaluation of muscle relaxation of patients under neuromuscular block. The strength of the muscle response is measured with an acceleration sensor.
- **Screens** provide flexible viewing of patient information during different procedures or phases of an anesthesia case.
- **Respiratory Loops.** The IntelliVue Patient Monitor can generate three types of respiratory loops and display one real-time loop and up to six stored loops simultaneously. This helps early detection of patient airway problems (for example, atelectasis, bronchospasm) and ventilator problems (for example, leaks and kinked tubes).

Critical and Cardiac Care Features

- The MX500 performs multi-lead **arrhythmia analysis** on the patient's ECG waveform at the bedside. It analyzes for ventricular arrhythmias, calculates heart rate, and generates alarms, including asystole, bradycardia, ventricular fibrillation.
- Up to 12 leads of **ST segment analysis** can be performed on adult patients at the bedside, measuring ST segment elevation and depression, and generating alarms and events. The user can trend ST changes, set high and low alarm limits, and set both ST and isoelectric measurement points. ST points can be set either relative to the J-point or directly by selecting a numeric value. Using ST Snippets, one-second wave segments can be compared with a baseline segment for each measured ST lead.
- **QT/QTc Interval Monitoring** provides the measured QT interval, the calculated heart-rate corrected QTc value, and a ΔQTc value, which tracks variation in the QT interval in relation to a baseline value.
- **SO₂** and **ScvO₂** measurements provide guidance for the treatment of sepsis treatment protocols.
- The **Parameter Histogram** View of the Vital Signs Trend allows the clinician to see, at a glance, the stability of the patient's condition for a selected time period.
- **ST Map** application shows ST changes over time in two multi-axis spider diagrams.
- **STE Map** adds gender-specific STE (ST Elevation) limits to ST Map. ST values violating these limits are indicated in red.
- **10-electrode lead ECG** data can be measured in diagnostic quality using conventional electrode placement with 10 electrodes. Alternatively it can be measured using the EASI lead system with five electrodes in EASI placement, or the Hexad lead system with six electrodes².
- High-performance pulse oximetry technologies perform accurately even in cases with low perfusion.
- Choice of Microstream, sidestream, or mainstream **CO₂ monitoring** for high-quality measurements with intubated and non-intubated patients.
- **Continuous cardiac output** and advanced hemodynamic assessment are provided using the PiCCOTM method without a pulmonary catheter³.
- **Integrated Pulmonary Index (IPI)**⁴ enables clinicians to quickly and easily assess a patient's ventilatory status and monitor changes in a patient's condition, facilitating more timely interventions.
- **Pulse Pressure Variation (PPV)** is calculated from beat-to-beat arterial pressure values. Pulse pressure is the difference between the systolic and diastolic pressure values for a single beat. Pulse pressure variation is defined as the maximal pressure less the minimum pressure divided by the average of these two pressures.
- **Clinical calculations** enable stored and manually entered data to be used to perform hemodynamic, ventilation and oxygenation calculations. Calculated data is displayed in both indexed and non-indexed format.
- **BIS** monitoring provides sedation assessment in critical and cardiac care environments.

² EASI/Hexad-derived 10-electrode lead ECGs and their measurements are approximations to conventional 10-electrode lead ECGs. As the 10-electrode lead ECG derived with EASI/Hexad is not exactly identical to the 10-electrode lead conventional ECG obtained from an electrocardiograph, it should not be used for diagnostic purposes.

³ PiCCOTM is a trademark of Pulsion Medical Systems AG

⁴ Microstream CO₂ only

¹ May not be available in all countries



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- **Spirometry** measurements help to manage ventilator settings and weaning.

Neonatal Monitoring Features

- Transcutaneous gas (TcGas) monitoring helps to optimize respiratory therapy in neonates.
- The Oxygen CardioRespiroGram (oxyCRG) screens provide a simultaneous presentation of up to three high-resolution trends:
 - Beat-to-beat heart rate (btbHR)
 - An oxygenation measurement trend (SpO₂)
 - Compressed respiration wave (Resp)
 This customized display gives clinicians a convenient overview of the neonatal patient's most important vital signs, helping them to identify significant events.
- Continuous oxyCRG recordings can be made at the bedside on the integrated recorder, and reports can be printed on a locally- or centrally-connected printer.
- Dual SpO₂ measurement provides clinical support through comparison and trending of the pulse oximetry values from two distinct patient sites.
- Trended values can also be viewed in the form of a histogram. The SpO₂ histograms can be trend histograms or real-time histograms with 1-second samples.
- Car Seat Assessment Record (CAR). This is a special period of event surveillance for neonates during a car seat test. During the CAR period, a real-time SpO₂ histogram is also generated with 1-second samples.
- Neonatal Event Review (NER), for automatic detection of patient status deterioration. NER is optimized for monitoring neonatal patients. For each event, an episode of four minutes of data sampled four times a second is stored, to help you keep a record of rapid changes in the condition of neonatal patients. Combi-events correlate apnea events with bradycardia and/or desaturations.
- The aEEG¹ presentation is a trend display of the amplitude-integrated EEG (aEEG). It uses amplitude compression samples. A trend of the sum of the electrode impedances of the respective lead is shown below the aEEG presentation as a quality indicator that supports interpretation of the aEEG. The monitor stores 24 hours of aEEG and electrodes impedances for all four channels.

IntelliVue Applications

Advanced Clinical Solutions

Clinicians are continuously drawing mental images from their observations of patients' vital signs. The IntelliVue's clinical decision support applications offer this dynamic "mind's eye view" directly on the monitoring screen display.

ProtocolWatch

ProtocolWatch allows clinicians to run clinical protocols that can monitor developments in the patient's condition. The SSC Sepsis Protocol runs on the ProtocolWatch application and is used in screening for severe sepsis, and monitoring its treatment.

Guardian Early Warning Scoring (Guardian EWS)

The Early Warning Scoring application provides fast, automated early warning scoring. Guardian EWS is fully customizable to match your hospital's clinical protocols:

- Configurable scoring parameters and thresholds
- Up to 20 parameters per EWS protocol
- Configurable MEWS thresholds
- Configurable action list
- Up to five EWS protocols per monitor

Guardian EWS provides three basic types of scoring:

- Single Parameter Scoring (SPS)
- Multiple Parameter Scoring, for example:
 - Modified Early Warning Scoring (MEWS)
 - UK National Early Warning Scoring (NEWS)
- Body System Structural Scoring, for example:
 - Pediatric Early Warning Scores (Tucker Schema)
 - Adult Body System Scores

Vital signs and clinical observations can be configured for early warning scoring.

- Vital signs, for example: pulse, temperature
- Clinical observations, for example: AVPU, concern
- Using customized labels, clinical observations can be labeled and defined according to a hospital's particular requirements at the time of installation
- ADT data, for example: weight, age
- Lab data
- Documentation

Escalating Monitoring: If a patient's condition is deteriorating or a closer observation is indicated in a particular situation, the monitor can be left with the patient and switched to a monitor profile that allows the vital signs to be checked with increased frequency.

Frequent Vitals: The monitor comes with the Frequent Vitals additional profile that can be used if some vital signs must be checked more frequently.

ST Map

ST Map provides a graphical display that can help clinicians recognize ST changes and their location in the heart more easily. ST Map collects ST values created from the frontal (limb leads) and horizontal (chest leads) plane into an integrated display. The maps are multi-axis portraits of the patient's ST segments as measured with the ST/AR arrhythmia algorithm.

Advanced Event Surveillance

Events are electronic records of episodes in the patient's condition. They can be used to drive alert notification to assist compliance to any protocol that is being used by the clinician.

Horizon Display

Horizon trends provide clinicians with a graphical visualization tool that enables the patients' current clinical status to be detected at a glance. By combining parameters together on the display, the clinician is assisted in their cognitive process of pattern recognition.

Loops

Up to six loops of each type can be stored and compared to detect respiratory changes more easily.

¹ Patient monitor software option C60



Screen Display Flexibility

Up to 20 different screens can be created per monitor, which means the clinician has the ability to have a screen created to match a specific clinical scenario in which the data that matters is displayed.

This streamlines the information that needs to be processed and interpreted to make the right decision at the right time.

Trends

- A **standard** trends database configuration is provided, designed to suit specific application areas. Patient data from up to 50 (100) measurement numerics can be sampled every 12 seconds, 1 minute, or 5 minutes, and stored for a period ranging from 4 to 48 hours.
- **Tabular Trends** (Vital Signs) show data for all measurement numerics in tabular form. Tabular Trends can either be viewed in a separate window or permanently displayed on specially designed screens.
- Each **NBP measurement** generates a column in the Vital Signs trend table. The values for the other measurements are added to provide a complete vital signs set for the NBP measurement time.
- With **Graphic Trends**, up to three rows of measurement trends can be displayed in graphic form, each combining up to four measurements. Graphic Trends can either be viewed in a separate window or permanently displayed on specially designed screens.
- **Screen Trends** permanently display trend data for periodic and aperiodic parameters in graphical format on special screens. The displayed time period can be set to 30 min, 1 h, 2 h, or 4 h.
- **High-Resolution Trends** allow the user to track fast-changing measurement trends with beat-to-beat resolution (four samples/second). The number of high-resolution trends available for display depends on the wave option purchased (for example eight for option A08).
- **Horizon Trends** show the deviation from a stored baseline.
- Trended values can be viewed in the form of a histogram. The SpO₂ histograms can be Trend Histograms with 1-second samples.
- Navigation arrows provide easy access to the stored trends. Trend data can be documented on a locally- or centrally-connected printer.
- With **Event Surveillance**, changes in patients' condition are automatically detected and an electronic record of data called an Episode is stored. The Episode can store:
 - 15 seconds of high-resolution wave trace
 - 4 minutes of data sampled 4 times a second, or
 - 20 minutes of data sampled every 12 seconds.

Event triggers can use the preset alarm limits or they can be user-defined. With user-defined triggers, event episodes are stored even when alarms are paused. A Manual Event SmartKey enables manual episode storage.

Event Annotation allows immediate or retrospective annotation of events using a user-defined list of event markers such as 'ventilated'.

Events can be stored in a database for retrospective review, and episode data including graphic event reviews can be documented on a locally- or centrally-connected printer. In addition, episode data without graphic elements can be documented on the integrated recorder¹. Events are also marked on the Event Line of an Information Center.

- The **Basic Event Surveillance** package and the **Neonatal Event Surveillance** package include one Event Group. The Basic Event Surveillance package can store 25 events over 24 hours.
- The **Advanced Event Surveillance** package offers increased storage capability, enabling the monitor to store up to:
 - 25 events for 8 hours
 - 25 events for 24 hours
 - 50 events for 8 hours
 - 50 events for 24 hours

Up to six user-defined Event Groups can be configured, each made up of up to four measurements. All six groups can be active at the same time. Advanced user-configurable trigger mechanisms allow the clinician to define event triggers combining information from up to four measurements. Either alarm limits or user-defined thresholds or deviations can be configured as event triggers. The user can set event notifications in order to be notified when an event is detected.

Transport Features

- The monitor's portable design with integrated ergonomic handle and (optional) compact bedhanger means it can be used for in-hospital transport.
- The monitor can operate using battery² power for 2-2.5 hours, depending on the monitor configuration, to let you safely and easily monitor patients during procedures or in-hospital transfer.
- The transition from bedside monitoring to transport is smooth and easy, with no need to disconnect patient cables or adjust any measurement or monitor settings.
- The monitor's network capability means it is ready for use as an integrated part of the hospital system.
- Specially-designed mounting solutions let you quickly disconnect the monitor for transport and reconnect to the mount after transport.

Patient Management

- **Universal Admission/Discharge/Transfer (ADT):** ADT information is shared between the networked monitor and the Philips Information Center. Information need only be entered once.
- **Stat Admit:** Allows you to admit a patient with a temporary patient identification. It can be used in cases when the patient ID is unknown or when the data is not yet available.
- **Quick Admit:** Allows you to quickly admit a patient using only a limited set of demographic data. You can enter the data with the keyboard or a barcode scanner.
- Patients can be transferred by disconnecting the Multi-Measurement Module, X2, or X3 from a monitor, and then reconnecting it at a new monitor. Patient demographics are stored in the Multi-Measurement Module, X2, or X3, so they do not have to be re-entered at the new monitor.

1. Integrated recorder is optional, see: ** on page 16

2. Battery required, see: ** on page 16



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Patient Data Documentation

An extensive range of Patient Reports can be printed:

- Event Review and Episode Reports
- 10-lead electrode lead ECG Reports
- Vital Signs
- Graphic Trends
- Cardiac Output Reports
- Wedge Procedure Reports
- Calculations Reports
- Histogram Reports
- Loops Report
- ST Map Reports
- QT Reports
- Alarm Limit Reports
- Drug Calculator Reports
- Real-time Wave Reports
- OxyCRG Reports

Report templates can be defined in advance, enabling print-outs tailored to each hospital's specific requirements to be started quickly. Reports can be printed on a locally- or centrally-connected printer, and can be initiated manually or automatically at user-defined intervals.

Recordings

The M1116C plug-in recorder records numerics for all active measurements and up to three wave forms. It can be used for local recording in the integrated module slots.

Electronic strip recording (option C10) allows alarm-triggered and manually started electronic strips to be captured in the monitor print database. They can then be reviewed on the monitor, and printed in the form of reports when a printer is available.

Alarms

The alarm system can be configured to present either the traditional HP/Agilent/Philips alarm sounds or sounds compliant with the IEC 60601-1-8 Standard.

Depending on the screen layout, alarm limits are permanently visible on the main screen. When an alarm limit is exceeded, it is signaled by the monitor in the following ways:

- An alarm tone sounds, graded according to severity.
- An alarm message is shown on the screen, color-coded according to severity.
- The numeric of the alarming measurement flashes on the screen.
- Alarm lamps flash for red and yellow alarms and are illuminated for technical INOPs.

The alarm-limit review page offers an overview of alarm limit settings and the possibility to modify these settings for all parameters.

A **Smart Alarm Delay** feature helps reduce the number of pulse-oximetry nuisance alarms¹.

If the monitor is connected via a network to the Information Center, alarming is simultaneous at the monitor and at the Information Center.

The nurse call relay has active open and closed contacts and a user-definable delay time.

Alarms are graded and prioritized according to severity:

- **Red Alarms***** identify a potentially life-threatening situation for a patient.
- **Yellow Alarms**** indicate conditions violating preset vital signs limits.
- **Yellow Alarms*** indicate arrhythmia alarms.
- **Technical Alarms (INOPs)** are triggered by signal quality problems, equipment malfunction, or equipment disconnect.

The Audio off/Pause Alarms function allows the user to switch off alarm tones with one touch or click while retaining visual alarm messages.

All alarms can be paused indefinitely or for one, two, three, five, or ten minutes depending on their configuration.

Alarm strip recordings are available on the integrated recorder or on a centrally-connected recorder.

Patented AutoLimits help caregivers manage alarms more effectively, automatically adapting the alarm limits to the patient's currently measured vital signs within a safe margin defined individually for each patient.

Visual and/or audible latching and non-latching alarm handling is available.

Alarm Advisor

Alarm Advisor provides feedback on recurring and continuous alarm limit violations. The information provided helps the clinician in adapting alarm limits more specifically for individual patients. Alarm Advisor can be enabled for:

- HR (low and high limit alarm, yellow and short yellow).
- PVCs/minute (high limit alarm).
- SpO₂ (low and high limit alarm).
- Pressure - ART, ABP, Ao, P (low and high limit alarm).
- RR (low and high limit alarm).
- awRR (low and high limit alarm).

Alarm Advisor can be switched on and off for each individual alarm (for example, for an SpO₂ low alarm, an HR low alarm, and so on).

Profiles

Profiles are predefined configuration settings for screens, measurement settings, and monitor properties. Each profile can be designed for a specific application area and patient category, for example OR adult, or ICU neonatal. Profiles enable a quick reaction to patient and care location changes: activating a profile with a particular patient category (adult, pediatric, or neonatal) automatically applies suitable alarm and safety limits and saves time usually spent carrying out a complete set-up procedure.

A selection of profiles for common monitoring situations is provided with the monitor. Profiles can also be created directly on the monitor or remotely on a PC and transferred to the monitor using the IntelliVue Support Tool. These created profiles can be changed, added to, renamed, or deleted.

Networking Capabilities

The monitor can operate as part of a networked system (wired/wireless) using the Philips IntelliVue Clinical Network interface. This includes:

- DHCP/BootP
- QoS Tagging
- 802.11 WLAN or Smart-hopping Interface (1.4 or 2.4 GHz)

¹ Not available in the USA and territories relying on FDA Market clearance.
The Smart Alarm Delay functionality is currently not available in China or in clinical environments under SFDA control.



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Other Bed Overview Capability

The Other Bed window lets you view a subset of the waveform and numeric information from another bed in the same Care Group on the hospital network. Other Bed information can either be viewed in a separate window or permanently displayed on specially designed screens. The alarm status of a care group or unit can be displayed on the monitor's screen. The Other Bed window can be configured to pop-up automatically when an alarm occurs at another bed.

Clinical Calculation Set

The clinical calculation set consists of Hemodynamic, Oxygenation, and Ventilation calculations.

Hemodynamic Calculations:

- Cardiac Index (C.I.)
- Stroke Volume (SV)
- Stroke Index (SI)
- Systemic Vascular Resistance (SVR)
- Systemic Vascular Resistance Index (SVRI)
- Pulmonary Vascular Resistance (PVR)
- Pulmonary Vascular Resistance Index (PVRI)
- Left Cardiac Work (LCW)
- Left Cardiac Work Index (LCWI)
- Left Ventricular Stroke Work (LVSWS)
- Left Ventricular Stroke Work Index (LVSWSI)
- Right Cardiac Work (RCW)
- Right Cardiac Work Index (RCWI)
- Right Ventricular Stroke Work (RVSWS)
- Right Ventricular Stroke Work Index (RVSWSI)
- Extra Vascular Lung Water Index (EVLWI)
- Intrathoracic Blood Volume Index (ITBVI)
- Global End Diastolic Volume Index (GEDVI)

Oxygenation Calculations:

- Arterial Oxygen Content (CaO_2)
- Venous Oxygen Content (CvO_2)
- Arteriovenous Oxygen Content (CavO_2)
- Oxygen Availability (DO_2)
- Oxygen Availability Index (DO_2I)
- Oxygen Consumption (VO_2)
- Oxygen Consumption Index (VO_2I)
- Oxygen Extraction Ratio (O_2ER)
- Alveolar-Arterial Oxygen Difference (AaDO_2)
- Percent Arteriovenous Shunt (Qs/Qt)

Ventilation Calculations:

- Minute Volume (MINVOL)
- Compliance (COMP)
- Dead Space (Vd)
- Dead Space/Tidal Volume Ratio (Vd/TV)
- Alveolar Ventilation (ALVENT)

Drug Calculator

The Drug Calculator allows you to calculate the fourth value when three of the following values are entered: dose, amount, volume, rate of infusion.

A titration table and drip table can be displayed and printed.

Measurement units can be converted (for example, lbs to kg). The Drug Calculator can also be configured to include a list of commonly used drugs using the IntelliVue Support Tool.

Service Features

The IntelliVue Support Tool helps technical personnel to:

- Carry out configuration, upgrades, and troubleshooting via the network, or on an individual monitor.
- Share configuration settings between monitors.
- Back up the monitor settings.
- Document configuration settings.

A password-protected:

- **Service Mode** ensures only trained staff can access service tests and tasks.
- **Configuration Mode** allows trained users to customize the monitor configuration.

Device Connections

The monitor can be connected to the following Multi-Measurement Modules:

- X1 (M3001A/M3001AL)
- X2 (M3002A)
- X3 (867030)
- MMX (867036)

The following Measurement Extensions can be connected to the Multi-Measurement Modules:

- 867039 Hemodynamic Extension
- 867040 Capnography Extension
- 867041 Microstream CO_2 Extension
- M3012A Hemodynamic Extension
- M3014A Capnography Extension
- M3015A Microstream CO_2 Extension
- M3015B Microstream CO_2 Extension

The monitor can also be connected to:

- A PC running the IntelliVue XDS Solution¹
- External devices via an IntelliBridge EC10 Interface Board
- Gas Analyzers
- A Philips or Patient Information Center (for example, PIC IX)
- An Adaptive Secondary Display (an off-the-shelf VESA-compliant display (non-touch))

Standard Interface Connections

Network Interface

The network interface provides the system with networking capability via a wired network connection.

Device Interface (USB Interface)

This interface allows connection of USB devices to the monitor, for example: mouse, keyboard, barcode scanner, Remote Control 865244, PCL5-supported printer.

¹ Requires the relevant IntelliVue XDS options to be installed on either the patient monitor, or on a PC running the XDS Solution with an activated license. Refer to the IntelliVue XDS Solution Technical Data Sheet for details.



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Further Optional Connection Interfaces

MIB/RS232 (two port) Interface Board (Option J13)

The Additional dual MIB/RS232 I/O boards can be installed. The MIB ports can be independently configured to be used for:

- Input for connection to a touchscreen.
- Numeric, wave, and alarm data export using a computer interface, to an automated anesthesia record keeper or a personal computer (not available in all countries).
- Data export can be configured for up to two MIB ports on the monitor. However only the first configured port provides wave export.
- Connection to a gas analyzer.
- Connection to iTemp (Philips Tympanic Temperature Module).

Adaptive Secondary Display (Option J15)

The Adaptive Secondary Display activates the DVI video interface. The output of this interface mirrors the content of the monitor display. The output supports VESA display timings allowing off-the-shelf displays to be used with the DVI output.

Remote Device Interface (Option J23)

Remote Device Interface provides a connector on the patient monitor for connection to the Remote Alarm Device.

Device (USB) Interface (Option J25)

The USB Interface adds a USB port on the right-hand side of the monitor.

Flexible Nurse Call Interface (Option J30)

The Flexible Nurse Call Interface provides a means for alarms generated on the monitor to be signaled on an external device such as a nurse call system, a beeper or a light. It provides three general alarm relays and one power fail alarm. The external device is connected to the alarm relay and alarms are triggered by criteria defined by the user. It has active open and closed contacts and a user-definable delay time.

IntelliBridge EC10 Interface Board (Option J32)

The IntelliBridge External Device Connection implements the physical layer of the ISO/IEEE 11073-30200 standard.

Driver software is available to support connectivity with a wide range of external medical devices.

In case the IntelliBridge EC5 ID Module is used to provide device identification, it also acts as a hardware adapter to the device-specific connector.

Wireless Infrastructure (Option J35)

- Wireless Infrastructure enables the monitor to function within a WLAN. The WLAN infrastructure is an IEEE 802.11 a/b/g/n network in the 2.4 GHz or 5 GHz bands.
- Smart-hopping Interface options, J45 (1.4 GHz [USA only]) and J47 (2.4 GHz) enable communication with a Philips IntelliVue Information Center (PIC) or a Patient Information Center IX (PIC IX), using the Philips Cellular Telemetry System (CTS), cellular infrastructure.
- The Short-Range Radio option (J46) provides wireless connectivity to the IntelliVue Remote Control.

Additional components are required to complete the system. Refer to the IntelliVue Clinical Network documentation for further information.

Advanced System Interface (Option J40)

The Advanced System Interface supports:

- An isolated RS232/5 V interface
- A Basic Nurse Call connector and two additional USB Connectors
- Input for connection to a touchscreen
- Numeric, wave, and alarm data export using a computer interface, to an automated anesthesia record keeper or a personal computer¹
- Connection to a gas analyzer

Remote Applications

With the appropriate connections you can access pre-configured applications made available by your hospital. The applications are hosted remotely on either a Citrix® XenApp® server or a standard IT Web server and can be displayed and operated on the bedside monitor screen.

Monitor Specifications

See the Technical Data Sheets for IntelliVue X1, IntelliVue X2, IntelliVue X3, and MMX Multi-Measurement Modules, Measurement Extensions, and plug-in module specifications.

Safety Specifications

The monitor, together with the X1 Multi-Measurement Module (M3001A/M3001AL), X2 Multi-Measurement Module M3002A, X3 Patient Monitor/Multi-Measurement Module (867030), MMX Multi-Measurement Module (867036), and all Measurement Extensions, comply with the Medical Device Directive 93/42/EEC and, among other standards, with:

- IEC 60601-1, Ed. 3:2012-08 (cons.)
- EN 60601-1:2006 + AC:2010 + A1:2013, Ed. 3
- ANSI/AAMI ES60601-1:2005/(R)2012, Ed. 3 (cons.)
- CAN/CSA-C22.2 No. 60601-1:14, Ed. 3 (cons.)
- IEC 60601-1-2:2007, Ed. 3
- EN 60601-1-2:2007 + AC:2010, Ed. 3
- IEC 60601-1-6:2010 + A1:2013
- EN 60601-1-6:2010
- IEC 60601-1-8:2006 + A1:2012
- EN 60601-1-8:2007 + A1:2013
- IEC 60601-2-49:2011
- EN 60601-2-49:2015

All applied parts are Type CF unless otherwise specified. They are protected against damage from defibrillation and electrosurgery. The possibility of hazards arising from software errors was minimized in compliance with:

- ISO 14971:2007
- EN ISO 14971:2012
- ANSI/AAMI ISO 14971:2010
- IEC 62304:2006
- EN 62304:2006 + AC 2008

¹ May not be available in all countries



Physical Specifications

Product	Max. Weight	W x H x D
MX500 Monitor	6.3 kg (13.9 lb)	327 x 288 x 190 mm (12.9 x 11.3 x 7.5 in)
865244 Remote Control	0.4 kg (0.9 lb)	53 x 172 x 40 mm (2.1 x 6.8 x 1.6 in)
866406 Remote Alarm Device	0.4 kg (0.9 lb)	261 x 32 x 81 mm (10.3 x 1.3 x 3.2 in)

Environmental Specifications

MX500 Monitors

Item	Condition	Range
Temperature Range	Operating	0–40°C (32–104°F) Or, 0–35°C (32–95°F): • When charging the battery • M3002A is mounted on back, or • With Smart-hopping Interface
	Storage	–20–60°C (–4–140°F)
Humidity Range	Operating	15–95% RH non-condensing
	Storage	5–95% RH non-condensing
Altitude Range	Operating	–500–3000 m (–1640–9842 ft)
	Storage	–500–4600 m (–1640–15091 ft)
Ingress Protection		IP21

Remote Control 865244

Item	Condition	Range
Temperature Range	Operating	0–40°C (32–104°F)
	Storage	–20–60°C (–4–140°F)
Humidity Range	Operating	15–95% RH non-condensing
	Storage	5–95% RH non-condensing
Altitude Range	Operating	–500–3000 m (–1640–9842 ft)
	Storage	–500–4600 m (–1640–15091 ft)

Performance Specifications

MX500 Power Specifications

Power Consumption	<70 W average
Line Voltage	100–240 V
Current	1.2–0.5 A
Frequency	50/60 Hz

WXGA (16:10) Display 12-inch

Type	308 mm active matrix color LCD (TFT)
Resolution	1280 x 800
Refresh Rate	59.9 Hz
Useful Screen	261.1 x 163.2 mm (10.28 x 6.43 in)
Pixel Pitch	0.204 x 0.204

Indicators

Alarms Off	Red (crossed out alarms symbol) LED
Alarms	Red/yellow/light blue (cyan) LED
On/Standby/Error	Green/red LED integrated in power switch
External Power	Green LED
Battery	Red–Green–Yellow LED

Sounds

• Audible feedback for user input
• Prompt tone
• QRS tone, or SpO ₂ modulation tone
• Four different alarm sounds
• Remote tone alarms on other beds in network
• Tone for Timer expired

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Display Wave Speeds	
Available for Standard Waves	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s with ±5% accuracy (guaranteed only for integrated displays)
Available for EEG and BIS Waves	6.25 mm/s, 12.5 mm/s, 15 mm/s, 25 mm/s, 30 mm/s, 50 mm/s with ±5% accuracy (guaranteed only for integrated displays)
Trends	
Resolution	100 numerics with: • 4 h @ 12 sec • 24 h @ 1 min • 48 h @ 5 min
High Res Trend Waves	
Measurements Available	HR, SpO ₂ , Resp, Pulse, tcpO ₂ , Perf, tcpCO ₂ , CO ₂ , ABP, PAP, CVP, ICP, CPP, BIS, CCO, AWP, Anesthetic Agents, ΔSpO ₂ inO ₂
Resolution	Measurement samples are taken at a resolution of 4 samples per second
Update Speed	Waves are drawn at a speed of 3 cm/minute
Events	
Information	Trigger condition and time, event classification and associated detailed view of episode data.
Episode Data	Configurable: • 4 minutes of high-resolution trend, or • 20 minutes of numerics trend @ 12 sec resolution, or • 15 seconds of 4 waves @ 125 samples/sec (Snapshot) including all current numerics, alarms and INOPs.
Capacity (max.)	25 or 50 events for either 8 or 24 hours
Alarm Signal	
System Delay	<4 seconds
Pause Duration	1, 2, 3 minutes or infinite, depending on configuration
Extended Alarm Pause	5 or 10 minutes
Review Alarms	
Information	All alarms/INOPs, main alarms on/off, alarm silence, and time of occurrence
Capacity	300 items
Real-Time Clock	
Range	From: January 1, 1997, 00:00 To: December 31, 2080, 23:59
Accuracy	Better than 4 seconds per day
Hold Time	• If powered by AC: Infinite • Without power or battery: At least 48 hours (typical: > 72 hours)
Buffered Memory	
Contents	Active settings, trends, patient data, real-time reports, events, review alarms
Hold Time	• If powered by AC: Infinite • Without power: At least 8 hours
865244 Remote Control Performance Specifications	
Power (when not connected to the USB interface of the monitor)	Two AA primary cells



Interface Specifications

Network

Standard	10Base-T and 100Base-TX (IEEE 802.3), auto-negotiation, full- and half-duplex
Connector	RJ45 (8 pin)
Isolation	Basic Insulation: • Reference Voltage: 250 V • Test Voltage: 1500 V

USB Interface

Standard	USB 2.0 high-speed
Connector	USB series 'Standard A' receptacle
Power	Low power port 4.4 V minimum, maximum load for all ports together 500 mA
Isolation	None

USB Interface (Two Ports)

Standard	USB 2.0 full-speed (embedded host)
Connector	USB series 'Standard A' receptacle
Power	Low power port 4.4 V min., max. load for all ports together 500 mA
Isolation	None

Video Interface^a

Connector	DVI-I (Digital Single Link)
Digital Video Signals	Single Link TMDS
HSYNC/VSYNC Signals	TTL
Vertical Frequency	59.9 Hz
Horizontal Frequency	49.3 Hz
Pixel Clock	71.0 MHz $\pm 0.5\%$
Resolution	VESA 1280 x 800 at 60 Hz, Reduced Blanking

a. Requires option J15 to enable video output

Dual MIB/RS232 Interface^a

Standard	IEEE 11073-30200
Connector	RJ45 (8 pin)
Mode	Software-controllable: • BCC (Rx/D/TxD cross over), or • DCC (Rx/D/TxD straight through)
Power	5 V $\pm 5\%$, 100 mA (max.)
Isolation	Basic Insulation: • Reference Voltage: 250 V • Test Voltage: 1500 V

a. Optional: See "Interface Options" on page 16

Flexible Nurse Call Interface^a

Connector	20 pin MDR (Mini D-Ribbon), active open and closed contacts
Contact	≤ 100 mA, ≤ 24 V dc
Isolation	Basic Insulation: • Reference Voltage: 250 V • Test Voltage: 1500 V
Delay	$<$ (Configured Latency +0.5 sec)

a. Optional: See "Interface Options" on page 16 and "Hardware Upgrade Options (866374)" on page 20

Basic Nurse Call Relay

Connector	Modular Jack 6P6C, active open and closed contact
Contact	≤ 100 mA, ≤ 24 V dc
Isolation	Basic Insulation: • Reference Voltage: 250 V • Test Voltage: 1500 V
Delay	Configured Latency +0.5 sec

IntelliBridge EC10 Interface Board^a

Connector	Modular Jack 8P8C
Connectivity	RS232/LAN
Power	5 V $\pm 5\%$ @ 0-100 mA ^b
Isolation	Double Insulation: • Reference Voltage: 250 V • Test Voltage: 4000 V

a. Optional: See "Interface Options" on page 16

b. Used to supply the IntelliBridge EC5 Module



Smart-hopping Interface^a 1.4 GHz (USA Only)	
Type	Internal WMTS Adapter
Technology	Compatible with Philips Cellular Telemetry System (CTS), cellular infrastructure
Frequency Band	WMTS, 1395-1400 MHz and 1427-1432 MHz
Modulation Technique	GFSK
Effective Radiated Power	Max. 10 dBm ERP (9 mW)

a. Optional: See "Interface Options" on page 16

Smart-hopping Interface^a 2.4 GHz	
Type	Internal ISM Adapter
Technology	Compatible with Philips Cellular Telemetry System (CTS), cellular infrastructure
Frequency Band	2.4 GHz ISM
Modulation Technique	GFSK
Effective Radiated Power	Max. 18 dBm ERP (64 mW)

a. Optional: See "Interface Options" on page 16

Advanced System Interface^a RS232/5 V	
Standard	IEEE 11073 30200
Connector	RJ45 (8 pin)
Mode	BCC (Rx/D/TxD cross over)
Power	5 V $\pm$ 5%, 100 mA (max.)
Isolation	Basic Insulation • Reference Voltage: 250 V • Test Voltage: 1500 V

a. Optional: See "Interface Options" on page 16

Remote Device Interface^a	
Connectors	14 pin MDR (Mini D Ribbon)
Input Voltage	18 V $\pm$ 5%
Input Power	1.8 W
Serial Signals	RS-422 compliant
Alarm Tones	Generated by Monitor

a. Optional: See "Interface Options" on page 16

802.11 Wireless Interface^a (Wireless Network Adapter)	
Type	Internal Wireless Adapter
Technology	IEEE 802.11a/b/g/n
Frequency Band	2.4 GHz and 5 GHz Band
USA	• 2.400-2.483 GHz • 5.15-5.35 GHz • 5.72-5.825 GHz
Europe	• 2.400-2.483 GHz • 5.15-5.35 GHz • 5.470-5.725 GHz
Japan	• 2.400-2.483 GHz • 5.15-5.25 GHz • 5.25-5.35 GHz • 5.470-5.725 GHz
China	• 2.400-2.483 GHz • 5.725-5.85 GHz
Modulation Technique 802.11b/g/n	• DSSS (CCK, DQPSK, DBPSK) • OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
Modulation Technique 802.11a/n	• OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
Bandwidth	20/40 MHz (nominal)
Effective Radiated Power (ERP) Max.	• 2.400-2.483 GHz: 16 dBm (40 mW) • 5.150-5.725 GHz: 15 dBm (32 mW) • 5.745-5.825 GHz: 13 dBm (20 mW)

a. Optional: See "Interface Options" on page 16

Short-Range Radio Interface^a	
Type	Internal SRR Interface
Technology	IEEE 802.15.4
Frequency Band	2.4 GHz ISM (2.400-2.483 GHz)
Modulation Technique	DSSS (O -QPSK)
Effective Radiated Power	Max. 0 dBm (1 mW)

a. Optional: See "Interface Options" on page 16



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Measurement Server Link (MSL)

Connectors	MSL Out (proprietary)
Voltage	48 V $\pm$ 10%
Power	12 W
Power Sync.	5 V CMOS Level, 78.125 kHz (typical)
LAN Signals	IEEE 802.3 10Base-T compliant
Serial Signals	RS-422 compliant

ECG Sync Output/Analog ECG Output

General	Connector	(1/4 in stereo phone jack with tip, ring, sleeve)
	Isolation	None
	Short Circuit Current	<13 mA
Analog ECG Output (ring, tip) (Ring/Channel 2 is configurable to either Analog ECG Output or Digital Pulse Output)	Gain Error	<15%
	Baseline Offset Error	<150 mV
	Bandwidth	1-100 Hz
	Output Voltage Swing	$\pm$ 4 V (min.)
	Signal Delay	<20 ms
	Signal delay with older versions of the M3001A Multi-Measurement Module ^a	<30 ms
Digital Pulse Output (ring) (Ring/Channel 2 is configurable to either Analog ECG Output or Digital Pulse Output)	Output Low Voltage Level	<0.4 V @ I = -1 mA
	Output High Voltage Level	>2.4 V @ I = 1 mA
	Pulse Width	100 ms $\pm$ 10 ms (active high)
	Pulse Rise Time	<1 ms
	Signal Delay	<25 ms
	Signal delay with older versions of the M3001A Multi-Measurement Module ^a	<35 ms

^a Identifiable with the serial number prefix DE227 or DE441 and option string A01

Battery Specifications

Philips high-power lithium ion battery M4605A, 10.8 V 6000 mAh:

- Weight: 490 g per battery.
- Status LEDs indicate charge status of batteries.
- Safety: Complies with UL1642 (UL recognized).
- Electromagnetic Compatibility: Complies with the requirements for FCC Type B Computing Device, and EN 61000-4-2 and EN 61000-4-3.
- Communication Standard: Complies with the SMBus specification v1.1.

Battery Operating Time

New and fully charged battery:

- Basic Monitoring Configuration: 3 hours (brightness set to optimum, Multi-Measurement Module connected, NBP measurement every 15 minutes).
- Extended Monitoring Configuration: 2.5 hours (brightness set to optimum, Multi-Measurement Module and Measurement Extension connected, NBP every 15 minutes, Recorder, Pressure, Temperature Modules connected).

Battery Charge Time

- Monitor switched off: 3 hours.
- Monitor in use: Up to 5 hours, depending on monitor configuration.

Ordering Information

Ordering information for the 866064 (MX500) is given here. See the individual Technical Data Sheets for detailed ordering information for the Philips Multi-Measurement Modules, Measurement Extensions, and plug-in modules.

Monitor Capability Options

Basic Functionality	866064	Option
General Care Software (Default) ^a		H02
Intensive Care Software		H12
Neonatal Care Software		H22
Anesthesia Software		H32
Cardiac Care Software		H42

^a Check availability in your country



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Application Options¹

Measurement Capability	866064	Option
Support Two Additional Pressures		M06
Support One Additional SpO ₂		M20
Clinical Packages	866064	Option
Customization Packet		CP0
Extended ECG Capabilities		CP2
Clinical Data Visualization		CP3
Extended Alarming Capabilities		CP4
Access to Information		CP5
Clinical Applications	866064	Option
Drug Calculator		C05
Basic Event Surveillance		C06
Advanced Event Surveillance		C07
Parameter Histograms		C09
eDocumentation		C10
Alarm Advisor		C46

XDS Connectivity

Options	866064	Option
XDS Connectivity		X00
XDS Clinical Workstation		X30
XDS Database		X40

ProtocolWatch

ProtocolWatch	866064	Option
Severe Sepsis Screening		P01
SSC Sepsis Protocol		P02
IntelliVue Guardian EWS		P05

¹ Availability may depend on choice of Hxx option

Hardware Options

Hardware	866406	Option
Remote Alarm Device		A01
Hardware Add-Ons	866064	Option
Remote Control		E00
Bed Hanger Mount		E21
Quick Release Mount		E22
One Li-ion Battery		E24

Interface Options

Wired Interfaces^a	866064	Option
MIB/RS232 (2 ports) Interface ^b		J13
Adaptive Secondary Display		J15
Remote Device Interface		J23
USB Interface		J25
Flexible Nurse Call Interface		J30
IntelliBridge EC10 Interface Board		J32
Advanced System Interface		J40

a. Check availability in your country

b. Hardware supports multiple boards of this type

Wireless Interfaces^a	866064	Option
802.11 Wireless Interface		J35
Smart-hopping Interface 1.4 GHz ^b		J45
Short-Range Radio		J46
Smart-hopping Interface 2.4 GHz		J47

a. Check availability in your country

b. USA only



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Measurement Options

Measurements	Product No.	Option
Multi-Measurement Modules		
X1 Multi-Measurement Module Including Resp, ECG (inc. EASI/ Hexad), NBP, and Pressure/ Temperature See the Multi-Measurement Module Technical Data Sheet for details	M3001A	
Philips FAST SpO ₂		A01
Masimo SET SpO ₂		A03 ^a
Nellcor OxiMax SpO ₂		A04 ^a
Add Press/Temp		C06
Add Press/Temp and Conventional 10-Electrode Lead ECG		C12
X1 Multi-Measurement Module Including Resp, ECG (inc. EASI/ Hexad), NBP, Masimo rainbow SET SpO ₂ , and Pressure/Temperature See the Multi-Measurement Module Technical Data Sheet for details	M3001AL	A05
Add Press/Temp		C06
Add Press/Temp and Conventional 10-Electrode Lead ECG		C12
X2 Multi-Measurement Module Including Resp, ECG (inc. EASI/ Hexad), NBP, and Pressure/ Temperature See the IntelliVue X2 Patient Monitor Technical Data Sheet for details	M3002A	
Philips FAST SpO ₂		A01
Masimo SET SpO ₂		A03 ^a
Nellcor OxiMax SpO ₂		A04 ^a
Masimo rainbow SET SpO ₂		A05
Add Press/Temp		C06
Add Respiration CO ₂ ready ^b		C14
X3 Patient Monitor/ Multi-Measurement Module See the IntelliVue X3 Patient Monitor Technical Data Sheet for details	867030	
Three Wave Capability		A03
Four Wave Capability		A04
Five Wave Capability		A05
Dual SpO ₂		B02

Measurements	Product No.	Option
Respiration CO ₂ Ready		B03
Dual Pressure and Temperature		B06
Philips FAST SpO ₂		SP1
Masimo rainbow SET SpO ₂		SP5
Nellcor OxiMax SpO ₂		SP6
MMX Multi-Measurement Module See the IntelliVue MMX Technical Data Sheet for details	867036	
Dual SpO ₂		B02
Respiration CO ₂ Ready		B03
Dual Pressure and Temperature		B06
Philips FAST SpO ₂		SP1
Masimo rainbow SET SpO ₂		SP5
Nellcor OxiMax SpO ₂		SP6
Measurement Extensions		
Microstream CO₂ Extension Including Microstream CO ₂ Measurement	867041	
Dual Invasive Pressure, Temperature, and Cardiac Output		B05
Dual Invasive Pressure, Temperature		B06
Dual Invasive Pressure, Temperature, Cardiac Output, and PICCO		B10 ^c
Capnography Extension Including Mainstream or Sidestream CO ₂ Measurement	867040	
Dual Invasive Pressure, Temperature, and Cardiac Output		B05
Dual Invasive Pressure, Temperature		B06
Dual Invasive Pressure, Temperature, Cardiac Output, and PICCO		B10 ^d
Hemodynamic Extension	867039	
Dual Invasive Pressure, Temperature, and Cardiac Output		B05
Dual Invasive Pressure, Temperature		B06
Dual Invasive Pressure, Temperature, Cardiac Output, and PICCO		B10
Microstream CO₂ Extension	M3015A	

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Measurements	Product No.	Option
Add Press/Temp		C06
Microstream CO₂ Extension Including Dual Invasive Pressure and Temperature Measurements	M3015B	C08
Hemodynamic Extension Including Press, Temp, Press/Temp	M3012A	
Add C.O.		C05
Add C.O./CCO		C10
Capnography Extension	M3014A	
Add Press, Press/Temp and C.O.		C05
Add Press and Press/Temp		C07
Add Press, Press/Temp and C.O./CCO		C10
Measurement Modules		
See Module Technical Data Sheets for details		
Invasive Blood Pressure	M1006B ^a	
SO ₂	M1011A	
Cardiac Output with Optional CCO	M1012A	
Spirometry	M1014A	
Philips FAST SpO ₂	M1020B	A01
Nellcor OxiMax SpO ₂	M1020B	A04 ^a
EEG	M1027B	
Temperature	M1029A	
BIS	M1034B	
Thermal Array Recorder	M1116C	
IntelliBridge EC10	865115	
NMT	865383	
G7m Gas Analyzer	866173	
Masimo rainbow SET SpO ₂	867191	SP5
Masimo SET SpO ₂	867192	SP3
Gas Analyzers		
IntelliVue TcG10 ^a	865298	

a. Check availability in your country.

b. Not available with option A05

c. Option B10 is not available for the 867041 Microstream CO₂ extension in the USA and territories relying on FDA market clearance

d. Option B10 is not available for the 867040 Capnography Extension in the USA and territories relying on FDA market clearance

e. Option C01 provides an analog output signal

Related Products

Product	Product No.	Option
Input Devices		
Slimline Keyboard with Protective Cover	M8024A	A01
Mouse; Wired	M8024A	B01
Trackball; Wired	M8024A	C01
Trackball; Wireless	M8024A	C02
Tabletop Wired Trackball	M8024A	C03
Remote Control	865244	
IntelliVue Support Tool (DVD) Orderable via InCenter: http://www3.medical.philips.com/resources/hsg/docs/en-us/custom/intellivue_order.asp	M3086A	

Accessories

External Battery Charger	865432
IntelliVue Battery Extension (provides additional power to a combination of Measurement Extension and M3002A IntelliVue X2 Multi-Measurement Module for situations when no mains power is available, for example, during transport).	865297

Cables

Length	Description	Product/Option
MSL Cables		
0.75 m	Monitor to Multi-Measurement Module	M8022A SC1
2 m	Monitor to Multi-Measurement Module	M8022A SC2
4 m	Monitor to Multi-Measurement Module	M8022A SC4
10 m	Monitor to Multi-Measurement Module	M8022A SC6
MIB/RS232 Cables		
1.5 m	Serial Cable	M8022A SR2
3.0 m	Serial Cable	M8022A SR3



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Length	Description	Product/Option
10.0 m	Serial Cable	M8022A SR6
15.0 m	Serial Cable	M8022A SR7
25.0 m	Serial Cable	M8022A SR9
Touch Cables		
1.5 m	Touch Cable	M8022A TC2
3.0 m	Touch Cable	M8022A TC3
10.0 m	Touch Cable	M8022A TC6
15.0 m	Touch Cable	M8022A TC7
25.0 m	Touch Cable	M8022A TC9
Basic Nurse Call Relay Cables		
3.0 m	Standard (Backward Compatible) Nurse Paging Relay Cable ^a	M8022A NS3
10.0 m	Cable	M8022A NS6
Advanced Nurse Call Relay Cables		
10.0 m	Cable	M8022A NC6
ECG Out Cable		
3.0 m	Standard ECG Out Cable ^b	M8022A SY3
25.0 m	ECG Sync Extension Cable	M8022A SY9
Remote Alarm Device Cables		
1.5 m	Connect Cable	M8022A HF2
3.0 m	Connect Cable	M8022A HF3
10.0 m	Connect Cable	M8022A HF6
15.0 m	Connect Cable	M8022A HF7
25.0 m	Connect Cable	M8022A HF9

a. One end terminated with 6P6C connector; other end w/o connector.
b. Both ends terminated with a 1/4 in phone plug.

Software Upgrade Options (866364)

Description	Option
Waves	
Upgrade from 4 to 6 waves	A06
Upgrade from 6 to 8 waves ^a	A08
Clinical Applications	
Drug Calculator	C05
Basic Event Surveillance	C06
Advanced Event Surveillance	C07
Parameter Histograms	C09
eDocumentation	C10
Alarm Advisor	C46
aEEG	C60
Interfaces	
Adaptive Secondary Display	J15
ProtocolWatch	
Severe Sepsis Screening	P01
SSC Sepsis Protocol	P02
Measurement Capability Options	
Support One Additional SpO ₂	M20
XDS Connectivity Options	
XDS Connectivity	X00
XDS Clinical Workstation	X30
XDS Database	X40
Software	
Upgrade to Current Software Revision	SUM

a. Check availability in your country.



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Hardware Upgrade Options (866374)

Description	Option
Interfaces	
MIB/RS232 Interface (2 ports)	J13
Remote Device Interface	J23
USB Interface	J25
Flexible Nurse Call Interface	J30
IntelliBridge EC10 Interface Board	J32
802.11 Wireless Interface	J35
Advanced System Interface	J40
Smart-hopping Interface 1.4 GHz ^a	J45
Short-Range Radio	J46
Smart-hopping Interface 2.4 GHz	J47

^a USA only

Mounting Information

For mounting hardware, contact your local Philips sales representative. For more information, see: <http://www.usa.philips.com/healthcare/solutions/patient-monitoring/mounting-solutions>

Documentation

All documentation is available in .pdf format on documentation DVD that is shipped with the product. Additionally, a predefined number of the Instructions for Use ships with each order.

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866064 complies with the requirements of the Council Directive 93/42/EEC of 14 June 1993 (Medical Device Directive) as amended.

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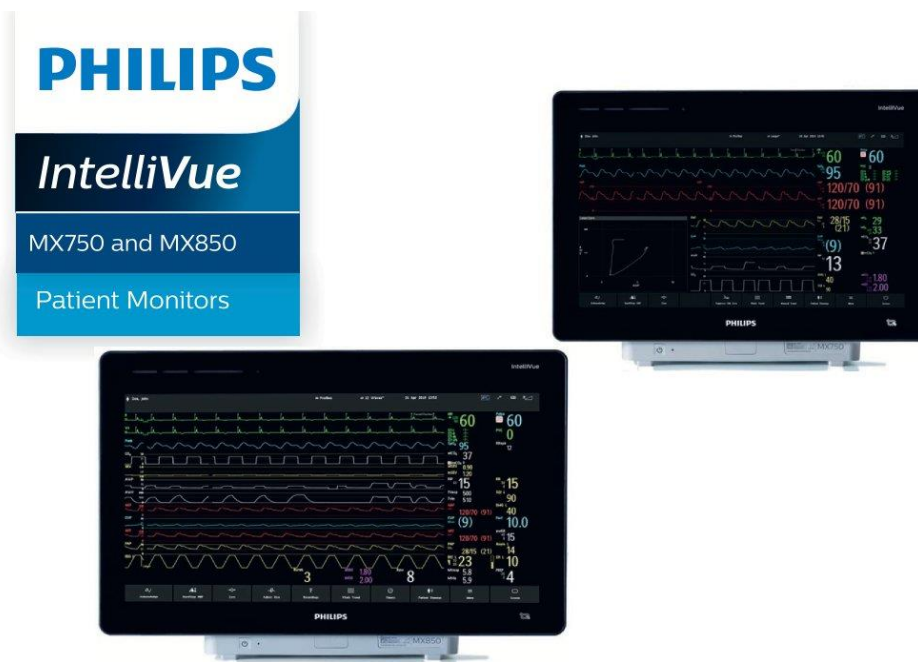


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Apéndice B del Anexo 1. Ficha técnica del monitor multiparamétrico Philips IntelliVue MX850.



IntelliVue MX750 and MX850 Patient Monitors

Philips 866471 & 866470, technical data sheet

Release N.01

The IntelliVue MX750 and MX850 Patient Monitors offer a flexible and modular monitoring solution, designed to suit a broad spectrum of needs. The monitor can be connected to the Philips Multi-Measurement Module family with its extensions, plug-in measurement modules, and the IntelliVue gas analyzers to extend its functionality with plug-and-play convenience. Dedicated configurations are available for the anesthesia, critical, cardiac, and neonatal care environments. The built-in Citrix (r) Xen (r) receiver and the HTML5 web applications platform, and the optional integrated PC (IPC) allows access to relevant patient information residing on the hospital's intranet.

Features

- Intuitive user interface.
- Easy-to-read, easy-to-use touchscreen.
- Simple menu hierarchy gives fast access to all basic monitoring tasks.
- Contactless identification and communication via RFID and NFC
- Screen layouts are easily adjustable, allowing flexible display of measurement information.

- The monitor can be configured to automatically vary the screen brightness to the ambient light conditions. The range within which this adaption is made is configurable.
- Previous/Next Screen function provides access to the 10 most recently used screens including the last three modified screens.
- Temperature, height, and weight can be configured either in metric or imperial units. Pressure measurements can be displayed in kPa or mmHg. Gases can be displayed in kPa or mmHg.
- Patient data management with tabular and graphic trends, and high-resolution trends to track changes with beat-to-beat resolution.
- Drug, ventilation, hemodynamic, and oxygenation calculations.
- User or case-specific profiles enable rapid case turnover.
- Patented automatic alarm limits help clinicians provide care more efficiently.
- Alarm Advisor provides feedback on recurring and continuous alarm limit violations, helping clinicians to adapt alarm limits more specifically for individual patients.

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- Event Surveillance including neonatal event review (NER) for automatic detection of patient status deterioration.
 - IntelliVue early warning scoring (EWS) calculates a score based on vital signs to help recognize early signs of deterioration in patients.
 - Tympanic Temperature measurement^{1,2}. In-Ear SpotCheck thermometer delivers accurate temperature readings in less than two seconds.
 - Bed-to-bed overview provides clinicians with an overview of all the patient beds in their care.
 - Choice of input devices: touchscreen, trackball, USB keyboard, mouse, or barcode scanner.
 - Capable of functioning in a wireless infrastructure.
 - Graphical measurement window shows which measurements are being measured by which device, making it easier to resolve measurement label conflicts.
 - The Timers application enables notifications to be set when a specific time period has expired.
 - Additional independent display capability using IntelliVue XDS Remote Display, IntelliVue AD75 and AD85 Active Displays³, or the IPC.
- Note:** The AD75/AD85 Active Display is not available in the USA and territories relying on FDA market clearance, and may also not be available in other geographies.
- The IPC can host Windows applications and safely share the display with the monitor's real-time system or drive a second display, independent of size and resolution. The content displayed on the second display can be different from the content on the main display of the monitor and can show either real-time vital signs information, PC applications, or both at the same time. A separate isolated LAN interface allows access to the hospital's network independent of the monitor. Six USB interfaces provide connectivity to external computer devices, for example, printers or input devices such as the touch interface of the selected display.
 - Bedside information access using the IPC, Citrix (r) Xen (r) receiver, HTML5 web application functionality, and/or the IntelliVue XDS Clinical Workstation.
 - XDS Database (option X40) enables the collection and storage of vital signs information (numeric data only - no waves), for example, heart rate, pressure on an external SQL database.

Indications for Use

The monitors are indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.

The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI ECT1).

¹ Requires Option J13 - MIB/RS232 (2 ports) interface

² See the IntelliVue Tympanic Temperature Module (Philips 866149) TDS for further details.

³ See the IntelliVue AD75 and AD85 Active Displays TDS for further details.

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.

The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

The IntelliVue NMT Module is intended to be used as an objective neuromuscular transmission monitor, using accelerometry for measuring the muscle contraction following an electrical stimulation of a peripheral nerve. The NMT Module is intended to be used with adult and pediatric patients.

The Masimo rainbow SET measurement is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRac). The Masimo rainbow SET measurement is indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused.

Modularity

The monitor's functionality can be extended by connecting the Philips Multi-Measurement Modules with extensions, Philips plug-in modules via the FMX-4, and gas analyzers - with plug-and-play convenience.

The monitor is available as standalone or networked solution.

The monitor's modular design allows new capabilities to be added in the future as monitoring requirements change. This upgradability provides the security of knowing the monitor can be enhanced and updated as practices and technologies advance, protecting long-term investments.

Main components

Display

The MX750 monitor has a 19 inch Full HD color LCD (TFT) display with a wide viewing angle, providing high-resolution waveform and data presentation.

The MX850 monitor has a 22 inch Full HD color LCD (TFT) display with a wide viewing angle, providing high-resolution waveform and data presentation.

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Remote display

IntelliVue XDS Remote Display allows the remote display of an IntelliVue Patient Monitor¹ on a PC connected to the same network. It can be configured to allow remote operation of the patient monitor. It is intended to be used as an additional independent display for viewing and operation by clinicians and nurses.

Integrated PC (IPC)²

The IPC is a fan-less, medical grade PC residing within the monitor and as such designed for continuous operation in the patient vicinity.

The IPC is shipped with Windows 7 as the operating system and can host applicable applications. These applications can be:

- Windows applications, such as Internet Explorer,
- Philips applications such as iSite clients or an application launch pad,
- Third party applications
- Hospital owned and developed software.

The IPC is designed as an "open" PC and can be serviced and maintained by the hospital's IT department as well as by Philips.

A separate isolated LAN interface allows access to the hospital's network independent of the monitor.

The IPC can safely share the main display with the monitor (single display setup) and/or be used with a standard or a medical grade display (dual display setup), either provided by Philips or another manufacturer.

The IPC supports displays with or without touch operation.

The IPC has six USB ports (five at the rear and one at the side of the monitor) supporting High-Speed mode for computer peripherals such as keyboard, mouse, barcode scanner, touch display, and so forth

User interface

The graphical user interface is designed for fast and intuitive operation, and ensures clinicians quickly feel at ease using the monitor.

- Configurable SmartKeys with intuitive icons allow monitoring tasks to be performed quickly and easily, directly on the monitor screen.
- Waves and numerics are color-coded, colors are customizable.
- The MX750 supports up to 12 waves simultaneously.
- The MX850 supports up to 16 waves simultaneously.
- For 12-lead ECG monitoring, the monitors can display 12 real-time ECG waves, with a rhythm strip and all ST values.
- Flexible screen layout allows optimal use of the available display space, for example, waves can be overlapped or wave size can adjust dynamically depending on the number of waves configured for the space.
- The Basic Help provides on-screen operating help, explaining INOP and alarm messages.

Touchscreen operation

The MX750 and MX850 patient monitors have screens that use capacitive touch technology. This technology supports multi-finger touch and swipe gestures. (similar to a smartphone).

Contactless identification and communication

Contactless identification via RFID (Radio Frequency Identification) and communication via NFC (Near Field Communication). User identification functionality that allows users to log in at the monitor and provides permissions for specific actions at the monitor.

Input devices

Supported input devices include the following

USB-compatible off-the-shelf computer accessories:

- **Mouse:** Any specified USB mouse or trackball may be used for data entry.
- **Barcode scanner:** A USB barcode scanner in 'keyboard emulation mode' can be used via a USB connection.
- **Computer keyboard:** A USB-compatible off-the-shelf keyboard can be connected to the monitor for data entry.
- **Simulated keyboard:** If alpha or numeric data entry is required, for example to enter patient demographics, an on-screen keyboard is automatically displayed.

Input devices can be used individually or in combination.

IntelliVue AD75 and AD85 Active Displays

The AD75 and AD85 Active Displays can be used as additional independent displays for viewing screens generated by the (wired LAN) connected IntelliVue MX750 or MX850 patient monitor. The Active Displays provide encrypted audio and visual alarm signals for alarms generated by the connected patient monitor. The Active Displays can operate the connected patient monitor including start/stop of physiological measurements, change measurement modes, change alarm limits and acknowledge alarms.

Note: The AD75/AD85 Active Display is not available in the USA and territories relying on FDA market clearance, and may also not be available in other geographies.

X3 patient monitor/Multi-Measurement Module (867030)

The X3 can be used:

- As a stand-alone patient monitor.
 - As a Multi-Measurement Module for the IntelliVue family of patient monitors.
- The X3 can be connected to the monitor via an FMX-4 Module Rack.



It can also be placed in patient vicinity connecting it to the monitor via cable. It sends measurement waves and numerics to the monitor and generates alarms and INOPs.

The X3 can simultaneously monitor ECG (using 3-, 5-, 6-, or 10-lead sets, including arrhythmia and ST monitoring), respiration, oxygen saturation of arterial blood (SpO₂³), noninvasive blood pressure (NBP), two invasive pressures, temperature, and CO₂. The X3 stores trend data, patient demographic information and measurement settings.

Combining its role as Multi-Measurement Module with that of stand-alone monitor, the X3 is particularly suited to transport situations. When the X3 is disconnected from the host monitor, it continues to monitor the patient as a stand-alone monitor running on battery power, eliminating the need for a separate transport monitor.

1. Requires a PC running the IntelliVue XDS Software

2. Optional

3. Choice of Philips FAST SpO₂, Masimo SET SpO₂, Nellcor Oximax SpO₂ or Masimo rainbow SET SpO₂ (including certain Masimo rainbow parameters)

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When the X3 is reconnected to a host monitor, it resumes its role as a Multi-Measurement Module, uploading trend data, patient demographic information and measurement settings, and allowing fully continuous monitoring.

The X3 can operate using battery power for over five hours with basic monitoring configuration to let you safely and easily monitor patients during in-hospital transfer. During in-hospital transport, the X3 can power the Measurement Extensions 867039, 867040, and 867041.

MMX Multi-Measurement Module (867036)

The MMX Multi-Measurement Module can be connected to the monitor via an FMX-4 Module Rack. It can also be placed in patient vicinity connecting it to the monitor via cable.

It sends measurement waves and numerics to the monitor and generates alarms and INOPs.

The MMX can simultaneously monitor ECG (using 3-, 5-, 6-, or 10-lead sets, including arrhythmia and ST monitoring), respiration, oxygen saturation of arterial blood (SpO₂), noninvasive blood pressure (NBP), two invasive pressures, temperature, and CO₂. Diagnostic 12-lead capability is optionally available.

The MMX stores trend data, patient demographic information and measurement settings and transfers it to a connected IntelliVue Patient Monitor.



X1 Multi-Measurement Module (M3001A/M3001AL)

The X1 Multi-Measurement Module can be connected to the monitor via an FMX-4 Module Rack. It can also be placed in patient vicinity connecting it to the monitor via cable.

It sends measurement waves and numerics to the monitor and generates alarms and INOPs.

The X1 can simultaneously monitor ECG (using 3-, 5-, 6-, or 10-lead sets, including arrhythmia and ST monitoring), respiration, oxygen saturation of arterial blood (SpO₂), noninvasive blood pressure (NBP), and either invasive pressure or temperature. Diagnostic 12-lead capability is optionally available. The X1 stores trend data, patient demographic information and measurement settings and transfers it to a connected IntelliVue Patient Monitor.



X2 Multi-Measurement Module (M3002A)

The X2 can be used:

- As a stand-alone patient monitor.
- As a Multi-Measurement Module for the IntelliVue family of patient monitors.



The X2 Multi-Measurement Module can be connected to the monitor via an FMX-4 Module Rack.

It can also be placed in patient vicinity connecting it to the monitor via cable. It sends measurement waves and numerics to the monitor and generates alarms and INOPs.

The X2 can simultaneously monitor ECG (using 3-, 5-, 6-, or 10-lead sets, including arrhythmia and ST monitoring), respiration, oxygen saturation of arterial blood (SpO₂), noninvasive blood pressure (NBP), and either invasive pressure and temperature, or CO₂. The X2 stores trend data, patient demographic information and measurement settings.

Combining its role as a Multi-Measurement Module with that of stand-alone monitor, the X2 is particularly suited to transport situations. When the X2 is disconnected from the host monitor, it continues to monitor the patient as a stand-alone monitor running on battery power, eliminating the need for a separate transport monitor.

When the X2 is reconnected to a host monitor, it resumes its role as a Multi-Measurement Module, uploading trend data, patient demographic information and measurement settings, and allowing fully continuous monitoring. The X2 can operate using battery power for over three hours with basic monitoring configuration to let you safely and easily monitor patients during in-hospital transfer.

Measurement extensions

The following Measurement Extensions can be slotted onto an X1, X2, X3, or MMX:

- The **867039 Hemodynamic Extension**: Adds temperature, two pressures, and optionally cardiac output/PiCCO.
- The **867040 Capnography Extension**: Adds mainstream or sidestream capnography, and optionally temperature, two pressures, and cardiac output/PiCCO².
- The **867041 Microstream® CO₂ Extension**: Adds Microstream capnography, and optionally temperature, two pressures, and cardiac output/PiCCO⁴.
- The **M3012A Hemodynamic Extension**: Adds temperature, pressure, an additional pressure or a temperature and optionally cardiac output/PiCCO.
- The **M3014A Capnography Extension**: Adds mainstream or sidestream capnography, and optionally one pressure plus either a pressure or a temperature and cardiac output/PiCCO.
- The **M3015B Microstream CO₂ Extension**: Adds Microstream CO₂, two pressures and a temperature.

1. Choice of Philips FAST SpO₂, Masimo SET SpO₂, Nellcor Oximax SpO₂ or Masimo rainbow SET SpO₂ (including certain Masimo rainbow parameters).

2. PiCCO is not available for the 867040 Capnography Extension in the United States and territories relying on FDA market clearance.

3. Microstream is a registered trademark of Orion Systems Ltd.

4. PiCCO is not available for the 867041 Microstream CO₂ extension in the United States and territories relying on FDA market clearance.

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Module Racks with plug-in modules



4-Slot Module Rack FMX-4 (866468) with Multi-Measurement Module Mount

The FMX-4 is available with four slots for plug-in measurement modules (with, or without a Multi-Measurement Module Mount on the side). The Patient Monitors can have up to two FMX-4 Module Racks, a maximum of eight plug-in modules are supported. The maximum number of specific module types that can be used simultaneously in an FMX-4 is: four pressure modules, four temperature modules, four IntelliBridge modules (any combination). The patient monitors support up to two pulse oximetry channels and four invasive pressure channels simultaneously (sourced either by plug-in modules or Multi-Measurement Modules).

Plug-in modules

Individual plug-in measurement modules are available:

- M1006B Invasive Blood Pressure
- M1011A Intravascular Oxygen Saturation Module (SO₂)
- M1012A Cardiac Output/Continuous Cardiac Output
- M1020B SpO₂
- M1027B Electroencephalograph (EEG/aEEG)
- M1029A Temperature
- M1034B Bispectral Index (BIS™)¹
- 865383 Neuromuscular Transmission (NMT)
- 866173 G7m Gas Analyzer
- 867191 SpO₂ (Masimo rainbow SET)
- 867192 SpO₂ (Masimo SET)
- 867184 Masimo O₃
- 867185 Masimo CO₂
- M1116B Thermal Array Recorder
- M1116C Thermal Array Recorder
- 865115 IntelliBridge EC10

IntelliVue gas analyzers

The G7m Gas Analyzer Module measures the five most commonly used anesthetic gases, as well as N₂O and CO₂. It also provides inspiration and expiration values for display on IntelliVue Patient Monitors and the values required for MAC calculation in the IntelliVue Patient Monitors.

The IntelliVue G7m Gas Analyzer features automatic agent identification and mixed-agent measurement capability.

Advanced O₂ technology based on paramagnetic measurements is included with the G7m.

Mounting

The standard mounting options enable flexible, space saving placement of the monitor for an ergonomic work space.

Applications for specific care settings

Anesthesia features

- The **IntelliVue G7m Gas Analyzer Module** measures the five most commonly used anesthetic gases, as well as N₂O and CO₂.
- The **BIS Module** assesses the level of consciousness in the OR, providing a measure of the effect of anesthetic agents.
- The **IntelliBridge EC10 Module** provides external-device interface capability to external devices at the bedside which have a serial RS232 and/or LAN interface.
- The **EEG module** determines coma prognosis and extent of cerebral insult. CSA information can be either permanently displayed on specially designed screens or viewed in a separate window. **Burst Suppression Ratio (BSR)** indicates the amount of time within an interval spent in the suppressed state.
- The **NMT Module** together with the NMT Patient Cable offers automatic measurements of muscle response to electrical stimuli delivered via electrodes placed over a peripheral nerve. This enables the evaluation of muscle relaxation of patients under neuromuscular block. The strength of the muscle response is measured with an acceleration sensor.
- **Screens** provide flexible viewing of patient information during different procedures or phases of an anesthesia case.
- **Respiratory Loops:** The IntelliVue Patient Monitor can generate three types of respiratory loops and display one realtime loop and up to six stored loops simultaneously. This helps early detection of patient airway problems (for example, atelectasis, bronchospasm) and ventilator problems (for example, leaks and kinked tubes).

Critical and cardiac care features

- The monitor performs multi-lead **arrhythmia analysis** on the patient's ECG waveform at the bedside. It analyzes ventricular arrhythmias, calculates heart rate, and generates alarms, including asystole, bradycardia, and ventricular fibrillation.
- Up to 12 leads of **ST segment analysis** can be performed on adult patients at the bedside, measuring ST segment elevation and depression, and generating alarms and events. The user can trend ST changes, set high and low alarm limits, and set both ST and isoelectric measurement points. ST points can be set either relative to the J-point or directly by selecting a numeric value. Using ST Snippets, one-second wave segments can be compared with a baseline segment for each measured ST lead.
- **QT/QTc interval monitoring** provides the measured QT interval, the calculated heart-rate corrected QTc value, and a ΔQTc value, which tracks variation in the QT interval in relation to a baseline value.
- **SvO₂** and **ScvO₂** measurements provide guidance for the treatment of sepsis treatment protocols.
- The **Parameter Histogram** View of the Vital Signs Trend allows the clinician to see, at a glance, the stability of the patient's condition for a selected time period.
- **ST Map** application shows ST changes over time in two multi-axis spider diagrams.
- **STE Map** adds gender-specific STE (ST Elevation) limits to ST Map. ST values violating these limits are indicated in red.

¹ Bispectral Index and BIS are registered trademarks of Covidien AG and/or its affiliates

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- **12-lead ECG** data can be measured in diagnostic quality using conventional electrode placement with 10 electrodes. Alternatively it can be measured using the EASI lead system with five electrodes in EASI placement, or the Hexad lead system with six electrodes¹.
- High-performance pulse oximetry technologies perform accurately even in cases with low perfusion.
- Choice of sidestream, or mainstream **CO₂ monitoring** for high-quality measurements with intubated and non-intubated patients.
- **Continuous cardiac output** and advanced hemodynamic assessment are provided using the PiCCO™ method without a pulmonary catheter².
- **Integrated Pulmonary Index (IPI)**³ enables clinicians to assess a patient's ventilatory status and monitor changes in a patient's condition, facilitating more timely interventions.
- **Pulse Pressure Variation (PPV)** is calculated from beat-to-beat arterial pressure values. Pulse pressure is the difference between the systolic and diastolic pressure values for a single beat. Pulse pressure variation is defined as the maximal pressure less the minimum pressure divided by the average of these two pressures.
- **Clinical calculations** enable stored and manually entered data to be used to perform hemodynamic, ventilation and oxygenation calculations. Calculated data is displayed in both indexed and non-indexed format.
- **BIS** monitoring provides sedation assessment in critical and cardiac care environments.

Neonatal monitoring features

- The Oxygen CardioRespiroGram (**OxyCRG**) screens provide a simultaneous presentation of up to three high-resolution trends:
 - Beat-to-beat heart rate (bthHR)
 - An oxygenation measurement trend (SpO₂ or tcpO₂)
 - Compressed respiration wave (Resp)
 This customized display gives clinicians a convenient overview of the neonatal patient's most important vital signs, helping them identify significant events.
- Continuous oxyCRG recordings can be made at the bedside on the M1116C plug-in recorder and reports can be printed on a locally- or centrally-connected printer.
- Dual SpO₂ measurement provides clinical support through comparison and trending of the pulse oximetry values from two distinct patient sites, for example pre- and postductal saturations.
- Trended values can also be viewed in the form of a histogram. The SpO₂ histograms can be trend histograms or real-time histograms with one-second samples.
- Car Seat Assessment Record (CAR). This is a special period of event surveillance for neonates during a car seat test. During the CAR period, a real-time SpO₂ histogram is also generated with one-second samples.

1. EASI/Hexad-derived 12-lead ECGs and their measurements are approximations to conventional 12-lead ECGs. The 12-lead ECG derived with EASI/Hexad should not be used for diagnostic purposes as it is not identical to the 12-lead conventional ECG obtained from an electrocardiograph.

2. PiCCO™ is a trademark of Pulsion Medical Systems AG

3. Microstream CO₂ only

- Neonatal event review (NER), for automatic detection of patient status deterioration. NER is optimized for monitoring neonatal patients. For each event, an episode of four minutes of data sampled four times a second is stored, to help you keep a record of rapid changes in the condition of neonatal patients. Combi-events correlate apnea events with bradycardia and/or desaturations.
- The aEEG⁴ presentation is a trend display of the amplitude-integrated EEG (aEEG). It uses amplitude compression samples. A trend of the sum of the electrode impedances of the respective lead is shown below the aEEG presentation as a quality indicator that supports interpretation of the aEEG. The monitor stores 24 hours of aEEG and electrodes impedances for all four channels.

IntelliVue applications

Advanced clinical solutions

Clinicians are continuously drawing mental images from their observations of patients' vital signs. IntelliVue's Clinical Decision Support applications offer this dynamic "mind's eye view" directly on the monitoring screen display.

ProtocolWatch

ProtocolWatch allows clinicians to run clinical protocols that can monitor developments in the patient's condition. The SSC Sepsis Protocol runs on the ProtocolWatch application and is used in screening for severe sepsis, and monitoring its treatment.

IntelliVue early warning scoring (IntelliVue EWS)

The early warning scoring application provides fast, automated early warning scoring. IntelliVue EWS is fully customizable to match your hospital's clinical protocols:

- Configurable scoring parameters and thresholds
- Up to 20 parameters per EWS protocol
- Configurable MEWS thresholds
- Configurable Action List
- Up to 10 EWS protocols per monitor

IntelliVue EWS provides three basic types of scoring:

- Single Parameter Scoring (SPS)
- Multi-parameter scoring, for example:
 - Modified Early Warning Scoring (MEWS)
 - UK National Early Warning Scoring (NEWS)
- Body System Structural Scoring, for example:
 - Pediatric Early Warning Scores (Tucker Schema)
 - Adult Body System Scores

Vital signs and clinical observations can be configured for early warning scoring.

- Vital signs, for example: pulse, temperature
- Clinical observations, for example: AVPU, concern
- Using customized labels, clinical observations can be labeled and defined according to a hospital's particular requirements at the time of installation
- ADT data, for example: weight, age
- Lab data
- Documentation

4. Patient monitor software option C60

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ST Map

ST Map provides a graphical display that can help clinicians recognize ST changes and their location in the heart more easily. ST Map collects ST values created from the frontal (limb leads) and horizontal (chest leads) plane into an integrated display. The maps are multi-axis portraits of the patient's ST segments as measured with the ST/AR arrhythmia algorithm.

Advanced event surveillance

Events are electronic records of episodes in the patient's condition defined by customizable multi-parameter triggers. They can be used to drive alert notification to assist compliance to any protocol that is being used by the clinician.

Horizon view

Horizon trends provide clinicians with a graphical visualization tool that enables the patient's current clinical status to be detected at a glance. By combining parameters together on the display, the clinician is assisted in their cognitive process of pattern recognition.

Loops

Up to six loops of each type can be stored and compared to detect respiratory changes more easily.

Screen display flexibility

Up to 20 different screens can be created per monitor, meaning the clinician can have a screen created to match a specific clinical scenario on which the data that matter is displayed.

This streamlines the information that needs to be processed and interpreted to make the right decision at the right time.

Trends

- A **standard** trends database configuration is provided, designed to suit specific application areas. Depending on the configuration, patient data from up to 50 or 100 measurement numerics can be sampled every 12 seconds, 1 minute, or 5 minutes, and stored for a period ranging from 4 to 96 hours.
- **Tabular Trends** (Vital Signs) show data for all measurement numerics in tabular form. Tabular Trends can either be viewed in a separate window or permanently displayed on specially designed screens.
- Each NBP measurement generates a column in the Vital Signs trend table. The values for the other measurements are added to provide a complete vital signs set for the NBP measurement time.
- With **Graphic Trends**, up to three rows of measurement trends can be displayed in graphic form, each combining up to four measurements. Graphical Trends can either be viewed in a separate window or permanently displayed on specially designed screens.
- **Screen Trends** permanently display trend data for periodic and aperiodic parameters in graphical format on special screens. The displayed time period can be set to 30 minutes or 1, 2, or 4 hours.
- **High-Resolution Trends** allow the user to track fast-changing measurement trends with beat-to-beat resolution (four samples/second). The number of high-resolution trends available for display depends on the wave option purchased (for example eight for option A08).
- **Horizon Trends** show the deviation from a stored baseline.
- Trended values can be viewed in the form of a histogram. The SpO₂ histograms can be Trend Histograms with one-second samples.

- Navigation arrows provide easy access to the stored trends. Trend data can be documented on a locally- or centrally-connected printer.
- With **Event Surveillance**, changes in patients' condition are automatically detected according to user-defined multi-parameter triggers and an electronic record of data, called an Episode, is stored. The Episode can store:
 - 15 seconds of high-resolution wave trace
 - 4 minutes of data sampled 4 times a second, or
 - 20 minutes of data sampled every 12 seconds.

Event triggers can use the preset alarm limits or they can be user-defined. With user-defined triggers, event episodes are stored even when alarms are paused. A Manual-Event SmartKey enables manual episode storage.

Event Annotation allows immediate or retrospective annotation of events using a user-defined list of event markers such as 'ventilated'.

Events can be stored in a database for retrospective review, and episode data including graphic Event Reviews can be documented on a locally- or centrally-connected printer. In addition, episode data without graphic elements can be documented on the M1116C plug-in recorder. Events are also marked on the Event Line of an Information Center.

- The **basic event surveillance** package and the **neonatal event surveillance** package each include one Event Group. The basic event surveillance package can store 25 events over 24 hours.
- The **advanced event surveillance** offers increased storage capability, enabling the monitor to store up to:
 - 25 events for 8 hours
 - 25 events for 24 hours
 - 50 events for 8 hours
 - 50 events for 24 hours
 - 300 events over 7 days

Up to 10 user-defined Event Groups can be configured, each made up of up to four measurements. Up to six groups can be active at the same time. Advanced user-configurable trigger mechanisms allow the clinician to define event triggers combining information from up to four measurements. Either alarm limits or user-defined thresholds or deviations can be configured as event triggers. The user can set event notifications to be notified when an event is detected.

Patient management

- **Universal admission/discharge/transfer (ADT)**: ADT information is shared between the networked monitor and the Philips Information Center. Information need only be entered once.
- **Stat Admit**: Allows you to admit a patient with a temporary patient identification. It can be used in cases when the patient ID is unknown or when the data is not yet available.
- **Quick Admit**: Allows you to quickly admit a patient using only a limited set of demographic data. You can enter the data with the keyboard or a barcode scanner.
- Patients can be transferred by disconnecting the Multi-Measurement Module from a monitor, and then reconnecting it at a new monitor. Patient demographics are stored in the Multi-Measurement Module so they do not have to be reentered at the new monitor.

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Patient data documentation

An extensive range of patient reports can be printed:

- Event Review and Episode Reports
- 12-lead ECG Reports
- Vital Signs
- Graphic Trends
- Cardiac Output Reports
- Wedge Procedure Reports
- Calculations Reports
- EEG Reports
- Histogram Reports
- Loops Report
- ST Map Reports
- QT Reports
- Alarm Limit Reports
- Drug Calculator Reports
- Real-time Wave Reports
- OxyCRG Reports

Report templates can be defined in advance, enabling printouts tailored to each hospital's specific requirements to be started quickly. Reports can be printed on a locally- or centrally-connected printer, and can be initiated manually or automatically at user-defined intervals.

Recordings

The M1116C plug-in recorder records numerics for all active measurements and up to three waveforms. It can be used for local recording in the integrated module slots.

Alarms

The alarm system can be configured to present either the traditional HP/Agilent/Philips alarm sounds or sounds compliant with the IEC 60601-1-8 Standard.

Depending on the screen layout, alarm limits are permanently visible on the main screen. When an alarm limit is exceeded, it is signaled by the monitor as follows:

- An alarm tone sounds, graded according to severity.
- An alarm message is shown on the screen, color-coded according to severity.
- The numeric of the alarming measurement flashes on the screen.
- Alarm lamps flash for red and yellow alarms and are illuminated for technical INOPs.

The alarm-limit review page offers an overview of alarm limit settings and the possibility to modify these settings for all parameters.

A **Smart Alarm Delay** feature helps reduce the number of pulse oximetry nuisance alarms.

If the monitor is connected via a network to the Information Center, alarming is simultaneous at the monitor and at the Information Center.

The nurse call relay has active open and closed contacts and a user-definable delay time.

Alarms are graded and prioritized according to severity:

- **Red Alarms***** identify a potentially life-threatening situation for a patient.
- **Yellow Alarms**** indicate conditions violating preset vital signs limits.
- **Yellow Alarms*** indicate arrhythmia alarms.
- **Technical alarms (INOPs)** are triggered by signal quality problems, equipment malfunction, or equipment disconnect.

The Audio off/Pause Alarms function allows the user to switch off alarm tones with one touch or click while retaining visual alarm messages.

All alarms can be paused indefinitely or for one, two, three, five, or 10 minutes depending on their configuration.

Alarm strip recordings are available on the M1116C plug-in recorder or on a locally- or centrally-connected recorder.

Patented 'AutoLimits' help caregivers manage alarms more effectively, automatically adapting the alarm limits to the patient's currently measured vital signs within a safe margin defined individually for each patient.

Visual and/or audible latching and non-latching alarm handling is available.

Alarm Advisor

Alarm Advisor provides feedback on recurring and continuous alarm limit violations. The information provided helps the clinician in adapting alarm limits more specifically for individual patients.

Alarm Advisor can be enabled for:

- HR (low and high limit alarm, yellow and short yellow).
- PVCs/minute (high limit alarm).
- SpO₂ (low and high limit alarm).
- Pressure - ART, ABP, Ao, P (low and high limit alarm).
- RR (low and high limit alarm).
- awRR (low and high limit alarm).

Alarm Advisor can be switched on and off for each individual alarm (for example, for an SpO₂ low alarm, an HR low alarm, and so on).

Profiles

Profiles are predefined configuration settings for screens, measurement settings, and monitor properties. Each profile can be designed for a specific application area and patient category, for example OR adult, or ICU neonatal. Profiles enable a quick reaction to patient and care location changes: activating a profile with a particular patient category (adult, pediatric, or neonatal) automatically applies suitable alarm and safety limits and saves time usually spent carrying out a complete setup procedure.

A selection of profiles for common monitoring situations is provided with the monitor.

Profiles can also be created directly on the monitor or remotely on a PC and transferred to the monitor using the IntelliVue Support Tool. These created profiles can be changed, added to, renamed, or deleted.

A selection of profiles for common monitoring situations is provided with the monitor.

Networking capabilities

The monitor can operate as part of a networked system (wired/wireless) using the Philips IntelliVue Clinical Network interface. This includes:

- DHCP/BootP
- QoS Tagging
- 802.11 WLAN
- WMM on wireless networks

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Other Bed Overview

The Other Bed window lets you view a subset of the waveform and numeric information from another bed in the same Care Group on the hospital network. Other Bed information can either be viewed in a separate window or permanently displayed on specially designed screens. The alarm status of a care group or unit can be displayed on the monitor's screen. The Other Bed window can be configured to pop up automatically when an alarm occurs at another bed. The Other Bed Overview can only be displayed on the main monitor.

Clinical calculation set

The clinical calculation set consists of Hemodynamic, Oxygenation, and Ventilation calculations.

Hemodynamic calculations:

- Cardiac Index (C.I.)
- Stroke Volume (SV)
- Stroke Index (SI)
- Systemic Vascular Resistance (SVR)
- Systemic Vascular Resistance Index (SVRI)
- Pulmonary Vascular Resistance (PVR)
- Pulmonary Vascular Resistance Index (PVRI)
- Left Cardiac Work (LCW)
- Left Cardiac Work Index (LCWI)
- Left Ventricular Stroke Work (LVSU)
- Left Ventricular Stroke Work Index (LVSU)
- Right Cardiac Work (RCW)
- Right Cardiac Work Index (RCWI)
- Right Ventricular Stroke Work (RVSU)
- Right Ventricular Stroke Work Index (RVSU)
- Extra Vascular Lung Water Index (EVLWI)
- Intrathoracic Blood Volume Index (ITBVI)
- Global End Diastolic Volume Index (GEDVI)

Oxygenation calculations:

- Arterial Oxygen Content (CaO_2)
- Venous Oxygen Content (CvO_2)
- Arteriovenous Oxygen Content (CavO_2)
- Oxygen Availability (DO_2)
- Oxygen Availability Index (DO_2I)
- Oxygen Consumption (VO_2)
- Oxygen Consumption Index (VO_2I)
- Oxygen Extraction Ratio (O_2ER)
- Alveolar-Arterial Oxygen Difference (AaDO_2)
- Percent Arteriovenous Shunt (Qs/Qt)

Ventilation calculations:

- Minute Volume (MINVOL)
- Compliance (COMP)
- Dead Space (Vd)
- Dead Space/Tidal Volume Ratio (Vd/TV)
- Alveolar Ventilation (ALVENT)

Drug Calculator

The Drug Calculator allows you to calculate the fourth value when three of the following values are entered: dose, amount, volume, rate of infusion.

A titration table and drip table can be displayed and printed.

Measurement units can be converted (for example, lbs to kgs). The Drug Calculator can also be configured to include a list of commonly used drugs using the IntelliVue Support Tool.

Service features

The IntelliVue Support Tool helps technical personnel to:

- Carry out configuration, upgrades, and troubleshooting via the network, or on an individual monitor.
- Share configuration settings between monitors.
- Back up the monitor settings.
- Document configuration settings.

A password-protected:

- **Service Mode** ensures that only trained staff can access service tests and tasks.
- **Configuration Mode** allows trained users to customize the monitor configuration.

Device connections

The monitor can be connected to the following

Multi-Measurement Modules:

- X1 (M3001A/M3001AL)
- X2 (M3002A)
- X3 (867030)
- MMX (867036)

The following Measurement Extensions can be connected to the Multi-Measurement Modules:

- 867039 Hemodynamic Extension
- 867040 Capnography Extension
- 867041 Microstream CO_2 Extension
- M3012A Hemodynamic Extension
- M3014A Capnography Extension
- M3015A Microstream CO_2 Extension
- M3015B Microstream CO_2 Extension

The monitor can also be connected to:

- IntelliVue AD75 and AD85 Active Displays

Note: The AD75/AD85 Active Display is not available in the USA and territories relying on FDA market clearance, and may also not be available in other geographies.

- A PC running the IntelliVue XDS Software¹
- External devices via an IntelliBridge EC10 Module
- One or two FMX-4 Module Racks
- Plug-in measurement modules (in conjunction with FMX-4)
- Tympanic Temperature Module 866149
- A Philips Patient Information Center (for example, PIC iX)

Standard interface connections

Network interface

The network interface provides the system with networking capability via a wired network connection.

Device Interface (USB Interface)

This interface allows USB devices to be connected to the monitor, for example: mouse, keyboard, barcode scanner, PCL5-supported Printer.

RS232 interface (standard)

The standard RS232 port can be used to connect, for example, an IntelliVue G1/G5 gas analyzer.

¹ Requires the relevant IntelliVue XDS options to be installed on either the patient monitor, or on a PC running the IntelliVue XDS Software with an activated license. See the IntelliVue XDS Software Technical Data Sheet for details

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Further optional connection interfaces

MIB/RS232 (two port) interface board (option J13)

Additional dual MIB/RS232 I/O boards can be installed. The MIB ports can be independently configured to be used for:

- Numeric, wave, and alarm data export using a computer interface, to an automated anesthesia recordkeeper or a personal computer (not available in all countries).
- Data export can be configured for up to two MIB ports on the monitor. However only the first configured port provides wave export.
- Connection to a gas analyzer.
- Connection to iTemp (Philips tympanic thermometer).

Flexible nurse call interface (option J30)

The Flexible Nurse Call Interface provides a means for alarms generated on the monitor to be signaled on an external device such as a nurse call system, a beeper or a light. It provides three general alarm relays and one power fail alarm. The external device is connected to the alarm relay and alarms are triggered by criteria defined by the user. It has active open and closed contacts and a user-definable delay time.

Wireless infrastructure (option J35)

- Wireless Infrastructure enables the monitor to function within a WLAN. The WLAN infrastructure is an IEEE 802.11 a/b/g/n network in the 2.4 GHz or 5-GHz bands.

Additional components are required to complete the system. See the IntelliVue Clinical Network documentation for further information.

Monitor specifications

See the individual Technical Data Sheets for IntelliVue X1, IntelliVue X2, IntelliVue X3, and MMX Multi-Measurement Modules, Measurement Extensions, FMX-4 Module Rack, and plug-in module specifications.

Safety specifications

The monitors, together with the X3 Patient Monitor/Multi-Measurement Module (867030), MMX Multi-Measurement Module (867036), the current generation Measurement Extensions (867039, 867040, 867041), and all compatible plug-in modules comply with the Medical Device Directive 93/42/EEC and, among other standards, with:

- IEC 60601-1, Ed. 3.1:2012-08 (cons.)
- EN 60601-1:2006 + AC:2010 + A1:2013, Ed. 3
- ANSI/AAMI ES60601-1:2005/(R)2012, Ed. 3 (cons.)
- CAN/CSA-C22.2 No. 60601-1.14, Ed. 3 (cons.)
- IEC 60601-1-2:2014, Ed. 4
- EN 60601-1-2:2015, Ed. 4
- IEC 60601-1-6:2010 + A1:2013
- EN 60601-1-6:2010 + A1:2015
- IEC 60601-1-8:2006 + A1:2012
- EN 60601-1-8:2007 + A1:2013
- IEC 80601-2-49:2011
- EN 80601-2-49:2015

Classification (according to IEC 60601-1): Class 1, Type CF, Continuous Operation. The BIS, NMT, and tympanic temperature measurements, and the G7m Gas Analyzer use a Type BF applied part. They are protected against damage from defibrillation and electrosurgery.

The possibility of hazards arising from software errors was minimized in compliance with:

- ISO 14971:2007
- EN ISO 14971:2012
- ANSI/AAMI ISO 14971:2010
- IEC 62304:2006
- EN 62304:2006 + AC 2008

This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme à la norme NMB-001 du Canada.

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Physical specifications

Product	Max. Weight	W x H x D
MX750 Monitor	10 kg (22. lb)	477 x 350 x 217 mm (18.8 x 13.8 x 8.5 in)
MX850 Monitor	11 kg (24.3 lb)	544 x 388 x 217 mm (21.4 x 15.3 x 8.5 in)

Environmental specifications

MX850 and MX750 Monitors

Item	Condition	Range
Temperature range	Operating	0–40°C (32–104°F) Or, with iPC installed: 0–35°C (32–95°F)
	Storage	–20–60°C (–4–140°F)
Humidity range	Operating	15–95% RH non-condensing
	Storage	5–95% RH non-condensing
Altitude range	Operating	–500–3000 m (–1640–9842 ft)
	Storage	–500–4600 m (–1640–15091 ft)
Ingress protection		IP21

Display specifications

MX850 Monitor 22 inch Full HD

Type	547 mm active matrix color LCD (TFT)
Resolution	1920 x 1080 (Full HD)
Useful Screen	476.6 mm x 268.1 mm
Pixel Size	0.248 mm x 0.248 mm

MX750 Monitor 19 inch Full HD

Type	469 mm active matrix color LCD (TFT)
Resolution	1920 x 1080 (Full HD)
Useful screen	409 mm x 230 mm
Pixel size	0.213 mm x 0.213 mm

Performance specifications

Power specifications	
Power consumption	<200-W average
Line voltage	100 to 240 V
Current	1.9 to 0.9 A
Frequency	50/60 Hz

Indicators

Alarms off	Red or yellow LED (with crossed out alarms symbol)
Alarms	Red/yellow/light blue (cyan) LED
On/Standby/Error	Green/red LED integrated in power switch
External power	Green LED

Sounds

• Audible feedback for user input
• Prompt tone
• QRS tone, or SpO ₂ modulation tone
• Four different alarm sounds
• Remote tone alarms on other beds in network
• Tone for timer expired

Display wave speeds

Available for standard waves	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s with ±5% accuracy (guaranteed only for integrated displays)
Available for EEG and BIS waves	6.25 mm/s, 12.5 mm/s, 15 mm/s, 25 mm/s, 30 mm/s, 50 mm/s with ±5% accuracy (guaranteed only for integrated displays)

Trends

Resolution	50 or 100 numerics @ 12 seconds, 1 minute, 5-minute resolution
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Trends	
Information	Multiple choices of number of numerics, resolution and duration depending on trend option and application area. Standard Database Configuration Options: H02, H12, H22, H32, H42: • 50 Parameters for: 12 hours @ 12 secs, 48 hours @ 1 min, 96 hours @ 5 min • 50 Parameters for: 24 hours @ 12 secs, 24 hours @ 1 min, 24 hours @ 5 min • 100 Parameters for: 4 hours @ 12 secs, 24 hours @ 1 min, 96 hours @ 5 min
High Res trend waves	
Measurements available	HR, SpO ₂ , Resp, Pulse, tcpO ₂ , Perf, tcpCO ₂ , CO ₂ , ABP, PAP, CVP, ICP, CPP, BIS, CCO, AWP, Anesthetic Agents, Δ SpO ₂ , InO ₂
Resolution	Measurement samples are taken at a resolution of 4 samples per second
Update speed	Waves are drawn at a speed of 3 cm/minute
Events	
Information	Trigger condition and time, event classification and associated detailed view of episode data
Episode data	Configurable: • 4 minutes of high-resolution trend or • 20 minutes of numerics trend @ 12-sec resolution or • 15 seconds of 4 waves @ 125 samples/sec (Snapshot) including all current numerics, alarms and INOPs.
Capacity (max.)	30 events for 7 days
Alarm signal	
System delay	<4 seconds
Pause duration	1, 2, 3 minutes or infinite, depending on configuration
Extended alarm pause	5 or 10 minutes
Review alarms	
Information	All alarms/INOPs, main alarms on/off, alarm acknowledge, Alarm duration, and time of occurrence
Capacity	300 items
Real-Time clock	
Range	From: January 1, 1997, 00:00 To: December 31, 2080, 23:59
Accuracy	Better than 4 seconds per day
Hold time	• If powered by AC: Infinite • Without power or battery: At least 48 hours
Buffered memory	
Contents	Active settings, trends, patient data, real-time reports, events, review alarms
Hold time	• If powered by AC: Infinite • Without power: At least 8 hours
MX750/850 interface specifications	
Network	
Standard	IEEE802.3 10Base-T and 100Base-TX, auto negotiation, full and half-duplex, IEEE802.3af
Connector	RJ45 (8 pin)
Isolation	Basic insulation: • Reference voltage: 250 V • Test voltage: 1500 V
RS232 (standard)	
Connector	RJ45 (8-pin)
Power	None
Isolation	Basic insulation: • Reference voltage: 250 V • Test voltage: 1500 V
USB interface	
Standard	USB 2.0 high-speed (embedded host)
Connector	USB series 'Standard A' receptacle

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USB interface		802.11 wireless interface (wireless network adapter) ^a	
Power	Low-power port 4.4 V minimum, maximum load for all ports together 500 mA	Technology	IEEE 802.11a/b/g/n
Isolation	None	Frequency band	2.4 GHz and 5-GHz band
MIB/RS232 (optional I/O board)		United States	• 2.400-2.483 GHz • 5.15-5.35 GHz • 5.72-5.825 GHz
Standard	ISO/IEC 11073-30200 compliant	Europe	• 2.400-2.483 GHz • 5.15-5.35 GHz • 5.470-5.725 GHz
Connector	RJ45 (8-pin)	Japan	• 2.400-2.483 GHz • 5.150-5.250 GHz • 5.250-5.350 GHz • 5.470-5.725 GHz
Mode	Software-controllable: • BCC (Rx/D/TxD cross over) or • DCC (Rx/D/TxD straight through)	China	• 2.400-2.483 GHz • 5.725-5.850 GHz
Power	5 V $\pm$ 5%, 100 mA (max.)	Modulation technique 802.11b/g/n	• DSSS (CCK, DQPSK, DBPSK) • OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
Isolation	Basic Insulation: • Reference Voltage: 250 V • Test Voltage: 1500 V	Modulation technique 802.11a/n	OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
Flexible nurse call interface (optional I/O Board)		Effective isotropically radiated power (EIRP)	Below 20 dBm
Connector	20-pin MDR (Mini D-Ribbon), active open and closed contacts	WLAN infrastructure	For operation with full capacity, a WLAN infrastructure is recommended that provides: • A minimum RF signal (RSSI) level of -67 dBm (or higher) in all areas of monitor use. • A minimum signal-to-noise ratio (SNR) of 25 dB in all areas of monitor use. See the <i>IntelliVue Network Specification</i> document for details.
Contact	≤ 100 mA, ≤ 24 V dc		
Isolation	Basic Insulation: • Reference Voltage: 250 V • Test Voltage: 1500 V		
Delay	< [Configured Latency +0.5] seconds		
Basic nurse call relay^a		^a Optional: See "Interface options" on page 15 ^a	
Connector	Modular Jack 6P6C, active open and closed contact	Near Field Communication interface (NFC)	
Contact	≤ 100 mA, ≤ 24 V dc	Technology	• NFCIP-1, NFCIP-2 protocol • ISO/IEC 14443A, ISO/IEC 14443B • FeliCa PCD mode • MIFARE PCD encryption mechanism • NFC Forum tag 1 to 4 • ISO/IEC 15693/ICODE
Isolation	Basic insulation: • Reference Voltage: 250 V • Test Voltage: 1500 V	Band	13.56 MHz
Delay	< [Configured Latency +0.5] seconds	Modulation	ASK (active mode) or load modulation (passive mode)
^a With one general relay. The relay is configurable.		Bandwidth	106 kbit/s, 212 kbit/s, 424 kbit/s, 848 kbit/s (depending on technology used)
802.11 wireless interface (wireless network adapter) ^a			
Type	Internal wireless adapter		

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Measurement server link (MSL)

Connectors	MSL out (Proprietary)
Voltage	56 V $\pm$ 10% DC18
Power	45 W
Power synchronization	5 V CMOS Level; 78.125 kHz (typical)
LAN signals	10Base-T (IEEE802.3i) and 100Base-TX (IEEE 802.3u) compliant
Serial signals	RS-422 compliant

ECG sync output/analog ECG output

General	Connector	(1/4 inch stereo phone jack with tip, ring, sleeve)
	Isolation	None
Analog ECG output (ring, tip)	Gain error	<15%
	Baseline offset error	<150 mV
	Bandwidth	1-100 Hz
	Output voltage swing	$\pm$ 4 V (min.)
	Signal delay	<20 ms per AAMI EC13
	Signal delay with older versions of the M3001A Multi-Measurement Module	<30 ms per AAMI EC13
Digital pulse output (ring)	Pacemaker pulse	filtered and included in ECG output signal
	Output low-voltage level	<0.4 V @ I= -1 mA
	Output high-voltage level	>2.4 V @ I= 1 mA
	Pulse width	100 ms $\pm$ 10 ms (active high)
	Pulse rise time	<1 ms (from 0.4 V to 2.4 V)
	Signal delay	<25 ms per AAMI EC13
	Signal delay with older versions of the M3001A Multi-Measurement Module	<35 ms per AAMI EC13

iPC specifications^{1,2}

iPC PC1 components	Specification
Processor	Intel Core i5-4300U
Graphics	Intel HD Graphics 4400
Hard drive	Solid-State Drive 100 GB or bigger
RAM	8 GB
iPC PC1 interfaces	
Ethernet LAN	
Connector	RJ45
LAN signals	IEEE 802.3 1000Base-T compliant, isolated according to IEC 60601-1
USB	
Six external ports (five at the rear, one on the right-hand side) Type A connectors	
Top connector on rear and connector on right side	USB 2.0 supporting Hi-Speed mode
Lower four connectors on rear (with blue inserts)	USB 3.0 supporting SuperSpeed mode
Audio	
Microphone input stereo	3.5-mm audio jack
Headphone output stereo	3.5-mm audio jack
Two displayport outputs	
DisplayPort 1.2	Supports resolutions up to 2560 x 1600 at 60 Hz

1. iPC PC1 may not be available in all countries

2. Optional. See *** on page 15

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Ordering information

Ordering information for the 866470 (MX850) and 866471 (MX750) is given here. See the individual Technical Data Sheets for detailed ordering information for the Multi-Measurement Module family, Measurement Extensions, and plug-in modules.

Measurement capability options ¹

Care area options	Option
Intensive care software	H12
Neonatal care software	H22
Anesthesia software	H32
Cardiac care software	H42

Clinical packages	Option
Extended ECG capabilities	CP2
Extended alarm capabilities	CP4

Clinical features

Waveform capability	Option
6 Real-time wave segments (MX750 only)	A06
8 Real-time wave segments (MX750 only)	A08
12 Real-time wave segments (MX750 & MX850)	A12
16 Real-time wave segments (MX850 only)	A16

Clinical applications	Option
Advanced event surveillance	C07
Alarm Advisor	C46
HEXAD	C54
aEEG	C60

ProtocolWatch	Option
Severe Sepsis Screening	P01
SSC Sepsis Protocol	P02
IntelliVue EWS	P05

¹ One Hxx option and one Axx option must be chosen

Hardware options - 866470 & 866471

Description	Option
Hardware add-ons	
866468 FMX-4 without Multi-Measurement Module mount	---
866468 FMX-4 with Multi-Measurement Module mount	E20
Integrated PC	
Integrated PC (iPC) 2G	PC1

Interface options

Wired interfaces ^a	Option
MIB/RS232 (2 ports) interface ^b	J13
Flexible nurse call interface	J30

^a Check availability in your country

^b Hardware supports multiple boards of this type

Wireless Interfaces ^a	Option
802.11 wireless Interface	J35

^a Check availability in your country

Care area software bundles - Hxx option dependent

Software	Option
Intensive Care Software: Intensive Care software consists of the standard set of clinical and operational patient monitoring functions plus Basic Event Surveillance, the extended ECG capabilities (Full Arrhythmia, ST Analysis, ST/STE Map and QT/QtC), the alarm visualization toolset (Alarm Review and Alarm Limits page, direct access to Auto Limits) as well as the data visualization tools (Horizon Trends, Pressure-Volume Loops, Parameter Histograms and Short graphical trends), together with the ability to customize screens. Smart Alarm Delay capability and connectivity to the Patient Information Center PIC iX are also a part of this software package. Two remote display connections are included for MX850, and one remote display connection is included for MX750, for use with the XDS Remote Display application on a PC. The XDS Clinical Workstation and XDS Database functionality are also included.	H12

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Software	Option
Neonatal Care Software: Neonatal Care Software offers you the standard set of clinical and operational patient monitoring functionality. In addition, the package includes a neonatal event review with car seat testing and parameter histograms, the extended trends database and drug calculator. Other functions are the Smart Alarm Delay capability and the amplitude EEG (aEEG) presentation of EEG waveforms. The software package also allows you to customize your screens and to connect to the Philips Information Center PIIC iX. Two remote display connections are included for MX850, and one remote display connection is included for MX750, for use with the XDS Remote Display application on a PC. The XDS Clinical Workstation and XDS Database functionality are also included.	H22
Anesthesia Care Software: Anesthesia Software offers you the standard set of clinical and operational patient monitoring functionality. In addition, the package includes basic event surveillance, the extended trend database, ST-analysis and various data visualization tools: Horizon Trends, pressure-volume loops, Parameter Histograms and Short graphical trends. The software package also allows you to customize your screens and to connect to the Philips Information Center PIIC iX. Two remote display connections are included for MX850, and one remote display connection is included for MX750, for use with the XDS Remote Display application on a PC. The XDS Clinical Workstation and XDS Database functionality are also included.	H32
Cardiac Care Software: Cardiac Care Software offers you the standard set of clinical and operational patient monitoring functionality. In addition, the package includes basic event surveillance, the extended trends database, and the following cardiac options: full arrhythmia, ST-analysis, ST/STE-map, QT/QtC, and HEXAD (12-lead ECG derived from 6 leads). Also included are the alarm visualization toolset and the Smart Alarm Delay capability as well as the following data visualization tools: horizon trends, pressure-volume loops, parameter histograms, and short graphical trends. The software package also allows you to customize your screens and to connect to the Philips Information Center PIIC iX. Two remote display connections are included for MX850, and one remote display connection is included for MX750, for use with the XDS Remote Display application on a PC. The XDS Clinical Workstation and XDS Database functionality are also included.	H42

Measurement options

Measurements	Product No.	Option
Multi-Measurement Modules		
X1 Multi-Measurement Module Including Resp, ECG (inc. EASI/Hexad), NBP, and Pressure/Temperature See the IntelliVue X1 Technical Data Sheet for details	M3001A	
Philips FAST SpO ₂		A01
Masimo SET SpO ₂		A03 ^a
Nellcor OxiMax SpO ₂		A04 ^a
Add Press/Temp		C06
Add Press/Temp and Conventional 12-Lead ECG		C12
X1 Multi-Measurement Module Including Resp, ECG (inc. EASI/Hexad), NBP, Masimo rainbow SET SpO₂, and Pressure/Temperature See the IntelliVue X1 Technical Data Sheet for details	M3001AL	A05
Add Press/Temp		C06
Add Press/Temp and Conventional 12-Lead ECG		C12
X2 Multi-Measurement Module Including Resp, ECG (inc. EASI/Hexad), NBP, and Pressure/Temperature See the IntelliVue X2 Technical Data Sheet for details	M3002A	
Philips FAST SpO ₂		A01
Masimo SET SpO ₂		A03 ^a
Nellcor OxiMax SpO ₂		A04 ^a
Masimo rainbow SET SpO ₂		A05
Add Press/Temp		C06
Add Respiration CO ₂ ready ^b		C14
X3 Patient Monitor/Multi-Measurement Module See the IntelliVue X3 Technical Data Sheet for details	867030	
Three Wave Capability		A03
Four Wave Capability		A04
Five Wave Capability		A05
Dual SpO ₂		B02
Respiration CO ₂ Ready		B03

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Measurements	Product No.	Option	Measurements	Product No.	Option
Dual Pressure and Temperature		B06	Dual Invasive Pressure, Temperature, Cardiac Output, and PiCCO		B10 ^c
Philips FAST SpO ₂		SP1			
Masimo rainbow SET SpO ₂		SP5	Microstream CO₂ Extension Including Microstream CO ₂ Measurement	867041	
Nellcor OxiMax SpO ₂		SP6			
MMX Multi-Measurement Module See the IntelliVue MMX Technical Data Sheet for details	867036		Dual Invasive Pressure, Temperature, and Cardiac Output		B05
Dual SpO ₂		B02	Dual Invasive Pressure, Temperature		B06
Respironics CO ₂ Ready		B03	Dual Invasive Pressure, Temperature, Cardiac Output, and PiCCO		B10 ^d
Dual Pressure and Temperature		B06			
Philips FAST SpO ₂		SP1	Module Rack (for plug-in measurement modules)		
Masimo rainbow SET SpO ₂		SP5	FMX-4 Module Rack	866468	
Nellcor OxiMax SpO ₂		SP6	Add Multi-Measurement Module mount		E20
Measurement extensions			Plug-in measurement modules		
			See Module Technical Data Sheets for details		
Hemodynamic Extension Including Press, Temp, Press/Temp	M3012A		Invasive Blood Pressure	M1006B ^a	
Add C.O.		C05	SO ₂	M1011A	
Add C.O./CCO		C10	Cardiac Output with Optional CCO	M1012A	
Capnography Extension	M3014A		Philips FAST SpO ₂	M1020B	A01
Add Press, Press/Temp and C.O.		C05	Nellcor OxiMax SpO ₂	M1020B	A04 ^a
Add Press and Press/Temp		C07	EEG/aEEG	M1027B	
Add Press, Press/Temp and C.O./CCO		C10	Temperature	M1029A	
Microstream CO₂ Extension Including dual invasive pressure and Temperature Measurements	M3015B	C08	BIS Module	M1034B	
Hemodynamic Extension	867039		Thermal Array Recorder	M1116B/C	
Dual Invasive Pressure, Temperature, and Cardiac Output		B05	IntelliBridge EC10	865115	
Dual Invasive Pressure, Temperature		B06	NMT	865383	
Dual Invasive Pressure, Temperature, Cardiac Output, and PiCCO		B10	G7m Gas Analyzer	866173	
Capnography Extension Including Mainstream or Sidestream CO ₂ Measurement	867040		Masimo rainbow SET SpO ₂	867191	SP5
Dual Invasive Pressure, Temperature, and Cardiac Output		B05	Masimo SET SpO ₂	867192	SP3
Dual Invasive Pressure, Temperature		B06			

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Measurements	Product No. Option
Gas analyzers	
IntelliVue TcG10 ^a	865298
a. Check availability in your country b. Not available with option A05 c. Option B10 is not available for the 867040 Capnography Extension in the United States and territories relying on FDA market clearance d. Option B10 is not available for the 867041 Microstream CO₂ Extension in the United States and territories relying on FDA market clearance e. Option C01 provides an analog output signal	

Related products

Product	Product/Option
IntelliVue Support Tool (DVD) orderable via: http://www.2.forms.healthcare.philips.com/LP=463	M3086A

Cables

Length	Description	Product/option
MSL cables		
0.75 m	Monitor to Multi-Measurement Module	M8022A SC1
2 m	Monitor to Multi-Measurement Module	M8022A SC2
4 m	Monitor to Multi-Measurement Module	M8022A SC4
10 m	Monitor to Multi-Measurement Module	M8022A SC6
15 m	Monitor to Multi-Measurement Module	M8022A SC7
25 m	Monitor to Multi-Measurement Module	M8022A SC9
MIB/RS232 cables		
1.5 m	Serial cable	M8022A SR2
3.0 m	Serial cable	M8022A SR3
10.0 m	Serial cable	M8022A SR6
15.0 m	Serial cable	M8022A SR7
25.0 m	Serial cable	M8022A SR9

Length	Description	Product/option
Basic nurse call relay cables		
3.0 m	Standard (backward compatible) Nurse Paging Relay Cable ^a	M8022A NS3
10.0 m	Cable	M8022A NS6
Advanced nurse call relay cables		
3.0 m	Cable	M8022A NC3
10.0 m	Cable	M8022A NC6

ECG out cables		
3.0 m	Standard ECG out cable ^b	M8022A SY3
25.0 m	ECG sync extension cable	M8022A SY9
a. Standard (backward compatible) connector. One end terminated with 6P6C connector, other end w/o connector. b. Both ends terminated with a 1/4 in phone plug		

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Software upgrade options

For: 866473 IntelliVue MX850 and 866474 IntelliVue MX750

Description	Option
SLCP (Software Licensed Controlled Product) waves	
Upgrade from 6 to 8 waves (MX750 only)	A68
Upgrade from 6 to 12 waves (MX750 only)	A6C
Upgrade from 8 to 12 waves (MX750 only)	A8C
Upgrade from 12 to 16 waves (MX850 only)	ACF
Clinical applications	
Neonatal CDS package	C04
Advanced event surveillance	C07
Alarm Advisor	C46
HEXAD	C54
aEEG	C60
Clinical packages	
Extended ECG capabilities	CP2
Extended alarm capabilities	CP4
Care areas	
Intensive care software	H12
Neonatal care software	H22
Anesthesia care software	H32
Cardiac care software	H42
ProtocolWatch	
Severe Sepsis Screening	P01
SSC Sepsis Protocol	P02
Early Warning Scoring	P05

Hardware upgrade options

For: 866473 IntelliVue MX850 and 866474 IntelliVue MX750

Description	Option
Wired interfaces	
MIB/RS232 interface	J13
Flexible nurse call interface	J30
a. Hardware supports multiple boards of this type	
Wireless interfaces	
802.11 Wireless Interface ^a	J35
a. May not be available in all countries	

Mounting information

For mounting hardware, contact your local Philips sales representative. For more information, see: <https://www.usa.philips.com/healthcare/solutions/patient-monitoring/mounting-solutions>

Documentation

All documentation is available in .pdf format on documentation DVD that is shipped with the product. Additionally, a predefined number of the Instructions for Use ships with each order.

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866471 & 866470 comply with the requirements of the Council Directive 93/42/EEC of 14 June 1993 (Medical Device Directive) as amended.

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Apéndice C del Anexo 1. Ficha técnica del ventilador mecánico Getinge Servo-i.

DATA SHEET

VENTILATION
SERVO-i[®] ADULT

MAQUET
GETINGE GROUP

CRITICAL CARE



HIGHLIGHTS

- For adult and pediatric patients
- Intuitive user interface
- Designed for cost-efficiency
- Flexible placement
- Modular – interchangeable plug-in units
- Enables Heliox delivery
- NAVA[®] - improved synchrony and unique monitoring capabilities
- For invasive as well as non invasive ventilation
- The Open Lung Tool[®] and Stress Index - tools for lung protection.
- Available in MR and Transport editions for continuity of ventilatory care

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SERVO-i VENTILATOR FAMILY SERVO-i[®] ADULT

SERVO-i Configurations

The SERVO-i[®] Ventilator family consists of four configurations:



Infant
Adult
UBE
Universal Basic Edition
UEE
Universal Extended Edition



Standard Configuration
Options
Not applicable

The SERVO-i Ventilator family addresses the very different requirements of neonatal, pediatric and adult needs from a single ventilation platform. All four configurations are the same ventilator, equipped with different functions. They can be customized and upgraded with different options for future needs. (SERVO-i Adult and SERVO-i Infant can also be upgraded to SERVO-i Universal.) The same ventilator can be used at the bedside, during transport* and in the MR-room* facilitating training, operation and maintenance, increasing efficiency and flexibility.

*An agreement with MAQUET must be signed, see conditions in the SERVO-i MR declaration (Order no. 66 71 670) and the Interhospital Transport Declaration (Order no. 66 64 721) respectively.

Stress Index

NIV NAVA[®]

NAVA[®]

Heliox

Nasal CPAP

NIV PC

NIV PS

Bi-Vent

Y Sensor Measuring

CO₂ Analyzer

Nebulizer

Alarm output connector

Open Lung Tool[®]

Automode[®]

SIMV (PRVC) + PS

PRVC

VS

SIMV (VC) + PS

VC

SIMV (PC) + PS

PC

PS/CPAP

All patient category software

KEY TO ABBREVIATIONS

NAVA	Neurally Adjusted Ventilatory Assist
NIV	Non-invasive ventilation
SIMV	Synchronized Intermittent Mandatory Ventilation
PRVC	Pressure Regulated Volume Control
VS	Volume Support
VC	Volume Control
PS	Pressure Support
PC	Pressure Control
CPAP	Continuous Positive Airway Pressure

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TECHNICAL SPECIFICATIONS SERVO-i[®] ADULT

The system – General		Non-operating conditions	
CE 0413	The device complies with requirements of Medical Device Directive 93/42/EEC.	Impact:	Peak acceleration: 15 g. Pulse duration: 6 ms. Number of impacts: 1000.
Classification:	Class I equipment. According to IEC/EN 60 601-1.	Storage temperature:	-25 to +60° C (-13 to 140° F)
Standards:	IEC/EN 60 601-1 (Type B). IEC/EN 60 601-2-12. EN 794-1.	Storage Relative Humidity:	< 95%
Noise level:	<50 dBA, measured at 0.3 m distance.	Storage Atmospheric Pressure:	470 to 1060 hPa
IP classification	IP 20	Power supply	
Electromagnetic compatibility (EMC):		Power supply, automatic range selection:	100 – 120 V AC ±10%, 50 – 60 Hz, or 220 – 240 V AC ±10%, 50 – 60 Hz.
■ Emission:	According to IEC/EN 60601-1-2 (Edition 2:2001).	Plug-in battery module:	
■ Immunity- Extended test to 30 v/m:	According to IEC/EN 60601-1-2.	■ Battery backup:	Two battery modules are delivered with the ventilator. Up to six battery modules can be included.
The 'EMC Declaration, Information to the Responsible Organization' is available from MAQUET.		■ Battery capacity:	Rechargeable, 12 V, 3.5 Ah each.
■ Recharge time:		■ Recharge time:	Approximately 3 h/battery.
■ Battery backup time:		■ Battery backup time:	At least 3 h, when using six batteries.
Patient range (all ventilation modes):	Weight 10 – 250 kg.	External 12 V DC:	12.0 V – 15.0 V DC, 10 A
Operating conditions		Max power consumption:	At 100 – 120 V: 2 A, 190 VA, 140 W. At 220 – 240 V: 1 A, 190 VA, 140 W.
Operating temperature:	+10 to +40°C		
Relative humidity:	15 to 95% non-condensing		
Atmospheric pressure:	660 to 1060 hPa		
Lowest pressure in breathing system:	-400 cmH ₂ O		



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| Critical Care | **SERVO-i[®] ADULT** | 5 |

TECHNICAL SPECIFICATIONS

SERVO-i[®] ADULT

The ventilator – General

Dimensions:	(See dimensional drawings page 15)
■ User Interface:	W 355 x D 53 x H 295 mm
■ Patient Unit:	W 300 x D 205 x H 415 mm
Weight:	Approximately 20 kg (Patient Unit 15 kg, User Interface 5 kg)
Method of triggering:	Flow, pressure and Edi (optional)
Max. operating pressure:	Approximately 115 cmH ₂ O
Bias flow:	2 l/min

Gas supply

Inlet gas pressure Air/O ₂ :	200 – 650 kPa / 2.0 – 6.5 bar / 29 – 94 PSI
Connection standards available:	AGA, DISS, NIST, or French standard.
Unavailable gas/loss of gas pressure:	The flow from an unavailable gas (air or O ₂) is automatically compensated for so that the patient gets the preset volume and pressure.

Patient system gas connectors

Conical fittings:	Male 22 mm / female 15 mm. In accordance with ISO 5356-1.
Gas exhaust port:	Male 30 mm cone

User interface

Weight:	Approximately 5 kg
Attachment:	Can be attached to the mobile cart, a table, rail or pole (15 – 30 mm diameter).

Screen

Type:	TFT-LCD module
Size:	31 cm (12.1") diagonal
Viewing area:	246.0 x 184.5 mm

Inspiratory channel

Pressure drop:	Max. 6 cmH ₂ O at a flow of 1 l/s
Internal compressible factor:	Max. 0.1 ml/cmH ₂ O
Gas delivery system:	Microprocessor controlled valve
Inspiratory flow range:	0 to 3.3 l/s

Expiratory channel

Pressure drop:	Max. 3 cmH ₂ O at a flow of 1 l/s
Internal compressible factor:	Max. 0.1 ml/cmH ₂ O
PEEP regulation:	Microprocessor controlled valve
Rise time, expiratory flow measurement:	<12 ms for 10 – 90 % response at flow of 0.05 – 3.2 l/s
Expiratory flow range:	0 to 3.2 l/s

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| 6 | **SERVO-i[®] ADULT** | Critical Care |

TECHNICAL SPECIFICATIONS **SERVO-i[®] ADULT**

Alarms	
Airway pressure (upper):	
■ Invasive ventilation:	16 – 120 cmH ₂ O
■ Non Invasive Ventilation:	16 – 40 cmH ₂ O
Expired minute volume (Upper alarm limit):	0.5 – 60 l/min
Expired Minute Volume (Lower alarm limit):	0.5 – 40 l/min
No patient effort (Apnea) alarm	15 – 45 s
Automatic return to support mode on patient triggering	
No consistent patient effort:	Yes, described in User's manual
Respiratory frequency:	1 – 160 breaths/min
High end expiratory pressure:	0 – 55 cmH ₂ O
Low end expiratory pressure:	0 – 47 cmH ₂ O. Note. Setting the alarm to 0 (zero) is equal to alarm off.
High continuous pressure:	Set PEEP level + 15 cmH ₂ O exceeded for more than 15 seconds.
O ₂ concentration:	Set value ±5 vol% or ≤18 vol%
Gas supply:	Below 200 kPa / 2.0 bar / 29 PSI and above 650 kPa / 6.5 bar / 94 PSI
Battery:	Limited battery capacity: 10 min. No battery capacity: less than 3 min. Low battery voltage.

Alarms	
End-tidal CO ₂ (upper and lower limit):	0.5 – 20%. 4 – 100 mm Hg. 0.5 – 14 kPa.
Leakage out of range in NIV:	Yes. Described in the User's manual.
Technical:	Yes. Described in the User's manual.
Autoset (alarm limits) specification:	Invasive ventilation, controlled modes only
■ High airway pressure:	Mean peak pressure +10 cmH ₂ O or at least 35 cmH ₂ O.
■ Upper minute volume:	Expiratory minute volume + 50%.
■ Lower minute volume:	Expiratory minute volume – 50%.
■ Upper respiratory frequency:	Breathing frequency + 40%.
■ Lower respiratory frequency:	Breathing frequency – 40%.
■ High end expiratory pressure:	Mean end expiratory pressure + 5 cmH ₂ O.
■ Low end expiratory pressure:	Mean end expiratory pressure – 3 cmH ₂ O.
■ Upper end tidal carbon dioxide concentration (etCO ₂):	End tidal carbon dioxide concentration + 25%.
■ Lower end tidal carbon dioxide concentration (etCO ₂):	End tidal carbon dioxide concentration – 25%.

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TECHNICAL SPECIFICATIONS SERVO-i[®] ADULT

Ventilation Modes – Invasive ventilation

Controlled ventilation:

- PC Optional
- VC Can be configured with alternative flow patterns
 - VC with flow adaptation,
 - VC without flow adaptation,
 - VC with decelerating flow
- PRVC Optional

Supported ventilation:

- VS Optional
- PS/CPAP

Combined ventilation:

- SIMV (VC) + PS: Comes with the corresponding controlled ventilation mode. (Optional)
- SIMV (PC) + PS: Comes with the corresponding controlled ventilation mode. (Optional)
- SIMV (PRVC) + PS Comes with the corresponding controlled ventilation mode. (Optional)
- Bi-Vent Pressure controlled ventilation on two independently adjustable levels, allowing unrestricted spontaneous breathing on both levels. (Optional)

Automode

Control mode: VC <—> Support mode: VS
Control mode: PC <—> Support mode: PS
Control mode: PRVC <—> Support mode: VS
(Optional)

Ventilation modes – Non-invasive Ventilation (optional)

NIV PC

NIV PS

Ventilation modes - NAVA (optional)

NAVA

Neurally Adjusted Ventilatory Assist via endotracheal tube or tracheostomy

NIV NAVA

Neurally Adjusted Ventilatory Assist via non-invasive patient interfaces

Waveform and loop presentations

Real time waveforms - up to 4 waveforms can be displayed simultaneously:

- Pressure
- Flow
- Volume
- CO₂ Requires SERVO-i CO₂ Analyzer option
- Edi Requires SERVO-i NAVA option

Loops:

- Volume / Pressure* *A reference loop and three overlaying loops can be displayed.
- Flow / Volume* *Displayed simultaneously with Open Lung Tool graphical trends, if requested.

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TECHNICAL SPECIFICATIONS **SERVO-i[®] ADULT**

Monitoring	Displayed value	Trended value*
Breathing frequency:	Yes	Yes
Spontaneous breaths per minute (RRsp):	No	Yes
Peak Airway Pressure:	Yes	Yes
Mean Airway Pressure:	Yes	Yes
Pause Airway Pressure:	Yes	Yes
End Expiratory Pressure:	Yes	Yes
CPAP Pressure:	Yes	Yes
Inspired Tidal Volume:	Yes	Yes
Expired Tidal Volume:	Yes	Yes
Inspired Minute Volume:	Yes	Yes
Expired Minute Volume:	Yes	Yes
Leakage fraction in NIV (%):	Yes	Yes
Ti/Ttot:	Yes	No
I:E ratio:	Yes	No
Total PEEP:	Yes	No
Edi peak:	Yes	Yes
Edi min:	Yes	Yes
O ₂ Concentration (measured):	Yes	Yes
CO ₂ End tidal concentration (etCO ₂):	Yes	Yes
CO ₂ Minute elimination (CO ₂):	Yes	Yes
Tidal CO ₂ elimination (VTCO ₂):	Yes	Yes
MV _e sp / MV _e :	Yes	No
Spontaneous Exp. Minute Volume (MV _e sp):	Yes	Yes
*Stored trend values for up to 24 hours		

Monitoring	Displayed value	Trended value*
End Expiratory Flow:	Yes	Yes
Static Compliance:	Yes	Yes
Dynamic Compliance:	Yes	Yes
Stress Index	Yes	Yes
Inspiratory Resistance	Yes	Yes
Expiratory Resistance	Yes	Yes
Elastance	Yes	Yes
Time Constant	Yes	No
P0.1:	Yes	Yes
Work of Breathing patient:	Yes	Yes
Work of Breathing ventilator	Yes	Yes
Shallow Breathing Index (SBI)	Yes	Yes
Supply pressure (O ₂ and air):	Yes	No
Battery remaining time:	Yes	No
Barometric pressure:	Yes	No

Log function

Event log:	Alarms. Ventilator settings. Apnea periods. Immediate functions.
Service log:	Technical alarms. Test results. Preventive maintenance. Service history. Configuration log.

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TECHNICAL SPECIFICATIONS **SERVO-i[®] ADULT**

Parameter settings: Parameter:	Setting range:
Inspiratory tidal volume (ml):	100 – 2000
Inspiratory minute volume (l/min):	0.5 – 60
Apnea, time to alarm (s):	15 – 45
Automode Trigger timeout (s):	7 – 12
PC/PS above PEEP (cmH ₂ O)	0 – (120 - PEEP)
PC/PS above PEEP in NIV (cmH ₂ O)	0 – (32 - PEEP)
PEEP (cmH ₂ O)	0 – 50
PEEP in NIV (cmH ₂ O)	2 – 20
CPAP pressure (cmH ₂ O):	–
CMV frequency (breaths/min):	4 – 100
SIMV frequency (breaths/min):	1 – 60
Breath cycle time, SIMV (s):	1 – 15
P _{High} (cmH ₂ O)	(PEEP +1) – 50
T _{High} (s):	0.2 – 10
T _{PEEP} (s):	0.2 – 10
PS above P _{High} (cmH ₂ O):	0 – (120 - P _{High})
O ₂ concentration (%):	21 – 100
I:E ratio:	1:10 – 4:1

Parameter settings: Parameter:	Setting range:
T _{Insp} (s):	0.1 – 5
NAVA level (cmH ₂ O/μV):	0 – 15
Edi trigger sensitivity (μV):	0.1 – 2.0
T _{Pause} (s):	0 – 1.5
T _{Pause} (% of breath cycle time):	0 – 30
Flow trigger sensitivity level (fraction of bias flow):	0 – 100%
Press. trigg sensitivity (cmH ₂ O)	-20 – 0
Insp. rise time (% of breath cycle time):	0 – 20
Insp. rise time (s):	0 – 0.4
Insp. cycle off (% of peak flow):	1 – 70
Insp. cycle off in NIV (% of peak flow):	10 – 70
Nebulizer time (min):	5 – 30

Backup settings Parameter:	Setting range:
Inspiratory tidal volume (ml):	100 – 2000
PC above PEEP (cmH ₂ O)	5 – (120 - PEEP)
PC above PEEP in NIV	5 – (32 - PEEP)
CMV frequency (breaths/min):	4 – 100
I:E ratio:	1:10 – 4:1
T _{Insp} (s):	0.1 – 5

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TECHNICAL SPECIFICATIONS **SERVO-i[®] ADULT**

Parameter:	Setting range
Oxygen breaths:	100% for 1 minute
Start breath:	Initiation of 1 breath (In SIMV mode initiation of 1 mandatory breath)
Pause hold:	Insp. or exp (0 – 30 seconds)
Alarm silence/reset:	2 minute silence and reset of latched alarms
Compliance compensation:	On/Off
Automode (optional with Universal Basic Edition):	Automode On/Off
Nebulizer (optional)	5 - 30 min./Continuous/Off
Backup ventilation	Backup On/Off

Suction Support	
Pre oxygenation time:	Max. 2 min
Post oxygenation time:	Max. 1 min
Suction phase time:	No maximum level
Adjustable oxygen level:	21 – 100 %

Saving of data	
Recording of current waveform and parameter values:	20 seconds of data will be recorded (10 seconds before and 10 seconds after activation).

Communication/Interface	
Serial port:	RS-232C - isolated. For data communication via the Communication Interface Emulator (CIE).
Second serial port (optional)	See information above.
Alarm output connector (optional)	
Connector:	4-pole Modular connector
Ratings:	Max 40 V DC, Max 500 mA, Max 20 W
Network connection (optional):	MIB (Medical Information Bus) monitor connection
Data transfer (optional)	Via Ventilation Record Card
Screen picture transfer (optional)	Via Ventilation Record Card

Non-invasive Ventilation (optional)	
Max. leakage compensation level:	
■ Adult	65 l/min
Leakage overrange detection:	Automatic
Disconnect detection:	Automatic
Disconnect flow:	Configurable
■ Low:	7.5 l/min
■ High:	40 l/min
■ Disabled	Deactivates disconnect detection
Connect detection:	Manual, or automatic via bias flow



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TECHNICAL SPECIFICATIONS SERVO-i[®] ADULT

Open Lung Tool (OLT) (optional with Universal Basic Edition)

Three simultaneous graphical trends, presented breath-by-breath:	1. EIP and PEEP (End Inspiratory Pressure and Positive End Expiratory pressure). 2. VT_i and VT_e (Inspiratory and Expiratory Tidal volume). 3. C_{dyn i} and VT_{CO₂}* (Dynamic inspiratory Compliance [= VT_i/(EIP – PEEP)] and Tidal CO₂ elimination*).
	* Requires SERVO-i CO ₂ Analyzer option.

Values stored breath by breath: Up to 21.600 breaths.

Cursor function: A cursor can be moved with the main rotary dial or via the touch screen. When moving it along the graph, the numeric parameter values valid for that actual moment will be shown.

Zoom function: Time resolution of the x-axis can be selected in five different steps.

Time marking: Hours and minutes (when values are measured).

Stress Index (optional)

Presented values:	■ SI (Stress Index) ■ PEEP (Positive End Expiratory pressure). ■ VT_e (Expiratory Tidal volume).
Stored values:	■ 120 values stored in graph ■ Stored trend values up to 24 hours
Cursor function:	A cursor can be moved with the main rotary dial. When moving it along the graph, the numeric parameter values valid for that actual moment will be shown.
Time marking:	Hours and minutes (when values are measured).

NAVA (optional)

Standards:	IEC/EN 60601-1 (Type CF, defibrillator proof)
Size:	
■ Edi module:	154 x 90 x 21 mm
■ Edi catheter cable:	Length: 2 m
Weight - Edi module:	0.25 kg
Power source - Edi module supply voltage:	Powered from SERVO-i. <3 W at 12 V (normal operation)
Parameters:	Edi waveform Edi leads waveforms NAVA estimated pressure waveform (Pest)
Edi catheters:	6 Fr, length 49 cm 6 Fr, length 50 cm 8 Fr, length 100 cm 8 Fr, length 125 cm 12 Fr, length 125 cm 16 Fr, length 125 cm

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TECHNICAL SPECIFICATIONS SERVO-i[®] ADULT

SERVO-i CO ₂ Analyzer (optional)		SERVO-i CO ₂ Analyzer – Performance	
Standard:	EN 864, ISO 9918. IEC/EN 60601-1 (Type BF, defibrillator proof)	Measuring method:	Mainstream, dual-wavelength, non-dispersive infrared.
Size:		Parameters:	Capnogram. CO ₂ End tidal concentration (etCO ₂). CO ₂ Minute elimination ($\dot{V}CO_2$). Tidal CO ₂ elimination (VTCO ₂).
■ CO ₂ Analyzer Module:	154 x 90 x 43 mm	Measuring range:	0 to 100 mm Hg CO ₂ partial pressure. 0 to 13.3 kPa CO ₂ partial pressure. 0 to 13.2% CO ₂ volume (at a barometric pressure of 1013 hPa).
■ Sensor:	32.0 x 42.4 x 21.6 mm	Step response time:	<25 ms (10 to 90% step response).
Weight:		Warm-up time:	30 s to initial CO ₂ indication, max. 5 min to full specification.
■ CO ₂ Analyzer Module:	0.45 kg	Oxygen concentration compensation:	Automatic. Values supplied from the SERVO-i Ventilator System.
■ Sensor:	18 g	Barometric pressure compensation:	Automatic. Values supplied from the SERVO-i Ventilator System.
■ Airway adapter:	10 g	Digitizing rate:	87 Hz
Connectors and cables:		Airway adapter dead space:	<5 ml
■ CO ₂ Analyzer Module:	15-pole D-sub female connector.		
■ Sensor:	20-pole, 2.4 m cable.		
Power source:			
■ CO ₂ Analyzer Module supply voltage:	Powered from the SERVO-i.		
■ Power consumption:	≤ 8 W at 12 V, during warm up. ≤ 6.5 W at 12 V, during normal operation.		
■ Sensor:	Powered from the CO ₂ Analyzer Module.		



TECHNICAL SPECIFICATIONS SERVO-i[®] ADULT

Y Sensor measuring (optional)

Size:	
■ Y Sensor Module:	154 x 90 x 43 mm
■ Y sensor adult:	Length 84 mm
Weight:	
■ Y Sensor Module:	0.4 kg
■ Y sensor adult:	10.5 g
Sensor material:	Makrolon polycarbonate.
Tubing:	2.0 m. Medical grade PVC.
Power source – Y Sensor	Powered from the SERVO-i.
Module supply voltage:	<5 W at 12 V (normal operation).

Y Sensor measuring – Performance

Measuring method:	Fixed orifice, differential pressure.
Parameters:	Airway pressure. Airway flow. Inspiratory and expiratory volumes.
Measuring range:	2 to 180 l/min
Airway adapter dead space:	< 9.0 ml

Servo Ultra Nebulizer (optional)

Weight:	Approx. 125 g
Dimensions:	H 105 mm x L 108 mm x W 60 mm
Connection cable length:	2.0 m
Nebulizer T-piece connections:	Inlet/outlet: 22/15 mm outer/inner diameter and 22 mm inner diameter, ISO standard. Pediatric patient tubes: Adapters 22/10 mm outer diameter and 15/10 mm outer diameter.
Internal volume:	60 ml
Ultrasonic generator frequency:	2.4 MHz
Particle size (water):	Mass Median Diameter (MMD) = approximately 4.0 µm, measured distally in endotracheal tube 8 mm inner diameter.
Output from nebulizer (water) – minimum water flux:	Min. 0.1 ml water/min at 0.1 l gas flow/s. Min. 0.3 ml water/min at 0.5 l gas flow/s. Min. 0.5 ml water/min at 1.0 l gas flow/s.
Buffer liquid:	Sterile water
Max. medication temperature:	55° C (131° F)
Volume, medication cup:	Max. 10 ml
Noise level:	Max. 50 dBA, measured at 0.3 m distance.

Aeroneb Nebulizer Systems (optional)

Weight - Aeroneb module:	Approx. 216 g
Dimensions - Aeroneb module:	H 105 mm x L 108 mm x W 60 mm
Connection cable length:	2.0 m
Particle size (water):	1 - 5 mass median aerodynamic diameter (MMAD)
Flow rate:	>2 ml/min
Volume - nebulizer unit	■ Pro - 10 ml ■ Solo - 6 ml
Residual volume:	10 %



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TECHNICAL SPECIFICATIONS

SERVO-i[®] ADULT

SERVO-i Mobile Cart (optional)		SERVO-i IV Pole (optional)	
Weight:	20 kg	Max load (total):	6 kg
Dimensions:	H 1015 mm x L 640 mm x W 560 mm (see dimensional drawing below)	Gas trolley (optional)	
SERVO-i Drawer kit (optional)		Max load:	2x10 kg bottles
Weight:	4.5 kg	Docking:	Dockable to SERVO-i Mobile Cart. Dockable to a separate wall clamp.
Dimensions:	H 240 mm x L 210 mm x W 300 mm	Compressor Mini (optional)	
SERVO-i Holder (optional)		See separate data sheet.	
Weight:	3.5 kg	Service	
Dimensions:	H 352 mm x L 247 mm x W 159 mm (see dimensional drawing below)	Regular maintenance:	Once every 12 months or at least after 5000 operating hours.
SERVO-i Shelf Base (optional)		Note	
Weight:	1.2 kg	For inaccuracies and more detailed technical specifications please refer to the User's manual.	
Dimensions:	H 29 mm x L 205 mm x W 159 mm (see dimensional drawing below)	ORDERING INFORMATION	
Gas cylinder restrainer (optional)		SERVO-i, Ventilator and accessories: See separate information: "SERVO-i, Version 6.1 — System Flow Chart" (Order no: 66 70 102).	
Max load:	2 x 5-liter bottles		

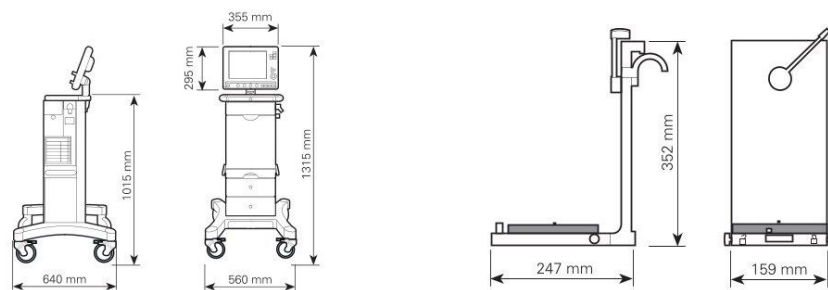


TECHNICAL SPECIFICATIONS SERVO-i[®] ADULT

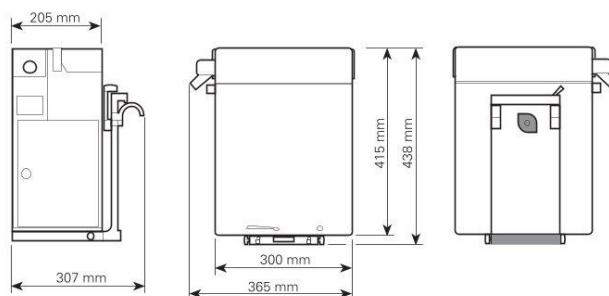
Dimensional drawings

SERVO-i on Mobile Cart

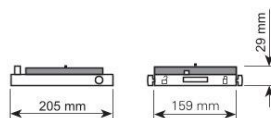
SERVO-i Holder



SERVO-i (patient unit) on SERVO-i Holder



SERVO-i Shelf Base





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Order No. 66 70 107 • Printed in Sweden • 111116 • Rev. 12 English • Data Sheet

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Apéndice D del Anexo 1. Ficha técnica del ventilador mecánico Getinge Servo-u.



Personalized ventilation for better outcomes

Every patient comes with special challenges. Whether it's a 300 gram newborn or a 300 kg adult, someone suffering from acute respiratory failure or chronic pulmonary disease, the needs and complexities will differ. That is why we are committed to innovating personalized ventilation solutions that help protect the lung and diaphragm, speed up weaning and support better outcomes.

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The Servo-u universal ventilator system

Servo-u delivers outstanding clinical performance across all patient categories and meets the latest international product standards for product safety, biocompatibility, electromagnetic compatibility, connectivity and cybersecurity.



50 years of Servo innovation

Based on 50 years of groundbreaking clinical innovation, Servo-u gives you many options for personalized lung protection and weaning. All are easy to understand, implement and use, making it simple to integrate advanced personalized ventilation strategies into your daily patient care. This truly universal ventilator lets you switch between invasive and non-invasive modes, as well as High Flow therapy, for treatment of all patient categories, from neonates to adults.

Less time on ventilation

Unique tools and therapies support you at every stage. For example, our Open Lung 'tool' with Stress Index™ and Transpulmonary Pressure tools allow you to assess lung stress. And our groundbreaking Neurally Adjusted Ventilatory Assist (NAVA) ventilation mode shortens the time of weaning and mechanical ventilation* and increases the number of ventilator-free days** for adult patients in the ICU with acute respiratory failure, according to randomized controlled trials.

Freeing up hospital beds

All of this may translate to a significantly improved health economy, enabling hospitals to free up precious ICU beds and resources. Similar trials on pediatric and neonatal patients also show an increased rate of successful extubations** and that NAVA shortens the time of mechanical ventilation.** In short, personalized ventilation that makes a difference.



Simple to learn, safer to use

Our Servo ventilator development has always built on close collaboration with intensive care clinicians around the world. The result is continuous innovation, higher levels of patient safety and a superior user experience.^{1,2}



Intuitive touchscreen

The intuitive touchscreen makes Servo-u a breeze to learn and use. Help menus, recommendations and prompts help staff to orientate quickly and receive guidance. The interface also simplifies knowledge sharing, where it is easy to retrieve screenshots and recordings or connect to a larger screen.



Ergonomic design

Servo-u features an ergonomic design. The screen can be rotated through 360°, which means you can place the ventilator anywhere around the bed, depending on clinical requirements. You can also mount Servo-u on a ceiling supply unit or shelf. The system is light and compact, making it highly suitable for intra-hospital transport.

All you need, at your fingertips



Pre-use check automation

The Pre-use check and Patient circuit test are there to ensure optimal system performance. Upon completion of a set of automated calibrations and tests, the results including any identified recommendations, are presented to you.



Safety Scale® parameters

The system's Safety Scale tool makes parameter changes quick and intuitive, while dynamic images illustrate how those changes may affect ventilation.



Direct access to alarms

Tap the related numerical value field to quickly adjust a specific alarm setting, regardless of its status. Where applicable, this also allows permanent silencing or deactivation.



Context-based guidance

Servo-u provides extensive guidance for everything from Pre-use check to initial parameter setting and throughout the entire treatment.



View configuration

Several views are available to tailor the information displayed to the user and the clinical situation: Basic, Advanced, Loops, Distance, Family, Servo Compass and Pex & PL.



Alarm management

The 360° lamp and active alarm parameter light up when an alarm is triggered to make it visually recognizable from any view point. On-screen checklists help you to manage each active alarm and reduce undesired alarms.



Workflow support

Smart workflows are available for special procedures, such as Disconnection, Recruitment maneuvers and EIT and Pex catheter placement and positioning.



Screenshots and recordings

You can take screenshots and record high-resolution waveforms for 30 s. Recruitment maneuvers are manually or automatically recorded and also saved in the Library.



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Personalized lung protection, breath by breath

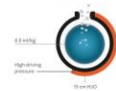
Recent clinical studies suggest that many ventilators lack effective bedside decision-support tools. It's a problem that results in protective ventilation strategies being delayed or inconsistently applied. Ultimately, this can harm the patient and worsen the outcome.^{13, 14}

To avoid these situations, Servo-u offers you the complete toolkit for personalized ventilation. It enables you to detect risks early and support timely and consistent implementation of personalized protective ventilation strategies, in line with the latest international guidelines.^{15, 16} In other words, the right support for each patient, at the right time.

«These new tools have the potential to make a significant difference in terms of patient outcomes. They are far ahead of what we are using today!»¹⁷

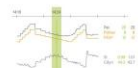


Tools for lung protection



Servo Compass

Servo Compass[®] makes it easy to see when plateau/driving pressure or tidal volume per predicted body weight (V_T/PBW) are off pre-defined targets and interventions are needed.^{*} Precisely calculated Dynamic Compliance (C_{dyn}) and Stress Index (SI) complete the picture, helping you detect changes in lung volume and verify over-distension.¹⁸



Open Lung Tool

Open Lung Tool trends (OLT trends) helps you assess lung mechanics and gas exchange - breath-by-breath, in real time and retrospectively. It provides flexibility and guidance when personalizing PEEP and driving pressure during recruitment maneuvers, prone positioning and extra corporeal life support. Stress index, carbon dioxide elimination and transpulmonary pressure are also fully integrated.



Auto SRM

Auto SRM is an automatic workflow for Stepwise Recruitment. Manoeuvres based on the Open Lung approach.¹⁹ The tool guides you smoothly through recruitment, decremental PEEP titration, re-recruitment and post-recruitment personalization of PEEP and driving pressure, based on optimal C_{dyn}. Diagnostic features include assessment of recruitability and additional decision support when patients do not respond to the recruitment manoeuvre.²⁰



Auto RM

Auto RM allows quick recruitment after patient disconnection, suction or surgery. It keeps recruitment settings used in Auto SRM, and provides opportunity to delegate recruitment when fewer physicians are available, e.g. during the night. Post-recruitment summary is provided, with color coded results and a shortcut to OLT trends, in case additional titration of settings based on breath-by-breath data is desired.



Transpulmonary pressure monitoring

Transpulmonary pressure represents the true distending pressure across the lungs, defined as the difference between alveolar and pleural pressures, with airway and esophageal pressures serving as surrogates for calculation.

Esophageal pressure

Esophageal pressure (Pes) measurement is a minimally invasive monitoring method that allows precise differentiation between the mechanical properties of the lungs and the chest-wall complex. This provides a foundation for determining transpulmonary pressure (PL). To simplify the process and improve accuracy, we have developed an automated maneuver to validate both the positioning and inflation of the esophageal catheter's air-filled balloon.

Transpulmonary pressure

Our diagnostic view displays real-time esophageal (Pes) and transpulmonary pressure waveforms, essential for evaluating both controlled and spontaneous ventilation. It simplifies the relationship between airway and transpulmonary pressures. Additionally, OLT trends combine transpulmonary pressure with driving pressure, stress index, and CO₂ elimination, offering a comprehensive breath-by-breath analysis.

Clinical context for Pes & PL

In ARDS patients, targeting PEEP to optimize transpulmonary pressure can improve compliance and oxygenation while reducing driving pressures, a factor associated with improved 28-day mortality rates.²¹ For the most severe ARDS cases, transpulmonary pressure monitoring may provide critical guidance in avoiding ECMO or in adopting strategies that increase the likelihood of successfully weaning patients from ECMO support.²²⁻²⁴





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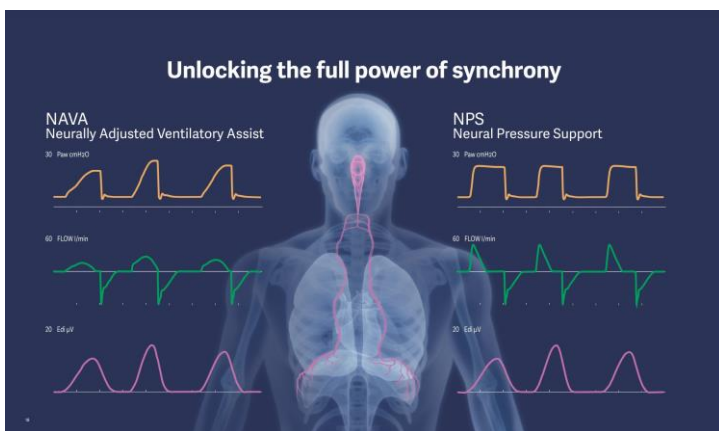
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Personalized weaning with Lung- and Diaphragm- Protective Ventilation

Recent clinical studies reveal that diaphragm weakness is prevalent (23–84%) in ICU patients and consistently associated with poor outcome.^{1,2} Servo-u lets you monitor the patient's diaphragm activity (Edi) to personalize ventilation for successful weaning. It offers several options to start weaning your patients earlier and liberate them from the ventilator.

+ NAVA shortens time of mechanical ventilation by almost 35%.^{3,4}



Monitor Edi – the vital sign of respiration, from day zero

Careful monitoring and management of the patient's respiratory drive (Edi) and inspiratory effort is recommended to minimize risk of ventilator induced diaphragm dysfunction (VIDD) and patient self-inflicted lung injury (P-SILI).^{1,2} Edi monitoring is available in all non-invasive and invasive ventilation modes, High-Flow therapy and in Standby.



Protect the lungs and diaphragm with full synchrony

Neurally Adjusted Ventilatory Assist (NAVA) utilizes the patient's Edi signal to deliver personalized, lung-protective spontaneous breathing, with higher diaphragmatic efficiency, while minimizing periods of over- and under-assistance.^{1,2,3,4} It may also improve the patient's ICU experience by reducing the need for sedation, thereby enhancing comfort and sleep quality.^{1,2,3,4} NAVA shortens the time of weaning and mechanical ventilation³ and increases the number of ventilator-free days.^{1,2}



Protect and activate the diaphragm to wean earlier

Early Edi respiratory drive and effort monitoring help safeguard diaphragm activity.^{1,2,3,4} With the Edi waveform continuously displayed on the ventilator, you can promptly identify issues such as diaphragm inactivity, over-sedation, patient-ventilator asynchrony, over- or under-assistance, and increased work of breathing during weaning trials.^{1,2,3,4}



Protect the lungs and diaphragm with partial synchrony

Neural Pressure Support (NPS) delivers time-synchronized pressure support (PS), which may reduce the incidence of premature expiratory cycling. This may minimize the risk of harmful eccentric diaphragm contractions, which are common with conventional flow-cycled PS.^{1,2,3,4} The faster pressurization rate compared to NAVA may offer advantages in managing restrictive ARDS and obstructive COPD patients, particularly those with high respiratory drive and excessive lung-distending forces.^{1,2,3,4}



A complete set of adaptive NIV modes for all patient categories

Non-invasive ventilation is used to reduce pulmonary complications, such as atelectasis and pneumonia, in patients with acute and chronic respiratory failure and to support weaning by preventing re-intubations.

The Servo-u NIV modes feature advanced leakage compensation to meet patients' inspiratory flow and expiratory pressure demands, even in cases of significant leaks. Trigger sensitivity, expiratory cycling, and ventilation monitoring are continuously and automatically adjusted. The NIV workflow is supported by functions such as configuration and permanent silencing of alarms, weaning position, disconnect/incorrect management and a smooth and seamless transition between High Flow therapy, NIV and back.

Neurally synchronized ventilation modes are designed to enhance patient-ventilator interaction, remaining unaffected by challenges such as leakage or Auto-PEEP. These advanced modes ensure precise synchronization with the patient's neural activity, promoting comfort and optimal respiratory support.^{1,2,3,4}





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Improving care with integrated cost-efficient therapies

Integrated therapies expand the use of the Servo-u while limiting the need for stand-alone therapy devices. High Flow therapy, nebulization that does not affect breath delivery or Heliox therapy can be used by themselves or in combinations to provide a personalized and cost-effective respiratory therapy.²⁶



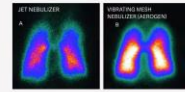
High Flow therapy

High Flow therapy is integrated, so there is no need to switch to stand-alone systems. It reduces the patient's work-of-breathing by providing an accurate flow of humidified oxygen, improving comfort and tolerance.²⁶



Aerogen® nebulizer

This fully integrated vibrating mesh nebulizer does not affect breath delivery and offers significantly higher lung deposition compared to jet nebulizers²⁷. It can be used with a broad range of pharmaceuticals, and its closed-circuit medication filling design helps mitigate the transmission of patient-generated infectious aerosols.²⁸ Additionally, its virtually silent drug delivery maintains a calm environment for your patients.



Heliox therapy

Heliox is a low-density mix of helium and oxygen that helps reduce the work of breathing (WOB), as well as plateau and driving pressure in patients with obstructed airways, such as adults with chronic obstructive pulmonary disease (COPD), or children with bronchiolitis or asthma. It improves aerosol deposition by up to 50% thanks to reduced gas turbulence and less aerosol-particle-impaction loss in the tubing and patient airways.²⁹⁻³²



Edi real-time respiratory drive monitoring will precisely quantify the effect of the above therapies.^{34,35}

Pediatric patients

Every child admitted to a Pediatric Intensive Care Unit (PICU) deserves a chance at a healthy future, where the smallest details in care can make a big difference.

We are passionate about helping to improve the respiratory care of the most critically ill children, ensuring that both they and their families remain at the centre of attention as they await recovery from critical illness.

In the extended pediatric patient category, Servo-u now offers:

- A maximum respiratory flow rate of 120 liters per minute to allow responsive and accurate ventilation with leak compensation for a wide pediatric patient range, from 2 to 50 kg.
- Advanced monitoring tools to empower bedside clinicians in decision-making for non-invasive ventilation (NIV), aiming to reduce sedatives and complications through improved synchrony.
- Invasive ventilation options to enhance gas exchange, reduce oxygen consumption, and support respiratory muscles.
- Research tools to increase knowledge in this area to identify strategies that can improve pediatric patient care.



Neonatal patients

In the Neonatal Intensive Care Unit (NICU), balancing gas exchange while minimizing work of breathing and discomfort in fragile premature infants is a critical challenge. Prioritizing lung, diaphragm, and brain protection is essential to improving long-term neurodevelopmental outcomes.

Non-invasive ventilation strategies

The increased usage of non-invasive ventilation modes is widely recognized as a preferred strategy to avoid potentially harmful intubation and its associated risks. Servo-u supports advanced patient monitoring and offers modes such as NIV NAVA, NIV PC, Nasal CPAP, and High Flow therapy, promoting gentle and effective respiratory care.

Baby-driven or volume-targeted ventilation?

When intubation is indicated, NAVA allows synchronization with the neonate, enabling them to control their ventilatory pattern and tidal volumes. This approach minimizes the risk of over- or under-ventilation while improving oxygenation and blood gas levels.³³⁻³⁷ If instead a volume-targeted mode is preferred, PRiNC adjusts inspiratory pressure automatically to accommodate changes in respiratory system mechanics. It also regulates controlled and assisted breaths separately, reducing tidal volume variation and driving pressure.

» Servo-u is the only universal ventilator offering both conventional and neural ventilation modes, providing tailored support to help premature babies breathe, sleep, and grow.³⁸





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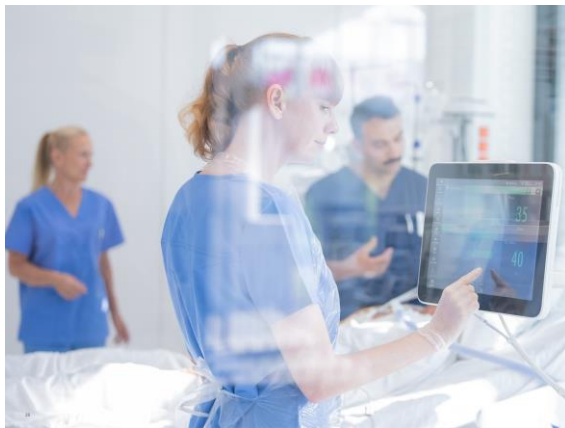
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A sustainable solution based on efficiency and responsibility

Servo-u is a sustainable solution built with durable, responsibly sourced, high-quality components to ensure maximum uptime. Its modular design evolves with your clinical and technical needs, supported by expert knowledge. The result? Increased productivity, reduced waste, and a healthier environment for everyone.

Sustainability through efficiency

Optimized use of a ventilator system can improve patient outcomes and decrease healthcare costs. This makes it essential to prioritize the total life cycle costs required to maintain state-of-the-art clinical performance.

Lasting, high-performance operation

Servo-u shares parts and platforms with other Servo models, featuring hot-swappable batteries and a reusable respiratory cassette with a one-of-a-kind ultrasonic flow sensor for reliable measurements. All original parts and accessories are designed for durable, high-performance operation.

Biocompatibility

All Servo ventilators have been constructed with high-quality materials meeting stringent biocompatibility standards, carefully selected to support patient safety by minimizing the potential release of any sensitizing and allergenic chemicals.

Design for reprocessing

Servo ventilator parts are designed for reprocessing and long-lasting operation. This is a legacy we continue to honor, that started already with the original Servo ventilator.



A virtual twin of the physical ventilator

Servo TwinView provides medical staff with remote near real-time data from Servo ventilator systems. This can help facilitate streamlining work in the ICU, enhancing day-to-day workflows for clinicians and provide a better environment for patients.

Training and onboarding

Students and supervisors can follow procedures in real time without disturbing patients. Real patient data contributes to a deeper understanding, and large groups can participate in discussions while familiarizing themselves with the ventilator user interface.

Rounding and handover

During the daily handover, Servo TwinView provides the ICU team with an extensive overview of the patients. Ventilator data is continuously updated, and clinicians can discuss information and plan treatments of critically ill patients without needing to enter the ICU rooms.

Planning and management

Using the Live View, ICU coordinators get an overview of current ventilator availability, location and status, as well as patients soon to be released – supporting them in the overall planning of ICU procedures.



Service and support with Getinge Care

With almost 250 service centers globally, we are always close at hand. To maximize uptime, ask us about local service agreements.

Our **Getinge Care package** comes in four different levels of support depending on your needs. Whatever your specific situation, our skilled service technicians and staff, many of whom are clinicians, are always there to support you.

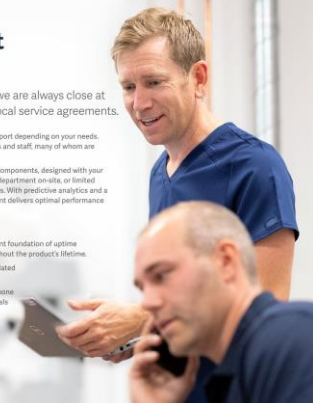
Getinge Care service plans are built with a variety of different components, designed with your hospital's success in mind. Whether you have a full biomedical department on-site, or limited in-house personnel, we have a service plan that suits your needs. With predictive analytics and a variety of preventive service plans, we make sure your equipment delivers optimal performance over its entire lifetime.

With Getinge Care you will receive:

Preventive maintenance with maintenance kits as an important foundation of uptime assurance helping keep your equipment up and running throughout the product's lifetime.

Original spare parts that are designed, manufactured, and validated to ensure performance, uptime and provide for patient safety.

Our certified and experienced technicians which are the backbone of our service offering. These highly-trained Getinge professionals are ready to promptly support you wherever needed.



FleetView – Device Lifecycle Management

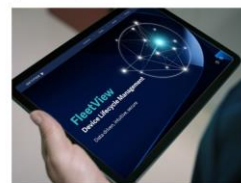
Imagine having a seamless, remote overview and a unified maintenance plan for all Getinge devices across your entire organization.

Connect devices, users, and operations

With FleetView, you can make that vision a reality. Most of our innovative products spanning all categories are primed for connection. Additionally, your installed base of Getinge devices can easily be integrated, enabling a comprehensive device data network, improving operational efficiency and staff satisfaction.

Maximize capacity and enable better care

In the ICU, FleetView provides a bird's-eye view of life-saving equipment performance and usage. By guaranteeing uptime and offering invaluable usage insights, it enables you to optimize capacity and facilitates increased focus on patient care.



Ventilation modes	Lung protection tools		Miscellaneous Information	
Pressure ventilation	PC	CO ₂ analyzer	Screen	W/ TFT LCD touchscreen
	PRVC	Open Lung Test (OLT)	Dimensions patient unit	W 300 x D 235 x H 420 mm
	Bi-synchPRV	Auto SIMV	max. max. connector	800 mm
	PC-CPAP	Auto SIMV		
	VS	CO ₂ trends	Weight	- 23 kg (patient unit) or 16 kg (control console)
	NPS	Stress index		- 30 kg max module cart.
	AutoA	Compensatory pressure	Batteries, hot swappable	6.2 modules
	AutoA+ ¹		Backup back up time	At least 15 min (with 8 batteries)
Non-invasive ventilation	PC-PS	Weaning tools	Neulization	Aerogen, integrated
	PC-PS		O ₂ measurement	O ₂ sensor (optional)
	-VC-VE		Respiratory vital sign	Full plug-in module
	SBM		Respiratory pressure	Full plug-in module
	-PS(-) + PPS		Flow	Full flow transducer plug-in module
	-VCP(-) + PS		Transducer	Capnograph 5 plug-in module
Non-invasive ventilation	NI-VCP	Connectivity specifications	External device interfaces	3 x RS-232C ports, VGA, USB, Remote access
	NI-VPS			
	NI-VCP			
	Smart CRAP			
Breathing therapies		HL7		
		WS-1		
	High Flow			
	Heating			
	Heating system (external)			

Note: Not all modes/options are available in the standard configuration. Please contact your local Getinge representative for further information. Refer to the Servo-s datasheet for additional technical specifications.

Accessories – tailored for ergonomic and streamlined care



Consumables – approved and optimized for Servo-u





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Apéndice E del Anexo 1. Ficha técnica de la bomba de infusión Fresenius Kabi Agilia® SP MC / Agilia® SP MC WiFi.



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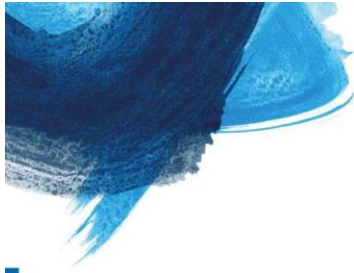


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**FRESENIUS
KABI**
caring for life



Agilia® SP MC
Agilia® SP MC WiFi

Advanced syringe infusion pumps

Wide flow rate ranging from 0.1-1200
mL/h and an accuracy of $\pm 3\%$

Adaptable to all protocols

Up to 19 embedded drug libraries

Easy and intuitive to use

Stand alone or rack mounted
infusion pump with alarm

2 pressure modes and Dynamic
Pressure System (DPS)

Agilia and Vigilant are registered trademarks by Fresenius Kabi in selected countries. Due to our policy of continuous product development as well as changes in standards, the features described are subject to change. Please contact us for the most updated information.



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Date of preparation: October 2017 IFZ65



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*Este contrato está subvencionado por el Instituto de Salud Carlos III (ISCIII) y por la Unión Europea con cargo a los fondos NextGenerationEU, que financian las actuaciones del Mecanismo para la Recuperación y la Resiliencia (MRR). Expediente UICC24/00044: “Unidad para el avance de la Investigación Clínica en niños y adolescentes”.

Agilia® SP MC & Agilia® SP MC WiFi

Infusion

Flow rate range
Flow rate is adjustable on the syringe capacity (0.1 mL/h increment).
0.01 minimum increments instead of 0.1 mL/h is activated when the max patient weight is set to 20 kg in the drug library.
Flow rate can be limited according to drug name (soft and hard limits with Agilia Vigilant Drug Lib. IV Medication Safety System).

Flow rate accuracy
± 1% on mechanism; ± 2 % on syringes.

Syringes capacities
5, 10, 20, 30/35, 50/60, CC.

Type of syringe
Up to 100 types.

Infusion Modes
• mL/h mode.

• Dose rate mode: ng/h, ng/kg/min, ng/kg/h, microg/h, microg/kg/min, microg/kg/h, ng/min, ng/h, ng/24h, ng/kg/24h, ng/kg/h, kcal/h, kcal/24h, kcal/kg/h, kcal/kg/24h, mL/min, mL/kg/min, mL/kg/h, U/min, U/h, U/kg/min, U/kg/h, kcal/h, kcal/24h, kcal/kg/h, kcal/kg/24h, mL/min, mL/kg/min, mL/kg/h, U/min, U/h, U/kg/min, U/kg/h, With or without loading dose.
• Volume or dose / Time: 0.1 - 999.9 mL; 0.0 h 01 - 96 h 00.
• Volume limit: 0.1 - 999 mL.

Volume/Dose infused
Volume: 0.1 - 999.9 mL / Dose: 0.1 - 999.999 units

Priming
3 modes: mandatory, not mandatory, or advised / Rate: 1200 mL/h.

Bolus
• Bolus Rate: 50 - 1200 mL/h (50 mL/h increment)
Programmed bolus (dose or volume / time): 0.1 - 999.9 mL;
0.1 - 999.9 units / 1 min - 24 h.

Loading dose
Dose or volume / time: 0.1 - 99.9 units / 00 min 01 - 59 min 59 rate
auto-calculation.

End infusion (WT & VL)
KVO: adjustable from 0.1 to 5 mL/h, continuous infusion or stop.

Fast start
Priming every prime set by default resulting in fast start if user does not prime with bolus button ensuring programmed flow rate to be reached faster.

Pause
Programming from 1 minute to 24 hours, increments from minute to minute.

Data log event
1500 data log events in real time.

Graphical history
Volume / dose infused, pressure, flow rate.

Night mode
The key only decreases the brightness of the screen and the green lights. The key beep can eventually be turned off. The night mode can be programmed manually or automatically in a variable time range.

Profiles
Basic profile: infusion without any display of the drug names.
19 Custom profiles configurable with Agilia Vigilant Drug Lib.
Custom profiles: infusion with display of the drug names.
Configuration only. Custom pump configuration without Drug Name.

Technical specifications

Wireless LAN (For Agilia SP MC WiFi only)

Manual number
Protection for the ongoing infusion thanks to "Push-Guard".

Display
IPS-type LCD monochrome, size 66 mm x 33 mm
(256 x 128 pixels).

Switched clamp
Voltage clamp that allows the fixation on a rail or on a pole
(Pole: 20-40 mm max. / Rail: 25-35 x 10 mm).

Stackability
Up to 3 devices self-stackable on a pole.

Dimensions (h/w/d) / weight
128 h / 59.5 w / 14 mm d / 25 kg.

Battery
Battery capacity: 7.2 V 2.2 Ah - Li-Ion Smart battery, remaining battery life and battery charge level available on the display.

Battery Life (when fully charged):
• Agilia SP MC WiFi (WiFi disabled / not used):
> 13 h at 5 mL/h.

• Agilia SP MC WiFi (WiFi enabled):
> 9 h at 5 mL/h.

Battery recharge:
• Pump ON: 6 h.
• Pump OFF: 20 h.

Waterproof effectiveness
IP22.

Power supply
100 V - 240 V - / 50 / 60 Hz with functional earth.

Compliance

Electromagnetic compatibility EMC
IEC 60601-1-2, IEC 60601-2-24

Medical Device Directive
CE 023 marking in compliance with the Council Directive 93/42/EEC

Electrical Compliance
Protection against leakage current: Defibrillation-proof type Cf
Protection against electric shocks class I in accordance with IEC 60601-1

Alarm system
IEC 60601-1-8

Usability Engineering
IEC 60601-1-6 and IEC 62366



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Fdo. Jose Luis de Unzueta Roch

*Nota.- El presente documento ha sido firmado y se encuentra dentro del expediente referenciado.

Fin del documento.