



Telemonitoring for Home-assisted Ventilation: A Narrative Review

✉ Jason Ackrivo¹, Lauren Elman², and John Hansen-Flaschen¹

¹Pulmonary, Allergy, and Critical Care Division, Department of Medicine, and ²Department of Neurology, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania

ORCID IDs: 0000-0003-4379-1255 (J.A.); 0000-0003-4706-950X (L.E.); 0000-0003-1989-7244 (J.H.-F.)

Abstract

The recent advent of remote ventilator telemonitoring has the potential to revolutionize home-assisted ventilation care in the United States and elsewhere. Home ventilation machines (i.e., respiratory assist devices and portable ventilators) can now wirelessly transmit usage and performance data to cloud-based web servers for remote access by participating clinicians. In this Focused Review, we provide an update on available technology, suggest practical applications for clinical care and research, and review supporting literature. Remote monitoring permits early data review, refinement of device settings to optimize ventilatory function, and troubleshooting if a new problem arises after initial setup. Data from home spirometry and noninvasively measured blood gas tensions can complement ventilator data to reflect physiological response. Acknowledging a paucity of published outcome studies, remote telemonitoring may be a cost-effective

strategy to reduce emergency room visits, urgent clinic appointments, and hospitalizations. Ongoing clinical trials in Europe aim to expand on the benefit of this rapidly evolving technology. However, several barriers may hinder widespread implementation, especially in the United States. Clinicians must familiarize themselves with each ventilator manufacturer's proprietary software to safely leverage this technology for improving care. Legal and ethical considerations threaten clinician interest. Medical insurance payers must adapt a reimbursement scheme to incentivize clinicians and durable medical equipment companies to perform this time-consuming service. Cohort-level ventilator data will facilitate multicenter clinical trials focused on improving the respiratory care of this vulnerable population.

Keywords: chronic respiratory failure; noninvasive ventilation; telemedicine; telemonitoring; home ventilation

(Received in original form January 13, 2021; accepted in final form June 17, 2021)

✉ This article is open access and distributed under the terms of the Creative Commons Attribution Non-Commercial No Derivatives License 4.0. For commercial usage and reprints, please e-mail Diane Gern.

CME will be available for this article at www.atsjournals.org.

Supported by National Heart, Lung, and Blood Institute grant F32 HL-144145 and grant K23 HL-151879.

Correspondence and requests for reprints should be addressed to Jason Ackrivo, M.D., M.S.C.E., Pulmonary, Allergy, and Critical Care Division, Department of Medicine, Perelman School of Medicine at the University of Pennsylvania, 3600 Spruce Street, 5048 West Gates Building, Philadelphia, PA 19104. E-mail: jackrivo@upenn.edu.

This article has an online supplement, which is accessible from this issue's table of contents at www.atsjournals.org.

Ann Am Thorac Soc Vol 18, No 11, pp 1761–1772, Nov 2021

Copyright © 2021 by the American Thoracic Society

DOI: 10.1513/AnnalsATS.202101-033CME

Internet address: www.atsjournals.org

The approximately 80-year practice of home-assisted ventilation has been bolstered by a remarkable series of technological advances (1, 2). In the early 1950s,

availability of commercially produced negative-pressure Cuirass (shell) ventilators freed polio victims from dependence on institutionalized care and confinement to

tank respirators ("iron lung"). Shortly after the turn of the 21st century, the replacement of piston-driven ventilation pumps by microprocessor-controlled turbine flow

generators enabled the miniaturization of ventilators to the size of slim briefcases that could be battery operated and mounted on the back of power wheelchairs. Over the past decade, refinement of ever more sophisticated lunch-box-sized ventilators connected to comfortable, low-profile, self-sealing facial interfaces has progressively improved the quality of life for children and adults living at home with assisted ventilation. Most recently, the advent of remote telemonitoring software now facilitates routine quantitative management of noninvasive ventilation.

At the core of the new monitoring modalities are cloud-based platforms that provide clinicians access to frequently updated home ventilator use and performance data. These programs can enable physicians to manage long-term ventilatory support with individualized precision approaching a level previously achievable only in hospital critical care units. However, evidence of clinical benefit is limited, and important pragmatic obstacles impede widespread adoption of these new technologies.

The purpose of this narrative review is to update readers on availability and application of internet-accessible telemonitoring systems for bilevel respiratory assist devices (RADs) and portable ventilators used to treat chronic hypercapnic respiratory failure. We found our source articles by performing a PubMed search using the terms home ventilator monitoring, home respiratory monitoring, home ventilation monitoring, home ventilation, telemonitoring, telemedicine, ethics of telemedicine, and/or outpatient billing.

With acknowledgment that European respiratory societies and medical centers have pioneered standardizing home ventilator monitoring and management (3–5), we offer a perspective on the application of home ventilator telemonitoring in the United States. We focus on monitoring home ventilation for adults; however, the telemonitoring systems described here also have applicability to the management of chronic ventilation for children and individuals living within long-term care facilities.

Ventilator Data Collection Methods

Two types of devices are used for long-term domiciliary mechanical ventilation: bilevel

devices and portable ventilators, also known as “RADs,” and “life-support machines,” respectively.

RADs, identified by Healthcare Common Procedural Coding System codes E0470 and E0471, evolved over several decades from machines used to treat sleep apnea. Two RADs commonly used in the United States today are the Philips Resironics Dreamstation and the ResMed AirCurve (Table 1). Current models support several pressure-targeted modes of ventilation, including bilevel positive airway pressure (bilevel PAP) and volume assured pressure support delivered exclusively through single-limb passive circuits. Most RADs incorporate built-in humidifiers. Several of these devices enable remote settings adjustment.

Portable ventilators (Healthcare Common Procedural Coding System codes E0465, E0466, and E0467) for domiciliary use evolved from inpatient acute care ventilators. The two home ventilators, or “life support” devices, most commonly used in the United States are the Philips Resironics Trilogy series and ResMed Astral (Table 1). In addition to single-limb passive circuits, portable ventilators support single-limb active and dual-limb active circuits suitable for long-term invasive ventilation and a broad range of ventilatory modes, including mouthpiece ventilation. Mouthpiece ventilation is a method of daytime ventilation that permits intermittent breaths as needed from a mouthpiece positioned just outside the patient’s mouth. A flexible support arm guides a passive circuit back to the ventilator, which is typically attached to the rear of the patient’s wheelchair. Portable ventilators are equipped with customizable alarms and incorporate a built-in battery but generally do not include a built-in humidifier.

Both RADs and ventilators record hourly use and performance data to internal memory. While using a single-limb passive circuit, the device directly measures the duration and timing of device use, the timing and duration of each respiratory cycle, the fraction of breaths triggered and cycled by the patient, inspiratory flow rates, and end-expiratory and peak inspiratory pressures. Devices calculate tidal volume, minute ventilation, and circuit leak, among other parameters. Some devices also estimate the frequency of apneas and hypopneas. The accuracy of such device estimates is discussed in a later section.

Data generated by remotely functioning electronic devices can be accessed synchronously (continuously as data is generated) or asynchronously, which involves deferred data transfer (5). The U.S. Food and Drug Administration supports only asynchronous data access. Data recordings occur any time a patient uses the device, permitting monitoring of nocturnal, diurnal, or even 24-hour use.

A commonly employed method for asynchronous monitoring involves a “manual download” via universal serial bus storage device or Secure Digital (SD) card. Clinicians can access manually downloaded data indirectly after a representative of a respiratory durable medical equipment (DME) company acquires the data from the device during a home visit by asking a patient or caregiver to mail the SD card to the clinician or by downloading the data directly from the storage device during a face-to-face office visit. By any means, manual data download offers the benefit of data security but can delay clinical assessments depending on the duration of delay from data acquisition until transfer to the clinician. If data is needed urgently, a DME company representative may need to visit the patient to interrogate the device (Figure 1A).

More recently, cloud-based data monitoring has enabled remote transfer (or asynchronous) “telemonitoring” of ventilator data. Certain RADs and all portable ventilators can be configured to automatically communicate data at least daily to an internet server via a modem or a Bluetooth-enabled cell phone transmitter (Table 2). Data transfer occurs in an encrypted manner compliant with the Health Insurance Portability and Accountability Act. The server stores patient data within a unique, password-protected account specific to each institution, medical group, and/or individual clinician. Clinicians can instantly assess current and past usage (Figure 1B) and performance data. Available displays include hourly usage (Figure 2), daily parameter averages (Figure 3), and a detailed analysis of minute-by-minute changes within a single night (Figure 4). Within the program, clinicians can also create “rules” that act as alerts to an aberrant parameter.

Remote data collection offers the advantages of frequent data transfers and granular analysis, thus facilitating rapid refinement of face mask selection, device settings, and troubleshooting of acute respiratory events. Disadvantages include the

FOCUSED REVIEW

Table 1. Commonly used respiratory assist devices (with a back-up rate) and portal ventilators in the United States

Device	Manufacturer	Device models	HCPCS Code
Respiratory Assist Devices			
	Philips Respironics (Philips, Amsterdam, The Netherlands)	BiPAP S/T BiPAP AVAPS	
DreamStation			E0471
	ResMed (Sydney, Australia)	AirCurve 10 ST AirCurve 10 ST-A	
AirCurve			
Home Ventilators (Life Support Devices)			
	Philips Respironics (Philips, Amsterdam, The Netherlands)	Trilogy 100*, 200*	
Trilogy		Trilogy Evo	
	ResMed (Sydney, Australia)	100, 150	E0465 E0466
Astral			
	Breas (Mölnlycke, Sweden)	Vivo 45, Vivo 65	
Vivo			
	Ventec Life Systems (Bothel, Washington, United States of America)	VOCSN	E0467
VOCSN			

Definition of abbreviations: HCPCS = Healthcare Common Procedural Coding System; BiPAP = bilevel positive airway pressure; ST and S/T = spontaneous/timed.

*Philips Respironics has replaced the Trilogy 100 and 200 with the Trilogy Evo.

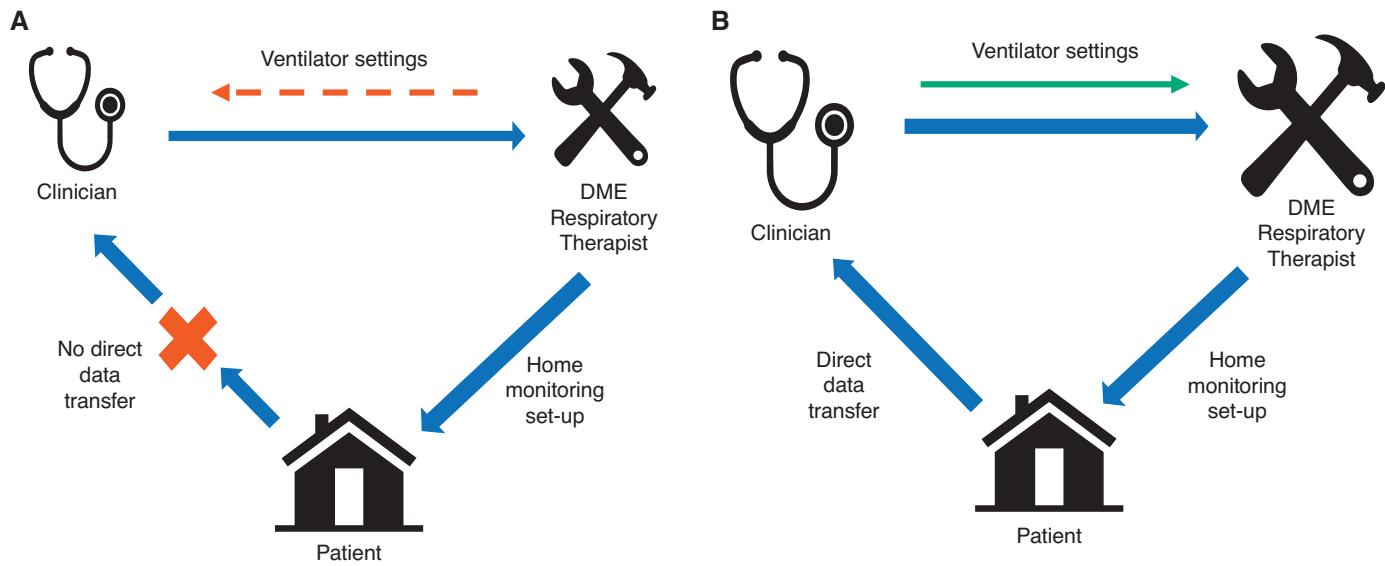


Figure 1. (A) Manual download approach with disconnect between patient and clinician, necessitating durable medical equipment company facilitating ventilator settings. (B) Telemonitoring approach with improved connectivity between patient and clinician, permitting clinician-directed ventilator settings. DME = durable medical equipment.

potential for superfluous data, information overload, and security concerns.

monitoring, requiring clinicians to acclimate to each.

Ventilator Manufacturer-Specific Platforms

Ventilator manufacturers use proprietary software for ventilator data

Philips Respiration

The Philips Respiration Encore Anywhere software package accepts remote cloud and manual data downloads from SD cards. Reports have limited customizable features and typically include overall ventilator

parameter metrics recorded since the last download. Standardized displays with small graphs and arbitrary *y*-axis scales complicate the detection of rapid changes in ventilation.

The Encore Anywhere platform is being supplanted by Care Orchestrator, a robust cloud-based platform designed to support a broad range of respiratory devices. Trilogy and Trilogy Evo can communicate to Care

Table 2. Features of ventilator telemonitoring platforms

Monitoring Platform	Manufacturer	Device Models	Data Push Frequency	Connection	Integration of External Monitors
Care Orchestrator	Philips Respiration (Philips, Amsterdam, The Netherlands)	DreamStation, Trilogy, Trilogy Evo	Daily or every 8 h	WiFi*, cellular, Bluetooth	SpO_2 , PtcCO_2 [†]
AirView	ResMed (Sydney, Australia)	AirSense, AirCurve 10, AirMini, Astral, Stellar	Daily	Cellular	SpO_2
Multi-View [‡]	Ventec Life Systems (Bothel, Washington, United States)	VOCSEN	—	Cellular, WiFi, GPS, Bluetooth	SpO_2 , etCO_2 , heart rate
EveryWare [‡]	Breas (Mölnlycke, Sweden)	Vivo 45, Vivo 65	—	Cellular	FIO_2 , SpO_2 , etCO_2 , PtcCO_2 , thoracoabdominal effort belt [§]

Definition of abbreviations: etCO_2 = end-tidal carbon dioxide; GPS = global positioning system; NIV = noninvasive ventilation; PtcCO_2 = transcutaneous carbon dioxide; SpO_2 = peripheral capillary oxygen saturation; WiFi = wireless fidelity.

Partially adapted by permission from Reference 4.

*WiFi used for DreamStation model only.

[†] PtcCO_2 monitoring available for Trilogy Evo model only.

[‡]As of this writing, Ventec Life Systems Multi-View and Breas EveryWare have not yet been commercially released in the United States.

[§]Thoracoabdominal effort belt monitoring is pending clearance by the U.S. Food and Drug Administration.

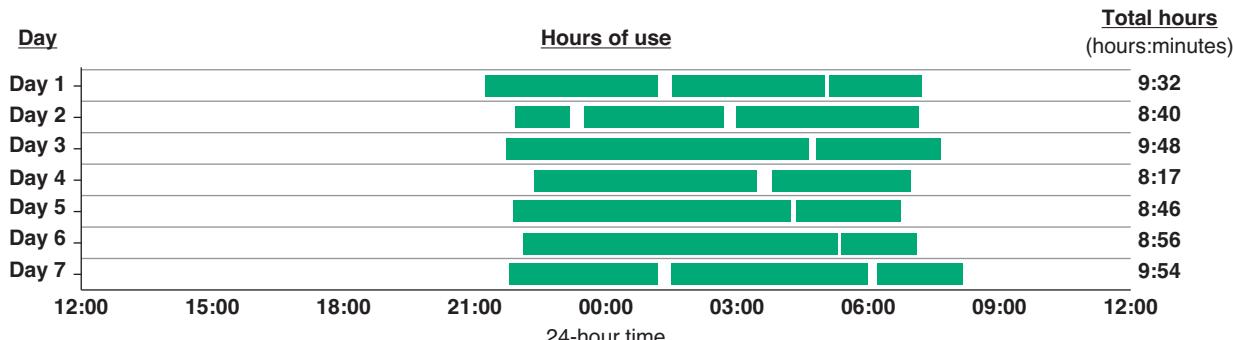


Figure 2. Care Orchestrator display of hourly ventilator usage by day.

Orchestrator with a Bluetooth cellular hub that is about the size of a deck of cards, which plugs into an electrical outlet in the patient's home. Uploads occur every 8 hours as long as the Bluetooth hub is within range of the device, whereas DreamStation data upload every 24 hours. Users can personalize reports, displays, and alerts. Data review timelines can span a variety of customized time scales, ranging from long-term (several months) to short-term trends (every 5 minutes).

As of November 2020, Philips Respirronics has enabled direct integration of the Trilogy Evo with either a pulse oximeter or Sentec transcutaneous carbon dioxide (CO_2) monitor. These accessory data outputs display alongside ventilator parameters within Care Orchestrator.

ResMed

AirView is a cloud-based platform for ResMed. Compatible devices include AirSense, AirMini, AirCurve, Stellar, and Astral. AirSense and AirCurve have connectivity built into the device, whereas Stellar and Astral require a separate modem. Users have access to a wide variety of customizable features. AirView, in contrast to Care Orchestrator, displays 95% ranges around parameter medians. Patients and rule sets can be created for notifications by disease process, ventilation mode, device adherence, and alert type.

Ventec Life Systems (Ventec)

VOCSN, by Ventec Life Systems, is the first multifunction ventilator, which is named for the five device functions: ventilator, oxygen concentrator, cough assist, suction, and nebulizer. VOCSN Multi-View tracks usage and trending information across all five device therapies. Online Multi-View is due for U.S. release in 2021. It will incorporate

pulse oximetry, end-tidal CO_2 , and heart rate.

Breas

Breas has an online data platform, EveryWare. Compatible devices include the Vivo 45 and Vivo 65. In addition to typical ventilator parameters, EveryWare has integration of fraction of inspired oxygen, peripheral capillary oxygen saturation, and end-tidal CO_2 . EveryWare is scheduled for release in the United States in 2021.

Data Reliability and Accuracy

Remote ventilator data accuracy and reliability are paramount, especially for parameters such as tidal volume and minute ventilation that are calculated from directly measured flow and pressure profiles. During noninvasive ventilation, unintentional leaks can significantly affect data accuracy. Comparing a test lung versus bedside dynamic output of the ResMed VPAP III found a strong correlation in leak volume and minute ventilation with low bias but wide limits of agreement in minute ventilation (-1.8 to 1.9 L/min) (6). Leaks vary depending on the inspiratory and expiratory pressures, inspiratory:expiratory ratio, and respiratory rate (6). Multiple studies have found an increased leak and underestimation of tidal volumes, with bias increasing at higher pressure settings (7, 8). On a test lung and mannequins, Borel and colleagues showed that at an inspiratory PAP (IPAP) of 14 cm H_2O with an unintentional leak ≥ 40 L/min leads to significant reductions in tidal volume (9). Unintentional leaks significantly increased at an IPAP of 18 cm H_2O .

Excessive mask leak can disrupt sleep and introduce inaccuracies in reported ventilatory parameters. Therefore, reducing leak should generally take priority over other refinements. The upper limits of accepted leak values provided by manufacturers vary depending on the characteristics of the interface and pressures used. Clinicians are encouraged to apply caution in interpreting calculated measures of tidal volume and minute ventilation at unintended leak rates above 40 L/min.

Normative ranges may vary more between patients rather than within patients, as demonstrated by Jeganathan and colleagues (10). Thus, intervention thresholds should be tailored to each patient's unique physiology.

Additional Monitoring Devices

Monitoring of alternative devices can complement home ventilator data. Recent technological advances have enabled remote monitoring of spirometry, overnight pulse oximetry, partial pressure of carbon dioxide, relevant sleep parameters, and coordination of respiratory muscle groups (Table 3). Selective application of these tools can enable the detection of early respiratory insufficiency or estimate physiologic responses to a ventilation regimen.

Several companies (e.g., NuvoAir, Medical International Research, and Monitored Therapeutics Incorporated) now offer home spiroimeters with telemonitoring capability. These devices may detect early need for assisted ventilation in home-bound patients, particularly those with amyotrophic lateral sclerosis (ALS) (11). The assessment of variations in pulse oximetry may be an economical method for detecting intermittent nocturnal hypoventilation;

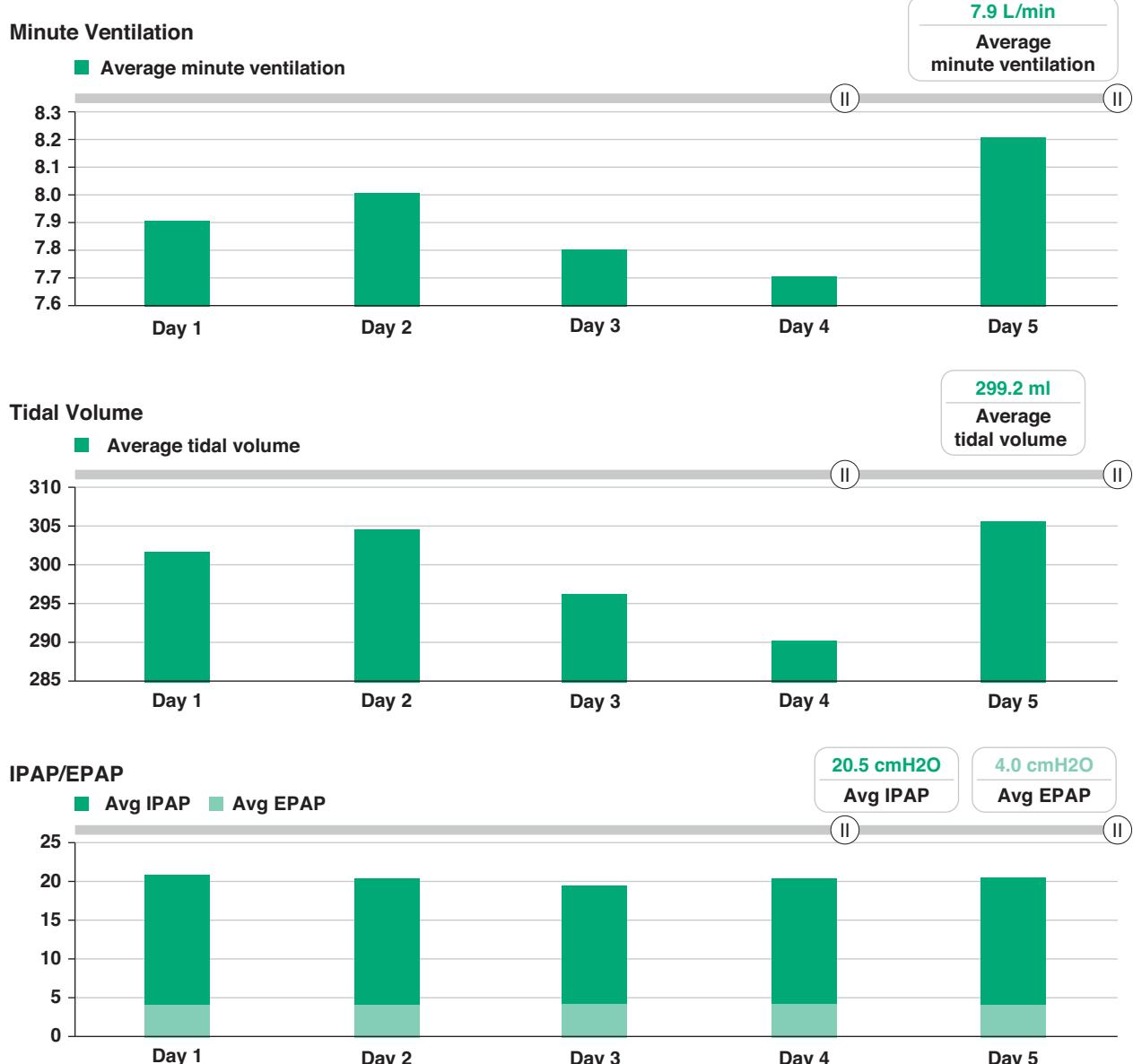


Figure 3. Care Orchestrator display of average daily minute ventilation, tidal volume, and airway pressures. Avg = average; EPAP = expiratory positive airway pressure; IPAP = inspiratory positive airway pressure.

however, data are conflicted on improved outcomes (12, 13).

Arterial blood gas testing remains the gold standard but is largely impractical for monitoring home ventilation. Noninvasive carbon dioxide monitoring is expensive but likely more sensitive to hypoventilation than pulse oximetry (14, 15). CO₂ can be measured noninvasively by sampling exhaled air at the end of expiration or by transcutaneous measurement of CO₂ (Ptc_{CO₂}) in arterialized subcutaneous capillary blood.

End-tidal estimates of carbon dioxide can provide useful information if the patient

is breathing spontaneously in the absence of airflow obstruction or if ventilated via tracheostomy; however, end-tidal CO₂ measurements may be unreliable for monitoring under a face mask used for noninvasive ventilation. In general, Ptc_{CO₂} monitoring more closely tracks carbon dioxide measured by arterial puncture and can be used for spot checks or continuous monitoring during mask ventilation (Figure 5) (15, 16).

As nocturnal hypoventilation typically occurs prior to daytime hypoventilation in progressive neuromuscular disease, sleep

testing is particularly useful for assessment of early respiratory insufficiency. However, most home sleep testing kits require placement of sensors at the nose and mouth and are thus not suitable for patients undergoing noninvasive or invasive ventilation. The Home WatchPAT 300 (Itamar Medical) and disposable WatchPat One are wrist- and finger-mounted home sleep-monitoring devices that use peripheral arterial signal to estimate overnight sleep time, sleep staging, and apnea-hypopnea events (17).

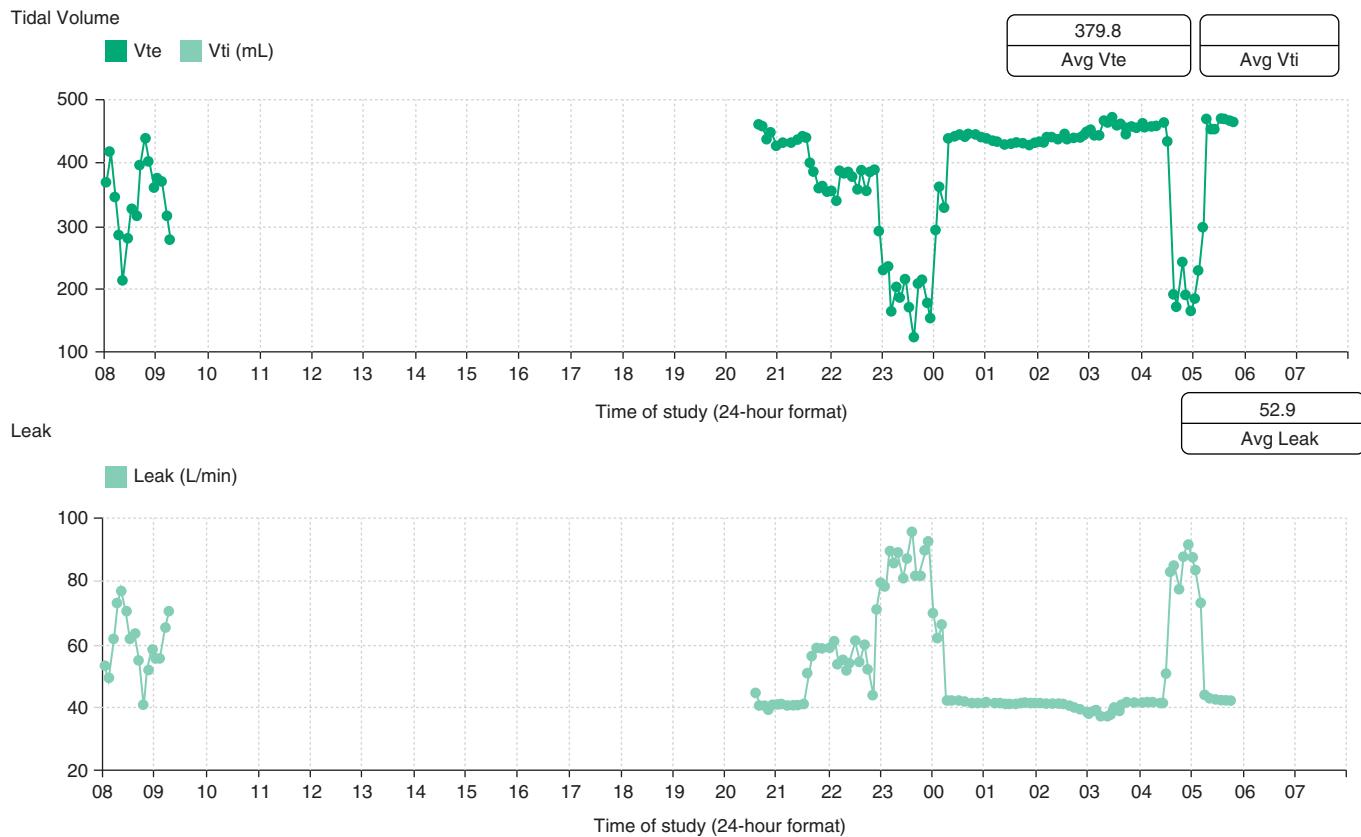


Figure 4. Care Orchestrator overnight recording showing tidal volume varying with leak. Avg = average; Vte = exhaled tidal volume; Vti = inhaled tidal volume.

Thoracoabdominal effort belts may reveal unrewarded respiratory efforts to assess patient–ventilator asynchrony (18). Breas Vivo 45 enables monitoring of chest and abdominal effort belt signals alongside other ventilator parameters.

Clinicians wishing to implement monitoring using these additional devices should acknowledge the significant time requirement that may not be fully reimbursed (*see REIMBURSEMENT section*). In addition, DME companies receive perpetual monthly

reimbursement for ventilators services, whereas RAD reimbursements cease after 13 months. Thus, DME companies may hesitate or refuse to perform intensive monitoring services for patients with RADs long term.

technology, it is not surprising that we lack data convincingly demonstrating beneficial outcomes. Limited evidence from several published studies encourages further research.

A prospective single-blinded controlled trial in 39 patients with ALS investigated weekly remote telemonitoring of noninvasive ventilation versus usual care (19). The intervention group experienced reduced emergency room visits and inpatient admissions, with a trend toward improved

Evidence for Telemonitoring

Considering that cloud-based monitoring of home ventilator use is a relatively new

Table 3. Examples of telemonitoring options beyond a ventilator

Monitor	Relative Price	Suggested Use	Limitations
Pulse oximeter	\$	Qualifying for home ventilator, detecting respiratory decompensation	Poor vascular perfusion, low sensitivity for hypoventilation
Spirometry	\$\$	Detect respiratory insufficiency, follow disease progression	Bulbar weakness, patient motivation
End-tidal carbon dioxide	\$\$\$	Carbon dioxide trend, ventilator titration (if tracheostomy)	Bias, requires closed system
Transcutaneous carbon dioxide	\$\$\$\$	Monitoring ventilation, ventilator titration	Cost, high maintenance, thick skin, poor vascular perfusion

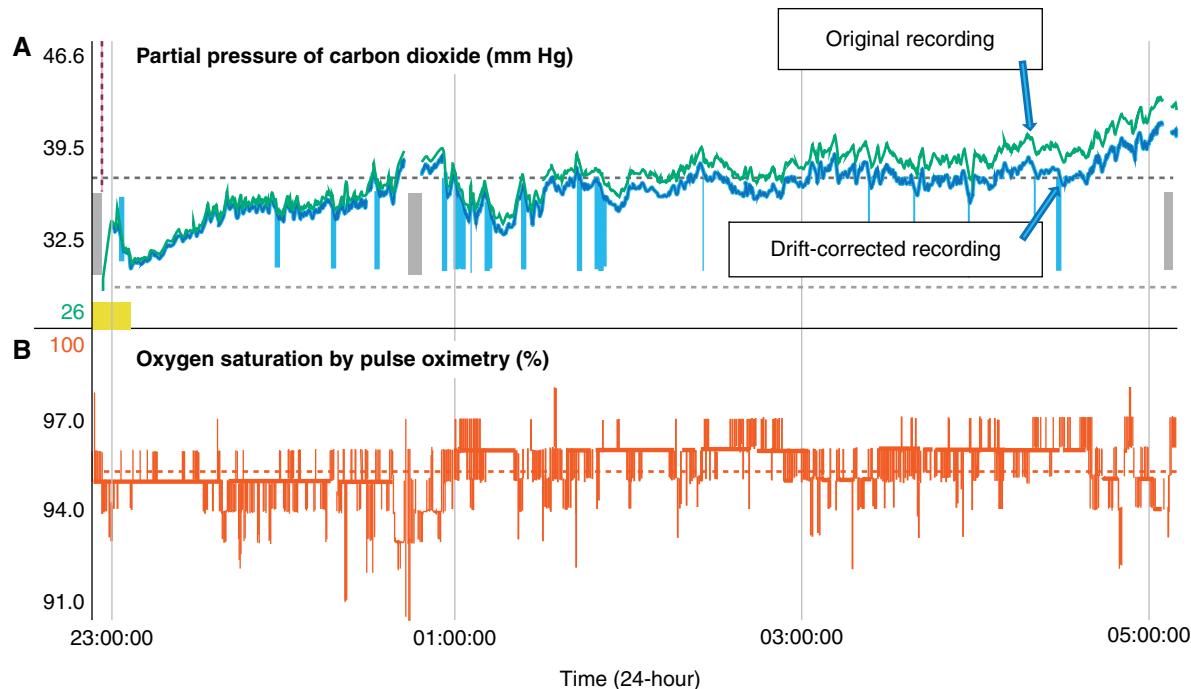


Figure 5. Overnight transcutaneous carbon dioxide and pulse oximetry recording for a patient with amyotrophic lateral sclerosis. (A) Overnight transcutaneous carbon dioxide and (B) pulse oximetry recording.

survival. Ensuring device adherence in ALS by home monitoring may improve survival (20–22).

A prospective controlled trial of 40 patients with ALS in Europe estimated that home ventilator telemonitoring saved the UK National Health Service approximately €700 per patient per year (23). In an Italian pilot study, weekly home ventilator monitoring and as-needed telephone consultations were associated with high patient satisfaction and reduced hospital visits by approximately 63% (24).

A single-center randomized controlled trial in the Netherlands compared inpatient versus home initiation of ventilation in 77 patients with chronic respiratory failure (25). Compared with inpatient initiation of ventilation, the home group had a noninferior improvement in both Pa_{CO₂} and quality of life. Median per patient costs were significantly lower in the home group.

A 2018 longitudinal, within-group, repeated-measures study assessed the impact of telemonitoring of 52 adults with chronic hypercapnia already established on home ventilation (26). After initiation of home monitoring, 79% of patients received a prescription for an alternative face mask, and 87% required a ventilator settings modification. Coincident with these changes,

statistically significant improvements were observed in average hourly use per night and achievement of the targeted tidal volume.

Home ventilator monthly downloads in 44 patients with chronic obstructive pulmonary disease suggested that elevated respiratory rate and percentage of patient-triggered breaths may help predict respiratory exacerbations (27). Patients, home caregivers, and clinicians reported favorable experience of cloud-based monitoring in a qualitative study (28).

Ongoing clinical trials in France, the United Kingdom, and the Netherlands aim to shed light on the benefits of home ventilator telemonitoring (4, 5). Until more studies become available, recommendations favoring home ventilation telemonitoring rely on the plausible but unproven supposition that the benefits of longitudinal, quantitative assessment of device use and function exceed the risks and it is overall cost effective. Continuous PAP device tracking received similar skepticism in the 1990s. Home monitoring for managing sleep apnea is now widely accepted as standard of care (29). Potential drawbacks to remote telemonitoring include physician time reimbursement and medicolegal risks, as highlighted in detail later in this paper.

Clinical Applications of Ventilator Use and Performance Monitoring

Initial Setup

The initiation of long-term assisted ventilation can be performed in a hospital, sleep laboratory, outpatient clinic, or at home. In-hospital, in-laboratory, or in-office setup enables the prescribing team to customize face mask selection and device settings. Simultaneous monitoring of peripheral capillary oxygen saturation and Ptc_{CO₂} enables titration of device settings to achieve target blood gas tensions (Figure 6).

Hospital or sleep laboratory initiation enables frequent review of ventilator data and gas exchange with rapid settings adjustment. In a cohort of mostly neuromuscular disease, a randomized trial of sleep study titrations significantly improved device adherence and patient–ventilator synchronization (30). Inpatient observation over two or three nights can optimize mask selection and ventilator settings.

Alternately, a respiratory therapist employed by a DME company can initiate noninvasive ventilation at home. A randomized controlled trial comparing the



Figure 6. Patient undergoing titration of noninvasive ventilation with a ResMed Astral in an outpatient clinic while monitoring peripheral capillary oxygen saturation and transcutaneous carbon dioxide simultaneously (image obtained and published with patient permission).

initiation of ventilator settings at home versus in the hospital found no significant differences in PaCO_2 and quality of life after 6 months, with home initiation costing significantly less (25).

Regardless of initial setup location, the goals of noninvasive ventilation are multifold: 1) patient comfort, 2) achieving target tidal volume and minute ventilation, 3) reducing atelectasis and excessive dead space associated with small tidal volumes, 4) reversing hypoventilation, and 5) maximizing patient quality of life. Selim and colleagues have published a detailed guide to selecting initial ventilator settings according to disease physiology (31).

Refinement of Initial Settings

Home ventilator monitoring should commence promptly after initial device setup because ventilator parameters often vary considerably under conditions of home care from those observed during initial titration in other settings. Marked variability in respiratory rate, tidal volume, and leak may occur overnight with changes in sleep stage and body position. Device alarms that remain silent during a daytime titration in a sitting position can frequently interrupt sleep while lying supine at home.

Accordingly, after the initiation of assisted ventilation, we schedule a return visit

within 1–3 weeks to review home monitoring data, readjust device settings, or replace the face mask as indicated. Sometimes several iterations are required to achieve optimal ventilation at home.

Troubleshooting and Long-Term Monitoring

Remote ventilator monitoring facilitates reactive and proactive troubleshooting after initial optimization. A reactive monitoring approach involves responding to a patient or caregiver notification of worrisome

respiratory symptoms or concerns about ventilator function. Importantly, reactive monitoring of cloud-based ventilator data can enable rapid assessment and adjustment of settings during mild to moderate respiratory decompensation caused by respiratory infections, aspiration episodes, excessive dosing of a respiratory suppressant, or other acute events. Guided by home monitoring, therapeutic intervention early after onset of a decompensation event may prevent the need for an urgent visit to the clinic or a hospital emergency department.

A proactive monitoring approach involves surveying ventilator data on a regular basis to identify smoldering issues. Several cloud-based ventilator monitoring software packages allow setting customized alerts to “push” a notification to the clinician. In a multicenter case-control study of 48 pediatric patients (median age, 16 yr), a home monitoring protocol with daily ventilator data transmissions led to reduced hospitalizations, fewer emergency room visits, shorter median hospital length of stay, and trend toward improved caregiver satisfaction (32).

A common scenario includes a patient receiving inadequate exhaled tidal volume relative to the set target tidal volume. Ventilator data review can help steer a clinician toward the most likely etiology. Data review can verify patient adherence (see Figure E1 in the online supplement). As discussed previously, inappropriate mask leak is a common culprit (Figure E2). A patient in volume assured pressure support mode may have inappropriately low IPAP settings, which can be recognized by the

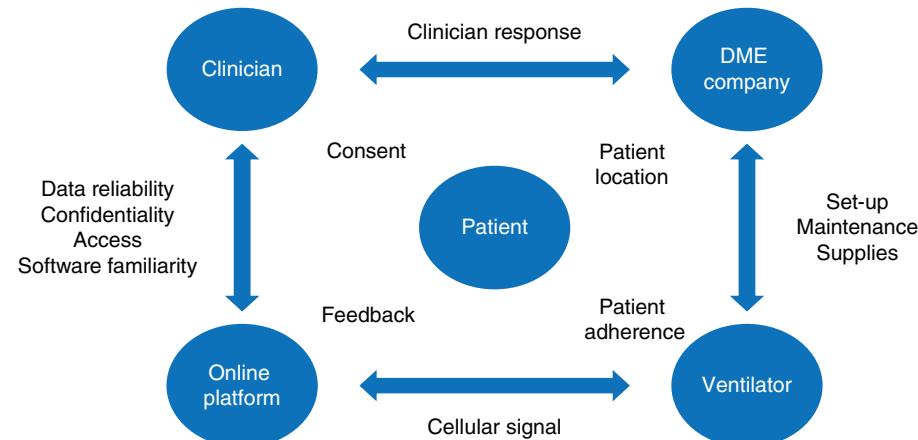


Figure 7. Multiple areas of vulnerability in a remote telemonitoring system.

ventilator “pinned” at the IPAP maximum setting during use (Figure E3). Reviewing apnea–hypopnea index can help identify if obstructive events require adjustment in expiratory pressure settings. In spontaneous/timed mode (which includes Trilogy’s AVAPS-AE), patients with advanced neuromuscular disease may have difficulty maintaining inspiratory flow and thus experience early spontaneous breath cycling, contributing to short inspiratory times and an increased percentage of patient-triggered breaths (Figure E4). A low percentage of spontaneous cycling can be associated with diaphragm fatigue and can be addressed with longer, fixed inspiratory times (33). For a detailed review of common clinical scenarios with supporting monitoring data examples and potential solutions, see the online supplement.

Longitudinal monitoring of daily hourly use has implications for insurance reimbursement. Centers for Medicare & Medicaid Services (CMS) covers the costs for obstructive sleep apnea therapy if the patient is using their RAD for a least 4 hours per day on 70% of days (34). Several insurance companies have extended these coverage criteria to the use of RADs and home ventilators for chronic respiratory failure. Daily monitoring can help patients avoid unnecessary out-of-pocket costs.

Legal and Ethical Issues

Legal ramifications of remote ventilator monitoring and home care should be examined through the same lens as in-person

encounters. Remote monitoring systems contain several layers of vulnerability (Figure 7): 1) patient consent, 2) security and fidelity of transmitted data, 3) the competence and confidentiality of the DME provider in managing monitoring devices, and 4) clinician access and competency in interpretation of data with the ability to respond to problems.

The risks associated with these vulnerabilities are multifold and include equipment or system failure, patient nonadherence, inaccurate or unreliable data, loss of data confidentiality, lack of clinician familiarity with a particular platform, and delays in clinician response (35, 36). Other hazards and ethical concerns may emerge in time. At least two caveats are apparent presently: 1) home telemonitoring should be applied only with informed consent (3, 37),

Table 4. Medicare Physician Fee Schedule billable services potentially applicable to home respiratory device management and monitoring (38)

Codes	Location	Service	Description
Prolonged Visit Services			
99356	Inpatient or observation visit	Prolonged same day physician services rendered at the bedside and on the patient's floor or unit in a hospital	Add-on E/M services beyond the usual service time. Use 99356 for the first hour (threshold > 29 min) and 99357 for each additional 30 min beyond the first hour (threshold > 74 min).
99357			
G2212*	Outpatient visit	Prolonged service same day	Appended to 99215 or 99205 for each additional 15 min of E/M service with or without direct patient contact beyond 55 min for 99215 or 75 min for 99205.
99358	Unspecified	Prolonged non-face-to-face service on a different day as a face-to-face patient care visit within a calendar month	E/M service on any day before or after an office visit. Use 99358 after the first 30 min (threshold > 29 min) and 99359 for each additional 30 min beyond the first hour (threshold > 74 min) [†] .
99359			
Remote Physiologic Monitoring Services			
99091	Unspecified	Collection and interpretation of transmitted physiologic data	Collection and interpretation of physiologic data digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified healthcare professional, requiring a minimum of 30 min of time within a calendar month.
99457	Unspecified	Remote physiologic monitoring management services	Remote physiologic monitoring management services, clinical staff/physician/other qualified healthcare professional time requiring interactive communication with an established patient/caregiver during the month. Use 99457 the first 20 min and 99458 each additional 20 min once in a calendar month.
99458			

Definition of abbreviation: E/M = evaluation and management.

*99417 is the American Medical Association Current Procedural Terminology code that is analogous to G2212.

[†]Cannot be billed for services performed on the same day as an office visit because of G2212 guidelines. As of this writing, it is not clear how consistently payers will cover 99358 and 99359 for services performed on a different calendar day.

and 2) unless transportation to a healthcare facility is unachievable, telemedicine should not replace an in-person visit that is clinically necessary.

Reimbursement

In response to a dramatic recent increase in home use of life support ventilators and other related concerns, CMS is currently reviewing qualifying indications and reimbursement for provision of ventilatory assistive devices by DME companies. In the meantime, many DME companies are reluctant to invest in telemonitoring of home respiratory devices. Some are wary of the legal liability of failure to respond promptly and effectively to recorded data.

Front-line clinicians who venture into home telemonitoring and active management of respiratory support devices face time-consuming obligations to develop expertise in strategically interpreting and optimizing device-generated data. Particularly for outpatient clinicians, the initiation and refinement of mask fitting and device settings can take time beyond what has been covered historically by commonly used evaluation and management (E/M) visit codes.

Recognizing the challenges and benefits of high-complexity outpatient and home care, the American Medical Association has considerably expanded the portfolio of Current Procedural Terminology (CPT) codes for E/M services. Additionally, between 2018 and 2021, CMS implemented a series of updates in the Medicare Physician Fee Schedule designed to improve

reimbursement and streamline documentation requirements for high-intensity outpatient E/M services (38). Updates particularly germane to physician-directed monitoring and management of home RADs include provision of billing codes for prolonged office visits and remote physiologic monitoring (Table 4).

Select CPT codes can capture clinicians' extended care coordination time. The add-on code G2212 covers extended services performed on the same day as an outpatient visit, with thresholds beginning at 75 minutes for 99205 and 55 minutes for 99215. Medicare's 2020 rules enabling outpatient telemedicine visits for the coronavirus disease (COVID-19) pandemic were continued for the duration of the Public Health Emergency. CPT codes 99358/9 bill Medicare for non-face-to-face care services performed by a clinician exceeding 29 minutes rendered on a single calendar day before or after the day of an office visit.

CMS began reimbursing for remote physiologic monitoring services in 2019. These codes (99457/8 and 99091) are intended to incentivize remote monitoring of physiologic data such as minute ventilation and respiratory rate. ResMed has prepared a reference guide for the application of these codes (39). Increasing acceptance by insurance payers of the billing codes outlined in Table 4 together with the transitional care codes (99495/6) and advanced care planning codes (99497/8) should encourage more U.S. physicians to engage actively in telemonitoring and quantitative management of home-assisted ventilation.

Perspective and Future Considerations

Remote telemonitoring of long-term assisted ventilation has developed dramatically over the last two decades and is now routinely available in many countries. Quantitative home monitoring holds promise for improving precision in home ventilator management with the long-term goals of minimizing adverse events and maximizing patient quality of life. Widespread application of new noninvasive assessment tools could obviate emergency hospitalization for unrecognized chronic hypoventilation and might reduce admissions for acute on chronic hypercapnic respiratory failure.

Further clinical outcomes research is needed to support the development of guidelines for effective and safe use of this powerful technology. Private health insurers can help accelerate adoption by assuring adequate reimbursement of both DME companies and prescribing clinicians for provision and interpretation of home monitoring data.

Routine, cloud-based recording of home ventilators also offers enormous potential for multicenter clinical research trials aimed at optimizing the respiratory care of patients with chronic respiratory failure. ■

Author disclosures are available with the text of this article at www.atsjournals.org.

Acknowledgment: The authors thank Howard Panitch, M.D., and Scott Manaker, M.D., Ph.D., for critical review of the manuscript prior to initial submission. They also thank representatives of Philips Respironics, ResMed, Ventec Life Systems, and Breas for fact-checking sections of the manuscript relevant to their products and service.

References

- 1 Mehta S, Hill NS. Noninvasive ventilation. *Am J Respir Crit Care Med* 2001;163:540–577.
- 2 Díaz Lobato S, Mayoralas Alises S. Modern non-invasive mechanical ventilation turns 25. *Arch Bronconeumol* 2013;49:475–479.
- 3 Ambrosino N, Vitacca M, Dreher M, Isetta V, Montserrat JM, Tonia T, et al.; ERS Tele-Monitoring of Ventilator-Dependent Patients Task Force. Tele-monitoring of ventilator-dependent patients: a European Respiratory Society Statement. *Eur Respir J* 2016;48: 648–663.
- 4 Borel JC, Palot A, Patout M. Technological advances in home non-invasive ventilation monitoring: reliability of data and effect on patient outcomes. *Respirology* 2019;24:1143–1151.
- 5 Canal JMM, Suárez-Girón M, Egea C, Embid C, Matute-Villacís M, Martínez L de M, et al. Posicionamiento de la Sociedad Española de Neumología y Cirugía Torácica en el uso de la telemedicina en los trastornos respiratorios del sueño y ventilación mecánica. *Arch Bronconeumol* 2021;57:281–290.
- 6 Rabec C, Georges M, Kabeya NK, Baudouin N, Massin F, Reybet-Degat O, et al. Evaluating noninvasive ventilation using a monitoring system coupled to a ventilator: a bench-to-bedside study. *Eur Respir J* 2009; 34:902–913.
- 7 Contal O, Vignaux L, Combescure C, Pepin JL, Jolliet P, Janssens JP. Monitoring of noninvasive ventilation by built-in software of home bilevel ventilators: a bench study. *Chest* 2012;141: 469–476.
- 8 Fauroux B, Leroux K, Pépin JL, Lofaso F, Louis B. Are home ventilators able to guarantee a minimal tidal volume? *Intensive Care Med* 2010; 36:1008–1014.
- 9 Borel JC, Sabil A, Janssens JP, Couteau M, Boulon L, Lévy P, et al. Intentional leaks in industrial masks have a significant impact on

- efficacy of bilevel noninvasive ventilation: a bench test study. *Chest* 2009;135:669–677.
- 10 Jeganathan V, Rautela L, Conti S, Saravanan K, Rigoni A, Graco M, et al. Typical within and between person variability in non-invasive ventilator derived variables among clinically stable, long-term users. *BMJ Open Respir Res* 2021;8:e000824.
 - 11 Geronimo A, Simmons Z. Evaluation of remote pulmonary function testing in motor neuron disease. *Amyotroph Lateral Scler Frontotemporal Degener* 2019;20:348–355.
 - 12 Vitacca M, Bianchi L, Guerra A, Fracchia C, Spanevello A, Balbi B, et al. Tele-assistance in chronic respiratory failure patients: a randomised clinical trial. *Eur Respir J* 2009;33:411–418.
 - 13 Chatwin M, Hawkins G, Panicchia L, Woods A, Hanak A, Lucas R, et al. Randomised crossover trial of telemonitoring in chronic respiratory patients (TeleCRAFT trial). *Thorax* 2016;71:305–311.
 - 14 Georges M, Nguyen-Baranoff D, Griffon L, Foignot C, Bonniaud P, Camus P, et al. Usefulness of transcutaneous PCO₂ to assess nocturnal hypoventilation in restrictive lung disorders. *Respirology* 2016;21:1300–1306.
 - 15 Arrestad S, Tollefson E, Kleiven AL, Qvarfort M, Janssens JP, Skjønsberg OH. Validity of transcutaneous PCO₂ in monitoring chronic hypoventilation treated with non-invasive ventilation. *Respir Med* 2016;112:112–118.
 - 16 Hutmam SE, Windisch W, Storre JH. Techniques for the measurement and monitoring of carbon dioxide in the blood. *Ann Am Thorac Soc* 2014;11:645–652.
 - 17 Yalamanchali S, Farajian V, Hamilton C, Pott TR, Samuelson CG, Friedman M. Diagnosis of obstructive sleep apnea by peripheral arterial tonometry: meta-analysis. *JAMA Otolaryngol Head Neck Surg* 2013;139:1343–1350.
 - 18 Lujan M. Usefulness of Effort belts during NIV. Sweden: Breas Medical; 2018 [accessed 2021 Jan 4]. Available from: <https://breas.com/wp-content/uploads/2019/05/Usefulness-of-Effort-Belts-during-NIV.pdf>.
 - 19 Pinto A, Almeida JP, Pinto S, Pereira J, Oliveira AG, de Carvalho M. Home telemonitoring of non-invasive ventilation decreases healthcare utilisation in a prospective controlled trial of patients with amyotrophic lateral sclerosis. *J Neurol Neurosurg Psychiatry* 2010;81:1238–1242.
 - 20 Ackrivo J, Hsu JY, Hansen-Flaschen J, Elman L, Kawut SM. Noninvasive ventilation use is associated with better survival in amyotrophic lateral sclerosis. *Ann Am Thorac Soc* 2021;18:486–494.
 - 21 Kleopa KA, Sherman M, Neal B, Romano GJ, Heiman-Patterson T. Bipap improves survival and rate of pulmonary function decline in patients with ALS. *J Neurol Sci* 1999;164:82–88.
 - 22 Berlowitz DJ, Howard ME, Fiore JF Jr, Vander Hoorn S, O'Donoghue FJ, Westlake J, et al. Identifying who will benefit from non-invasive ventilation in amyotrophic lateral sclerosis/motor neurone disease in a clinical cohort. *J Neurol Neurosurg Psychiatry* 2016;87:280–286.
 - 23 Lopes de Almeida JP, Pinto A, Pinto S, Ohana B, de Carvalho M. Economic cost of home-telemonitoring care for BiPAP-assisted ALS individuals. *Amyotroph Lateral Scler* 2012;13:533–537.
 - 24 Bertini S, Picariello M, Gorini M, Renda T, Augustynen A, Villella G, et al. Telemonitoring in chronic ventilatory failure: a new model of surveillance, a pilot study. *Monaldi Arch Chest Dis* 2012;77:57–66.
 - 25 Hazenberg A, Kerstjens HAM, Prins SCL, Vermeulen KM, Wijkstra PJ. Initiation of home mechanical ventilation at home: a randomised controlled trial of efficacy, feasibility and costs. *Respir Med* 2014;108:1387–1395.
 - 26 Mansell SK, Cutts S, Hackney I, Wood MJ, Hawksworth K, Creer DD, et al. Using domiciliary non-invasive ventilator data downloads to inform clinical decision-making to optimise ventilation delivery and patient compliance. *BMJ Open Respir Res* 2018;5:e000238.
 - 27 Borel JC, Pelletier J, Taleux N, Briault A, Arnol N, Pison C, et al. Parameters recorded by software of non-invasive ventilators predict COPD exacerbation: a proof-of-concept study. *Thorax* 2015;70:284–285.
 - 28 Mansell SK, Kilbride C, Wood MJ, Gowing F, Mandal S. Experiences and views of patients, carers and healthcare professionals on using modems in domiciliary non-invasive ventilation (NIV): a qualitative study. *BMJ Open Respir Res* 2020;7:e000510.
 - 29 Schwab RJ, Badr SM, Epstein LJ, Gay PC, Gozal D, Kohler M, et al.; ATS Subcommittee on CPAP Adherence Tracking Systems. An official American Thoracic Society statement: continuous positive airway pressure adherence tracking systems. The optimal monitoring strategies and outcome measures in adults. *Am J Respir Crit Care Med* 2013;188:613–620.
 - 30 Hannan LM, Rautela L, Berlowitz DJ, McDonald CF, Cori JM, Sheers N, et al. Randomised controlled trial of polysomnographic titration of noninvasive ventilation. *Eur Respir J* 2019;53:1802118.
 - 31 Selim BJ, Wolfe L, Coleman JM III, Dewan NA. Initiation of noninvasive ventilation for sleep related hypoventilation disorders: advanced modes and devices. *Chest* 2018;153:251–265.
 - 32 Trucco F, Pedemonte M, Racca F, Falsaperla R, Romano C, Wenzel A, et al. Tele-monitoring in paediatric and young home-ventilated neuromuscular patients: a multicentre case-control trial. *J Telemed Telecare* 2019;25:414–424.
 - 33 Nicholson TT, Smith SB, Siddique T, Sufit R, Ajroud-Driss S, Coleman JM III, et al. Respiratory pattern and tidal volumes differ for pressure support and volume-assured pressure support in amyotrophic lateral sclerosis. *Ann Am Thorac Soc* 2017;14:1139–1146.
 - 34 Centers for Medicare and Medicaid Services. Decision memo for continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA) (CAG-00093N) 2015 [accessed 2021 Sep 7]. Available from: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33800>.
 - 35 Stanberry B. Legal and ethical aspects of telemedicine. *J Telemed Telecare* 2006;12:166–175.
 - 36 Greene J, Yellowlees PM. Electronic and remote prescribing: administrative, regulatory, technical, and clinical standards and guidelines, April 2013. *Telemed J E Health* 2014;20:63–74.
 - 37 Bauer KA. The ethical and social dimensions of home-based telemedicine. *Crit Rev Biomed Eng* 2000;28:541–544.
 - 38 Peters SG. New billing rules for outpatient office visit codes. *Chest* 2020;158:298–302.
 - 39 ResMed Quick reference guide: Assisting healthcare professionals with information on coverage and billing of remote monitoring CPT codes. ResMed Corp; 2021 [accessed 2021 Sep 7]. Available from: https://document.resmed.com/documents/articles/1013491r11_Remote_Patient_Monitoring_Guide-Amer_Eng.pdf.