

In brief

Oxygen saturation monitors/pulse oximeters for COVID-19

29 September 2021

Background

- Remote home monitoring models for COVID-19 aim to manage high-risk patients at home to avoid unnecessary hospital admissions and escalate cases of deterioration in a timely way. Oxygen (O₂) saturation monitors, or pulse oximeters, can be used at home to detect COVID-19 associated hypoxia.
- [Home oximetry requires clinical support](#), such as regular phone contact from a health professional in a virtual ward setting.¹
- Symptoms of COVID-19 can range from mild illness to pneumonia. Most people experience mild illness and can recover at home. Treatment is aimed at relieving symptoms and includes rest, fluid intake and pain relievers. However, there are a variety of COVID-19 disease trajectories, and care at home requires assessment of risk and monitoring of changes in clinical parameters.
- Oximetry has been identified as an important element in providing home care for COVID-19 patients and monitoring the need for escalation.
- The UK [Medicines and Healthcare Products Regulatory Agency](#) does not recommend the use of oximeters at home unless under the advice of a qualified clinician. Pulse oximeters are regulated as medical devices.²
- The [NHS recommends](#) ensuring any pulse oximeter used at home has a valid CE, UKCA or CE UKNI mark.³ They have a [patient leaflet](#) on how to use a pulse oximeter.⁴
- In the US, pulse oximeters are regulated by the [Food and Drug Administration](#) (FDA).⁵ Pulse oximeters reviewed by the FDA are only available with a [prescription](#) and may be prescribed for home use. Over-the-counter oximeters do not undergo FDA review.⁶
- There is [limited data on the accuracy of inexpensive pulse oximeters](#), including stand-alone finger oximeters and phone-based products.⁷
- An [observational study](#) during COVID-19 found that low-cost pulse oximeters sold to consumers may produce inaccurate readings, although some perform similarly to more expensive options.⁸

1. O₂ saturation monitors in fully vaccinated people

- No evidence was found specific to using O₂ saturation monitors for remote monitoring in fully vaccinated people.

2. Which patients benefit from the use of O₂ saturation monitors?

Source	Summary
The implementation of remote home monitoring models during the	<ul style="list-style-type: none"> • Inclusion criteria for remote home monitoring may include: <ul style="list-style-type: none"> ○ higher risk patients selected by e.g. age, comorbidities ○ safety e.g. oxygen saturation levels and NEWS2 scores.

Source	Summary
<p>COVID-19 pandemic in England⁹</p> <p>Vindrola-Padros, et al. April 2021</p>	<ul style="list-style-type: none"> • Patients may be risk-stratified to determine frequency of monitoring.
<p>Remote home monitoring (virtual wards) for confirmed or suspected COVID-19 patients: a rapid systematic review¹⁰</p> <p>Vindrola-Padros, et al. June 2021</p>	<ul style="list-style-type: none"> • Patient populations considered appropriate for home monitoring: <ul style="list-style-type: none"> ○ Adult (over 18 years) patients with COVID-19 symptoms (suspected and confirmed cases) ○ One model excluded patients over 65 years with significant comorbidities. ○ One model excluded pregnant women and only included patients with SpO₂ above 92% at initial assessment. ○ Comorbidities mentioned with greater frequency were hypertension, asthma and obesity.
<p>Remote management of covid-19 using home pulse oximetry and virtual ward support¹</p> <p>Greenhalgh, et al. March 2021</p>	<ul style="list-style-type: none"> • UK guidelines recommend that assessment and monitoring of breathless, unwell, or high-risk patients with suspected COVID-19 should include pulse oximetry. • Flowchart outlines a process for selecting patients for, and supporting them in, a home oximetry and virtual ward service.
<p>Remote patient monitoring program for hospital discharged COVID-19 patients¹¹</p> <p>Gordon, et al. October 2020</p>	<ul style="list-style-type: none"> • Patients were eligible for the remote monitoring program (including pulse oximeter) if they had a diagnosis of COVID-19, were able to activate a patient portal account, were being discharged home, and were able to complete a survey in English or Spanish. • Exclusion criteria included: <ul style="list-style-type: none"> ○ those aged <18 years ○ comorbid highly symptomatic non-COVID conditions e.g. advanced heart failure with dyspnea ○ cognitive or behavioural health barriers ○ conditions limiting ability to work with devices or lack of working phone ○ discharge to a facility.
<p>Reengineering the Discharge Transition Process of COVID-19 Patients Using Telemedicine, Remote Patient Monitoring, and Around-the-Clock Remote Patient Monitoring from the Emergency Department and Inpatient Units¹²</p>	<ul style="list-style-type: none"> • Inclusion criteria are: <ul style="list-style-type: none"> ○ adult patients >18 years ○ oxygen saturation <92% during hospital stay ○ patient discharged home ○ patient reliability i.e. patient or family member able to use pulse oximeter. • Patients discharged to a skilled nursing facility were excluded.

Source	Summary
Kodama, et al. December 2020	
<p>An emergency system for monitoring pulse oximetry, peak expiratory flow, and body temperature of patients with COVID-19 at home: Development and preliminary application¹³</p> <p>Motta, et al. March 2021</p>	<ul style="list-style-type: none"> • Pulse oximetry monitoring is essential for identifying hypoxemia, especially in the elderly and patients with comorbidities. • 24 volunteers were selected for the study, including 12 COVID-19 positive patients with asymptomatic to mild disease over the age of 18 years.
<p>Smartphone Biosensor With App Meets FDA/ISO Standards for Clinical Pulse Oximetry and Can Be Reliably Used by a Wide Range of Patients¹⁴</p> <p>Browne, et al. February 2021</p>	<ul style="list-style-type: none"> • Remote clinical pulse oximetry may support triage and initial treatment of symptomatic COVID-19 patients. • Comorbidity exclusion criteria are as follows: <ul style="list-style-type: none"> ○ coarctation of the aorta ○ severe peripheral vascular disease ○ severe anaemia ○ severe sickle cell disease ○ methemoglobinemia.
<p>e-CoVig: A Novel mHealth System for Remote Monitoring of Symptoms in COVID-19¹⁵</p> <p>Raposo, et al. May 2021</p>	<ul style="list-style-type: none"> • Remote monitoring system designed for mild or asymptomatic patients at home or in isolated accommodations.
<p>Analysis of an Ambulatory Care Pathway for Patients With COVID-19 Utilising Remote Pulse Oximetry at a London District General Hospital¹⁶</p> <p>Kyriakides, et al. January 2021</p>	<ul style="list-style-type: none"> • Home pulse oximetry was used to aid discharge from ED and avoid hospital admission. • Inclusion criteria for discharge for home monitoring are: <ul style="list-style-type: none"> ○ confirmed or suspected COVID-19 ○ oxygen saturation rate of 90-94% ○ ability to use pulse oximeter correctly ○ discharge decision by registrar or consultant.
<p>A Novel Large Scale Integrated Telemonitoring Program for COVID-19¹⁷</p> <p>Shaw, et al. February 2021</p>	<ul style="list-style-type: none"> • Standardised criteria to determine which patients would receive a pulse oximeter: <ul style="list-style-type: none"> ○ age >75 years ○ body mass index (BMI) >30 kg/m² ○ history of chronic lung disease. • Criteria were adjusted with more data and experience e.g. with the help of obstetrics and/or gynaecology (OB/GYN) physicians who joined the program, a less restrictive set of criteria was created to determine which OB patients should receive a device.

Source	Summary
<p>Novel Use of Home Pulse Oximetry Monitoring in COVID-19 Patients Discharged From the Emergency Department Identifies Need for Hospitalisation¹⁸</p> <p>Shah, et al. August 2020</p>	<ul style="list-style-type: none"> • Inclusion criteria: <ul style="list-style-type: none"> ○ age >18 years ○ COVID-19 infection or suspected infection ○ patient discharged to home ○ resting oxygen rate >92% on discharge. • Exclusion criteria: <ul style="list-style-type: none"> ○ admission to hospital or discharged to nursing facility ○ pregnancy ○ home oxygen use.
<p>Using pulse oximetry to monitor high-risk patients with COVID-19 at home¹⁹</p> <p>Rodriguez November 2020</p>	<ul style="list-style-type: none"> • Pulse oximetry for patients with COVID-19 who are at higher risk for severe disease: <ul style="list-style-type: none"> ○ aged >65 years ○ long-term care residents ○ immunocompromised patients ○ those with comorbidities (e.g. chronic lung disease or moderate-severe asthma, chronic heart disease, severe obesity, diabetes, chronic renal disease, hepatic disease). • Education and training provided on proper use of at-home device.
<p>Home monitoring reduced short stay admissions in suspected COVID-19 patients: COVID-box project²⁰</p> <p>Dirikgil, et al. August 2021</p>	<ul style="list-style-type: none"> • Home monitoring could be allocated to patients with suspected COVID-19 with moderate symptoms or risk of worse prognosis due to underlying comorbidities.
<p>Developing a pulse oximetry home monitoring protocol for patients suspected with COVID-19 after emergency department discharge²¹</p> <p>Gootenberg, et al. May 2021</p>	<ul style="list-style-type: none"> • Eligible patients were adults discharge from ED with suspected COVID-19. • Exclusion criteria include: <ul style="list-style-type: none"> ○ oxygen saturation <92% at rest or <90% ambulatory ○ heart rate >110 beats per minute ○ inability to use device.
<p>COVID-19-The impact of variable and "low normal" pulse oximetry scores on Oximetry@Home services and clinical pathways: Confounding variables?²²</p> <p>Harland, et al. June 2021</p>	<ul style="list-style-type: none"> • NHS England recommended home oximetry monitoring for patients with mild COVID-19 symptoms at high risk of deterioration with oxygen saturation >95%.

Source	Summary
<p>The use of telemonitoring in managing the COVID pandemic: a pilot implementation study²³</p> <p>McKinstry, et al. August 2021</p>	<ul style="list-style-type: none"> • Pulse oximeters were provided to patients attending COVID-19 assessment centres who were fit for discharge but at risk of deterioration.
<p>Grey literature</p>	
<p>Pulse oximetry to detect early deterioration of patients with COVID-19 in primary and community care settings²⁴</p> <p>NHS January 2021</p>	<ul style="list-style-type: none"> • Home oximetry is recommended for patients most at risk of poor outcomes to monitor and identify 'silent hypoxia' and rapid deterioration. • Criteria include: <ul style="list-style-type: none"> ○ a diagnosis of COVID-19, and ○ symptomatic aged 65 years or older; or ○ symptomatic under 65 years and clinically extremely vulnerable to COVID-19.
<p>COVID-19 clinical management: living guidance, 25 January 2021²⁵</p> <p>World Health Organization January 2021</p>	<ul style="list-style-type: none"> • Conditional recommendation for home pulse oximetry monitoring in symptomatic patients at risk for severe disease who are not hospitalised. • Must be part of a larger package of care including education and follow-up. • No benefit for asymptomatic patients. • No evidence for use in special populations.
<p>Spotlight on virtual care: COVID-19 remote monitoring²⁶</p> <p>NSW Health June 2021</p>	<ul style="list-style-type: none"> • People with COVID-19 who meet all these criteria: <ul style="list-style-type: none"> ○ Low or moderate acuity ○ Assessed as suitable to undertake home monitoring based on physical, mental, social, literacy and cognitive function ○ Do not require hospital admission ○ Willing to participate in home monitoring • Exclusions apply to some home remote monitoring services for patients such as residential aged care facility residents.
<p>Home-care guidelines for adult patients with mild COVID-19²⁷</p> <p>Royal Australian College of General Practitioners (RACGP)</p>	<p>A management plan will need to be put in place for people eligible for home care. This should include considering the use of pulse-oximetry to self-monitor oxygen saturation for patients at higher risk of complications.</p>

3. Return and reuse of O₂ saturation monitors

Source	Summary
<p>Developing a pulse oximetry home monitoring protocol for patients suspected with COVID-19 after emergency department discharge²¹</p> <p>Gootenberg, et al. May 2021</p>	<ul style="list-style-type: none"> After the seven-day follow-up period, all subjects were sent an envelope with return postage to return the pulse oximeter device to be cleaned and reused.
<p>Remote patient monitoring program for hospital discharged COVID-19 patients¹¹</p> <p>Gordon, et al. October 2020</p>	<ul style="list-style-type: none"> Patients were provided with a self-addressed stamped envelope for return of pulse oximeter.
Grey literature	
<p>Pulse oximetry to detect early deterioration of patients with COVID-19 in primary and community care settings²⁴</p> <p>NHS January 2021</p>	<ul style="list-style-type: none"> Decontaminate/clean pulse oximeters on return from a home care setting and check before reuse.
<p>COVID-19 clinical management: living guidance, 25 January 2021²⁵</p> <p>World Health Organization January 2021</p>	<ul style="list-style-type: none"> Where possible, use disposable or dedicated equipment, including pulse oximeters. If equipment is shared, clean and disinfect between each patient.
<p>COVID oximetry at home toolkit: Procedure for decontamination of remote monitoring pack²⁸</p> <p>Wessex Academic Health Science Network, NHS 2021</p>	<ul style="list-style-type: none"> Pulse oximeter to be returned in zip-lock bag. Member of staff to wear gloves and wash hands after cleaning pulse oximeter with actichlor solution. Pulse oximeter placed in new zip-lock bag for next patient.

To inform this brief, PubMed and Google searches were conducted using terms COVID-19 AND (pulse oximetry OR oxygen saturation monitor) AND (vaccin* OR home monitoring OR remote) on 2 September 2021.

References

1. Greenhalgh T, Knight M, Inada-Kim M, et al. Remote management of covid-19 using home pulse oximetry and virtual ward support. *BMJ*. 2021;372:1-8. DOI: 10.1136/bmj.n677
2. Medicines and Healthcare products Regulatory Agency. Guidance: The use and regulation of pulse oximeters (information for healthcare professionals) [Internet]. United Kingdom: Medicines and Healthcare products Regulatory Agency; 26 March 2021 [cited 15 September 2021]. Available from: <https://www.gov.uk/guidance/the-use-and-regulation-of-pulse-oximeters-information-for-healthcare-professionals#home-use-of-pulse-oximeters>
3. National Health Service (NHS). How to look after yourself at home if you have coronavirus (COVID-19) [Internet]. United Kingdom: NHS; 2 September 2021 [cited 15 September 2021]. Available from: <https://www.nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/how-to-treat-symptoms-at-home/>
4. National Health Service (NHS). Using a pulse oximeter to check you are OK [Internet]. United Kingdom: NHS; 2 September 2021 [cited 15 September 2021]. Available from: <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/06/Pulse-Oximeter-Easy-Read-final-online-v4.pdf>
5. U.S. Food and Drug Administration. Guidance document: Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff [Internet]. USA: U.S. Food and Drug Administration; March 2013 [cited 15 September 2021]. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-premarket-notification-submissions-510ks-guidance-industry-and-food-and-drug>
6. U.S. Food and Drug Administration. Pulse Oximeter Accuracy and Limitations: FDA Safety Communication [Internet]. USA: U.S. Food and Drug Administration; March 2013 [cited 15 September 2021]. Available from: <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>
7. Luks AM, Swenson ER. Pulse Oximetry for Monitoring Patients with COVID-19 at Home. Potential Pitfalls and Practical Guidance. *Ann Am Thorac Soc*. 2020 Sep;17(9):1040-6. DOI: 10.1513/AnnalsATS.202005-418FR
8. Lipnick MS, Feiner JR, Au P, et al. The Accuracy of 6 Inexpensive Pulse Oximeters Not Cleared by the Food and Drug Administration: The Possible Global Public Health Implications. *Anesth Analg*. 2016 Aug;123(2):338-45. DOI: 10.1213/ane.0000000000001300
9. Vindrola-Padros C, Sidhu MS, Georghiou T, et al. The implementation of remote home monitoring models during the COVID-19 pandemic in England. *EClinicalMedicine*. 2021;34:1-7. DOI: 10.1016/j.eclinm.2021.100799
10. Vindrola-Padros C, Singh KE, Sidhu MS, et al. Remote home monitoring (virtual wards) for confirmed or suspected COVID-19 patients: a rapid systematic review. *EClinicalMedicine*. 2021;37:1-8. DOI: 10.1016/j.eclinm.2021.100965
11. Gordon WJ, Henderson D, DeSharone A, et al. Remote Patient Monitoring Program for Hospital Discharged COVID-19 Patients. *Appl Clin Inform*. 2020 Oct;11(5):792-801. DOI: 10.1055/s-0040-1721039

12. Kodama R, Arora S, Anand S, et al. Reengineering the Discharge Transition Process of COVID-19 Patients Using Telemedicine, Remote Patient Monitoring, and Around-the-Clock Remote Patient Monitoring from the Emergency Department and Inpatient Units. *Telemed J E Health*. 2020; Dec 14:1-6. DOI: 10.1089/tmj.2020.0459
13. Motta LP, Silva PP, Borguezan BM, et al. An emergency system for monitoring pulse oximetry, peak expiratory flow, and body temperature of patients with COVID-19 at home: Development and preliminary application. *PloS one*. 2021;16(3):1-19. DOI: 10.1371/journal.pone.0247635
14. Browne SH, Bernstein M, Pan SC, et al. Smartphone Biosensor With App Meets FDA/ISO Standards for Clinical Pulse Oximetry and Can Be Reliably Used by a Wide Range of Patients. *Chest*. 2021 Feb;159(2):724-32. DOI: 10.1016/j.chest.2020.08.2104
15. Raposo A, Marques L, Correia R, et al. e-CoVig: A Novel mHealth System for Remote Monitoring of Symptoms in COVID-19. *Sensors (Basel)*. 2021 May 13;21(10):1-18. DOI: 10.3390/s21103397
16. Kyriakides J, Khani A, Coleman R, et al. Analysis of an Ambulatory Care Pathway for Patients With COVID-19 Utilising Remote Pulse Oximetry at a London District General Hospital. *Cureus*. 2021 Jan 29;13(1):1-6. DOI: 10.7759/cureus.12979
17. Shaw JG, Sankineni S, Olaleye CA, et al. A Novel Large Scale Integrated Telemonitoring Program for COVID-19. *Telemed J E Health*. 2021; Feb 5:1-5. DOI: 10.1089/tmj.2020.0384
18. Shah S, Majmudar K, Stein A, et al. Novel Use of Home Pulse Oximetry Monitoring in COVID-19 Patients Discharged From the Emergency Department Identifies Need for Hospitalization. *Acad Emerg Med*. 2020 Aug;27(8):681-92. DOI: 10.1111/acem.14053
19. Rodriguez C. Using pulse oximetry to monitor high-risk patients with COVID-19 at home. *Nursing*. 2020 Nov;50(11):15-6. DOI: 10.1097/01.NURSE.0000718376.94916.eb
20. Dirikgil E, Roos R, Groeneveld GH, et al. Home monitoring reduced short stay admissions in suspected COVID-19 patients: COVID-box project. *The European respiratory journal*. 2021;58(2):1-4. DOI: 10.1183/13993003.00636-2021
21. Gootenberg DB, Kurtzman N, O'Mara T, et al. Developing a pulse oximetry home monitoring protocol for patients suspected with COVID-19 after emergency department discharge. *BMJ Health Care Inform*. 2021 Jul;28(1):1-8. DOI: 10.1136/bmjhci-2021-100330
22. Harland N, Greaves J, Fuller E. COVID-19-The impact of variable and "low normal" pulse oximetry scores on Oximetry@Home services and clinical pathways: Confounding variables? *Nurs Open*. 2021 Jun 23;1-4. DOI: 10.1002/nop2.957
23. McKinstry B, Alexander H, Maxwell G, et al. The use of telemonitoring in managing the COVID pandemic: a pilot implementation study. *JMIR Form Res*. 2021 Aug 24. DOI: 10.2196/20131
24. National Health Service (NHS). Pulse oximetry to detect early deterioration of patients with COVID-19 in primary and community care settings [Internet]. United Kingdom: NHS; 12 January 2021 [cited 15 September 2021]. Available from: <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/06/C0445-remote-monitoring-in-primary-care-jan-2021-v1.1.pdf>
25. World Health Organization. COVID-19 clinical management: living guidance, 25 January 2021 [Internet]. Geneva: World Health Organization; 19 February 2021 [cited 15 September 2021]. Available from: <https://apps.who.int/iris/handle/10665/338882>

26. Agency for Clinical Innovation. Spotlight on virtual care: COVID-19 remote monitoring [Internet]. Australia: Agency for Clinical Innovation; June 2021 [cited 15 September]. Available from: https://aci.health.nsw.gov.au/_data/assets/pdf_file/0009/657531/Virtual-care-initiative-COVID-19-remote-monitoring.pdf
27. Royal Australian College of General Practitioners. Home-care guidelines for adult patients with mild COVID-19 [Internet]. Australia: Royal Australian College of General Practitioners; August 2020 [cited 15 September 2021]. Available from: <https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Home-care-guidelines-for-adult-patients-with-mild-COVID-19.pdf>
28. Wessex Academic Health Science Network NHS. Procedure for decontamination of remote monitoring pack [Internet]. United Kingdom: Wessex Academic Health Science Network NHS; 2021 [cited 15 September 2021]. Available from: https://wessexahsn.org.uk/img/projects/handling_of_covid_remote_pack_protocol_winchester_pcn.pdf

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