

# NM27C512 524,288-Bit (64K x 8) High Performance CMOS EPROM

## **General Description**

The NM27C512 is a high performance 512K UV Erasable Electrically Programmable Read Only Memory (EPROM). It is manufactured using National's proprietary 0.8 micron CMOS AMG™ EPROM technology for an excellent combination of speed and economy while providing excellent reliability.

The NM27C512 provides microprocessor-based systems storage capacity for portions of operating system and application software. Its 90 ns access time provides nowait-state operation with high-performance CPUs. The NM27C512 offers a single chip solution for the code storage requirements of 100% firmware-based equipment. Frequently-used software routines are quickly executed from EPROM storage, greatly enhancing system utility.

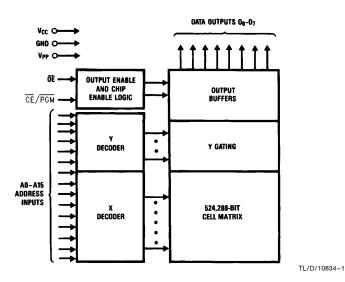
The NM27C512 is configured in the standard JEDEC EPROM pinout which provides an easy upgrade path for systems which are currently using standard EPROMs.

The NM27C512 is one member of a high density EPROM Family which range in densities up to 4 Megabit.

#### **Features**

- High performance CMOS
  - 90 ns access time
- Fast turn-off for microprocessor compatibility
- Manufacturers identification code
- JEDEC standard pin configuration
  - 28-pin DIP package
  - 32-pin chip carrier

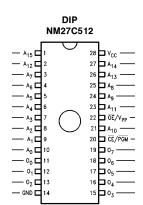
## **Block Diagram**



TRI-STATE® is a registered trademark of National Semiconductor Corporation. NSC800™ is a trademark of National Semiconductor Corporation. AMG™ is a trademark of WSI, Inc.

# **Connection Diagrams**

27C080	27C040	27C020	27C010	27C256
A <sub>19</sub>	XX/V <sub>PP</sub>	XX/V <sub>PP</sub>	XX/V <sub>PP</sub>	
A <sub>16</sub>	A <sub>16</sub>	A <sub>16</sub>	A <sub>16</sub>	
A <sub>15</sub>	A <sub>15</sub>	A <sub>15</sub>	A <sub>15</sub>	$V_{PP}$
A <sub>12</sub>	A <sub>12</sub>	A <sub>12</sub>	A <sub>12</sub>	A <sub>12</sub>
A <sub>7</sub>	A <sub>7</sub>	A <sub>7</sub>	A <sub>7</sub>	A <sub>7</sub>
A <sub>6</sub>	A <sub>6</sub>	A <sub>6</sub>	A <sub>6</sub>	A <sub>6</sub>
A <sub>5</sub>	A <sub>5</sub>	A <sub>5</sub>	A <sub>5</sub>	A <sub>5</sub>
$A_4$	A <sub>4</sub>	A <sub>4</sub>	A <sub>4</sub>	$A_4$
A <sub>3</sub>	A <sub>3</sub>	A <sub>3</sub>	A <sub>3</sub>	A <sub>3</sub>
A <sub>2</sub>	A <sub>2</sub>	A <sub>2</sub>	A <sub>2</sub>	A <sub>2</sub>
A <sub>1</sub>	A <sub>1</sub>	A <sub>1</sub>	A <sub>1</sub>	A <sub>1</sub>
A <sub>0</sub>	A <sub>0</sub>	A <sub>0</sub>	A <sub>0</sub>	A <sub>0</sub>
O <sub>0</sub>	Ο <sub>0</sub>	O <sub>0</sub>	O <sub>0</sub>	O <sub>0</sub>
01	01	01	O <sub>1</sub>	01
02	02	02	02	02
GND	GND	GND	GND	GND



27C256	27C010	27C020	27C040	27C080
	V <sub>CC</sub>	Vcc	V <sub>CC</sub>	V <sub>C</sub> C
	XX/PGM	XX/PGM	A <sub>18</sub>	A <sub>18</sub>
V <sub>CC</sub>	XX	A <sub>17</sub>	A <sub>17</sub>	A <sub>17</sub>
A <sub>14</sub>	A <sub>14</sub>	A <sub>14</sub>	A <sub>14</sub>	A <sub>14</sub>
A <sub>13</sub>	A <sub>13</sub>	A <sub>13</sub>	A <sub>13</sub>	A <sub>13</sub>
A <sub>8</sub>	A <sub>8</sub>	A <sub>8</sub>	A <sub>8</sub>	A <sub>8</sub>
A <sub>9</sub>	A <sub>9</sub>	A <sub>9</sub>	A <sub>9</sub>	A <sub>9</sub>
A <sub>11</sub> OE	A <sub>11</sub> OE	A <sub>11</sub> OE	A <sub>11</sub> OE	A <sub>11</sub>
ŌĒ			ŌĒ	OE/ <sub>VPP</sub>
A <sub>10</sub>	A <sub>10</sub> CE	A <sub>10</sub>	A <sub>10</sub>	A <sub>10</sub>
CE/PGM	CE	CE	CE/PGM	CE/PGM
07	07	07	07	07
O <sub>6</sub>	O <sub>6</sub>	06	O <sub>6</sub>	O <sub>6</sub>
05	O <sub>5</sub>	05	O <sub>5</sub>	O <sub>5</sub>
04	$O_4$	04	04	O <sub>4</sub>
O <sub>3</sub>	O <sub>3</sub>	Ο3	Ο <sub>3</sub>	O <sub>3</sub>

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Note: Compatible EPROM pin configurations are shown in the blocks adjacent to the NM27C512 pins.

### Commercial Temp Range (0°C to +70°C)

Parameter/Order Number	Access Time (ns)*
NM27C512 Q, N, V 90	90
NM27C512 Q, N, V 120	120
NM27C512 Q, N, V 150	150
NM27C512 Q, N, V 200	200

### Military Temp Range ( $-55^{\circ}$ C to $+125^{\circ}$ C)

Parameter/Order Number	Access Time (ns)*
NM27C512 QM 200	200

### Pin Names

A0-A15	Addresses	
CE	Chip Enable	
ŌĒ	Output Enable	
00-07	Outputs	
PGM	Program	
XX	Don't Care (During Read)	

### Extended Temp Range ( $-40^{\circ}$ C to $+85^{\circ}$ C)

Parameter/Order Number	Access Time (ns)*
NM27C512 QE, NE, VE 90	90
NM27C512 QE, NE, VE 120	120
NM27C512 QE, NE, VE 150	150
NM27C512 QE, NE, VE 200	200

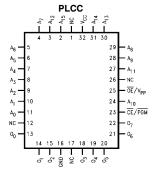
**Note:** Surface mount PLCC package available for commercial and extended temperature ranges only.

Package Types: NM27C512 Q, N, V XXX Q = Quartz-Windowed Ceramic DIP Package

N = Plastic OTP DIP Package

V = PLCC Package

• All packages conform to the JEDEC standard.



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<sup>\*</sup>All versions are guaranteed to function for slower speeds.

# **Absolute Maximum Ratings** (Note 1)

If Military/Aerospace specified devices are required, please contact the National Semiconductor Sales Office/Distributors for availability and specifications.

Storage Temperature  $-65^{\circ}\text{C to } + 150^{\circ}\text{C}$ 

All Input Voltages Except A9 with

Respect to Ground -0.6V to +7V

 $V_{\mbox{\footnotesize{PP}}}$  and A9 with Respect to Ground  $-0.7\mbox{\footnotesize{V}}$  to  $+14\mbox{\footnotesize{V}}$ 

V<sub>CC</sub> Supply Voltage with Respect to Ground

-0.6V to +7V

**ESD Protection** 

(MIL Std. 883, Method 3015.2)

>2000V

All Output Voltages with

Respect to Ground

 $V_{\hbox{\footnotesize CC}}\,+\,1.0V$  to GND -0.6V

# **Operating Range**

Range	Temperature	V <sub>CC</sub>	Tolerance
Comm'l	0°C to +70°C	+5V	±10%
Industrial	-40°C to +85°C	+5V	±10%
Military	-55°C to +125°C	+5V	±10%

# **Read Operation**

# **DC Electrical Characteristics**

Symbol	Parameter	Test Conditions	Min	Max	Units
V <sub>IL</sub>	Input Low Level		-0.5	08	V
V <sub>IH</sub>	Input High Level		2.0	V <sub>CC</sub> + 1	٧
V <sub>OL</sub>	Output Low Voltage	I <sub>OL</sub> = 2.1 mA		0.4	V
V <sub>OH</sub>	Output High Voltage	$I_{OH} = -2.5 \text{ mA}$	3.5		V
I <sub>SB1</sub>	V <sub>CC</sub> Standby Current (CMOS)	$\overline{\text{CE}} = V_{\text{CC}} \pm 0.3V$		100	μΑ
I <sub>SB2</sub>	V <sub>CC</sub> Standby Current	CE = V <sub>IH</sub>		1	mA
I <sub>CC1</sub>	V <sub>CC</sub> Active Current	$\overline{CE} = \overline{OE} = V_{IL}$ f = 5 MHz		40	mA
I <sub>CC2</sub>	V <sub>CC</sub> Active Current CMOS Inputs	\overline{\overline{CE}} = GND, f = 5 MHz Inputs = V <sub>CC</sub> or GND, I/O = 0 mA C, I Temp Ranges		35	mA
Ірр	V <sub>PP</sub> Supply Current	$V_{PP} = V_{CC}$		10	μΑ
V <sub>PP</sub>	V <sub>PP</sub> Read Voltage		V <sub>C</sub> - 0.7	V <sub>CC</sub>	V
ILI	Input Load Current	V <sub>IN</sub> = 5.5V or GND	-1	1	μΑ
ILO	Output Leakage Current	V <sub>OUT</sub> = 5.5V or GND	-10	10	μΑ

# **AC Electrical Characteristics**

Symbol	Parameter	90		120		150		200		Units
	i arameter	Min	Max	Min	Max	Min	Max	Min	Max	Onits
t <sub>ACC</sub>	Address to Output Delay		90		120		150		200	
t <sub>CE</sub>	CE to Output Delay		90		120		150		200	
toE	OE to Output Delay		40		50		50		50	
t <sub>DF</sub>	Output Disable to Output Float		35		25		45		55	ns
t <sub>OH</sub>	Output Hold from Addresses, CE or OE, Whichever Occurred First	0		0		0				

## Capacitance $T_A = +25$ °C, f = 1 MHz (Note 2)

Symbol	Parameter	Conditions	Тур	Max	Units
C <sub>IN1</sub>	Input Capacitance except OE/V <sub>PP</sub>	V <sub>IN</sub> = 0V	6	12	pF
C <sub>OUT</sub>	Output Capacitance	V <sub>OUT</sub> = 0V	9	12	pF
C <sub>IN2</sub>	OE/V <sub>PP</sub> Input Capacitance	V <sub>IN</sub> = 0V	20	25	pF

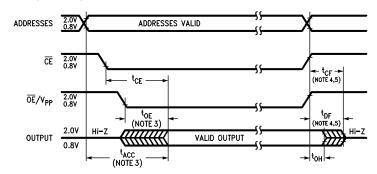
# **AC Test Conditions**

Output Load 1 TTL Gate and Timing Measurement Reference Level (Note 9)

 $\begin{array}{ccc} C_L = 100 \text{ pF (Note 8)} & Inputs & 0.8 \text{V and 2V} \\ Input Rise \text{ and Fall Times} & \leq 5 \text{ ns} & Outputs & 0.8 \text{V and 2V} \\ \end{array}$ 

Input Pulse Levels 0.45V to 2.4V

# AC Waveforms (Notes 6, 7)



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**Note 1:** Stresses above those listed under "Absolute Maximum Ratings" may cause permanent damage to the device. This is a stress rating only and functional operation of the device at these or any other conditions above those indicated in the operational sections of this specification is not implied. Exposure to absolute maximum rating conditions for extended periods may affect device reliability.

Note 2: This parameter is only sampled and is not 100% tested.

Note 3:  $\overline{\text{OE}}$  may be delayed up to  $t_{\text{ACC}}$  –  $t_{\text{OE}}$  after the falling edge of  $\overline{\text{CE}}$  without impacting  $t_{\text{ACC}}$ .

Note 4: The  $t_{\mbox{\footnotesize{DF}}}$  and  $t_{\mbox{\footnotesize{CF}}}$  compare level is determined as follows:

High to TRI-STATE, the measured  $V_{OH1}$  (DC) - 0.10V; Low to TRI-STATE, the measured  $V_{OL1}$  (DC) + 0.10V.

Note 5: TRI-STATE may be attained using  $\overline{\text{OE}}$  or  $\overline{\text{CE}}$ .

Note 6: The power switching characteristics of EPROMs require careful device decoupling. It is recommended that at least a 0.1 µF ceramic capacitor be used on every device between V<sub>CC</sub> and GND.

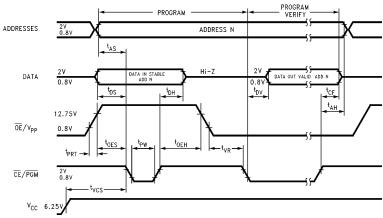
Note 7: The outputs must be restricted to  $V_{CC}\,+\,1.0V$  to avoid latch-up and device damage.

Note 8: 1 TTL Gate:  $I_{OL}=$  1.6 mA,  $I_{OH}=-400~\mu$ A.  $C_L$ : 100 pF includes fixture capacitance.

Note 9: Inputs and outputs can undershoot to  $-2.0\mathrm{V}$  for 20 ns Max.

Symbol	Parameter	Conditions	Min	Тур	Max	Units
t <sub>AS</sub>	Address Setup Time		1			μs
toes	OE Setup Time		1			μs
t <sub>DS</sub>	Data Setup Time		1			μs
t <sub>VCS</sub>	V <sub>CC</sub> Setup Time		1			μs
t <sub>AH</sub>	Address Hold Time		0			μs
t <sub>DH</sub>	Data Hold Time		1			μs
t <sub>CF</sub>	Chip Enable to Output Float Delay	$\overline{OE} = V_{IL}$	0		60	ns
t <sub>PW</sub>	Program Pulse Width		95	100	105	μs
t <sub>OEH</sub>	OE Hold Time		1			μs
$t_{DV}$	Data Valid from CE	$\overline{OE} = V_{IL}$			250	ns
t <sub>PRT</sub>	OE Pulse Rise Time during Programming		50			ns
t <sub>VR</sub>	V <sub>PP</sub> Recovery Time		1			μs
Ірр	V <sub>PP</sub> Supply Current during Programming Pulse	$\overline{CE} = V_{IL}$ $\overline{OE} = V_{PP}$			30	mA
Icc	V <sub>CC</sub> Supply Current				50	mA
T <sub>R</sub>	Temperature Ambient		20	25	30	°C
V <sub>CC</sub>	Power Supply Voltage		6	6.25	6.5	V
V <sub>PP</sub>	Programming Supply Voltage		12.5	12.75	13	V
t <sub>FR</sub>	Input Rise, Fall Time		5			ns
V <sub>IL</sub>	Input Low Voltage			0	0.45	V
V <sub>IH</sub>	Input High Voltage		2.4	4		V
t <sub>IN</sub>	Input Timing Reference Voltage		0.8		2	V
tout	Output Timing Reference Voltage		0.8		2	V

# **Programming Waveforms**



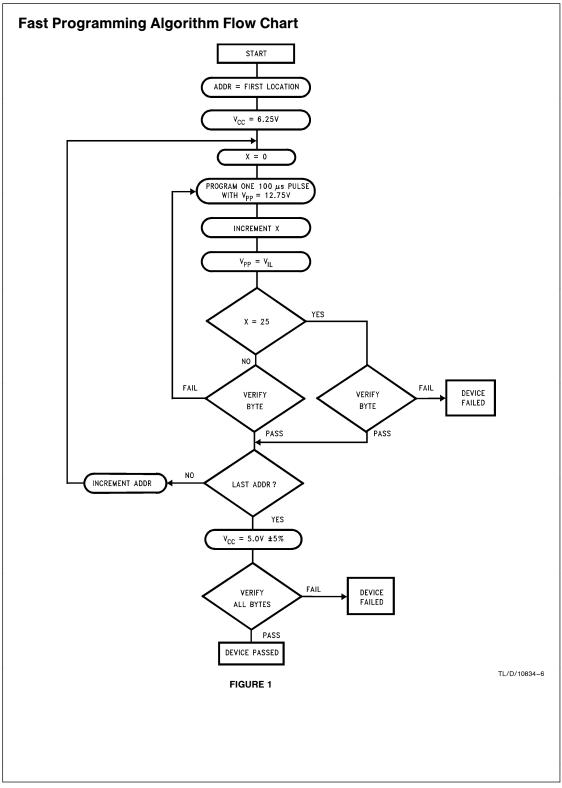
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Note 1: National's standard product warranty applies to devices programmed to specifications described herein.

Note 2:  $V_{CC}$  must be applied simultaneously or before  $V_{PP}$  and removed simultaneously or after  $V_{PP}$ . The EPROM must not be inserted into or removed from a board with voltage applied to  $V_{PP}$  or  $V_{CC}$ .

Note 3: The maximum absolute allowable voltage which may be applied to the V<sub>PP</sub> pin during programming is 14V. Care must be taken when switching the V<sub>PP</sub> supply to prevent any overshoot from exceeding this 14V maximum specification. At least a 0.1 μF capacitor is required across V<sub>CC</sub> to GND to suppress spurious voltage transients which may damage the device.

Note 4: Programming and program verify are tested with the fast Program Algorithm at typical power supply voltages and timings.



## **Functional Description**

#### **DEVICE OPERATION**

The six modes of operation of the EPROM are listed in Table I. It should be noted that all inputs for the six modes are at TTL levels. The power supplies required are  $V_{CC}$  and OE/Vpp. The OE/Vpp power supply must be at 12.75V during the three programming modes, and must be at 5V in the other three modes. The  $V_{CC}$  power supply must be at 6.25V during the three programming modes, and at 5V in the other three modes.

#### **Read Mode**

The EPROM has two control functions, both of which must be logically active in order to obtain data at the outputs. Chip Enable (CE/PGM) is the power control and should be used for device selection. Output Enable (OE/V<sub>PP</sub>) is the output control and should be used to gate data to the output pins, independent of device selection. Assuming that addresses are stable, address access time (t<sub>ACC</sub>) is equal to the delay from CE to output (t<sub>CE</sub>). Data is available at the outputs t<sub>OE</sub> after the falling edge of OE, assuming that CE has been low and addresses have been stable for at least tacc-toe.

#### Standby Mode

The EPROM has a standby mode which reduces the active power dissipation by over 99%, from 385 mW to 0.55 mW. The EPROM is placed in the standby mode by applying a CMOS high signal to the CE/PGM input. When in standby mode, the outputs are in a high impedance state, independent of the OE input.

#### **Output Disable**

The EPROM is placed in output disable by applying a TTL high signal to the OE input. When in output disable all circuitry is enabled, except the outputs are in a high impedance state (TRI-STATE).

#### **Output OR-Typing**

Because the EPROM is usually used in larger memory arrays, National has provided a 2-line control function that accommodates this use of multiple memory connections. The 2-line control function allows for:

- a) the lowest possible memory power dissipation, and
- b) complete assurance that output bus contention will not occur.

To most efficiently use these two control lines, it is recommended that CE/PGM be decoded and used as the primary device selecting function, while OE/V<sub>PP</sub> be made a common connection to all devices in the array and connected to the READ line from the system control bus.

This assures that all deselected memory devices are in their low power standby modes and that the output pins are active only when data is desired from a particular memory device.

#### **Programming**

CAUTION: Exceeding 14V on pin 22 (OE/V $_{\rm PP}$ ) will damage the EPROM.

Initially, and after each erasure, all bits of the EPROM are in the "1's" state. Data is introduced by selectively programming "0's" into the desired bit locations. Although only "0's" will be programmed, both "1's" and "0's" can be presented in the data word. The only way to change a "0" to a "1" is by ultraviolet light erasure.

The EPROM is in the programming mode when the OE/V<sub>PP</sub> is at 12.75V. It is required that at least a 0.1  $\mu\text{F}$  capacitor be placed across V<sub>CC</sub> to ground to suppress spurious voltage transients which may damage the device. The data to be programmed is applied 8 bits in parallel to the data output pins. The levels required for the address and data inputs are TTI

When the address and data are stable, an active low, TTL program pulse is applied to the CE/PGM input. A program pulse must be applied at each address location to be programmed.

The EPROM is programmed with the Fast Programming Algorithm shown in *Figure 1*. Each Address is programmed with a series of 100  $\mu$ s pulses until it verifies good, up to a maximum of 25 pulses. Most memory cells will program with a single 100  $\mu$ s pulse.

The EPROM must not be programmed with a DC signal applied to the CE/PGM input.

Programming multiple EPROM in parallel with the same data can be easily accomplished due to the simplicity of the programming requirements. Like inputs of the parallel EPROM may be connected together when they are programmed with the same data. A low level TTL pulse applied to the CE/PGM input programs the paralleled EPROM.

#### **Program Inhibit**

Programming multiple EPROMs in parallel with different data is also easily accomplished. Except for CE/PGM all like inputs (including OE/ $V_{PP}$ ) of the parallel EPROMs may be common. A TTL low level program pulse applied to an EPROM's CE/PGM input with OE/ $V_{PP}$  at 12.75V will program that EPROM. A TTL high level CE/PGM input inhibits the other EPROMs from being programmed.

#### **Program Verify**

A verify should be performed on the programmed bits to determine whether they were correctly programmed. The verify is accomplished with OE/V<sub>PP</sub> and CE at V<sub>IL</sub>. Data should be verified T<sub>DV</sub> after the falling edge of CE.

## AFTER PROGRAMMING

Opaque labels should be placed over the EPROM window to prevent unintentional erasure. Covering the window will also prevent temporary functional failure due to the generation of photo currents.

#### MANUFACTURER'S IDENTIFICATION CODE

The EPROM has a manufacturer's identification code to aid in programming. When the device is inserted in an EPROM programmer socket, the programmer reads the code and then automatically calls up the specific programming algorithm for the part. This automatic programming control is only possible with programmers which have the capability of reading the code.

The Manufacturer's Identification code, shown in Table II, specifically identifies the manufacturer and device type. The code for NM27C512 is "8F85", where "8F" designates that it is made by National Semiconductor, and "85" designates a 512K part.

The code is accessed by applying 12V  $\pm 0.5V$  to address pin A9. Addresses A1-A8, A10-A16, and all control pins

## Functional Description (Continued)

are held at V $_{\rm IL}$ . Address pin A0 is held at V $_{\rm IL}$  for the manufacturer's code, and held at V $_{\rm IH}$  for the device code. The code is read on the eight data pins, O $_0$ -O $_7$ . Proper code access is only guaranteed at 25°C  $\pm$ 5°C.

#### **ERASURE CHARACTERISTICS**

The erasure characteristics of the device are such that erasure begins to occur when exposed to light with wavelengths shorter than approximately 4000 Angstroms (Å). It should be noted that sunlight and certain types of fluorescent lamps have wavelengths in the 3000Å–4000Å range.

The recommended erasure procedure for the EPROM is exposure to short wave ultraviolet light which has a wavelength of 2537Å. The integrated dose (i.e., UV intensity  $\times$  exposure time) for erasure should be minimum of 15W-sec/cm².

The EPROM should be placed within 1 inch of the lamp tubes during erasure. Some lamps have a filter on their tubes which should be removed before erasure. Table III shows the minimum EPROM erasure time for various light intensities.

An erasure system should be calibrated periodically. The distance from lamp to device should be maintained at one inch. The erasure time increase as the square of the distance from the lamp (if distance is doubled the erasure time increases by factor of 4). Lamps lose intensity as they age.

When a lamp is changed, the distance has changed, or the lamp has aged, the system should be checked to make certain full erasure is occurring. Incomplete erasure will cause symptoms that can be misleading. Programmers, components, and even system designs have been erroneously suspected when incomplete erasure was the problem.

#### SYSTEM CONSIDERATION

The power switching characteristics of EPROMs require careful decoupling of the devices. The supply current, I<sub>CC</sub>, has three segments that are of interest to the system designer: the standby current level, the active current level, and the transient current peaks that are produced by voltage transitions on input pins. The magnitude of these transient current peaks is dependent of the output capacitance loading of the device. The associated V<sub>CC</sub> transient voltage peaks can be suppressed by properly selected decoupling capacitors. It is recommended that at least a 0.1  $\mu$ F ceramic capacitor be used on every device between  $V_{\mbox{\footnotesize CC}}$  and GND. This should be a high frequency capacitor of low inherent inductance. In addition, at least a 4.7 µF bulk electrolytic capacitor should be used between  $V_{\mbox{\footnotesize CC}}$  and GND for each eight devices. The bulk capacitor should be located near where the power supply is connected to the array. The purpose of the bulk capacitor is to overcome the voltage drop caused by the inductive effects of the PC board traces.

### **Mode Selection**

The modes of operation of the NM27C512 are listed in Table I. A single 5V power supply is required in the read mode. All inputs are TTL levels excepts for  $V_{PP}$  and A9 for device signature.

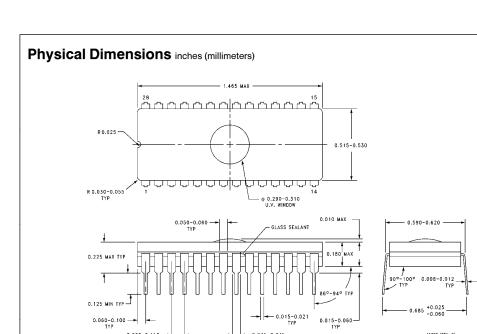
**TABLE I. Mode Selection** 

Pins Mode	CE/PGM	ŌĒ/V <sub>PP</sub>	V <sub>CC</sub>	Outputs
Read	V <sub>IL</sub>	V <sub>IL</sub>	5.0V	D <sub>OUT</sub>
Output Disable	X (Note 1)	V <sub>IH</sub>	5.0V	High Z
Standby	V <sub>IH</sub>	X	5.0V	High Z
Programming	V <sub>IL</sub>	12.75V	6.25V	D <sub>IN</sub>
Program Verify	V <sub>IL</sub>	V <sub>IL</sub>	6.25V	D <sub>OUT</sub>
Program Inhibit	V <sub>IH</sub>	12.75V	6.25V	High Z

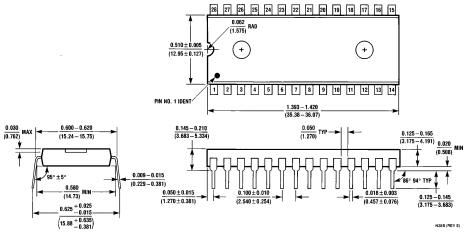
Note 1: X can be V<sub>IL</sub> or V<sub>IH</sub>.

**TABLE II. Manufacturer's Identification Code** 

Pins	A0 (10)	A9 (24)	07 (19)	06 (18)	05 (17)	04 (16)	03 (15)	02 (13)	01 (12)	00 (11)	Hex Data
Manufacturer Code	V <sub>IL</sub>	12V	1	0	0	0	1	1	1	1	8F
Device Code	V <sub>IH</sub>	12V	1	0	0	0	0	1	0	1	85

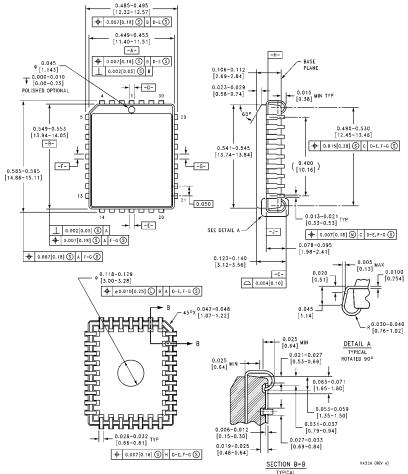


UV Window Cavity Dual-In-Line Cerdip Package (JQ) Order Number NM27C512Q NS Package Number J28CQ



28-Lead Plastic One-Time-Programmable Dual-In-Line Order Number NM27C512N NS Package Number N28B

# Physical Dimensions inches (millimeters) (Continued)



32-Lead Plastic Leaded Chip Carrier (PLCC) Order Number NM27C512V NS Package Number VA32A

#### LIFE SUPPORT POLICY

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- 1. Life support devices or systems are devices or systems which, (a) are intended for surgical implant into the body, or (b) support or sustain life, and whose failure to perform, when properly used in accordance with instructions for use provided in the labeling, can be reasonably expected to result in a significant injury to the user.
- A critical component is any component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.



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